Biocidal Products Committee (BPC)

Opinion on the application for approval of the active substance:

Formic Acid

Product type: 4

EECHA/BPC/327/2022

Adopted

08 June 2022

Opinion of the Biocidal Products Committee

on the application for approval of the active substance Formic Acid for product type 4

In accordance with Article 89(1) of Regulation (EU) No 528/2012 of the European Parliament and of the Council 22 May 2012 concerning the making available on the market and use of biocidal products (BPR), the Biocidal Products Committee (BPC) has adopted this opinion on the approval in product type 4 of the following active substance:

Common name:	**Formic Acid**
Chemical name:	**Methanoic Acid**
EC No.:	**200-579-1**
CAS No.:	**64-18-6**

Existing active substance

This document presents the opinion adopted by the BPC, having regard to the conclusions of the evaluating Competent Authority. The assessment report, as a supporting document to the opinion, contains the detailed grounds for the opinion.

Process for the adoption of the BPC opinion

Formic acid was notified as an existing active substance by BASF SE and KEMIRA OYJ. In the period 2007 to 2009, the BE eCA received the dossier and numerous updates from the two applicants. Following redefinition, in September 2015 a new dossier for Formic Acid was submitted. The ED Expert Group was consulted in June 2019 and the ENV Working Group (WG-IV-19) in an Early-WG-discussion in the same year. The evaluating Competent Authority Belgium submitted an assessment report and the conclusions of its evaluation to the European Chemicals Agency (ECHA) on 15 September 2021.

In order to review the assessment report and the conclusions of the evaluating Competent Authority, the Agency organised consultations via its Working Group Meetings (WG-I 2022) and BPC (BPC-43). Revisions agreed upon were presented and the assessment report and the conclusions were amended accordingly.

Adoption of the BPC opinion

Rapporteur: Belgium

The BPC opinion on the application for approval of the active substance Formic Acid in product type 4 was adopted on 8 June 2022.

The BPC opinion was adopted by consensus.The opinion is published on the ECHA webpage at: http://echa.europa.eu/regulations/biocidal-products-regulation/approval-of-active-substances/bpc-opinions-on-active-substance-approval.

Detailed BPC opinion and background

1. Overall conclusion

The overall conclusion of the BPC is that the Formic Acid in product type 4 may be approved. The detailed grounds for the overall conclusion are described in the assessment report.

2. BPC Opinion

2.1. BPC Conclusions of the evaluation

a) Presentation of the active substance including the classification and labelling of the active substance

This evaluation covers the use of formic acid in product type 4. Specifications for the reference source are established.

The physico-chemical properties of the active substance and biocidal product have been evaluated and are deemed acceptable for the appropriate use, storage and transportation of the active substance and biocidal product.

Validated analytical methods are available for the active substance as manufactured and for the relevant and significant impurities.

Validated analytical methods are available for the relevant matrices (soil, water surface, drinking water, air, animal and human body fluids and tissues, food and feedstuffs).

A harmonised classification according to Regulation (EC) No 1272/2008 is available for formic acid. The current classification and labelling for formic acid according to Regulation (EC) No 1272/2008 (CLP Regulation) is:

Current Classification according to the CLP Regulation	
Hazard Class and Category Codes	Skin Corr. 1A; H314
Labelling	
Pictogram codes	GHS05
Signal Word	Danger
Hazard Statement Codes	H314
Specific Concentration limits, M-Factors	Skin Corr. 1B; H314: 10% ≤ C < 90% Skin Corr. 1A; H314: C ≥ 90% Skin Irrit. 2; H315: 2% ≤ C < 10% Eye Irrit. 2; H319: 2% ≤ C < 10%

The eCA submitted a CLH dossier in 2021. RAC agreed in June 2022 on the following classification and labelling for formic acid according to Regulation (EC) No 1272/2008:

Proposed Classification according to the CLP Regulation	
Hazard Class and Category Codes	Met. Corr. 1 ; H290 Flam. Liq. 3 ; H226 Acute tox. 4; H302 Acute tox. 3 ; H331 Skin corr. 1A, H314 Eye dam./irrit. 1, H318
Labelling	
Pictogram codes	GHS02 GHS05 GHS06
Signal Word	Danger
Hazard Statement Codes	H290 H226 H302 H331 H314EUH071
Specific Concentration limits, M-Factors	Flammable liquid 3 ; H226: C ≥ 85% Acute tox. 4; H302: ATE 500 mg/kg Acute tox. 3; H331: ATE 7.4 mg/L (vapours) Skin Corr. 1B; H314: 10% ≤ C < 90% Skin Corr. 1A; H314: C ≥ 90% Skin Irrit. 2; H315: 2% ≤ C < 10% Eye Irrit. 2; H319: 2% ≤ C < 10%

b) Intended use, target species and effectiveness

The active substance formic acid is intended to be used for PT4 applications as broadspectrum surface disinfectant against bacteria, yeasts and fungi for professional use.

The use includes surface/equipment disinfection via concentrated formulations to be diluted.

In the context of a decision on the approval of formic acid for PT4 applications, 2 intended uses are considered: surface disinfection via CIP (with circulation – totally enclosed procedure) or trigger spraying procedures using RTU products.

For the active substance formic acid, efficacy towards bacteria, yeasts and fungi has been demonstrated. The evaluated representative product has shown bactericidal and fungicidal/yeasticidal efficacy.

Formic acid has an acidulant action (dependent on low pH-value) and corrosion which causes enzyme denaturation and inhibition, cellular structure disruption, and impairment of cellular metabolic pathways. Due to this unspecific mode of action, the development of resistance towards formic acid has not been observed and is not expected.

c) Overall conclusion of the evaluation including need for risk management measures

Human health

The primary endpoint for formic acid is its corrosiveness. Formic acid is severely irritating and corrosive to the eyes, skin, and mucous membranes (gastrointestinal and respiratory tract) and may cause permanent damage. Due to the corrosivity of formic acid, local effects must be expected at all dose levels.

Corrosive intoxication might mediate systemic injury as metabolic acidosis, intravascular hemolysis, and renal failure.

Formic acid is not mutagenic, carcinogenic or a reproductive toxicant. There is no evidence that it is immunotoxic nor is it identified as endocrine disruptor for humans.

Due to the local irritating effect care should be taken that appropriate risk mitigation measures and personal protection are applied during use in order to avoid contact with skin and eye.

A second issue is the high vapour pressure of formic acid and the resulting inhalation of formic acid vapours. The conclusions presented below are drawn with the assumption that ventilation rates are sufficiently high.

The table below summarises the exposure scenarios assessed:

Summary table: human health scenarios			
Scenario	**Primary or secondary exposure and description of scenario**	**Exposed group**	**Conclusion**
RTU spraying – small surface disinfection	Primary exposure: applying a RTU trigger spray to small surfaces (food preparation areas) to be disinfected	Professionals	Acceptable with PPE for 2% and higher a.s. in-use-concentration (gloves, eye protection) RMM: ventilation

Summary table: human health scenarios			
Cleaning-in-place	Primary exposure: semi-automated mixing and loading; application; maintenance and repair; disposal of containers	Professionals	Acceptable with PPE (gloves, eye protection, coverall, boots) RMM: ventilation
Entry of treated area after RTU spraying – small surface disinfection	Secondary exposure: inhalation of vapours	Professional bystanders	Acceptable RMM: ventilation
Cleaning-in-place	Secondary exposure: inhalation of vapours	Professional bystanders	Acceptable with PPE (gloves, eye protection, coverall, boots) RMM: ventilation

The risk assessment performed for formic acid for the PT4 use covers professional cleaning-in-place (CIP), professional small surface disinfection by RTU trigger spraying, and indirect exposure resulting from the uses. Key factors in identifying safe uses are the corrosive nature of formic acid and its high vapour pressure.

Exposure for professional application by CIP was assessed as acceptable when sufficient ventilation is applied, and appropriate PPE are considered during mixing and loading and maintenance and repair. RPE are required when ventilation is insufficient. Professional bystanders are expected to use the same set of PPE as the professional user.

Exposure for professional application by small surface disinfection - RTU trigger spraying was assessed as acceptable when sufficient ventilation is applied; additionally, the use of appropriate PPE is required for 2% and higher a.s. in-use-concentration. Relevant bystander exposure is considered acceptable when sufficient ventilation is applied.

At product authorisation stage, secondary exposure of the general public (via the dermal, oral and inhalation route) as a result of professional use may have to be assessed according to the intended use; alternatively, the intended uses may have to be restricted by appropriate RMM.

Dietary exposure to formic acid from the representative uses is considered highly unlikely. At product authorisation, the need for an assessment of dietary exposure should be reviewed in relation to the inclusion of a rinsing step after application.

For formic acid currently default MRLs of 0.01 mg/kg apply according to Art.18(1)(b) Reg 396/2005.

Environment

Formic acid is the simplest carboxylic acid and is a natural compound occurring at significant concentrations in all environmental compartments. In aquatic compartment, formic acid and formats salts dissociate in formate anions which shows a low toxicity to fish, invertebrates and algaes. Formic acid and formate anion have not potential for bioaccumulation in both aquatic and terrestrial organism. The active substance is readily biodegradable, with a half-

life for biodegradation in soil of < 1 day. Formic acid is not identified as endocrine disruptor for non target organisms.

The table below summarises the exposure scenarios assessed:

Summary table: environment scenarios		
Scenario	**Description of scenario including environmental compartments**	**Conclusion**
Cleaning-in-place – professional use	The biocidal product is a formulated concentrate to be diluted to a use concentration of 50 g a.s./L (5% a.s.). Indirect releases occur via STP to the aquatic compartment (surface water and sediment) as well as due to sewage sludge application on agricultural soil to the terrestrial compartment (soil and groundwater).	Acceptable
Small surface disinfectant, RTU trigger spray – professional use	The biocidal product is a ready to use product containing 50 g a.s./L. An application rate of 18 mL of the diluted product per square meter is assumed. Indirect releases occur via STP to the aquatic compartment (surface water and sediment) as well as due to sewage sludge application on agricultural soil to the terrestrial compartment (soil and groundwater).	Acceptable

Cleaning-in-place:

No unacceptable risks for soil, groundwater, surface water, sediment and the STP were identified for the evaluated use.

Small surface disinfectant:

No unacceptable risks for soil, groundwater, surface water, sediment and the STP were identified for the evaluated use.

Overall conclusion

Exposure for professional application by CIP was assessed as acceptable when sufficient ventilation is applied, and appropriate PPE are considered during mixing and loading and maintenance and repair. RPE are required when ventilation is insufficient. Professional bystanders are expected to use the same set of PPE as the professional user.

Exposure for professional application by small surface disinfection - RTU trigger spraying was assessed as acceptable when sufficient ventilation is applied; additionally, the use of appropriate PPE is required for 2% and higher a.s. in-use-concentration. Relevant bystander exposure was also assessed as acceptable when sufficient ventilation is applied.

At product authorisation stage, secondary exposure of the general public as a result of professional use will have to be assessed; alternatively, the intended uses may have to be restricted by appropriate RMM.

About Cleaning-in-place procedures, no unacceptable risks for soil, groundwater, surface water, sediment and the STP were identified for the evaluated use.

About small surface disinfection, no unacceptable risks for soil, groundwater, surface water, sediment and the STP were identified for the evaluated use.

2.2. Exclusion, substitution and POP criteria

2.2.1. Exclusion and substitution criteria

The table below summarises the relevant information with respect to the assessment of exclusion and substitution criteria:

Property		Conclusions	
CMR properties	Carcinogenicity (C)	No classification required	Formic acid does not fulfil criterion (a), (b) and (c) of Article 5(1)
	Mutagenicity (M)	No classification required	
	Toxic for reproduction (R)	No classification required	
PBT and vPvB properties	Persistent (P) or very Persistent (vP)	Not P or vP	Formic acid does not fulfil criterion (e) of Article 5(1) and does not fulfil criterion (d) of Article 10(1)
	Bioaccumulative (B) or very Bioaccumulative (vB)	Not B or vB	
	Toxic (T)	Not T	
Endocrine disrupting properties	Section A of Regulation (EU) 2017/2100: ED properties with respect to humans	No	Formic acid does not fulfil Article 5(1)(e) and does not fulfil Article 10(1)(e)
	Section B of Regulation (EU) 2017/2100: ED properties with respect to non-target organisms	No	
	Article 57(f) and 59(1) of REACH	No	
	Intended mode of action that consists of controlling target organisms via their endocrine system(s).	No	
Respiratory sensitisation properties	No classification required. Formic acid does not fulfil criterion (b) of Article 10(1)		
Concerns linked to critical effects other than those related to endocrine disrupting properties	Formic acid does not fulfil criterion (e) of Article 10(1).		
Proportion of non-active isomers or impurities	Formic acid does not fulfil criterion (f) of Article 10(1).		

Consequently, the following is concluded:

Formic acid does not meet the exclusion criteria laid down in Article 5 of Regulation (EU) No 528/2012.

Formic acid does not meet the conditions laid down in Article 10 of Regulation (EU) No 528/2012, and is therefore not considered as a candidate for substitution.

The exclusion and substitution criteria were assessed in line with the "Note on the principles for taking decisions on the approval of active substances under the BPR"[1], "Further guidance on the application of the substitution criteria set out under Article 10(1) of the BPR"[2] and "Implementation of scientific criteria to determine the endocrine –disrupting properties of active substances currently under assessment[3]" agreed at the 54th, 58th and 77th meeting respectively, of the representatives of Member States Competent Authorities for the implementation of Regulation 528/2012 concerning the making available on the market and use of biocidal products. This implies that the assessment of the exclusion criteria is based on Article 5(1) and the assessment of substitution criteria is based on Article 10(1)(a, b, d, e and f).

For the endocrine-disrupting properties as defined in Regulation (EU) No 2017/2100, properties of formic acid have been sufficiently investigated and based on the available evidence, the substance does not meet the ED criteria for human health and the environment according to the criteria laid down in Regulation (EU) No 2017/2100.

2.2.2. POP criteria

Formic acid does not meet the PBT criteria and does not fulfil criteria for being a persistent organic pollutant (POP).

2.3. BPC opinion on the application for approval of the active substance Formic acid in product type 4

In view of the conclusions of the evaluation, it is proposed that formic acid shall be approved and be included in the Union list of approved active substances, subject to the following specific conditions:

1. Specification: minimum purity of the active substance evaluated: Min. 99% w/w

2. The authorisations of biocidal products are subject to the following condition(s):

    a. The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any uses covered by an application for authorisation, but not addressed in the Union level risk assessment of the active substance.

[1] See document: Note on the principles for taking decisions on the approval of active substances under the BPR (available from https://circabc.europa.eu/d/a/workspace/SpacesStore/c41b4ad4-356c-4852-9512-62e72cc919df/CA-March14-Doc.4.1%20-%20Final%20-%20Principles%20for%20substance%20approval.doc)
[2] See document: Further guidance on the application of the substitution criteria set out under article 10(1) of the BPR (available from https://circabc.europa.eu/d/a/workspace/SpacesStore/dbac71e3-cd70-4ed7-bd40-fc1cb92cfe1c/CA-Nov14-Doc.4.4%20-%20Final%20-%20Further%20guidance%20on%20Art10(1).doc)
[3] See document: Implementation of scientific criteria to determine the endocrine –disrupting properties of active substances currently under assessment (https://circabc.europa.eu/sd/a/48320db7-fc33-4a91-beec-3d93044190cc/CA-March18-Doc.7.3a-final-%20EDs-%20active%20substances%20under%20assessment.docx).

b. In view of the risks identified for the uses assessed, the product assessment shall pay particular attention to:

   i. Professionals.

c. For products that may lead to residues in food or feed, the need to set new or to amend existing maximum residue levels (MRLs) in accordance with Regulation (EC) No 470/2009 of the European Parliament and of the Council or Regulation (EC) No 396/2005 of the European Parliament and of the Council shall be verified, and any appropriate risk mitigation measures shall be taken to ensure that the applicable MRLs are not exceeded.

Formic acid meets the criteria for classification according to Regulation (EC) 1272/2008 as skin corrosive of category 1A and eye damage of category 1. The active substance does not fulfil the criteria according to Article 28(2)(a) to enable inclusion in Annex I of Regulation (EU) 528/2012.

2.4. Elements to be taken into account when authorising products

The following recommendations and risk mitigation measures have been identified for the uses assessed. Authorities should consider these risk mitigation measures when authorising products, together with possible other risk mitigation measures, and decide whether these measures are applicable for the concerned product:

a. If an unacceptable risk is identified for professional users, safe operational procedures and appropriate organizational measures shall be established. Products shall be used with appropriate personal protective equipment where exposure cannot be reduced to an acceptable level by other means.

b. If an unacceptable risk is identified for the general public, indirect exposure should be avoided by implementation of appropriate risk mitigation measures. If the risk cannot be reduced to an acceptable level by appropriate risk mitigation measures or by other means, these uses should not be authorised.

c. An assessment of the risk in food and feed areas may be required at product authorisation where use of the product may lead to contamination of food and feeding stuffs.

2.5. Requirement for further information

Sufficient data have been provided to verify the conclusions on the active substance, permitting the proposal for the approval of formic acid.

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