

BILLING CODE 4510-26-C

## VIII. Federalism

OSHA reviewed the proposed updates to the HCS according to the most recent Executive order on federalism (E.O. 13132, 64 FR 43255), which requires that Federal agencies, to the extent possible, refrain from limiting State policy options, consult with States before taking actions that would restrict States' policy options and take such actions only when clear constitutional and statutory authority exists and the problem is of national scope. The Executive order generally allows Federal agencies to preempt State law only with the expressed consent of Congress. Federal agencies must limit preemption of State law to the extent possible.

Under section 18 of the OSH Act, 29 U.S.C. 667, Congress expressly provides that States and U.S. territories may adopt, with Federal approval, a plan for the development and enforcement of occupational safety and health standards. OSHA refers to such States and territories as State Plan States. Occupational safety and health standards developed by State Plan States must be at least as effective in providing safe and healthful employment and places of employment as the Federal standards and, when applicable to products that are distributed or used in interstate commerce, must be required by compelling local conditions and not unduly burden interstate commerce. 29 U.S.C. 667(c)(2). Subject to these requirements, State Plan States are free to develop and enforce their own requirements for safety and health standards.

In States without OSHA-approved State plans, Congress expressly provides for OSHA standards to preempt State occupational safety and health standards in areas addressed by the Federal standards. In these States, the proposed revisions to the HCS would limit State policy options in the same manner as every standard or amendment to a standard promulgated by OSHA. In States with OSHA-approved State plans, the proposed revisions to the HCS would not significantly limit State policy options to adopt stricter standards.

OSHA previously concluded that promulgation of the HCS complies with E.O. 13132 (77 FR 17687), and reaffirms that finding with respect to the proposed revisions to that standard.

## VIX. State Plan States

When Federal OSHA promulgates a new standard or more stringent

amendment to an existing standard, the 28 States and U.S. territories with their own OSHA-approved occupational safety and health plans ("State Plan States") must amend their standards to reflect the new standard or amendment or show why such action is unnecessary, *e.g.*, because an existing State standard covering this area is "at least as effective" as the new Federal standard or amendment. 29 CFR 1953.5(a). The State standard must be at least as effective as the final Federal rule, and, when applicable to products that are distributed or used in interstate commerce, must be required by compelling local conditions and not unduly burden interstate commerce. 29 U.S.C. 667(c)(2). State Plans must adopt the Federal standard or complete their own standard within six months of the promulgation date of the final Federal rule. When OSHA promulgates a new rule or amendment that does not impose additional or more stringent requirements than existing standards, State Plan States are not required to amend their standards, although OSHA may encourage them to do so.

The 22 States and territories with OSHA-approved occupational safety and health plans that cover public and private-sector employees are Alaska, Arizona, California, Hawaii, Indiana, Iowa, Kentucky, Maryland, Michigan, Minnesota, Nevada, New Mexico, North Carolina, Oregon, Puerto Rico, South Carolina, Tennessee, Utah, Vermont, Virginia, Washington, and Wyoming. Another six states and territories have OSHA-approved occupational safety and health plans that cover State and local government employees only: Connecticut, Illinois, Maine, New Jersey, New York, and the Virgin Islands.

## X. Unfunded Mandates Reform Act

OSHA reviewed this proposal according to the Unfunded Mandates Reform Act of 1995 (UMRA), U.S.C. 1501 *et seq.*, and Executive Order 13132 (64 FR 43255). As discussed in the Preliminary Economic Analysis, OSHA has preliminarily concluded that the proposed revisions to the HCS will not impose a Federal mandate on the private sector in excess of \$100 million (adjusted annually for inflation) in expenditures in any one year.

As noted previously, OSHA's standards do not apply to State and local governments except in States that have elected voluntarily to adopt a State Plan approved by the agency. Consequently, this proposal does not meet the definition of a "Federal intergovernmental mandate." See 2 U.S.C. 658(5).

The OSH Act does not cover tribal governments in the performance of traditional governmental functions, though it generally does cover tribal governments when they engage in commercial activity. The proposed changes to the HCS would not require tribal governments to expend, in the aggregate, \$100 million or more in any one year for their commercial activities.

For these reasons, for the purposes of the UMRA, OSHA certifies that this proposal would not mandate that State, local, or tribal governments adopt new, unfunded regulatory obligations of, or increase expenditures by the private sector by, more than \$100 million in any year. In any event, the Preliminary Economic Analysis constitutes a written statement containing a qualitative and quantitative assessment of the anticipated costs and benefits. See 2 U.S.C. 1532.

## XI. Protecting Children From Environmental Health and Safety Risks

Executive Order 13045 (62 FR 19885), requires that Federal agencies submitting covered regulatory actions to OMB's Office of Information and Regulatory Affairs (OIRA) for review pursuant to E.O. 12866 provide OIRA with (1) an evaluation of the environmental health or safety effects that the planned regulation may have on children, and (2) an explanation of why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the agency. E.O. 13045 defines "covered regulatory actions" as rules that are likely to (1) be economically significant under E.O. 12866 (*i.e.*, a rulemaking that has an annual effect on the economy of \$100 million or more, or would adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities), and (2) concern an environmental health risk or safety risk that an agency has reason to believe may disproportionately affect children. In this context, the term "environmental health risks and safety risks" means risks to health or safety that are attributable to products or substances that children are likely to come in contact with or ingest (*e.g.*, through air, food, water, soil, or product use).

OSHA has preliminarily determined that the proposed revisions to the HCS are not economically significant under E.O. 12866 (see Section VII of this preamble) and that the standard would not pose environmental health or safety

risks to children as set forth in E.O. 13045.

## XII. Environmental Impacts

OSHA has reviewed the proposed revisions to the HCS according to the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321 *et seq.*), the regulations of the Council on Environmental Quality (40 CFR part 1500), and the Department of Labor's NEPA procedures (29 CFR part 11). As a result of that review, OSHA has made a preliminary determination that the proposed regulatory changes will have no impact on air, water, or soil quality; plant or animal life; or the use of land or aspects of the external environment. Therefore, OSHA preliminarily concludes that the proposed revisions to the HCS would have no significant environmental impacts.

## XIII. Consultation and Coordination With Indian Tribal Governments

OSHA reviewed the proposed revisions to the HCS in accordance with E.O. 13175 on "Consultation and Coordination with Indian Tribal Governments" (65 FR 67249), and determined that it does not have "tribal implications" as defined in that order. The amendments, if promulgated, would not have substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

## XIV. Issues and Options Considered

OSHA is providing this issues and options section to solicit stakeholder input on various regulatory issues and to allow for some potential regulatory flexibility with respect to the content of any final rule resulting from this rulemaking. While OSHA invites stakeholders to comment on all aspects of this proposal, this section identifies specific areas of interest to the agency. OSHA is including certain issues and questions in this section to assist stakeholders as they review the proposal and consider the comments they plan to submit. However, to fully understand the questions, and to provide substantive input and feedback in response to them, the agency suggests commenters review the other sections of the preamble that address these issues in detail. Some issues and options that have cost implications are discussed more thoroughly in the Preliminary Economic Analysis (see Section VII. Preliminary Economic Analysis and Initial Regulatory Flexibility Analysis).

### A. Issues

In this section, OSHA solicits public feedback on specific issues associated with the proposed revisions to the HCS. It should be noted that the proposed regulatory text provided at the end of this document only includes those paragraphs that OSHA is proposing to change. Therefore, the agency is putting a marked-up version (redline strike out) of the text of the current rule on its web page and in the docket to help readers identify and understand the proposed changes in context (OSHA HCS Redline, 2020, Document ID 0222). The marked-up text will be found on [www.osha.gov](http://www.osha.gov) under Hazard Communication in the subject index.

OSHA has organized this issues section to follow the order of the preamble and requests that feedback be organized, to the extent possible, in similar order. Comments and feedback on particular provisions should contain the heading of the section (e.g., Regulatory Text, Appendix A), the associated issue number, and, where appropriate, the paragraph in the standard that the comment is addressing. Comments addressing more than one section or paragraph should include all relevant references. Submitting comments in an organized manner with clear reference to the issue(s) raised will enable all participants to better understand the issues the commenter addressed and how they addressed them. Some commenters may confine their interest (and comments) to the issues that specifically affect them; correspondingly they will benefit from being able to quickly identify comments on these issues in others' submissions. While the agency welcomes relevant comments on any aspect of this proposal, OSHA is especially interested in responses, supported by evidence and explanations, to the following issues and questions:

#### Timeframe for Updates to the HCS

Since aligning the HCS with the GHS Rev. 3 in 2012, OSHA has intended for the HCS to stay current with more recent revisions of the GHS. The GHS is updated biennially through published revisions; most recently, revision 8 was published in July 2019 (UN GHS, Rev. 8, Document ID 0065). Regulatory authorities around the world have implemented the GHS at stages ranging from revision 1 through revision 5. Few regulatory authorities have put programs in place to update their regulations on a routine schedule. The European Union (EU) has made the most regular updates, and has most

recently implemented the GHS Rev. 5 in August, 2016 (ECHA, 2016, Document ID 0177). In March 2019, the European Commission (EC) published the adaptation of technical progress (ATP) to EC regulation 1272/2008 (the Classification, Labelling, and Packaging (CLP) regulation) to align with both the sixth and seventh revised editions of the GHS (EC, 2019, Document ID 0176). These changes to the EC regulation become effective October 17, 2020. Other regulatory authorities, such as those in Canada, Australia, and New Zealand, have indicated that they will continue to update their regulations to align with the GHS and are in the process of aligning with Rev. 7; however, none of these countries have a mandate on how often they should do so (Canada, 2019, Document ID 0172; Australia, 2020, Document ID 0168; New Zealand, 2018, Document ID 0187). Similarly, to date, OSHA has not adopted a specific timeframe for regularly updating the HCS to implement GHS updates.

As stated previously, OSHA is proposing to align the HCS with the GHS Rev. 7, consistent with the actions of most of the countries listed above (EC, 2019, Document ID 0176; Canada, 2019, Document ID 0172; Australia, 2020, Document ID 0168; New Zealand, 2018, Document ID 0187). A more thorough explanation of OSHA's preliminary decision to align the HCS with the GHS Rev. 7 is detailed in the introduction to Section XV.

OSHA requests public comment on whether the agency should adopt a schedule for updates to the HCS standard (e.g., every four years or every two revisions of the GHS) or wait until there are significant changes to the GHS before initiating rulemaking. More frequently updating the HCS to align with the GHS may provide greater protection for workers and reduce uncertainty for manufacturers, distributors, and employers. For example, in the GHS Rev. 7, several hazard classes have been updated to include additional hazard sub-categories and improved hazard information that will increase clarity and, therefore, protections for workers.

OSHA is interested in receiving public comment about the utility, costs, or other issues that might be associated with regular updates and about specific timeframes or criteria that OSHA should consider when determining when and whether to update the HCS. Specifically, would longer time periods between updates and realignment with the GHS and other standards be more or less burdensome for employers, especially those that operate

internationally? Would regular, shorter time periods provide more stability? How would longer or shorter periods between realignment affect worker protection?

#### Regulatory Text

(1) Under paragraph (f), *Labels and other forms of warning*, OSHA is proposing changes to paragraphs (f)(5) (bulk shipments) and (f)(11) (released-for-shipment) and is also proposing to add a new paragraph (f)(12) containing provisions specific to labelling on small containers.

(a) OSHA is requesting comments on the proposed additions to paragraph (f)(5), which would be newly titled *Transportation*. Proposed paragraph (f)(5)(ii) would provide that labels for bulk shipments may be placed on the immediate container or may be transmitted with the shipping papers or bills of lading or by other technological or electronic means as long as the label is immediately available to workers in printed form at the receiving end of the shipment. OSHA requests comments on the usefulness and effectiveness of allowing these alternate approaches for labeling bulk shipments.

(b) OSHA is proposing to update paragraph (f)(11) to provide that chemicals that have been released for shipment and are awaiting future distribution need not be relabeled to incorporate new significant information about hazards; however, the chemical manufacturer or importer would still have to provide the updated label for each individual container with each shipment. The purpose of this proposal is to account for the long distribution cycles of some products and the potential hazards workers could face in relabeling the immediate containers of hazardous chemicals (e.g., chemical exposures, ergonomic issues). OSHA requests comments on whether it is appropriate to use “released for shipment” as the cutoff point for relabeling requirements, as opposed to, for example, the time of shipment. Would the proposed provision reduce worker protections, considering OSHA is also proposing to require that the updated label be sent with the shipment? Would the proposed change result in any cost savings?

(c) OSHA is proposing a new paragraph (f)(12) addressing labeling requirements for small containers. All of the provisions in this proposed paragraph would apply only where the chemical manufacturer, importer, or distributor can demonstrate that it is not feasible to use pull-out labels, fold-back labels, or tags containing the full label information required by paragraph (f)(1).

Paragraph (f)(12)(ii), as proposed, would provide that labels for small containers less than or equal to 100 ml capacity must include just the product identifier, pictogram(s), signal word, chemical manufacturer’s name and phone number, and a statement that the full label information for the hazardous chemical is provided on the immediate outer package. In addition, proposed (f)(12)(iii) would eliminate labeling requirements for small containers less than or equal to 3 ml capacity where the manufacturer, importer, or distributor can demonstrate that any label would interfere with the normal use of the container; in such cases, however, the proposed revisions to the standard would require the container to bear, at a minimum, the product identifier. For example, the product identifier could be etched on a small glass vial. This would ensure that each small container can be identified and linked with the full label information on the immediate outer package. OSHA is also proposing a provision at paragraph (f)(12)(iv), applicable to all small containers covered by paragraph (f)(12)(ii) or (iii), providing that the immediate outer package must include (1) the full label information for each hazardous chemical in the immediate outer package; and (2) a statement indicating that the small container(s) inside must be stored in the immediate outer package (bearing the complete label) when not in use. OSHA requests comments on the feasibility of, and any cost savings associated with, these proposed provisions for the labeling of small containers (both 100 ml and less and 3 ml and less). The agency also requests information on whether the proposed labeling requirements would be adequate to provide for safe handling and storage of chemicals in small containers. In addition, OSHA is interested in receiving comments on two specific alternatives to proposed paragraph (f)(12). First, instead of adopting proposed paragraph (f)(12), should OSHA simply allow for case-by-case exemptions if full labeling is not feasible? Second, should the agency require a showing that a full label would interfere with the normal use of the container before permitting the use of abbreviated labels on containers with a capacity of 100 ml and less (similar to the condition OSHA is proposing in paragraph (f)(12)(iii) for containers with a capacity of 3 ml and less)? Please provide reasons for your answers.

(2) Under paragraph (g) *Safety data sheets*, OSHA is proposing a change to paragraph (g)(10), which addresses the form and storage of safety data sheets,

to allow SDSs to be stored, rather than designed, in a way that covers groups of hazardous chemicals in a work area. The original term “design” was used when OSHA did not require a specific format for material safety data sheets (MSDSs), but now that OSHA requires SDSs to be in a standard 16-section format, the agency is proposing to clarify that this paragraph refers to storage only. OSHA requests comments regarding whether this proposed revision would require significant changes to current practices.

(3) Under paragraph (i), *Trade secrets*, OSHA is proposing two significant changes.

(a) First, OSHA is proposing to allow manufacturers, importers, and employers to withhold a chemical’s concentration range as a trade secret.

(b) Second, in proposed paragraphs (i)(1)(iv)(A) through (M), OSHA is proposing the use of prescriptive concentration ranges in lieu of the actual concentration or concentration range whenever the actual concentration or concentration range is claimed as a trade secret; the proposed ranges are the same as those required by Canada, a major trading partner of the United States (Canada, 2019, Document ID 0172).

OSHA currently does not permit manufacturers to claim concentration ranges as trade secrets (Colau, 2017, Document ID 0098; Nelson, 2017, Document ID 0099), and is requesting comments on its proposal to do so. Specifically, the agency is interested in any experience stakeholders have had with developing SDSs using the prescribed concentration ranges and any concerns stakeholders have about using concentration ranges on the SDS. The agency is also requesting comments addressing the adequacy of hazard information provided by these ranges. Do these ranges provide sufficient information for downstream manufacturers to conduct hazard classifications? Are the ranges prescribed too wide to provide sufficient information to protect workers (i.e., should they be narrowed)? Notably, proposed paragraph (i)(1)(v) provides that the prescribed concentration range used must be the narrowest range possible. If the exact concentration range falls between 0.1% and 30% (proposed paragraphs (i)(1)(iv)(A) through (G)) and does not fit entirely into one of the prescribed concentration ranges, a single range created by the combination of two applicable consecutive ranges could be disclosed instead, provided that the combined concentration range does not include any range that falls entirely outside the

exact concentration range in which the ingredient is present. OSHA invites comments on whether it should allow combinations among all ranges (*i.e.*, all of the ranges (up to 100% concentration) listed in proposed paragraphs (i)(1)(iv)(A) through (M)) or whether the rule applicable to combining ranges should be even more restrictive (*e.g.*, only for the ranges (up to 10% concentration) listed in proposed paragraphs (i)(1)(iv)(A) through (E)). OSHA is also interested in receiving comments on whether there are any economic implications associated with including the prescribed concentration ranges.

#### Appendix B

OSHA is proposing several substantive updates to appendix B (as outlined in Section XV, Summary and Explanation). These include the addition of a new hazard class (desensitized explosives) and several new hazard categories (unstable gases and pyrophoric gases in the Flammable Gases class and nonflammable aerosols in the Aerosols class). OSHA has preliminarily determined that the addition of these specific hazard classes and categories would better differentiate between the hazards and better communicate hazards on labels for downstream users. OSHA is requesting comments on whether these changes provide improved safety through more targeted hazard statements, precautionary statements and pictograms.

#### Appendix C

OSHA has proposed numerous changes to appendix C, many of which are editorial, clarifying, or organizational in nature and are designed to clarify requirements for preparing labels. The agency is also proposing some substantive changes to correspond to proposed changes to appendix B or the regulatory text. In paragraph C.2.4.10, OSHA is proposing to require prioritization of certain precautionary statements related to medical response (see Section XV, Summary and Explanation, Appendix C, Proposed Revisions to Table C.2.4.). The agency requests comments on the particular system of prioritization specified in proposed C.2.4.10 and on whether the proposed prioritization provisions would improve clarity on labels.

#### Appendix D

Many of the issues related to changes proposed for appendix D are discussed in the summary and explanation of the regulatory text (see Section XV,

Summary and Explanation, Regulatory Text), specifically in the discussion of OSHA's proposed changes to paragraphs (c), (g), and (i). OSHA requests comments on the following additional issues:

OSHA is proposing changes to section 2 of the SDS to emphasize that hazards identified under normal conditions of use that result from a chemical reaction must appear on the SDS, even though these hazards do not need to be listed on the label. This proposed change would simply reorganize the information presented in the SDS, as discussed in Section XV (Summary and Explanation, Appendix D). OSHA is requesting comments on whether the text OSHA is proposing for paragraph (c) in section 2 would clarify when it is appropriate to include information on the hazards associated with a change in the chemical's physical form or chemical reaction under normal conditions of use and the type of information that should be presented in section 2 of the SDS.

With some conditions, the HCS currently requires section 3 of the SDS to include the chemical name and concentration (exact percentage) or concentration ranges of all ingredients which are classified as "health hazards" in accordance with paragraph (d) of § 1910.1200. OSHA is not proposing to change this requirement, but is interested in comments on whether it should be expanded to include all classified chemicals (*i.e.*, also physical hazards and HNOCSs). Such a requirement would be similar to the EU REACH regulations, which require SDS preparers to list the classification of each hazardous ingredient (ECHA, 2016, Document ID 0177). Would expanding the requirements for section 3 in this way ensure that both users and manufacturers fully understand any potential hazard when handling the chemical? Would such a change result in the provision of additional information that would allow downstream manufacturers to more accurately classify their products where the mixture in question is one of their ingredients?

The use of newer electronic technology, such as quick response (QR) codes and radio-frequency identification (RFID), on package labels give responsible parties the ability to communicate information on chemical hazards in a variety of formats. In the December 2018 session of the UN Sub-committee, the members of an informal working group on labeling of small containers agreed to extend its scope beyond small containers and, accordingly, to change its name to

"Practical Labelling Issues." Among other activities proposed for the biennium 2019–2020, the working group planned to "[r]eview the existing digital means of communication that can be used to convey the GHS hazard information to users (*e.g.*, electronic label, QR code etc.)," "consider the development of general principles and criteria on the provision of this information digitally," and "develop guidance and examples wherever appropriate." (UN GHS, 2019, Document ID 0198; UN Secretariat, 2019, Document ID 0196).

As an example, a paper presented at the December 2018 session of the UN sub-committee noted that there are international efforts "actively promoting the application of electronic labels for chemicals" in such industrial processes as production; management of cylinders, laboratory samples, and warehouse operations; and the supervision of competent persons (UN GHS, 2019, Document ID 0198). The paper noted that common types of electronic labels include QR codes and RFID. The paper also discussed efforts to develop national standards on electronic labeling "to establish a complete integrated information managing standard system based on chemical electronic labels and safety data" in order to "further ensure the effectiveness of chemical safety supervision, promote the implementation of the Globally Harmonized System of Classification and Labelling of Chemicals, and facilitate . . . trade." Among the benefits of practical labeling cited by the sub-committee expert are the convenience and efficiency derived from "unified information collection," "dynamic management," and "real-time monitoring"; the ability to store a large capacity of information, reaching multiple mega-byte levels; and "[improvement in] the level of safety management in complex scenarios." (UN GHS, 2018, Document ID 0082).

OSHA invites comments on the use of electronic labeling for chemical packaging. If a future revision to the HCS permitted some form of electronic labeling, what technological, economic, and security challenges would affected employers face? The agency also requests comments on the types of electronic chemical labeling already in existence or under development. For employers already implementing electronic labeling programs in the United States or in other countries, please provide information on the types of electronic coding systems utilized in the program and the costs incurred and benefits achieved from the program.

What back-up measures are in place to ensure immediate access to the hazard information? OSHA is interested in information about workers' experiences with the use of electronic labels. OSHA also requests comments on foreseeable challenges that OSHA should consider (e.g., worker accessibility to electronic label information).

#### Preliminary Economic Analysis

(1) As explained in the preliminary economic analysis (see Section VII.F. Compliance Costs and Cost Savings), some chemical production and logistics employees who receive training under the provisions of the existing HCS would need to receive additional training to become familiar with the updates to SDSs and labels for impacted aerosols, desensitized explosives, and flammable gases. OSHA has preliminarily determined that the incremental training costs employers would incur for these employees will be relatively small (estimated annualized training costs of \$120,158 for all affected employers). OSHA also believes that users of aerosols, desensitized explosives, and flammable gases in the workplace are already trained on the hazards of these chemicals and therefore would need to devote only a trivial amount of time, if any time at all, to additional training associated with the reclassification of these chemicals. Per the discussion of this issue in the preliminary economic analysis (see "Costs Associated with Training Employees" in Section VII.F. Compliance Costs and Cost Savings), OSHA acknowledges that some user training might be required for non-flammable aerosols not under pressure; the agency has preliminarily concluded, however, that such training time would be negligible given that, as discussed in Section XV.C (see Section XV, Summary and Explanation for Appendix B), most aerosols are currently classified as gases under pressure and therefore are already covered under the HCS. The agency requests comments on all of its preliminary conclusions regarding training time for users of reclassified chemicals.

(2) For purposes of estimating the costs associated with the proposed new hazard classification requirements, OSHA estimates that a Health & Safety Specialist would spend 1.75 hours per SDS for establishments with fewer than 100 employees; 1.25 hours per SDS for establishments with 100–499 employees; and 0.75 hours per SDS for establishments with 500 or more employees (see "Costs Associated with Reclassifications and Revisions to Safety Data Sheets and Labels" in Section

VII.F, Compliance Costs and Cost Savings). At a loaded hourly wage of \$56.87, this results in estimated unit costs of \$101.51, \$72.51, and \$43.50 per SDS for small, medium, and large establishments, respectively. OSHA invites interested parties to comment on these estimates.

(3) For purposes of estimating the costs associated with revising labels and SDSs to conform to the revisions OSHA is proposing to mandatory language in the appendices, OSHA estimates that a Health & Safety Specialist would spend 0.7 hours per SDS for establishments with fewer than 100 employees; 0.5 hours per SDS for establishments with 100–499 employees; and 0.3 hours per SDS for establishments with 500 or more employees (see "Revisions to SDSs and Labels Due to Revised Precautionary Statements," in Section VII.F. Compliance Costs and Cost Savings). At a loaded hourly wage of \$56.39, this results in estimated unit costs of \$40.60, \$29.00, and \$17.40 per SDS for small, medium, and large establishments, respectively. OSHA invites interested parties to comment on these estimates.

(4) To estimate the costs (cost savings) associated with the proposed released-for-shipment provisions in paragraph (f)(11), OSHA presented a cost methodology that required estimating four factors: (1) Cost savings (estimated relabeling costs) as a percentage of the value of the products needing relabeling; (2) the percentage of products in the affected NAICS industries that would be warehoused for more than six months; (3) the percentage of products warehoused for more than six months that would require relabeling in any particular year due to a manufacturer-initiated labeling change;<sup>58</sup> and (4) the percentage of all products in the NAICS industries that would be covered by the proposed revisions to the HCS. The estimated percentages are shown in Table VI–17: Calculation of the Percentage Loss Avoided Due to the Proposed Released-for-Shipment Provision. OSHA requests public comments on its estimates for each of the four factors described above and shown in Table VI–17.

(5) As described in the PEA (see "Released for Shipment" in Section VII.F. Compliance Costs and Cost Savings), OSHA anticipates that the proposed modifications to paragraph (f)(11) addressing chemicals that have been released for shipment would result in cost savings for manufacturers and

distributors of certain products—those with large (and typically infrequent) production runs and lengthy shelf lives (often five years or longer) that, during production, are labeled, boxed, palletized, and shipped, and then go through the distribution chain usually without the chemical contents, packaging, or label being disturbed. OSHA identified six industries (NAICS 325311 Nitrogenous fertilizer manufacturing, NAICS 325312 Phosphatic fertilizer manufacturing, NAICS 325314 Fertilizer (mixing only) manufacturing, NAICS 325510 Paint and coating manufacturing, NAICS 424910 Farm supplies merchant wholesalers, and NAICS 424950 Paint, varnish, and supplies merchant wholesalers) that it expects would be impacted by the proposed modifications to paragraph (f)(11); see Table VI–17 in Section VII.D. Health and Safety Benefits and Unquantified Positive Economic Effects. OSHA invites comments on whether other industries would be affected by this proposed modification and whether there might be other cost or health effects resulting from this proposed modification that OSHA did not consider in this proposal.

(6) Also with respect to the estimate of cost savings associated with the proposed released-for-shipment provisions, OSHA assumes that if the relabeling costs associated with paragraph (f)(11) exceed the value of the product, manufacturers and wholesalers will discard the product rather than pay to relabel it. There may be some disposal costs for the discarded material, but there may also be some salvage value to the improperly-labeled product. In the preliminary economic analysis (see "Released for Shipment" in Section VII.F. Compliance Costs and Cost Savings), OSHA estimates, without further information on the distribution of the costs, that the average labeling cost is approximately 50 percent of the value of the products requiring relabeling. The agency invites comments on this assumption.

#### B. Options

In this section, OSHA presents a list of options that are under consideration for the proposed update to the HCS. The agency is requesting public comment on these options.

#### Regulatory Text

(1) OSHA is proposing, in paragraph (i), to mandate the use of prescriptive concentration ranges whenever an actual concentration or concentration range is being claimed as a trade secret. This change is being proposed, in part, to better align with Canada's Workplace

<sup>58</sup> That is, a labeling change resulting from new information obtained by the manufacturer and not from a new legal requirement.

Hazardous Materials Information System (WHMIS), allowing manufacturers, importers, and employers the ability to use the same SDS for both U.S. and Canadian workplaces. However, the agency is also considering a non-mandatory option for this provision. Under this scenario, OSHA would provide non-mandatory guidance on the use of concentration ranges, but would not require their use. This would allow manufacturers, importers, and employers flexibility to follow the current HCS requirements (which do not require the use of any concentration ranges when the actual concentration is claimed as a trade secret) or move to a system that aligns with WHMIS. OSHA is requesting comments on this option. Would this option provide beneficial flexibility to manufacturers, importers, and employers? Would this option be too confusing, and potentially weaken protective effects that would be associated with providing prescribed concentration ranges? How would this affect employee safety and comprehension?

(2) Under paragraph (i), OSHA is also considering allowing manufacturers and importers to provide their own ranges as long as the range is narrower than any

prescribed range. This alternative could allow manufacturers and importers to provide downstream users with more precise information while still being able to claim a trade secret. This would be consistent with an approach Health Canada is considering (Canada, 2019, Document ID 0172). OSHA is seeking comments on the usefulness and viability of this option.

#### Revision 8 Changes

The GHS Rev. 8 was published in July 2019 and contains many changes from Rev. 7, including updates to certain hazard classification criteria, systematic updates to the definitions in the health hazard chapters, updates to hazard and precautionary statements, and updated labeling examples. An overview of the changes can be found in Document ID 0243. As discussed more thoroughly in the introduction to the Summary and Explanation (see Section XV), OSHA has preliminarily decided to use this proposed update to align the HCS with the GHS Rev. 7. However, OSHA has also identified specific updates found in the GHS Rev. 8 that are significant enough to warrant consideration in this rulemaking. Below, the agency highlights several updates from the GHS Rev. 8 and invites public comments on

whether OSHA should consider adopting these updates.

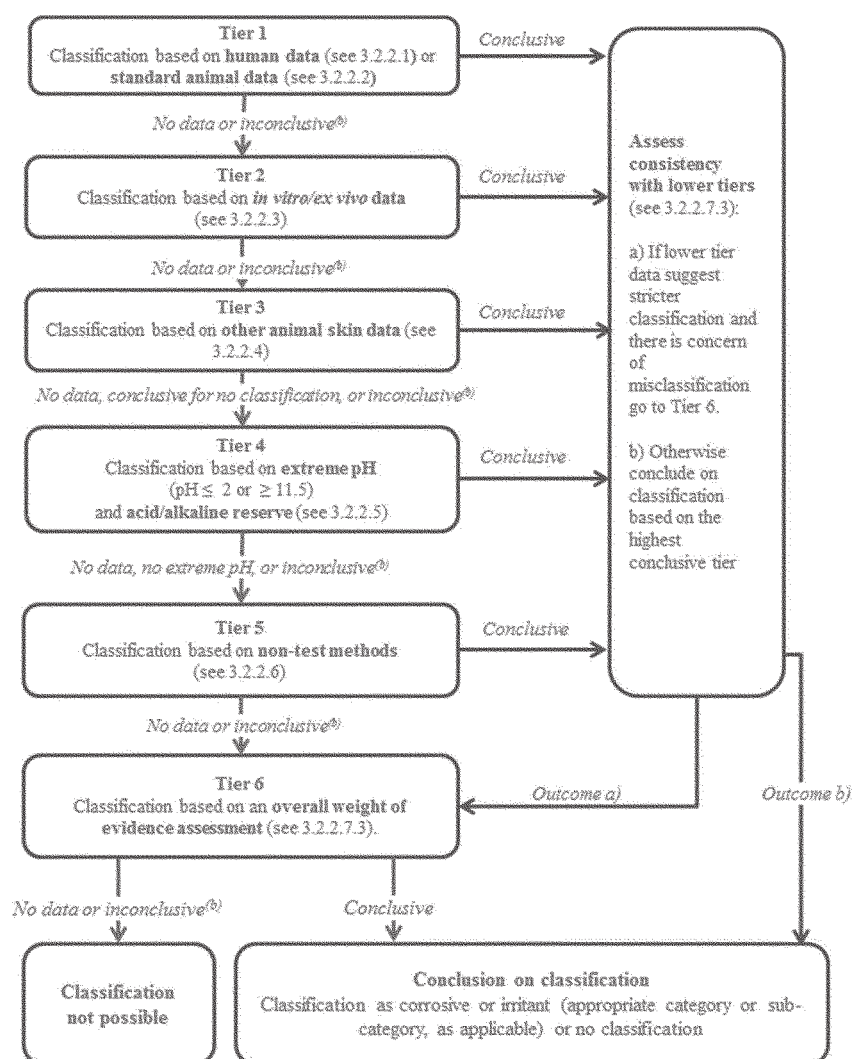
#### 1. Appendix A (Based on the GHS Rev. 8)

OSHA is proposing substantial revisions to appendix A.2 (skin corrosion/irritation) that reflect changes the UN subcommittee adopted through the GHS Rev. 7. However, the GHS Rev. 8, published in July 2019 (UN GHS, 2019, Document ID 0065), expanded the use of non-animal test methods in Chapter 3.2 (skin corrosion/irritation). These changes include recognition of specific *in vitro* test methods, reorganization of the chapter, reorganization of the tiered approach with an updated Figure 3.2.1 to reflect those changes, as well as descriptive text on use of new test methods, structure activity relationship (SAR) and read across methods, and an updated decision logic diagram. The expansion of non-animal test methods for use in hazard classification could potentially result in cost savings, as hazard testing for new chemicals could be done using potentially cheaper (non-animal) test methods. If OSHA were to adopt these changes, they would be reflected in appendix A.2 Skin Corrosion/Irritation.

**BILLING CODE 4510-26-P**

Table XIII.1 Tiered Approach to Classification of Chemicals for Skin Irritation/Corrosion

(from the GHS Rev. 8 Table 3.2.1)



## BILLING CODE 4510-26-C

Table 3.2.1 from the GHS Rev. 8 (shown above) provides an update to the tiered approach for classification. In recognition of the advancements made in non-animal test methods, the update includes an elevation in acceptance of *in vitro* data to tier 2 of the approach. The updated tiered approach also includes consideration of conflicting lower-tiered data when the lower tier suggests a higher classification level. In addition to the changes in the table, Rev. 8 updates the background information to provide additional guidance for how to use non-animal test data to classify chemicals. Adopting these updates in the HCS would not require a re-evaluation of chemicals already classified because the overall tiered approach for evaluating existing

data has been retained. The agency believes the greatest benefit would be for new chemicals where no existing data currently exists. Although OSHA does not require testing, OSHA currently encourages chemical manufacturers wanting to develop hazard information for new chemicals to utilize non-animal testing strategies to develop hazard information. Should OSHA adopt Chapter 3.2 from the GHS Rev. 8 with all of the revisions to the classification scheme? Please explain your opinion and provide any relevant data or other information.

## 2. Appendix B (Based on the GHS Rev. 8)

In this NPRM, OSHA is proposing updates to the classification and labeling of aerosols that will align with

the GHS Rev. 7. However, the GHS Rev. 8 contains several significant additional changes in the aerosol chapter. OSHA requests comments on whether the agency should adopt two specific changes that appear in the GHS Rev. 8. First, the GHS Rev. 8 lists classification criteria for aerosols as text in a table (see the GHS table 2.3.1, Criteria for aerosols), similar to other hazard chapters, rather than referring classifiers to the decision logics. When OSHA revised the HCS in 2012, the agency declined to adopt the GHS decision logics and used its own text for classification of flammable aerosols (§ 1910.1200, appendix B). OSHA has preliminarily determined that there are no substantive differences between OSHA's current text and the text

TABLE XIV—REV. 8 CLASSIFICATION CRITERIA FOR AEROSOLS  
[From the GHS Rev. 8 Table 2.3.1]

| Category | Criteria                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
|----------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1 .....  | <p>(1) Any aerosol that contains <math>\geq 85\%</math> flammable components (by mass) and has a heat of combustion of <math>\geq 30</math> kJ/g;</p> <p>(2) Any aerosol that dispenses a spray that, in the ignition distance test, has an ignition distance of <math>\geq 75</math> cm; or</p> <p>(3) Any aerosol that dispenses a foam that, in the foam flammability test, has:</p> <p>(a) a flame height of <math>\geq 20</math> cm and a flame duration of <math>\geq 2</math> s; or</p> <p>(b) a flame height of <math>\geq 4</math> cm and a flame duration of <math>\geq 7</math> s.</p>                                                                                                                                                                                                                                                                                                                                                                                                             |
| 2 .....  | <p>(1) Any aerosol that dispenses a spray that, based on the results of the ignition distance test, does not meet the criteria for Category 1, and which has:</p> <p>(a) A heat of combustion of <math>\geq 20</math> kJ/g;</p> <p>(b) a heat of combustion of <math>&lt; 20</math> kJ/g along with an ignition distance of <math>\geq 15</math> cm; or</p> <p>(c) a heat of combustion of <math>&lt; 20</math> kJ/g and an ignition distance of <math>&lt; 15</math> cm along with either, in the enclosed space ignition test:</p> <p style="padding-left: 40px;">A time equivalent of <math>\leq 300</math> s/m<sup>3</sup>; or</p> <p style="padding-left: 40px;">a deflagration density of <math>\leq 300</math> g/m<sup>3</sup>; or</p> <p>(2) Any aerosol that dispenses a foam that, based on the results of the aerosol foam flammability test, does not meet the criteria for Category 1, and which has a flame height of <math>\geq 4</math> cm and a flame duration of <math>\geq 2</math> s.</p> |
| 3 .....  | <p>(1) Any aerosol that contains <math>\leq 1\%</math> flammable components (by mass) and that has a heat of combustion <math>&lt; 20</math> kJ/g; or</p> <p>(2) Any aerosol that contains <math>&gt; 1\%</math> (by mass) flammable components or which has a heat of combustion of <math>\geq 20</math> kJ/g but which, based on the results of the ignition distance test, the enclosed space ignition test or the aerosol foam flammability test, does not meet the criteria for Category 1 or Category 2.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |

statements to align with the GHS Rev. 7. However, the GHS Rev. 8 includes additional revisions to precautionary statements, most notably an overhaul of the medical response precautionary statements (UN GHS, 2019, Document ID 0065). These precautionary statements were revised for the GHS Rev. 8 because, among other reasons, manufacturers and suppliers had difficulty choosing the appropriate wording where options were given (*e.g.*, choosing between calling a poison center or doctor, or choosing between medical advice or attention) (UN GHS, 2019, Document ID 0065).

TABLE XV—REVISED MEDICAL RESPONSE STATEMENTS FROM THE GHS REV. 8

| Code       | Response precautionary statements            | Hazard class                                                                                                                                                                                                                                                                                                                      | Hazard category                                                                                      | Conditions for use                                                                                                                                                                                                                 |
|------------|----------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| P316 ..... | Get emergency medical help immediately.      | Acute toxicity, oral (chapter 3.1) .....<br>Acute toxicity, dermal (chapter 3.1) .....<br>Acute toxicity, inhalation (chapter 3.1).<br>Skin corrosion (chapter 3.2) .....<br>Respiratory sensitization (chapter 3.4).<br>Specific target organ toxicity, single exposure; (chapter 3.8).<br>Aspiration hazard (chapter 3.10) .... | 1, 2, 3 .....<br>1, 2, 3.<br>1, 2, 3.<br>1, 1A, 1B, 1C.<br><br>1, 1A, 1B.<br><br>1, 2.<br><br>1, 2.  | Competent Authority or manufacturer/supplier may add, 'Call' followed by the appropriate emergency telephone number, or the appropriate emergency medical help provider, for example, a Poison Centre, Emergency Centre or Doctor. |
| P317 ..... | Get medical help .....                       | Gases under pressure (chapter 2.5)<br>Acute toxicity, oral (chapter 3.1) .....<br>Acute toxicity, dermal (chapter 3.1)<br>Acute toxicity, inhalation (chapter 3.1).<br>Skin irritation (chapter 3.2) .....<br>Serious eye damage (chapter 3.3)<br>Eye irritation (chapter 3.3) .....<br>Skin sensitization (chapter 3.4) .....    | Refrigerated liquefied gas.<br>4, 5.<br>4, 5.<br>4, 5.<br><br>2, 3.<br>1.<br>2/2A, 2B.<br>1, 1A, 1B. |                                                                                                                                                                                                                                    |
| P318 ..... | If exposed or concerned, get medical advice. | Germ cell mutagenicity (chapter 3.5).<br>Carcinogenicity (chapter 3.6) .....                                                                                                                                                                                                                                                      | 1, 1A, 1B, 2.<br>1, 1A, 1B, 2.                                                                       |                                                                                                                                                                                                                                    |

TABLE XV—REVISED MEDICAL RESPONSE STATEMENTS FROM THE GHS REV. 8—Continued

| Code       | Response precautionary statements    | Hazard class                                                                                                                                                                                                                                                                                                                                                     | Hazard category                                                        | Conditions for use |
|------------|--------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------|--------------------|
| P319 ..... | Get medical help if you feel unwell. | Reproductive toxicity (chapter 3.7)<br>Reproductive toxicity, effects on or via lactation (chapter 3.7).<br>Specific target organ toxicity, single exposure; respiratory tract irritation (chapter 3.8).<br>Specific target organ toxicity, single exposure; narcotic effects (chapter 3.8).<br>Specific target organ toxicity, repeated exposure (chapter 3.9). | 1, 1A, 1B, 2.<br>Additional category.<br><br>3.<br><br>3.<br><br>1, 2. |                    |

As the new statements used in the GHS Rev. 8 provide standardized language and do not require manufacturers and suppliers to decide which statement is most appropriate, adopting these statements in the HCS as part of this rulemaking might save manufacturers or importers time and/or money compared to the existing statements. OSHA also believes that these statements could improve hazard communication and worker safety by more effectively conveying the type of medical action that is necessary. OSHA seeks comments on the potential benefits or drawbacks associated with adopting these revised medical response statements, or other precautionary statements that are part of the GHS Rev. 8, as a part of this rulemaking (see also Summary and Explanation, Section XV.D. Appendix C). OSHA's existing enforcement policy, as described in the OSHA hazard communication directive (OSHA, 2015, Document ID 0007), addresses situations in which employers may use precautionary statements from a more recent version of the GHS; does the policy described in the directive provide sufficient flexibility?

#### Incorporation by Reference

OSHA is proposing to revise the general incorporation by reference section, 29 CFR 1910.6, to include updated test methods referenced in the proposed revisions to the HCS. OSHA does not intend to require chemicals already classified using an earlier version of a consensus standard to be reclassified. OSHA believes that requiring the reclassification of chemicals based on updated test methods could result in unnecessary economic impacts and create unnecessary confusion for stakeholders. OSHA is considering ways to clarify this in the final regulatory text, *e.g.*, by including a provision in the Dates section of the rule stating that chemicals classified based on older test methods, prior to the effective date of the rule, do

not need to be reclassified, and invites comments on this topic.

#### XV. Summary and Explanation of the Proposed Modifications to the Hazard Communication Standard

This section of the preamble explains OSHA's proposed changes to the HCS (29 CFR 1910.1200). OSHA is proposing to align this modification of the HCS with the GHS Rev. 7 (UN GHS, 2017, Document ID 0060). The agency has preliminarily decided to base most of the GHS alignment on Rev. 7 for several reasons, even though Rev. 8 of the GHS was issued in July 2019 (UN GHS, 2019, Document ID 0065). First, OSHA began its work to update the standard prior to the release of Rev. 8. While OSHA has always intended the HCS to be evergreen, preparation for amending any standard is a time-consuming process and changing course would have resulted in a significant delay to this rulemaking. Second, the U.S.'s major trading partners (Canada, Europe, Australia, and New Zealand) are all preparing to align with Rev. 7 (Canada, 2019, Document ID 0172; Australia, 2020, Document ID 0168; New Zealand, 2018, Document ID 0187; EC, 2019, Document ID 0176). Third, OSHA has discussed the potential for adopting some of the most consequential changes from Rev. 8 in the Issues and Options section (see Section XIV, Issues and Options Considered).

In general, OSHA has received broad support for this rulemaking. During OSHA's informal discussion with stakeholders in November 2016 about the potential changes to the HCS (Docket No. OSHA–2016–005), the agency received feedback supporting continued alignment of the HCS with the GHS and Health Canada, as well as support for addressing various implementation issues under the existing HCS (API, 2016, Document ID OSHA–2016–0005–0026; ACC, 2016, Document ID OSHA–2016–0005–0014; NGFA, 2016, Document ID OSHA–2016–0005–0018; AFIA, 2016,

Document ID OSHA–2016–0005–0017). The proposed changes are intended to improve and enhance worker protection with regard to hazard communication by incorporating new hazard classes and categories, improving and streamlining precautionary statements, and providing additional clarification of existing regulatory requirements. The following is a discussion, by provision, of the proposed revisions to the standard.

In the discussion of the proposed modifications to the appendices, OSHA describes certain proposed changes that would affect multiple hazard classes. OSHA discusses some changes in general terms and indicates where those changes occur. However, to aid stakeholders, so they can see the proposed changes in context, OSHA is placing in the docket and on its website a redline strikeout version of all of the proposed revisions to the current HCS and appendices (OSHA HCS Redline, 2020, Document ID 0222; <https://www.osha.gov/dsg/hazcom/>).

#### A. Incorporation by Reference

OSHA is proposing to update the general incorporation by reference section, 29 CFR 1910.6, to include the national/international consensus standards listed below. OSHA does not intend to require chemicals already classified using an earlier version of a consensus standard to be reclassified. OSHA believes that requiring the reclassification of chemicals based on updated test methods could result in unnecessary economic impacts and create unnecessary confusion for stakeholders. OSHA is considering ways to clarify this in the final regulatory text, *e.g.*, by including a provision in the DATES section of the rule stating that chemicals classified based on older test methods, prior to the effective date of the rule, do not need to be reclassified, and invites comments on this topic.

In places where OSHA is proposing to cite to new or updated national/international consensus standards in the regulatory text and appendix B, OSHA

is proposing to include the title, edition/version, and year of the standard in the relevant reference for the benefit of stakeholders and for ease of compliance. OSHA is not currently proposing to add/update *all* existing references to consensus standards in the regulatory text and appendix B, but recognizes that in some places in the existing text consensus standards are cited without specific reference to the year, edition, or full title of the relevant standard. In such cases, stakeholders need to consult with § 1910.6 to find more details regarding the specific consensus standard that has been incorporated by reference in the HCS. For example, appendix B, Section B.6.3 (Flammable Liquids), incorporates by reference ASTM D1078, and § 1910.6 specifies that the version of that standard incorporated by reference is the one approved on May 15, 2005. Since there are many versions of ASTM D1078 available, OSHA realizes that the general reference to ASTM D1078 in appendix B could cause confusion to those classifying new chemicals. OSHA is requesting comments on whether additional information (year, edition/version, full title) should be added to all of the references to consensus standards that are already incorporated by reference in the HCS.

OSHA is proposing to incorporate by reference (in § 1910.6) the materials below. A brief description of each consensus standard is provided in the text below. A description of their use can be found in the Regulatory Text, Appendices, and Summary and Explanation for the Regulatory Text and Appendices (see Section XV.A and D) where the standard is referenced. Each standard is available for purchase through the publication agencies listed below:

- Regulatory Text—Paragraph c (Definitions)

- ASTM D 4359–90 (2019)—Standard Test Method for Determining Whether a Material is a Liquid or a Solid, Re-approved 2019: This consensus standard provides specific details regarding the test methods used to determine whether a viscous material is a liquid or solid.

- ASTM, International: <https://astm.org/Standard/standards-and-publications.html>.

- European Agreement Concerning the International Carriage of Dangerous Goods by Road (ADR): This consensus standard provides test methods for determining the specific physical characteristics of a liquid.

- <https://shop.un.org/series/european-agreement-concerning->

*international-carriage-dangerous-goods-road-adr*.

- Appendix B.1.3—Explosives

- UN ST/SG/AC.10/30/Rev.6, UN Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria, Part I: This consensus standard provides test methods to determine if a substance has explosive properties, the degree of sensitivity of the explosive properties, and stability of explosive properties. The consensus standard also provides information on the procedures for classification of explosive materials.

- [https://www.unece.org/tans/danger/publi/manual/maual\\_e.html](https://www.unece.org/tans/danger/publi/manual/maual_e.html).

- Appendix B.2.3—Flammable Gases

- ISO 10156:2010, Gases and Gas Mixtures—Determination of Fire Potential and Oxidizing Ability for the Selection of Cylinder Valve Outlets, Third Edition, April, 2010: This consensus standard provides specific details of the methods used to determine flammability of a gas or gas mixture. The standard also provides methods for determining if a gas or gas mixture is more or less oxidizing than air under atmospheric conditions. The intention of the standard is for classifying gases and gas mixtures as flammable gases and can be used to select the appropriate gas cylinder valve outlet for the flammability classification.

- International Organization for Standards: <https://iso.org/store.html>.

- ISO 817:2014 Refrigerants—Designation and safety classification: This consensus standard establishes a safety classification system based on the toxicity and flammability of the refrigerant. It also provides guidance on how to determine a refrigerant concentration limit.

- International Organization for Standards: <https://iso.org/store.html>.

- IEC 60079–20–1 ed. 1.0 (2010–01) Explosive atmospheres—Part 20–1: Material characteristics for gas and vapor classification—Test methods and data: This consensus standard provides guidance for classification of gas-air mixtures and vapor-air mixtures under normal conditions of pressure/temperature while also providing guidance on the appropriate selection of equipment. In addition, the standard provides guidance for determining the auto-ignition temperature of gas-air mixtures and vapor-air mixtures with additional information provided to guide selection of appropriate equipment for use in hazardous areas.

- International Electrotechnical Commission: <https://iec.ch/index/htm#buy>.

- DIN 51794 Determining the ignition temperature of petroleum products: This consensus standard provides detailed information on test methods used to determine the ignition temperature of petroleum products. The standard applies to flammable gases and liquids in a specific range of ignition temperature (75–650 °C) with particular emphasis on mineral oils hydrocarbons and their mixtures,

- German Institute of Standards: <https://din.de/en/about-standards/buy-standards>.

- UN ST/SG/AC.10/30/Rev.6, UN Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria, Part III: This standard provides test methods for determining the flammability of aerosols and gases. The standard provides additional information on the criteria used in classifying gases with regards to their flammability.

- [https://www.unece.org/tans/danger/publi/manual/maual\\_e.html](https://www.unece.org/tans/danger/publi/manual/maual_e.html).

- Appendix B.4—Oxidizing Gases

- ISO 10156: 2010, Gases and Gas Mixtures—Determination of Fire Potential and Oxidizing Ability for the Selection of Cylinder Valve Outlets, Third Edition, April, 2010: This consensus standard provides specific details of the methods used to determine flammability of a gas or gas mixture. The standard also provides methods for determining if a gas or gas mixture is more or less oxidizing than air under atmospheric conditions. The standard provides information on criteria that may be used for classifying gases and gas mixtures as flammable gases and may be used to select the appropriate gas cylinder valve outlet for the flammability classification.

- <https://www.iso.org/store.html>.

- Appendix B.14.2—Oxidizing Solids

- UN ST/SG/AC.10/30/Rev.6, UN Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria, Part III: This section of the standard provides detailed test methods for determining the potential of a solid substance to increase the burning potential or burning intensity of a combustible substance when the two are thoroughly mixed. The standard also provides schematic with criteria on classifying solid substances based on the oxidizing potential.

- [https://www.unece.org/tans/danger/publi/manual/maual\\_e.html](https://www.unece.org/tans/danger/publi/manual/maual_e.html).

- Appendix B.17.2—Desensitized Explosives

- UN ST/SG/AC.10/30/Rev.6, UN Recommendations on the Transport of

Dangerous Goods, Manual of Tests and Criteria, Part V: This section of the Manual identifies criteria for classification of desensitized explosives, and addresses the proper storage of these substances. The standard provides testing criteria and guidance on classifying, storing, and properly transporting goods according to their physical hazards.

- [https://www.unece.org/tans/danger/publi/manual/maual\\_e.html](https://www.unece.org/tans/danger/publi/manual/maual_e.html).

- UN ST/SG/AC.10/30/Rev.6, UN Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria, Part II: This standard provides information on the definition of desensitized explosives, the test methods used to evaluate a substance's ability to suppress its explosive properties when thoroughly mixed as a homogenous liquid and provides the criteria used to classify these substances based on their desensitizing properties.

- [https://www.unece.org/tans/danger/publi/manual/maual\\_e.html](https://www.unece.org/tans/danger/publi/manual/maual_e.html).

- Appendix B.17.3—Desensitized Explosives

- UN ST/SG/AC.10/30/Rev.6, UN Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria, Part II: This standard provides information on the definition of desensitized explosives, the test methods used to evaluate a substance's ability to suppress its explosive properties when thoroughly mixed as a homogenous liquid and provides the criteria used to classify these substances based on their desensitizing properties.

- [https://www.unece.org/tans/danger/publi/manual/maual\\_e.html](https://www.unece.org/tans/danger/publi/manual/maual_e.html).

The proposed inclusion of UN ST/SG/AC.10/30/Rev.6, UN Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria, in some sections of appendix B (B.1, B.2, B.3, B.4, B.14, and B.17) would align with the GHS Rev. 7 (UN GHS, 2017, Document ID 0060). However, an earlier version of UN ST/SG/AC.10 (Rev. 4) was incorporated by reference as part of the 2012 rulemaking and OSHA is not currently proposing to update all of the Rev. 4 references to Rev. 6 as part of this rulemaking. OSHA requests comments on whether it should, in the final rule, update all of the existing references to UN ST/SG/AC.10/30 to Rev.6 or add Rev. 6 references to the existing Rev. 4 references such that they would be alternative options for compliance.

UN ST/SG/AC.10/Rev.4 is included in the proposed regulatory text as part of the revision to the structure of § 1910.6(bb).

Copies of the standards are available for purchase from the issuing

organizations at the addresses or through the other contact information listed in § 1910.6 for these private standards organizations. The UN documents are available at no cost through the contact information listed above. In addition, in accordance with § 1910.6(a)(4), these standards are available for inspection at any Regional Office of the Occupational Safety and Health Administration (OSHA), or at the OSHA Docket Office, U.S. Department of Labor, 200 Constitution Avenue NW, Room N-3508, Washington, DC 20210; telephone: 202-693-2350 (TTY number: 877-889-5627). Due to copyright issues, OSHA cannot post consensus standards on the OSHA website or through *regulations.gov*.

### B. Regulatory Text

OSHA has proposed numerous revisions to the HCS regulatory text. The discussion of the proposed modifications is organized by paragraphs to the regulatory text with each modification/addition, and the reasons for and anticipated impact of each, described in detail below. Stakeholders can examine the redline strikeout version of the regulatory text at the OSHA HCS web page (<https://www.osha.gov/dsg/hazcom/>) or in the docket of this rulemaking (OSHA, 2020, Document ID 0222).

#### Paragraph (a) Purpose

Existing paragraph (a)(1) of the HCS states that the purpose of the standard is to ensure that the hazards of all chemicals produced or imported are classified, and that information concerning the classified hazards is transmitted to employers and employees. This provision currently explains that the requirements of the standard are intended to be consistent with the GHS Rev. 3. As the changes in this proposal would align the HCS with the GHS Revision 7, OSHA proposes to change the reference from Rev. 3 to Rev. 7.

#### Paragraph (b) Scope and Application

The scope section of the HCS identifies the chemicals that are (and are not) covered by the standard. Existing paragraph (b)(6)(x) excludes nuisance particulates from the standard where the chemical manufacturer or importer can establish that they do not pose any physical or health hazard covered by the standard. OSHA proposes a slight revision to this provision to make clear that nuisance particulates are excluded if they do not pose any physical hazard, health hazard, or other hazards (*i.e.*, hazard not otherwise classified (HNOC)) covered by the standard. This proposal

would clarify that all hazards covered by the standard must be considered when evaluating nuisance particulates.

#### Paragraph (c) Definitions

OSHA proposes to update three existing definitions and to add eight new terms and definitions to the HCS. In addition, the agency is proposing to eliminate one definition from the standard.

OSHA is proposing to add a definition of the term *Bulk Shipment* to the standard. The addition of this definition supports proposed paragraph (f)(5)(ii), which clarifies labeling requirements for bulk shipments of hazardous chemicals. The proposed definition would state that “bulk shipment” means any hazardous chemical transported where the mode of transportation (vehicle) comprises the immediate container (*e.g.*, contained in tanker truck, rail car, or intermodal container).

OSHA is proposing to add the term *Combustible Dust* to the standard. In updating the HCS in 2012, OSHA did not include a definition of combustible dust because the agency was considering a combustible dust rulemaking and the UNSCEGHS was also considering combustible dust classification and communication issues (see 77 FR at 17705). However, OSHA has not promulgated a combustible dust standard. Since 2012, the UNSCEGHS has adopted a definition; the GHS Rev. 7 defines combustible dust as “finely divided solid particles of a substance or mixture that are liable to catch fire or explode on ignition when dispersed in air or other oxidizing media” (definition adopted from ISO/IEC 80079-20-2 as referenced in UN GHS, 2017, Document ID 0060). OSHA has preliminarily determined that this definition is consistent with existing OSHA guidance on combustible dust hazards and proposes to adopt this definition (OSHA, 2020, Document ID 0190; OSHA, 2009, Document ID 0255). OSHA has several standards that use the term “combustible dust,” but do not define the term (*e.g.*, § 1910.272, Grain Handling Facilities). OSHA believes the proposed definition of the term for the HCS is consistent with the use of that term in those other standards.

OSHA is also proposing to revise the definition of *exposure* or *exposed*. The definition currently provides, in relevant part, that exposure or exposed means that an employee is subjected in the course of employment to a chemical that is a physical or health hazard. OSHA proposes to revise the definition to mean an employee is subjected in the course of employment to a “hazardous chemical,” rather than to “a chemical

that is a physical or health hazard,” to clarify that the HCS covers the hazards of all hazardous chemicals, including those considered to be HNOCs.

OSHA is proposing to include three new definitions for the terms *Gas*, *Liquid*, and *Solid*. The agency is proposing to include these terms to align with the GHS Rev. 7 (UN GHS, 2017, Document ID 0060). Although not included in the GHS, OSHA is proposing to add the temperature in equivalent degrees Fahrenheit and pressure in equivalent pounds per square inch (PSI) to the GHS definitions of gas and liquid because those measurements are more commonly used in the U.S.

Consistent with the GHS, OSHA proposes to define gas as a substance which (i) at 122 °F (50 °C) has a vapor pressure greater than 43.51 PSI (300 kPa) (absolute); or (ii) is completely gaseous at 68 °F (20 °C) at a standard pressure of 14.69 PSI (101.3 kPa). Also consistent with the GHS, OSHA proposes to adopt the definition of liquid as a substance or mixture which at 122°F (50 °C) has a vapor pressure of not more than 43.51 PSI (300 kPa (3 bar)), which is not completely gaseous at 68°F (20 °C) and at a standard pressure of 101.3 kPa, and which has a melting point or initial melting point of 68 °F (20 °C) or less at a standard pressure of 14.69 PSI (101.3 kPa). Furthermore, in accordance with the GHS, OSHA is proposing to include the following as part of the definition of liquid: A viscous substance or mixture for which a specific melting point cannot be determined shall be subjected to ASTM D4359–90 (the Standard Test Method for Determining Whether a Material Is a Liquid or a Solid (2019)); or to the test for determining fluidity (penetrometer test) prescribed in section 2.3.4 of Annex A of the European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR, 2019). Finally, OSHA proposes to adopt the GHS definition of solid as a substance or mixture which does not meet the definitions of liquid or gas.

Although OSHA did not include these terms in the 2012 update to the HCS, the agency is now proposing to include these definitions in order to improve clarity and ensure consistency in hazard communication both domestically and internationally. The agency anticipates that including these terms in the standard will clarify provisions under appendices B and D for classification of hazardous chemicals and preparation of SDSs. OSHA does not anticipate that these new definitions will impact other existing standards for construction or general industry. OSHA is requesting

comments on its preliminary decision to include these definitions in this update.

OSHA is proposing to update the definition of *hazardous chemical* to delete the reference to pyrophoric gas because OSHA is proposing to classify this hazard as a physical hazard in the flammable gas hazard class (see discussion of proposed revisions to appendix B.2) and it is no longer necessary to list it separately in the definition. Concomitantly, OSHA is proposing to delete the separate definition for *pyrophoric gas*.

OSHA proposes to add a definition for *immediate outer package* to mean the first packaging enclosing the container of hazardous chemical. While all containers of chemicals must be labeled, as discussed in the Summary and Explanation for paragraph (f), below, OSHA is proposing revised labeling requirements for small containers. Proposed paragraph (f)(12) would relax labeling requirements for small containers, but would require complete label information on the “immediate outer package.” For example, in the case of a kit, the container would be whatever surrounds the chemical itself (e.g., a vial), and the immediate outer package would be the first box or package surrounding the container.

The agency is also proposing to update the definition of *physical hazard* to mean a chemical that is classified as posing one of the following hazardous effects: Explosive; flammable (gases, liquids, or solids); aerosols; oxidizer (liquid, solid or gas); self-reactive; pyrophoric (liquid or solid); self-heating; organic peroxide; corrosive to metal; gas under pressure; in contact with water emits flammable gas; or desensitized explosive. The proposed definition also explicitly states that the criteria for determining whether a chemical is classified as a physical hazard are detailed in appendix B of the standard. The proposal would make two substantive changes to the current definition: (1) It would move the reference to aerosols out of the parenthetical following the word “flammable”; and (2) it would add a reference to desensitized explosives. These proposed revisions are intended to reflect the proposed new hazard classes for aerosols and desensitized explosives in appendix B in accordance with the GHS Rev. 7. These changes are discussed in greater detail in the Summary and Explanation of appendix B.

OSHA is proposing to add a definition of *Physician or other licensed health care professional (PLHCP)* to the standard. OSHA proposes to define this term as an individual whose legally

permitted scope of practice (i.e., license, registration, or certification) allows the individual to independently provide or be delegated the responsibility to provide some or all of the health care services referenced in paragraph (i) of the standard. The new definition is necessary in light of OSHA’s proposal to replace the phrase “physician and nurse” in paragraph (i), trade secrets with the term “PLHCP” to be consistent with other OSHA standards that use the term PLHCP, and to better reflect current medical practices. That change is discussed in greater detail in the Summary and Explanation of paragraph (i). OSHA believes the proposed definition of “PLHCP” is consistent with the way the agency has defined that term in all health standards promulgated since the bloodborne pathogen standard, 29 CFR 1910.1030, in 1991.

OSHA is also proposing to add a new definition, *released-for-shipment*, to mean a chemical that has been packaged and labeled in the manner in which it will be distributed or sold. This is a new term OSHA is proposing to use in paragraphs (f)(1) and (11) related to updating labels when new hazard information becomes available. OSHA notes that this definition is similar, but not identical to, the definition used by the U.S. Environmental Protection Agency’s (EPA’s) Pesticide Registration and Classification Procedures regulation, 40 CFR 152.3. EPA defines a product as released for shipment when the producer has packaged and labeled it in the manner in which it will be distributed or sold, or if it is stored in an area where finished products are ordinarily held for shipment. OSHA is not proposing to include chemicals that are stored in an area where finished products are usually held (but not packaged and labeled) in the definition of “released for shipment” because there do not appear to be any feasibility issues with ensuring that such chemicals are labeled with the most updated information. The agency is requesting comments on whether the proposed definition is appropriate for application to the HCS. OSHA is also interested in understanding whether the slight differences between OSHA’s and EPA’s definitions will pose any compliance issues for entities dealing with both OSHA and EPA labeling requirements. See the discussion of the proposed revisions to paragraph (f) for additional details.

#### Paragraph (d) Hazard Classification

OSHA is proposing two changes to paragraph (d)(1). OSHA proposes to revise the second sentence of paragraph

(d)(1) to read that for each chemical, the chemical manufacturer or importer shall determine the hazard classes, and where appropriate, the category of each class that apply to the chemical being classified *under normal conditions of use and foreseeable emergencies*. The language OSHA is proposing to add at the end of that sentence (“under normal conditions of use and foreseeable emergencies”) simply reiterates the scope language currently in paragraph (b)(2) and OSHA’s longstanding position that hazard classification must cover the normal conditions of use and foreseeable emergencies. As OSHA explained in its compliance directive for the HCS (OSHA, 2015, Document ID 0007), for example, known intermediates, by-products, and decomposition products that are produced during normal conditions of use or in foreseeable emergencies must be addressed in the hazard classification.

OSHA also proposes to add a new sentence to paragraph (d)(1) stating that the hazard classification shall include any hazards associated with a change in the chemical’s physical form or resulting from a reaction with other chemicals under normal conditions of use. OSHA believes this language is necessary because there has been some confusion about whether chemical reactions that occur during normal conditions of use must be considered during classification. The agency’s intent has always been to require information on SDSs that would identify all chemical hazards that workers could be exposed to under normal conditions of use and in foreseeable emergencies (see paragraph (b)(2)). This issue has been raised, for instance, when multiple chemicals are sold together with the intention that they be mixed together before use. For example, epoxy syringes contain two individual chemicals in separate sides of the syringe that are mixed under normal conditions of use. While OSHA intends for the hazards created by the mixing of these two chemicals to be considered in classification, those hazards need only appear on the SDS (see appendix D to § 1910.1200—Safety Data Sheets, section 3) and not on the label. For additional information, please see the Summary and Explanation for appendix D.

#### Paragraph (e) Written Hazard Communication Plan

OSHA is proposing a minor editorial correction in paragraph (e)(4). OSHA has found that an inadvertent misprint occurred in the print version of the CFR. Specifically, in the print version of the

CFR, paragraph (e)(4) references § 1910.20 instead of § 1910.1020. Notably, this error is reflected only in the print version of the CFR; the eCFR ([www.ecfr.gov](http://www.ecfr.gov)) is correct. OSHA proposes to fix this error so that the print and electronic versions of the standard are the same.

#### Paragraph (f) Labels and Other Forms of Warning

Paragraph (f) of the HCS provides requirements for labeling. OSHA is proposing to modify paragraphs (f)(1), (5), and (11), and is also proposing a new paragraph (f)(12).

Paragraph (f)(1), *Labels on shipped containers*, currently specifies what information is required on shipped containers of hazardous chemicals and also provides that HNOCs do not have to be addressed on the containers. OSHA proposes to revise paragraph (f)(1) to provide that, in addition to HNOCs, hazards resulting from a reaction with other chemicals under normal conditions of use do not have to be addressed on shipped containers. OSHA believes this information is not appropriate on containers because it might confuse users about the immediate hazards associated with the chemical in the container. However, information on hazards resulting from a reaction with other chemicals under normal conditions of use is important for downstream users, and OSHA is not proposing to change the existing requirements for these hazards to be indicated on SDSs (under appendix D) and addressed in worker training where applicable (under paragraph (h)). OSHA also proposes to add the word “distributor” to the third sentence of paragraph (f)(1) to make it consistent with the first sentence.

In new paragraph (f)(1)(vii), OSHA is proposing to add a requirement that the label include the date a chemical is released for shipment. The agency is proposing this change in conjunction with changes in paragraph (f)(11) related to relabeling of containers that are released for shipment but have not yet been shipped. Providing the date a chemical is released for shipment on the label would allow manufacturers and distributors to more easily determine their obligations when new hazard information becomes available.

Paragraph (f)(5) specifies label requirements that apply to the transport of hazardous chemicals from workplace to workplace. OSHA proposes to add the heading “Transportation” to this paragraph and to add two new paragraphs to (f)(5) that specify requirements related to transportation of hazardous chemicals.

OSHA is proposing to add new paragraph (f)(5)(ii) to address the transport of bulk shipments of hazardous chemicals (*e.g.*, in tanker trucks or rail cars). The proposed paragraph would specify that labels for bulk shipments of hazardous chemicals may either be on the immediate container or may be transmitted with shipping papers, bills of lading, or other technological or electronic means so that the information is immediately available in print to workers on the receiving end of the shipment. The proposed paragraph would codify policy from a 2016 guidance document that OSHA created jointly with DOT’s Pipeline Hazardous Materials Safety Administration (PHMSA), with the intent of providing stakeholders with clarity for how to properly label bulk chemicals in transport (PHMSA, 2016, Document ID 0244). OSHA requests comments on whether it is appropriate to add proposed paragraph (f)(5)(ii) to the HCS and whether the addition of that paragraph would provide clarity regarding labeling of bulk chemical shipments.

Under the current HCS, appendix C, paragraph C.2.3.3 provides that where a pictogram required by the DOT appears on a shipped container, the HCS pictogram for the same hazard (specified in C.4) shall not appear. This provision was intended to prevent confusion associated with having two different representations of the same hazard on the container (77 FR 17728). However, after learning that DOT updated its regulations to indicate that it does not consider the HCS pictogram to conflict with the DOT pictogram, OSHA no longer believes that having both pictograms will create confusion for workers handling the chemical. Accordingly, OSHA proposes to: (1) Delete the language currently in paragraph C.2.3.3 from appendix C; and (2) adopt new paragraph (f)(5)(iii) to provide that where a DOT pictogram appears on a label for a shipped container, the appendix C pictogram for the same hazard is allowed, but is not required, on the HCS label.

For example, in the case where a chemical is shipped in only its immediate container, such as a 55-gallon drum containing a flammable liquid, both a DOT label and an OSHA-compliant label would be required. Under the current standard, the flame pictogram on the OSHA-compliant label would be prohibited because the DOT label would contain the equivalent pictogram. The proposed rule would allow, but not require, the flame pictogram to appear on the OSHA-compliant label. This means chemical

manufacturers could use the same labels for shipping containers and for containers that are solely used in the workplace; this would avoid information loss and eliminate the need to develop or print additional labels.

Paragraph (f)(11) currently requires that chemical manufacturers, importers, distributors, or employers who become newly aware of any significant information regarding the hazards of a chemical revise the labels within six months of becoming aware of the new information and ensure that labels on containers of hazardous chemicals shipped after that time contain the new information. OSHA recognizes that, on some occasions, a chemical manufacturer or importer may become aware of significant hazard information after a chemical has already been labeled but before it ships. Therefore, OSHA proposes to add a sentence to paragraph (f)(11) providing that chemicals that have been released for shipment and are awaiting future distribution need not be relabeled; however, the proposed sentence also states that the chemical manufacturer or importer must provide the updated label for each individual container with each shipment. The purpose of this proposal is to account for the long distribution cycles of some products and the potential hazards workers could face in relabeling the immediate containers of hazardous chemicals that have already been prepared for shipment.

Following publication of the 2012 updates to the HCS, OSHA received feedback related to difficulties some chemical manufacturers were having complying with paragraph (f)(11), particularly in the case of chemicals that travel through long distribution cycles (Kenyon, 2017, Document ID 0182). Many products have straightforward supply chains and are packaged, labeled, and promptly shipped downstream. Other products, for example in the agrochemical sector, are packaged and labeled when they leave the chemical manufacturer's facility, but they may reside at a warehouse or distribution facility for extended periods of time (e.g., several years) before being shipped downstream. There are also instances where products may be returned from the downstream users to the distribution facility and then shipped to other customers (NGFA, 2016, Document ID OSHA-2016-0005-0018; AFIA, 2016, Document ID OSHA-2016-0005-0017).

The act of relabeling these products in warehouses or distribution facilities has the potential to pose occupational safety and health risks to employees. Relabeling each individual container

may require that employees open already secure packaging, a process that may result in potential chemical exposures. Furthermore, OSHA believes re-labeling of sealed hazardous chemical containers is not a common practice in warehouses and that warehouses may lack the equipment necessary to relabel products in a safe and effective manner.

OSHA has previously recognized the complexities involved with relabeling existing stock of hazardous chemicals. Following promulgation of the 2012 updates to the HCS, the HCS compliance directive (OSHA, 2015, Document ID 0007) provided enforcement guidance on the labeling of existing stock. Before June 1, 2015 (for manufacturers and importers), and before December 1, 2015 (for distributors), OSHA permitted chemical manufacturers, importers, and distributors with existing stock that was packaged (e.g., boxed, palletized, shrink wrapped, etc.) for shipment and labeled in accordance with the pre-2012 version of the HCS to ship those containers downstream without relabeling the containers with HCS 2012-compliant labels. However, the chemical manufacturer or importer generally had to provide an HCS 2012-compliant label for each individual container shipped and the appropriate HCS 2012-compliant SDS(s) with each shipment. After June 1, 2015, chemical manufacturers and importers of hazardous chemicals were required to ensure that each container was labeled with an HCS 2012-compliant label prior to shipping, and all distributors were generally required to ensure any chemicals shipped after December 1, 2015, were labeled in accordance with the 2012 updates to the HCS. OSHA used this enforcement policy as a basis for the proposed revisions to paragraph (f)(11).

OSHA has preliminarily determined that the proposed changes to paragraph (f)(11) would adequately address issues with long distribution cycles while still ensuring chemical users receive the most current hazard information. OSHA invites comments on the proposed revisions to this paragraph. In particular, OSHA requests comments on whether the proposed changes would adequately address issues associated with relabeling in cases of long distribution cycles, whether the proposed changes would provide sufficient flexibility, and whether the proposed revisions would alleviate safety concerns that would otherwise be associated with the relabeling of packaged stock.

OSHA is proposing a new paragraph, (f)(12), to address small container

labeling. Currently, the HCS requires that all shipped containers be labeled with the information specified in paragraph (f)(1). The HCS, as updated in 2012, requires considerably more information on the label than the standard required previously; labels must include all hazards, as well as pictograms and precautionary statements. Many stakeholders have told OSHA that they have difficulties including all of the required information from paragraph (f)(1) on the labels they use for small containers. In some cases, the information becomes too small for a person to read it, and while it is sometimes possible to use alternate types of labels (such as pull-out labels or tags), it is not always feasible to do so (Watters, 2013, Document ID 0200; Collatz, 2015, Document ID 0174; Blankfield, 2017, Document ID 0170). In response to these concerns, through letters of interpretation and the HCS directive (OSHA, 2015, Document ID 0007; Watters, 2013, Document ID 0200; Collatz, 2015, Document ID 0174; Blankfield, 2017, Document ID 0170), OSHA provided a practical accommodation to address situations where it is infeasible to provide all HCS-required label information directly on small containers through the use of pull-out labels, fold-back labels, or tags. The practical accommodation allows limited information to be included on the small container label, but requires complete label information to be provided on the outside packaging. OSHA proposes to incorporate this practical accommodation into the standard in new paragraph (f)(12).

OSHA is proposing that all of the small container labeling provisions apply only where the chemical manufacturer, importer, or distributor can demonstrate that it is not feasible to use pull-out labels, fold-back labels, or tags containing the full label information required by paragraph (f)(1). Proposed paragraph (f)(12)(ii)(A) through (E) would provide that labels on small containers that are less than or equal to 100 milliliter (ml) capacity must include, at minimum: Product identifier; pictogram(s); signal word; chemical manufacturer's name and phone number; and a statement that the full label information for the hazardous chemical is provided on the immediate outer package. Additionally, proposed paragraph (f)(12)(iii) would provide that no labels are required for small containers of 3 ml capacity or less where the chemical manufacturer, importer, or distributor can demonstrate that any label would interfere with the normal use of the container; however,

that same proposed paragraph would state that if no label is required, the container must bear, at minimum, the product identifier. For example, the product identifier (e.g., CAS number) could be etched on a 3 ml glass vial (container) to ensure that the identifier remains fixed to the vial. This type of identification would ensure that the chemical in the small container can be identified and matched with the chemical's full label information.

Proposed paragraph (f)(12)(iv) would provide that for any small container covered by paragraph (f)(12)(ii) or (iii), the immediate outer package must include the full label information required by paragraph (f)(1) for each hazardous chemical in the immediate outer package, along with a statement that the small container(s) inside must be stored in the immediate outer package bearing the complete label when not in use. This proposed paragraph would also state that labels affixed to the immediate outer package must not be removed or defaced, as required by existing paragraph (f)(9).

OSHA believes that proposed paragraph (f)(12) would provide chemical manufacturers, importers and distributors with flexibility in labeling small containers. The proposed paragraph is consistent with the small packaging examples provided in the GHS Annex 7: *Examples of Arrangements of the GHS Label Elements* (UN GHS, 2016, Document ID 0197), and would result in better alignment with Health Canada's *Hazardous Product Regulations (HPR)* small capacity container requirements (Health Canada, 2015, Document ID 0051). Specifically, the HPR, under 5.4(1), provides exemptions from certain labeling requirements (such as precautionary statements) for small capacity containers of 100 ml or less. In addition, under 5.4(2), the HPR provides labeling exemptions for containers of 3 ml or less if the label interferes with the normal use of the hazardous product. OSHA requests comments on the feasibility of the proposed small container labeling provisions. The agency also requests feedback about whether the proposed changes would improve safe handling and storage for chemicals in small containers.

#### Paragraph (g) Safety Data Sheets

SDSs provide important safety information to employers and employees on the use of hazardous chemicals in the workplace. Additionally, SDSs provide detailed technical information and serve as a reference source for exposed employees, industrial hygienists, safety

professionals, emergency responders, health care professionals, and other interested parties. While OSHA believes that information in SDSs has greatly improved with the standardized, 16-section format prescribed in the 2012 updates to the HCS, the agency is proposing two minor changes to paragraph (g) to ensure consistency and accessibility of the SDSs.

The proposed revisions to paragraph (g) are confined to paragraphs (g)(2) and (10). The purpose of paragraph (g)(2) is to identify what information must be included on an SDS. The first part of existing paragraph (g)(2) states that the chemical manufacturer or importer preparing the SDS shall ensure that it is in English. However, as permitted by paragraph (g)(1), some chemical manufacturers and importers may obtain, rather than prepare, SDSs. To minimize any potential confusion between paragraphs (g)(1) and (2), OSHA is proposing to revise paragraph (g)(2) by removing the reference to preparing the SDS. The first part of the first sentence in paragraph (g)(2) would be revised to read simply that the chemical manufacturer or importer shall ensure that the SDS is in English. This is a technical clarification intended to ensure consistency with paragraph (g)(1).

Paragraph (g)(10) addresses the form and storage of SDSs. The original intent of paragraph (g)(10) was to allow employers alternatives to SDSs within a plant site (see 48 FR 53337). Alternatives to SDSs, such as written operating procedures and manuals, are generally permitted. Existing paragraph (g)(10) also permits employers to design SDSs to cover groups of hazardous chemicals in a work area where it may be more appropriate to address the hazards of a process rather than individual chemicals. In any case, paragraph (g)(10) requires the employer to ensure that the required information is provided for each hazardous chemical and is readily accessible to employees. However, with the update to the HCS in 2012, OSHA changed the requirements of the SDS from a performance-oriented format to a standardized format. Standardizing the SDS format improved hazard communication by ensuring users could quickly find relevant information (see 77 FR 17596–98). Because SDSs now have a standardized format and are specific to individual hazardous chemicals, they are not permitted to be designed to cover groups of hazards, as currently provided in paragraph (g)(10). Therefore, OSHA is proposing a change to paragraph (g)(10) that would allow SDSs to be stored, rather than designed, in a way to cover

groups of hazardous chemicals in a work area. OSHA believes that this change would allow employers flexibility in how they keep SDSs in the workplace while also ensuring that the mandatory 16-section SDS is maintained. The agency is requesting comments regarding whether this proposed revision would require stakeholders to make any significant changes to their current practices.

#### Paragraph (i) Trade Secrets

This paragraph describes certain conditions under which a chemical manufacturer, importer, or employer may withhold the specific chemical identity (e.g., chemical name), other specific identification of a hazardous chemical, or the exact percentage (concentration) of the substance in a mixture, from the SDS. OSHA is proposing three significant changes within paragraph (i)(1) and the paragraphs thereunder. First, OSHA is proposing to revise paragraph (i)(1) to allow for concentration ranges to be claimed as a trade secret and to specify that it is section 3 of the SDS from which trade secret information may be withheld.

Second, OSHA is proposing new paragraph (i)(1)(iv), which would require that when an ingredient's exact concentration or concentration range is claimed as a trade secret, the SDS must provide the ingredient's concentration as a concentration range selected from a prescribed list of ranges. These ranges are in proposed paragraphs (i)(1)(iv)(A) through (M) as follows: (1) From 0.1% to 1%; (2) from 0.5% to 1.5%; (3) from 1% to 5%; (4) from 3% to 7%; (5) from 5% to 10%; (6) from 7% to 13%; (7) from 10% to 30%; (8) from 15% to 40%; (9) from 30% to 60%; (10) from 45% to 70%; (11) from 60% to 80%; (12) from 65% to 85%; and (13) from 80% to 100%. These ranges are consistent with those used in Canada, first described under the WHMIS 1988 Controlled Products Regulation (CPR) and re-implemented in 2018 under the HPR (Canadian Gazette II, 2018, Document ID 0101). Using the same concentration ranges as Canada, one of the U.S.'s major trading partners, is part of the two countries' efforts through the Regulatory Cooperation Council to align hazard communication to the greatest extent possible.

OSHA has received numerous inquiries about the use of trade secrets for concentration ranges (Colau, 2017, Document ID 0098; Nelson, 2017, Document ID 0099). Although chemical manufacturers and importers are permitted to use concentration ranges rather than an exact percentage on the

SDS when there is batch-to-batch variability in the production of a mixture or for a group of substantially similar mixtures with similar chemical composition, OSHA does not currently allow trade secret status for a concentration range (see 77 FR 17731). However, in response to feedback from stakeholders who have indicated that there are instances where a concentration range is also a trade secret, OSHA has preliminarily determined it is appropriate to permit concentration ranges to be claimed as trade secrets as long as the ranges prescribed in proposed paragraphs (i)(1)(iv)(A) through (M) are used (Nelson, 2017, Document ID 0099; Colau, 2017, Document ID 0098).

Third, proposed new paragraph (i)(1)(v) would require that the concentration range used on the SDS be the narrowest range possible. This proposed paragraph would also provide that if the actual concentration range falls between 0.1% and 30% and does not fit entirely into one of the prescribed ranges in proposed paragraphs (i)(1)(iv)(A) through (G), a single range created by the combination of two applicable consecutive ranges between (i)(1)(v)(A) and (G) may be disclosed instead, provided that the combined concentration range does not include any range that falls entirely outside the exact range in which the ingredient is present. For example, a chemical manufacturer that wishes to claim the concentration of a specific ingredient (e.g., 2.5%) as a trade secret would have to use the prescribed range in proposed paragraph (i)(1)(iv)(C) of 1% to 5%. If the ingredient is in the mixture at a concentration range of 0.9% to 2%, then the chemical manufacturer could combine the prescribed ranges in proposed paragraphs (i)(1)(iv)(B) and (C), resulting in a range of 0.5% to 5% on the SDS. If the ingredient is in the mixture at a concentration range of 5% to 7%, the chemical manufacturer would have to use the range in proposed paragraph (i)(1)(iv)(D) of 3% to 7%, because it is narrower than the range in proposed paragraph (i)(1)(iv)(E) of 5% to 10%.

OSHA is requesting comments on the proposed revisions to paragraph (i)(1). Specifically, the agency is interested in any experience stakeholders have had with developing SDSs using the prescribed concentration ranges and any concerns stakeholders have about using concentration ranges on SDSs. The agency is also requesting comments addressing the adequacy of hazard information provided by these ranges. Do these ranges provide sufficient information for downstream chemical

manufacturers to conduct hazard classifications? Are the ranges listed in proposed paragraphs (i)(1)(iv)(A) through (M) too wide (should they be narrowed)? Should OSHA allow combinations among all ranges (e.g., (i)(1)(v)(A) through (M)) or should the allowance for combining ranges be even more restrictive than proposed (e.g., (i)(1)(v)(A) through (E))?

OSHA is also proposing other changes in paragraph (i) to reflect the proposal to permit concentration ranges to be claimed as trade secrets and to adopt the “PLHCP” terminology in lieu of references to “physician or nurse.” See discussion of proposed changes to paragraph (c), Definitions, where OSHA explains that it is proposing to replace the phrase “physician and nurse” with “PLHCP” to be consistent with other OSHA standards and to better reflect current medical practices. The specific changes OSHA is proposing are as follows:

- OSHA is proposing to revise paragraph (i)(1)(iii) to change “percentage” to “concentration or concentration range.”
- OSHA is proposing to move existing paragraph (i)(1)(iv) to paragraph (i)(1)(vi) and to change “percentage” to “exact concentration or concentration range.”
- In paragraph (i)(2), OSHA is proposing to change “physician or nurse” to “PLHCP” and to replace “percentage of composition” with “concentration or concentration range.”
- OSHA is proposing to revise paragraph (i)(3) to change “percentage composition” to “exact concentration or concentration range” and to change the parenthetical from “(i.e., physician, industrial hygienist, toxicologist, epidemiologist, or occupational health nurse)” to “(e.g., PLHCP, industrial hygienist, toxicologist, or epidemiologist).”

#### Paragraph (j) Dates

OSHA is proposing to implement the revised provisions over a two-year phase-in period. OSHA proposes that the revisions become effective 60 days after the publication date (paragraph (j)(1)) and that chemical manufacturers, importers, and distributors evaluating substances comply with all modified provisions of the HCS no later than one year after the effective date (paragraph (j)(2)). OSHA also proposes that chemical manufacturers, importers, and distributors evaluating mixtures comply with all modified provisions no later than two years after the effective date (paragraph (j)(3)).

Proposed paragraph (j) would replace the regulatory text currently in

paragraph (j), as the dates specified in existing paragraph (j) have all passed. This proposed paragraph is based in part on stakeholder comments and the agency’s experience implementing the 2012 updates to the HCS. In 2012, OSHA did not stagger the compliance dates for substances and mixtures; however, OSHA believes that such a tiered approach may ease the compliance burden for manufacturers of mixtures that may rely on the hazard information in the SDSs from their ingredient suppliers to update the labels and SDSs for the mixtures. The changes OSHA is proposing in this update are far less complicated than the 2012 revision and would result in no change in hazard classification for the vast majority of chemicals. Additionally, the proposed update to paragraph (f)(11) addressing relabeling requirements for chemicals that have been released for shipment would also reduce the need for a lengthier implementation period. OSHA is requesting comments regarding the adequacy and appropriateness of the proposed compliance dates and on the feasibility of implementing a tiered compliance approach for substances and mixtures.

#### C. Appendix A

OSHA is proposing to update appendix A in several respects. The proposed changes are discussed in order of revisions to specific health hazards in appendix A, followed by general changes to definitions and terminology, clarification of mandatory requirements, and corrections. OSHA preliminarily concludes that all of the proposed changes to appendix A will improve classification and communication of hazards and thus better protect workers. Many of the proposed changes would align the HCS with the GHS Rev. 7. Aligning the HCS with the GHS would ease compliance burdens for U.S. stakeholders who must also comply with international requirements for hazard classification and communication.

OSHA is providing a redline strikeout version of appendix A, which reflects all of OSHA’s proposed revisions, in the docket and on the OSHA website (OSHA HCS Redline, 2020, Document ID 0222; <https://www.osha.gov/dsg/hazcom/>). This will allow interested parties to view all of the proposed changes in context. OSHA strongly encourages stakeholders to review that document in conjunction with the discussion of the proposed revisions below, as the discussion below does not fully describe all of the non-substantive or editorial changes OSHA is proposing.

## Revisions to Health Hazards in Appendix A

### General Classification Considerations

In Paragraph A.0.1, OSHA proposes to add a note from Paragraph 1.3.3.1.3 of the GHS Rev. 7 (UN GHS, 2017, Document ID 0060), providing that where impurities, additives, or individual constituents of a substance or mixture have been identified and are themselves classified, they should be taken into account during classification if they exceed the cut-off value/concentration limit for a given hazard class. OSHA did not include this note in the HCS in 2012 because the definition of “substance” in paragraph (c) references additives and impurities, and therefore the classification of substances necessarily takes impurities and additives into account. Nonetheless, the agency now believes that this note is useful to align with the GHS and has added this note as proposed A.0.1.3. Including this provision would clarify that manufacturers and importers must consider the hazards of all classified components when classifying chemicals. This would help ensure accurate classification of chemicals and therefore improve protections for workers.

OSHA also proposes to modify the introduction of paragraph A.0.4.1 to include mandatory language. The current text indicates that the sequence in the process of classification of mixtures is recommended. OSHA proposes to revise A.0.4.1 to read “Except as provided in A.0.4.2, the process of classification of mixtures is based on the following sequence” to specify that this process is mandatory.

### Acute Toxicity—(Appendix A.1)

In appendix A.1, OSHA proposes to revise the definition of acute toxicity to refer to serious adverse health effects (*i.e.*, lethality) occurring after a single or short-term oral, dermal, or inhalation exposure to a substance or mixture. (The current definition refers to adverse effects occurring following oral or dermal administration of a single dose of a substance, or multiple doses given within 24 hours, or an inhalation exposure of 4 hours.) This change is being proposed to align with the GHS Rev. 7 (UN GHS, 2017, Document ID 0060; UN GHS, 2016, Document ID 0131).

OSHA also proposes to revise the classification criteria for substances in A.1.2.1 to note that while some *in vivo* methods determine LD<sub>50</sub>/LC<sub>50</sub> values directly, other newer *in vivo* methods (*e.g.*, using fewer animals) consider other indicators of acute toxicity, such

as significant clinical signs of toxicity, which are used by reference to assign the hazard category. This change is being proposed to align with classification criteria in the GHS Rev. 7 (UN GHS, 2017, Document ID 0060; UN GHS, 2016, Document ID 0131).

OSHA is also proposing slight revisions to Table A.1.1, “Acute toxicity hazard categories and acute toxicity estimate (ATE) values defining the respective categories”, to align with the GHS Rev. 7 (UN GHS, 2017, Document ID 0060; UN GHS, 2016, Document ID 0131). The GHS presents the ATE range in Table A.1.1 using the term “ATE” to express the range, while the HCS currently uses the term “AND.” Therefore, OSHA proposes to change the “AND” in the acute toxicity estimate (ATE) ranges to “ATE” to align with the GHS Rev. 7. This modification would not change the classification criteria itself, but would be more technically accurate and consistent with the way the table is expressed in the European Commission’s (EC) Classification, Labelling, and Packaging of Substances and Mixtures (CLP) regulation (ECHA, 2017, Document ID 0256).

In paragraph A.1.2.3, OSHA proposes to include a new sentence at the end of the paragraph to clarify that both data from animal tests and human studies should be considered in evaluating acute toxicity. The new text states that in cases where data from human experience (*i.e.*, occupational data, data from accident databases, epidemiology studies, clinical reports) is also available, it should be considered in a weight of evidence approach consistent with the principles described in A.0.3. To ensure human data is considered in classifying chemicals for all acute toxicity hazard categories, the GHS added this clarifying text in paragraph 3.1.2.3 (UN GHS, 2016, Document ID 0131). OSHA is proposing these changes to paragraph A.1.2.3 to align with the GHS Rev. 7.

OSHA also proposes a new paragraph A.1.2.4, which is intended to correspond to Chapter 3.1, (paragraph 3.1.2.6.5) in the GHS Rev. 7 (UN GHS, 2017, Document ID 0060). This proposed paragraph would provide that in addition to classification for inhalation toxicity, if data are available that indicate that the mechanism of toxicity was corrosivity of the substance or mixture, the classifier must consider whether the chemical is corrosive to the respiratory tract. This proposed paragraph would clarify that the hazard *corrosive to the respiratory tract* is covered under the HCS. OSHA did not explicitly include the *corrosive to the respiratory tract* hazard in the HCS in

2012, but explained in OSHA 3844: *Hazard Communication: Hazard Classification Guidance for Manufacturers, Importers and Employers* (OSHA, 2016, Document 0008) that this hazard should be considered during classification. The Hazard Classification guidance explains that if the classifier has data indicating that there is acute inhalation toxicity with corrosion of the respiratory tract that leads to lethality, then the substance or mixture may be labeled with the additional hazard statement “*corrosive to the respiratory tract*.” However, if the classifier has data that indicates acute inhalation toxicity with corrosion of the respiratory tract and the effect does not lead to lethality, then the hazard may be addressed in the Specific Target Organ Toxicity hazard classes (see appendices A.8 and A.9). OSHA is including these clarifications in proposed A.1.2.4.1 and A.1.2.4.2, but is modifying the “may” language from the guidance to “must” language to ensure that *corrosive to the respiratory tract* is appropriately considered during the classification process.

In Figure A.1.1 and paragraph A.1.3.6.2.2, OSHA proposes to correct the cross-reference from A.1.3.6.2.3 to A.1.3.6.2.4. OSHA also proposes to amend paragraph A.1.3.6.2.3. If a mixture contains an ingredient of unknown acute toxicity at a concentration of at least 1 percent, paragraph A.1.3.6.2.3 currently requires a statement that “X” percent of a mixture consists of ingredient(s) of unknown toxicity on the label and SDS. OSHA proposes to revise this paragraph to require the statement to differentiate by route of exposure. For example, the statement(s) could read, “x % of the mixture consists of ingredient(s) of unknown acute oral toxicity” or “x % of the mixture consists of ingredient(s) of unknown acute dermal toxicity.” Given that it is possible to have unknown ingredients for more than one relevant route of exposure (*e.g.*, oral, dermal, inhalation), differentiating the statement by route would be helpful to chemical users. This proposed change would align with paragraph 3.1.3.6.2.2 in the GHS Rev. 7 (UN GHS, 2017, Document ID 0060; UN GHS, 2010, Document 0089).

OSHA also proposes to delete the second paragraph in A.1.3.6.2.3 because it is duplicative of the first paragraph.

### Skin Corrosion/Irritation and Serious Eye Damage/Eye Irritation—(Appendices A.2 and A.3)

OSHA is proposing more extensive revisions to the sections on skin corrosion/irritation and serious eye

damage/irritation (appendices A.2 and A.3) than it is proposing for the other health hazard sections in appendix A of the HCS. These two sections correspond to Chapters 3.2 and 3.3 in the GHS. The UNSCEGHS, in its 16th Session, assembled an informal working group to review the content of Chapters 3.2 and 3.3 in the GHS, and to propose editorial revisions in order to enhance clarity and user-friendliness in the application of the criteria (UN GHS, 2016, Document 0131). The group's primary focus was to change the order of the text to ensure that the classification strategy was clear, and to change the testing scheme to more of an evaluation scheme, since the GHS, like the HCS, is test method neutral. The work of the informal working group was not complete before OSHA published its updates to the HCS in 2012. The working group has since completed its efforts to clarify the skin corrosion/irritation and serious eye damage/irritation chapters. The work was approved by the UNSCEGHS in 2012 (UN GHS, 2012, Document ID 0212). Accordingly, OSHA is now proposing to revise appendices A.2 and A.3 to incorporate all of the modifications that were made to the GHS skin corrosion/irritation and serious eye damage/irritation chapters agreed to by the UNSCEGHS up to and including the GHS Rev. 7. This would ensure that OSHA remains aligned with the GHS. OSHA is not proposing any completely new provisions for the HCS; however, OSHA is proposing to revise the two appendices to align the language and format of the HCS with the GHS Rev. 7.

In appendix A.2, skin corrosion/irritation, OSHA proposes to modify paragraph A.2.1.2 to clarify the sequence in which data should be evaluated when classifying for skin corrosion/irritation using a tiered evaluation approach. The proposal would align the language in this paragraph with the tiered approach in Figure A.2.1. The first tier is existing human data, followed by existing animal data, followed by *in vitro* data, and then other sources of information.

The proposed changes to the skin corrosion/irritation criteria in paragraph A.2.2 are mainly editorial in nature. The classification criteria would remain the same, but the presentation of the information would be rearranged in a clearer, more logical fashion. In addition, OSHA is proposing new paragraph A.2.2.2.2, which is intended to provide classifiers with factors to be taken into consideration when evaluating irritant responses.

The proposed changes in paragraph A.2.3 are also mainly editorial in nature.

The criteria would remain the same, but clarifying text would be introduced into the section and the criteria would be presented in a more logical sequence.

OSHA also proposes to include a new note to Table A.2.3, "Concentration of ingredients of a mixture classified as skin Category 1 or 2 that would trigger classification of the mixture as hazardous to skin (Category 1 or 2)," to indicate how to classify the mixture when data are available for sub-categorization of Category 1. The proposed note would align with the note to Table 3.2.3 in the GHS Rev. 7 (UN GHS, 2017, Document ID 0060; UN GHS, 2012, Document ID 0132), and OSHA believes that it provides useful information for classifiers.

Figure A.2.1, "Tiered evaluation of skin corrosion and irritation potential", would remain largely the same under OSHA's proposed revisions to the appendix. However, OSHA is proposing to revise the title to "Tiered evaluation for skin corrosion and irritation." OSHA is also proposing to revise Steps 1a, 1b, and 1c of Figure A.2.1 to clarify that the parameter being evaluated is existing human or animal skin corrosion/irritation data. In addition, OSHA is proposing to modify the finding in Step 4 to clarify that high acid/alkaline reserve or no data for acid/alkaline reserve should be considered when the pH is  $\leq 2$  or  $\geq 11.5$ . OSHA is also proposing some revisions to the footnotes of Figure A.2.1.

- In proposed footnote (1), OSHA is proposing to revise the current footnote to include an additional sentence indicating that although human data from accident or poison center databases can provide evidence for classification, absence of incidents is not itself evidence for a not classified determination. In addition, the reference to evidence from ethically-conducted human clinical studies would be removed. The text indicating that there is no internationally accepted test method for human skin irritation testing would also be removed.

- In proposed footnote (3), OSHA is proposing to revise the existing note to exclude the examples currently provided.

- In proposed footnote (6), OSHA is proposing to revise the current note to clarify that all available information on a substance *must* (instead of *should*) be considered in making a determination based on the total weight of evidence. OSHA is also proposing a new sentence at the end of the footnote to indicate that negative results from applicable validated skin corrosion/irritation *in vitro* tests are considered in the total weight of evidence evaluation.

In paragraph A.2.4, OSHA is proposing to include in A.2.4.1.1 language stating that the tiered approach must be taken into account when evaluating mixtures. In addition, a new paragraph A.2.4.1.2 is proposed to indicate that when considering testing of mixtures, classifiers must use the tiered approach to help ensure an accurate classification, as well as to avoid unnecessary animal testing. This proposed paragraph also indicates that if there are no other data on the mixture besides pH, and the pH is extreme (pH  $\leq 2$  or pH  $\geq 11.5$ ), that information is sufficient to classify the mixture as corrosive to the skin. However, if the acid/alkaline reserve suggests that the mixture may not be corrosive despite the extreme pH, then further evaluation may be necessary.

In Table A.2.4, "Concentration of ingredients of a mixture for which the additivity approach does not apply, that would trigger classification of the mixture as hazardous to skin," OSHA proposes to delete the phrase "for which additivity does not apply" where it appears in the text of the table in order to reduce redundancy, as that language is already included in the title of the table. However, OSHA is proposing to modify the title of Table A.2.4 from "for which additivity does not apply" to "when additivity does not apply" to be consistent with the GHS Rev.7 (UN GHS, 2017, Document ID 0060).

In appendix A.3, serious eye damage/eye irritation, OSHA proposes to modify A.3.1.2 to clarify the sequence in which data should be evaluated when classifying for serious eye damage/eye irritation using a tiered evaluation approach. The proposal would align the language in this paragraph with the tiered approach in Figure A.3.1. The first tier is existing human data, followed by existing animal data, followed by *in vitro* data, and then other sources of information.

The changes OSHA is proposing in paragraphs A.3.2 and A.3.3, including Tables A.3.1 and A.3.2, are mainly editorial in nature. The classification criteria in these paragraphs would remain the same, but the presentation of the information would be rearranged and additional headings would be included to provide a clearer, more logical sequence. All of these proposed changes would conform with the GHS Rev. 7 (UN GHS, 2017, Document ID 0060; UN GHS, 2012, Document 0132).

Proposed paragraph A.3.2 provides a summary of the classification criteria for substances that is provided in Tables A.3.1 and A.3.2. In addition, proposed paragraph A.3.3.6 is a reorganization of existing paragraphs A.3.3.3 and A.3.3.4.

It would provide guidance on using the tiered approach and making weight of evidence decisions and also indicates a preference for not conducting new animal tests.

Under OSHA's proposed revisions, Figure A.3.1, "Tiered Evaluation for serious eye damage and eye irritation", currently titled "Evaluation strategy for serious eye damage and eye irritation", would remain largely the same. However, as in Figure A.2.1, OSHA is proposing to revise Steps 1a, 1b, and 1c to clarify that the parameter being evaluated is existing human or animal serious eye damage/eye irritation data. In addition, OSHA is proposing to modify the finding in Step 4 to clarify that high acid/alkaline reserve or no data for acid/alkaline reserve should be considered when the pH is  $\leq 2$  or  $\geq 11.5$ . OSHA is also proposing modifications to the footnotes of Figure A.3.1 to reflect the most recent test methods.

- In proposed footnote (3), OSHA is proposing to include an additional sentence that emphasizes that expert judgement should be exercised when making determinations from existing animal data indicating serious eye damage/eye irritation, as not all skin irritants are eye irritants.

- In proposed footnote (4), OSHA is proposing to include OECD Test Guideline 460 (Fluorescein leakage (FL)) as an additional example of an internationally accepted, scientifically validated test method for identifying eye corrosives and severe irritants. OSHA is also proposing an additional sentence for this footnote to indicate that there are presently no scientifically validated and internationally accepted *in vitro* test methods for identifying eye irritation.

- In proposed footnote (6), OSHA is proposing to revise existing language to make it clear that all available information on a substance *must* (instead of *should*) be considered in making a determination based on the total weight of evidence. In addition, OSHA is proposing to add two new sentences at the end of the footnote to indicate that the total weight of evidence, including information on skin irritation, may lead to classification for eye irritation and that negative results from applicable scientifically validated *in vitro* tests are considered in the total weight of evidence evaluation.

In paragraph A.3.4, OSHA is proposing several minor editorial changes to ensure consistency in the terminology used. For example, OSHA is proposing to use the term "serious eye damage" (rather than "eye corrosion") throughout the text to reflect the name of the hazard class.

Germ Cell Mutagenicity—(Appendix A.5)

OSHA is proposing to add a definition for germ cell mutagenicity in A.5.1.1 explaining that germ cell mutagenicity refers to heritable gene mutations, including heritable structural and numerical chromosome aberrations in germ cells occurring after exposure to a substance or mixture. OSHA is proposing this definition to align with the GHS Rev. 7 (UN GHS, 2017, Document ID 0060; UN GHS, 2016, Document ID 0131). Because of this new paragraph, the subsequent numbering of existing paragraphs in A.5.1 would be adjusted accordingly.

In A.5.4, *Examples of scientifically validated test methods*, paragraph A.5.4.2, OSHA proposes to delete the Mouse spot test (OECD 484) as an example of an *in vivo* somatic cell mutagenicity test, as it was deleted by the OECD on April 2, 2014. This change is consistent with the GHS Rev. 7 (UN GHS, 2017, Document ID 0060; UN GHS, 2014, Document 0087) and ensures that hazard classifications are being conducted with the most current scientific principles.

Reproductive Toxicity—(Appendix A.7)

In appendix A.7, Reproductive toxicity, OSHA proposes to revise the "effects on or via lactation" hazard category classification criteria to align with OSHA publication 3844 *Hazard Classification Guidance for Manufacturers, Importers and Employers* (OSHA 3844, 2016, Document 0008). During the development of the guidance document, it became apparent to OSHA that there were issues with regard to the classification criteria in existing Figure A.7.1(b). The hazard category for effects on or via lactation captures two separate effects:

- Substances that can interfere with lactation; and
- substances and their metabolites that may be transmitted through breast milk to children in amounts sufficient to cause concern for the health of the breast feeding child.

However, the current criteria do not adequately distinguish between these two separate effects. The first issue has both grammatical and substantive aspects and is found in the second sentence of Figure A.7.1(b), which currently reads:

"Chemicals that are absorbed by women and have been shown to interfere with lactation or that may be present (including metabolites) in breast milk in amounts sufficient to cause concern for the health of a breastfed

child, shall be classified to indicate *this property hazardous to breastfed babies*."

The italicized phrase is not grammatically correct and is also not correct as a matter of substance because it ignores the effects on lactation. As such, OSHA proposes to delete the text to indicate this property "hazardous to breastfed babies." In addition, the categories of evidence currently listed in paragraphs (a) through (c) of Figure A.7.1(b) all provide evidence for effects *via* lactation rather than effects *on* lactation. To be more accurate, and to avoid confusion on how to apply the criteria for effects on lactation, OSHA proposes to modify the third sentence in the Figure to read: "Classification for effects *via* lactation shall be assigned on the basis of:" These proposed changes would not affect the classification of substances or mixtures as reproductive toxicants; however, they would be more accurate and provide more clarity for classifiers.

OSHA proposes to modify paragraph A.7.2.5.1 to include OECD Test Guideline 443, *Extended One Generation Reproductive Toxicity Study*, as an additional method for one or two generation toxicity testing. Additionally, in Table A.7.1 "Cut-off values/concentration limits of ingredients of a mixture classified as reproductive toxicants or for effects on or via lactation that trigger classification of the mixture", OSHA is proposing a correction to the top left heading from "ingredients classified as" to "ingredient classified as." OSHA believes that the use of the word "ingredients" in this context may be confusing, as it may suggest that the additivity principle should be applied. Therefore, OSHA is proposing this change for clarity. These proposed modifications in appendix A.7 are consistent with the GHS Rev. 7 (UN GHS, 2017, Document ID 0060; UN GHS, 2014, Document ID 0221).

Specific Target Organ Toxicity-Single Exposure—(Appendix A.8)

In appendix A.8, OSHA proposes to make a correction to paragraph A.8.1.6 to correctly name the hazard class as "specific target organ toxicity—single exposure" instead of "specific organ systemic toxicity single exposure." Also, in paragraph A.8.2.1.7.3, OSHA proposes to delete the erroneous inclusion of the second use of the word "evidence" in the second sentence.

OSHA proposes to include the concept of "relevant ingredient" when classifying mixtures containing Category 3 ingredients using the additivity approach. Under the HCS, as updated in

2012, the additivity principle was introduced in paragraph A.8.3.4.5. However, a “relevant ingredient” for this procedure had not been established. Proposed new paragraph A.8.3.4.6 would provide that in cases where the additivity approach is used for Category 3 ingredients, the “relevant ingredients” of a mixture are those which are present in concentrations  $\geq 1\%$  (w/w for solids, liquids, dusts, mists, and vapors and v/v for gases), unless there is a reason to suspect that an ingredient present at a concentration  $< 1\%$  is still relevant when classifying the mixture for respiratory tract irritation or narcotic effects. This proposed paragraph would align with the GHS Rev. 7 (UN GHS, 2017, Document ID 0060; UN GHS, 2014, Document 0221).

#### Aspiration Hazard—(Appendix A.10)

The proposed changes to appendix A.10 would provide clarification on the classification criteria for mixtures when data are available for all ingredients or only for some ingredients. OSHA is proposing new paragraph A.10.3.3.1 to clarify that the concept of “relevant ingredient” applies and that relevant ingredients are those that are present in concentrations of at least 1%. In addition, a new heading, “Category 1,” is proposed as new paragraph A.10.3.3.2. Proposed A.10.3.3.2.1 and A.10.3.3.2.2 would clarify that the principle of additivity applies in appendix A.10, but OSHA is not proposing any substantive changes to the classification criteria. These proposed changes would align with the GHS Rev. 7 (UN GHS, 2017, Document ID 0060; UN GHS, 2014, Document 0221).

#### Changes to Definitions and Terminology, Clarification of Mandatory Requirements, and Corrections Definitions

OSHA proposes to update appendix A to include changes to the health hazard definitions to reflect those adopted by the GHS Rev. 7 (UN GHS, 2017, Document ID 0060; UN GHS, 2016, Document ID 0131). Since OSHA revised the HCS in 2012, the UNSCEGHS has revised all of the health hazard definitions in the GHS. These modifications to the health hazard definitions were incorporated as a result of the work of the UNSCEGHS Practical Classification Issues working group. The scope of the working group is to clarify the GHS classification criteria, as appropriate, and to provide working examples to illustrate application of the criteria. The previous health hazard definitions were not consistent with

respect to form or content, and many of the definitions were taken directly from the OECD test guidelines.

The UNSCEGHS determined that the definitions should be more general and neutral with respect to test guidelines and that test guideline criteria should not be part of a definition. The group also determined that the health hazard definitions should be clear and concise and that there should be a clear differentiation between “definitions” and “general considerations” text. OSHA is proposing to adopt all of the revised health hazard definitions from the GHS Rev. 7 in appendix A, as well as corresponding changes to text throughout the appendix. For example, in some cases OSHA is proposing to remove OECD test guidelines from definitions and to move them to paragraphs outlining classification criteria. The health hazard definitions that OSHA is proposing in appendix A are:

- Acute toxicity refers to serious adverse health effects (*i.e.*, lethality) occurring after a single or short-term oral, dermal, or inhalation exposure to a substance or mixture.
- Skin corrosion refers to the production of irreversible damage to the skin; namely, visible necrosis through the epidermis and into the dermis occurring after exposure to a substance or mixture.
- Skin irritation refers to the production of reversible damage to the skin occurring after exposure to a substance or mixture.
- Serious eye damage refers to the production of tissue damage in the eye, or serious physical decay of vision, which is not fully reversible, occurring after exposure of the eye to a substance or mixture.
- Eye irritation refers to the production of changes in the eye, which are fully reversible, occurring after exposure of the eye to a substance or mixture.
- Respiratory sensitization refers to hypersensitivity of the airways occurring after inhalation of a substance or mixture.
- Skin sensitization refers to an allergic response occurring after skin contact with a substance or mixture.
- Germ cell mutagenicity refers to heritable gene mutations, including heritable structural and numerical chromosome aberrations in germ cells occurring after exposure to a substance or mixture.
- Carcinogenicity refers to the induction of cancer or an increase in the incidence of cancer occurring after exposure to a substance or mixture.

- Reproductive toxicity refers to *adverse effects on sexual function and fertility* in adult males and females, as well as developmental toxicity in the offspring, occurring after exposure to a substance or mixture.

- Specific target organ toxicity-single exposure (STOT-SE) refers to specific, non-lethal toxic effects on target organs occurring after a single exposure to a substance or mixture.

- Specific target organ toxicity-repeated exposure (STOT-RE) refers to specific toxic effects on target organs occurring after repeated exposure to a substance or mixture.

- Aspiration hazard refers to severe acute effects such as chemical pneumonia, pulmonary injury or death occurring after aspiration of a substance or mixture.

- Aspiration means the entry of a liquid or solid chemical directly through the oral or nasal cavity, or indirectly from vomiting, into the trachea and lower respiratory system.

#### Terminology Issues

The HCS is currently somewhat inconsistent in the way the terms “hazard category” and “toxicity category” are used throughout appendix A. In some cases the terms are used interchangeably, while in other instances the terms are intended to have different meanings. OSHA has reviewed appendix A and is proposing revisions to ensure that these terms are used appropriately and consistently. As such, OSHA proposes to delete the term “toxicity category” and replace it with “hazard category” in various places, including paragraphs A.0.5, A.1, A.8, A.9, and A.10. These proposed changes would align with the GHS Rev. 7 (UN GHS, 2017, Document ID 0060; UN GHS, 2012, Document 0084).

#### Mandatory Language

OSHA is proposing to update a number of provisions in appendix A to make it clear that those provisions are mandatory. For example, OSHA proposes to change the term “should” to “must” in paragraph A.3.4.3.3. The change would clarify that the cut-off value/concentrations in Table A.3.3 are mandatory when determining if a mixture must be classified as seriously damaging to the eye or an eye irritant.

#### Corrections

OSHA proposes to correct a few errors that currently exist in the HCS. OSHA erroneously did not include appendix A.4, respiratory or skin sensitization, in the list of health hazards referenced in the “concentration of mixtures” paragraph at A.0.5.1.3. OSHA proposes

to add a reference to appendix A.4 in paragraph A.0.5.1.3 to clarify that the concentration of mixtures bridging principle applies to respiratory and skin sensitization. Similarly, appendix A.4 was also erroneously excluded from the list of health hazards referenced in the “interpolation within one toxicity category” paragraph at A.0.5.1.4. Thus, OSHA also proposes to add a reference to appendix A.4 in paragraph A.0.5.1.4 to clarify that the interpolation bridging principle applies to respiratory and skin sensitization. In addition, OSHA proposes to correct the cross-reference from A.1.3.6.2.3 to A.1.3.6.2.4 in Figure A.1.1 and paragraph A.1.3.6.2.2.

#### D. Appendix B

OSHA is proposing a number of changes to appendix B. First, since the HCS was aligned with the GHS in 2012, new physical hazard classes or hazard categories have been added to the GHS Rev. 7 (UN GHS, 2017, Document ID 0060). OSHA proposes to adopt those additions. Second, the GHS Rev. 7 (UN GHS, 2017, Document ID 0060) contains several updates to consensus standards and testing methods. Although the HCS does not require testing and permits classifiers to use data from literature or experience for classification purposes, OSHA is proposing to update consensus standards and testing methods referenced in appendix B in accordance with the GHS Rev. 7 to ensure that data considered for classification incorporate updated scientific principles. Third, OSHA is proposing certain corrections and clarifications to appendix B to address (1) previous inadvertent omissions from the GHS or the HCS; (2) changes made to the GHS to improve clarity or technical accuracy; and (3) how some hazard classes should be evaluated in light of the addition of new hazard classes in the GHS. These proposed changes are discussed below and would align the HCS with the GHS while improving the classification and communication of hazards<sup>59</sup> and maintaining or enhancing worker safety and health. Additionally, as noted elsewhere, aligning the HCS with the GHS would ease compliance burdens for U.S. stakeholders that must also comply with international requirements for hazard classification and communication.

OSHA is also proposing to make a limited number of changes to appendix B that arise out of its implementation of the HCS, as updated in 2012. These changes, explained below, would clarify

compliance requirements. OSHA believes that all of these proposed changes maintain existing safety and health protections while easing or having no effect on the compliance burdens for regulated entities.

Finally, OSHA explains below that it is not proposing to incorporate one update reflected in the GHS Rev. 7 because that particular update is inconsistent with the scope of the HCS.

OSHA is providing a redline strike out version of appendix B, which reflects all of OSHA’s proposed revisions, in the docket and on the OSHA website (OSHA, 2020, Document ID 0222; <https://www.osha.gov/dsg/hazcom>). This will allow interested parties to view all of the proposed changes in context. OSHA strongly encourages stakeholders to review that document in conjunction with the discussion of the proposed revisions below, as the discussion below does not fully describe all of the non-substantive or editorial changes OSHA is proposing. Explosives—(Appendix B.1)

OSHA is proposing a few minor amendments to appendix B.1, Explosives. The first change that OSHA is proposing involves a clarification to the classification criteria for Division 1.6 explosives in B.1.2(f). Under the GHS Rev. 3, one of the criteria for classification of an article [OSHA uses the term “item” in the HCS] as a Division 1.6 explosive is that it contains “only” extremely insensitive detonating chemicals (UN GHS, 2009, Document ID 0085). The GHS Rev. 7 (UN GHS, 2017, Document ID 0060) states that the criteria is met if the article [“item” in the HCS] “predominantly” contains extremely insensitive detonating chemicals. OSHA is proposing to make the same change to paragraph B.1.2(f) of appendix B in the HCS. Changing the criteria from containing “only” extremely insensitive detonating chemicals to “predominantly” containing extremely insensitive detonating chemicals is more technically accurate and better aligns with the guidance in test series 7 in the UN Manual of Tests and Criteria (UN TDG, 2016, Document ID 0151). OSHA believes that consistency in the use of terms will reduce confusion for chemical manufacturers or importers when classifying explosives.

OSHA is also proposing to add two notes from the GHS (UN GHS, 2017, Document ID 0060) to appendix B, paragraph B.1.3.1, that are related to the addition of the desensitized explosives hazards class (proposed appendix B.17), which is discussed later in this document. The first new note OSHA is

proposing to add (Note 2) would provide that explosives for which explosive properties have been suppressed or reduced must be classified as desensitized explosives. The second new note OSHA proposes (Note 3) would provide that some chemicals that are exempt from classification as explosives under UN Recommendations on the Transport of Dangerous Goods guidelines still have explosive properties, which must be communicated in section 2 (Hazard identification) and section 9 (Physical and chemical properties) of the SDS, as appropriate. The notes would be incorporated in the HCS with edits to change these provisions from recommendations in the GHS to requirements in the HCS (e.g., “may be a candidate for classification as” in the GHS would be revised to “shall be classified as” in the HCS) and to revise the GHS terminology to terminology more appropriate for the HCS (e.g., “substances and mixtures” in the GHS would be revised to “chemicals” in the HCS).

#### Flammable Gases—(Appendix B.2.)

OSHA is proposing several changes to the Flammable Gases hazard class (appendix B.2). Most significantly, OSHA is proposing to subdivide Category 1 of this class into two subcategories, 1A and 1B, and to specify that pyrophoric gases and chemically unstable gases are to be classified as Category 1A. These proposed changes would provide more detailed information about the flammable gas hazards and track changes made in the GHS Rev. 7 (UN GHS, 2017, Document ID 0060) since OSHA updated the HCS in 2012. These proposed changes would allow downstream users to have a better understanding of the severity of the hazards associated with flammable gases. Downstream users could then use this information to take appropriate precautions or determine if a substitute chemical is less hazardous.

The HCS currently lists two categories for flammable gases—Category 1 (Extremely flammable) and Category 2 (flammable)—that are based on the percentage of the gas in a mixture with air that is ignitable and on ranges of flammability in air. In practice, with the current criteria, almost all flammable gases (except ammonia and methyl bromide, which are treated separately) are classified as Category 1. This means that, for hazard identification and communication purposes, no distinctions are being drawn between gases that exhibit a wide spectrum of flammable properties. OSHA has preliminarily concluded that Category 1

<sup>59</sup> Specific changes to the hazard and precautionary statements are discussed below in the section on appendix C.

is too broad and can lead downstream users to choose a chemical without realizing that an alternative choice is actually less flammable. For example, 2,3,3,3-Tetrafluoropropene is a non-ozone depleting refrigerant which ignites less rapidly or violently than some other flammable gases. Many of these types of gases were developed as a result of the Montreal and Kyoto protocols, international treaties intended to phase out gases that are ozone depleting (UN GHS, 2016, Document ID 0138). However, with the current classification system, propane, which has a rapid, explosive ignition with a burn velocity of 46 cm/s, and 2,3,3,3-Tetrafluoropropene (R-1234yf), which has a slow, weak ignition, with a burn velocity of 1.5 cm/s, would both be classified as Category 1 gases, thus making it appear that the two gases are equally flammable when in fact 2,3,3,3-Tetrafluoropropene is considerably less flammable (UN GHS, 2016, Document ID 0138).

OSHA and DOT actively participated in the UN negotiations (joint informal working group) in 2015 to ensure that flammable gases are properly evaluated, classified and communicated. The joint informal working group activities included identifying, gathering, and reviewing data on “less flammable” gases, including the conduct of numerous burning velocity tests using approved test methods, as well as tests to demonstrate ignition behavior, flame propagation, and the speed of the flame front (UN GHS, 2016, Document ID 0254).

The revised classification criteria in Table 2.2.1 in Chapter 2.2 of the GHS Rev. 7 (UN GHS, 2017, Document ID 0060) reflect recommendations made by the joint informal working group. The joint informal working group agreed that all flammable gases currently classified as Category 1 flammable gases should remain so. This decision allows the transport classification and communication scheme to remain the same. However, the joint informal working group agreed that Category 1 should be separated into two sub-categories, Category 1A and Category 1B, when data is available on burning velocity and lower flammability limit. This separation allows for more precise classification of chemicals and more appropriate communication of the hazards associated with flammable gases.

This proposed approach for classifying flammable gases is also consistent with the approach described in ANSI/ASHRAE Standard 34–2013—Designation and Safety Classification of Refrigerants (ANSI/ASHRAE, 2013,

Document ID 0160). The ANSI/ASHRAE standard allows refrigerant gases (which can be category 1A or 1B) to be classified based on both the lower flammability limit and burning velocity (see Figure 6.1.4 and Section 6.1.3.2.1 (ANSI/ASHRAE, 2013, Document ID 0160). OSHA’s proposed cut-off for the burning velocity for category 1A and 1B chemicals is the same as that in the ASHRAE standard. Therefore, the proposed approach is consistent with accepted scientific principles and industry norms.

OSHA has preliminarily concluded that the classification scheme in Table 2.2.1 of the GHS Rev. 7 (UN GHS, 2017, Document ID 0060) maintains safety for workers while allowing for more precise hazard classification and communication. Therefore, OSHA is proposing to replace Table B.2.1 of the HCS with the criteria from Table 2.2.1 in the GHS Rev. 7 (UN GHS, 2017, Document ID 0060). The only modification that OSHA proposes making to the GHS Table 2.2.1 is to add units of measurement used in the United States (*e.g.*, degrees Fahrenheit). Under the proposed new table, all flammable gases that are currently classified as Category 1 flammable gases would be classified as Category 1A, unless data on flammability limit or fundamental burning velocity indicates that the gas should be classified as Category 1B. For a gas to be classified in Category 1B, data would have to show that its lower flammability limit is more than 6% by volume in air or its fundamental burning velocity is less than 10 cm/s; in addition, the gas could not be either pyrophoric or chemically unstable. Since the HCS does not require testing, the data required to classify a gas as a Category 1B flammable gas could be obtained from literature. However, if data is lacking in the literature, then testing would be necessary to establish that a newly-developed flammable gas qualifies for classification as a Category 1B flammable gas. The joint informal working group compiled a list of data available on burning velocity and flammability limits for pure flammable gases (OSHA, 2017, Document ID 0164).

When OSHA revised the HCS in 2012, pyrophoric gases were not classified under the GHS, Rev. 3 (UN GHS, 2009, Document ID 0085). Therefore, to ensure that the hazards of pyrophoric gases would continue to be covered and communicated, OSHA maintained the approach taken in the HCS starting in 1994. This involved addressing pyrophoric gases under the definition of “hazardous chemical” and maintaining a definition for “pyrophoric gas” in

paragraph (c) of the HCS (77 FR 17704). While OSHA retained the definition for “pyrophoric gas” when it updated the HCS in 2012, the agency explained it also intended to continue to work with the UNSCEGHS to add the pyrophoric gas hazard to the GHS, along with two other hazards that OSHA covered under the HCS but that were not classified under the GHS: Simple asphyxiants and combustible dust (77 FR 17704). Since OSHA revised the HCS in 2012, the UNSCEGHS updated the criteria for flammable gases to include pyrophoric gases (UN GHS, 2014, Document ID 0086; UN GHS, 2017, Document ID 0060). The UNSCEGHS agreed that pyrophoric gases, as well as chemically unstable gases, should always be classified as Category 1A flammable gases because of the nature of these two types of gases; pyrophoric gases ignite spontaneously in air at temperatures of 54 °C (130 °F) or below, and chemically unstable gases are able to react explosively even in the absence of air or oxygen. Under the GHS Rev. 7 (UN GHS, 2017, Document ID 0060), pyrophoric gases and chemically unstable gases are both classified as Category 1A. OSHA preliminarily agrees with this decision and proposes incorporating it into appendix B.2.

If, as proposed, OSHA adds pyrophoric gases as a sub-category of flammable gases in appendix B.2, and, as proposed, includes a definition of pyrophoric gas in appendix B.2., it would no longer be necessary to include these gases as part of the definition of “hazardous chemical” or to include a definition for “pyrophoric gas” in § 1910.1200(c). Therefore, OSHA proposes to delete those terms in § 1910.1200(c). OSHA also proposes to incorporate the definition of “pyrophoric gas” found in the GHS Rev. 7 (UN GHS, 2017, Document ID 0060), in paragraph B.2.1. OSHA currently defines pyrophoric gas as a chemical in the gaseous state that “will ignite” spontaneously in air at a temperature of 130 °F (54.4 °C) or below. The GHS Rev. 7 defines a pyrophoric gas as a flammable gas that is “liable to ignite” spontaneously in air at a temperature of 54 °C (130 °F) or below (UN GHS, 2017, Document ID 0060). The change in the definition from a gas that “will ignite” to a gas that is “liable to ignite” was made because some pyrophoric gases may have a delayed ignition time (UN GHS, 2013, Document ID 0086). OSHA preliminarily finds the term “liable to ignite” to be more accurate, from a technical perspective. OSHA does not believe that these changes would have a significant impact on the scope of

gases considered pyrophoric gases, nor does OSHA expect that chemical manufacturers or importers would need to reclassify chemicals due to these changes.

As noted above, OSHA proposes adding a new sub-category for chemically unstable gases to the flammable gases hazard class to allow for more accurate communication of the hazards associated with those gases. OSHA proposes to adopt the GHS Rev. 7 definition of a chemically unstable gas, *i.e.*, a flammable gas that is able to react explosively even in the absence of air or oxygen (UN GHS, 2017, Document ID 0060), in paragraph B.2.1. Consistent with the GHS Rev. 7 (UN GHS, 2017, Document ID 0060), under proposed Table B.2.1, a Category 1A chemically unstable gas would be further sub-characterized into one of two categories based on the temperature and pressure at which it becomes unstable. The proposed criteria for Category 1A/A chemically unstable gases are flammable gases which are chemically unstable at 20 °C (680 °F) and a standard pressure of 101.3 kPa (14.7 psi). The proposed criteria for Category 1A/B chemically unstable gases are flammable gases which are chemically unstable at a temperature greater than 20 °C (680 °F) and/or a pressure greater than 101.3 kPa (14.7 psi).

As chemically unstable gas is a subcategory of flammable gases, any chemical that meets the criteria for chemically unstable gas meets the current definition of flammable gas. While these hazards are currently classified in flammable gases under the HCS the UNSCEGHS noted that these gases exhibit slightly different behaviors and have the propensity to react dangerously even in the absence of any reaction partner (*e.g.*, air or oxygen) and should have different hazard communication elements (UN GHS, 2010, Document ID 0210). Types of flammable gases or gas mixtures that might be candidates for classification as chemically unstable are flammable gases with functional groups such as triple-bonds, adjacent or conjugated double-bonds, halogenated double-bonds, and strained rings (UN GHS, 2010, Document ID 0210). Because chemical manufacturers are currently classifying chemically unstable gases as flammable gases, OSHA does not consider these gases to be a new hazard. Instead, OSHA believes the addition of chemically unstable gases as a separate category in the appendix for flammable gases (appendix B.2) would improve the way the hazards of these gases are identified, evaluated, and communicated.

The GHS Rev. 7 (UN GHS, 2017, Document ID 0060) added three clarifying notes under Table 2.2.1 that were not included in the GHS Rev. 3 (UN GHS, 2009, Document ID 0085). The notes provide guidance on the classification of flammable gases under the new hazard categories. OSHA is proposing to add these notes to the HCS following Table B.2.1 (as new Note 2, Note 3, and Note 4) because they allow for better hazard classification.

The GHS Rev. 7, in Chapter 2.2.4.2, provides additional guidance on the classification of flammable gases, including the new hazard categories of pyrophoric gases, chemically unstable gases, and 1B flammable gases (UN GHS, 2017, Document ID 0060). It includes updated references to consensus standards and test methods (*i.e.*, ISO 10156:2010), and new references to consensus standards and test methods related to the new hazard categories (*i.e.*, ISO 817:2014, IEC 60079–20–1 ed1.0 (2010–01), or DIN 51794, and Part III of UN of the Manual of Tests and Criteria). OSHA proposes to adopt these changes in the HCS appendix B.2.3, with edits to make the GHS criteria mandatory (*i.e.*, changing “should” to “shall”), to add U.S. units of measurement (*e.g.*, Fahrenheit), and to add statements that cited standards and test methods are incorporated by reference under 29 CFR 1910.6. This proposed modification would also align with the GHS Rev. 7 (UN GHS, 2017, Document ID 0060). However, OSHA does not intend to require those already classified using an earlier version of ISO 10156, only those classifying new chemicals or chemicals not already classified. To incorporate this guidance from the GHS Chapter 2.2.4.2, OSHA is proposing edits to existing paragraph B.2.3. (B.2.3.1, as proposed) and new paragraphs B.2.3.2, B.2.3.3, and B.2.3.4.

#### Aerosols—(Appendix B.3)

OSHA is proposing to follow the GHS Rev. 7 (UN GHS, 2017, Document ID 0060) by expanding the existing Flammable Aerosols hazard class (appendix B.3) to include non-flammable aerosols as well as flammable ones. Under the GHS Rev. 3 and the current HCS, Chapter 2.3 and appendix B.3, respectively, were titled “Flammable Aerosols.” Under the GHS Rev. 3, the hazards presented by non-flammable aerosols were either not classified at all or, more likely, were classified in another hazard class or physical hazard class (*e.g.*, gases under pressure) (UN GHS, 2009, Document ID 0085). Flammable aerosols were likely to be classified as both

flammable aerosols and gases under pressure.

OSHA believes that most aerosols are classified as gases under pressure under the GHS Rev. 3 (and accordingly under the existing HCS) because of the design criteria of the aerosols (ERG, 2015, Document ID 0163) under DOT regulations. Under DOT regulations, aerosols are non-refillable receptacles containing a gas compressed, liquefied, or dissolved under pressure, and the highest permissible pressure is 180 psig at 130 °F (see 49 CFR 171.8, 173.306). Accordingly, under DOT regulations, most aerosols meet the current HCS criteria for gases under pressure, which are gases contained in a receptacle at a pressure of 200 kPa (29 psi) or more, or which are liquefied or liquefied and refrigerated (see existing paragraph B.5.1 in appendix B.5). However, OSHA believes that classifying aerosols as gases under pressure may not accurately identify the hazards of aerosols because aerosol containers differ from pressurized gas cylinders in terms of container characteristics and failure mechanisms, as described further below.

Since the GHS Rev. 3 (UN GHS, 2009, Document ID 0085), the UNSCEGHS and the UN Sub-committee of Experts on the Transport of Dangerous Goods (UNSCETDG) agreed to rename Chapter 2.3 “Aerosols” and to add a new non-flammable aerosol hazard category, Category 3, to the aerosols hazard class (UN GHS, 2018, Document ID 0249). This hazard category captures aerosols that (1) contain 1% or less flammable components (by mass); and (2) have a heat of combustion that is less than 20 kJ/g.

Before proposing to adopt this category for non-flammable aerosols, OSHA reviewed the impact of this change to ensure that it would not compromise worker safety and health. OSHA assessed the hazards associated with aerosol containers and compressed gas cylinders. An ERG study evaluated how aerosol products and gases under pressure differ in terms of container characteristics, failure mechanisms, and previous incidents (ERG, 2015, Document ID 0009).

The ERG report concluded that sizes and pressures of compressed gas cylinders far exceed those of hand-held containers typically used for aerosol products (ERG, 2015, Document ID 0009). The report also noted differences in failure mechanisms for pressurized cylinders versus aerosols (ERG, 2015, Document ID 0009). As an example, increased temperatures can result in the release of container contents from the activation of pressure relief devices on

cylinders, whereas increased temperatures can result in the bursting of aerosol cans, which do not contain pressure relief devices. Also, hazards from falling cylinders include the release of contents following the valve breaking, the cylinder becoming a projectile or pinwheel, or the crushing of employees in the area; although aerosol containers can be damaged if they are dropped or punctured, they do not pose the same hazards as falling cylinders.

ERG reported that occupational incidents involving cylinders included explosions during high temperature activities (such as welding) and explosions resulting from mechanical deformation (e.g., from falling cylinders), over-pressurization of cylinders (e.g., from overfilling, which can result in a rupture of the cylinder), or leaks due to corrosion (ERG, 2015, Document ID 0009). Most incidents with aerosol cans involved explosions following heating or puncture of the can (ERG, 2015, Document ID 0009). The ERG report concluded that although non-flammable aerosol cans do not present a significant fire hazard, they can present a hazard from bursting resulting from thermal content expansion during heating. (ERG, 2015, Document ID 0009).

In addition to the ERG report, OSHA also considered data from the agency's Fatality and Catastrophe Information Summary (FatCat) database, located at <https://www.osha.gov/pls/imis/accidentsearch.html> (Document ID 0204), to evaluate the nature and severity of injuries and fatalities resulting from the use of aerosols and compressed gases. To determine if an incident was related to aerosols or compressed gas cylinders, OSHA searched for the keywords "aerosol," "spray," or "foam" (to identify aerosols), and the keywords "compressed," "cylinder," or "CNG" (to identify compressed gases). The data reviewed is available in the docket (OSHA, 2019, Document ID 0204).

From 1995 to 2014 there were more incidents related to the use of compressed gas cylinders than to the use of aerosol containers, but the percentage of the incidents that resulted in fatalities was similar (29% versus 28%, respectively). However, as explained below, fatalities are more likely to be associated with the container itself when compressed gas receptacles are in use as compared to situations involving aerosol containers. (OSHA, 2019, Document 0204).

Fatalities associated with use of compressed gas cylinders and aerosol containers primarily fall into three

categories: (1) Incidents due to the contents of the container, such as flash fires or explosions; (2) incidents due to the container itself, such as incidents related to pressure, container failure, or ruptures; and (3) incidents unrelated to the use of the container, such as heart attacks or falls. A higher percentage of fatalities fell into the second category (incidents related to the container itself) for compressed gas cylinders (64% of the compressed gas cylinder fatalities) than for aerosol containers (17% of the aerosol fatalities). Conversely, a greater proportion of fatalities related to aerosols were attributed to reasons other than the container itself (83% for aerosol containers versus 36% for cylinders) (OSHA, 2019, Document ID 0204). This included fatalities related to the contents of the container and those in the third, "miscellaneous," category (where the fatality could not be directly related to the use of the container, e.g., situations such as heart attacks, falls, lack of training that occurred while employees were working with, or that generally related to, the use of aerosol or compressed gas cylinders) (OSHA, 2019, Document 0204). Thus, it appears that employees are at greater risk of a fatality due to the failure of the container if they are working with compressed gas cylinders than they are if they are working with aerosol cans.

Following a review of the data and the ERG report, OSHA preliminarily concludes that a new category for non-flammable aerosols is appropriate. OSHA believes this category would allow the hazards of non-flammable aerosols to be more appropriately classified and communicated, resulting in improved worker protection. The new hazard category would provide downstream users with more appropriate communication on the label by adding precautionary statements: *Keep away from heat, hot surfaces, sparks, open flames and other ignition sources; No smoking; and Do not pierce or burn, even after use* (see appendix C). Additionally, this new classification would ensure compressed gas pictograms are not included on aerosol labels, eliminating the risk of "over warning" about the hazards of aerosol containers (UN, 2010, Document ID 0095).

Specific changes OSHA is proposing include: Updating the aerosol hazard class to include non-flammable aerosols (hazard Category 3 in Table B.3.1), changing the name of appendix B.3 from "Flammable Aerosols" to "Aerosols," replacing the phrase "flammable aerosols" with "aerosols" throughout appendix B.3, as appropriate, and adding clarifying information from the

GHS Rev. 7 to paragraph B.3.2 (UN GHS, 2017, Document ID 0060). For example, OSHA is proposing to revise Note 2 to B.3.2.1 to explain that aerosols do not fall within the scope of gases under pressure, but may fall within the scope of other hazard classes. OSHA's preliminary conclusion that aerosols (flammable and non-flammable) should not also be classified as gases under pressure would ensure that the appropriate hazard warnings are presented on aerosol containers.

OSHA is proposing to adopt the GHS Rev. 7 (UN GHS, 2017, Document ID 0060) criteria for a non-flammable aerosol (i.e., an aerosol that does not meet the criteria for Category 1 or 2, contains less than or equal to 1 percent flammable components (by mass), and has a heat of combustion less than 20 kJ/g), and to add those criteria as new Category 3 in Table B.3.1. This new category, Category 3, would update hazard communication requirements to better reflect the true hazards of non-flammable aerosols. This would result in changing the labeling for any such aerosols that are currently classified as compressed gases. In these situations, the "gas cylinder" pictogram would become unnecessary, as this hazard class would no longer be considered a compressed gas, the signal word "danger" would change to "warning," due to the decreased hazard, and a hazard statement of "contains gas under pressure; may explode if heated" would change to "pressurized container, may burst if heated", which would more accurately reflect the hazards associated with this category (see proposed appendix C.4.16). As discussed above, OSHA believes that this approach would better differentiate between the hazards associated with compressed gases and the hazards associated with aerosols.

#### Oxidizing Gases—(Appendix B.4)

OSHA proposes to revise the note in B.4.1, and the text in the "Additional classification considerations" paragraph at B.4.3, to clarify that the provisions are referring to the most recent version of the ISO 10156 standard, (ISO, 10156, 2010). This proposed change would provide more clarity on the definition and classification of oxidizing gases and lead to more accurate classification and improved communication. This proposed modification would also align with the GHS Rev. 7 (UN GHS, 2017, Document ID 0060). However, OSHA does not intend to require those already classified using an earlier version of ISO 10156, only those classifying new chemicals or chemicals not already classified.

**Gases Under Pressure—(Appendix B.5)**

OSHA is proposing to change the definition of gases under pressure in B.5.1 to align with the GHS Rev. 7 (UN GHS, 2017, Document ID 0060). OSHA proposes to add a temperature of 20 degrees Celsius (68 degrees Fahrenheit) to the definition so that the full definition would define gases under pressure as gases which are contained in a receptacle at a pressure of 200 kPa (29 psi) (gauge) or more at 20 °C (680 °F), or which are liquefied or liquefied and refrigerated. The change is intended to clarify that the pressure of the receptacle is measured at standard conditions. OSHA is also proposing to add a note to Table B.5.1 to clarify that aerosols should not be classified as gases under pressure. This proposed change is a consequence of OSHA's proposal to add a new hazard category for non-flammable aerosols, as discussed previously.

**Flammable Liquids—(Appendix B.6)**

OSHA is proposing to make three clarifying changes to the flammable liquid hazard class in appendix B.6. First, OSHA is proposing to add a reference to the Flammable Liquids standard, specifically 29 CFR 1910.106(a)(14), in paragraph B.6.3 in order to provide additional guidance about methods that can be used to determine flashpoint.

Second, after updating the HCS in 2012, OSHA realized there may be a concern with ensuring that information needed to determine the appropriate storage for flammable liquids is adequately documented on the SDS. Per 29 CFR 1910.106(a)(5), when an accurate boiling point is unavailable, or for mixtures which do not have a constant boiling point, the boiling point may be based on the 10% point of a distillation performed in accordance with the Standard Method of Test for Distillation of Petroleum Products, ASTM D-86-62. Together with an appropriately measured flash point, this boiling point can be used to categorize the mixture for use with Table H-12 in § 1910.106 to determine the maximum allowable container size and type. Use of a boiling point reported in section 9 of an SDS (physical properties), which is based on the "first drop" (or initial) distillation temperature in D-86, will likely be conservative, but may lead to more restrictive storage requirements than would be the case using the 10% distillation point (see appendix D, section 9(f)). OSHA is proposing to add a clarifying footnote to B.6.3 explaining that to determine the appropriate container size and container type for a

flammable liquid, the boiling point must be determined by the methods specified under OSHA's Flammable Liquids standard (29 CFR 1910.106(a)(5)) and listed on the SDS. In addition, the proposed note would explain that the chemical manufacturer, importer, or distributor must clearly note on the SDS (in sections 7 and 9) if a calculation other than initial boiling point was used for storage purposes. OSHA did not intend for the updated HCS classification requirements for flammable liquids to impact the longstanding storage requirements under 29 CFR 1910.106 and views this proposed note as a method to ensure that the proper container size and type will be used for storing flammable liquids and that all necessary information is appropriately communicated on the SDS. OSHA is not proposing any changes to the classification criteria for flammable liquids under the HCS. OSHA is requesting comments on whether a footnote like the one proposed for B.6.3 should also be inserted in appendix D, section 9.

Finally, OSHA realized that a note regarding cross-classification of aerosols was inadvertently omitted from appendix B.6 (flammable liquids). In appendix B.3 (flammable aerosols), note 2 to the classification criteria currently indicates that "[f]lammable aerosols do not fall additionally within the scope of flammable gases, flammable liquids, or flammable solids." The HCS currently contains a cross-referencing note in appendix B.2 (flammable gases), but OSHA inadvertently omitted the statement in appendix B.6 (flammable liquids). OSHA is therefore proposing to add a note stating that aerosols should not be classified as flammable liquids in appendix B.6, following Table B.6.1, for consistency and to minimize confusion. This would align with the GHS Rev. 7 (UN GHS, 2017, Document ID 0060).

**Flammable Solids—(Appendix B.7)**

The only change proposed to appendix B. 7 (flammable solids) is a new note (Note 2) following Table B.7.1 stating that aerosols should not be classified as flammable solids. As with flammable liquids, the UNSCEGHS observed this omission in the flammable solids chapter, and the GHS Rev. 7 includes this note (UN GHS, 2017, Document ID 0060).

**Self-Heating Chemicals—(Appendix B.11)**

OSHA proposes adding a note to Table B.11.1. This proposed note would explain that classification of solid chemicals shall be based on tests

performed on the chemical as presented. For example, if the chemical is presented for supply or transport in a physical form different from that which was tested and which is considered likely to materially alter its performance in a classification test, classification must be based on testing of the chemical in the new form. Although this note was included in the GHS Rev. 3 (UN GHS, 2009, Document ID 0085), and incorporated into appendices B.1, B.7, B.10, B.12 and B.14 in the HCS in 2012, it was inadvertently omitted from appendix B.11. OSHA is proposing to add the note to be consistent with the GHS and the way the HCS treats other physical hazards.

**Chemicals Which, in Contact With Water, Emit Flammable Gases—(Appendix B.12)**

OSHA proposes to update the classification criteria for Category 3 of this hazard class in Table B.12.1. In the GHS Rev. 3 (UN GHS, 2009, Document ID 0085) and the existing HCS, one of the criteria for a Category 3 classification is that the maximum rate of evolution of the flammable gas is "equal to or greater than 1 liter per kilogram of chemical per hour." However, this criteria does not accurately reflect the corresponding criteria in Test N.5 (test method for substances which, in contact with water, emit flammable gases) in Part III, sub-section 33.4.1.4.4.4 of the UN Manual of Tests and Criteria (UN TDG, 2016, Document ID 0151), which provides that the maximum rate of evolution of the flammable gas is *greater* than 1 liter per kilogram of chemical per hour. OSHA proposes to delete the words "equal to or" in the Category 3 criteria in Table B.12.1 to make the classification criteria consistent with the criteria in the test method. This will align the HCS with the GHS Rev.7 (UN GHS, 2017, Document ID 0060) and would not affect worker protections.

**Oxidizing Solids—(Appendix B.14)**

OSHA is proposing to add a second set of classification criteria to B.14.2 and to Table B.14.1 based on a new UN test method. Under the GHS Rev. 3 (UN GHS, 2009, Document, ID 0085), classification of oxidizing solids was based only on Test O.1 from Part III, sub-section 34.4.1 of the UN Manual of Tests and Criteria (UN TDG, 2016, Document ID 0151). This is reflected in the current HCS, appendix B.14. However, the test material used as the reference mixture in Test O.1 has been noted to pose a cancer hazard and is difficult to purchase. Therefore, a new test, Test O.3, Gravimetric tests for

oxidizing solids, has been added to Part III, sub-section 34.4.3 of the UN Manual of Tests and Criteria (UN TDG MTC, 2016, Document ID 0151). This new test underwent a thorough evaluation, including round robin testing, led by the UNSCETDG (UN SCETDG, 2016, Document ID 0150). Test O.3 uses a reference mixture of calcium peroxide and cellulose, whereas Test O.1 uses the reference substances potassium bromate and cellulose (UN TDG, 2016, Document ID 0165).

Consistent with the GHS Rev. 7 (UN GHS, 2017, Document ID 0060), OSHA proposes to allow oxidizing solids to be classified using either Test O.1 or Test O.3. Since the proposed classification criteria would allow the use of data from either Test O.1 or O.3, data from existing classifications could be used and no new testing would be required for substances or mixtures that were previously classified based on Test O.1.

OSHA also proposes to update Note 1 to Table B.14.1 to reflect a 2017 revision to the International Maritime Solid Bulk Cargoes Code for testing of explosion hazards (IMSBC, 2017, Document ID 0141).

#### Corrosive to Metals—(Appendix B.16)

OSHA is not proposing to make any changes to appendix B.16, Corrosive to Metals. This is notable because OSHA has preliminarily decided not to adopt a note that was added in the GHS Rev. 7. Table 2.16.2 in Chapter 2.16 of the GHS Rev. 7 (UN GHS, 2017, Document ID 0060) contains a note stating: “Where a substance or mixture is classified as corrosive to metals but not corrosive to skin and/or eyes, some competent authorities may allow the labelling provisions described in 1.4.10.5.5.” Chapter 1.4.10.5.5 contains labeling provisions that apply to “substances or mixtures which are in the finished state as packaged for consumer use.” OSHA has preliminarily concluded that the note in question, and the labeling provisions it refers to, are not applicable to the HCS because the HCS applies only to use of chemicals in the workplace, and not to consumer products (see 29 CFR 1910.1200(b)(5)(v)). Therefore, OSHA is not proposing to adopt the note found in Table 2.16.2 of Chapter 2.16 of the GHS Rev. 7.

#### Desensitized Explosives—(Appendix B.17)

OSHA is proposing to follow the GHS Rev. 7 (UN GHS, 2017, Document ID 0060) by adding a new physical hazard class for desensitized explosives. Desensitized explosives are chemicals that are treated in such a way to

stabilize the chemical or reduce or suppress its explosive properties. These types of chemicals can pose a hazard in the workplace when the stabilizer is removed, either as part of the normal work process or during storage of the chemical. Therefore, it is important that the hazards be identified and appropriately communicated.

In the HCS, as revised in 2012, OSHA acknowledged, consistent with the GHS Rev. 3 (UN GHS, 2009, Document ID 0085), that these chemicals are considered explosives if the wetting agent is removed, by including the precautionary statement “keep wetted with” and instructing the chemical manufacturer, importer, or distributor to specify appropriate material for wetting *if drying out increases the explosion hazard* (see existing appendix C at C.4.14). However, the hazard statement, signal word, pictogram and other precautionary statements required under existing C.4.14 are geared to more conventional explosives. This gap in communication was recognized as early as 2005, when the UNSCEGHS noted that desensitized explosives may become explosive under certain circumstances—especially after long term storage and during handling and use (UN GHS, 2005, Document ID 0206). The UNSCEGHS examined the issue of hazard classification for desensitized explosives and concluded a new hazard class was warranted to ensure the appropriate hazard statement, signal word and precautionary statements for desensitized explosives were incorporated into the GHS (UN GHS, Report, 2014, Document ID 0087). The GHS Rev. 7 (UN GHS, 2017, Document ID 0060; UN GHS, 2016, Document ID 0142) separately classified desensitized explosives with a full set of unique label elements (including the appropriate signal word, hazard statement, pictogram, and precautionary statements). As separately classified, desensitized explosives are labeled with a flame pictogram rather than the explosive bomb used for explosives, and the precautionary statements are tailored to the specific traits of desensitized explosives (*e.g., Avoid heating under confinement or reduction of the desensitizing agent.*).

OSHA reviewed the UNSCEGHS reports (UN GHS, 2014, Document ID 0087) on desensitized explosives and has preliminarily concluded that the hazard class should also be added to the HCS to improve communication about these hazards. While the chemicals captured by the desensitized explosives hazard class are currently covered under the scope of the HCS as explosives, OSHA believes there is a benefit to

providing classification criteria and corresponding hazard communication specific to this hazard. Adding the proposed new hazard class to the HCS would ensure downstream users receive more accurate hazard information on labels and in SDSs for these chemicals.

For these reasons, and to align with the GHS, OSHA proposes to add the desensitized explosives hazard class to the HCS as appendix B.17. Proposed appendix B.17 provides relevant definitions and general considerations, specifies applicable classification criteria, and includes information about additional classification considerations for this hazard class. It also references several sections from the UN Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria that will be incorporated by reference. As with all hazard classes, the GHS Rev. 7 (UN GHS, 2017, Document ID 0060) does not require testing and allows classifiers to use data reported in the literature (UN TDG, 2016, Document ID 0151) that was generated using specified (or equivalent) test methods. Proposed appendix C.4.30, discussed later in this document, contains proposed communication elements for desensitized explosives.

Proposed appendix B.17 is based on Chapter 2.17 of the GHS Rev. 7 (UN GHS, 2017, Document ID 0060). OSHA is proposing to adopt most of the classification language on desensitized explosives from Chapter 2.17 of the GHS Rev. 7 (UN GHS, 2017, Document ID 0060) to minimize deviations from the GHS. However, OSHA has carefully reviewed each of the hazard classification criteria within the context of the HCS and is proposing to modify some of the language. These edits include changing some recommendations in the GHS to mandatory requirements in the HCS (*i.e.*, changing “should” to “shall”); revising some terms in the GHS to more accurately reflect terminology in the HCS (*e.g.*, changing “manufacturer/supplier” to “manufacturers, importers, and distributors”); revising text to make it clear that data for classification can be obtained from the literature; and removing references to classifications for transportation that do not apply under the HCS. Some of the GHS text stressing where a classification scheme is for scenarios other than transportation would also be removed (*e.g.*, terms referring to storage, supply, and use); this change is being proposed because the HCS does not cover transportation, and it is therefore not necessary to include such language in appendix B of the HCS. OSHA also proposes adding a definition for “phlegmatized” in a

footnote because many stakeholders may be unfamiliar with that term from the UN Recommendations (UN GHS, 2017, Document ID 0060).

OSHA is not proposing to include portions of the GHS Chapter 2.17 that do not relate specifically to the method of classification for desensitized explosives; this is the same approach OSHA took in the 2012 update. For example, similar to how OSHA has addressed the other hazard classes, OSHA is not proposing to adopt the decision logics from the GHS in appendix B.17; OSHA may, however, use them in guidance materials. Also, OSHA did not include text relating to hazard communication in proposed appendix B.17 because this information is contained in proposed appendix C.

#### *E. Appendix C*

OSHA is proposing a number of updates to appendix C of the HCS in an effort to improve communication of hazard information on labels. These proposed changes will: (1) Address labeling requirements for the new hazard classes and categories in appendix B (physical hazards); (2) align the HCS with the GHS Rev. 7; and (3) improve alignment of the HCS and Health Canada's labeling requirements in furtherance of the goals of the RCC.

Appendix C is the mandatory appendix that includes the requirements and instructions for the allocation of label elements. Paragraph (f)(2) of the HCS requires the chemical manufacturer, importer, or distributor to ensure that the information provided on the label is in accordance with appendix C. Appendix C provides hazard statements, signal words, pictograms, and precautionary statements for all four essential aspects of hazardous chemical management (prevention, response, storage and disposal), as well as general labeling instructions.

As discussed in the 2009 NPRM proposing to align the HCS with the GHS, the precautionary statements, unlike the hazard statements, were not harmonized (but were merely codified) under the GHS, meaning that numbers were assigned to them. This meant that the statements were not yet considered to be part of the harmonized text (like hazard statements); rather they were included in the GHS as suggested language (74 FR 50282–83). OSHA chose to add these statements in the final HCS rule in 2012 (77 FR 17574). However, since the promulgation of the updates to the HCS in 2012, the UNSCEGHS has continued work to improve the utility of precautionary statements by providing better guidance on the allocation of statements,

updating the statements to provide better protection, and adding new statements for new hazard classes and categories. OSHA is proposing a number of changes based on new precautionary statements and instructions in the GHS Rev. 7. Additionally, since 2012, OSHA has continued to work with other Federal agencies on crosscutting labeling issues. The updates proposed in appendix C would ensure alignment with DOT labeling regulations and are expected to provide the same level of protection for workers as the current HCS. OSHA is also proposing updates to appendix C based on the agency's cooperation with Health Canada under the RCC. The RCC was reaffirmed through a memorandum of understanding that was signed in June 2018 (RCC, 2019, Document ID 0217), with the expectation of aligning efforts for international trade requirements between the two countries.

Overall, OSHA expects that the proposed changes to appendix C would provide improved safety information and greater detail and clarity for downstream users. They also would provide better consistency that bridges the jurisdictional differences between countries and Federal agencies. Aligning the HCS with the GHS and other Federal or international regulations would ease compliance burdens for U.S. stakeholders that must also comply with those requirements. The changes that OSHA is proposing would lead to improved communication of hazard information, which would maintain or enhance the safety and health of workers.

The changes OSHA is proposing to appendix C are extensive. OSHA addresses the substantive proposed changes in the discussion below, and a redline strike out version of appendix C, which reflects all of OSHA's proposed revisions, is available in the docket and on the OSHA website (OSHA HCS Redline Document, 2020, Document ID 0222; <https://www.osha.gov/dsg/hazcom/>). This will allow interested parties to view all of the proposed changes in context. OSHA strongly encourages stakeholders to review that document in conjunction with the discussion of the proposed revisions below, as the discussion below does not fully describe all of the non-substantive or editorial changes OSHA is proposing. Proposed Changes to C.1–C.3

The instructions currently found in the beginning of appendix C (see C.1–C.3) provide directions and information about the signal words, pictograms, hazard statements and precautionary statements required per C.4. OSHA is

proposing changes to C.1–C.3 to align with the GHS Rev. 7, better harmonize the HCS with DOT regulations, and better harmonize the HCS with Health Canada.

First, OSHA proposes to revise Figure C.1—Hazard Symbols and Classes to include “HNOC (non-mandatory)” as a hazard identified by the exclamation mark pictogram. This proposed change reflects OSHA's agreement with Health Canada to permit the exclamation mark pictogram to be used for HNOCs. While OSHA does not require labelling for HNOC hazards, Health Canada requires a pictogram, signal word, hazard statements, and precautionary statements for HNOCs. In order to ensure that U.S. and Canadian requirements can simultaneously be met for HNOCs, OSHA and Health Canada have provided guidance allowing an exclamation mark pictogram to be used for HNOCs (OSHA, 2016, Document ID 0103). Use of the exclamation mark pictogram would not be mandatory under the HCS.

Relatedly, OSHA is proposing a number of additional changes. As discussed above, OSHA is proposing to move the current C.2.3.3 from appendix C to paragraph (f)(5) in the text of the standard, so that all of the instructions related to the transport of hazardous chemicals and DOT are in one section of the HCS. OSHA is also proposing to add a new paragraph C.2.3.3, which would allow the exclamation mark pictogram to be used for HNOCs if the words “Hazard Not Otherwise Classified” or the letters “HNOC” appear below the pictogram on the label. Health Canada and OSHA have agreed that the exclamation mark pictogram is an appropriate symbol for the HNOC, HHNOC (Health Hazards Not Otherwise Classified), and PHNOC (Physical Hazards Not Otherwise Classified) classifications. Additionally, because any pictogram may appear only once on a label, OSHA is also proposing to add a new paragraph at C.2.3.4 to specify that if multiple hazards require use of the same pictogram, it may not appear a second time on the label. This includes when the exclamation mark pictogram would be used, including as supplemental information for another hazard, such as HNOC. OSHA is requesting comments on these proposed changes, and is particularly interested in comments on whether the agency should require the exclamation mark pictogram to be used for HNOCs.

The remaining changes proposed for C.2 reflect updates to the GHS that are intended to provide additional flexibility to the label preparer while still communicating the required

information. OSHA is proposing to add new paragraph C.2.4.7 to note that precautionary statements may contain minor textual variations from the text prescribed elsewhere in appendix C (e.g., spelling variations, synonyms or other equivalent terms), as long as those variations assist in the communication of safety information without diluting or compromising the safety advice. This proposed new paragraph would also provide that any variations must be used consistently throughout the label and SDS. Because of the proposed addition of new paragraph C.2.4.7, OSHA is also proposing to renumber existing paragraphs C.2.4.7 and C.2.4.8 to become C.2.4.8 and C.2.4.9, respectively.

OSHA is also proposing to add a new paragraph, C.2.4.10, to further address cases where substances or mixtures may trigger multiple precautionary statements for medical responses. Consistent with the GHS Rev. 7 (UN GHS, 2017, Documents ID 0060), OSHA is proposing principles for addressing situations where a substance or mixture is classified for a number of hazards and triggers multiple precautionary statements for medical responses (e.g., calling a poison center/doctor/. . . and getting medical advice/attention). Proposed paragraph C.2.4.10 would provide for a system of prioritization for precautionary statements. Under proposed C.2.4.10(a), labels would usually need only include one precautionary statement reflecting the response at the highest level with the greatest urgency, combined with at least one route of exposure or symptom “IF” statement. For example, the statement, “Immediately call a poison center/doctor/. . .” would be prioritized over the less urgent “call a poison center/doctor.”

OSHA believes there is value in including more than one precautionary statement related to medical response to address both immediate (acute) and long-term (chronic) medical concerns; appropriate medical care may be different depending on whether there is a medical emergency (e.g., chemical burns) or concerns about potential diseases (e.g., cancer) due to prolonged exposures. However, OSHA also understands the difficulty involved in providing a long list of medical responses and that this could lead to confusion, particularly when immediate action is required. Therefore, proposed paragraph C.2.4.10(b) would allow for (but not require) combination of medical response statements. This means that if a chemical has, for example, inhalation and skin contact hazards that would require the same level of medical

response, both of these routes of entry could be listed in a combined statement. Proposed paragraph C.2.4.10(c) would prohibit the combination of medical response statements where the statements “Get medical advice/attention if you feel unwell” and “Get immediate medical/advice attention” are both indicated. In those cases, both statements should appear without prioritization. OSHA is requesting comments on whether precautionary statements for medical responses should be prioritized and seeks input on the best method(s) to use for prioritization.

#### Proposed Revisions to C.4

OSHA is proposing to update the hazard label elements for specific hazard classes and categories. The following discussion on proposed revisions to C.4 is organized according to: (1) Labeling changes resulting from the addition of hazard classes and categories in appendix B (new subcategories for flammable gases (C.4.15), Aerosols category 3 (C.4.16), and desensitized explosives (C.4.30)); (2) revisions to hazard statements, hazard categories and notes; (3) revisions to precautionary statements; and (4) the GHS revisions that OSHA is not proposing to adopt. In the discussion of precautionary statements, OSHA will explain the proposed changes to the statements and indicate what hazard classes/categories trigger these statements. As noted previously, a redline strike out version of appendix C is available in the docket and on OSHA’s website so interested parties can see all of the proposed changes in context (OSHA HCS Redline, 2020, Document ID 0222; <https://www.osha.gov/dsg/hazcom/>).

#### Proposed Revisions Based on Additions of Hazard Classes and Categories

OSHA is proposing a number of consequential revisions to appendix C based on the proposed additions of hazard classes and categories to appendix B. As discussed in the Summary and Explanation for appendix B, OSHA is proposing a number of changes to the flammable gas hazard class. The changes would include: (1) Subdividing category 1 flammable gases into categories 1A and 1B; (2) adding pyrophoric gases into category 1A; and (3) adding chemically unstable gases into category 1A (further subdivided into chemically unstable gas A and chemically unstable gas B). The proposed hazard and precautionary statements for those gases, consistent with the GHS Rev. 7 (UN GHS, 2017, Document ID 0060) are in C.4.15. Each type of category 1A gas (including

pyrophoric gases and chemically unstable gases) would require the hazard statement “Extremely flammable gas,” as is currently required for category 1 gases. On the other hand, the hazard statement for the new category 1B flammable gases would be “Flammable gas.” Additional hazard and precautionary statements would be added to communicate hazards specific to, and precautions that need to be taken for, pyrophoric and chemically unstable gases.

As also discussed in the Summary and Explanation for appendix B, OSHA is proposing to add non-flammable aerosols to the existing “Flammable Aerosols” hazard class and to rename the class “Aerosols.” Consequently, in appendix C, OSHA proposes to adopt the GHS Rev. 7 (UN GHS, 2017, Document ID 0060) hazard and precautionary statements for non-flammable aerosols in C.4.16. OSHA believes that these communication requirements would better address the true hazards of aerosols. In cases where aerosols are currently labeled as gases under pressure, the proposal would require the label to be updated to include the flame pictogram for hazard categories 1 and 2 (no pictogram would be required for hazard category 3) and the signal word “warning” (if “danger” is not required due to flammability); the hazard statement “pressurized container, may burst if heated” would also be required. These changes would better differentiate the hazards of non-flammable aerosols from those of gases under pressure.

Finally, OSHA is also proposing to adopt the hazard class of desensitized explosives in appendix B, and consequently to adopt, in appendix C, the pictogram, signal word, hazard statements, and precautionary statements for desensitized explosives from the GHS Rev. 7 (UN GHS, 2017, Document ID 0060). Under the proposal, the labeling information for desensitized explosives would be at C.4.30.

For flammable gases, aerosols, and desensitized explosives, OSHA is proposing to adopt the GHS Rev. 7 (UN GHS, 2017, Document ID 0060) hazard communication information with only minor editorial revisions, such as the use of HCS instead of GHS terminology (e.g., “manufacturer, importer or distributor” instead of “manufacturer/supplier or the competent authority” in conditional instructions). OSHA believes that the information called for by the GHS Rev. 7 (UN GHS, 2017, Document ID 0060) effectively communicates the hazards of those substances and the precautions that need to be taken when handling them.

Therefore, requiring the information to appear on labels would improve hazard communication and enhance worker safety. In addition, because the changes would align the HCS with the GHS, adopting them would ease compliance burdens for U.S. stakeholders that must also comply with international requirements for hazard communication.

#### Proposed Revisions to Hazard and Precautionary Statements, Hazard Categories, and Notes

OSHA is proposing to revise a number of hazard and precautionary statements to align with the GHS Rev. 7. The hazard and precautionary statements in the current HCS were adopted from the GHS Rev. 3. Since the HCS was last updated in 2012, the UNSCEGHS has continued to discuss the utility and readability of the label elements, including hazard and precautionary statements, in order to improve the information presented. The specific goals of the UNSCEGHS are to make labeling information more comprehensible and useable by explaining and clarifying ambiguous or unhelpful instructions or statements and eliminating inconsistencies in statements (UN GHS, 2018, Document ID 0095; UN GHS, 2018, Document ID 0213). In addition, the UNSCEGHS is considering how precautionary statements could be consolidated or combined to save label space and make labels more readable and clear, all of which improve the safety message (UN GHS, 2018, Document ID 0095; UN GHS, 2018, Document ID 0213). OSHA shares these goals with the UNSCEGHS because they lead to better communication of hazards and therefore maintain or enhance protection of worker safety and health. Unless otherwise discussed below, OSHA is proposing to adopt the updated communication information presented in the GHS Rev. 7 (UN GHS, 2017, Document ID 0060) with only minor editorial revisions, such as using the HCS terminology instead of the GHS terminology (e.g., “manufacturer, importer or distributor” instead of “manufacturer/supplier or the competent authority” in conditional instructions).

#### Proposed Revisions to Tables C.4.1, C.4.2, and C.4.3 (Acute Toxicity Tables)

OSHA is proposing to consolidate hazard category information for acute toxicity—oral, C.4.1. The change would involve deleting the table for acute toxicity—oral, category 3 and combining categories 1, 2, and 3 in one table, since all three categories have the same

precautionary statements. None of the substantive communication information for categories 1, 2, or 3 would change, and the intent of the proposed modification is simply to make C.4.1 more concise.

#### Proposed Revisions to Precautionary Statements

The original GHS (UN GHS Rev. 1, 2005, Document ID 0215) precautionary statements were developed from existing classification systems, including the IPCS International Chemical Safety Card (ICSC) Compilers Guide (IPCS International, 2012, Document ID 0158), the American National Standards (ANSI Z129.1 2010, Document ID 0102), the EU classification and labelling directives, the Emergency Response Guidebook (UN TDG, 2016, Document ID 0218), and the Pesticide Label Review Manual of the United States Environmental Protection Agency (EPA, 2018, Document ID 0056). Since publication of the updates to the HCS in 2012, the UNSCEGHS has continued its ongoing review of the precautionary statements to ensure they are allocated to the correct hazard class and/or category, reduce redundancies, simplify and clarify the statements, and clarify and refine the conditions of use. This section discusses OSHA’s proposed revisions to precautionary statements in appendix C.4. The intent or reasons provided below for the proposed changes reflect OSHA’s preliminary agreement with explanations provided by the UNSCEGHS, unless otherwise specified. The changes are organized according to the column headings found in the C.4 tables (i.e., prevention, response, storage, and disposal).

#### Proposed Changes in Prevention Column

Wear protective equipment (e.g., gloves/protective clothing).

A precautionary statement for acute toxicity—dermal (categories 1–4) (Table C.4.2), skin corrosion/irritation (categories 1A–1C) (Table C.4.4), eye damage/irritation (categories 1 and 2A) (Table C.4.5), and sensitization—skin (Table C.4.7) specifies personal protective equipment, such as “wear protective gloves” or “wear eye protection/face protection.” Instructions for the statement currently indicate that the chemical manufacturer, importer, or distributor is “to specify type of equipment.” OSHA proposes to revise the instruction to state that the chemical manufacturer, importer, or distributor may further specify type of equipment where appropriate. The intent of this proposed revision is to clarify that label

preparers may provide additional specification about the type of protective equipment, where appropriate, and to align with the GHS Rev. 7 (UN GHS, 2017, Document ID 0060).

Because specific hazards may require specific protective equipment or instructions, current precautionary statements and instructions for certain health hazards (e.g., germ cell mutagenicity, see Table C.4.8; carcinogenicity, see Table C.4.9; and reproductive toxicity, see Table C.4.10) and the majority of physical hazard classes specify one or more types of personal protective equipment and indicate that the chemical manufacturer, importer, or distributor is to specify the type of equipment. The types of equipment currently listed in the HCS were adopted from the GHS Rev. 3 and vary for the different hazard classes. In 2010, the UNSCEGHS recommended that the precautionary statement “Wear protective gloves/protective clothing/eye protection/face protection” be used for the hazard classes of germ cell mutagenicity (C.4.8), carcinogenicity (C.4.9), reproductive toxicity (C.4.10), explosives (C.4.14) and unstable explosives (C.4.30) (UN GHS, 2010, Document ID 0149), and this statement was included in the HCS in 2012. In 2015, the UNSCEGHS noted that hearing protection should often be worn when handling explosives and other physical hazards, such as desensitized explosives, because an explosion would result in a potentially hazardous noise level (UN GHS, 2015, Document ID 0219). Accordingly, the UNSCEGHS revised the precautionary statement to read, “Wear protective gloves/protective clothing/eye protection/face protection/hearing protection. . .” (UN GHS, 2016, Document ID 0147). Adding the term “/hearing protection. . .” provides flexibility because hearing protection and other equipment can be selected when appropriate and not selected if not relevant. Adding the ellipsis at the end of the statement allows other types of personal protective equipment to be listed as necessary. The UNSCEGHS also revised the instruction for the precautionary statement to make it clear that it is referring to personal protective equipment. Consistent with the GHS Rev. 7 (UN GHS, 2017, Document ID 0060) OSHA is proposing to adopt this revised precautionary statement and instruction for all relevant hazards: germ cell mutagenicity (C.4.8), categories 1A, 1B, and 2; carcinogenicity (C.4.9), categories 1A, 1B, and 2; reproductive toxicity (C.4.10), categories 1A, 1B, and 2; explosives (C.4.14),

unstable and division 1.1–1.5; flammable gases (C.4.15), category 1A, pyrophoric; flammable liquids (C.4.19), categories 1, 2, 3, and 4; flammable solids (C.4.20), categories 1 and 2; self-reactive substances and mixtures (C.4.21), categories Types A, B, C, D, E, and F; pyrophoric liquids (C.4.22), category 1; pyrophoric solids (C.4.23), category 1; self-heating substances and mixtures (C.4.24), categories 1, and 2; substances and mixtures which, in contact with water, emit flammable gases (C.4.25), categories 1, 2, and 3; oxidizing liquids (C.4.26), categories 1, 2, and 3; oxidizing solids (C.4.27), categories 1, 2, and 3; organic peroxides (C.4.28), categories Types A, B, C, D, E, and F; and desensitized explosives (proposed new C.4.30), categories 1, 2, 3, and 4.

#### Avoid Contact During Pregnancy/While Nursing

In Table C.4.10, for reproductive toxicity (effects on or via lactation), OSHA is proposing to revise a precautionary statement that currently says to avoid contact “during pregnancy/while nursing” so it reads “during pregnancy and while nursing.” This proposed revision would clarify that the chemical manufacturer, importer or distributor is not to choose between “during pregnancy” and “while nursing” but is to include both scenarios on the label. This proposed change would align with the GHS Rev. 7 (UN GHS, 2017, Document ID 0060; UN GHS, 2012, Document ID 0155).

#### Do Not Handle Until all Safety Precautions Have Been Read and Understood

For unstable explosives (Table C.4.14), OSHA is proposing to delete the precautionary statement about not handling until all safety precautions have been read and understood. A statement to obtain special instructions before use is already included and that statement is shorter and more relevant to safety. This proposed change would align with the GHS Rev. 7 (UN GHS, 2017, Document ID 0060; UN GHS, 2012, Document ID 0155).

#### Do Not Subject to Grinding/Shock/Friction

OSHA also proposes adding the precautionary statement “Do not subject to grinding/shock/friction/. . .” to the table for unstable explosives (Table C.4.14). That statement is already included for the other explosives categories, and is also relevant for unstable explosives. For each of the explosives categories that contain that statement, an explanatory conditional

note clarifying that the statement applies only if the explosive is mechanically sensitive would also be added. These proposed changes would align with the GHS Rev. 7 (UN GHS, 2017, Document ID 0060; UN GHS, 2012, Document ID 0152; UN GHS 2012, Document ID 0153).

#### Keep Away From Heat/Sparks/Open Flames/Hot Surfaces

A number of the hazard classes that include flammable chemicals currently require precautionary statements and instructions about keeping away from ignition sources (heat/sparks/open flames/hot surfaces). Those statements generally require the chemical manufacturer, importer, or distributor to select one or more of the ignition sources listed, as applicable. OSHA is proposing to include more ignition sources in the statement and to require that they all be listed on the label. With that change, the statement would read, “Keep away from heat, hot surfaces, sparks, open flames, and other ignition sources.” OSHA believes this change, which is consistent with the GHS Rev. 7 (UN GHS, 2017, Document ID 0060; UN GHS, 2012, Document ID 0152), would improve hazard communication by making users aware of additional ignition sources that should be avoided. The change would be made to precautionary statements for explosives (divisions 1.1–1.5 in Table C.4.14), flammable gases (Table C.4.15), aerosols (Table C.4.16), flammable liquids (Table C.4.19), flammable solids (Table C.4.20), self-reactive substances and mixtures (Table C.4.21), pyrophoric liquids (Table C.4.22), pyrophoric solids (Table C.4.23), oxidizing liquids (Table C.4.26), oxidizing solids (Table C.4.27), organic peroxides (Table C.4.28), and desensitized explosives (Table C.4.30).

#### Keep Wetted With

A conditional instruction used for division 1.1–1.3 and 1.5 explosives in Table C.4.14 currently states that the chemical manufacturer, importer, or distributor is to include the precautionary statement “Keep wetted with. . .” under conditions where drying would increase the explosion hazard, except as needed for manufacturing or operating processes. The GHS Rev. 7 changes the conditional instruction to clarify that the “Keep wetted with. . .” statement should be used for “substances or mixtures which are wetted, diluted, dissolved or suspended with a phlegmatizer to reduce or suppress their explosive properties” (UN GHS, 2017, Document ID 0060; UN GHS, 2012, Document ID 0152; UN GHS, 2012, Document ID

0153). OSHA is proposing to make the same change in order to clarify when the “Keep wetted with. . .” statement is appropriate.

The “Keep wetted with. . .” precautionary statement also appears in proposed C.4.30, desensitized explosives. Consistent with the GHS Rev. 7 (UN GHS, 2017, Document ID 0060), OSHA is not proposing to add the conditional statement that appears in C.4.14 because, by definition, desensitized explosives are phlegmatized to suppress their explosive properties, and therefore the “Keep wetted with. . .” statement is appropriate for all desensitized explosives. OSHA requests comment on these proposed changes.

#### Keep Only in Original Container

OSHA proposes to revise the statement “Keep only in original container” to “Keep only in original packaging” for self-reactive substances and mixtures (Table C.4.21), organic peroxides (Table C.4.28), and corrosive to metals (Table C.4.29). The revised statement would also be added to explosives in division 1.1–1.5 (Table C.4.14). OSHA believes that this proposed change is appropriate because the term “packaging” is more inclusive than “container” and would include the transport packaging as well as the immediate container. These proposed changes are consistent with the GHS Rev. 7 (UN GHS, 2017, Document ID 0060; UN GHS, 2012, Document ID 0152).

#### Ground/Bond Container and Receiving Equipment

Several hazard classes require the precautionary statement “Ground/bond container and receiving equipment” for chemicals that are electrostatically sensitive. OSHA proposes changing “Ground/bond” to “Ground and bond” to clarify that both of those precautions are to be included on the label. Appendix C.2.4.2, states that when a “/” is used the label preparer has a choice and should choose the most appropriate phrase. However, in this case, both “ground and bond” should be stated together to appropriately protect against electrostatically sensitive chemicals. These proposed changes would apply to explosives (division 1.1–1.5 in Table C.4.14), flammable liquids (categories 1–3 in Table C.4.19), and flammable solids (Table C.4.20). In addition, OSHA is proposing to revise existing conditional instructions to clarify that the need for grounding and bonding applies to flammable liquids only if they are volatile and may generate an explosive atmosphere (Table C.4.19) and to

explosives and flammable solids only if they are electrostatically sensitive (Tables C.4.14 and C.4.20). OSHA is also proposing to add the “ground and bond” precautionary statement and similar conditional notes (“if electrostatically sensitive and able to generate an explosive atmosphere”) to self-reactive substances and mixtures (Table C.4.21) and organic peroxides (Table C.4.28) because the precaution is also appropriate for those hazard classes. These proposed changes would align with the GHS Rev. 7 (UN GHS, 2017, Document ID 0060; UN GHS, 2012, Document ID 0152).

#### Keep/Store Away From Clothing, and Other Combustible Materials

OSHA is proposing to standardize precautionary statements regarding combustible materials for oxidizing chemicals. Currently, the tables for oxidizing gases (Table C.4.17), oxidizing liquids (Table C.4.26, hazard categories 2 and 3), and oxidizing solids (Table C.4.27, hazard categories 2 and 3) require the precautionary statement “Keep/Store away from clothing/. . . /combustible materials,” along with instructions for the chemical manufacturer, importer, or distributor to specify incompatible materials. OSHA proposes to change the statement to read: “Keep away from clothing and other combustible materials,” and to delete the instruction regarding incompatible materials, to make the statement more consistent with the statement currently applicable to hazard category 1 in both oxidizing liquids (Table C.4.26) and oxidizing solids (Table C.4.27). OSHA believes the proposed change is appropriate because the general term “combustible materials” encompasses any other materials that are incompatible with oxidizers. In addition, OSHA believes the term “keep” is adequate to encompass storage as well as use, and that eliminating the choice between “keep” and “store” would avoid confusion and improve consistency. Finally, OSHA is also proposing to remove the redundant statement “Take any precaution to avoid mixing with combustibles/. . .” under oxidizing liquids (Table C.4.26) and oxidizing solids (Table C.4.27), since this information is duplicative of the “keep away from” statement. These proposed changes are consistent with the GHS Rev. 7 (UN GHS, 2017, Document ID 0060; UN GHS, 2012, Document ID 0152).

OSHA is proposing to remove the “keep/store away from clothing/. . . /combustible materials” precautionary statement, along with its instruction, for

self-reactive substances and mixtures (Table C.4.21) and organic peroxides (Table C.4.28). The wording of the precautionary statement is pertinent to oxidizing properties, which readily give oxygen or other oxidizing material, and therefore more readily support combustion. Neither self-reacting chemicals nor organic peroxides have oxidizing properties, so the statement is not appropriate for them. Both self-reacting chemicals and organic peroxides have alternate storage statements that are designed to more accurately address their particular chemical properties. These proposed changes would also align with the GHS Rev. 7 (UN GHS, 2017, Document ID 0060; UN GHS, 2012, Document ID 0152; UN GHS, 2012, Document ID 0153).

#### Keep Valves and Fittings Free From Oil and Grease

For oxidizing gases (Table C.4.17), a precautionary statement currently allows the chemical manufacturer, importer, or distributor to specify that either “reduction valves” or “valves and fittings” be kept free from oil and grease. OSHA is proposing to revise the statement to “Keep valves and fittings free from oil and grease.” OSHA believes the change is appropriate because all valves and fittings must be kept free of oil and grease, not just the reduction valves attached to pressure receptacles. This proposed change is consistent with the GHS Rev. 7 (UN GHS, 2017, Document ID 0060; UN GHS, 2010, Document ID 0149).

#### Wear Cold Insulating Gloves/Face Shield/Eye Protection

OSHA is proposing to revise the precautionary statement for refrigerated liquefied gases (Table C.4.18), which currently provides that either cold insulated gloves, a face shield, or eye protection is to be used. The proposed change would clarify the intent of the precautionary statement, which is that cold-insulating gloves are to be used in addition to either a face shield or eye protection. This proposed change would align with the GHS Rev. 7 (UN GHS, 2017, Document ID 0060; UN GHS, 2012, Document ID 0152; UN GHS, 2012, Document ID 0153).

#### Keep Container Tightly Closed

The precautionary statement “Keep container tightly closed” is used for flammable liquids (categories 1–3 in Table C.4.19). The GHS Rev. 7 contains a conditional instruction indicating that the statement is to be used if the liquid is volatile and may generate an explosive atmosphere (UN GHS, 2017,

Document ID 0060). OSHA is proposing to add this conditional instruction to the precautionary statement for flammable liquids (categories 1–3) because it clarifies the types of flammable liquids for which the statement applies.

OSHA also proposes to add the precautionary statement “Keep container tightly closed” to pyrophoric liquids (Table C.4.22) and pyrophoric solids (Table C.4.23). OSHA believes it is important to add that statement because for both pyrophoric liquids and pyrophoric solids it is necessary to avoid ignition via contact with air. Because the precaution applies to all chemicals in these hazard classes, OSHA does not believe a conditional note is necessary. These proposed changes would also align with the GHS, Rev. 7 (UN GHS, 2017, Document ID 0060; UN GHS, 2012, Document ID 0152; UN GHS, 2012, Document ID 0153).

#### Take Precautionary Measures Against Static Discharge

For flammable liquids (Table C.4.19, hazard categories 1–3), OSHA proposes to revise the precautionary statement “Take precautionary measures against static discharge” to “Take action to prevent static discharge.” The revision would simply shorten the statement and clarify what action needs to be taken. OSHA also proposes to add a note that this precautionary statement is to be used if the liquid is volatile and may generate an explosive atmosphere. These proposed changes are consistent with the GHS Rev. 7 (UN GHS, 2017, Document ID 0060; UN GHS, 2012, Document ID 0152; UN GHS, 2012, Document ID 0153).

#### Flammable Liquids/Solids Conditional Instructions

OSHA is proposing additional conditional instructions for flammable liquids (Table C.4.19) and flammable solids (Table C.4.20). Some categories of flammable liquids (categories 1–3) and flammable solids (categories 1 and 2) contain a precautionary statement specifying the use of “explosion-proof [electrical/ventilating/lighting/. . .] equipment.” OSHA believes that SDS and label creators are not actually properly and specifically identifying the prevention measures for the particular chemical, but rather are listing the entire line without the required details. For liquids, OSHA proposes a new conditional instruction to clarify that the statement is required if the chemical is volatile and may generate an explosive atmosphere. For both liquids and solids, a conditional instruction would be added to indicate that text in

square brackets may be used to specify specific electrical, ventilating, lighting or other equipment if necessary and as appropriate. These proposed changes would align with the GHS Rev. 7 (UN GHS, 2017, Document ID 0060; UN GHS, 2012, Document ID 0152; UN GHS, 2012, Document ID 0153).

OSHA is also proposing to add a conditional instruction to the precautionary statement to use non-sparking tools for flammable liquids (categories 1–3, Table C.4.19). The statement would clarify that the precautionary statement is only needed if the liquid is volatile and may generate an explosive atmosphere, and if the minimum ignition energy is very low (<0.1 mJ). The precautionary statement has very limited applicability for flammable liquids and therefore OSHA believes that the conditions need to be specified. This proposed change is also consistent with the GHS Rev. 7 (UN GHS, 2017, Document ID 0060; UN GHS, 2012, Document ID 0152; UN GHS, 2012, Document ID 0153).

#### Keep Cool

For self-reactive substances and mixtures and organic peroxides (Tables C.4.21 and C.4.28), OSHA is proposing to move the precautionary statement “Keep cool” from the storage column to the prevention column. The precautionary statement is not needed in the storage column because that column includes a precautionary statement about storage temperatures not to be exceeded, and as discussed below, OSHA is proposing to add conditional instructions to that column to inform users of when a storage temperature would need to be listed. Under the prevention column, OSHA is proposing to include a conditional instruction indicating that the precautionary statement may be omitted if storage temperatures are included on the label. This proposed revision would not materially change the information that is presented on the label, and is consistent with the GHS Rev. 7 (UN GHS, 2017, Document ID 0060; UN GHS, 2012, Document ID 0152; UN GHS, 2012, Document ID 0153).

For self-heating substances and mixtures (Table C.4.24), a combined precautionary statement currently instructs the user to keep cool and protect from sunlight. OSHA is proposing that a conditional instruction be added to indicate that “Keep cool” can be omitted where storage temperatures are listed on the label. Because “Protect from sunlight” still needs to be included if specific storage temperatures are listed on the label, OSHA is proposing to delete the

combined statement under the prevention column, and to list only “Keep cool” (and the new conditional instruction) in that column. The statement: “Protect from sunlight” would be moved to the storage column, similar to the way this is handled for other hazard classes. OSHA believes that these proposed changes would provide the label preparer better instructions and would provide the appropriate level of information on the label without repetition. These proposed changes would also align with the GHS Rev. 7 (UN GHS, 2017, Document ID 0060; UN GHS, 2012, Document ID 0152; UN GHS, 2012, Document ID 0153).

#### Do Not Allow Contact With

OSHA is proposing to add the conditional note “if emphasis of the hazard statement is deemed necessary” to precautionary statements indicating that contact is not to be allowed with air (for pyrophoric gases (proposed C.4.15, category 1A), pyrophoric liquids (C.4.22), and pyrophoric solids (C.4.23)) or water (for substances and mixtures that emit flammable gases in contact with water (C.4.25, categories 1 and 2)). Because the hazard phrases, which are also included on labels for these categories, already warn about the hazards of these respective chemicals when they contact air or water, adding this precautionary statement as well could be repetitive. However, depending on the specific chemical, the label preparer may feel that added emphasis is warranted. These proposed changes would align with the GHS Rev. 7 (UN GHS, 2017, Document ID 0060; UN GHS, 2012, Document ID 0152; UN GHS, 2012, Document ID 0153).

#### Handle Contents Under Inert Gas

For substances and mixtures which, in contact with water, emit flammable gases (Table C.4.25), OSHA proposes changing the precautionary statement “Handle under inert gas. Protect from moisture” to “Handle and store contents under inert gas/. . . Protect from moisture.” This would clarify that these substances should always be under inert atmospheres. In addition, conditional instructions would be added to indicate that if the substance or mixture reacts readily with moisture in air, then the chemical manufacturer, importer or distributor also has to specify the appropriate liquid or gas if inert gas is not appropriate. The new statement would provide greater clarity and is needed because inert gas is not appropriate in some cases (e.g., white phosphorus should be handled and stored under water) (UN GHS, 2010,

Document ID 0149). This proposed change is consistent with the GHS Rev. 7 (UN GHS, 2017, Document ID 0060; UN GHS, 2012, Document ID 0152; UN GHS, 2012, Document ID 0153).

OSHA is also proposing to add the statement “Handle and store contents under inert gas/. . .” to pyrophoric liquids (C.4.22) and pyrophoric solids (C.4.23). A conditional statement would note that the manufacturer, importer, or distributor is to specify the appropriate liquid or gas if inert gas is not appropriate. Pyrophoric chemicals, by definition, are likely to ignite when in contact with air. Both Tables C.4.22 and C.4.23 currently contain the following statement in the storage column: “Store contents under . . . Chemical manufacturer, importer, or distributor to specify appropriate liquid or inert gas.” In light of the language OSHA is proposing to include in the prevention column, OSHA would delete this language from the storage column. OSHA believes that the language being proposed for the prevention column would emphasize that pyrophoric chemicals must be handled, as well as stored, under inert atmospheres. OSHA notes that the statements OSHA is proposing to add to the prevention column for Tables C.4.22 (pyrophoric liquids) and C.4.23 (pyrophoric solids) regarding handling and storing contents under inert gas were included in the GHS Rev. 5, but were inadvertently omitted from Rev. 7 (UN GHS, 2016, Document ID 0211; UN GHS, 2017, Document ID 0060). If OSHA finalizes the language as proposed, it will work with the UNSCEGHS to have this statement reinstated in future GHS revisions.

#### Wear Fire/Flame Resistant/Retardant Clothing

Category 1 oxidizing liquids (C.4.26) and category 1 oxidizing solids (C.4.27) currently have the precautionary statement “Wear fire/flammable resistant/retardant clothing.” The intent of that statement is to alert the users of the chemical that they should wear either fire resistant or flame retardant clothing, not for the label preparer to choose between the terms “fire” and “flame” or “resistant” and “retardant”. Therefore, OSHA proposes to replace the existing statement with “Wear fire resistant or flame retardant clothing.” This would clarify the intent of this statement and is consistent with the GHS Rev. 7 (UN GHS, 2017, Document ID 0060; UN GHS, 2012, Document ID 0152; UN GHS, 2012, Document ID 0153).

### Proposed Changes in Response Column

For the response column, a number of the proposed revisions in appendix C are simply editorial and are made to improve clarity, correct simple omissions of a word or phrase, or more efficiently and concisely combine different precautionary statements. For example, OSHA is proposing to add the phrase “If on skin” to the statement “Brush off loose particles from skin” (see C.4.23 (pyrophoric solids) and hazard categories 1 and 2 in C.4.25 (substances and mixtures which, in contact with water, emit flammable gases)) because those statements are always combined in the GHS Rev. 7 (UN GHS, 2017, Document ID 0060), and the additional phrase would add clarity. Another example is OSHA’s proposal to add the phrase “In case of fire” at the beginning of the precautionary statements related to fire fighting for unstable explosives, as is already done for other explosives categories (see C.4.14). In a number of cases, OSHA is proposing to reorganize the precautionary statements and to remove redundant wording to improve clarity. For example, in C.4.14, instead of listing the individual statements and providing conditions of use, OSHA would now list the statements grouped together (except for materials for Division 1.4S, which have another set of statements as explained below).

The following discussion does not address proposed changes that are simply editorial in nature (although all proposed revisions can be found in the redlined version of appendix C that is available as part of the rulemaking record (OSHA HCS Redline, 2020, Document ID 0222) and on OSHA’s website (<https://www.osha.gov/dsg/hazcom>). The discussion below highlights the substantive changes OSHA is proposing to make to the response column in appendix C.

### Take Off Immediately All Contaminated Clothing. Rinse Skin With Water/ Shower

The existing precautionary statements for skin corrosion/irritation (categories 1A to 1C in C.4.4) and flammable liquids (categories 1–3 in C.4.19) indicate that if the chemical is on hair or skin, the affected individual is to immediately take off all contaminated clothing and rinse skin with “water/ shower.” OSHA proposes to revise the statement to instruct the affected individual to rinse skin with “water [or shower],” and to add a conditional note indicating that the text in square brackets is to be used where the chemical manufacturer, importer or

distributor considers it appropriate for the specific chemical. The reason for the proposed change is that a deluge shower might be most appropriate for the chemical, and the use of the square brackets allows for selection of the most appropriate wording. The proposed change would align with the GHS Rev. 7 (UN GHS, 2017, Document ID 0060; UN GHS, 2012, Document ID 0152; UN GHS, 2012, Document ID 0153).

### Get Medical Advice/Attention

A number of health hazards (*i.e.*, skin corrosion/irritation (category 2 in Table C.4.4), eye damage/irritation (categories 2A and 2B in Table C.4.5), sensitization—skin (Table C.4.7), germ cell mutagenicity (Table C.4.8), carcinogenicity (Table C.4.9), reproductive toxicity (Table C.4.10), specific target organ toxicity—repeated exposure (Table C.4.12), and refrigerated liquefied gases (Table C.4.18)) have combined precautionary statements that include the statement “get medical advice/attention.” OSHA is proposing to add an instruction indicating that the chemical manufacturer, importer, or distributor is to select medical advice or attention as appropriate. This is to alert label preparers that they should provide more specific instruction on the type of medical assistance needed based on the chemical hazard and to align with the GHS Rev. 7 (UN GHS, 2017, Document ID 0060).

### If Breathing Is Difficult, Remove Person to Fresh Air and Keep Comfortable for Breathing

A precautionary statement used for sensitization—respiratory (Table C.4.6) currently states “If inhaled: If breathing is difficult, remove person to fresh air and keep comfortable for breathing.” OSHA is proposing to remove the phrase “if breathing is difficult.” This is because including two conditions, “if inhaled” and “if breathing is difficult,” is confusing and unnecessary. Removal of the phrase would also make the precautionary statement consistent with the statement as it appears in other hazard classes in appendix C.4, such as acute toxicity—inhalation (Table C.4.3). This proposed change is consistent with the GHS Rev. 7 (UN GHS, 2017, Document ID 0060; UN GHS, 2010, Document ID 0149).

### Take Off Contaminated Clothing and Wash it Before Reuse

A precautionary statement for skin sensitization (Table C.4.7) currently says to wash contaminated clothing before reuse. OSHA is proposing to add the phrase “Take off contaminated clothing and” to this precautionary statement.

The UNSCEGHS previously recommended that this additional phrase be used for acute toxicity—dermal; skin irritation, category 2; and sensitization—skin (UN GHS, 2010, Document ID 0154). The phrase was inadvertently omitted for skin sensitization in the GHS Rev. 3 (UN GHS, 2009, Document ID 0085), and accordingly in the updates to the HCS in 2012, but it has since been added to the GHS Rev. 7 (UN GHS, 2017, Document ID 0060; UN GHS, 2010, Document ID 0149; UN GHS, 2010, Document ID 0154).

### If Exposed or Concerned

For specific target organ toxicity (single exposure) (Table C.4.11), OSHA is proposing to revise a precautionary statement indicating “If exposed” to “If exposed or concerned.” The revision, which would be consistent with language currently used for the germ cell mutagenicity (Table C.4.8), carcinogenicity (Table C.4.9), and reproductive toxicity (Table C.4.10) hazard classes, would maintain consistency throughout C.4 and with the GHS Rev. 7 (UN GHS, 2017, Document ID 0060). In 2010, a GHS subcommittee recommended that wherever “If exposed” is used, it be revised to “If exposed or concerned,” since the user of the chemical may not have evidence of exposure (UN GHS, 2010, Document ID 0154).

### Division 1.4 Explosives (C.4.14) Precautionary Statements

For Division 1.4 explosives, the HCS currently provides fire-fighting precautionary statements and instructions on when to apply them (Table C.4.14). OSHA is proposing two changes to these statements. First, OSHA is proposing to change the instruction note from “for explosives are 1.4S ammunition and components thereof” to “for explosives of division 1.4 (compatibility group S) in transport packaging.” This revision would provide clarity about when the note applies and there is no intended change in meaning. Second, OSHA is proposing to revise the precautionary statement “Fight fire with normal precautions from a reasonable distance” to the statement “Fight fire remotely due to the risk of explosion.” OSHA believes the proposed new statement is more appropriate and protective because it specifies the explosion risk due to fire associated with 1.4 compatibility group S (1.4S) explosives. These proposed changes would align with the GHS Rev. 7 (UN GHS, 2017, Document ID 0060; UN GHS, 2012, Document ID 0152; UN GHS, 2012, Document ID 0153).

**Eliminate All Ignition Sources, if Safe To Do So**

For category 1 and 2 flammable gases (C.4.15), a precautionary statement currently instructs the user to eliminate all ignition sources if safe to do so. OSHA proposes to revise the statement to “In case of leakage, eliminate all ignition sources.” The term “in case of leakage” would be added to stress that it is important to eliminate flammable gas leaks, even where the leaking gas is not burning, because the leak could create an explosive atmosphere. The term “if safe to do so” would be deleted because it could discourage quick action. Eliminating gas leaks would not be expected where a fire would hinder that action. OSHA is also proposing to add this statement to pyrophoric gases 1A and chemically unstable gases A and B. These proposed changes would be consistent with the GHS Rev. 7 (UN GHS, 2017, Document ID 0060; UN GHS, 2012, Document ID 0152).

**In Case of Fire Use . . . To Extinguish**

For self-reactive substances and mixtures (type A) (C.4.21), OSHA is proposing to delete the precautionary statements “In case of fire use . . . to extinguish” (along with its explanatory note) and “Fight fire remotely due to the risk of explosion.” In place of the language OSHA is proposing to delete, OSHA proposes to use language stating “In case of fire: Explosion risk. Do NOT fight fire when fire reaches explosives.” These changes would align with the GHS Rev. 7 (UN GHS, 2017, Document ID 0060) and are proposed because it is dangerous to fight a fire involving this type of material and individuals should always be advised against it (UN GHS, 2012, Document ID 0152; UN GHS, 2012, Document ID 0153). OSHA is not proposing to change the existing statement about evacuating the area.

For type B self-reactive substances and mixtures (C.4.21), OSHA is proposing to combine existing precautionary statements and to delete duplicate phrases that would occur with the new combination. OSHA does not intend these changes to alter the meaning of the statements. OSHA is proposing to use brackets around the statement “Use . . . to extinguish” with a conditional note to indicate that the text in square brackets is to be included if water increases risk. This is to preserve the conditions of use with the new combination of phrases. These proposed changes would align with the GHS Rev. 7 (UN GHS, 2017, Document ID 0060; UN GHS, 2012, Document ID 0095).

**Fire and Explosion Hazards for Organic Peroxides (C.4.28)**

Precautionary statements and instructions related to fire and explosion hazards or fire-fighting procedures were not included in the GHS Rev. 3 (UN GHS, 2009, Document ID 0085), or in the current HCS, for organic peroxides (C.4.28). The UNSCEGHS has since adopted these precautionary statements (UN GHS, 2012, Document ID 0095). As in GHS Rev. 7 (UN GHS, 2017, Document ID 0060), OSHA is proposing to adopt the same precautionary statements in the response column for organic peroxides (C.4.28) as for self-reactive substances and mixtures (C.4.21). OSHA believes it is appropriate to include these statements for organic peroxides, as well as for self-reactive substances and mixtures, because the fire and explosion hazards of the two classes of compounds are equivalent (UN GHS, 2012, Document ID 0152; UN GHS, Document ID 0153; UN GHS, 2012, Document ID 0095).

**Immerse in Cool Water/Wrap With Wet Bandages**

For pyrophoric liquids (C.4.22), pyrophoric solids (C.4.23), and substances and mixtures which in contact with water emit flammable gases (C.4.25), a precautionary statement currently indicates that if the substance is on the skin, the user should “immerse in cool water/wrap with wet bandages.” For pyrophoric liquids (C.4.22) and solids (C.4.23), OSHA is proposing to change the forward slash to an “or” so that the statement would read “Immerse in cool water or wrap in wet bandages.” The change is proposed to make clear that the chemical manufacturer, importer, or distributor is not to choose one action or the other but is to include both actions on the label. In the case of substances and mixtures which, in contact with water, emit flammable gases, OSHA is proposing to delete “wrap in wet bandages” from the statement so that the complete statement reads “Brush off loose particles from skin and immerse in cool water.” This change is proposed because, for these chemicals, a large volume of water is needed and wrapping in wet bandages is not enough to address problems caused by the heat of the reaction (UN GHS, 2012, Document ID 0095). These proposed changes would align with the GHS Rev. 7 (UN GHS, 2017, Document ID 0060; UN GHS, 2012, Document ID 0152; UN GHS, 2012, Document ID 0153).

**Proposed Changes in Storage Column Store Away From Other Materials**

For self-reactive substances and mixtures (C.4.21), self-heating substances and mixtures (C.4.24), and organic peroxides (C.4.28), OSHA proposes to revise the precautionary statement “Store away from other materials” to “Store separately.” OSHA believes that the revised statement is preferable because it is shorter and more appropriate. OSHA is also proposing to add the “Store separately” precautionary statement to category 1 oxidizing liquids (C.4.26) and category 1 oxidizing solids (C.4.27) because those chemicals are not compatible with other chemicals and thus must be stored separately. These proposed changes are consistent with the GHS Rev. 7 (UN GHS, 2017, Document ID 0060; UN GHS, 2012, Document ID 0152; UN GHS, 2012, Document ID 0153).

**Store Contents Under. . . .**

For pyrophoric liquids (C.4.22) and solids (C.4.23), OSHA proposes to delete a precautionary statement that says “Store contents under . . . ,” along with the instructional note that the chemical manufacturer, importer, or distributor is to specify the appropriate liquid or inert gas. The UNSCEGHS recommended that the statement be deleted from the storage column because it adopted the statement “Handle and store contents under inert gas/ . . . ,” along with a similar instructional note, in the prevention column (UN GHS, 2012, Document ID 0152; UN GHS, 2012, Document ID 0153). OSHA believes placing the statement in the prevention column is more appropriate, as there it would warn the downstream user that pyrophoric chemicals must be under inert gas not only during storage but at all times, including during processing and use. This modification was inadvertently omitted from the text in the GHS Rev. 7, and the U.S. will work with the U.N. to submit a paper to add this statement to pyrophoric liquids (C.4.22) and solids (C.4.23) in a future revision of the GHS.

**Maintain Air Gap Between Stacks/Pallets**

For self-heating substances and mixtures (C.4.24), OSHA is proposing to revise the precautionary statement that currently says “[m]aintain air gap between stacks/pallets” so it reads instead “[m]aintain air gap between stacks or pallets.” The change would clarify that chemical manufacturers, importers or distributors are not to choose between “stacks” or “pallets”

but are to include both words on the label. This proposed change would align with the GHS Rev. 7 (UN GHS, 2017, Document ID 0060; UN GHS, 2012, Document ID 0152; UN GHS, 2012, Document ID 0153).

#### Store in Corrosive Resistant/ . . . Container With a Resistant Inner Liner

A precautionary statement for the corrosive to metals (C.4.29) class currently says to store in a “corrosive resistant/ . . . container with a resistant inner liner.” OSHA is proposing to change the word “corrosive” to “corrosion” because it is the technically correct term. In addition, a new conditional instruction would be inserted to indicate that the precautionary statement may be omitted if the statement “Keep only in original packaging” is included on the label. This would eliminate the redundancy of including both statements. These proposed changes would align with the GHS Rev. 7 (UN GHS, 2017, Document ID 0060; UN GHS, 2012, Document ID 0152; UN GHS, 2012, Document ID 0153).

#### Instructional Notes

For acute toxicity—inhalation (C.4.3) (category 1–3) and specific organ toxicity (single exposure, category 3) (C.4.11), OSHA is proposing minor, non-substantive edits to the conditional instruction for precautionary statements about keeping the container tightly closed and storing in a well-ventilated place. OSHA proposes to revise the note from “if product is volatile so as to generate hazardous atmosphere” to “if the chemical is volatile and may generate a hazardous atmosphere.” The intent of these edits is to improve clarity and make the instruction more consistent with a newly added instruction for flammable liquids (C.4.19). This proposed change is consistent with the GHS Rev. 7 (UN GHS, 2017, Document ID 0060; UN GHS, 2012, Document ID 0152; UN GHS, 2012, Document ID 0153).

For flammable liquids (C.4.19), OSHA is proposing to add a clarifying instruction indicating that the precautionary statement “Store in a well ventilated place. Keep cool” applies to flammable liquids in category 1 and other flammable liquids that are volatile and may generate an explosive atmosphere. However, for category 4 flammable liquids, OSHA is proposing to delete “Keep cool,” because these liquids are less volatile and have a flashpoint above 60 °C and therefore are unlikely to generate a hazardous concentration of vapor during storage; OSHA believes the precautionary

statement “Store in a well ventilated place” is the appropriate level of protection. These proposed changes would align with the GHS Rev. 7 (UN GHS, 2017, Document ID 0060; UN GHS, 2012, Document ID 0152; UN GHS, 2012, Document ID 0153).

For explosives (C.4.14), OSHA is proposing minor edits to precautionary statements and instructions for storing in accordance with local/regional/national/international regulations. The edits are intended to clarify that the chemical manufacturer, importer, or distributor is to specify the applicable regulations. These proposed changes are consistent with the GHS Rev. 7 (UN GHS, 2017, Document ID 0060; UN GHS, 2012, Document ID 0152; UN GHS, 2012, Document ID 0153).

Aerosols (C.4.16), self-reactive substances (C.4.21), self-heating substances and mixtures (C.4.24), and organic peroxides (C.4.28) currently include precautionary statements addressing storage temperatures not to be exceeded, with temperatures listed in degrees Celsius/Fahrenheit. The GHS has added an instruction that the chemical manufacturer should use the applicable temperature scale for the region they are supplying (UN GHS, 2017, Document ID 0060; UN GHS, 2012, Document ID 0152; UN GHS, 2012, Document ID 0153). In other OSHA standards, the primary temperature scale used is Fahrenheit. Therefore, OSHA is proposing to require only the Fahrenheit scale in the precautionary statements. However, the chemical manufacturer, importer or distributor would still be permitted to include the temperature in Celsius (as noted by parens ( )) in addition to Fahrenheit.

In addition, for self-reactive substances and mixtures (C.4.21) and organic peroxides (C.4.28), OSHA proposes to add conditional instructions to two precautionary statements. The first conditional instruction would clarify that the statement to store in a well-ventilated place should not be used for temperature-controlled substances and mixtures or organic peroxides because condensation and freezing may occur. The second would clarify that a storage temperature is only needed if temperature control is required or deemed necessary. OSHA also proposes moving the precautionary statement “Keep cool” to the prevention column, as discussed above under the section on proposed changes to the prevention column. These proposed changes would align with the GHS Rev. 7 (UN GHS, 2017, Document ID 0060; UN GHS, 2012, Document ID 0152; UN GHS, 2012, Document ID 0153).

#### Proposed Changes in Disposal Column

For most of the health and physical hazards addressed by appendix C, the rule currently includes a precautionary statement to dispose of contents/ container in accordance with local/ regional/national/international regulations (to be specified). OSHA is proposing to add an instructional note in all relevant places in the appendix indicating that the chemical manufacturer, importer or distributor is to specify whether the disposal requirements apply to the contents, the container, or both. This proposed change would align with the GHS Rev. 7 (UN GHS, 2017, Document ID 0060; UN GHS, 2012, Document ID 0152; UN GHS, 2012, Document ID 0153).

The tables for explosives (C.4.14), except for hazard category division 1.6, currently include the precautionary statement to dispose of contents/ container in accordance with local/ regional/national/international regulations (to be specified). However, this precautionary statement may not give users the information needed to safely dispose of explosives, particularly malfunctioning, expired, or non-used explosives where special care is needed. This is of particular concern for explosives such as fireworks, signal flares and ammunition. Ill-formulated advice on the label may lead to the disposal of such explosive waste in a way that poses a risk, *e.g.*, to the workers that handle the waste (UN GHS, 2015, Document ID 0156). Therefore, OSHA is proposing to change the precautionary note for explosives (C.4.14) to read: “Refer to manufacturer, importer, or distributor . . . for information on disposal, recovery, or recycling.” An instructional note would be added to indicate that the chemical manufacturer, importer, or distributor is to specify the appropriate source of information, in accordance with local/ regional/national/international regulations as applicable. The change is proposed to address the recycling or recovery of unexploded fireworks or other unused explosive cartridges and signal flares, which can result in unsafe conditions and should only be performed by specialists. This proposed change is consistent with the GHS Rev. 7 (UN GHS, 2017, Document ID 0060; UN GHS, 2015, Document ID 0214; UN GHS, 2015, Document ID 0213).

#### Proposed Revisions to Label Elements for OSHA Defined Hazards (C.4.31)

OSHA is proposing a few changes to label elements for OSHA defined hazards (currently at C.4.30 and proposed to be renumbered as C.4.31).

This section of appendix C addresses the labeling of hazards that are not classified under the GHS, but that the HCS specifically defines as hazards that must be communicated on the label and SDS.

First, OSHA is proposing to delete the entry for “Pyrophoric Gas.” In the GHS Rev. 7, pyrophoric gases are now a category under the hazard class of flammable gases, and OSHA proposes to include them there as well.

OSHA is also proposing a change to the “Combustible Dust” hazard statement. When OSHA finalized the revisions to the HCS in 2012, the GHS did not address classification of combustible dust; however, it used combustible dust as an example of “Other hazards which do not result in classification” (UN GHS, 2009, Document ID 0085). In the GHS Rev. 5, the UN updated A.4.3.2.3 to include a statement “May form explosible dust-air mixture if dispersed” for dust explosion hazards to provide guidance on the type of statement that should be used in the case of dust explosion hazards (combustible dust) (UN GHS, 2012, Document ID 0251). Subsequently, OSHA initiated UNSCEGHS discussions regarding combustible dust hazards. The UNSCEGHS adopted an annex (Annex 11) that provides additional guidance on hazard identification, the factors that contribute to a dust explosion hazard, and the need for risk assessment, prevention, mitigation, and communication (UN GHS, 2017, Document ID 0157). OSHA is now proposing to allow either the previously required statement, “may form combustible dust concentrations in air,” or the statement suggested in the GHS Annex 4, “[m]ay form explosible dust-air mixture.” OSHA is proposing to add square brackets after both statements containing the following language: “if small particles are generated during further processing, handling or by other means.” This bracketed language is designed to indicate that this language should be added when the material can create a combustible dust hazard during the processing or handling of the chemical. OSHA is not proposing any changes to the signal word of “warning” or any pictogram requirements. These changes are the result of working papers presented to the UNSCEGHS meetings for discussion in December of 2017 (UN GHS, 2017, Document ID 0157).

#### GHS Revisions That OSHA Is Not Proposing To Adopt

There are a small number of revisions in the GHS Rev. 7 that OSHA is not proposing to adopt for the HCS. In general, OSHA does not propose to

adopt any statements or conditional instructions that address consumer products because the HCS does not cover communication of hazards to consumers. This section discusses specific provisions in the GHS Rev. 7 (UN GHS, 2017, Document ID 0060) that OSHA is not proposing to adopt.

A number of tables for inhalation hazards in appendix C.4 (*i.e.*, acute toxicity—inhalation (C.4.3, categories 3 and 4), respiratory sensitization (C.4.6), skin sensitization (C.4.7), and specific target organ toxicity—single exposure (C.4.11, category 3)) contain a precautionary statement that says “Avoid breathing dust/fume/gas/mist/vapors/spray.” A conditional note in the GHS Rev. 7 (UN GHS, 2017, Document ID 0060) indicates that this precautionary statement is not needed where the precautionary statement “Do not breathe dust/mist/fume/gas/vapors/spray” is included on the label. Also, for skin corrosion/irritation (C.4.4, category 2), the GHS Rev. 7 (UN GHS, 2017, Document ID 0060) contains a conditional note indicating that the statement “If skin irritation occurs: Get medical advice/attention” may be omitted if the statement “If skin irritation or rash occurs: Get medical advice or treatment” is used. OSHA is not proposing to adopt these conditional instructions because it believes that proposed appendix C.2.4.8 (currently C.2.4.7), which provides instructions for the precedence of precautionary statements, already provides the necessary flexibility.

In the GHS Rev. 7, the precautionary statements about explosion-proof equipment and taking action to prevent static discharge include a conditional instruction indicating that these precautionary statements can be omitted if national or local legislation contains provisions that are more specific (UN GHS, 2017, Document ID 0060). OSHA is not proposing to adopt this instruction because the agency believes these precautionary statements contain important information that should always be included on labels. Although some OSHA and consensus standards address the use of explosion-proof equipment and preventing static discharge for flammable liquids or solids, they do not address hazard communication. Therefore, OSHA does not believe they are specific enough to justify omitting the relevant precautionary statement from labels. Label preparers can add more specific supplementary information from standards as long as it complies with paragraph C.3. For example, they may reference OSHA’s flammable liquids standard (29 CFR 1910.106), which

addresses the requirements for electrical equipment in workplaces that store or handle flammable liquids. OSHA requests comments on its preliminary decision not to include the conditional instruction from the GHS.

Under the HCS, a precautionary statement for gases under pressure (C.4.18) currently says “Protect from sunlight.” The GHS Rev. 7 contains a conditional instruction indicating that this precautionary statement “may be omitted for gases filled in transportable gas cylinders in accordance with packing instruction P200 of the UN Recommendations on the Transport of Dangerous Goods, Model Regulations, unless those gases are subject to (slow) decomposition or polymerization, or the competent authority provides otherwise” (UN GHS, 2017, Document ID 0060). These special packaging instructions under P200 are not applicable to cylinders used in the U.S.; therefore, OSHA is not proposing to add this conditional instruction to C.4.18 (UN GHS, 2017, Document ID 0060).

#### F. Appendix D

OSHA is proposing several changes to appendix D. These changes are being proposed to align with the GHS Rev. 7 (UN GHS, 2017, Document ID 0060) to clarify existing requirements where stakeholders have expressed confusion, and to ensure consistency with updated scientific principles. A redline strike out version of appendix D, which reflects all of OSHA’s proposed revisions, is available in the docket and on the OSHA website (OSHA HCS Redline 2020, Document ID 0222); <https://www.osha.gov/dsg/hazcom/>). This will allow interested parties to view all of the proposed changes in context. OSHA strongly encourages stakeholders to review that document in conjunction with the discussion of the proposed revisions below.

In the introductory section of appendix D, OSHA proposes to add a sentence stating that while each section of the SDS must contain all of the specified information, preparers of SDSs are not required to present the information in any particular order within each section. OSHA proposes this change to help clarify that while all required information must be present on the SDS, there are no mandates about the order in which the information is presented within each section. Because the information within each section can be listed in any order, OSHA does not anticipate any increased burden on SDS preparers from this change.

In section 1, Identification, OSHA is proposing revisions to clarify that the address and telephone number provided

on the SDS must be domestic. Although OSHA explained in a 2016 letter of interpretation that a U.S. telephone number and U.S. address are required for the SDS and label (Lee, 2016, Document ID 0090), OSHA believes it is important to codify this requirement in the text of the HCS to minimize any future confusion.

In section 2, Hazard(s) identification, OSHA is proposing to clarify where and how chemical hazard information should be presented. First, OSHA proposes to clarify that paragraph (a) must include any hazards associated with a change in the chemical's physical form under normal conditions of use, an issue the agency has addressed in several LOIs (Cawthorn, 2014, Document ID 0238; McCarthy, 2015, Document ID 0185; Fox, 2008; Document ID 0239). For example, for a chemical that poses a combustible dust hazard when processed (but not in the form in which it is shipped), the combustible dust hazard must be included in section 2(a). OSHA is also proposing a new paragraph (c) covering hazards identified under normal conditions of use that result from a chemical reaction (changing the chemical structure of the original substance or mixture). One example of such a reaction under normal conditions of use is the chemical change and subsequent physical effects of adding water to ready-mix concrete or cement, which creates additional hazards besides those present before the water is added (MST; 1995, Document ID 0253). This information is already required on the SDS (Boros, 2014, Document ID 0171), but OSHA believes that adding this language in paragraph (c) of section 2 would provide a clear and separate location for chemical manufacturers, distributors and importers to place this information. To accommodate the new material being proposed for paragraph (c), OSHA is proposing to move existing paragraphs (c) and (d) to paragraphs (d) and (e). OSHA notes that if it adopts the proposed revisions to section 2, hazards associated with chemicals as shipped, as well as hazards associated with a change in the chemical's physical form under normal conditions of use, would be presented in paragraph (a), and new hazards created by a chemical reaction under normal conditions of use would be presented in paragraph (c). OSHA believes this would sufficiently differentiates the different types of hazards presented under normal conditions of use, but welcomes stakeholder comments on this issue.

In section 3, OSHA is proposing several changes. Under the subheading "For Substances (d)" OSHA is

proposing to add "(constituents)" to clarify the term "additives." OSHA intends that any individual part of an "additive" that contributes to the classification of that material needs to be listed in section 3 of the SDS. OSHA is also proposing to revise the information provided for mixtures. In addition to the information required for substances, section 3 requires the chemical name of all ingredients in a mixture that are classified as health hazards. OSHA proposes also requiring the CAS number or other unique identifier for these ingredients. CAS numbers are unique numerical identifiers assigned by the American Chemical Society (ACS) (CAS, 2020, Document ID 0173). CAS numbers are internationally recognized as being reliable and readily validated, are unique to only one compound, substance or chemical, and provide a common link between various nomenclature that may be used as descriptors for the substance or compound (UN, 2005, Document ID 0130; CAS, 2020, Document ID 0173). CAS numbers have been generated for all substances identified from the scientific literature from 1957 to the present, with some substances identified as far back as the early 1900s (CAS, 2020, Document ID 0173; UN, 2005, Document ID 0130). OSHA believes that this information provides the downstream user with important information, since it provides a unique descriptor of the chemical where the chemical identity may be ambiguous.

OSHA is proposing an additional change in section 3 to reflect the proposed revision to paragraph (i) (*Trade secrets*), which would allow for concentration ranges to be withheld as a trade secret. When the concentration or concentration range is withheld as a trade secret, the chemical composition range would have to be provided in accordance with the prescribed concentration ranges in paragraphs (i)(1)(iv)(A) through (M). As explained in the summary and explanation section for paragraph (i), this would create an alignment with the WHMIS under Health Canada (Canadian Gazette II, 2018, Document ID 0101).

Section 8 of the SDS includes information on exposure controls/personal protection. Section 8(a) currently requires the SDS to include the OSHA permissible exposure limit (PEL), American Conference of Governmental Industrial Hygienists (ACGIH) Threshold Limit Value (TLV), and any other exposure limit used or recommended by the chemical manufacturer, importer, or employer preparing the SDS, when available.

OSHA has received questions about whether this requirement applies to individual ingredients and constituents in the mixture, and has explained that it applies to any ingredient or constituent identified in section 3 of the SDS (McVeigh, 2013, Document ID 0088). To clarify this point, OSHA is proposing to revise section 8(a) to state that it applies to all ingredients or constituents listed in section 3. OSHA notes, however, that if the ingredient or constituent does not have an OSHA PEL, ACGIH TLV or any other exposure limit used or recommended by the SDS preparer, then the ingredient or constituent would not need to be listed in section 8.

In addition, OSHA is also proposing to revise section 8 to add language indicating that SDS preparers must also include a "range" of exposure limits whenever a range is used or recommended by the chemical manufacturer, importer, or employer preparing the SDS. This revision would acknowledge new tools, such as occupational exposure banding or hazard banding methods described by NIOSH and the United Kingdom Health and Safety Executive (NIOSH, 2017, Document ID 0106; HSE, 2013, Document ID 0104). Hazard banding and occupational exposure banding provide a concentration range (band) based on toxicity and hazard information associated with a known chemical with similar properties; this range can inform appropriate risk management decisions where a specific occupational exposure limit (OEL) or permissible exposure limit (PEL) is not available or out of date (NIOSH, 2017, Document ID 0106). This type of information has been developed and validated over the last few decades and these types of exposure ranges can provide hazard information on chemicals that can help reduce risk to workers, even if limited toxicological information is available (NIOSH, 2017, Document ID 0106). As noted by NIOSH and the U.S. EPA, more than 85,000 chemicals are in commerce, with only approximately one thousand having been assessed for hazard and toxicity (either through an authoritative entity or peer-reviewed process) (NIOSH, 2017, Document ID 0106; EPA, 2016, Document ID 0058).

OSHA is proposing several updates to section 9, Physical and chemical properties. OSHA proposes to revise section 9 to align with the GHS Rev. 7 by listing the required physical and chemical properties of the chemical in the same order that appears in the GHS (UN GHS, 2017, Document ID 0060). While OSHA does not require SDS

preparers to list the physical and chemical properties in any particular order, the agency is proposing this change in order to simplify preparation for those chemical manufacturers that may prepare SDSs for global distribution. Other proposed changes to section 9 include: Replacing “appearance” with “physical state” and “color”; eliminating “odor threshold” and “evaporation rate” as separate required properties; adding the term “kinematic” to the property “viscosity” in order to better define the appropriate parameter to be characterized (*i.e.*, kinematic as opposed to dynamic viscosity); and adding “particle characteristics” as a new physical property. Particle characteristics apply to solids only and the description should include the particle size (median and range) and, if available and appropriate, further properties such as size distribution (range), shape and aspect ratio, and specific surface area. Particle characteristics can be an important indicator of the potential for a solid particle to pose a hazard as particles that are less than 100 microns increase the likelihood of exposure, especially through the route of inhalation (UN GHS, 2017, Document ID 0060; UN GHS, 2016; Document ID 0143, UN GHS, 2014, Document ID 0129).

OSHA is proposing one change to section 10 of the SDS, Stability and reactivity. Section 10(c) requires preparers to include the possibility of hazardous reactions, and OSHA is proposing to clarify that this includes hazardous reactions associated with foreseeable emergencies. The proposed language is consistent with the language OSHA is proposing for paragraph (d)(1) (*Hazard classification*).

In addition, OSHA is proposing to revise section 11, Toxicological information, to align with the GHS Rev. 7 (UN GHS, 2017, Document ID 0060) by adding interactive effects as paragraph (e). In light of that proposed change, OSHA is proposing to move existing paragraph (e) to paragraph (f). OSHA also proposes to add a new paragraph (g), providing that when specific chemical data or information is not available, SDS preparers must indicate if alternative information is used and the method used to derive the information (*e.g.*, where the preparer is using information from a class of chemicals rather than the exact chemical in question and using structure activity relationships (SAR) to derive the toxicological information). SAR and QSAR (quantitative SAR) are predictive tools that utilize the properties from known chemical

structures and properties in relation to their biological activity to predict activities and properties of untested chemicals based on their structural similarity to tested chemicals (EPA, 2016, Document ID 0179). Read across is another predictive technique that uses information on an endpoint from a known (tested) substance to predict endpoint information from a similar (but unknown or untested) substance (ECHA, 2016, Document ID 0178). Specific, detailed examples of read across, SAR and QSAR are provided on the OECD’s website for chemical safety—assessment of chemicals (OECD, 2019, Document ID 0091; EPA, 2016, Document ID 0179; ECHA, 2016, Document ID 0178). This proposed change reflects the advancement in the scientific application of computational toxicology to hazard assessment and identification and would align with the GHS Rev. 7 (Ballabio, 2018, Document ID 0128; Idakwo, 2020, Document ID 0123; OECD, Document ID 0091; Mangiatori, 2016, Document ID 0122; UN GHS, 2017, Document ID 0060).

Finally, OSHA is proposing to change non-mandatory section 14(f), Transport information, to read “Transport in bulk according to IMO instructions”<sup>60</sup> instead of “Transport in bulk (according to Annex II of MARPOL 73/78 and the IBC Code)”<sup>61</sup> to be consistent with text in the GHS Rev. 7 (IMSBC, 2017, Document ID 0141). This change is an update to the reference that previously only covered liquefied gases in bulk. The proposed change would provide guidance that the information in section 14 covers all bulk transport regardless of the physical form of the cargo, in accordance with IMO instruments: *e.g.*, Annex II or Annex V of MARPOL 73/789, the IBC code<sup>10</sup>, the IMSBC<sup>62</sup> code and the IGC<sup>63</sup> code. This change would also reflect standardization of conventions for the technology and safety upgrades in the IMO (a global standard-setting authority for the safety, security and environmental performance of international shipping under the United Nations).

#### XVI. Authority and Signature

This document was prepared under the direction of Loren Sweatt, Principal Deputy Assistant Secretary of Labor for Occupational Safety and Health, U.S.

<sup>60</sup> IMO Means the International Maritime Organization.

<sup>61</sup> MARPOL means the International Convention for prevention of Pollution from Ships.

<sup>62</sup> IMSBC Code means the International Maritime Solid Bulk Cargoes Code, as amended.

<sup>63</sup> IGC Code means The International Code of the Construction and Equipment of Ships Carrying Liquefied Gases in Bulk, as amended.

Department of Labor, 200 Constitution Avenue NW, Washington, DC 20210. It is issued under the authority of sections 4, 6, and 8 of the Occupational Safety and Health Act of 1970 (29 U.S.C. 653, 655, 657); 5 U.S.C. 553; section 304, Clean Air Act Amendments of 1990 (Pub. L. 101–549, reprinted at 29 U.S.C.A. 655 Note); section 41, Longshore and Harbor Workers’ Compensation Act (33 U.S.C. 941); section 107, Contract Work Hours and Safety Standards Act (40 U.S.C. 3704); section 1031, Housing and Community Development Act of 1992 (42 U.S.C. 4853); section 126, Superfund Amendments and Reauthorization Act of 1986, as amended (reprinted at 29 U.S.C.A. 655 Note); Secretary of Labor’s Order No. 8–2020 (85 FR 58383–94); and 29 CFR part 1911.

#### List of Subjects in 29 CFR Part 1910

Chemicals, Diseases, Explosives, Flammable materials, Gases, Hazardous substances, Incorporation by reference, Labeling, Occupational safety and health, Safety, Signs and symbols.

Signed at Washington, DC, on December 28, 2020.

**Loren Sweatt,**

*Principal Deputy Assistant Secretary of Labor for Occupational Safety and Health.*

#### Proposed Amendments

For the reasons set forth in the preamble, chapter XVII of title 29, part 1910 of the Code of Federal Regulations is proposed to be amended as follows:

#### PART 1910—OCCUPATIONAL SAFETY AND HEALTH STANDARDS

■ 1. The authority citation for part 1910 continues to read as follows:

**Authority:** 33 U.S.C. 941; 29 U.S.C. 653, 655, 657; Secretary of Labor’s Order No. 12–71 (36 FR 8754); 8–76 (41 FR 25059), 9–83 (48 FR 35736), 1–90 (55 FR 9033), 6–96 (62 FR 111), 3–2000 (65 FR 50017), 5–2002 (67 FR 65008), 5–2007 (72 FR 31160), 4–2010 (75 FR 55355), 1–2012 (77 FR 3912), or 08–2020 (85 FR 58393); 29 CFR part 1911; and 5 U.S.C. 553, as applicable.

■ 2. Amend § 1910.6 by:

■ a. Revising the last sentence of paragraph (a)(4);

■ b. Adding paragraphs (h)(29) and (r)(2)(vi);

■ c. Redesignating paragraphs (r)(4) and (5) as paragraphs (r)(6) and (7), redesignating paragraph (r)(3) as paragraph (r)(4), and adding new paragraphs (r)(3) and (r)(5);

■ d. Revising paragraph (bb); and

■ e. Adding paragraphs (cc) and (dd).

The revisions and additions read as follows:

**§ 1910.6 Incorporation by reference.**

(a) \* \* \*

(4) \* \* \* For information on the availability of this material at NARA, email [fedreg.legal@nara.gov](mailto:fedreg.legal@nara.gov) or go to [www.archives.gov/federal-register/cfr/ibr-locations.html](http://www.archives.gov/federal-register/cfr/ibr-locations.html).

\* \* \* \* \*

(h) \* \* \*

(29) ASTM D 4359–90 (2019), Standard Test Method for Determining Whether a Material is a Liquid or a Solid, Re-approved 2019, IBR approved for § 1910.1200.

\* \* \* \* \*

(r) \* \* \*

(2) \* \* \*

(vi) International Organization for Standardization, ISO Central Secretariat, Chemin de Blandonnet 8 CP 401—1214 Vernier, Geneva, Switzerland; Telephone: +41 22 749 01 11; Fax: +41 22 733 34 30; Email: [central@iso.org](mailto:central@iso.org); website: <https://www.iso.org/store.html>.

(3) ISO 817:2014, Refrigerants—Designation and safety classification. Third Edition, June, 2014, IBR approved for appendix B to § 1910.1200.

\* \* \* \* \*

(5) ISO 10156:2010, Gases and Gas Mixtures—Determination of Fire Potential and Oxidizing Ability for the Selection of Cylinder Valve Outlets, Third Edition, April, 2010, IBR approved for appendix B to § 1910.1200.

\* \* \* \* \*

(bb) Except as noted, copies of the standards listed in this paragraph (bb) are available for purchase from United Nations Publications, P.O. Box 960 Herndon, VA 20172; telephone: 1-703-661-1571; fax: 1-703-996-1010; email: [order@un.org](mailto:order@un.org).

(1) European Agreement Concerning the International Carriage of Dangerous Goods by Road (ADR), section 2.3.4 of Annex A, 2019, IBR approved for § 1910.1200. Website: <https://shop.un.org/series/european-agreement-concerning-international-carriage-dangerous-goods-road-adr>.

(2) UN ST/SG/AC.10/Rev.4, The UN Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria, Fourth Revised Edition, 2003, IBR approved for appendix B to § 1910.1200. Copies available from:

(i) Bernan, 15200 NBN Way, Blue Ridge Summit, PA 17214; telephone: 1-800-865-3457; fax: 1-800-865-3450; email: [customercare@bernan.com](mailto:customercare@bernan.com); website: <http://www.bernan.com>;

(ii) Renouf Publishing Co. Ltd., 812 Proctor Avenue, Ogdensburg, NY 13669–2205; telephone: 1-888-551-7470; Fax: 1-888-551-7471; email: [orders@renoufbooks.com](mailto:orders@renoufbooks.com); website: <http://www.renoufbooks.com>; and

(iii) United Nations Publications, Customer Service, c/o National Book Network, 15200 NBN Way, P.O. Box 190, Blue Ridge Summit, PA 17214; telephone: 1-888-254-4286; fax: 1-800-338-4550; email: [unpublications@nbnbooks.com](mailto:unpublications@nbnbooks.com).

(3) UN ST/SG/AC.10/30/Rev.6, The UN Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria, Sixth Revised Edition, 2015, IBR approved for appendix B to § 1910.1200. Website: [https://www.unece.org/trans/danger/publi/manual/manual\\_e.html](https://www.unece.org/trans/danger/publi/manual/manual_e.html).

(cc) The following material is available for purchase from International Electrotechnical Commission through ANSI, 25 West 43rd Street, 4th Floor, New York, NY 10036; telephone: 1-212-642-4963; fax: 1-212-398-0023; website: <https://www.iec.ch>.

(1) IEC 60079–20–1 ed. 1.0 (2010–01) Explosive atmospheres—Part 20–1: Material characteristics for gas and vapor classification—Test methods and data, IBR approved for appendix B to § 1910.1200.

(2) [Reserved]

(dd) The following material is available for purchase from German Institute for Standardization (DIN) through ANSI, 25 West 43rd Street, 4th Floor, New York, NY 10036; telephone: 1-212-642-4963; fax: 1-212-398-0023; <https://din.de/en/about-standards/buy-standard>.

(1) DIN 51794—Determining the ignition temperature of petroleum products, 2003, IBR approved for appendix B to § 1910.1200.

(2) [Reserved]

■ 3. Amend § 1910.1200:

■ a. By revising paragraphs (a)(1) and (b)(6)(x);

■ b. In paragraph (c):

■ i. By removing the period following the subject heading and adding a colon in its place;

■ ii. By adding in alphabetical order definitions for “Bulk shipment” and “Combustible dust”;

■ iii. By revising the definition of “Exposure or exposed”;

■ iv. By adding in alphabetical order a definition for “Gas”;

■ v. By revising the definition of “Hazardous chemical”;

■ vi. By adding in alphabetical order definitions for “Immediate outer package” and “Liquid”;

■ vii. By revising the definition of “Physical hazard”;

■ viii. By adding in alphabetical order a definition for “Physician or other licensed health care professional (PLHCP)”;

■ ix. By removing the definition of “Pyrophoric gas”; and

■ x. By adding in alphabetical order definitions for “Released for shipment” and “Solid”;

■ c. By revising paragraphs (d)(1), (e)(4), and (f)(1), (5), and (11);

■ d. By adding paragraph (f)(12);

■ e. By revising paragraphs (g)(2) introductory text, (g)(10), (i)(1) and (2), (i)(3) introductory text, and (j); and

■ f. By revising appendices A through D.

The revisions and additions read as follows:

**§ 1910.1200 Hazard communication.**

(a) \* \* \*

(1) The purpose of this section is to ensure that the hazards of all chemicals produced or imported are classified, and that information concerning the classified hazards is transmitted to employers and employees. The requirements of this section are intended to be consistent with the provisions of the United Nations Globally Harmonized System of Classification and Labeling of Chemicals (GHS), Revision 7. The transmittal of information is to be accomplished by means of comprehensive hazard communication programs, which are to include container labeling and other forms of warning, safety data sheets and employee training.

\* \* \* \* \*

(b) \* \* \*

(6) \* \* \*

(x) Nuisance particulates where the chemical manufacturer or importer can establish that they do not pose any physical hazard, health hazard, or other hazards covered under this section;

\* \* \* \* \*

(c) \* \* \*

**Bulk shipment** means any hazardous chemical transported where the mode of transportation (vehicle) comprises the immediate container (*i.e.*, contained in tanker truck, rail car, or intermodal container).

\* \* \* \* \*

**Combustible dust** means finely divided solid particles of a substance or mixture that are liable to catch fire or explode on ignition when dispersed in air or other oxidizing media.

\* \* \* \* \*

**Exposure or exposed** means that an employee is subjected in the course of employment to a hazardous chemical, and includes potential (*e.g.*, accidental or possible) exposure. “Subjected” in terms of health hazards includes any route of entry (*e.g.*, inhalation, ingestion, skin contact or absorption).

\* \* \* \* \*

**Gas** means a substance which—at 122 °F (50 °C) has a vapor pressure greater than 43.51 PSI (300 kPa) (absolute); or

is completely gaseous at 68 °F (20 °C) at a standard pressure of 14.69 PSI (101.3 kPa).

\* \* \* \* \*

*Hazardous chemical* means any chemical which is classified as a physical hazard or a health hazard, a simple asphyxiant, combustible dust, or hazard not otherwise classified.

\* \* \* \* \*

*Immediate outer package* means the first package enclosing the container of hazardous chemical.

\* \* \* \* \*

*Liquid* means a substance or mixture which at 122 °F (50 °C) has a vapor pressure of not more than 43.51 PSI (300 kPa (3 bar)), which is not completely gaseous at 68 °F (20 °C) and at a standard pressure of 101.3 kPa, and which has a melting point or initial melting point of 68 °F (20 °C) or less at a standard pressure of 14.69 PSI (101.3 kPa). A viscous substance or mixture for which a specific melting point cannot be determined shall be subjected to ASTM D 4359–90 (2019) (Standard Test Method for Determining Whether a Material Is a Liquid or a Solid) (incorporated by reference; see § 1910.6); or to the test for determining fluidity (penetrometer test) prescribed in the European Agreement Concerning the International Carriage of Dangerous Goods by Road (ADR), section 2.3.4 of Annex A (2019) (incorporated by reference; see § 1910.6).

\* \* \* \* \*

*Physical hazard* means a chemical that is classified as posing one of the following hazardous effects: Explosive; flammable (gases, liquids, or solids); aerosols; oxidizer (liquid, solid or gas); self-reactive; pyrophoric (liquid or solid); self-heating; organic peroxide; corrosive to metal; gas under pressure; in contact with water emits flammable gas; or desensitized explosive. The criteria for determining whether a chemical is classified as a physical hazard are detailed in appendix B to this section.

*Physician or other licensed health care professional (PLHCP)* means an individual whose legally permitted scope of practice (i.e., license, registration, or certification) allows the individual to independently provide or be delegated the responsibility to provide some or all of the health care services referenced in paragraph (i) of this section.

\* \* \* \* \*

*Released for shipment* means a chemical that has been packaged and labeled in the manner in which it will be distributed or sold.

\* \* \* \* \*

*Solid* means a substance or mixture which does not meet the definitions of liquid or gas.

\* \* \* \* \*

(d) \* \* \*

(1) Chemical manufacturers and importers shall evaluate chemicals produced in their workplaces or imported by them to classify the chemicals in accordance with this section. For each chemical, the chemical manufacturer or importer shall determine the hazard classes, and where appropriate, the category of each class that apply to the chemical being classified under normal conditions of use and foreseeable emergencies. The hazard classification shall include any hazards associated with a change in the chemical's physical form or resulting from a reaction with other chemicals under normal conditions of use. Employers are not required to classify chemicals unless they choose not to rely on the classification performed by the chemical manufacturer or importer for the chemical to satisfy this paragraph (d)(1).

\* \* \* \* \*

(e) \* \* \*

(4) The employer shall make the written hazard communication program available, upon request, to employees, their designated representatives, the Assistant Secretary and the Director, in accordance with the requirements of § 1910.1020(e).

\* \* \* \* \*

(f) \* \* \*

(1) *Labels on shipped containers.* The chemical manufacturer, importer, or distributor shall ensure that each container of hazardous chemicals leaving the workplace is labeled, tagged or marked. Hazards not otherwise classified and hazards resulting from a reaction with other chemicals under normal conditions of use do not have to be addressed on the container. Where the chemical manufacturer, importer, or distributor is required to label, tag or mark the following shall be provided:

- (i) Product identifier;
- (ii) Signal word;
- (iii) Hazard statement(s);
- (iv) Pictogram(s);
- (v) Precautionary statement(s);
- (vi) Name, address, and telephone number of the chemical manufacturer, importer, or other responsible party; and
- (vii) Date chemical is released for shipment.

\* \* \* \* \*

(5) *Transportation.* (i) Chemical manufacturers, importers, or distributors shall ensure that each container of hazardous chemicals leaving the workplace is labeled, tagged,

or marked in accordance with this section in a manner which does not conflict with the requirements of the Hazardous Materials Transportation Act (49 U.S.C. 1801 *et seq.*) and regulations issued under that Act by the Department of Transportation.

(ii) The label for bulk shipments of hazardous chemicals may be on the immediate container or may be transmitted with the shipping papers, bills of lading, or other technological or electronic means so that it is immediately available to workers in printed form on the receiving end of shipment.

(iii) Where a pictogram required by the Department of Transportation under title 49 of the Code of Federal Regulations appears on the label for a shipped container, the pictogram specified in appendix C.4 of this section for the same hazard is not required on the label.

\* \* \* \* \*

(11) *Release for shipment.* Chemical manufacturers, importers, distributors, or employers who become newly aware of any significant information regarding the hazards of a chemical shall revise the labels for the chemical within six months of becoming aware of the new information, and shall ensure that labels on containers of hazardous chemicals shipped after that time contain the new information. Chemicals that have been released for shipment and are awaiting future distribution need not be relabeled; however, the chemical manufacturer or importer must provide the updated label for each individual container with each shipment. If the chemical is not currently produced or imported, the chemical manufacturer, importer, distributor, or employer shall add the information to the label before the chemical is shipped or introduced into the workplace again.

(12) *Small container labelling.* (i) This paragraph (f)(12) applies where the chemical manufacturer, importer, or distributor can demonstrate that it is not feasible to use pull-out labels, fold-back labels, or tags containing the full label information required by paragraph (f)(1) of this section.

(ii) For a container less than or equal to 100 ml capacity, the chemical manufacturer, importer, or distributor must include, at a minimum, the following information on the label of the container:

- (A) Product identifier;
- (B) Pictogram(s);
- (C) Signal word;
- (D) Chemical manufacturer's name and phone number; and
- (E) A statement that the full label information for the hazardous chemical

is provided on the immediate outer package.

(iii) For a container less than or equal to 3 ml capacity, where the chemical manufacturer, importer, or distributor can demonstrate that any label interferes with the normal use of the container, no label is required, but the container must bear, at a minimum, the product identifier.

(iv) For all small containers covered by paragraph (f)(12)(ii) or (iii) of this section, the immediate outer package must include:

(A) The full label information required by paragraph (f)(1) of this section for each hazardous chemical in the immediate outer package. The label must not be removed or defaced, as required by paragraph (f)(9) of this section.

(B) A statement that the small container(s) inside must be stored in the immediate outer package bearing the complete label when not in use.

(g) \* \* \*

(2) The chemical manufacturer or importer shall ensure that the safety data sheet is in English (although the employer may maintain copies in other languages as well), and includes at least the following section numbers and headings, and associated information under each heading, in the order listed (See appendix D to this section for the specific content of each section of the safety data sheet):

\* \* \* \* \*

(10) Safety data sheets may be kept in any form, including as operating procedures, and may be stored in such a way to cover groups of hazardous chemicals in a work area where it may be more appropriate to address the hazards of a process rather than individual hazardous chemicals. However, the employer shall ensure that in all cases the required information is provided for each hazardous chemical, and is readily accessible during each work shift to employees when they are in their work area(s).

\* \* \* \* \*

(i) \* \* \*

(1) The chemical manufacturer, importer, or employer may withhold the specific chemical identity, including the chemical name, other specific identification of a hazardous chemical, or the exact percentage (concentration) or concentration range of the substance in a mixture, from section 3 of the safety data sheet, provided that:

(i) The claim that the information withheld is a trade secret can be supported;

(ii) Information contained in the safety data sheet concerning the

properties and effects of the hazardous chemical is disclosed;

(iii) The safety data sheet indicates that the specific chemical identity and/or concentration or concentration range of composition is being withheld as a trade secret;

(iv) If the concentration or concentration range is being claimed as a trade secret then the safety data sheet provides the ingredient's concentration as one of the prescribed ranges in paragraphs (i)(1)(iv)(A) through (M) of this section.

(A) From 0.1% to 1%;

(B) From 0.5% to 1.5%;

(C) From 1% to 5%;

(D) From 3% to 7%;

(E) From 5% to 10%;

(F) From 7% to 13%;

(G) From 10% to 30%;

(H) From 15% to 40%;

(I) From 30% to 60%;

(J) From 45% to 70%;

(K) From 60% to 80%;

(L) From 65% to 85%; and

(M) From 80% to 100%.

(v) The prescribed concentration range used must be the narrowest range possible. If the exact concentration range falls between 0.1% and 30% and does not fit entirely into one of the prescribed concentration, a single range created by the combination of two applicable consecutive ranges (e.g., between (i)(1)(iv)(A) and (G)) may be disclosed instead, provided that the combined concentration range does not include any range that falls entirely outside the exact concentration range in which the ingredient is present.

(vi) The specific chemical identity and exact concentration or concentration range is made available to health professionals, employees, and designated representatives in accordance with the applicable provisions of this paragraph (i).

(2) Where a treating PLHCP determines that a medical emergency exists and the specific chemical identity and/or specific concentration or concentration range of a hazardous chemical is necessary for emergency or first-aid treatment, the chemical manufacturer, importer, or employer shall immediately disclose the specific chemical identity or percentage composition of a trade secret chemical to that treating PLHCP, regardless of the existence of a written statement of need or a confidentiality agreement. The chemical manufacturer, importer, or employer may require a written statement of need and confidentiality agreement, in accordance with the provisions of paragraphs (i)(3) and (4) of this section, as soon as circumstances permit.

(3) In non-emergency situations, a chemical manufacturer, importer, or employer shall, upon request, disclose a specific chemical identity or exact concentration or concentration range, otherwise permitted to be withheld under paragraph (i)(1) of this section, to a health professional (e.g., PLHCP, industrial hygienist, toxicologist, or epidemiologist) providing medical or other occupational health services to exposed employee(s), and to employees or designated representatives, if:

\* \* \* \* \*

(j) *Dates.* (1) This section is effective [DATE 60 DAYS AFTER DATE OF PUBLICATION OF FINAL RULE IN THE **FEDERAL REGISTER**].

(2) Chemical manufacturers, importers, and distributors evaluating substances shall be in compliance with all modified provisions of this section no later than [DATE ONE YEAR AFTER EFFECTIVE DATE OF FINAL RULE].

(3) Chemical manufacturers, importers, and distributors evaluating mixtures shall be in compliance with all modified provisions of this section no later than 24 months after [DATE TWO YEARS AFTER EFFECTIVE DATE OF FINAL RULE].

\* \* \* \* \*

## Appendix A to § 1910.1200—Health Hazard Criteria (Mandatory)

### A.0 General Classification Considerations

#### A.0.1 Classification

A.0.1.1 The term “hazard classification” is used to indicate that only the intrinsic hazardous properties of chemicals are considered. Hazard classification incorporates three steps:

(a) Identification of relevant data regarding the hazards of a chemical;

(b) Subsequent review of those data to ascertain the hazards associated with the chemical;

(c) Determination of whether the chemical will be classified as hazardous and the degree of hazard.

A.0.1.2 For many hazard classes, the criteria are semi-quantitative or qualitative and expert judgment is required to interpret the data for classification purposes.

A.0.1.3 Where impurities, additives or individual constituents of a substance or mixture have been identified and are themselves classified, they should be taken into account during classification if they exceed the cut-off value/concentration limit for a given hazard class.

#### A.0.2 Available Data, Test Methods and Test Data Quality

A.0.2.1 There is no requirement for testing chemicals.

A.0.2.2 The criteria for determining health hazards are test method neutral, i.e., they do not specify particular test methods, as long as the methods are scientifically validated.

A.0.2.3 The term “scientifically validated” refers to the process by which the reliability and the relevance of a procedure are established for a particular purpose. Any test that determines hazardous properties, which is conducted according to recognized scientific principles, can be used for purposes of a hazard determination for health hazards. Test conditions need to be standardized so that the results are reproducible with a given substance, and the standardized test yields “valid” data for defining the hazard class of concern.

A.0.2.4 Existing test data are acceptable for classifying chemicals, although expert judgment also may be needed for classification purposes.

A.0.2.5 The effect of a chemical on biological systems is influenced, by the physico-chemical properties of the substance and/or ingredients of the mixture and the way in which ingredient substances are biologically available. A chemical need not be classified when it can be shown by conclusive experimental data from scientifically validated test methods that the chemical is not biologically available.

A.0.2.6 For classification purposes, epidemiological data and experience on the effects of chemicals on humans (e.g., occupational data, data from accident databases) shall be taken into account in the evaluation of human health hazards of a chemical.

#### A.0.3 *Classification Based on Weight of Evidence*

A.0.3.1 For some hazard classes, classification results directly when the data satisfy the criteria. For others, classification of a chemical shall be determined on the basis of the total weight of evidence using expert judgment. This means that all available information bearing on the classification of hazard shall be considered together, including the results of valid *in vitro* tests, relevant animal data, and human experience such as epidemiological and clinical studies and well-documented case reports and observations.

A.0.3.2 The quality and consistency of the data shall be considered. Information on chemicals related to the material being classified shall be considered as appropriate, as well as site of action and mechanism or mode of action study results. Both positive and negative results shall be considered together in a single weight-of-evidence determination.

A.0.3.3 Positive effects which are consistent with the criteria for classification, whether seen in humans or animals, shall normally justify classification. Where evidence is available from both humans and animals and there is a conflict between the findings, the quality and reliability of the evidence from both sources shall be evaluated in order to resolve the question of classification. Reliable, good quality human data shall generally have precedence over other data. However, even well-designed and conducted epidemiological studies may lack a sufficient number of subjects to detect relatively rare but still significant effects, or to assess potentially confounding factors. Therefore, positive results from well-

conducted animal studies are not necessarily negated by the lack of positive human experience but require an assessment of the robustness, quality and statistical power of both the human and animal data.

A.0.3.4 Route of exposure, mechanistic information, and metabolism studies are pertinent to determining the relevance of an effect in humans. When such information raises doubt about relevance in humans, a lower classification may be warranted. When there is scientific evidence demonstrating that the mechanism or mode of action is not relevant to humans, the chemical should not be classified.

A.0.3.5 Both positive and negative results are considered together in the weight of evidence determination. However, a single positive study performed according to good scientific principles and with statistically and biologically significant positive results may justify classification.

#### A.0.4 *Considerations for the Classification of Mixtures*

A.0.4.1 Except as provided in A.0.4.2, the process of classification of mixtures is based on the following sequence:

(a) Where test data are available for the complete mixture, the classification of the mixture will always be based on those data;

(b) Where test data are not available for the mixture itself, the bridging principles designated in each health hazard chapter of this appendix shall be considered for classification of the mixture;

(c) If test data are not available for the mixture itself, and the available information is not sufficient to allow application of the above-mentioned bridging principles, then the method(s) described in each chapter for estimating the hazards based on the information known will be applied to classify the mixture (e.g., application of cut-off values/concentration limits).

A.0.4.2 An exception to the above order or precedence is made for Carcinogenicity, Germ Cell Mutagenicity, and Reproductive Toxicity. For these three hazard classes, mixtures shall be classified based upon information on the ingredient substances, unless on a case-by-case basis, justification can be provided for classifying based upon the mixture as a whole. See chapters A.5, A.6, and A.7 for further information on case-by-case bases.

A.0.4.3 Use of cut-off values/concentration limits

A.0.4.3.1 When classifying an untested mixture based on the hazards of its ingredients, cut-off values/concentration limits for the classified ingredients of the mixture are used for several hazard classes. While the adopted cut-off values/concentration limits adequately identify the hazard for most mixtures, there may be some that contain hazardous ingredients at lower concentrations than the specified cut-off values/concentration limits that still pose an identifiable hazard. There may also be cases where the cut-off value/concentration limit is considerably lower than the established non-hazardous level for an ingredient.

A.0.4.3.2 If the classifier has information that the hazard of an ingredient will be evident (i.e., it presents a health risk) below

the specified cut-off value/concentration limit, the mixture containing that ingredient shall be classified accordingly.

A.0.4.3.3 In exceptional cases, conclusive data may demonstrate that the hazard of an ingredient will not be evident (i.e., it does not present a health risk) when present at a level above the specified cut-off value/concentration limit(s). In these cases the mixture may be classified according to those data. The data must exclude the possibility that the ingredient will behave in the mixture in a manner that would increase the hazard over that of the pure substance. Furthermore, the mixture must not contain ingredients that would affect that determination.

A.0.4.4 Synergistic or antagonistic effects

When performing an assessment in accordance with these requirements, the evaluator must take into account all available information about the potential occurrence of synergistic effects among the ingredients of the mixture. Lowering classification of a mixture to a less hazardous category on the basis of antagonistic effects may be done only if the determination is supported by sufficient data.

A.0.5 Bridging principles for the classification of mixtures where test data are not available for the complete mixture

A.0.5.1 Where the mixture itself has not been tested to determine its toxicity, but there are sufficient data on both the individual ingredients and similar tested mixtures to adequately characterize the hazards of the mixture, these data shall be used in accordance with the following bridging principles, subject to any specific provisions for mixtures for each hazard class. These principles ensure that the classification process uses the available data to the greatest extent possible in characterizing the hazards of the mixture.

##### A.0.5.1.1 Dilution

For mixtures classified in accordance with A.1 through A.10 of this appendix, if a tested mixture is diluted with a diluent that has an equivalent or lower toxicity classification than the least toxic original ingredient, and which is not expected to affect the toxicity of other ingredients, then:

(a) The new diluted mixture shall be classified as equivalent to the original tested mixture; or

(b) For classification of acute toxicity in accordance with A.1 of this appendix, paragraph A.1.3.6 (the additivity formula) shall be applied.

##### A.0.5.1.2 Batching

For mixtures classified in accordance with A.1 through A.10 of this appendix, the toxicity of a tested production batch of a mixture can be assumed to be substantially equivalent to that of another untested production batch of the same mixture, when produced by or under the control of the same *chemical manufacturer*, unless there is reason to believe there is significant variation such that the toxicity of the untested batch has changed. If the latter occurs, a new classification is necessary.

##### A.0.5.1.3 Concentration of mixtures

For mixtures classified in accordance with A.1, A.2, A.3, A.4, A.8, A.9, or A.10 of this appendix, if a tested mixture is classified in Category 1, and the concentration of the

ingredients of the tested mixture that are in Category 1 is increased, the resulting untested mixture shall be classified in Category 1.

**A.0.5.1.4 Interpolation within one hazard category**

For mixtures classified in accordance with A.1, A.2, A.3, A.4, A.8, A.9, or A.10 of this appendix, for three mixtures (A, B and C) with identical ingredients, where mixtures A and B have been tested and are in the same hazard category, and where untested mixture C has the same toxicologically active ingredients as mixtures A and B but has concentrations of toxicologically active ingredients intermediate to the concentrations in mixtures A and B, then mixture C is assumed to be in the same hazard category as A and B.

**A.0.5.1.5 Substantially similar mixtures**

For mixtures classified in accordance with A.1 through A.10 of this appendix, given the following set of conditions:

- (a) Where there are two mixtures: (i) A + B; (ii) C + B;

- (b) The concentration of ingredient B is essentially the same in both mixtures;

- (c) The concentration of ingredient A in mixture (i) equals that of ingredient C in mixture (ii);

- (d) And data on toxicity for A and C are available and substantially equivalent; *i.e.*, they are in the same hazard category and are not expected to affect the toxicity of B; then

If mixture (i) or (ii) is already classified based on test data, the other mixture can be assigned the same hazard category.

**A.0.5.1.6 Aerosols**

For mixtures classified in accordance with A.1, A.2, A.3, A.4, A.8, or A.9 of this appendix, an aerosol form of a mixture shall be classified in the same hazard category as the tested, non-aerosolized form of the mixture, provided the added propellant does not affect the toxicity of the mixture when spraying.

**A.1 Acute Toxicity**

**A.1.1 Definition**

*Acute toxicity* refers to serious adverse health effects (*i.e.*, lethality) occurring after a

single or short-term oral, dermal, or inhalation exposure to a substance or mixture.

**A.1.2 Classification Criteria for Substances**

A.1.2.1 Substances can be allocated to one of four hazard categories based on acute toxicity by the oral, dermal or inhalation route according to the numeric cut-off criteria as shown in Table A.1.1. Acute toxicity values are expressed as (approximate) LD50 (oral, dermal) or LC50 (inhalation) values or as acute toxicity estimates (ATE). While some *in vivo* methods determine LD<sub>50</sub>/LC<sub>50</sub> values directly, other newer *in vivo* methods (*e.g.*, using fewer animals) consider other indicators of acute toxicity, such as significant clinical signs of toxicity, which are used by reference to assign the hazard category. See the footnotes following Table A.1.1 for further explanation on the application of these values.

**Table A.1.1: Acute toxicity hazard categories and acute toxicity estimate (ATE) values defining the respective categories**

| Exposure route                                                                                                                                                                            | Category 1 | Category 2      | Category 3      | Category 4        |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------|-----------------|-----------------|-------------------|
| <b>Oral (mg/kg bodyweight)</b><br><u>see:</u> <a href="#"><i>Note (a)</i></a><br><a href="#"><i>Note (b)</i></a>                                                                          | ATE ≤ 5    | >5 ATE ≤ 50     | >50 ATE ≤ 300   | >300 ATE ≤ 2000   |
| <b>Dermal (mg/kg bodyweight)</b><br><u>see:</u> <a href="#"><i>Note (a)</i></a><br><a href="#"><i>Note (b)</i></a>                                                                        | ATE ≤ 5    | >50 ATE ≤ 200   | >200 ATE ≤ 1000 | >1000 ATE ≤ 2000  |
| <b>Inhalation - Gases (ppmV)</b><br><u>see:</u> <a href="#"><i>Note (a)</i></a><br><a href="#"><i>Note (b)</i></a><br><a href="#"><i>Note (c)</i></a>                                     | ATE ≤ 100  | >100 ATE ≤ 500  | >500 ATE ≤ 2500 | >2500 ATE ≤ 20000 |
| <b>Inhalation - Vapors (mg/l)</b><br><u>see:</u> <a href="#"><i>Note (a)</i></a><br><a href="#"><i>Note (b)</i></a><br><a href="#"><i>Note (c)</i></a><br><a href="#"><i>Note (d)</i></a> | ATE ≤ 0.5  | >0.5 ATE ≤ 2.0  | >2.0 ATE ≤ 10.0 | >10.0 ATE ≤ 20.0  |
| <b>Inhalation –<br/>Dusts and Mists (mg/l)</b><br><u>see:</u> <a href="#"><i>Note (a)</i></a><br><a href="#"><i>Note (b)</i></a><br><a href="#"><i>Note (c)</i></a>                       | ATE ≤ 0.05 | >0.05 ATE ≤ 0.5 | >0.5 ATE ≤ 1.0  | >1.0 ATE ≤ 5.0    |

*Note:* Gas concentrations are expressed in parts per million per volume (ppmV).

Notes to Table A.1.1:

- (a) The acute toxicity estimate (ATE) for the classification of a substance is derived using the LD<sub>50</sub>/LC<sub>50</sub> where available;
- (b) The acute toxicity estimate (ATE) for the classification of a substance or ingredient in a mixture is derived using:
  - (i) the LD<sub>50</sub>/LC<sub>50</sub> where available. Otherwise,
  - (ii) the appropriate conversion value from Table 1.2 that relates to the results of a range test, or
  - (iii) the appropriate conversion value from Table 1.2 that relates to a classification category;
- (c) Inhalation cut-off values in the table are based on 4 hour testing exposures. Conversion of existing inhalation toxicity data which has been generated according to 1 hour exposure is achieved by dividing by a factor of 2 for gases and vapors and 4 for dusts and mists;
- (d) For some substances the test atmosphere will be a vapor which consists of a combination of liquid and gaseous phases. For other substances the test atmosphere may consist of a vapor which is nearly all the gaseous phase. In these latter cases, classification is based on ppmV as follows: Category 1 (100 ppmV), Category 2 (500 ppmV), Category 3 (2500 ppmV), Category 4 (20000 ppmV).

The terms “dust”, “mist” and “vapor” are defined as follows:

- (i) Dust: solid particles of a substance or mixture suspended in a gas (usually air);
- (ii) Mist: liquid droplets of a substance or mixture suspended in a gas (usually air);
- (iii) Vapor: the gaseous form of a substance or mixture released from its liquid or solid state.

A.1.2.3 The preferred test species for evaluation of acute toxicity by the oral and

inhalation routes is the rat, while the rat or rabbit are preferred for evaluation of acute

dermal toxicity. Test data already generated for the classification of chemicals under

existing systems should be accepted when reclassifying these chemicals under the harmonized system. When experimental data for acute toxicity are available in several animal species, scientific judgment should be used in selecting the most appropriate LD<sub>50</sub> value from among scientifically validated tests. In cases where data from human experience (*i.e.*, occupational data, data from accident databases, epidemiology studies, clinical reports) is also available, it should be considered in a weight of evidence approach consistent with the principles described in A.0.3.

A.1.2.4 In addition to classification for inhalation toxicity, if data are available that indicates that the mechanism of toxicity was

corrosivity of the substance or mixture, the classifier must consider if the chemical is *corrosive to the respiratory tract*. Corrosion of the respiratory tract is defined as destruction of the respiratory tract tissue after a single, limited period of exposure analogous to skin corrosion; this includes destruction of the mucosa. The corrosivity evaluation could be based on expert judgment using such evidence as: Human and animal experience, existing (*in vitro*) data, pH values, information from similar substances or any other pertinent data.

A.1.2.4.1 If the classifier determines the chemical is corrosive to the respiratory tract and data are available that indicate that the effect leads to lethality, then the chemical

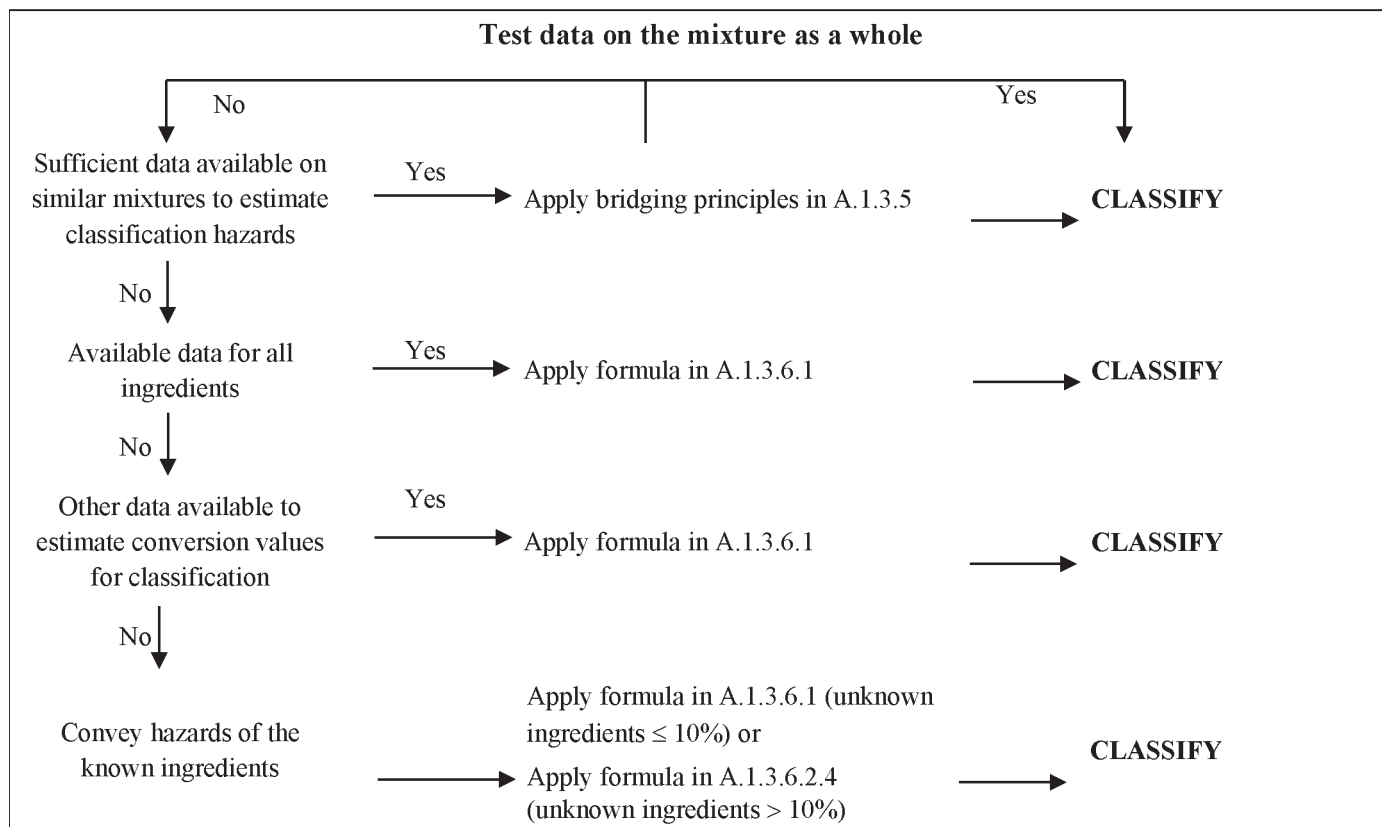
must be labelled with the hazard statement “corrosive to the respiratory tract.”

A.1.2.4.2 If the classifier determines the chemical is corrosive to the respiratory tract and the effect does not lead to lethality, then the chemical must be addressed in the Specific Target Organ Toxicity hazard classes (see A.8 and A.9).

#### A.1.3 Classification Criteria for Mixtures

A.1.3.1 The approach to classification of mixtures for acute toxicity is tiered, and is dependent upon the amount of information available for the mixture itself and for its ingredients. The flow chart of Figure A.1.1 indicates the process that must be followed:

**Figure A.1.1: Tiered approach to classification of mixtures for acute toxicity**



A.1.3.2 Classification of mixtures for acute toxicity may be carried out for each route of exposure, but is only required for one route of exposure as long as this route is followed (estimated or tested) for all ingredients and there is no relevant evidence to suggest acute toxicity by multiple routes. When there is relevant evidence of acute toxicity by multiple routes of exposure, classification is to be conducted for all appropriate routes of exposure. All available information shall be considered. The pictogram and signal word used shall reflect the most severe hazard category; and all relevant hazard statements shall be used.

A.1.3.3 For purposes of classifying the hazards of mixtures in the tiered approach:

(a) The "relevant ingredients" of a mixture are those which are present in concentrations  $\geq 1\%$  (weight/weight for solids, liquids, dusts, mists and vapors and volume/volume for gases). If there is reason to suspect that an ingredient present at a concentration  $< 1\%$  will affect classification of the mixture for acute toxicity, that ingredient shall also be considered relevant. Consideration of ingredients present at a concentration  $< 1\%$  is particularly important when classifying untested mixtures which contain ingredients that are classified in Category 1 and Category 2;

(b) Where a classified mixture is used as an ingredient of another mixture, the actual or derived acute toxicity estimate (ATE) for that mixture is used when calculating the classification of the new mixture using the formulas in A.1.3.6.1 and A.1.3.6.2.4.

(c) If the converted acute toxicity point estimates for all ingredients of a mixture are within the same category, then the mixture should be classified in that category.

(d) When only range data (or acute toxicity hazard category information) are available for ingredients in a mixture, they may be converted to point estimates in accordance with Table A.1.2 when calculating the classification of the new mixture using the formulas in A.1.3.6.1 and A.1.3.6.2.4.

#### A.1.3.4 Classification of Mixtures Where Acute Toxicity Test Data Are Available for the Complete Mixture

Where the mixture itself has been tested to determine its acute toxicity, it is classified according to the same criteria as those used for substances, presented in Table A.1.1. If test data for the mixture are not available, the

procedures presented below must be followed.

#### A.1.3.5 Classification of Mixtures Where Acute Toxicity Test Data Are Not Available for the Complete Mixture: Bridging Principles

A.1.3.5.1 Where the mixture itself has not been tested to determine its acute toxicity, but there are sufficient data on both the individual ingredients and similar tested mixtures to adequately characterize the hazards of the mixture, these data will be used in accordance with the following bridging principles as found in paragraph A.0.5 of this appendix: Dilution, Batching, Concentration of mixtures, Interpolation within one hazard category, Substantially similar mixtures, and Aerosols.

#### A.1.3.6 Classification of Mixtures Based on Ingredients of the Mixture (Additivity Formula)

A.1.3.6.1 Data available for all ingredients.

The acute toxicity estimate (ATE) of ingredients is considered as follows:

(a) \*Include ingredients with a known acute toxicity, which fall into any of the acute toxicity hazard categories, or have an oral or dermal  $LD_{50}$  greater than 2,000 but less than or equal to 5,000 mg/kg body weight (or the equivalent dose for inhalation);

(b) Ignore ingredients that are presumed not acutely toxic (e.g., water, sugar);

(c) Ignore ingredients if the data available are from a limit dose test (at the upper threshold for Category 4 for the appropriate route of exposure as provided in Table A.1.1) and do not show acute toxicity.

Ingredients that fall within the scope of this paragraph are considered to be ingredients with a known acute toxicity estimate (ATE). See note (b) to Table A.1.1 and paragraph A.1.3.3 for appropriate application of available data to the equation below, and paragraph A.1.3.6.2.4.

The ATE of the mixture is determined by calculation from the ATE values for all relevant ingredients according to the following formula below for oral, dermal or inhalation toxicity:

$$\frac{100}{ATE_{mix}} = \sum \frac{C_i}{ATE_i}$$

where:

$C_i$  = concentration of ingredient  $i$

$$\frac{100 - (\sum C_{unknown} \text{ if } > 10\%)}{ATE_{mix}} = \sum \frac{C_i}{ATE_i}$$

*Skin irritation* refers to the production of reversible damage to the skin occurring after exposure to a substance or mixture.

A.2.1.2 Skin corrosion/irritation shall be classified using a tiered approach as detailed in figure A.2.1. Emphasis shall be placed upon existing human data (See A.0.2.6), followed by existing animal data, followed by *in vitro* data and then other sources of information. Classification results directly

$n$  ingredients and  $i$  is running from 1 to  $n$   
ATE $_i$  = acute toxicity estimate of ingredient  $i$ .

A.1.3.6.2 Data are not available for one or more ingredients of the mixture

A.1.3.6.2.1 Where an ATE is not available for an individual ingredient of the mixture, but available information provides a derived conversion value, the formula in A.1.3.6.1 may be applied. This information may include evaluation of:

(a) Extrapolation between oral, dermal and inhalation acute toxicity estimates. Such an evaluation requires appropriate pharmacodynamic and pharmacokinetic data;

(b) Evidence from human exposure that indicates toxic effects but does not provide lethal dose data;

(c) Evidence from any other toxicity tests/assays available on the substance that indicates toxic acute effects but does not necessarily provide lethal dose data; or

(d) Data from closely analogous substances using structure/activity relationships.

A.1.3.6.2.2 This approach requires substantial supplemental technical information, and a highly trained and experienced expert, to reliably estimate acute toxicity. If sufficient information is not available to reliably estimate acute toxicity, proceed to the provisions of A.1.3.6.2.4.

A.1.3.6.2.3 In the event that an ingredient with unknown acute toxicity is used in a mixture at a concentration  $\geq 1\%$ , and the mixture has not been classified based on testing of the mixture as a whole, the mixture cannot be attributed a definitive acute toxicity estimate. In this situation the mixture is classified based on the known ingredients only. *Note:* A statement that  $\times$  percent of the mixture consists of ingredient(s) of unknown acute (oral/dermal/inhalation) toxicity is required on the label and safety data sheet in such cases; see appendix C to this section, Allocation of Label Elements and appendix D to this section, Safety Data Sheets.)

A.1.3.6.2.4 If the total concentration of the relevant ingredient(s) with unknown acute toxicity is  $\leq 10\%$  then the formula presented in A.1.3.6.1 must be used. If the total concentration of the relevant ingredient(s) with unknown acute toxicity is  $> 10\%$ , the formula presented in A.1.3.6.1 is corrected to adjust for the percentage of the unknown ingredient(s) as follows:

when the data satisfy the criteria in this section. In case the criteria cannot be directly applied, classification of a substance or a mixture is made on the basis of the total weight of evidence (See A.0.3.1). This means that all available information bearing on the determination of skin corrosion/irritation is considered together, including the results of appropriate scientifically validated *in-vitro* tests, relevant animal data, and human data

## A.2 Skin Corrosion/Irritation

### A.2.1 Definitions and General Considerations

A.2.1.1 *Skin corrosion* refers to the production of irreversible damage to the skin; namely, visible necrosis through the epidermis and into the dermis occurring after exposure to a substance or mixture.

such as epidemiological and clinical studies and well-documented case reports and observations.

#### A.2.2 Classification Criteria for Substances

Substances shall be allocated to one of the following categories within this hazard class:

- (a) Category 1 (skin corrosion)

This category may be further divided into up to three sub-categories (1A, 1B and 1C)

- (b) Category 2 (skin irritation)

##### A.2.2.1 Classification Based on Standard Animal Test Data

###### A.2.2.1.1 Skin Corrosion

A.2.2.1.2 A substance is corrosive to the skin when it produces destruction of skin

tissue, namely, visible necrosis through the epidermis and into the dermis, in at least one tested animal after exposure up to a 4-hour duration.

A.2.2.1.3 Three sub-categories of Category 1 are provided in Table A.2.1, all of which shall be regulated as Category 1.

TABLE A.2.1—SKIN CORROSION CATEGORY AND SUB-CATEGORIES <sup>a</sup>

|                       | Criteria                                                                                                                                                 |
|-----------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------|
| Category 1 .....      | Destruction of skin tissue, namely, visible necrosis through the epidermis and into the dermis, in at least one tested animal after exposure $\leq 4$ h. |
| Sub-category 1A ..... | Corrosive responses in at least one animal following exposure $\leq 3$ min during an observation period $\leq 1$ h.                                      |
| Sub-category 1B ..... | Corrosive responses in at least one animal following exposure $> 3$ min and $\leq 1$ h and observations $\leq 14$ days.                                  |
| Sub-category 1C ..... | Corrosive responses in at least one animal after exposures $> 1$ h and $\leq 4$ h and observations $\leq 14$ days.                                       |

<sup>a</sup> The use of human data is discussed in A.2.3.

#### A.2.2.2 Skin Irritation

A.2.2.2.1 A single irritant category (Category 2) is presented in the Table A.2.2. A substance is irritant to skin when it produces reversible damage to the skin following its application for up to 4 hours.

The major criterion for the irritant category is that at least 2 tested animals have a mean score of  $\geq 2.3 \leq 4.0$ .

A.2.2.2.2 An irritation category (Category 2) is provided that:

(a) Recognizes that some test substances may lead to effects which persist throughout the length of the test; and

(b) acknowledges that animal responses in a test may be variable.

A.2.2.2.3 Reversibility of skin lesions is another consideration in evaluating irritant responses. When inflammation persists to the end of the observation period in two or more test animals, taking into consideration alopecia (limited area), hyperkeratosis, hyperplasia and scaling, then a chemical should be considered to be an irritant.

A.2.2.2.4 Animal irritant responses within a test can be quite variable, as they are with corrosion. A separate irritant criterion accommodates cases when there is

a significant irritant response but less than the mean score criterion for a positive test. For example, a substance might be designated as an irritant if at least 1 of 3 tested animals shows a very elevated mean score throughout the study, including lesions persisting at the end of an observation period of normally 14 days. Other responses could also fulfill this criterion. However, it should be ascertained that the responses are the result of chemical exposure. Addition of this criterion increases the sensitivity of the classification system.

TABLE A.2.2—SKIN IRRITATION CATEGORY <sup>a b</sup>

|                             | Criteria                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|-----------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Irritant (Category 2) ..... | <ol style="list-style-type: none"> <li>(1) Mean score of <math>\geq 2.3 \leq 4.0</math> for erythema/eschar or for edema in at least 2 of 3 tested animals from gradings at 24, 48 and 72 hours after patch removal or, if reactions are delayed, from grades on 3 consecutive days after the onset of skin reactions; or</li> <li>(2) Inflammation that persists to the end of the observation period normally 14 days in at least 2 animals, particularly taking into account alopecia (limited area), hyperkeratosis, hyperplasia, and scaling; or</li> <li>(3) In some cases where there is pronounced variability of response among animals, with very definite positive effects related to chemical exposure in a single animal but less than the criteria above.</li> </ol> |

<sup>a</sup> Grading criteria are understood as described in OECD Test Guideline 404.

#### A.2.3 Classification in a Tiered Approach

A.2.3.1 A *tiered approach* to the evaluation of initial information shall be used (Figure A.2.1) recognizing that not all elements may be relevant.

A.2.3.2 Existing human and animal data including information from single or repeated exposure should be the first line of evaluation, as they give information directly relevant to effects on the skin.

A.2.3.3 Acute dermal toxicity data may be used for classification. If a substance is highly toxic by the dermal route, a skin corrosion/irritation study may not be practicable since the amount of test substance to be applied would considerably exceed the toxic dose and, consequently, would result in the death of the animals. When observations are made of skin corrosion/irritation in acute toxicity studies and are observed up through the limit dose,

these data may be used for classification provided that the dilutions used and species tested are equivalent. Solid substances (powders) may become corrosive or irritant when moistened or in contact with moist skin or mucous membranes.

A.2.3.4 *In vitro* alternatives that have been scientifically validated shall be used to make classification decisions.

A.2.3.5 Likewise, pH extremes like  $\leq 2$  and  $\geq 11.5$  may indicate skin effects, especially when associated with significant acid/alkaline reserve (buffering capacity). Generally, such substances are expected to produce significant effects on the skin. In the absence of any other information, a substance is considered corrosive (Skin Category 1) if it has a pH  $\leq 2$  or a pH  $\geq 11.5$ . However, if consideration of acid/alkaline reserve suggests the substance or mixture may not be corrosive despite the low or high pH value,

this needs to be confirmed by other data, preferably data from an appropriate validated *in vitro* test.

A.2.3.6 In some cases sufficient information may be available from structurally related substances to make classification decisions.

A.2.3.7 The tiered approach explains how to organize existing information on a substance and to make a weight of evidence decision about hazard assessment and hazard classification (ideally without conducting new animal tests). Although information might be gained from the evaluation of single parameters within a tier, consideration should be given to the totality of existing information and making an overall weight of evidence determination. This is especially true when there is conflict in information available on some parameters.

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Figure A.2.1: Tiered evaluation for skin corrosion and irritation

| Step | Parameter                                                                                        | Finding                                                                                       | Conclusion                                         |
|------|--------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------|----------------------------------------------------|
| 1a:  | Existing human or animal skin corrosion/irritation data <sup>a</sup> →                           | Skin corrosive →                                                                              | Category 1 <sup>b</sup>                            |
|      | ↓                                                                                                |                                                                                               |                                                    |
|      | Not corrosive/No data<br>↓                                                                       |                                                                                               |                                                    |
| 1b:  | Existing human or animal skin corrosion/irritation data <sup>a</sup> →                           | Skin irritant →                                                                               | Category 2 <sup>b</sup>                            |
|      | ↓                                                                                                |                                                                                               |                                                    |
|      | Not irritant/No data<br>↓                                                                        |                                                                                               |                                                    |
| 1c:  | Existing human or animal skin corrosion/irritation data <sup>a</sup> →                           | Not a skin corrosive or skin irritant →                                                       | Not classified                                     |
|      | ↓                                                                                                |                                                                                               |                                                    |
|      | No/Insufficient data<br>↓                                                                        |                                                                                               |                                                    |
| 2:   | Other, existing skin data in animals <sup>c</sup> →                                              | Yes; other existing data showing that substance may cause skin corrosion or skin irritation → | Category 1 <sup>b</sup> or Category 2 <sup>b</sup> |
|      | ↓                                                                                                |                                                                                               |                                                    |
|      | No/Insufficient data<br>↓                                                                        |                                                                                               |                                                    |
| 3:   | Existing <i>ex vivo/in vitro</i> data <sup>d</sup> →                                             | Positive: Skin corrosive →                                                                    | Category 1 <sup>b</sup>                            |
|      | ↓                                                                                                | Positive: Skin irritant →                                                                     | Category 2 <sup>b</sup>                            |
|      | No/Insufficient data/Negative response<br>↓                                                      |                                                                                               |                                                    |
| 4:   | pH-based assessment (with consideration of acid/alkaline reserve of the chemical) <sup>e</sup> → | pH ≤ 2 or ≥ 11.5 with high acid/alkaline reserve or no data for acid/alkaline reserve →       | Category 1                                         |
|      | ↓                                                                                                |                                                                                               |                                                    |

|    |                                                                                               |                                         |                                                        |
|----|-----------------------------------------------------------------------------------------------|-----------------------------------------|--------------------------------------------------------|
|    | Not pH extreme, no pH data or extreme pH with data showing low/no acid/alkaline reserve<br>↓  |                                         |                                                        |
| 5: | Validated Structure Activity Relationship (SAR) methods →<br>↓ ↘<br>No/Insufficient data<br>↓ | Skin corrosive →<br><br>Skin irritant → | Category 1 <sup>b</sup><br><br>Category 2 <sup>b</sup> |
| 6: | Consideration of the total weight of evidence <sup>f</sup> →<br>↓ ↘                           | Skin corrosive →<br><br>Skin irritant → | Category 1 <sup>b</sup><br><br>Category 2 <sup>b</sup> |
|    | No concern based on consideration of the sum of available data<br>↓                           |                                         |                                                        |
| 7: | Not classified                                                                                |                                         |                                                        |

<sup>a</sup> Existing human or animal data could be derived from single or repeated exposure(s), for example in occupational, consumer, transport or emergency response scenarios; or from purposely-generated data from animal studies conducted according to validated and internationally accepted test methods. Although human data from accident or poison center databases can provide evidence for classification, absence of incidents is not itself evidence for no classification as exposures are generally unknown or uncertain;

<sup>b</sup> Classify in the appropriate category/sub-category, as applicable;

<sup>c</sup> All existing animal data should be carefully reviewed to determine if sufficient skin corrosion/irritation evidence is available. In evaluating such data, however, the reviewer should bear in mind that the reporting of dermal lesions may be incomplete, testing and observations may be made on a species other than the rabbit, and species may differ in sensitivity in their responses;

<sup>d</sup> Evidence from studies using validated protocols with isolated human/animal tissues or other, non-tissue-based, though validated, protocols should be assessed. Examples of internationally accepted validated test methods for skin corrosion include OECD Test Guidelines 430 (Transcutaneous Electrical Resistance Test (TER)), 431 (Human Skin Model Test), and 435 (Membrane Barrier Test Method). An example of a validated internationally accepted in vitro test method for skin irritation is OECD Test Guideline 439 (Reconstructed Human Epidermis Test Method);

<sup>e</sup> Measurement of pH alone may be adequate, but assessment of acid or alkali reserve (buffering capacity) would be preferable. Presently there is no validated and internationally accepted method for assessing this parameter;

<sup>f</sup> All information that is available must be considered and an overall determination made on the total weight of evidence. This is especially true when there is conflict in information available on some parameters. Expert judgment should be exercised prior to making such a determination. Negative results from applicable validated skin corrosion/irritation in vitro tests are considered in the total weight of evidence evaluation.

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## A.2.4 Classification Criteria for Mixtures

## A.2.4.1 Classification of Mixtures When Data Are Available for the Complete Mixture

A.2.4.1.1 The mixture shall be classified using the criteria for substances, taking into account the tiered approach to evaluate data for this hazard class (as illustrated in Figure A.2.1).

A.2.4.1.2 When considering testing of the mixture, classifiers must use a tiered approach as included in the criteria for classification of substances for skin corrosion and irritation to help ensure an accurate classification, as well as to avoid unnecessary animal testing. In the absence of any other information, a mixture is considered corrosive (Skin Category 1) if it has a pH  $\leq 2$  or a pH  $\geq 11.5$ . However, if consideration of acid/alkaline reserve suggests the mixture may not be corrosive despite the low or high pH value, then further evaluation may be necessary.

## A.2.4.2 Classification of Mixtures When Data Are Not Available for the Complete Mixture: Bridging Principles

A.2.4.2.1 Where the mixture itself has not been tested to determine its skin corrosion/irritation potential, but there are sufficient data on both the individual ingredients and similar tested mixtures to adequately characterize the hazards of the mixture, these data will be used in accordance with the following bridging principles, as found in paragraph A.0.5 of this appendix: Dilution, Batching, Concentration of mixtures, Interpolation within one hazard category, Substantially similar mixtures, and Aerosols.

## A.2.4.3 Classification of Mixtures When Data Are Available for All Ingredients or Only for Some Ingredients of the Mixture

A.2.4.3.1 In order to make use of all available data for purposes of classifying the skin corrosion/irritation hazards of mixtures, the following assumption has been made and is applied where appropriate in the tiered approach:

The "relevant ingredients" of a mixture are those which are present in concentrations  $\geq 1\%$  (weight/weight for solids, liquids, dusts, mists and vapors and volume/volume for gases). If the classifier has reason to suspect that an ingredient present at a concentration  $< 1\%$  will affect classification of the mixture for skin corrosion/irritation, that ingredient shall also be considered relevant.

A.2.4.3.2 In general, the approach to classification of mixtures as corrosive or irritant to the skin when data are available on the ingredients, but not on the mixture as a whole, is based on the theory of additivity, such that each corrosive or irritant ingredient contributes to the overall corrosive or irritant properties of the mixture in proportion to its potency and concentration. A weighting factor of 10 is used for corrosive ingredients when they are present at a concentration below the concentration limit for classification with Category 1, but are at a concentration that will contribute to the classification of the mixture as an irritant. The mixture is classified as corrosive or irritant when the sum of the concentrations of such ingredients exceeds a cut-off value/concentration limit.

A.2.4.3.3 Table A.2.3 below provides the cut-off value/concentration limits to be used to determine if the mixture is considered to be corrosive or irritant to the skin.

A.2.4.3.4 Particular care shall be taken when classifying certain types of chemicals such as acids and bases, inorganic salts, aldehydes, phenols, and surfactants. The approach explained in A.2.4.3.1 and A.2.4.3.2 might not work given that many of such substances are corrosive or irritant at concentrations  $< 1\%$ . For mixtures containing strong acids or bases the pH should be used as classification criteria since pH will be a better indicator of corrosion than the concentration limits in Table A.2.3. A mixture containing corrosive or irritant ingredients that cannot be classified based on the additivity approach shown in Table A.2.3, due to chemical characteristics that make this approach unworkable, should be classified as skin corrosion Category 1 if it contains  $\geq 1\%$  of a corrosive ingredient and as skin irritation Category 2 when it contains  $\geq 3\%$  of an irritant ingredient. Classification of mixtures with ingredients for which the approach in Table A.2.3 does not apply is summarized in Table A.2.4 below.

A.2.4.3.5 On occasion, reliable data may show that the skin corrosion/irritation of an ingredient will not be evident when present at a level above the generic cut-off values/concentration limits mentioned in Tables A.2.3 and A.2.4. In these cases the mixture could be classified according to those data (See *Use of cut-off values/concentration limits*, paragraph A.0.4.3 of this appendix).

A.2.4.3.6 If there are data showing that (an) ingredient(s) may be corrosive or irritant to skin at a concentration of  $< 1\%$  (corrosive) or  $< 3\%$  (irritant), the mixture shall be classified accordingly (See *Use of cut-off values/concentration limits*, paragraph A.0.4.3 of this appendix).

TABLE A.2.3—CONCENTRATION OF INGREDIENTS OF A MIXTURE CLASSIFIED AS SKIN CATEGORY 1 OR 2 THAT WOULD TRIGGER CLASSIFICATION OF THE MIXTURE AS HAZARDOUS TO SKIN

[Category 1 or 2]

| Sum of ingredients classified as:                                   | Concentration triggering classification of a mixture as: |                        |
|---------------------------------------------------------------------|----------------------------------------------------------|------------------------|
|                                                                     | Skin corrosive                                           | Skin irritant          |
|                                                                     | Category 1                                               | Category 2             |
| Skin Category 1 .....                                               | $\geq 5\%$                                               | $\geq 1\%$ but $< 5\%$ |
| Skin Category 2 .....                                               | .....                                                    | $\geq 10\%$            |
| $(10 \times \text{Skin Category 1}) + \text{Skin Category 2}$ ..... | .....                                                    | $\geq 10\%$            |

**Note:** Where data are available and the sub-categories of skin Category 1 (corrosive) are used, the sum of all ingredients of a mixture classified as sub-category 1A, 1B or 1C respectively, must each be  $\geq 5\%$  in order to classify the mixture as either skin sub-category 1A, 1B or 1C. Where the sum of 1A ingredients is  $< 5\%$  but the sum of 1A + 1B ingredients is  $\geq 5\%$ , the mixture must be classified as sub-category 1B. Similarly, where the sum of 1A + 1B ingredients is  $< 5\%$  but the sum of 1A + 1B + 1C ingredients is  $\geq 5\%$  the mixture must be classified as sub-category 1C. Where at least one relevant ingredient in a mixture is classified as Category 1 without sub-categorization, the mixture must be classified as Category 1 without sub-categorization if the sum of all ingredients corrosive to skin is  $\geq 5\%$ .

TABLE A.2.4—CONCENTRATION OF INGREDIENTS OF A MIXTURE WHEN THE ADDITIVITY APPROACH DOES NOT APPLY, THAT WOULD TRIGGER CLASSIFICATION OF THE MIXTURE AS HAZARDOUS TO SKIN

| Ingredient:                                                             | Concentration: | Mixture classified as: Skin |
|-------------------------------------------------------------------------|----------------|-----------------------------|
| Acid with pH $\leq 2$ .....                                             | $\geq 1\%$     | Category 1.                 |
| Base with pH $\geq 11.5$ .....                                          | $\geq 1\%$     | Category 1.                 |
| Other corrosive (Category 1) ingredient .....                           | $\geq 1\%$     | Category 1.                 |
| Other irritant (Category 2) ingredient, including acids and bases ..... | $\geq 3\%$     | Category 2.                 |

### A.3 Serious Eye Damage/Eye Irritation

#### A.3.1 Definitions and General Considerations

A.3.1.1 *Serious eye damage* refers to the production of tissue damage in the eye, or serious physical decay of vision, which is not fully reversible, occurring after exposure of the eye to a substance or mixture.

*Eye irritation* refers to the production of changes in the eye, which are fully reversible, occurring after exposure of the eye to a substance or mixture.

A.3.1.2 Serious eye damage/eye irritation shall be classified using a tiered approach as detailed in Figure A.3.1. Emphasis shall be placed upon existing human data (See A.0.2.6), followed by existing animal data, followed by *in vitro* data and then other sources of information. Classification results directly when the data satisfy the criteria in this section. In case the criteria cannot be directly applied, classification of a substance or a mixture is made on the basis of the total weight of evidence (See A.0.3.1). This means

that all available information bearing on the determination of serious eye damage/eye irritation is considered together, including the results of appropriate scientifically validated *in vitro* tests, relevant animal data, and human data such as epidemiological and clinical studies and well-documented case reports and observations.

#### A.3.2 Classification Criteria for Substances

Substances are allocated to one of the categories within this hazard class, Category 1 (serious eye damage) or Category 2 (eye irritation), as follows:

(a) Category 1 (serious eye damage/irreversible effects on the eye): Substances that have the potential to seriously damage the eyes (see Table A.3.1).

(b) Category 2 (eye irritation/reversible effects on the eye): Substances that have the potential to induce reversible eye irritation (see Table A.3.2).

A.3.2.1 *Classification based on standard animal test data.*

A.3.2.1.1 Serious eye damage (Category 1)/Irreversible effects on the eye.

A single hazard category is provided in Table A.3.1, for substances that have the potential to seriously damage the eyes. Category 1, irreversible effects on the eye, includes the criteria listed below. These observations include animals with grade 4 cornea lesions and other severe reactions (e.g., destruction of cornea) observed at any time during the test, as well as persistent corneal opacity, discoloration of the cornea by a dye substance, adhesion, pannus, and interference with the function of the iris or other effects that impair sight. In this context, persistent lesions are considered those which are not fully reversible within an observation period of normally 21 days. Category 1 also contains substances fulfilling the criteria of corneal opacity  $\geq 3$  and/or iritis  $>1.5$  observed in at least 2 of 3 tested animals detected in a Draize eye test with rabbits, because severe lesions like these usually do not reverse within a 21-day observation period.

TABLE A.3.1—SERIOUS EYE DAMAGE/IRREVERSIBLE EFFECTS ON THE EYE CATEGORY <sup>a</sup>

|                                                                 | Criteria                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
|-----------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Category 1: Serious eye damage/Irreversible effects on the eye. | <p>A substance that produces:</p> <p>(a) In at least one animal effects on the cornea, iris or conjunctiva that are not expected to reverse or have not fully reversed within an observation period of normally 21 days; and/or</p> <p>(b) in at least 2 of 3 tested animals, a positive response of:</p> <p>(i) Corneal opacity <math>\geq 3</math>; and/or</p> <p>(ii) iritis <math>&gt;1.5</math>;</p> <p>calculated as the mean scores following grading at 24, 48 and 72 hours after instillation of the test material.</p> |

<sup>a</sup> Grading criteria are understood as described in OECD Test Guideline 405.

A.3.2.2 Eye irritation (Category 2)/Reversible effects on the eye.

A.3.2.2.1 A single Category 2 is provided in Table A.3.2 for substances that have the potential to induce reversible eye irritation.

When data are available, substances may be classified into Category 2A and Category 2B:

(a) For substances inducing eye irritant effects reversing within an observation time of normally 21 days, Category 2A applies.

(b) For substances inducing eye irritant effects reversing within an observation time of 7 days, Category 2B applies.

When a substance is classified as Category 2, without further categorization, the

classification criteria are the same as those for 2A.

A.3.2.3 For those substances where there is pronounced variability among animal responses, this information may be taken into account in determining the classification.

TABLE A.3.2—REVERSIBLE EFFECTS ON THE EYE CATEGORIES <sup>a</sup>

|                     | Criteria                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
|---------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Category 2/2A ..... | <p>Substances that have the potential to induce reversible eye irritation.</p> <p>Substances that produce in at least 2 of 3 tested animals a positive response of:</p> <p>(a) corneal opacity <math>\geq 1</math>; and/or</p> <p>(b) iritis <math>\geq 1</math>; and/or</p> <p>(c) conjunctival redness <math>\geq 2</math>; and/or</p> <p>(d) conjunctival edema (chemosis) <math>\geq 2</math></p> <p>calculated as the mean scores following grading at 24, 48 and 72 hours after instillation of the test material, and which fully reverses within an observation period of normally 21 days.</p> |
| Category 2B .....   | <p>Within Category 2A an eye irritant is considered mildly irritating to eyes (Category 2B) when the effects listed above are fully reversible within 7 days of observation.</p>                                                                                                                                                                                                                                                                                                                                                                                                                        |

<sup>a</sup> Grading criteria are understood as described in OECD Test Guideline 405.

#### A.3.3 Classification in a Tiered Approach

A.3.3.1 A tiered approach to the evaluation of initial information shall be used where applicable, recognizing that all elements may not be relevant in certain cases (Figure A.3.1).

A.3.3.2 Existing human and animal data should be the first line of analysis, as they give information directly relevant to effects

on the eye. Possible skin corrosion shall be evaluated prior to consideration of any testing for serious eye damage/eye irritation in order to avoid testing for local effects on eyes with skin corrosive substances.

A.3.3.3 *In vitro* alternatives that have been scientifically validated and accepted shall be used to make classification decisions.

A.3.3.4 Likewise, pH extremes like  $\leq 2$  and  $\geq 11.5$ , may indicate serious eye damage, especially when associated with significant acid/alkaline reserve (buffering capacity). Generally, such substances are expected to produce significant effects on the eyes. In the absence of any other information, a substance is considered to cause serious eye damage (Category 1) if it has a pH  $\leq 2$  or  $\geq 11.5$ .

However, if consideration of acid/alkaline reserve suggests the substance may not cause serious eye damage despite the low or high pH value, this needs needs to be confirmed by other data, preferably by data from an appropriate validated *in vitro* test.

A.3.3.5 In some cases sufficient information may be available from

structurally related substances to make classification decisions.

A.3.3.6 The tiered approach explains how to organize existing information and to make a weight-of-evidence decision about hazard assessment and hazard classification (ideally without conducting new animal tests).

Animal testing with corrosive substances should be avoided wherever possible.

Although information might be gained from the evaluation of single parameters within a tier, consideration should be given to the totality of existing information and making an overall weight of evidence determination. This is especially true when there is conflict in information available on some parameters.

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