Biocidal Products Committee (BPC)

Opinion on the application for approval of the active substance:

Formic Acid

Product type: 2

ECHA/BPC/325/2022

Adopted

08 June 2022

Opinion of the Biocidal Products Committee

on the application for approval of the active substance Formic Acid for product type 2

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 2 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 2019) 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 2 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 2 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 PT 2. 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 H314 EUH071
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 PT2 applications as broad spectrum sanitary surface disinfectant against bacteria, yeasts and fungi for both professional and private use. Private use includes general surface disinfection with RTU formulation and professional/industrial use includes dilution of a concentrated formulation.

In the context of a decision on the approval of formic acid for PT2 applications, three

intended uses have been considered for evaluation: CIP procedures (with circulation – totally enclosed procedure), toilet bowl disinfection by pouring with brushing and general surface disinfection by pouring with wiping.

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.

The high vapour pressure of formic acid implies the need for refinements such as improved assessment factors for ventilation, the use of air measurements and identification of acceptable risk mitigation measures per type of application.

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**
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: sufficient ventilation
Cleaning-in-place	Secondary exposure: inhalation of vapours	Professional bystanders	Acceptable with PPE (gloves, eye protection, coverall, boots) RMM: sufficient ventilation
Wiping	Primary exposure: manual use of RTU cleaning liquid on bathroom surfaces: shower box disinfection	Non-professionals	Not acceptable
Pouring, brushing	Primary exposure: toilet disinfection: pouring a RTU liquid, brushing the bowl and flushing the toilet	Non-professionals	Not acceptable
Entry of treated area	Secondary exposure: inhalation of vapours	General public (adults & children)	Not acceptable At product authorisation level: to be assessed whether refinement can be achieved based on final formulation, use pattern, in air AS measurements, calculation of safe re-entry time and RMM on rinsing surfaces, ventilation and re-entry when surfaces are dry

The risk assessment performed for formic acid, PT2, covers professional cleaning-in-place (CIP), non-professional bathroom disinfection (shower box disinfection, toilet disinfection) and secondary exposure due to entry of treated areas.

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. CIP disinfection in PT2 is suggested to occur mainly in cleanrooms i.e. for pharmaceuticals or cosmetics.

Exposure of non-professionals was assessed using scenarios for RTU wiping (shower box disinfection) and toilet disinfection; relevant bystander exposure was also assessed.

For toilet disinfection, a safe use could not be established with the current set of parameters and in the absence of any RMM.

For RTU wiping (shower box disinfection), a safe use could not be established with the current set of parameters and in the absence of any RMM.

For secondary inhalation exposure from the above non-professional applications no safe use can be identified for bystanders.

Both representative uses are based on dummy product formulations. Options for refinement (such as final formulation, use pattern, in-air formic acid concentration measurements, allocation of RMM to ensure the safe use for the non-professional user and general public) are limited at this stage. At product authorization level, the possibility to achieve acceptable uses should be assessed based on the actual product under evaluation, its use pattern and - if required for the risk assessment- actual measurements.

The high vapour pressure of formic acid and the resulting inhalation of formic acid vapours causes concern, which should be dealt with at product authorization level. Possible refinements that can be suggested involve final formulation, use pattern, in-air formic acid concentration measurements, and allocation of appropriate RMM to ensure the safe use for the non-professional user and the general public.

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**
Domestic sanitary disinfectant (bathroom and toilet cleaner) – general public	The biocidal product is a ready to use product containing 50 g a.s./L. A consumption of 7 mL/(cap*d) 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 – professional use	The biocidal product is a formulated concentrate of 85% a.s. which is diluted to 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

No unacceptable risks for soil, surface water, sediment and the STP were identified for the evaluated uses. The risk for the groundwater compartment is acceptable after refinement using FOCUS PEARL.

Overall conclusion

Formic acid is intended to be used in formulation for PT2 applications as broad-spectrum surface disinfectants. In the context of a decision on the approval of formic acid for PT2 applications, three intended uses have been considered for evaluation: CIP procedures (with circulation – totally enclosed procedure), toilet bowl disinfection by pouring and general surface disinfection by pouring with wiping. Sufficient efficacy has been demonstrated.

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 of non-professionals using RTU wiping (shower box disinfection) & performing toilet bowl disinfection was assessed as not acceptable with the current set of parameters and in the absence of any RMM. No safe use can be identified for bystanders of these non-professional applications as refinement options are limited for representative dummy products.

The high vapour pressure of formic acid and the resulting inhalation of formic acid vapours causes concern, which should be dealt with at product authorization level.

No unacceptable risks for soil, surface water, sediment and the STP were identified for the evaluated uses. The risk for the groundwater compartment is acceptable after refinement using FOCUS PEARL.

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	No	Formic acid does not meet the endocrine

Property		Conclusions	
	to humans		disruptor criteria for both human health and non-target organisms. Formic acid does neither fulfil Article 5(1)(e) nor 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. Forminc 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.

[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).

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 2

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.
    b. In view of the risks identified for the uses assessed, the product assessment shall pay particular attention to:
        i. professionals;
        ii. non-professional users;
        iii. secondary exposure of the general public and children.

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 industrial and/or 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. Unacceptable risks for non-professional ready-to-use wiping (shower box disinfection) and toilet disinfection are identified. If the risks cannot be reduced to an acceptable level by appropriate risk mitigation measures or by other means, these uses should not be authorised.

c. Unacceptable risks for bystanders of non-professional ready-to-use wiping (shower box disinfection) and toilet disinfection are identified. If the risks cannot be reduced to an acceptable level by appropriate risk mitigation measures or by other means, these uses should not be authorised.

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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