

Committee for Risk Assessment
RAC

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

formic acid ... %

EC Number: 200-579-1
CAS Number: 64-18-6

CLH-O-0000007128-73-01/F

Adopted
2 June 2022

ANNEX 2 - COMMENTS AND RESPONSE TO COMMENTS ON CLH PROPOSAL ON FORMIC ACID ...%**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.

ECHA accepts no responsibility or liability for the content of this table.

Substance name: Formic acid ...%

EC number: 200-579-1

CAS number: 64-18-6

Dossier submitter: Belgium

GENERAL COMMENTS

Date	Country	Organisation	Type of Organisation	Comment number
22.10.2021	France		MemberState	1
Comment received				
Page 8 : PHYSICOCHEMICAL PROPERTIES Viscosity FR : no data on purity of tested material is presented. Please clarify the materiel tested.				
Dossier Submitter's Response				
The test is performed on FA 85%, which is obtained by diluting FA 99% (99.3% Formic acid, the rest being mainly water) with pure water.				
RAC's response				
Thank you, noted.				

Date	Country	Organisation	Type of Organisation	Comment number
22.10.2021	Germany	BASF SE	Company-Manufacturer	2
Comment received				
Dear Sir or Madam, BASF SE does not agree with the proposed harmonized classification and labeling. For detailed information on the open hazard classes, please see the comments below. Please find background information for the comments in the attached documents. Best regards, reach@basf.com				
ECHA note – An attachment was submitted with the comment above. Refer to public attachment Public attachments BASF SE.zip				
Dossier Submitter's Response				
The comments have been addressed in their specific section.				
RAC's response				
Your comments are addressed in the specific sections.				

ANNEX 2 - COMMENTS AND RESPONSE TO COMMENTS ON CLH PROPOSAL ON FORMIC ACID ...%

Date	Country	Organisation	Type of Organisation	Comment number
19.10.2021	Germany		MemberState	3
Comment received				
<p>We would like to point out that there is only an entry for "Formic acid ... %" but not for pure formic acid itself in Annex VI of the CLP regulation. Due to different classification of pure formic acid and formic acid in aqueous solution, it should be considered whether the division of this entry would have benefit.</p> <p>We do not agree with the dossier submitter on evaluating the specific concentration limits (SCL) for classification for formic acid in aqueous solution as flammable liquids and corrosive to metals.</p> <p>Section 2.1, Table 5: Classification and Labelling: As the substance is classified and labeled with regard to acute inhalation and oral toxicity, the ATE values specified in the CLH dossier should be included here, so that formic acid-containing mixtures with regard to the hazard class "acute toxicity" (oral and inhalative) can be correctly classified: inhalation: ATE = 7.4 mg/L (vapours) oral: ATE = 730 mg/kg bw</p> <p>ECHA note – An attachment was submitted with the comment above. Refer to public attachment ST-SG-AC10-C3-2004-12e.pdf</p>				
Dossier Submitter's Response				
<p>Thank you for your comment. The classification of the Formic acid 99% as Corrosive to Metal is a difficult question that we tried to solve in the best way possible. Our position was the following: Formic Acid 85% is without a doubt Corrosive to metal, and meet all criterion for this classification. The test performed on Formic Acid 99% was performed for only 7 days and shows no impact on aluminium and only a light impact on steel. However, this is only due to an artefact linked to the very high concentration of Formic acid, with barely any amount of water. This absence of water means an artificial decrease of the dissociation of Formic acid, thus leading to a decrease in activity. However, this does not reflect the danger posed by formic acid 99%, as this means that the slightest addition of water, voluntarily or accidentally, would lead to a strong increase in its corrosivity. This fact is even recognised by the applicant, as transport in most steel container of FA99% is not proposed. Without the classification, the danger represented by Formic Acid 99% is therefore not accurately represented.</p> <p>Regarding the classification as Flammable liquid 3 (H226), it is to be remarked that only Formic acid 99% meets the criteria, with a Flash point = 49.5 °C. For Formic Acid 85%, the results are conclusive but not enough to meet the criteria.</p> <p>Regarding your request to add ATE values to Section 2.1, Table 5, we have no objections but would prefer to first see the values confirmed by RAC.</p>				
RAC's response				
<p>Thank you, your comments on physical hazards are addressed in the respective section.</p> <p>Your support for the DS's proposals on acute toxicity is noted. For the oral route RAC prefers the converted ATE of 500 mg/kg bw due to the possibly higher human sensitivity.</p>				

OTHER HAZARDS AND ENDPOINTS – Acute Toxicity

Date	Country	Organisation	Type of Organisation	Comment number
26.08.2021	Germany		Individual	4
Comment received				
<p>Taking into account the longtivity of the healing process we encountered curing burns by formic acid of the skin (legs), we recommend to upgrade the seriousness of acid burns of larynx (fumes of formic acid c>90%) and esophagus to H330 /H300.</p> <p>Also the term "toxic" does not seem to fit the "skull"-pictogram which (except in chemical labeling) worldwide stands for "deadly danger". So i.e. "threatning death by inhalation" (H331) or "risk of death by inhalation" (H330) seems more to the point.</p>				
Dossier Submitter's Response				
<p>Thank you for your comment.</p> <p>The classification for acute toxicity is based primarily on the dose/concentration that causes mortality (the Acute Toxicity Estimate, ATE), expressed here as LC₅₀ for acute toxicity via inhalation and LD₅₀ for acute toxicity via the oral route.</p> <p>The Acute toxicity – inhalation category assigned to formic acid at present (cat 3) is in agreement with the LC₅₀ of 7.4 mg/L. The Acute toxicity – oral category assigned to formic acid at present (cat 4) is in agreement with the LD₅₀ of 730 mg/kg bw. Moreover, in the C&L proposal for formic acid the additional phrase EUH071 'corrosive to the respiratory tract' is included.</p> <p>According to the CLP regulation the skull pictogram with signal word 'danger' is obligatory for substances classified as acute tox inhalation cat. 3.</p> <p>Human data need careful expert evaluation to properly judge the reliability of the findings. It should be acknowledged that human data often do not provide sufficiently robust evidence on their own to support classification. In eCA BE's view, we have appropriately taken into account those human data for which reliable information was available to establish our CLH proposal.</p>				
RAC's response				
<p>Thank you. Skin corrosion is already addressed by the existing harmonised classification as Skin Corr. 1A. As explained by the DS, classification for acute toxicity has to be based on comparison of the data with the classification criteria and corrosivity to the respiratory tract will be highlighted by EUH071.</p>				

Date	Country	Organisation	Type of Organisation	Comment number
22.10.2021	Germany	BASF SE	Company-Manufacturer	5
Comment received				
<p>BASF SE does not agree with the LC50 value for acute inhalation toxicity presented in the CLH report for formic acid (CAS 64-18-6) version 2 from 29th July 2021. According to the applicants, the LC50 value for acute inhalation toxicity should be changed from 7.4 mg/L to 7.85 mg/L, based on re-analysis of the raw data performed in 2014. The applicants claim that in the context of the CLH report this was already submitted in 2016.</p> <p>BE as the dossier submitter cites the REACH registration dossier of formic acid as reference for the LC50 of 7.4 mg/L (cf. Table 12 on p. 17 of the CLH report). However, in the REACH registration dossier, as published on the ECHA website, the Amendment of the study report is already included and thus refers to the corrected LC50 of 7.85 mg/L.</p> <p>Therefore, BASF SE asks to correct the LC50 from 7.4 mg/L to 7.85 mg/L.</p>				

ANNEX 2 - COMMENTS AND RESPONSE TO COMMENTS ON CLH PROPOSAL ON FORMIC ACID ...%

<p>Please find background information for the comments in the attached documents.</p> <p>ECHA note – An attachment was submitted with the comment above. Refer to public attachment Public attachments BASF SE.zip</p>
<p>Dossier Submitter’s Response</p> <p>Thank you for your comment.</p> <p>The LC₅₀ value that was originally included in the REACH dossier was 7.4 mg/L. Indeed an update of the LC₅₀ value to 7.85 mg/L has been performed in the REACH registration dossier, based on the applicant’s re-analysis of the test report.</p> <p>However, eCA BE does not accept this re-analysis. A justification for non-acceptance is included as confidential annex. The information and argumentation provided by the applicant in eCA BE’s view does not suffice to justify using 7.85 mg/L as LC₅₀ value. We would be in favour of adhering to the 7.4 mg/L LC₅₀ value for acute inhalation toxicity.</p> <p>ECHA note – An attachment was submitted with the Dossier Submitter’s comment above. Refer to confidential attachment confANNEX to comments CLH – comment5.docx</p>
<p>RAC’s response</p> <p>Thank you. RAC has analysed the raw data and concluded, in agreement with the DS, that the proposed update is unjustified and should not be accepted. A detailed analysis can be found in the RAC opinion.</p>

Date	Country	Organisation	Type of Organisation	Comment number
26.08.2021	Denmark		MemberState	6
Comment received				
DK CA BPR: Agree with DS Acute Tox 4, H302 (ATE 730 mg/kg bw) and acute tox 3, H331 (ATE 7.4 mg/l)				
Dossier Submitter’s Response				
Thank you.				
RAC’s response				
Thank you, noted. For acute oral toxicity RAC prefers the converted ATE of 500 mg/kg bw due to the possibly higher human sensitivity.				

OTHER HAZARDS AND ENDPOINTS – Eye Hazard

Date	Country	Organisation	Type of Organisation	Comment number
26.08.2021	Denmark		MemberState	7
Comment received				
DK CA BPR: Agree with DS.				
Dossier Submitter’s Response				
Thank you.				
RAC’s response				
Thank you, noted.				

OTHER HAZARDS AND ENDPOINTS – Physical Hazards

Date	Country	Organisation	Type of Organisation	Comment number
22.10.2021	France		MemberState	8
Comment received				
<p>Part 8.5 page 9. Flammable liquids FR: CLP report makes reference to a confidential annex that is not accessible. FR assumes that it explains the composition of formic acid tested. The usual temperature reported for flash point of formic acid is 69-71°C. Please explain the reasoning why the value of 49.5°C was retained or submit the confidential annex that explains this choice.</p> <p>Part 8.1 page 9 Explosives : Hazard class not assessed in this dossier. FR: Please clarify why this hazard class was not assessed as some data should be available for the assessment of formic acid in the dossier for approval of this active substance under the EU regulation 528/2012.</p>				
Dossier Submitter's Response				
<p>Thank you for your comment. Regarding the classification as Flammable liquid 3 (H226), it is to be remarked that only Formic acid 99% meets the criteria, with a Flash point = 49.5 °C. For Formic Acid 85%, the results are conclusive but not enough to meet the criteria.</p>				
RAC's response				
<p>Thank you for your comments. The flash point depends on formic acid concentration, solutions above ca. 85% have a flash point below 60 °C.</p>				

Date	Country	Organisation	Type of Organisation	Comment number
22.10.2021	Germany	BASF SE	Company-Manufacturer	9
Comment received				
<p>In the current CLH document the substance formic acid is defined as "85-99% aqueous solution". In one aspect (corrosivity to metals) this definition brings about unclarity for the classification. If this definition is to be kept, BASF SE proposes a different classification:</p> <ul style="list-style-type: none"> - Formic acid concentration ≥ 85% and < 99%, in mixtures with water: corrosive to metals H290 - Formic acid concentration ≥ 99% with ≤1% water: not corrosive to metals, no classification <p>As correctly suggested by the author of the CLH report, the absence of corrosivity for 99.4% formic acid is due to the lack of water, where formic acid does not dissociate. 99.4% formic acid does not contain ions and protons and hence it is not corrosive.</p> <p>The corrosivity to metals appears to be concentration-dependent, albeit in an opposite manner as intuitively expected, but fully plausible from a chemical point of view. Therefore, we propose to have a classification based on the level of formic acid in mixtures with water, as suggested in the beginning of the present document.</p> <p>Please find background information for the comments in the attached documents.</p>				

ANNEX 2 - COMMENTS AND RESPONSE TO COMMENTS ON CLH PROPOSAL ON FORMIC ACID ...%

ECHA note – An attachment was submitted with the comment above. Refer to public attachment Public attachments BASF SE.zip
Dossier Submitter’s Response
<p>Thank you for your comment.</p> <p>Please take note that we do not agree to not classify Formic Acid >99% for H290 (Corrosivity to metal). The classification of the Formic acid 99% as Corrosive to Metal is a difficult question that we tried to solve in the best way possible. Our position was the following: Formic Acid 85% is without a doubt Corrosive to metal, and meet all criterion for this classification. The test performed on Formic Acid 99% was performed for only 7 days and shows no impact on aluminium and only a light impact on steel. However, this is only due to an artefact linked to the very high concentration of Formic acid, which barely any amount of water. This absence of water means an artificial decrease of the dissociation of Formic acid, thus leading to a decrease in activity. However, this does not reflect the danger posed by formic acid 99%, as this means that the slightest addition of water, voluntarily or accidentally, would lead to a strong increase in its corrosivity. This fact is even recognised by the applicant, as transport in most steel container of FA99% is not proposed. Without the classification, the danger represented by Formic Acid 99% is therefore not accurately represented.</p>
RAC’s response
<p>Thank you. RAC agrees with the DS that no classification at $\geq 99\%$ would not be appropriate as the corrosion hazard will appear on dilution. Further, RAC notes that no data has been submitted to substantiate a specific concentration limit of 85%</p>

Date	Country	Organisation	Type of Organisation	Comment number
19.10.2021	Germany		MemberState	10

Comment received
<p>Flammable liquids: The flash point of formic acid with a high purity of 99.48 % was experimentally determined according to the Standard DIN EN ISO 13736 (Abel closed-cup method) and measured to be 49.5 °C. Since no further determinations of the flash point of formic acid at lower concentrations have been determined to establish the specific concentration limit, the value $C \geq 99\%$ for the classification as Flam. Liq. 3, H226 is not valid. Taken into account that a binary mixture of formic acid and water with $C = 89.1$ weight% has a flash point of 60 °C (conf. CHEMSAFE) this underlines, that the SCL of $C \geq 99\%$ is not warranted. The CLP hazard class of Flammable liquids covers liquids of flash point ≤ 60 °C. Moreover, the aqueous solutions of formic acid are assigned to UN 1779 and UN 3412 according to the United Nations Recommendations on the Transport of Dangerous Goods, Model Regulations, and should be considered due to relation between transport and CLP classifications regarding physical hazards.</p> <p>Corrosive to metals: For the harmonised classification as “Met. Corr. 1, H290” a specific concentration limit of $C \geq 85\%$ is proposed by the dossier submitter. The evaluation for the specific concentration limit results on two studies performed on formic acid at $C = 85\%$ and at $C = 99.4\%$. However, formic acid with a high purity of 99.4 % does not meet the criteria for classification. A positive test result is obtained for formic acid at $C = 85\%$. Since no further corrosion rates on steel for formic acid at lower concentrations have been</p>

ANNEX 2 - COMMENTS AND RESPONSE TO COMMENTS ON CLH PROPOSAL ON FORMIC ACID ...%

determined to establish the specific concentration limit, the value $C \geq 85\%$ for the classification as Met. Corr. 1, H290 is not valid. In this matter, we would like to refer to document ST/SG/AC.10/C.3/2004/12 submitted to the ECOSOC Sub-Committee of Experts on the Transport of Dangerous Goods in 2004 for the correct classification of formic acid (see attached file).

In order to assess the corrosion hazard for an appropriate classification and to determine a value for a SCL further tests according to UN Test C.1 (UN-MTC, Part III, Section 37, paragraph 37.4) are required.

ECHA note – An attachment was submitted with the comment above. Refer to public attachment ST-SG-AC10-C3-2004-12e.pdf

Dossier Submitter's Response

Thank you for your comment. The classification of the Formic acid 99% as Corrosive to Metal is a difficult question that we tried to solve in the best way possible. Our position was the following: Formic Acid 85% is without a doubt Corrosive to metal, and meet all criterion for this classification. The test performed on Formic Acid 99% was performed for only 7 days and shows no impact on aluminium and only a light impact on steel.

However, this is only due to an artefact linked to the very high concentration of Formic acid, with barely any amount of water. This absence of water means an artificial decrease of the dissociation of Formic acid, thus leading to a decrease in activity.

However, this does not reflect the danger posed by formic acid 99%, as this means that the slightest addition of water, voluntarily or accidentally, would lead to a strong increase in its corrosivity. This fact is even recognised by the applicant, as transport in most steel container of FA99% is not proposed. Without the classification, the danger represented by Formic Acid 99% is therefore not accurately represented.

However, we agree with your remark regarding the specific concentration limit at 85%, and it should be removed indeed.

Regarding the classification as Flammable liquid 3 (H226), it is to be remarked that only Formic acid 99% meets the criteria, with a Flash point = 49.5 °C. For Formic Acid 85%, the results are conclusive but not enough to meet the criteria. It seems that this information is somehow missing, and we will correct this fact.

RAC's response

Thank you, your comments and the attached information are highly appreciated.

Flammable liquids: The concentration limit should be set at $> 85\%$ based on the submitted data on flash point and in line with the UN Model Regulations.

Corrosive to metals: RAC agrees there is no information that could be used for setting a specific concentration limit.

PUBLIC ATTACHMENTS

1. Public attachments BASF SE.zip [Please refer to comment No. 2, 5, 9]
2. ST-SG-AC10-C3-2004-12e.pdf [Please refer to comment No. 3, 10]

CONFIDENTIAL ATTACHMENTS

1. confANNEX to comments CLH – comment5.docx [Please refer to response to comment No. 5]