

COMPILED COMMENTS ON CLH CONSULTATION

Comments provided during consultation are made available in the table below as submitted through the web form. Please note that the comments displayed below may have been accompanied by attachments which are listed in this table and included in a zip file if non-confidential. Journal articles are not confidential; however they are not published on the website due to Intellectual Property Rights.

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Last data extracted on 22.01.2024

Substance name: metam-sodium (ISO); sodium methyldithiocarbamate [1]; metam-potassium (ISO); potassium methyldithiocarbamate [2]
CAS number: 137-42-8 [1]; 137-41-7 [2]
EC number: 205-293-0 [1]; 205-292-5 [2]
Dossier submitter: Belgium

GENERAL COMMENTS

Date	Country	Organisation	Type of Organisation	Comment number
09.01.2024	Germany	<confidential>	Industry or trade association	1
Comment received				
<p>Concerning the endpoint developmental toxicity, we disagree with the position of the RMS and are of the opinion that minor developmental effects observed in studies in rats and rabbits do not support the proposed classification of Metam-sodium in Category 2 for reproductive toxicity.</p> <p>ECHA note – An attachment was submitted with the comment above. Refer to public attachment CLH Comment Devtox Metam 09JAN2024.docx</p> <p>ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment Supplementary document HCD rat skeletal.pdf</p>				

Date	Country	Organisation	Type of Organisation	Comment number
18.01.2024	Belgium	Taminco BV	Company-Manufacturer	2
Comment received				
<p>The applicant, Taminco BV, would like to point out the necessity of an exchange of information between all relevant stakeholders of the active substance / plant protection product (PPP) process and the CLH process, in order to ensure that any evaluation is based on the latest available data set (see section "Information on the CLH process" of this webform: "If the substance is an active ingredient in a plant protection product (PPP) or biocidal product (BP), comments submitted in this consultation may be used in the PPP/BP processes, and, comments received for the PPP/BP processes may be used in the CLH process").</p> <p>Hence the applicant assumes that any comments and supporting information submitted to EFSA in the public consultation phase and thereafter during the request for additional data will be made available by EFSA to ECHA and are as well taken into account in the CLH process by ECHA.</p> <p>The applicant will provide copies of the information referenced above to ECHA in case access will not be provided by EFSA. This relates to all hazard classes open for commenting. Comments on the main metabolite Methyl isothiocyanate (MITC) of the PPP active</p>				

substances metam-sodium (ISO) and metam-potassium (ISO) are submitted in the parallel consultation.

Overall conclusions on hazard class are provided in the field "Comments on the open hazard classes". A detailed feedback on specific hazard classes is provided as a public attachment (Taminco_Metam-sodium_Metam-potassium_Comments)

This public attachment includes both comments on the PPP active substances metam-sodium (ISO) and metam-potassium (ISO) and the main metabolite Methyl isothiocyanate (MITC) in one document. Parts regarding the main metabolite MITC are greyed out.

ECHA note – An attachment was submitted with the comment above. Refer to public attachment Taminco_Metam-sodium_Metam-potassium_Comments.pdf

PHYSICAL HAZARDS

Date	Country	Organisation	Type of Organisation	Comment number
18.01.2024	Belgium	Taminco BV	Company-Manufacturer	3
Comment received				
Vol. 1, 2.2.1.1.15 Corrosive to metals, p. 54: Taminco agrees to the classification as Met. Corr. 1, H290 for metam (incl. -sodium and -potassium). No further information or experimental data is available.				
ECHA note – An attachment was submitted with the comment above. Refer to public attachment Taminco_Metam-sodium_Metam-potassium_Comments.pdf				

HEALTH HAZARDS – Acute toxicity

Date	Country	Organisation	Type of Organisation	Comment number
18.01.2024	Belgium	Taminco BV	Company-Manufacturer	4
Comment received				
Vol. 1, 2.6.2.1.3 Conclusion on classification and labelling for acute oral toxicity, p. 73: The applicant Taminco agrees with RMS on the endpoint and assessment of the single studies for acute oral toxicity and supports the proposed classification for metam. The applicant however disagrees with the ATE of 500 mg/kg bw for metam as experimental LD50 values are available that can be used for the calculation of mixture toxicity. Note (b) for Table 3.1.1 in Regulation (EC) 1272/2008 stipulates that the ATE for classification of a substance in a mixture is derived using the LD50/LC50 where available. The converted ATE values listed in Table 3.1.2 should only be used when only range data or acute toxicity hazard category information is available (point (d) of 3.1.3.3 of Regulation (EC) 1272/2008). This is not the case for metam: an LD50 of 896 mg/kg bw was derived for metam sodium and an LD50 of 1000 mg/kg bw was derived for metam potassium.				
Vol. 1, 2.6.2.3.3 Conclusion on classification and labelling for acute inhalation toxicity, p. 80: The applicant agrees with RMS on the endpoint and assessment of the single studies for acute inhalation toxicity and supports the proposed classifications for metam. The applicant however disagrees with the ATE of 1.5 mg/L for metam as experimental LC50 values are available that can be used for the calculation of mixture toxicity. Note (b) for Table 3.1.1 in Regulation (EC) 1272/2008 stipulates that the ATE for classification of a substance in a mixture is derived using the LD50/LC50 where available. The converted ATE values listed in Table 3.1.2 should only be used when only range data or acute toxicity hazard category information is available (point (d) of 3.1.3.3 of Regulation (EC) 1272/2008). This is not the case for metam: an LC50 of 2.54 mg/L was derived for metam sodium and an LC50 of 3.04 mg/L for metam potassium.				
ECHA note – An attachment was submitted with the comment above. Refer to public				

attachment Taminco_Metam-sodium_Metam-potassium_Comments.pdf

HEALTH HAZARDS – Skin corrosion/irritation

Date	Country	Organisation	Type of Organisation	Comment number
18.01.2024	Germany		MemberState	5
Comment received				
2.6.2.4.3 Conclusion on classification and labelling for skin corrosion/irritation				
Based on the Acute Inhalation Toxicity, H332 classification in combination with classification as Skin Corrosive, H314, metam-sodium also needs to be labelled with EUH071: Corrosive to the respiratory tract (as per 3.2.4.2 of the CLP guidance).				

Date	Country	Organisation	Type of Organisation	Comment number
18.01.2024	Belgium	Taminco BV	Company-Manufacturer	6
Comment received				
Vol. 1, 2.6.2.5.3 Conclusion on classification and labelling for eye damage/eye irritation, p. 86:				
The applicant does not agree with the proposed classification as H318 for metam and MITC as existing eye irritation studies are available supporting that no separate classification for eye irritation is warranted and thus that classification as H314 (also covering potential eye damage) is sufficient. Applicant agrees that, in case no animal data were available, the skin corrosive properties of both substances would be sufficient to classify them as H318 to avoid unnecessary animal suffering. This is however not applicable here as existing animal data from 1991 and 2002 are already available supporting non-classification for this hazard category. Additionally, according to Regulation (EC) 1272/2008 labelling as H318 can be omitted in case the substance is already classified as H314 (cfr. note under Table 3.3.5).				
ECHA note – An attachment was submitted with the comment above. Refer to public attachment Taminco_Metam-sodium_Metam-potassium_Comments.pdf				

HEALTH HAZARDS – Serious eye damage/eye irritation

Date	Country	Organisation	Type of Organisation	Comment number
18.01.2024	Germany		MemberState	7
Comment received				
2.6.2.5.3 Conclusion on classification and labelling for serious eye damage/eye irritation				
The dossier states that the substance is to be classified as Eye Dam, 1, H318. Since the hazard class serious eye damage/eye irritation is independent of the hazard class skin corrosion/skin irritation, a classification in both endpoints (Skin Corr. 1, H314 and Eye Dam. 1, H318) is required in this case.				

HEALTH HAZARDS – Germ cell mutagenicity

Date	Country	Organisation	Type of Organisation	Comment number
22.12.2023	United Kingdom		Individual	8
Comment received				

Section 2.6.4. Metam sodium did not induce gene mutations bacteria in a robust Ames test, but there was evidence of induction of gene mutations in mouse lymphoma cells, particularly in the presence of S9. It did induce chromosomal aberrations in cultured human lymphocytes in both the absence and presence of S9, although the responses were generally weak, but there was also evidence of clastogenic effects in the mouse lymphoma assay. In several follow-up tests in vivo effects in an indicator endpoint (comets) were seen but only under conditions of tissue toxicity. Clear negative results were obtained in a robust rat bone marrow micronucleus test, with indirect evidence (liver toxicity) of systemic (and therefore bone marrow) exposure. Therefore there was no "positive evidence" that Metam sodium is genotoxic in somatic tissues in vivo. Classification as Muta2 is therefore not justified and Metam sodium should not be classified as a germ cell mutagen.

ECHA note – An attachment was submitted with the comment above. Refer to public attachment Comments on the genotoxicity of Metam v4.docx

Date	Country	Organisation	Type of Organisation	Comment number
18.01.2024	United Kingdom	<confidential>	Company-Manufacturer	9

Comment received

Please refer to the comments in document 'Metam CLH Report - comments on genotoxicity' in the Confidential Attachment 'Metam CLH Report - comments on reproductive and developmental toxicity and genotoxicity' for confidential comments on mutagenicity.

Please refer to the comments in the document 'Metam CLH Report - comments on genotoxicity_Redacted' in the Public Attachment 'Metam CLH Report - comments on reproductive and developmental toxicity and genotoxicity_redacted' for comments on mutagenicity in which confidential information has been redacted.

ECHA note – An attachment was submitted with the comment above. Refer to public attachment Metam CLH Report - comments on reproductive and developmental toxicity and genotoxicity_redacted.zip

ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment Metam CLH Report - comments on reproductive and developmental toxicity and genotoxicity.zip

Date	Country	Organisation	Type of Organisation	Comment number
21.12.2023	United States of America		Individual	10

Comment received

The proposal by the RMS to classify metam sodium as Muta Cat 2 , H341, "Suspected of causing genetic defects" is not supported by the available data. On the other hand, metam sodium is not classifiable for germ cell mutagenicity at this time based on the existing data.

ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment BG Comments Metam_122123.zip

Date	Country	Organisation	Type of Organisation	Comment number
18.01.2024	Belgium	Taminco BV	Company-Manufacturer	11

Comment received

Vol. 1, 2.6.4.2 Comparison with the CLP criteria regarding genotoxicity / germ cell mutagenicity (metam), p. 139:

The applicant agrees that classification in Category 1A or B is certainly not warranted. With regards to the proposed classification in Category 2, the applicant is of the opinion that there is not one single test available providing clear and unambiguously positive results for genotoxic properties of metam. Potential genotoxic effects observed in in vitro or in vivo studies were always accompanied by indication of cytotoxicity and consistently lacking a clear dose-response relationship. In addition, MITC, the main metabolite of metam formed by rapid degradation in animals, is devoid of a genotoxic potential and thus providing some supportive information for the weight of evidence of metam genotoxicity evaluation. Classification for germ cell mutagenicity category 2 may be considered on the basis of positive mammalian somatic cell mutagenicity tests in vivo, or other positive in vivo somatic cell genotoxicity tests that are supported by positive results from in vitro mutagenicity assays, or positive in vitro mammalian mutagenicity for substances that also show chemical structure activity relationship (SAR) to known germ cell mutagens. As the available in vivo somatic cell genotoxicity tests do not yield a positive result, nor does metam show SAR to known germ cell mutagens, Industry concluded that no classification for germ cell mutagenicity is warranted.

This was also suggested by the dossier submitter under 2.6.4.2: "As suggested here above and further discussed below, the genotoxicity package of metam indicated that, while there are some indications of interactions of metam with the genetic material the criteria for classification of this a.s. as Muta Category 2 are not fully met" and "RMS notes that a positive gene mutation assay in the presence of clearly negative bacterial gene mutation assays could possibly reflect "false positive" results, especially in the case when the test article would cause severe cytotoxicity. This could be the case with metam, in which case this would constitute an important argument for no classification instead of classification as Muta. 2".

Comments to the single studies are provided in the attached commenting sheet for metam ("Taminco_Metam-sodium_Metam-potassium_Comments").

ECHA note – An attachment was submitted with the comment above. Refer to public attachment Taminco_Metam-sodium_Metam-potassium_Comments.pdf

Date	Country	Organisation	Type of Organisation	Comment number
18.01.2024	Germany		MemberState	12

Comment received

B.6.4.4 Summary of genotoxicity

The comet assay is indicative of DNA damage, as opposed to induction of heritable mutations. For this purpose, a TGR or MN assay would be required. Nonetheless, according to Table 3.1.5 of the CLP Guidance, Muta. 2 is based on "other in vivo somatic cell genotoxicity tests which are supported by positive results from in vitro mutagenicity assays", in this case, the positive results in the MLA-TK, but also the in vitro CA tests. Genotoxicity is not a result of cytotoxicity as stated by the RMS, rather genotoxicity is seen together with cytotoxicity. The MoA is by electrophilic attack of cellular components including DNA. This means damage to the DNA is going to occur at the same doses as cellular damage. Unless repaired, genotoxic damage is typically sustained in surviving cells and passed on to subsequent generations. Thus, an animal may survive an initial toxic insult, but end up with cancer, as is evidenced in the carcinogenicity studies. Muta. 2 classification should be considered.

Date	Country	Organisation	Type of Organisation	Comment number
19.01.2024	United Kingdom	Health and Safety Executive	National Authority	13
Comment received				
METAM (Germ Cell Mutagenicity)				
<p>'In regards to the in vivo micronucleus assays, the DS mentions that bone marrow exposure was not demonstratively attained, in either study. However, it can be reasonably assumed that the substance/metabolites can reach the bone marrow based on the following: ADME data suggests that distribution is uniform; reported effects such as anaemia in repeated dose toxicity studies; evidence from studies with MITC (e.g. rat micronucleus assay, 2020 B.6.8.1.3.2/05) that the bone marrow could likely be reached.</p> <p>Furthermore, In the positive mammalian gene mutation (TK) in L5178Y mouse lymphoma cells (2019b; B.6.4.1.2/02), the DS mentions a reduction in 'relative total growth (RTG)'. The OECD TG 490 mentions that studies should aim to achieve a 10-20% reduction at a maximum. Please could the DS provide the numerical data for RTG, to aid the assessment of this study.'</p>				

HEALTH HAZARDS – Carcinogenicity

Date	Country	Organisation	Type of Organisation	Comment number
18.01.2024	Germany		MemberState	14
Comment received				
2.6.5 Summary of long-term toxicity and carcinogenicity				
<p>As noted in the summary, a "clear carcinogenic effect in the mouse, while the outcome in the rat is less convincing". Nevertheless, the carcinogenic effect in rats cannot be discounted.</p> <p>If there are (the same) carcinogenic effects (here, angiosarcoma) in two species, shouldn't this result in H350? This needs further discussion.</p>				

Date	Country	Organisation	Type of Organisation	Comment number
21.12.2023	United States of America		Individual	15
Comment received				
<p>The nasal tumors observed in rats exposed to high concentrations of MITC are due to the confounding effects of excessive cytotoxicity and as such a classification for carcinogenicity is not warranted.</p> <p>ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment BG Comments Metam_122123.zip</p>				

HEALTH HAZARDS – Reproductive toxicity

Date	Country	Organisation	Type of Organisation	Comment number
06.12.2023	France		Individual	16

Comment received
Independent expert opinion on the proposed CLH classification is given in attached document.
ECHA note – An attachment was submitted with the comment above. Refer to public attachment Public comment on Metam Reprotox_Dec2023.pdf

Date	Country	Organisation	Type of Organisation	Comment number
18.01.2024	Belgium	Taminco BV	Company-Manufacturer	17

Comment received
<p>Vol. 1, 2.6.6.2.2 Comparison with the CLP criteria regarding adverse effects on development (metam), p. 186:</p> <p>The applicant considers that no classification for reproductive toxicity (Cat. 2, H361d) is warranted for metam-sodium. The frequency of the defects observed is extremely low and there is clear evidence from each developmental toxicity study (and the 90-day repeated-dose toxicity study in rats) that they occurred in presence of distinct maternal toxicity (manifesting as effects on food consumption and body weight parameters), at the same level(s) as those at which these foetal defects are also observed. Furthermore, the pattern for the occurrence of these defects is the same in all studies:</p> <ul style="list-style-type: none"> • Observed at highest dose only (in the presence of distinct systemic toxicity) • No dose-relationship • Clear threshold for defects (in all studies) • Defects observed are known to be sensitive to maternal/foetal general toxicity <p>Consequently, these findings are not considered relevant for classification purposes (teratogenicity).</p> <p>According to Annex I: 3.7.2.4.3 and the CLP guidance section 3.7.2.2.1.1 (version 5, July 2017, page 401): Classification is not necessarily the outcome in the case of minor developmental changes, when there is only a small reduction in foetal/pup body weight or retardation of ossification when seen in association with maternal toxicity". Furthermore, classification in Category 2 for reproductive toxicity should be considered when "Such effects shall have been observed in the absence of other toxic effects, or if occurring together with other toxic effects the adverse effect on reproduction is considered not to be a secondary non-specific consequence of the other toxic effects".</p> <p>According to the applicant, the clear foetotoxic effects observed in various studies were always linked to maternal toxicity. The foetotoxic effects included foetal mortality (reduced live foetuses) and reduced foetal weight and were linked to reduced gravid uterus weight and increased post-implantation loss. Furthermore, the classification of metam-sodium as STOT-RE Cat. 1 is sufficient to also cover potential developmental defects triggered by general toxicity observed at doses not lower than those that have been basis for STOT-RE Cat. 1 classification. The anomalies or malformations reported were only observed at the highest, severely maternotoxic doses and are known to be sensitive to severe systemic toxicity. With regards to the malformations in rats, dossier submitter acknowledged that hydrocephalus, microphthalmia/anophthalmia lacked dose-dependency throughout the various studies. With regards to malformations observed in rabbits (meningocele, cleft palate), dossier submitter stated that "neither the number of affected litters nor the dose-dependency were convincing to attribute them unequivocally to the treatment with metam-sodium". In conclusion, classification in Category 2 for reproductive toxicity is not warranted.</p> <p>Comments to the single studies are provided in the attached commenting sheet for metam ("Taminco_Metam-sodium_Metam-potassium_Comments").</p>

ECHA note – An attachment was submitted with the comment above. Refer to public attachment Taminco_Metam-sodium_Metam-potassium_Comments.pdf

Date	Country	Organisation	Type of Organisation	Comment number
09.01.2024	Germany	<confidential>	Industry or trade association	18

Comment received

Developmental toxicity was evaluated in 4 main studies performed with Metam-sodium in rats and rabbits. Based on these studies an overall NOAEL for maternal toxicity can be established at a dose level of 5 mg/kg bw with minor or no findings at 10 mg/kg bw, some maternal toxicity at 20 to 40 mg/kg bw and severe maternal toxicity at dose levels higher than 60 mg/kg bw. Embryo- and or foetotoxicity were seen at dose levels at and above 20 mg/kg bw as well.

With respect to developmental toxicity, evidence of major defects was observed only at dose levels showing also severe maternal toxicity. One finding (meningocele, head) was consistently seen in the developmental toxicity studies in rats and rabbits, while single incidences of other major findings were without dose-relation and did not show a general pattern. Taking all findings into consideration, an overall NOAEL for developmental toxicity of Metam-sodium can be established at 5 mg/kg bw with major findings only observed at higher maternally toxic dose levels with a NOAEL of 40 mg/kg bw.

Based on an assessment of the findings on developmental toxicity it can be concluded that there is no sufficient evidence to consider Metam-sodium as primarily toxic to the development of rat and rabbit offspring, and that the factors contributing to the findings can be related to maternal toxicity, especially malnutrition, during the primary days of gestation.

Based on this assessment, there is no sufficient evidence of a direct effect of Metam-sodium on embryo-foetal development and therefore no classification into Category 2 for reproductive toxicity is warranted.

ECHA note – An attachment was submitted with the comment above. Refer to public attachment CLH Comment Devtox Metam 09JAN2024.docx

ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment Supplementary document HCD rat skeletal.pdf

Date	Country	Organisation	Type of Organisation	Comment number
18.01.2024	United Kingdom	<confidential>	Company-Manufacturer	19

Comment received

Please refer to the comments in document 'Metam CLH Report - comments on reproductive and development toxicity' in the Confidential Attachment 'Metam CLH Report - comments on reproductive and developmental toxicity and genotoxicity' for confidential comments on reproductive toxicity.

Please refer to the comments in the document 'Metam CLH Report - comments on reproductive and developmental toxicity_Redacted' in the Public Attachment 'Metam CLH Report - comments on reproductive and developmental toxicity and genotoxicity_redacted' for comments on reproductive toxicity in which confidential information has been redacted.

ECHA note – An attachment was submitted with the comment above. Refer to public attachment Metam CLH Report - comments on reproductive and developmental toxicity and genotoxicity_redacted.zip

ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment Metam CLH Report - comments on reproductive and developmental toxicity and genotoxicity.zip

ENVIRONMENTAL HAZARDS – Hazardous to the aquatic environment

Date	Country	Organisation	Type of Organisation	Comment number
08.01.2024	Netherlands		MemberState	20

Comment received

General comments

Thank you for sharing the CLH report with us. The report is well written. We disagree with the proposed environmental classifications. Specifically with the M-factor of 1 proposed for the H400 and H410 classification. On p.11 you write that the classifications of Metam and main degradation product MITC should be considered separately as, for all endpoints, Metam itself and MITC have been tested. We disagree with this approach and support the suggestion by ECHA to combine the datasets.

The environmental fate studies demonstrate that Metam degrades rapidly into MITC in different environmental media. MITC should therefore be considered a relevant degradation product. In such a case, the aquatic toxicity data of the degradation product should be taken into account for the classification of the parent compound, also when a full data set of the parent compound is available. MITC shows higher aquatic toxicity compared to Metam. The lowest acute effect value was determined to be 0.0038 mg/L for *H. azteca*, resulting in an H400 classification with an M-factor of 100. The lowest chronic effect value was determined to be 0.00774 mg/L for *Pimephales promelas* which would result in an H410 classification with an M-factor of 10 (considering MITC is not rapidly degradable), but as the most sensitive species in the acute dataset (*H. azteca*) was not tested in a chronic study, the acute value was used for the chronic classification, resulting in an M-factor of 100. We believe that these classifications should also be proposed for Metam sodium and Metam potassium.

In addition, it seems not all information from the REACH registration dossier is taken into account. For example, on P. 324: It is reported that no relevant data on ready biodegradability is available for MITC. However, in the REACH registration dossier, a OECD TG 301D study (2010) is provided. The study shows that MITC is not readily biodegradable (0%), this information is relevant for the classification of Metam sodium.

Also, the REACH registration dossier for Metam sodium mentions an acute toxicity study with Metam sodium on *Cypridopsis vidua* (48-h LC50 = 0.035 mg/L, supporting study 003), which is not included in the CLH report. Were these studies not provided or left out for another reason? Perhaps it is worthwhile to include these studies as well.

Date	Country	Organisation	Type of Organisation	Comment number
19.01.2024	United Kingdom	Health and Safety Executive	National Authority	21

Comment received

Metam-sodium:

The test item, metam-sodium and the degradant MITC were analysed in both the key acute and chronic aquatic toxicity studies used for the CLH proposal. The acute endpoint, *Daphnia magna* 48hr EC50 = 0.166 mg/L, and the chronic endpoints, *Pseudokirchneriella subcapitata* 72hr ErC10 = 0.0779 mg/L and NOEC = 0.0813 mg/L, were expressed as total metam-sodium calculated from the measured concentrations of metam-sodium and MITC.

We are unsure if this endpoint basis is standard for hazard classification and note that this appears inconsistent with how endpoints from other ecotoxicity studies with metam-sodium and metam-potassium in the CLH report have been determined based on measured concentrations of metam-sodium or metam-potassium alone .

The parallel CLH report for MITC shows that MITC is more toxic than metam. Consequently, it can be expected that MITC is driving the observed ecotoxicity in the studies with metam salts. The CLH report states that metam immediately and completely degrades into numerous degradants in the environment and biological matrices with the main degradant being the ultimate active substance, MITC. The fate data in the CLH report for metam salts also show that MITC is formed in significant quantities over timescales relevant for acute and chronic ecotoxicity. For example, the water-sediment simulation study with metam-potassium showed >70% MITC formed after 8 hours. Therefore, we consider it may be more appropriate to classify metam based on the hazard data for MITC directly. We note this would be consistent with the risk assessment for metam under the PPP regime which has been based on the hazard data for MITC as shown on page 634 of the CLH report. In addition, dazomet is another MITC generating PPP and MITC endpoints are used in its PPP risk assessment.

PUBLIC ATTACHMENTS

1. Metam CLH Report - comments on reproductive and developmental toxicity and genotoxicity_redacted.zip [Please refer to comment No. 9, 19]
2. Taminco_Metam-sodium_Metam-potassium_Comments.pdf [Please refer to comment No. 2, 3, 4, 6, 11, 17]
3. CLH Comment Devtox Metam 09JAN2024.docx [Please refer to comment No. 1, 18]
4. Comments on the genotoxicity of Metam v4.docx [Please refer to comment No. 8]
5. Public comment on Metam Reprotox_Dec2023.pdf [Please refer to comment No. 16]

CONFIDENTIAL ATTACHMENTS

1. Metam CLH Report - comments on reproductive and developmental toxicity and genotoxicity.zip [Please refer to comment No. 9, 19]
2. Supplementary document HCD rat skeletal.pdf [Please refer to comment No. 1, 18]
3. BG Comments Metam_122123.zip [Please refer to comment No. 10, 15]