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 21.11.2023

Substance name: dichloromethane
CAS number: 75-09-2
EC number: 200-838-9
Dossier submitter: Italy

GENERAL COMMENTS

Date	Country	Organisation	Type of Organisation	Comment number
16.11.2023	Belgium	<confidential>	Industry or trade association	1
Comment received				
As a food industry representative, we appreciate the opportunity to contribute to the public consultation on the CLH report on dichloromethane (DCM). Based on the scientific argumentation compiled by the ReachCentrum on behalf of the members of Chlorinated Solvents REACH Consortium, we believe that the current classification remains appropriate, allowing to safely use the solvent in some well-established food industry processes. ECHA note – An attachment was submitted with the comment above. Refer to public attachment ChlorSolv_response to CLH proposal on DCM_15.11.2023.pdf				

Date	Country	Organisation	Type of Organisation	Comment number
17.11.2023	United Kingdom	Health and Safety Executive (HSE)	National Authority	2
Comment received				
Carcinogenicity - Within the available animal dataset, the background incidence of some tumours is not provided/referred to (e.g. NTP studies). Therefore, would the DS be able to provide this information, if available, to aid with the assessment.				

Date	Country	Organisation	Type of Organisation	Comment number
31.10.2023	Belgium	<confidential>	Company-Importer	3
Comment received				
Methylene chloride was evaluated for human health risk and environmental risk by US EPA in accordance with the Frank R. Lautenberg Chemical Safety for the 21st Century Act. The final report on Risk Evaluation for Methylene Chloride lists multiple use scenarios where unreasonable risk was identified. Methylene chloride has been used in coatings and adhesives, e.g. contact adhesive formulations, for its solvency power and rendering the final formulation non-flammable. Commercially available today are alternative solvent solutions that can replace methylene chloride providing the same functionality (solvency and non-				

flammability) but do not have the toxicity concerns.

Date	Country	Organisation	Type of Organisation	Comment number
15.11.2023	Germany		MemberState	4
Comment received				
We would like to point out at this point that a change in classification from Carc. 2 to Carc. 1b also requires an amendment to Annex II Part 3 No. 3.1.1.3. The regulation laid down there refers to dichloromethane, which is classified as Carc. 2. Carcinogenicity (our comments here, since the webform is incomplete): The DE CA supports the proposed modification of the classification from Carc. 2 to Carc. 1B for dichloromethane. Based on the inhalation carcinogenicity studies in mice and rats reported in the dossier, the DE CA supports that there is clear evidence of carcinogenicity in both species. Inhalation treatment with dichloromethane of mice and rats resulted in significantly increased incidences of benign and malignant tumours in male and female animals compared to concurrent and historical controls. In more detail, exposure of male and female mice led to significantly increased incidences of bronchiolar-alveolar adenomas/carcinomas and hepatocellular adenomas/carcinomas above historical control incidences. In rats, inhalation of dichloromethane increased the incidence of mammary gland adenomas and fibroadenomas in males and females. The observed carcinogenic effects after inhalation of dichloromethane correlate with the available positive in vivo inhalation mutagenicity studies in mice. The DS did not discuss or propose to classify carcinogenicity only for the inhalation route. Oral carcinogenicity studies are also available but showed increased tumour incidences within the range of historical controls. However, these oral data are considered to be limited as the maximum tested dose level was only up to 500 mg/kg bw/d. Thus, the view not to restrict the classification to the inhalation route is supported, but a discussion on that point would be useful. Supportive human data is available but is considered insufficient for a Carc. 1A classification. There is no information given in the dossier if a SCL or GCL is to be applied.				

HEALTH HAZARDS – Germ cell mutagenicity

Date	Country	Organisation	Type of Organisation	Comment number
16.11.2023	France		MemberState	5
Comment received				
Mutagenicity: FR agrees with the classification proposal Muta. 2, H341, based on evidence of genotoxicity both in vitro and in vivo. Additionally, the effects observed in vivo were in association with the GST metabolic pathway operative also in humans. Since no studies reported positive effects on germ cells, the classification as Muta cat 1B is not appropriate for DCM.				

Carcinogenicity:
FR agrees with the classification proposal Carc 1B, H350 based on limited evidence in human studies and sufficient evidence of DCM carcinogenicity in animal studies (mice and rats). Evidences in humans are mainly based on two types of tumours: cancer of biliary tract, and, at less extent, on evidence concerning non-Hodgkin lymphoma. Various types of tumours are reported in rats and mice, in both males and females. All the tumours observed in the animal studies are relevant for human. Additionally, genotoxicity data support a plausible mode of action for DCM carcinogenicity.

Date	Country	Organisation	Type of Organisation	Comment number
16.11.2023	Belgium	Chlorinated Solvents REACH Consortium	Company-Manufacturer	6

Comment received

See the attachment, part 2.

ECHA note – An attachment was submitted with the comment above. Refer to public attachment ChlorSolv_response to CLH proposal on DCM_15.11.2023.pdf

Date	Country	Organisation	Type of Organisation	Comment number
08.11.2023	Italy	<confidential>	Company-Downstream user	7

Comment received

Mutagenicity
Many mutagenicity studies generated contradictory results. The proposed muta 2 (H341) may be acceptable.

Carcinogenicity
In our opinion, the best and more comprehensive review is "Evaluation of the carcinogenicity of dichloromethane in rats, mice, hamsters and humans" (Dekant et al, 2021). https://www.sciencedirect.com/science/article/pii/S0273230020302841
The summary is very clear:
"Carcinogenicity studies in rats, mice and hamsters have demonstrated a malignant tumor inducing potential of DCM only in the mouse (lung and liver) at 1000–4000 ppm whereas human data do not support a conclusion of cancer risk. Based on this, DCM has been classified as a cat. 2 carcinogen. Dose-dependent toxicokinetics of DCM suggest that DCM is a threshold carcinogen in mice, initiating carcinogenicity via the low affinity/high capacity GSTT1 pathway; a biotransformation pathway that becomes relevant only at high exposure concentrations.
Rats and hamsters have very low activities of this DCM-metabolizing GST and humans have even lower activities of this enzyme. Based on the induction of specific tumors selectively in the mouse, the dose- and species-specific toxicokinetics in this species, and the absence of a malignant tumor response by DCM in rats and hamsters having a closer relationship to DCM toxicokinetics in humans and thus being a more relevant animal model, the current classification of DCM as human carcinogen cat. 2 remains appropriate."

Although this review was mentioned in the CLH report (page 55), this review was not deeply discussed in order to refute its conclusion. Moreover in the CLH report there is no new carcinogenicity study which supports the proposed classification (Carc.1B). Therefore our

company does not agree with the proposed classification and support the current Carc.2 (H351) classification.

Date	Country	Organisation	Type of Organisation	Comment number
15.11.2023	Germany		MemberState	8
Comment received				
The DE-CA supports the proposed classification of dichloromethane as Muta. 2 (H341). According to the CLP classification criteria, classification in Muta. 2 may be based on positive results of at least one valid in vivo mammalian somatic cell mutagenicity test indicating mutagenic effects in somatic cells. There are three positive in vivo mammalian somatic cell mutagenicity tests with dichloromethane reported in the dossier, two in vivo micronucleus tests in mice and one in vivo chromosomal aberration test in mice (Allen et al. 1990). The tests were performed via the inhalation route which is considered a physiological route of substance treatment. A significant increase of micronucleated PCEs or NCEs compared to controls was observed at 2000, 4000 and 8000 ppm in the micronucleus tests and a significant increase in chromosomal aberrations compared to controls was found at 8000 ppm in the chromosomal aberration test. The tests were performed pre-guideline and have some shortcomings, e.g. missing positive controls, but in a weight-of-evidence approach the results are considered valid. Other available negative in vivo cytogenicity inhalation studies in mammals in the dossier are not considered to be contradictory as animals were treated with lower concentrations. The potential to induce chromosomal aberrations in vivo is supported by positive results in in vitro cytogenicity tests with dichloromethane. Classification of dichloromethane as Muta. 2 (H341) is considered warranted.				

Date	Country	Organisation	Type of Organisation	Comment number
31.10.2023	Belgium	<confidential>	Company-Importer	9
Comment received				
Methylene chloride was evaluated for human health risk and environmental risk by US EPA in accordance with the Frank R. Lautenberg Chemical Safety for the 21st Century Act. The final report on Risk Evaluation for Methylene Chloride can be found here: https://www.epa.gov/sites/default/files/2020-06/documents/1_mecl_risk_evaluation_final.pdf In March 2019 EPA issued a final rule, where the Agency made the determination that the use of methylene chloride in consumer paint and coating removal presents an unreasonable risk of injury to health due to acute human lethality. To address this unreasonable risk, the Agency prohibited the manufacture (including import), processing, and distribution in commerce of methylene chloride for paint and coating removal, including distribution to and by retailers; required manufacturers (including importers), processors, and distributors, except retailers, of methylene chloride for any use to provide downstream notification of these prohibitions; and required recordkeeping. The final rule took effect on May 28, 2019. Methylene chloride is currently manufactured, processed, distributed, used, and disposed of as part of additional industrial, commercial, and consumer conditions of use. Leading applications for methylene chloride include as a solvent in the production of pharmaceuticals and polymers, metal cleaning, production of HFC-32, and as an ingredient in adhesives and paint removers. EPA evaluated the various categories of conditions of use including: manufacturing; processing; distribution in commerce, industrial, commercial and consumer uses and disposal. EPA determined several unreasonable risks scenarios associated with the use of methylene chloride. The detailed problem formulation and risk assessment process				

and list of unreasonable risks have been detailed in the document. Some of the key highlights from the 'unreasonable risk' determination is as below.
Unreasonable Risks of Injury to Health: EPA's determination of unreasonable risk for specific conditions of use of methylene chloride listed are based on health risks to workers, ONUs, consumers, or bystanders from consumer use. For acute exposures, EPA evaluated unreasonable risk to the central nervous system, such as central nervous system depression and a decrease in peripheral vision, each of which can lead to workplace accidents and which are precursors to more severe central nervous system effects such as incapacitation, loss of consciousness, and death. For chronic exposures, EPA evaluated unreasonable risk of non-cancer liver effects (including vacuolization, necrosis, hemosiderosis and hepatocellular degeneration) as well as cancer (liver and lung tumors).
Unreasonable Risk of Injury to Health of Workers: EPA evaluated non-cancer effects from acute and chronic inhalation and dermal occupational exposures and cancer from chronic inhalation and dermal occupational exposures to determine if there was unreasonable risk to workers' health. The drivers for EPA's determination of unreasonable risk of injury for workers are central nervous system effects resulting from acute inhalation exposure, adverse effects to the liver due to chronic inhalation exposure, and cancer from chronic inhalation. EPA evaluated unreasonable risk to workers from dermal occupational exposure and determined unreasonable risk to workers from dermal exposure from one condition of use. A full description of EPA's unreasonable risk determination for each condition of use is in section 5.2.
Unreasonable Risk of Injury to Health of Occupational Non-Users (ONUs): EPA evaluated non-cancer effects to ONUs from acute and chronic inhalation occupational exposures and cancer from chronic inhalation occupational exposures to determine if there was unreasonable risk of injury to ONUs' health. The unreasonable risk determinations reflect the severity of the effects associated with the occupational exposures to methylene chloride and the assumed absence of PPE for ONUs, since ONUs do not directly handle the chemical and are instead doing other tasks in the vicinity of methylene chloride use.. For inhalation exposures, EPA, where possible, estimated ONUs' exposures and described the risks separately from workers directly exposed. When the difference between ONUs' exposures and workers' exposures cannot be quantified, EPA assumed that ONU inhalation exposures are lower than inhalation exposures for workers directly handling the chemical substance. A full description of EPA's unreasonable risk determination for each condition of use is in section 5.2.
Unreasonable Risk of Injury to Health of Consumers: EPA evaluated non-cancer effects to consumers from acute inhalation and dermal exposures to determine if there was unreasonable risk to consumers' health. A consumer condition of use sometimes was evaluated using multiple Consumer Exposure Scenarios. In the Draft Risk Evaluation, EPA used the results from each Consumer Exposure Scenario to draft separate preliminary unreasonable risk determinations, which resulted in multiple preliminary unreasonable risk determinations for a single condition of use (e.g., consumer use in metal degreasers had three unreasonable risk determinations). In this Final Risk Evaluation, EPA consolidated risk estimates for multiple exposure scenarios in order to present clearer unreasonable risk determinations and the unreasonable risk determinations adhere to the conditions of use as they were presented in the Problem Formulation. The exposure scenarios supporting the unreasonable risk determinations for the conditions of use are listed in the risk evaluation document.

Date	Country	Organisation	Type of Organisation	Comment number
17.11.2023	United Kingdom	Health and Safety Executive (HSE)	National Authority	10

Comment received
Where available, information on the positive control results would be useful to assess the in vivo mutagenicity data. Therefore, please would the DS provide this data, to aid the assessment.

Date	Country	Organisation	Type of Organisation	Comment number
17.11.2023	Germany	<confidential>	Company-Downstream user	11

Comment received
We refer to the response of the Chlorinated Solvents REACH Consortium and agree with their opinion that the proposed classification of dichloromethane (DCM) is not appropriate. In addition, we also want to comment on the economic impact of the proposed classification to our company as well as our customers: • Loss of turnover of approximately 2.7 mio. Euro per year for our company with an additional loss of 5 mio. Euro of turnover related to products which are not usable without the DCM containing products. • Reduction of approximately 30 jobs at our company alone. • We have approximately 140 customers which use our DCM containing adhesives. With the proposed classification, all of these production sites must be closed down. Our customers use DCM containing products due to the inflammability of DCM. There is no substitute for DCM, as other solvents would require explosion protection. This would result in investment costs that they cannot afford. We assume that approximately 2,000 jobs at our EU based customers will be lost due to the proposed classification.

PUBLIC ATTACHMENTS
1. ChlorSolv_response to CLH proposal on DCM_15.11.2023.pdf [Please refer to comment No. 1]
2. ChlorSolv_response to CLH proposal on DCM_15.11.2023.pdf [Please refer to comment No. 6]