

Biocidal Products Committee (BPC)

Opinion on the Union authorisation of the biocidal product family:

SODIUM HYPOCHLORITE LIQUID DISINFECTANT BIOCIDAL PRODUCT FAMILY

ECHA/BPC/349/2022

Adopted

19 August 2022

Opinion of the Biocidal Products Committee

on the Union authorisation of SODIUM HYPOCHLORITE LIQUID DISINFECTANT BIOCIDAL PRODUCT FAMILY

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:	SODIUM HYPOCHLORITE LIQUID DISINFECTANT BIOCIDAL PRODUCT FAMILY
Authorisation holder:	Reckitt Benckiser Production
Active substance common name:	active chlorine released from sodium hypochlorite (CAS number sodium hypochlorite: 7681-52-9)
Product types:	2 and 4

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 14 December 2018, recorded in R4BP3 under case number BC-NB046342-57, 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 22 July 2021. In order to review the draft PAR, the conclusions of the eCA and the draft SPC, the Agency organised consultations via the BPC (BPC-42) and its Working Groups (WG IV 2021). Revisions agreed upon were presented and the draft PAR and the draft SPC were finalised accordingly.

Adoption of the BPC opinion

Rapporteur: France

The BPC opinion on the Union authorisation of the biocidal product family was adopted via a written procedure after the BPC-42 meeting and was reached on 19 August 2022.

The BPC opinion was adopted by simple majority of the members present having the right to vote.

The opinion and the minority positions are published on the ECHA website.

Detailed BPC opinion and background

1. Overall conclusion

The overall conclusion of the BPC is that 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(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 **SODIUM HYPOCHLORITE LIQUID DISINFECTANT BIOCIDAL PRODUCT FAMILY** 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

France, as e-CA received an application from Reckitt Benckiser Production for union authorisation for the biocidal product family SODIUM HYPOCHLORITE LIQUID DISINFECTANT BIOCIDAL PRODUCT FAMILY.

The biocidal product family SODIUM HYPOCHLORITE LIQUID DISINFECTANT BIOCIDAL PRODUCT FAMILY containing 0.99 to 6.1% of sodium hypochlorite is a product type 2 (PT2) and 4 (PT4) intended to be used by professional and non-professional users for the disinfection of toilet bowls (PT2), drain pipes (PT2) and hard surfaces (PT 2 and 4).

2 co-formulants (sodium hydroxide and amines, C12-14 (even numbered)-alkyldimethyl, N-oxides) contained in the products of the biocidal product family SODIUM HYPOCHLORITE LIQUID DISINFECTANT BIOCIDAL PRODUCT FAMILY have been identified as a substance of concern for human health.

The biocidal product family SODIUM HYPOCHLORITE LIQUID DISINFECTANT BIOCIDAL PRODUCT FAMILY is composed of 9 Meta SPC: the Meta SPC 1 (A), 2 (B), 3 (C) and 9 (I) are used for the disinfection of toilet bowls (PT2); the Meta SPC 4 (D) and 5 (E) are used for the disinfection of drain pipes (PT2); the Meta SPC 6 (F), 7 (G) and 8 (H) are used for the disinfection of hard surfaces (domestic, institutional and medical areas) (PT 2 and 4).

The following intended claims were assessed:

Uses	Meta SPC	Application rate	Target organism	Condition of use
Disinfection of toilet bowls (PT2)	1 (A)	Ready to use product. Contact time: 15 min	Bacteria Yeasts Fungi Virus	Application by pouring. Professional and non-professional users.

Disinfection of toilet bowls (PT2)	2 (B)	Ready to use product.	Bacteria Yeasts Fungi	Application by pouring. Professional and non-professional users.
	3 (C)	Contact time: 15 min		
	9 (I)			
Disinfection of drain pipes (PT2)	4 (D)	Ready to use product. Contact time: 15 min	Bacteria Yeasts Fungi	Application by pouring. Professional and non-professional users.
	5 (E)	Ready to use product. Contact time: 15 min		
Disinfection of hard non porous surfaces (PT 2 and 4)	6 (F)	Ready to use product. Contact time: 5 min	Bacteria Yeasts Fungi Virus	Application by spraying. Professional and non-professional users.
	7 (G)	Ready to use product. Contact time: 5 min		
	8 (H)	Ready to use product. Contact time: 5 min		

Physico-chemical properties

The physico-chemical properties of the biocidal product family have been described and considered acceptable in the conditions of use detailed in the SPC.

The products of the family should not be stored above 30°C and should be kept protected from direct sunlight.

The following shelf life were determined:

Shelf life of the Meta SPC B: 18 months

Shelf life of the Meta SPC A, C, D, E, F, G, H and I: 24 months

Due to the nature of the active ingredient, the products should not be used in conjunction with acids or ammonia. For products with a content of active chlorine higher than 5% (products of Meta SPC I), the phrase EUH031 "contact with acids liberates toxic gas" is proposed. For products intended for general public and with a content of active chlorine higher than 1% (Meta SPC A, C, D, E H and I), the phrase EUH 206: "Warning! Do not use together with other products. May release dangerous gases (chlorine)" is applied.

SODIUM HYPOCHLORITE LIQUID DISINFECTANT BIOCIDAL PRODUCT FAMILY products from all Meta SPC are classified corrosive to metal H290 Met Corr. I.

The analytical methods provided are validated for the determination of sodium hypochlorite and sodium chlorate in the biocidal product family.

For Meta SPC F, the particle size distribution after storage for the TS6 spray type sprayhead is required post authorisation.

Efficacy

The SODIUM HYPOCHLORITE LIQUID DISINFECTANT BIOCIDAL PRODUCT FAMILY product family, have shown a sufficient efficacy in accordance with the requirements of the guidance on the Biocidal Products Regulation, Volume II Efficacy – Assessment and Evaluation (Parts B+C), Version 3.0, April 2018 for the following uses:

META-SPC A

- Use 1: Ready to use Disinfection for toilet bowls by pouring (PT 02 domestic and institutional areas) with dirty conditions:
 - Bacteria, yeast, fungi and virus: 15 min, room temperature
- Use 1: Ready to use Disinfection for toilet bowls by pouring (PT 02 medical area) with clean conditions:
 - Bacteria, yeast, fungi and virus: 15 min, room temperature

META-SPC B

- Use 1: Ready to use Disinfection for toilet bowls by pouring (PT 02 domestic and institutional areas) with dirty conditions:
 - Bacteria, yeast and fungi: 15 min, room temperature
- Use 1: Ready to use Disinfection for toilet bowls by pouring (PT 02 medical areas) with clean conditions:
 - Bacteria, yeast and fungi: 15 min, room temperature

META-SPC C/I

- Use 1: Ready to use Disinfection for toilet bowls by pouring (PT 02 domestic and institutional areas) with dirty conditions:
 - Bacteria, yeast and fungi: 15 min, room temperature
- Use 1: Ready to use Disinfection for toilet bowls by pouring (PT 02 medical areas) with clean conditions:
 - Bacteria, yeast and fungi: 15 min, room temperature

META-SPC D

- Use 1: Ready to use surface Disinfection for drain pipe by pouring (PT 02 domestic and institutional areas) with dirty conditions:
 - Bacteria, yeast and fungi: 15 min, room temperature

META-SPC E

- Use 1: Ready to use surface Disinfection for drain pipe by pouring (PT 02 domestic and institutional areas) with dirty conditions:
 - Bacteria, yeast and fungi: 15 min, room temperature

META-SPC F

- Use 1: Ready to use Disinfection on hard non porous surfaces by spraying (PT 02 domestic and institutional areas and PT04) with dirty conditions:
 - Bacteria, yeast and fungi: 5 min, room temperature

META-SPC G

- Use 1: Ready to use Disinfection on hard non porous surfaces by spraying (PT 02 domestic and institutional areas and PT 04) with dirty conditions:
 - Bacteria, yeast, fungi and virus: 5 min, room temperature
- Use 1: Ready to use Disinfection on hard non porous surfaces by spraying (PT 02 medical areas) with clean conditions:
 - Bacteria, yeast, fungi and virus: 5 min, room temperature

META-SPC H

- Use 1: Ready to use Disinfection on hard non porous surfaces by spraying (PT 02 domestic and institutional areas and PT 04) with dirty conditions:
 - Bacteria, yeast, fungi and virus: 5 min, room temperature
- Use 1: Ready to use Disinfection on hard non porous surfaces by spraying (PT 02 medical areas) with clean conditions:
 - Bacteria, yeast, fungi and virus: 5 min, room temperature

Human health

Products of SODIUM HYPOCHLORITE LIQUID DISINFECTANT BIOCIDAL PRODUCT FAMILY biocidal product family are classified, according to the CLP Regulation (EC) 1272/2008 as:

Meta SPC A, B, C, D, E and I

- Corrosivity for skin and eyes: Skin corr.1 – H314 and Eye dam.1 – H318

Meta SPC F and H

- Irritation for skin and eyes: Skin Irrit. 2 –H315 and Eye Irrit. 2 – H319

Meta SPC G

- Corrosivity for skin and eyes: Skin corr.1 – H314 and Eye dam.1 – H318
- EUH 071: Corrosive to the respiratory tract.

For the professional users, risks are acceptable for products of Meta SPC A, B, C, D, E, F, G, H and I considering the semi-quantitative and qualitative risk assessment for local effects, with the application of risk mitigation measures (RMM) and the wearing of personal protective equipment (PPE) listed below:

- Meta SPC A, B, C and I– Toilet bowls disinfection:
 - For application and brushing: gloves, coverall and chemical goggles.
- Meta SPC D and E – Drain pipe disinfection:
 - For application: gloves, coverall and chemical goggles.
- Meta SPC G - Hard surface disinfection by spraying:
 - For application: gloves, coverall, chemical goggles and respiratory protective equipment.
 - For post-application: gloves, coverall and chemical goggles.
- Meta SPC F and H - Hard surface disinfection by spraying:
 - For application and post-application: gloves, coverall, face shield / chemical goggles.

For the bystander, risks are acceptable for products of meta-SPC G considering the semi-quantitative and qualitative risk assessment for local effects, with the application of risk mitigation measures (RMM) listed below:

- Do not be present in the treatment area during application by spraying. If it is necessary to be present, wear the same RPE and PPE as the user.

For the non-professional users, risks are acceptable for products of meta-SPC A, B, C, D, E, F, H and I considering the semi-quantitative and qualitative risk assessment for local effects, with the application of risk mitigation measures (RMM) listed below:

- Meta-SPC A, B, C and I – Toilet bowls disinfection:
 - Do not touch the product during application.
 - Wash hand after use.
 - Avoid contact with skin and eyes.
 - Avoid splashes during application.
- Meta-SPC D and E – Drain pipe disinfection:
 - Do not touch the product during application.
 - Wash hand after use.
 - Avoid contact with skin and eyes.
- Meta-SPC F and H - Hard surface disinfection by spraying:
 - Product should be sprayed downward.
 - Wash hand after use.
 - Avoid contact with skin and eyes.

For the secondary exposure of general public, risk mitigation measures listed below should be added for meta-SPC F, G and H:

- Don't touch the surface until the surface is rinsed and dry.
- Children and pets should not be present during disinfection and until the surface is rinsed and dry.
- General public should not be present during application by spraying (only for meta-SPC G).

Substance of Concern (SoC)

According to the definition of a substance of concern laid down in the Guidance on the BPR Volume III Human Health – Part B and C Risk Assessment, some co-formulants have been identified as substances of concern.

In the Meta SPC A, B, C, D, E, G and I with a final classification of H314 - H318, Sodium Hydroxide (CAS 1310-73-2) is considered as Substance of Concern since this co-formulant participates in the corrosive pH.

In the Meta SPC F, classified H315/H319, since the active substance present at 0.99% does not classify the Meta SPC by itself, the two co-formulants Sodium Hydroxide and Amines, C12-14 (even numbered)-alkyldimethyl, N-oxides (308062-28-4) triggers the classification by additivity.

Therefore, in the Meta SPC F, Sodium Hydroxide and Amines, C12-14 (even numbered)-alkyldimethyl, N-oxides have been identified as substance of concern.

The resulting classification has therefore been taken into in the qualitative risk assessment.

Disinfection by-products (DBP) risk assessment

The presence of chlorate should also be taken into account in the systemic risk assessment. However, in the absence of harmonisation of the reference values for chlorate, no risk assessment can be performed. This should be addressed at the renewal of the active substance.

For all uses of biocidal products leading to the formation of DBPs, no guidance is currently available thus, no conclusion can be drawn. Due to insufficient data at present the full DBP evaluation cannot be carried out.

The current guidance (Volume V, Guidance on Disinfection By-Products) should be completed in order to be applicable during the active substance renewal. ECHA and the member states will work actively to address these issues (e.g. data lacking and harmonised toxicological reference values.).

Dietary risk assessment

PT2 biocidal products are not intended for application on surfaces that are used for direct contact with food or feeding stuffs. Therefore, residues in food or feed are not expected.

For PT 4 uses, residues in food, feed or drink must be further investigated. Due to the high reactivity of sodium hypochlorite, residues on surfaces degrade very rapidly. Hence, residue formation (other than chlorate) is assumed to be negligible for aqueous solutions of chlorine. Conversely, chlorate residues, a stable metabolite that can be formed from hypochlorite sodium in aqueous chlorine solutions, are considered relevant for dietary exposure from the uses of active substance as food area disinfectant.

Regarding professional use, considering the current knowledge about chlorate and the chlorate legislation limits (MRLs), there is no concern for the general public from indirect exposure to chlorate via food taking into account the following risk mitigation measure:

- For food commodities, ensure that the concentration of chlorate present in food does not exceed the MRL values set in regulation 2020/749.

Considering the non-professional uses, chlorate exposure cannot be limited using regulatory values. Hence, a food contamination with chlorate via treated surface was estimated using worst case scenario. Regarding the Dietary Risk Assessment there is no concern for the general public from indirect exposure to either available chlorine or chlorate in food.

Environment

SODIUM HYPOCHLORITE LIQUID DISINFECTANT BIOCIDAL PRODUCT FAMILY biocidal product family is classified for the environment as:

Meta SPC A, B, E, F and H

- Aquatic chronic cat. 3 - H412

Meta SPC C, D, G and I

- Aquatic acute cat. 1 - H400
- Aquatic chronic cat. 2 - H411

Risks are acceptable for all the environmental compartments considering a qualitative assessment of the active substance sodium hypochlorite and chlorate formed during storage leading to negligible emissions to the environment for:

- PT02 disinfection of toilets bowls, drain pipes and hard surfaces for non-professional and professional users,

- PT 04 disinfection of hard surfaces for non-professional and professional users.

Risks linked to chlorate formed during storage are acceptable for all uses considering a semi-qualitative assessment for groundwater and surface water intended for the abstraction of drinking water.

Disinfection by-products (DBP) risk assessment

For all uses of biocidal products leading to the formation of DBPs, no guidance is currently available thus, no conclusion can be drawn. Due to insufficient data at present the full DBP evaluation cannot be carried out. The current 'guidance' (Volume V, Guidance on Disinfection By-Products) covering PT2, 11 and 12 is a strategy and not a concrete assessment method. This guidance does not allow any harmonized DBP assessment.

Overall conclusion

According to the assessment performed for the biocidal product family SODIUM HYPOCHLORITE LIQUID DISINFECTANT BIOCIDAL PRODUCT FAMILY, conclusions are given for the following uses considering the appropriate instruction of uses and risk mitigation measures as indicated in the Summary of Product Characteristics:

Uses	Meta SPC	Application rate	Target organism	Condition of use	Conclusions
Disinfection of toilet bowls (PT2)	1 (A)	Ready to use product. Contact time: 15 min	Bacteria Yeasts Fungi Virus	Application by pouring. Professional and non-professional users.	Acceptable
Disinfection of toilet bowls (PT2)	2 (B)	Ready to use product. Contact time: 15 min	Bacteria Yeasts Fungi	Application by pouring. Professional and non-professional users.	Acceptable
	3 (C)				Acceptable
	9 (I)				Acceptable
Disinfection of drain pipes (PT2)	4 (D)	Ready to use product. Contact time: 15 min	Bacteria Yeasts Fungi	Application by pouring. Professional and non-professional users.	Acceptable
	5 (E)	Ready to use product. Contact time: 15 min	Bacteria Yeasts Fungi	Application by pouring. Professional and non-professional users.	Acceptable
Disinfection of hard non porous surfaces (PT2 and 4)	6 (F)	Ready to use product. Contact time: 5 min	Bacteria Yeasts Fungi	Application by spraying. Professional and non-professional users.	Acceptable
	7 (G)	Ready to use product. Contact time: 5 min	Bacteria Yeasts Fungi Virus	Application by spraying. Professional users	Acceptable
	8 (H)	Ready to use product. Contact time: 5		Application by spraying. Professional and non-	Acceptable

		min		professional users.	
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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 active chlorine released from sodium hypochlorite 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 is not required.

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 uses of the biocidal product family have been evaluated.

The chemical identity, quantity and technical equivalence requirements for the active substance in the biocidal product family are met.

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

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

1. the SODIUM HYPOCHLORITE LIQUID DISINFECTANT BIOCIDAL PRODUCT FAMILY is sufficiently effective;
2. the SODIUM HYPOCHLORITE LIQUID DISINFECTANT BIOCIDAL PRODUCT FAMILY has no unacceptable effects on the target organisms, in particular unacceptable resistance or cross-resistance or unnecessary suffering and pain for vertebrates;
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 family 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 family on non-target organisms,
 - the impact of the biocidal product family on biodiversity and the ecosystem.

The outcome of the evaluation, as reflected in the PAR, is that the uses 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 biocidal product family shall be authorised¹, for the use(s) described under section 2.1 of this opinion, subject to compliance with the proposed SPC.

The authorisation holder shall complete, within the stated timeframe, the actions set out in the table below:

Description	Due date
For Meta SPC F, the particle size distribution obtained with the TS6 spray type sprayhead after a long terme storage study (24 months) in commercial packaging is required post authorisation.	Not later than two years after the authorisation date.

It is noted that for the product family SODIUM HYPOCHLORITE LIQUID DISINFECTANT BIOCIDAL PRODUCT FAMILY the fact that data is to be provided after the authorisation is granted does not affect the conclusion on the fulfilment of the conditions under Article 19(1) on the basis of the existing data.

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¹ This is without prejudice of any specific conditions that might apply in the territory of Member State(s) in accordance with Article 44(5) of the BPR.