

**Committee for Risk Assessment**  
**RAC**

Annex 2  
**Response to comments document (RCOM)**  
to the Opinion proposing harmonised classification and  
labelling at EU level of

**Formaldehyde ...%**

**EC Number: 200-001-8**  
**CAS Number: 50-00-0**

CLH-O-0000007130-88-01/F

**Adopted**  
**2 June 2022**

**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: formaldehyde ...%**

**EC number: 200-001-8**

**CAS number: 50-00-0**

**Dossier submitter:**

**GENERAL COMMENTS**

Date	Country	Organisation	Type of Organisation	Comment number
08.10.2021	Germany	<confidential>	Company-Manufacturer	1
<b>Comment received</b>				
<p>On behalf of the REACH Consortium for formaldehyde we submit the following comments: We noticed that the CLH dossier on page 4-5 refers to the 100 % gas and to a 25-55 % solution of formaldehyde in water with concentration range of up to 7% w/w methanol. Since in practice formaldehyde is not handled as a gas, in comparison the boundary composition in the REACH dossiers considers a 30-60 % solution of formaldehyde in water with up to 3% w/w methanol. We would recommend to regulators to align the substance composition and proposals for classification in the CLH dossier with the current state of the REACH dossier, as to prevent possible confusion between the classification of formaldehyde and the classification of methanol, and also considering possible future changes to the classification of these two substances.</p>				
<b>Dossier Submitter’s Response</b>				
<p>Thank you for comment. The dossier is foreseen to classify “formaldehyde...%”. The formaldehyde gas is mentioned on page 4 and 5 to clarify that the pure substance formaldehyde is a gas.                      In addition, we agree that the classification of formaldehyde ...% should be done for a content of 0 % Methanol.</p> <p>We checked that the classification of formaldehyde should not be influenced by a methanol content of up to 7 % in an aqueous formaldehyde solution of 25-60 % for toxicological and ecotoxicological endpoints                      In addition, no clear effect of the composition on the toxicity was observed in the above mentioned concentration range. Furthermore, the possible effect of methanol on the endpoint acute toxicity is already addressed in the CLH report.</p>				

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<p>For the physical hazards the classification and labelling is influenced by the composition of the formaldehyde solution and this is already addressed by adding notes to the proposed classification. Therefore, we like to point out for the RAC that during the assessment it is taken care of this fact and that it has to be addressed if needed.</p>
<p>RAC's response</p>
<p>The Annex VI entry in the scope of the current CLH proposal covers aqueous solutions of formaldehyde. Formaldehyde gas is out of the scope. The Annex VI entry should cover all formaldehyde solutions on the market, including those with a methanol content above 3% or 7%. This is proposed to be covered by Note F.</p>

Date	Country	Organisation	Type of Organisation	Comment number
07.10.2021	Belgium	Formacare (Cefic sector group)	Industry or trade association	2

<p>Comment received</p>
<p>Formacare, a sector group of Cefic, welcomes the opportunity to provide comments to the proposal from the Dossier Submitter Germany (DS) to revise the existing classification of formaldehyde.</p> <p>Formacare represents the interests of the key European producers of formaldehyde and derivatives including aminoplast resins and glues, polyacetals, paraformaldehyde and polyols. All in all, Formacare represents around 95% of the formaldehyde produced in Europe and is the leading voice of this industry in dialogue with European policy-makers and regulators.</p> <p>Formaldehyde is a simple, naturally occurring substance made up of hydrogen, oxygen and carbon, with the formula CH<sub>2</sub>O. It is also naturally found in all organic forms of life, in trees, fruits, vegetables, fish, plants, animals and humans, and does not accumulate in the environment as readily biodegradable.</p> <p>As formaldehyde is an extremely versatile building block, it is used in a wide variety of applications in the construction, automotive and furniture industries. Because formaldehyde has excellent adhesive and binding properties, the majority of formaldehyde produced in the EU is made into resins which are then essential to produce for instance wood-based panels and particle boards which are used in construction and furniture making.</p> <p>Formaldehyde is a very well-known chemical, one of the very first that have been registered under REACH and benefitting from decades of extensive scientific research. It is already highly regulated and consumer and worker safety is ensured in the EU via CLH classifications, REACH restrictions and the implementation of a Binding Occupational Exposure Limit.</p> <p>In view of existing data, Formacare supports the reclassification proposal and particularly the differentiated, data-based classification of the acute toxicity as presented by the DS. Would regulators consider that scientific data warrants a different classification of formaldehyde than the one proposed by the DS, Formacare would support a scientific discussion involving all necessary experts from Industry and Authorities and under the umbrella of ECHA. To the best of our knowledge however, the available data does not warrant a different classification than as the one proposed by the dossier submitter.</p>

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<p>For clarification, Formacare noticed that the CLH dossier refers page 4-5 to a 25-55 % solution of formaldehyde in water with concentration of up to 7% w/w methanol. In the REACH dossier, the self-classification of formaldehyde considers a 30-60 % solution of formaldehyde in water with a concentration of up to 3% w/w methanol. We would therefore recommend to regulators to align the substance composition and proposals for classification in the CLH dossier with the current state of the REACH dossier, as to prevent possible confusion between the classification of formaldehyde and the classification of methanol, and also considering possible future changes to the classification of these two substances.</p> <p>Formacare remains at the disposal of authorities for further discussions and as appropriate, on the submitted information below regarding the hazard classes covered by the CLH dossier.</p> <p>ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment 50-00-0_Acut inh rat_ST_13I0310-06I017_2015-08-21.pdf</p>
<b>Dossier Submitter’s Response</b>
Thank you for the support. With regard to substance identification, please refer to our response to comment #1.
<b>RAC’s response</b>
Thank you. The Annex VI entry should cover all formaldehyde solutions on the market, including those with a methanol content above 3% or 7%. This is proposed to be covered by Note F.

**OTHER HAZARDS AND ENDPOINTS – Acute Toxicity**

Date	Country	Organisation	Type of Organisation	Comment number
08.10.2021	Germany	<confidential>	Company-Manufacturer	3
<b>Comment received</b>				
<p><b>Acute oral toxicity:</b> The formaldehyde REACH Consortium agrees with the data-based classification of formaldehyde for acute oral toxicity as category 4 (H302), as proposed by the Dossier Submitter.</p> <p><b>Acute dermal toxicity:</b> The formaldehyde REACH Consortium agrees with the proposed data-based classification for acute dermal toxicity as category 3 (H311), as proposed by the Dossier Submitter.</p> <p><b>Acute inhalation toxicity:</b> As existing studies on acute inhalation toxicity of formaldehyde were old, non-guideline and non-GLP and had various significant deficiencies, Formacare has sponsored a state - of- the -art, guideline and GLP compliant acute inhalation study in 2015, (Acute inhalation toxicity study in Wistar rats 4-hour vapor exposure (whole body), unpublished study, Project No.: 13I0310/06I017, 21 Aug. 2015) The formaldehyde REACH Consortium has access to this study and has included it in the REACH-Dossier. Under the study condition, the LC50 was &lt; 463 ppm (analytical concentration) in Wistar rats after 4- hours inhalation exposure to a vapor of Formaldehyde. This state-of-the-art study confirmed the results that the LC50 is clearly below 500 ppm and thus, classification with regard to acute inhalation toxicity (gases) as Category 2 (H330) is warranted. In the REACH-Dossier this more stringent classification is included as self-classification. In this respect, the current classification proposal for acute inhalation toxicity in the CLH dossier as category 2 (H330) would harmonise the existing self-</p>				

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<p>classification of industry and thus fully is supported by the REACH Consortium. The REACH Consortium also agrees with the proposed labelling as EUH071 ("corrosive to the respiratory tract"), as proposed by the Dossier Submitter.</p>
<p><b>Dossier Submitter's Response</b></p> <p>Thank you for the support. As the full text report of the newly submitted study had not been previously available to the DS, it was not included. However, as outlined in the CLH report, the summary data from the REACH dossier had been checked and no conflict was identified.</p>
<p><b>RAC's response</b></p> <p>Thank you, your support for the DS's proposal is noted. The new acute inhalation study (2015) has been included in the RAC assessment. RAC agrees with the proposed categories for acute oral and inhalation toxicity (cat. 4 and cat. 2 respectively) but proposes lower ATE values for reasons explained in the RAC opinion. As to acute dermal toxicity, RAC concludes that the existing classification should be removed because the available information on the key rabbit study is too limited and acute dermal toxicity testing is not required for substances classified as corrosive to the skin.</p>

Date	Country	Organisation	Type of Organisation	Comment number
07.10.2021	Belgium	Formacare (Cefic sector group)	Industry or trade association	4

<p><b>Comment received</b></p> <p>Acute oral toxicity: Formacare agrees with the data-based classification of formaldehyde for acute oral toxicity as category 4 (H302), as proposed by the Dossier Submitter.</p> <p>Acute dermal toxicity: Formacare agrees with the proposed data-based classification for acute dermal toxicity as category 3 (H311), as proposed by the Dossier Submitter.</p> <p>Acute inhalation toxicity: As existing studies on acute inhalation toxicity of formaldehyde were old, non-guideline and non-GLP and had various significant deficiencies, Formacare has sponsored a guideline and GLP compliant acute inhalation study in 2015 (see attached study report: BASF SE, Formaldehyde Acute inhalation toxicity study in Wistar rats 4-hour vapor exposure (whole body), unpublished study, Project No.: 13I0310/06I017, 21 Aug. 2015; Sponsor: Formacare)</p> <p>In short, under the current study condition, the LC50 was &lt; 463 ppm (analytical concentration) in Wistar rats after 4-hours inhalation exposure to a vapor of Formaldehyde.</p> <p>This study confirmed the results that the LC50 is clearly below 500 ppm and thus, classification with regard to acute inhalation toxicity (gases) as Category 2 (H330) is warranted. In its EU REACH dossier update in 2017, industry has already considered this more stringent classification as self-classification. This more stringent classification has also been considered in the safety data sheets accordingly since 2017. In this respect, the current classification proposal for acute inhalation toxicity in the CLH dossier as category 2 would harmonise the existing self-classification of industry and thus is supported by industry. Formacare also agrees with the proposed labelling as EUH071 ("corrosive to the</p>
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respiratory tract”), as proposed by the Dossier Submitter.
Would regulators consider that the available data related to Acute Toxicity warrants a different classification of formaldehyde than the one proposed by the DS, Formacare would support a scientific discussion involving all necessary experts from industry and Authorities and under the umbrella of ECHA. To the best of our knowledge however, the available data does not warrant a different classification than as the one proposed by the dossier submitter.
ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment 50-00-0_Acut inh rat_ST_13I0310-06I017_2015-08-21.pdf
<b>Dossier Submitter’s Response</b>
Thank you for the support. As the full text report of the newly submitted study had not been previously available to the DS, it was not included. However, as outlined in the CLH report, the summary data from the REACH dossier had been checked and no conflict was identified.
<b>RAC’s response</b>
Thank you, please see response to comment 3.

Date	Country	Organisation	Type of Organisation	Comment number
09.08.2021	Norway		Individual	5
<b>Comment received</b>				
The information provided shows currently the substance as Acute Tox 3, H301 (Toxic if swallowed), and the proposed change is Acute Tox 4, H302 (Harmful if swallowed), yet in both case, the substance is Acute Tox 3, H311 (Toxic in contact with skin). And new proposed is Acute Tox 2, H330 (Fatal if inhaled). So, with the proposed changes, the substance is fatal if inhaled, toxic in contact with skin, but harmful if swallowed. It is a bit difficult to comprehend a toxicity with skin contact, yet harmful when swallowed.				
<b>Dossier Submitter’s Response</b>				
Thank you for the support. The classification proposal was based on the data available and the criteria of the CLP Regulation. The DS is confident that the resulting classification reflects the legal requirements even if the higher potency on skin compared to the oral route may appear unusual. It can only be speculated that this difference may result from a higher capacity to “scavenge” the reactive formaldehyde molecule by the components of the gastro-intestinal tract including its mucosa.				
<b>RAC’s response</b>				
Thank you. In general, a higher potency after dermal exposure would indeed be unusual for systemic effects in the same species. The situation may however be different for local effects and in the presence of other variables (e.g. different species). Nevertheless, in this case RAC proposes to remove the acute dermal toxicity classification due to insufficient information on the key study and because acute dermal toxicity testing can be waived for substances classified as corrosive to the skin.				

**OTHER HAZARDS AND ENDPOINTS – Skin Sensitisation Hazard**

Date	Country	Organisation	Type of Organisation	Comment number
08.10.2021	Germany	<confidential>	Company-Manufacturer	6
<b>Comment received</b>				
Regarding skin sensitization, the REACH Consortium has already considered subcategory classification of Formaldehyde as Category 1A (H317) in its REACH dossier and				

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subsequently also in the material safety data sheets. In consequence, the REACH consortium agrees with the proposed official subcategory classification for skin sensitization.
<b>Dossier Submitter's Response</b>
Thank you for the support.
<b>RAC's response</b>
Thank you, RAC agrees with Skin Sens. 1A.

Date	Country	Organisation	Type of Organisation	Comment number
07.10.2021	Belgium	Formacare (Cefic sector group)	Industry or trade association	7
<b>Comment received</b>				
Regarding skin sensitization, industry has already considered subcategory classification of Formaldehyde as Category 1A (H317) in its EU REACH dossier update in 2017 and subsequently also in the material safety data sheets. In consequence, Formacare agrees with the proposed official subcategory classification for skin sensitization.				
Would regulators consider that the available data on Skin sensitization warrants a different classification of formaldehyde than the one proposed by the DS, Formacare would support a scientific discussion involving all necessary experts from industry and Authorities and under the umbrella of ECHA. To the best of our knowledge however, the available data does not warrant a different classification than as the one proposed by the dossier submitter.				
ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment 50-00-0_Acut inh rat_ST_13I0310-06I017_2015-08-21.pdf				
<b>Dossier Submitter's Response</b>				
Thank you for the support.				
<b>RAC's response</b>				
Thank you, RAC agrees with Skin Sens. 1A.				

**OTHER HAZARDS AND ENDPOINTS – Physical Hazards**

Date	Country	Organisation	Type of Organisation	Comment number
08.10.2021	Germany	<confidential>	Company-Manufacturer	8
<b>Comment received</b>				
The formaldehyde REACH Consortium agrees with the proposed classification as Flam. Gas 1B for formaldehyde gas as proposed by the Dossier Submitter because the criteria are formally fulfilled. However, the implications for formaldehyde solutions are not clear. The boundary composition in the REACH dossier considers a 30-60 % solution of formaldehyde in water with up to 3% w/w methanol.				
<b>Dossier Submitter's Response</b>				
The German CA would like to thank the Company for supporting our proposed classification as Flam. Gas 1B, H221 for formaldehyde gas. We agree that the implications on different classification of formaldehyde and for formaldehyde solutions are not clear. We would appreciate your proposal how to clarify the information on the composition for formaldehyde solutions.				
<b>RAC's response</b>				
The Annex VI entry in the scope of the current CLH proposal covers only aqueous solutions of formaldehyde. Flammability of aqueous solutions is addressed under the				

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hazard class of Flammable liquids. Flammability of formaldehyde gas is out of the scope of the current process.

Date	Country	Organisation	Type of Organisation	Comment number
07.10.2021	Belgium	Formacare (Cefic sector group)	Industry or trade association	9

**Comment received**

Formacare agrees with the proposed classification as Flam. Gas 1B as proposed by the Dossier Submitter because the criteria are formally fulfilled. However, Formaldehyde is placed on the market as a 30-60 % solution in water (see EU REACH Dossier) and Formaldehyde gas does not get packaged or transported. Thus, it has to be clarified what the implications of this classification of Formaldehyde gas on the marketed 30-60% solution in water are.

Would regulators consider that the available data related to Physical hazards warrants a different classification of formaldehyde than the one proposed by the DS, Formacare would support a scientific discussion involving all necessary experts from industry and Authorities and under the umbrella of ECHA. To the best of our knowledge however, the available data does not warrant a different classification than as the one proposed by the dossier submitter.

ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment 50-00-0\_Acut inh rat\_ST\_13I0310-06I017\_2015-08-21.pdf

**Dossier Submitter’s Response**

The German CA would like to thank Formacare (Cefic sector group) for supporting our proposed classification as Flam. Gas 1B, H221 for formaldehyde gas. We agree that the implications on different classification of formaldehyde and for formaldehyde solutions are not clear. We would appreciate your proposal how to clarify the information on the composition for formaldehyde solutions.

**RAC’s response**

Thank you, please see the response to comment 8.

Date	Country	Organisation	Type of Organisation	Comment number
06.10.2021	France		MemberState	10

**Comment received**

Self-reactive substance or mixture: According to CLP regulation, the substance is not subjected to classification if the heat of decomposition is below 300J/g. Results obtained according to DSC measurement are 350J/g at 220°C and 180J/g at 280°C. Additionally, it is concluded: “ However, because the decomposition temperature is above 200 °C, it can be assumed that their self-accelerating decomposition temperature (SADT) is greater than 75 °C for a 50 kg package. Therefore, the UN Test Series A to H for self-reactive substances and mixtures does not need to be conducted.” FR disagrees with this sentence. Results on a crucible with DSC cannot be extrapolated to a package of 50kg, meaning that a DSC measurement cannot be extrapolated to SADT test in such case. FR considers that this endpoint should be regarded as not conclusive in table 6.

Substance or mixture corrosive to metals : It should be clarified if results from DECHEMA Corrosion Handbook are in compliance with the method described in test C.1 of Manual UN RTDG (especially regarding the type of steel/aluminium, volume of solution used for the test, conditions tested i.e immersed/half immersed/vapour phase, ...). If this is not



<p>the case, the conclusion may be distorted due to possible deviations from test C.1. In this case, FR considers that this endpoint should be regarded as not conclusive in table 6.</p>
<p><b>Dossier Submitter's Response</b></p> <p>Self-reactive substance or mixture: Formaldehyde is a very well-known chemical and experience in production or handling shows that the aqueous formaldehyde solutions does not self-react. You need to check the stability of energetic materials before transporting and storing them. Here again, thermal analysis by DSC is a powerful technique since it allows a rapid screening with some milligrams of reaction mass. Using DSC measurement, a safety assessment is possible and the SADT can be estimated to be &gt;75 °C if the decomposition (Tonset) starts above 200 °C as this empirical rule for determination of a "safe" temperature is established as a common 200 °C rule. Otherwise, Formaldehyde solutions would not be assigned to UN number 2209 (Class 8) or UN 1198 (Class 3 + 8) in the Recommendations on the Transport of Dangerous Goods. Therefore, aqueous formaldehyde solutions are not considered to be self-reactive.</p> <p>Substance or mixture corrosive to metals : DECHEMA-Materials Data Sheets are a collection of all kind of resistance evaluations for various materials in certain media. Resistance evaluations usually base on standard test procedures like written in DIN 50905 and ASTM G-31 and, may be, other national standards, containing similar test set-up. Test set-up described in UN-Manual is according to these standards. The main crucial point is temperature, and occurrence of localized corrosion. So, if this is matched and perhaps results reported for higher temperatures suggest the same evaluation (i.e. relatively low corrosion rates), there is no reason not to use this "state of the art - knowledge", basing on scientific expertise, considering the properties of the product evaluated.</p> <p>As alternative, if, e.g. Formacare (Cefic sector group) or any other registrant have test results on metal corrosion, they are pleased to submit these studies for re-evaluation.</p>
<p><b>RAC's response</b></p> <p>Thank you for the comments. Self-reactive: Formaldehyde does not contain any groups associated with explosive or self-reactive properties, therefore no classification can be based on conclusive information. Corrosive to metals: There are indeed significant deficiencies (e.g. low temperature in the aluminium test, no information on localised corrosion, low level of detail), therefore RAC agrees that no classification is based on inconclusive data.</p>

**CONFIDENTIAL ATTACHMENTS**

1. 50-00-0\_Acut inh rat\_ST\_13I0310-06I017\_2015-08-21.pdf [Please refer to comment No. 2, 4, 7, 9]