Committee for Risk Assessment

RAC

Annex 2

Response to comments document (RCOM)

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

Sodium chlorate

EC Number: 231-887-4
CAS Number: 7775-09-9

CLH-O-0000007009-75-01/F

Adopted

10 June 2021

ANNEX 2 - COMMENTS AND RESPONSE TO COMMENTS ON CLH PROPOSAL ON SODIUM CHLORATE

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: Sodium chlorate
EC number: 231-887-4
CAS number: 7775-09-9
Dossier submitter:

GENERAL COMMENTS

Date	Country	Organisation	Type of Organisation	Comment number
01.07.2020	France	<confidential>	Company-Manufacturer	1
Comment received				
Industrial use of sodium chlorate is mainly to produce ClO2, which is already classified as Acute Tox 2*. The manufacturing process of sodium chlorate is made in such a way that exposure of sodium chlorate to workers is very low. Because NaClO3 reacts strongly with organic materials, contact with workers is controlled; accidental oral poisoning will not happen even in case of loss of containment. Fatalities via the oral route involving workers are not reported. We therefore suggest maintaining the acute tox 4 classification for sodium chlorate.				
Dossier Submitter's Response				
Thank you for your comment. Lack of reported adverse effects of workers exposed to NaClO3 is not sufficient evidence to exclude potential adverse effects of NaClO3 and does not negate positive results from animal studies or human case studies. Moreover, we also would like to remind you that exposure is not taken into consideration in the classification, since classification is based on the intrinsic hazardous properties of the substance.				
RAC's response				
Thank you for your comment. RAC agrees with the DS response.				

Date	Country	Organisation	Type of Organisation	Comment number
25.06.2020	Spain	Electroquimica de Hernani, S.A.	Company-Manufacturer	2
Comment received				
NaClO3 is a controlled product, not only in its production but also in its final uses, which are nowadays limited to industrial settings. Sodium chlorate's main use is the generation of chlorine dioxide for pulp bleaching. It was formerly used as an herbicide but this use was banned in Europe in 2008, so neither consumers or professional users have access to this product. The high level of containment of the industrial processes where only trained workers equipped with PPEs are involved in its production and use, give as a result safe working conditions which avoid direct exposure. There are not reports of fatalities involving the oral route in this context. In this light, we do not agree with the new classification from Acute Tox 4 to Acute Tox 3 since it will not guarantee any additional safety measure not covered in the current classification.				
Dossier Submitter's Response				
Thank you for your comment. Lack of reported adverse effects of workers exposed to NaClO3 is not sufficient evidence to exclude potential adverse effects of NaClO3 and does not negate positive results from animal studies or human case studies. Moreover, we also would like to remind you that exposure is not taken into consideration in the classification, since classification is based on the intrinsic hazardous properties of the substance. Discussion of the most appropriate risk management, and alternatives other than CLH is out of the scope of the current public consultation.				
RAC's response				
Thank you for your comment. RAC agrees with the DS response.				

Date	Country	Organisation	Type of Organisation	Comment number
19.06.2020	Spain	Ercros, S.A.	Company-Manufacturer	3
Comment received				
Sodium chlorate use is not permitted for general public, as it used to be when it was used as an herbicide. Nowadays, only industrial use is allowed. That means only well trained workers are involved in its management, both during its manufacturing and use. These workers are provided with the appropriate EPIs for preventing any harmful contact with all the substances involved in the industrial processes they deal with. No reporting of fatalities by sodium chlorate via the oral route are available. As there are no possibility of general public access to sodium chlorate, a stronger Acute Tox classification will not improve protection of anybody. We suggest keeping the current Acute Tox 4 classification for sodium chlorate.				
Dossier Submitter's Response				
Thank you for your comment.				

Lack of reported adverse effects of workers exposed to NaClO3 is not sufficient evidence to exclude potential adverse effects of NaClO3 and does not negate positive results from animal studies or human case studies.

Moreover, we also would like to remind you that exposure is not taken into consideration in the classification, since classification is based on the intrinsic hazardous properties of the substance.

Discussion of the most appropriate risk management, and alternatives other than CLH is out of the scope of the current public consultation.

RAC's response

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

Date	Country	Organisation	Type of Organisation	Comment number
15.06.2020	Sweden	Nouryon Pulp and Performance Chemicals AB	Company-Manufacturer	4

Comment received

Industrial use of sodium chlorate is mainly to produce ClO2, which is already classified as Acute Tox 2*. The manufacturing process of sodium chlorate is made in such a way that exposure of sodium chlorate to workers is very low. Because NaClO3 reacts strongly with organic materials, contact with workers is controlled; accidental oral poisoning will not happen even in case of loss of containment. Fatalities via the oral route involving workers are not known.
A stronger Acute Tox classification will not help to protect workers and could even cause confusion amongst industry. We therefore suggest maintaining the Acute Tox 4 classification for sodium chlorate.

ECHA note – An attachment was submitted with the comment above. Refer to public attachment Comments to Acute tox 3 classification_sodium chlorate_2020-06-15.pdf

Dossier Submitter's Response

Thank you for your comment.

Lack of reported adverse effects of workers exposed to NaClO3 is not sufficient evidence to exclude potential adverse effects of NaClO3 and does not negate positive results from animal studies or human case studies.

Moreover, we also would like to remind you that exposure is not taken into consideration in the classification, since classification is based on the intrinsic hazardous properties of the substance.

Discussion of the most appropriate risk management, and alternatives other than CLH is out of the scope of the current public consultation.

RAC's response

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

OTHER HAZARDS AND ENDPOINTS – Acute Toxicity

Date	Country	Organisation	Type of Organisation	Comment number
19.06.2020	Spain	Ercros, S.A.	Company-Manufacturer	5
Comment received				
The Guidance on the Application of the CLP Criteria (v.5, July 2017) states that "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". The proposal for Acute Tox 3 classification is based on human data from suicide or accidental poisoning incidents, without a systematic gathering of information; controlled studies on animals lead to quite higher ATE values. As only well trained and protected workers are expected to be in contact with sodium chlorate, these poisoning incidents are not expected to happen anymore. Therefore, we do not think the classification as Acute Tox 3 is sufficiently well founded and we do not support it.				
Dossier Submitter's Response				
Thank you for your comment. Please see our response to comment number 6. Classification is based on the intrinsic hazardous properties of the substance. Risk and risk reduction measures are not taken into consideration in the assessment.				
RAC's response				
Thank you for your comment. RAC agrees with the DS response.				

Date	Country	Organisation	Type of Organisation	Comment number
15.06.2020	Sweden	Nouryon Pulp and Performance Chemicals AB	Company-Manufacturer	6
Comment received				
Nouryon does not support the classification as Acute Tox 3 because this proposal is based on uncontrolled studies; i.e., poisoning cases that occurred in the 60`´s and 70´s, for which and LD50 value cannot be established. 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. The reported cases used for this classification proposal 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. 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 chlorate suggests 332 mg/kg bw as the relevant starting point for deriving the ATE.
See Table 9 of the CLH report and discussion on human data page 16.

ECHA note – An attachment was submitted with the comment above. Refer to public attachment Comments to Acute tox 3 classification_sodium chlorate_2020-06-15.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.

Date	Country	Organisation	Type of Organisation	Comment number
03.07.2020	Belgium		MemberState	7

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 sodium chlorate and potassium chlorate. Based on WoE and the lowest range within mortality observed in humans (71-214 mg/kg), sodium chlorate warrants classification with Acute Tox. 3, H301 with a ATE of 100 mg/kg bw.

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	8
Comment received				
FR agrees with the proposal of classification: Acute Tox category 3 and ATE.				
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
01.07.2020	France	<confidential>	Company-Manufacturer	9
Comment received				

We do not support the classification as Acute Tox 3 because this proposal is based on Human studies with many confusing factors; i.e., poisoning cases that occurred in the 70´s, for which and LD50 value cannot be established.

As mentioned above the reported cases are suicide and/or poisoning incidents; with various limitations of human data such as uncertainties relating to exposure assessment.

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.

In parallel existing animal studies report LD 50 values which justified and support acute toxicity cat 4 for sodium chlorate as reported by EFSA: . The EFSA scientific opinion also mention that "other publications" reported oral LD50 for sodium chlorate to be 1200 mg/kg b.w. (equivalent to 936 mg chlorate/kg bw) in rats (Lewis, 1996; HSDB, 2003; as cited in EFSA scientific opinion 2015) and the oral LD50 for potassium chlorate to be 1 870 mg/kg bw (equivalent to 1272 mg chlorate/kg bw) in rats (RTECS, 1994; as cited in EFSA scientific opinion 2015). In addition, In the Registry of Toxic Effects of Chemical Substances from NIOSH the oral LD50 in rat was 1870 mg/kg supporting acute toxicity

category 4 classification.
Dossier Submitter's Response
Thank you for your comment. Please see our response to comment number 6.
RAC's response
Thank you for your comment. RAC agrees with the DS response.

Date	Country	Organisation	Type of Organisation	Comment number
25.06.2020	Spain	Electroquimica de Hernani, S.A.	Company-Manufacturer	10
Comment received				
The proposal for Acute Tox 3 is based on reported studies which address instances of accidental poisoning or suicide rather than controlled and contextualised analyses. Most of them have not details, so there might be other factors influencing these results as underlying illnesses or a history of other substance abuse. Other uncertainties are related to the absorbed quantity due to vomiting, occurring sometimes rapidly after ingestion. On the other hand, there are reported cases of surviving at much higher doses and even controlled studies on animals lead to significantly higher ATE values. In view of the foregoing, we do not consider that changing the classification of NaClO3 is justified and we cannot support this proposal.				
Dossier Submitter's Response				
Thank you for your comment. Please see our response to comment number 6.				
RAC's response				
Thank you for your comment. RAC agrees with the DS response.				

Date	Country	Organisation	Type of Organisation	Comment number
23.06.2020	Finland	Kemira Oyj	Company-Manufacturer	11
Comment received				
We question the classification as Acute Tox 3 because this proposal is based on uncontrolled studies; i.e., poisoning cases that occurred in the 70´s, for which an LD50 value cannot be established. The reported cases in CLH report are suicide and/or poisoning incidents; these are not controlled studies and there may be underlying illness or a history of other substance abuse which is not clear from the publications as most of them do not have many details and only numbers are reported.				
Dossier Submitter's Response				
Thank you for your comment. Please see our response to comment number 6.				
RAC's response				
Thank you for your comment. RAC agrees with the DS response.				

Date	Country	Organisation	Type of Organisation	Comment number
23.06.2020	Germany		MemberState	12
Comment received				
The Swedish MSCA proposes to change the current Annex VI entry from Acute Tox. 4 (H302) for acute oral toxicity to Acute Tox. 3 (H301) for acute oral toxicity. The proposed classification as Acute Tox. 3, H301 is based on a WoE approach and expert judgement. A number of human case reports indicate lowest lethal doses of < 300 mg/kg bw. The German CA agrees with the classification as Acute Tox. 3 (H301) and with an oral acute toxicity estimate (ATE) of 100 mg/kg bw.				
Dossier Submitter's Response				
Thank you for your support.				
RAC's response				
Thank you for your comment. RAC noted.				

OTHER HAZARDS AND ENDPOINTS – Hazardous to the Aquatic Environment

Date	Country	Organisation	Type of Organisation	Comment number
19.06.2020	Spain	Ercros, S.A.	Company-Manufacturer	13
Comment received				
In page 34 of the CLH report, is concluded that no classification for environmental hazards is warranted for sodium chlorate according to the criteria in Annex I of the CLP Regulation (Commission Regulation (EU) No 286/2011). We support this conclusion.				
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
15.06.2020	Sweden	Nouryon Pulp and Performance Chemicals AB	Company-Manufacturer	14
Comment received				
We support the removal of environmental classification because as stated in the conclusions in page 34 of the CLH report "The observed acute aquatic toxicity for sodium chlorate is above the cut-off criterion of 1 mg/l. Sodium 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 chronic aquatic toxicity for sodium 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, sodium chlorate does therefore not need to be classified for the chronic aquatic hazard. As a conclusion, no classification for environmental hazards is warranted for sodium 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_sodium chlorate_2020-06-15.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.

Date	Country	Organisation	Type of Organisation	Comment number
03.07.2020	United Kingdom	HSE	National Authority	15
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. Sodium 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	16
Comment received				
BE CA supports the conclusion that sodium 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 7dNOErC 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
01.07.2020	France	<confidential>	Company-Manufacturer	17
Comment received				
We support the removal of environmental classification because as stated in the conclusions in page 34 of the CLH report "The observed acute aquatic toxicity for sodium chlorate is above the cut-off criterion of 1 mg/l. Sodium 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 chronic aquatic toxicity for sodium 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, sodium chlorate does therefore not need to be classified for the chronic aquatic hazard. As a conclusion, no classification for environmental hazards is warranted for sodium chlorate according to the criteria in Annex I of the CLP Regulation (Commission Regulation (EU) No 286/2011)."				
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 for environmental hazard is noted by RAC.				

Date	Country	Organisation	Type of Organisation	Comment number
25.06.2020	Spain	Electroquimica de Hernani, S.A.	Company-Manufacturer	18
Comment received				
We agree with the conclusion in page 34 of CLH report: According to the data, Sodium Chlorate does not need to be classified for the chronic acuatic hazard.				
Dossier Submitter's Response				
Thank you for your support.				
RAC's response				
Thank you for your comment. The support of DS proposal to remove classification of the substance is noted by RAC.				

Date	Country	Organisation	Type of Organisation	Comment number
23.06.2020	Finland	Kemira Oyj	Company-Manufacturer	19
Comment received				

We support removal of Aq Chronic 2 classification. As also CHL report states there are adequate chronic toxicity data available for all three trophic levels supporting the lowest chronic value above 1 mg/l. On top of this sodium chlorate is considered rapidly degradable.
Dossier Submitter's Response
Thank you for your support.
RAC's response
Thank you for your comment. The support of DS proposal to remove classification of the substance is noted by RAC.

PUBLIC ATTACHMENTS
1. Comments to Acute tox 3 classification_sodium chlorate_2020-06-15.pdf [Please refer to comment No. 4, 6, 14]