

## COMPILED COMMENTS ON CLH CONSULTATION

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Last data extracted on 29.07.2020

Substance name: Potassium chlorate

CAS number: 3811-04-9

EC number: 223-289-7

Dossier submitter:

### OTHER HAZARDS AND ENDPOINTS – Acute Toxicity

Date	Country	Organisation	Type of Organisation	Comment number
03.07.2020	Belgium		MemberState	1
Comment received				
<p>BE CA supports the proposed classification of potassium chlorate for the acute toxicity endpoint:</p> <ul style="list-style-type: none"> <li>• Oral route</li> </ul> <p>Marked species differences are demonstrated. Rodent studies show low acute toxicity after oral exposure while many human data report mortality after oral exposure to potassium chlorate and sodium chlorate. Based on WoE and the lowest range within mortality observed in humans (71-214 mg/kg), potassium chlorate warrants classification with Acute Tox. 3, H301 with a ATE of 100 mg/kg bw.</p> <ul style="list-style-type: none"> <li>• Inhalation route</li> </ul> <p>Results from studies in which substances with particle size with a MMAD &gt; 4 µm have been tested can generally not be used for classification. However the inhalation (dust/mist) LC50 &gt;5 mg/l does not indicate high toxicity and thus not warranting an acute toxicity classification for the inhalation route</p>				

Date	Country	Organisation	Type of Organisation	Comment number
23.06.2020	Germany		MemberState	2
Comment received				
<p>Acute toxicity via the oral route:</p> <p>The proposed classification for Acute Tox. 3, H301 is based on a WoE approach. A number of human case reports indicate lowest lethal doses of &lt; 300 mg/kg bw. The German CA agrees with the proposal to classify as Acute Tox. 3 (H301) and with an oral acute toxicity estimate – ATE of 100 mg/kg bw.</p> <p>Acute toxicity via the inhalation route:</p> <p>The proposal to remove Acute Tox. inhalation classification Category 4 (H332) is based on an OECD TG 436 acute inhalation study with potassium chlorate in rats showing an LC50 (4h) &gt; 5.1 mg/L of the test substance after inhalation for 4 hours. The German CA agrees that based on the available data the classification for acute toxicity via inhalation is not warranted. Thus, Acute Tox. 4 (H332) should be removed from CLP Annex VI.</p>				

Date	Country	Organisation	Type of Organisation	Comment number
02.07.2020	France		MemberState	3
Comment received				
<p>Acute toxicity by oral route: FR agrees with the proposal of classification: Acute Tox category 3 and ATE.</p> <p>Acute toxicity by inhalation route: FR agrees with the conclusion that classification of potassium chlorate for acute toxicity via inhalation is not warranted</p>				

Date	Country	Organisation	Type of Organisation	Comment number
22.06.2020	Sweden	Nouryon Pulp and Performance Chemicals	Company-Manufacturer	4
Comment received				
<p>The change of classification of potassium chlorate from Acute Tox 4 to Acute Tox 3 is based on several poisoning cases with sodium and potassium chlorate that occurred mostly in the 60's and 70's. The incidents were mostly suicide attempts and not related to industrial or professional use of potassium chlorate. Table 9, page 9-18.</p> <p>As the classification of potassium chlorate as Acute tox 4 is based on poisoning cases an LD50 value cannot be established and indeed according to the Guidance on the Application of the CLP Criteria (v.5, July 2017) "The minimum dose or concentration or range shown or expected to cause mortality after a single human exposure can be used to derive the human ATE directly, without any adjustments or uncertainty factors". However, having regard to the wording in the guidance ("can" as opposed to "shall"), we understand that this is not a mandatory principle.</p> <p>As mentioned above the reported cases are suicide and/or poisoning incidents; these are not controlled studies and there may be underlying illness or a history of other substance abuse. This is not clear from the publications as most of them do not have many details and only numbers are reported. As stated previously, due to vomiting occurring, sometimes rapidly after ingestion, the absorbed quantity is often uncertain. Therefore, variability occurs in the doses causing lethality.</p> <p>The guidance states that "minimum dose or concentration or range" "can be used" to derive the ATE directly.</p> <p>In the light of the quality of the data and related uncertainties we believe there is no logical choice to use the minimum dose as the basis for the ATE. As it is stated that in many cases, the lethal dose in human are above 20 g (332 mg/kg bw) (Helliwell and Nunn, 1979) and also NTP stated that death has been most frequently associated with doses of 20 g (333 mg/kw bw) or greater, although recovery has been noted in patients who ingested as much as 200 g (3333 mg/kw bw) (NTP 2005). Therefore, we do not agree with the suggested 83 mg/kg bw as the basis for ATE derivation and in the case of sodium and potassium chlorate still suggests 332 mg/kg bw as the relevant starting point for deriving the ATE.</p> <p>ECHA note – An attachment was submitted with the comment above. Refer to public</p>				

OTHER HAZARDS AND ENDPOINTS – Hazardous to the Aquatic Environment

Date	Country	Organisation	Type of Organisation	Comment number
03.07.2020	United Kingdom	HSE	National Authority	5
Comment received				
<p>We consider that more evidence is needed to justify that the substance is rapidly degradable and has a low bioaccumulation potential, although this will not impact on the proposed classification for the environment. In particular, it is unclear how relevant the non-standard ready biodegradability study using excess reducing agents is to determine whether the substance is rapidly degradable. The DS for the CLH report also assumed no significant bioaccumulation would occur based on complete dissociation in water and the high water solubility. We note that no measured BCF or BAF values were available, and the fate and essentiality of the metal ion (and counter ion) were not fully considered to determine whether the criteria for bioaccumulation potential were met according to the CLP guidance on inorganic substances.</p>				

Date	Country	Organisation	Type of Organisation	Comment number
03.07.2020	Belgium		MemberState	6
Comment received				
<p>BE CA supports the conclusion that potassium chlorate does not need to be classified for environmental hazards :</p> <ul style="list-style-type: none"> <li>- all acute aquatic toxic values for the 3 trophic levels &gt;1 mg/l</li> <li>- chronic values available for the 3 trophic levels. The most sensitive species for chronic aquatic toxicity is Lemna minor with a 7dNOEC of 11.5 mg/L for potassium chlorate (calculated based on the NOEC of 10 mg/l for sodium chlorate)</li> </ul>				

Date	Country	Organisation	Type of Organisation	Comment number
22.06.2020	Sweden	Nouryon Pulp and Performance Chemicals	Company-Manufacturer	7
Comment received				
<p>Nouryon supports the removal of the environmental classification (H411) of potassium chlorate. As stated in the CLH report, page 35 "The observed acute aquatic toxicity for potassium chlorate is above the cut-off criterion of 1 mg/l. Potassium chlorate does therefore not need to be classified for the acute aquatic hazard.</p> <p>Adequate chronic toxicity data are available for all three trophic levels. The observed chronic aquatic toxicity for potassium chlorate is above the cut-off criterion of 1 mg/l. Even if a worst-case considering that sodium chlorate is not rapidly degradable in the aquatic environment is applied, potassium chlorate does therefore not need to be classified for the chronic aquatic hazard.</p> <p>As a conclusion, no classification for environmental hazards is warranted for potassium chlorate according to the criteria in Annex I of the CLP Regulation (Commission Regulation (EU) No 286/2011)."</p> <p>ECHA note – An attachment was submitted with the comment above. Refer to public attachment comments to Acute tox 3 classification_potassium chlorate_2020-06-22.pdf</p>				

PUBLIC ATTACHMENTS

1. comments to Acute tox 3 classification\_potassium chlorate\_2020-06-22.pdf [Please refer to comment No. 4, 7]