

Ministry of Food and Drug Safety Notice No. 2022 – 403

of partial revision of regulations on cosmetic safety standards, etc.
(Proposed) Administrative notice

2022. 9.

Ministry of Food and Drug Safety

Ministry of Food and Drug Safety Notice No. 2022 – 403

In partly amending the 「Regulations on Cosmetic Safety Standards, etc.」 (Ministry of Food and Drug Safety Notice No. 2022–27, April 1. In accordance with Article 46 of the Administrative Procedure Act, the following announcement is made.

September 5, 2022

Minister of Food and Drug Safety

Administrative notice of partial revision of regulations on cosmetic safety standards, etc.

(draft)

1. Reason for revision

Based on the result of risk assessment pursuant to Article 8 of the Cosmetics Act and the status of excluded countries, some ingredients of hair dye are added to the list of ingredients that cannot be used in cosmetics to strengthen the safety management of cosmetics and protect public health.

2. Highlights

- Changed some hair dye ingredients among ingredients that require restrictions on use to ingredients banned for use in cosmetics (Annex 1, Annex 2)
 - Some of the ingredients for hair dye among the raw materials that require restrictions on use are deleted and reflected in the raw materials that cannot be used

3. Submit your comments

Any institution, organization or individual who has an opinion on this partially revised notice (draft) By September 26, 2022, please submit a written opinion stating the following to the Minister of Food and Drug Safety (refer to the Cosmetics Policy Division).

go. Opinion for or against notice (specify reasons for objection)

me. Name (in the case of an institution/organization, the name of the institution/organization and the name of the representative), address and phone number

All. Other notes, etc.

※ Where to send comments

- Ordinary mail: (Zip Code 28159) Osongsaeng 2 - ro, Osong-eup, Heungdeok-gu, Cheongju-si ,
Chungcheongbuk-do 187 Osong Health and Medical Administration Town Cosmetics Policy
Division, Ministry of Food and Drug Safety
- E-mail: fastests@korea.kr
- Tel: 043-719-3410, Fax: 043-719-3400

Ministry of Food and Drug Safety Notice No. 2022- like

The 「Regulations on Safety Standards for Cosmetics」 (Ministry of Food and Drug Safety Notice No. 2022-27, 2022. 4. 1.) in accordance with Article 8 of the 「Cosmetics Act」 has been amended and announced as follows .

2022 month Work

Minister of Food and Drug Safety

Partially revised and announced regulations on cosmetic safety standards, etc. (draft)

Part of the regulations on cosmetic safety standards, etc. will be amended as follows .

[Attached Table 1] , “ 2 -amino -6- chloro- 4 -nitrophenol and its salts (however , 2 -amino -6- chloro- 4 -nitrophenol is 2.0 as a hair dye component of the mixture according to usage and dosage in hair dye % or less) ” and “ 1-[(3 -aminopropyl) amino]-4-(methylamino) anthraquinone and salts thereof” are newly added as “ o -aminophenol” .

[Attached Table 1] , “catechol (pyrocatechol) ” (however , 1.5% or less is excluded as a hair dye component of the mixture according to usage and dose in oxidized hair dye) is changed to “catechol (pyrocatechol) ” .

[Annex 1] , “ m -phenylenediamine” and “ m -phenylenediamine hydrochloride ” are newly added between “o -phenylenediamine and its salts” and “phenylbutazone” .

[Attached Table 1] , “Pyrogallol (However , 2% or less as a hair dye component of the mixture according to usage and dosage for hair dye is excluded) ” is replaced with “Pyrogallol” .

[Appendix 2] , set “ * Hair dye ingredients” as in the attached sheet .

a d d e n d u m

Article 1 (Enforcement Date) This notice is effective **from the date** 6 months have elapsed after the notice .

Article 2 (Applicability to Changes in Safety Standards, etc.) This notice shall apply starting with cosmetics manufactured or imported (based on the date of customs clearance) by a cosmetics manufacturer or a responsible cosmetics distributor after the enforcement of the notice .

Article 3 (Applicability to Functional Cosmetics Review) This notice shall apply from the functional cosmetics review request (including amendments) submitted to the Director of Food and Drug Safety Evaluation Institute for the first time after the enforcement of the notification .

Article 4 (Transitional Measures for Manufacturing and Importation of Cosmetics Due to Changes in Safety Standards, etc.) It can be displayed or stored as

[Asterisk 2]

Raw materials requiring restrictions on use

* Hair dye ingredients

one Ryo number of people	when to use Concentration upper limit (%)	note
--------------------------	--	------

p- nitro -o- phenylenediamine	1.5% for oxidizing hair dye	Prohibited to use on other products
nitro -p -phenylenediamine	3.0% for oxidizing hair dye	Prohibited to use on other products
2- Methyl -5 -hydroxyethylaminophenol	0.5% for oxidizing hair dye	Prohibited to use on other products
2- Amino -4- Nitrophenol	2.5% for oxidizing hair dye	Prohibited to use on other products
2- Amino -5 -nitrophenol	1.5% for oxidizing hair dye	Prohibited to use on other products
2- Amino -3- Hydroxypyridine	1.0% for oxidizing hair dye	Prohibited to use on other products
4 -amino- m - cresol	1.5% for oxidizing hair dye	Prohibited to use on other products
5- amino- o - cresol	1.0% for oxidation hair dye	Prohibited to use on other products
5- Amino -6- chloro- o - cresol	1.0% for oxidation hair dye 0.5% for non-oxidizing hair dye	Prohibited to use on other products

m -Aminophenol	2.0% for oxidizing hair dye	Prohibited to use on other products
p -aminophenol	0.9% for oxidizing hair dye	Prohibited to use on other products
Hydrochloric acid 2,4 diaminophenoxyethanol	0.5% for oxidizing hair dye	Prohibited to use on other products
Toluene hydrochloride -2,5- diamine	3.2 % for oxidizing hair dye	Prohibited to use on other products
hydrochloric acid p -phenylenediamine	3.3% for oxidizing hair dye	Prohibited to use on other products
Hydroxypropylbis hydrochloride (N hydroxyethyl- p -phenylenediamine)	0.4% for oxidizing hair dye	Prohibited to use on other products
Toluene -2,5- diamine	2.0% for oxidizing hair dye	Prohibited to use on other products
p -phenylenediamine	2.0% for oxidizing hair dye	Prohibited to use on other products
N - phenyl -p -phenylenediamine and its salts	2.0 % as N - phenyl -p -phenylenediamine in oxidation hair dye	Prohibited to use on other products

picramic acid	0.6 % for oxidizing hair dye	Prohibited to use on other products
Sulfuric acid p-nitro- o-phenylenediamine	2.0% for oxidizing hair dye	Prohibited to use on other products
Sulfuric acid p-methylaminophenol	0.68% for oxidation hair dye	Prohibited to use on other products
5-amino- o - cresol sulfate	4.5% for oxidizing hair dye	Prohibited to use on other products
Sulfuric acid m-aminophenol	2.0% for oxidizing hair dye	Prohibited to use on other products
Sulfuric acid o-aminophenol	3.0% for oxidizing hair dye	Prohibited to use on other products
Sulfuric acid p-aminophenol	1.3% for oxidizing hair dye	Prohibited to use on other products
Toluene sulfate -2,5- diamine	3.6% for oxidizing hair dye	Prohibited to use on other products
Sulfuric acid m-phenylenediamine	3.0% for oxidizing hair dye	Prohibited to use on other products

Sulfuric acid p -phenylenediamine	3.8% for oxidizing hair dye	Prohibited to use on other products
Sulfuric acid N,N- bis (2 -hydroxyethyl)- p -phenylenediamine	2.9% for oxidizing hair dye	Prohibited to use on other products
2,6 -diaminopyridine	0.15 % for oxidizing hair dye	Prohibited to use on other products
Hydrochloric acid 2,4 -diaminophenol	0.5% for oxidizing hair dye	Prohibited to use on other products
1,5 -dihydroxynaphthalene	0.5% for oxidizing hair dye	Prohibited to use on other products
Sodium picraminate	0.6 % for oxidizing hair dye	Prohibited to use on other products
Sulfuric acid 2 -amino -5 -nitrophenol	1.5% for oxidizing hair dye	Prohibited to use on other products
sulfuric acid o -chloro- p -phenylenediamine	1.5% for oxidizing hair dye	Prohibited to use on other products
Sulfuric acid 1 -hydroxyethyl -4,5 -diaminopyrazole	3.0% for oxidizing hair dye	Prohibited to use on other products

Hydroxybenzomorpholine	1.0% for oxidation hair dye	Prohibited to use on other products
6-hydroxyindole	0.5% for oxidizing hair dye	Prohibited to use on other products
1-Naphthol (α -Naphthol)	2.0% for oxidizing hair dye	Prohibited to use on other products
resorcinol	2.0% for oxidizing hair dye	
2-Methylezorcinol	0.5% for oxidizing hair dye	Prohibited to use on other products
edible assets	4.0% for oxidizing hair dye	
Basic Orange 31 _	0.5% for oxidizing hair dye	Other usage standards are in accordance with 「Cosmetics Color Types, Standards, and Test Methods」
Basic Red 51 _	0.5% for oxidizing hair dye	Other usage standards are in accordance with 「Cosmetics Color Types,

		Standards, and Test Methods」
Basic Yellow 87 _	1.0% for oxidation hair dye	Other usage standards are in accordance with 「Cosmetics Color Types, Standards, and Test Methods」
Sodium Perborate Sodium Perborate Monohydrate hydrogen peroxide sodium percarbonate	12.0% as hydrogen peroxide in hair dye (including desalting and bleaching)	
sodium persulfate Ammonium Persulfate potassium persulfate		Used as an antioxidant in hair dye (including desalting and bleaching)
Indigofera tinctoria <i>leaf</i> powder	25% for non-oxidizing hair dye	Prohibited to use in other products
sulfate hydrate ($\text{FeSO}_4 \cdot 7\text{H}_2\text{O}$)	6% for non-oxidizing hair dye	Prohibited for use in oxidizing hair dyes
silver sulfate	0.4% for non-oxidizing hair dye	Prohibited for use in oxidizing hair dyes

Hematein	0.1% for non-oxidizing hair dye	Prohibited for use in oxidizing hair dyes
----------	---------------------------------	---

New/Structured Structure Comparison Table

hyeon line	dog affection not
<p>[Appendix 1] Raw materials that cannot be used</p> <p><God Lunar New Year></p> <p><u>Catechol (pyrocatechol) (However, 1.5% or less is excluded as a hair dye component of the mixture according to usage and dosage in oxidized hair dye)</u></p> <p><God Lunar New Year></p> <p><u>Pyrogallol (However, 2% or less is excluded as a hair dye component of the mixture according to usage and dose in hair dye)</u></p>	<p>[Appendix 1] Raw materials that cannot be used</p> <p><u>o-aminophenol</u></p> <p><u>Catechol (pyrocatechol)</u></p> <p><u>m-phenylenediamine</u> <u>Hydrochloric acid m-phenylenediamine</u></p> <p><u>pyrogallol</u></p>

[Appendix 2] Raw materials requiring restrictions on use

* Hair dye ingredients

one Ryo number of people	when to use Concentration upper limit (%)	note
(omit)	(omit)	(omit)
<u>o -Aminophenol</u>	3.0% for oxidizing hair dye	Prohibited to use on other products
(omit)	(omit)	(omit)
<u>hydrochloric acid m -phenylenediamine</u>	0.5% for oxidizing hair dye	Prohibited to use on other products
(omit)	(omit)	(omit)
<u>m -phenylenediamine</u>	1.0% for oxidation hair dye	Prohibited to use on other products
(omit)	(omit)	(omit)
<u>catechol (pyrocatechol)</u>	1.5% for oxidizing hair dye	Prohibited to use on other products
<u>pyrogallol</u>	2.0% for hair dye	Prohibited to use on other products
(omit)	(omit)	(omit)

[Appendix 2] Raw materials requiring restrictions on use

* Hair dye ingredients

one Ryo number of people	when to use Concentration upper limit (%)	note
(Same as current)	(Same as current)	(Same as current)
< Delete >	< Delete >	< Delete >
(Same as current)	(Same as current)	(Same as current)
< Delete >	< Delete >	< Delete >
(Same as current)	(Same as current)	(Same as current)
< Delete >	< Delete >	< Delete >
(Same as current)	(Same as current)	(Same as current)
< Delete >	< Delete >	< Delete >
< Delete >	< Delete >	< Delete >
(Same as current)	(Same as current)	(Same as current)

