Committee for Risk Assessment

RAC

Annex 2

Response to comments document (RCOM)

to the Opinion proposing harmonised classification and labelling at EU level of

Potassium chlorate

EC Number: 223-289-7
CAS Number: 3811-04-9

CLH-O-0000007010-92-01/F

Adopted

10 June 2021

COMMENTS AND RESPONSE TO COMMENTS ON CLH: PROPOSAL AND JUSTIFICATION

Comments provided during consultation are made available in the table below as submitted through the web form. Any attachments received are referred to in this table and listed underneath, or have been copied directly into the table.

All comments and attachments including confidential information received during the consultation have been provided in full to the dossier submitter (Member State Competent Authority), the Committees and to the European Commission. Non-confidential attachments that have not been copied into the table directly are published after the consultation and are also published together with the opinion (after adoption) on ECHA's website. Dossier submitters who are manufacturers, importers or downstream users, will only receive the comments and non-confidential attachments, and not the confidential information received from other parties. Journal articles are not confidential; however they are not published on the website due to Intellectual Property Rights.

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Substance name: Potassium chlorate
EC number: 223-289-7
CAS number: 3811-04-9
Dossier submitter:

OTHER HAZARDS AND ENDPOINTS – Acute Toxicity

Date	Country	Organisation	Type of Organisation	Comment number
03.07.2020	Belgium		MemberState	1
Comment received				
BE CA supports the proposed classification of potassium chlorate for the acute toxicity endpoint: • Oral route 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. • Inhalation route Results from studies in which substances with particle size with a MMAD > 4 µm have been tested can generally not be used for classification. However the inhalation (dust/mist) LC50 >5 mg/l does not indicate high toxicity and thus not warranting an acute toxicity classification for the inhalation route				
Dossier Submitter's Response				
Thank you for your support.				
RAC's response				
Thank you for your comment. RAC noted.				

Date	Country	Organisation	Type of Organisation	Comment number
23.06.2020	Germany		MemberState	2
Comment received				
Acute toxicity via the oral route: 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 < 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. Acute toxicity via the inhalation route: 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) > 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.				
Dossier Submitter's Response				
Thank you for your support.				
RAC's response				
Thank you for your comment. RAC noted.				

Date	Country	Organisation	Type of Organisation	Comment number
02.07.2020	France		MemberState	3
Comment received				
Acute toxicity by oral route: FR agrees with the proposal of classification: Acute Tox category 3 and ATE. Acute toxicity by inhalation route: FR agrees with the conclusion that classification of potassium chlorate for acute toxicity via inhalation is not warranted				
Dossier Submitter's Response				
Thank you for your support.				
RAC's response				
Thank you for your comment. RAC noted.				

Date	Country	Organisation	Type of Organisation	Comment number
22.06.2020	Sweden	Nouryon Pulp and Performance Chemicals	Company-Manufacturer	4
Comment received				
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. 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.

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.

The guidance states that "minimum dose or concentration or range" "can be used" to derive the ATE directly.

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.

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

Dossier Submitter's Response

Thank you for your comment.

As stated in the CLH-report, rats appear to have lower sensitivity to MetHB formation compared to humans and rat data are therefore not considered to be adequate for acute toxicity classification. Consequently, the assessment of acute toxicity needs to be based on available human data. We agree that evaluation of human data may be difficult due to various limitations, such as uncertainties relating to exposure assessment. However, as have been stated above and in the CLH-report, according to the Guidance on the Application of the CLP Criteria (3.1.2.3.1) *"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".*
Following the CLP guidance 3.1.2.3.1 and the guidance example in 3.1.5.1.1 an ATE derived from the available data needs to be set despite the various limitations of human data. There are several cases available in the CLH-proposal with human lethal doses (lowest lethal doses are summarised on page 17-18 in the CLH-report, ranging from 71 mg/kg bw to 214 mg/kg bw) that support category 3 rather than category 4. An ATE need to be set to protect also the most sensitive groups in the population, therefore it may be considered justified to select the lowest dose or dose ranges. Using a Weight of evidence approach and expert judgement we find it justified to use the converted Acute Toxicity point Estimate (cATpE), which is 100 mg/kg bw for category 3.

RAC's response
Thank you for your comment. RAC agrees with the DS response.

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				
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.				
Dossier Submitter's Response				
Thank you for your comment. Potassium chlorate is concluded in the CLH report to be rapidly biodegradable and non-bioaccumulative based on weight-of-evidence approaches. No standard studies to evaluate biodegradability and bioaccumulation are available. The conclusions are therefore drawn based on the non-standard tests described in section 11.3.1 and argumentation included in section 11.4. As indicated by UK and as concluded in section 11.7.2 the conclusions for biodegradability and bioaccumulation will have no impact on the proposed classification for the environment.				
RAC's response				
Thank you for your comment. The comment regarding the relevance of non-standard ready biodegradability study using excess reducing agents for determination whether the substance is rapidly degradable is noted by RAC. The comment regarding the bioaccumulation is noted by RAC. No data is available to RAC regarding the fate and essentiality of the metal ion (and counter ion).				

Date	Country	Organisation	Type of Organisation	Comment number
03.07.2020	Belgium		MemberState	6
Comment received				
BE CA supports the conclusion that potassium chlorate does not need to be classified for environmental hazards : - all acute aquatic toxic values for the 3 trophic levels >1 mg/l - 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)				
Dossier Submitter's Response				
Thank you for your support.				

RAC's response
Thank you for your comment. The support of DS proposal for no classification of the substance is noted by RAC.

Date	Country	Organisation	Type of Organisation	Comment number
22.06.2020	Sweden	Nouryon Pulp and Performance Chemicals	Company-Manufacturer	7

Comment received
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. 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. 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)." 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
Dossier Submitter's Response
Thank you for your support.
RAC's response
Thank you for your comment. The support of DS proposal for no classification of the substance is noted by RAC.

PUBLIC ATTACHMENTS
1. comments to Acute tox 3 classification_potassium chlorate_2020-06-22.pdf [Please refer to comment No. 4, 7]