Biocidal Products Committee (BPC)

Opinion on the application for approval of the active substance:

Citric acid

Product type: 2

ECHA/BPC/088/2016

Adopted

16 February 2016

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Opinion of the Biocidal Products Committee

on the application for approval of the active substance

citric 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:	**citric acid**
Chemical name(s):	**2-hydroxy-1,2,3-propanetricarboxylic acid**
EC No.:	**201-069-1**
CAS No.:	**77-92-9**

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 BPC opinions

Following the submission of an application by Kimberly-Clark Europe Ltd on 28 February 2006, the evaluating Competent Authority Belgium submitted an assessment report and the conclusions of its evaluation to the Commission on 23 August 2013. In order to review the assessment report and the conclusions of the evaluating Competent Authority, the Agency organised consultations via the BPC and its Working Groups (WG IV 2014). 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 approval of the active substance citric acid in product type 2 was adopted on 16 February 2016.

The BPC opinion was adopted by consensus.

Detailed BPC opinion and background

1. Overall conclusion

The overall conclusion of the BPC is that citric 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 citric acid in product type 2. The efficacy of acidic disinfectants, such as citric acid, is linked to the concentration of hydrogen (H^+) and hydroxyl (OH^-) ions, and function by destroying the bonds of nucleic acids and precipitating proteins. With regard to viral particles the acids will first destroy or disrupt the capsid proteins and then destroy the nucleic acids in the capsid.

The minimum purity of the active substance is > 99.5% (w/w). There are no significant or relevant additives or impurities. Specifications for the reference source are established.

Citric acid was initially notified as an existing active substance in product-type 1. After the Working Group on Efficacy meeting in September 2014, two issues were raised: whether an anti-viral tissue placed on the market with the claim 'kills 99,9 % of cold & flu viruses in the tissue' is a biocidal product or a treated article and, if considered a biocidal product, whether it would belong to product-type 1 (human hygiene) or 2 (disinfectants and algaecides not intended for direct application to humans or animals). A request to the Commission in accordance with Article 3(3) of the BPR was submitted by the Competent Authority (BE) to obtain a legally binding opinion on both issues. After a discussion at the 60th CA meeting on 21 May 2015, the Commission adopted the decision, that "an anti-viral tissue impregnated with citric acid and placed on the market with the claim "kills 99.9% of cold & flu viruses in the tissue" shall be considered as a biocidal product in accordance with Article 3(1)(a) of Regulation (EU) No 528/2012 and shall fall within product-type 2 as defined in Annex V to that Regulation" (Article 1 of Decision No 2015/1985[1])".

Citric acid is a well-known intermediate in carbohydrate metabolism (Krebs cycle). Citric acid occurs naturally in plant and animal tissues and fluids. Citric acid also occurs naturally in many food-stuffs and is often used as a food additive (E330). Citric acid is used in a wide range of topical medicines and cosmetics.

The physico-chemical properties of citric acid and the 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.

No harmonised classification is available for citric acid. A CLH dossier will be submitted for this active substance to ECHA by the evaluating Competent Authority. The proposed classification and labelling by the evaluating Competent Authority of the active substance citric acid based on the CLP Regulation is shown below.

[1] Commission Implementing Decision (EU) 2015/1985 of 4 November 2015 pursuant to Article 3(3) of Regulation (EU) No 528/2012 of the European Parliament and of the Council on an anti-viral tissue impregnated with citric acid.

Proposed classification according to the CLP Regulation	
Hazard Class and Category Codes	Skin Irrit.2 : H315 Eye Irrit.2 : H319
Labelling	
Pictograms	GHS07
Signal Word	Warning
Hazard Statement Codes	H315 (Causes skin irritation) H319 (Causes serious eye irritation)

b) Intended use, target species and effectiveness

In the context of a decision on the approval of citric acid for product-type 2, the only intended use claimed and evaluated, is the use of impregnated facial tissues.

The tissue is a 3-ply tissue of which the middle layer is impregnated with citric acid (7.5%). Citric acid is irreversibly bound into the tissue's matrix and would remain in the product throughout its lifecycle. Citric acid is intended to inactivate the viral load within the tissue after it has been used (i.e. when moisture after sneezing, coughing or blowing of the nose into the tissue hits the middle layer) in order to prevent transfer back to the hands, transmittance of the virus from hand to hand contact and transmittance to surfaces with which the tissue comes into contact.

The efficacy studies performed are sufficient at the approval stage. No efficacy tests were performed on citric acid alone or on the product used to impregnate the tissue. Efficacy tests have been performed with tissues treated with citric acid and show that citric acid is active against influenza viruses (A and B) and Respiratory Syncytial Virus (RSV) within 15 minutes. As the purpose of these treated tissues is to prevent transmittance of viruses from hand to hand or surface, 15 minutes is an unrealistic contact time. At the product authorization stage, efficacy tests with shorter contact times are required. Furthermore, at the product authorization stage, the efficacy tests need to be performed according to relevant EN standards on the product used to impregnate the tissues.

Citric acid is naturally present in almost all forms of life and it seems to be very unlikely that organisms can develop resistance to citric acid. Therefore, the development of a resistance management strategy is not required.

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

Human health

There is no evidence of genotoxic, carcinogenic, embryotoxic or teratogenic, neurotoxic potential of citric acid. The active substance is considered not to be a sensitiser.

The available data on citric acid indicate that it should be classified as a skin and eye irritant.

Based on the agreement reached after the discussion at the Human Health WG - Ad hoc follow-up on citric acid, the MRDT value of 100 mg/kg bw/d as a reference value is taken in order to perform the risk characterization for citric acid. Indeed, this quantity is added to the background level exposure from the diet, without inducing adverse effect and seems to be relevant in this case. Furthermore, there appears to be good correlation between this MRTD and the lowest dietary limit set by EFSA for inclusion into fruit and vegetable juices of 100 mg/kg bw/day, considering the limiting factor of irritation in the gastro-intestinal tract. A value for ADI has not been determined for this active substance as its toxicity is considered to be negligible.

Local effects are predominant for citric acid and systemic effects appear to be secondary toxicity. The biocidal product is not classified for local effects and no direct exposure to the active substance is foreseen, therefore a LRA is not necessary.

The table below summarises the exposure scenarios assessed for systemic effects.

Summary table: human health scenarios			
Scenario	**Primary or secondary exposure and description of scenario**	**Exposed group**	**Conclusion**
Application	Use of the tissues Dermal and oral primary exposure for adult, child, toddler and infant Acute scenario : 15 tissues /day Chronic scenario : 4 tissues / every day of the year Disposal of tissues: secondary exposure Negligible in comparison to exposure to citric acid from other sources, such as food.	General public	Acceptable

No unacceptable risks were identified for the general public for primary as well as secondary exposure.

Environment

The table below summarises the exposure scenarios assessed.

Summary table: environment scenarios		
Scenario	**Description of scenario including environmental compartments**	**Conclusion**
ESD Human Hygiene Biocidal Product (PT1) using the tonnage approach	Wastewater emission to STP. Emission to surface water through STP effluent. Emission to soil and groundwater through sewage sludge application.	Acceptable

There will be minimal release of the active substance from the use of the biocidal product to the environment. In general the tissue will be disposed of as domestic waste. The active substance is readily biodegradable and is naturally occurring in the environment, therefore additional concentrations of citric acid from this source will be negligible compared to the background concentration. Tissues sent to landfill will degrade rapidly prior to any potential release via leaching from the landfill site to soil and groundwater.

The active substance naturally occurs in all organisms and there is a mechanism for elimination of the substance via the Kreb's cycle. There is therefore no concern for bioaccumulation.

It is concluded that the use of citric acid in anti-viral facial tissues does not pose an unacceptable risk to the environment.

Overall conclusion

The use of citric acid in anti-viral facial tissues does not pose an unacceptable risk to the human health or to the environment.

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:

<table>
<tr><th colspan="2">Property</th><th colspan="2">Conclusions</th></tr>
<tr><td rowspan="3">CMR properties</td><td>Carcinogenicity (C)</td><td>No classification required.</td><td rowspan="3">Citric acid does not fulfil criterion (a), (b) or (c) of Article 5(1)</td></tr>
<tr><td>Mutagenicity (M)</td><td>No classification required.</td></tr>
<tr><td>Toxic for reproduction (R)</td><td>No classification required.</td></tr>
<tr><td rowspan="3">PBT and vPvB properties</td><td>Persistent (P) or very Persistent (vP)</td><td>Not P nor vP</td><td rowspan="3">Citric acid does not fulfil criterion (e) of Article 5(1) and criterion (d) of Article 10(1)</td></tr>
<tr><td>Bioaccumulative (B) or very Bioaccumulative (vB)</td><td>Not B nor vB</td></tr>
<tr><td>Toxic (T)</td><td>Not T</td></tr>
<tr><td>Endocrine disrupting properties</td><td colspan="3">Citric Acid is not considered to have endocrine disrupting properties. Citric acid does not fulfil criterion (d) of Article 5(1).</td></tr>
<tr><td>Respiratory sensitisation properties</td><td colspan="3">No classification required. Citric acid does not fulfil criterion (b) of Article 10(1).</td></tr>
<tr><td>Concerns linked to critical effects</td><td colspan="3">Citric acid does not fulfil criterion (e) of Article 10(1).</td></tr>
<tr><td>Proportion of non-active isomers or impurities</td><td colspan="3">The purity of citric acid is > 99.5%: no impurities are above the concentration limit of 1 g/kg. Citric acid does not fulfil criterion (f) of Article 10(1).</td></tr>
</table>

Consequently, the following is concluded:

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

Citric 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"[2] and in line with "Further guidance on the application of the substitution criteria set out under article 10(1) of the BPR"[3] agreed at the 54th and 58th 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).

2.2.2. POP criteria

Citric acid has not been identified as T and is not considered to be P nor B. Citric acid shows a half-life of 2.3 days in air and a vapour pressure well below the cut-off value of 1000 Pa. Thus, citric acid does not show a potential for long-range transport. Given the above, citric acid does not meet the criteria for being a persistent organic pollutant (POP).

2.3. BPC opinion on the application for approval of the active substance Citric Acid in product type 2

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

1. The active substance, as manufactured, shall have a minimum purity of 995 g/kg.

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

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

Since citric acid does not meet any of the criteria listed in Article 28(2) it does not give rise to concern as defined in this article. Therefore citric acid can be included in Annex I of Regulation (EU) No 528/2012.

2.4. Elements to be taken into account when authorising products

No specific element has been identified.

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 citric acid.

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[2] 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)
3 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)