

Biocidal Products Committee (BPC)

Opinion on the Union authorisation of the biocidal product family:

HCl Disinfecting Toilet Bowl Cleaner

ECHA/BPC/370/2022

Adopted

24 November 2022

Opinion of the Biocidal Products Committee

on the Union authorisation of biocidal product family HCl Disinfecting Toilet Bowl Cleaner

In accordance with Article 44(3) 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, the Biocidal Products Committee (BPC) has adopted this opinion on the Union authorisation of:

Name of the biocidal product family:	HCl Disinfecting Toilet Bowl Cleaner
Authorisation holder:	SC Johnson Europe Sàrl
Active substance common name:	Hydrochloric acid (CAS No: not applicable)
Product types:	PT 2

This document presents the opinion adopted by the BPC, having regard to the conclusions of the evaluating Competent Authority (eCA).

Process for the adoption of BPC opinions

Following the submission of an application on 2 May 2018, recorded in R4BP3 under case number BC-LA039435-53, the evaluating Competent Authority submitted a draft product assessment report (PAR) containing the conclusions of its evaluation and the draft Summary of Product Characteristics (SPC) to ECHA on 25 May 2022. In order to review the draft PAR, the conclusions of the eCA and the draft SPC, the Agency organised consultations via the BPC (BPC-45) and its Working Groups (WG-III-2022). Revisions agreed upon were presented and the draft PAR and the draft SPC were finalised accordingly.

Adoption of the BPC opinion

Rapporteur: Netherlands

The BPC opinion on the Union authorisation of the biocidal product family HCl Disinfecting Toilet Bowl Cleaner was reached on 24 November 2022.

The BPC opinion was adopted by consensus.

The opinion is published on the ECHA website.

Detailed BPC opinion and background

1. Overall conclusion

The biocidal product family is eligible for Union authorisation in accordance with Article 42(1) of Regulation (EU) No 528/2012 and falls within the scope of the Regulation (EU) No 528/2012 as defined in Article 3(1)(s).

The biocidal product family meets the conditions laid down in Article 19(6) of Regulation (EU) No 528/2012 and therefore may be authorised. The detailed grounds for the overall conclusion are described in the PAR.

The BPC agreed on the draft SPC of HCl Disinfecting Toilet Bowl Cleaner referred to in Article 22(2) of Regulation (EU) No 528/2012.

2. BPC Opinion

2.1 BPC Conclusions of the evaluation

a) Summary of the evaluation and conclusions of the risk assessment

General

The sections below are a concise summary of the evaluation and conclusions of the assessment of the biocidal product family.

HCl Disinfecting Toilet Bowl Cleaner is a disinfectant (bactericide) for indoor use. The product is to be used for disinfection of toilet bowls above the water line by general public (non-professionals).

The biocidal product family consists of one meta-SPC with two products that contain 6% HCl and only differ in perfume (*Marine* and *Citrus*). They share the same composition except for the fragrance. The products have the same active substance concentration (6% hydrochloric acid or HCl) as the representative product evaluated for the first approval of HCl. The risk assessment included in the first approval could therefore be partly used for of HCl Disinfecting Toilet Bowl Cleaner.

Two substances of concern (2,2'-(octadec-9-enylimino) bisethanol and Alcohols, C13-15-branched and linear, ethoxylated EO=8) have been identified due to human health concerns. The first substance is also identified as a substance of concern for environmental concerns.

PT	Authorised uses	Concerned meta SPC	Products
2	Bactericide - disinfection of toilet bowl above the water line – non-professionals	'100% Limescale'	'100% Limescale Marine' '100% Limescale Citrus'

Physico-chemical properties

The formulation type of the Disinfecting Toilet Bowl Cleaner biocidal product family is any other liquid (AL).

The supported shelf-life of all products is 4 years in HDPE.

The amount of the active substance was determined with validated NaOH titration.

The products of this biocidal product family are classified as possibly corrosive to metals (H290). The products are not classified for any other physical hazards.

Efficacy

The use "disinfection of toilet bowl above the water line" has been assessed. Efficacy against bacteria has been tested in phase 2 step 1 and phase 2 step 2 tests according to the international guidelines EN1276 and EN13697. These tests demonstrated sufficient efficacy according to the requirements for PT2 disinfection of non-porous surfaces according to the ECHA Guidance BPR Volume II Part B+C.

Human Health

The products of the Disinfecting Toilet Bowl Cleaner biocidal product family contain hydrochloric acid (HCl) as active substance. The products are classified with Skin corr. 1B (H314) and Eye Dam. 1 (H318). The level of inhalation exposure for the active substance is 47.7% (realistic use, 60 ml) and 85.3% (worst case, whole bottle) of the derived inhalation AEC of 3.75 mg/m³. The packaging is designed to minimise consumer exposure. The product has a swan neck with a nozzle that targets the product accurately when squeezed under the rim of the toilet.

In addition, the exposure during use is expected to be negligible through the use of the following risk mitigation measures:

- Avoid contact with skin and eyes;
- Apply only into the rim of the toilet to avoid skin contact;
- Avoid splashing;
- Wash hands thoroughly after handling;
- Do not breath vapour;
- Keep out of reach of children and non-target animals/pets;

Therefore, the risk to human health is acceptable for non-professionals.

Two substances of concern (2,2'-(octadec-9-enylimino) bisethanol and Alcohols, C13-15-branched and linear, ethoxylated EO=8) have been identified in this formulation due to their addition to the classification. The substances of concern identified have also been assessed and exposure is considered acceptable for non-professional users.

The risk assessment conducted for the products show that the exposure to the active substance and substances of concern are safe for human health for non-professional use.

Environment

The products of the Disinfecting Toilet Bowl Cleaner biocidal product family match the uses, % of active, dilution and product type that were already assessed in the first approval for hydrochloric acid. Hence, a qualitative risk assessment for the active substance was performed. Although the active substance is not classified as hazardous to the environment,

the product is nevertheless classified as H412 (harmful to the aquatic environment with long lasting effects) due to the presence and concentration of the co-formulant 2,2'-(octadec-9-enylimino) bisethanol. This substance was therefore assigned as a substance of concern and quantitatively assessed.

It can be concluded that risks to environmental compartments (surface water, air, and soil) are acceptable for hydrochloric acid and the substance of concern. The acceptable risk was determined by taking into account the fact that hydrochloric acid dissociates completely in water and that it has no bioaccumulation potential in organisms. The PNECs for the substance of concern were not exceeded in any of the exposed compartments.

Therefore, use of the products of the Disinfecting Toilet Bowl Cleaner biocidal product family with hydrochloric acid for toilet disinfection can be considered as safe for the environment.

The use of the products of the Disinfecting Toilet Bowl Cleaner biocidal product family with hydrochloric acid for toilet disinfection has been proven to be effective against bacteria are acceptable for non-professional use and can be considered as safe for the environment.

b) Presentation of the biocidal product family including classification and labelling

The description of the biocidal product and of the structure of the family is available in the SPC.

The hazard and precautionary statements of the biocidal product family according to the Regulation (EC) 1272/2008 is available in the SPC.

c) Description of uses proposed to be authorised

The uses claimed in the application and their assessment are described in the PAR. The description of the uses proposed to be authorised are available in the SPC.

d) Comparative assessment

The active substance hydrochloric acid contained in the biocidal product family does not meet the conditions laid down in Article 10(1) of Regulation (EU) No 528/2012 and is not considered a candidate for substitution. Therefore, a comparative assessment of the biocidal product family was not needed.

e) Overall conclusion of the evaluation of the uses proposed to be authorised

The physico-chemical properties, the safety for human and animal health and for the environment and the efficacy of the intended use of the biocidal product family have been evaluated.

The chemical identity, quantity and technical equivalence requirements for the active substance(s)/biocidal product family are met.

The physico-chemical properties of the biocidal product family are deemed acceptable for the appropriate use, storage and transportation of the biocidal product.

For the proposed authorised use, according to Article 19(1)(b) of the BPR, it has been concluded that:

1. the biocidal product family is sufficiently effective;
2. the biocidal product family has no unacceptable effects on the target organisms.;
3. the biocidal product family has no immediate or delayed unacceptable effects itself, or as a result of its residues, on the health of humans, including that of vulnerable groups, or animals, directly or through drinking water, food, feed, air, or through other indirect effects;
4. the biocidal product family has no unacceptable effects itself, or as a result of its residues, on the environment, having particular regard to the following considerations:
 - the fate and distribution of the biocidal product in the environment,
 - contamination of surface waters (including estuarial and seawater), groundwater and drinking water, air and soil, taking into account locations distant from its use following long-range environmental transportation,
 - the impact of the biocidal product on non-target organisms,
 - the impact of the biocidal product on biodiversity and the ecosystem.

The outcome of the evaluation, as reflected in the PAR, is that the use described in the SPC, may be authorised.

2.2 BPC opinion on the Union authorisation of the biocidal product family

As the conditions of Article 19(1) are met it is proposed that the biocidal product family shall be authorised, for the use described under section 2.1 of this opinion.