Biocidal Products Committee (BPC)

Opinion on the Union authorisation of the biocidal product family:

Active chlorine based products BPF – CID LINES NV

ECHA/BPC/288/2021

Adopted

6 October 2021
Opinion of the Biocidal Products Committee
on the Union authorisation of the biocidal product family
Active chlorine based products BPF – CID LINES NV

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: Active chlorine based products BPF – CID LINES NV

Authorisation holder: CID LINES NV

Active substance(s) common name: Active chlorine released from sodium hypochlorite (CAS number sodium hypochlorite 7681-52-9)

Product types: PT 2, 3, 4 and 5

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 19 December 2018, recorded in R4BP3 under case number BC-MY047028-07, 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 23 March 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-40) and its Working Groups (WG II 2021). Revisions agreed upon were presented and the draft PAR and the draft SPC were finalised accordingly.
Adoption of the BPC opinion

Rapporteur: Belgium

The BPC opinion on the Union authorisation of the biocidal product family was reached on 6 October 2021.

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

The opinion and the minority position including their grounds 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 Active chlorine based products BPF – CID LINES NV 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**

This BPC opinion concerns the biocidal product family 'Active Chlorine based products BPF – CID LINES NV'. The BPF contains 15 meta SPCs; its biocidal products belong to product types 2, 3, 4 and 5, and contain the active substance 'active chlorine released from sodium hypochlorite' in a range of 1.9% to 12.5%.

The BPF consists of a range of biocidal products for surface disinfection (PT 2, 3 and 4), and for drinking water disinfection (PT 5). They are intended for use indoors, for surfaces in households or institutions as well as in food industry and in farmhouses. Surface disinfection includes internal surfaces (CIP, human and veterinary drinking water systems), surfaces of dishes (ware washers) and hard surfaces. Animal drinking water disinfection is also included in this BPF.

All meta-SPCs are intended for professional use. Meta SPC 2 (PT 2 surface disinfection) and 3 (toilet disinfection) additionally contain non-professional uses.

The BPF contains the following co-formulants to be considered as substances of concern:

- Sodium hydroxide;
- Potassium hydroxide;
- Silicic acid, sodium salt;
- Amines, C12-14 (even numbered)-alkyldimethyl, N-oxides.

These substances carry a classification for local effects (skin corrosion/irritation and eye damage) and as such contribute to the classification of certain meta SPCs. The substance “amines, C12-C14 (even numbered)-alkyldimethyl, N-oxides” is also considered a substance of concern for environment.

Sodium chlorate is a degradation product of active chlorine which may be formed during storage and may cause concern for human health and environment. Where possible, the risks linked to formation of chlorate during storage have been included in the risk assessment.
The following uses and application methods are covered by the assessment:

<table>
<thead>
<tr>
<th>PT</th>
<th>Uses assessed</th>
<th>User category &amp; application methods</th>
<th>metaSPC / use #</th>
</tr>
</thead>
</table>
| 2  | Disinfectants for surfaces | Professional user:  
- coarse spraying or foaming  
- brushing or pouring+wiping  
- trigger spraying or foaming  
Non-professional user:  
- brushing or pouring+wiping  
- trigger spraying or foaming | Meta SPC 1 Use # 1.1  
Meta SPC 2 use # 2.1  
Meta SPC 7 use # 7.1  
Meta SPC 8 use # 8.1  
Meta SPC 9 use # 9.1  
Meta SPC 10 use # 10.1  
Meta SPC 12 use # 12.1  
Meta SPC 2 use # 2.1 |
| 2  | Disinfectants for toilets (inside) | Professional and non-professional user:  
- pouring under rim  
- CIP dosing in closed system | Meta SPC 3 use # 3.1  
Meta SPC 4 Use # 4.1  
Meta SPC 5 use # 5.1  
Meta SPC 6 use # 6.1  
Meta SPC 9 use # 9.2  
Meta SPC 11 use # 11.1  
Meta SPC 12 use # 12.2  
Meta SPC 13 use # 13.1  
Meta SPC 15 use # 15.1 |
| 2  | CIP use in industries (non food) | Professional user:  
- coarse spraying or foaming  
- brushing or pouring+wiping  
- dipping | Meta SPC 7 use # 7.2  
Meta SPC 8 use # 8.2  
Meta SPC 2 use # 2.1 |
| 3  | Disinfection of surfaces in farmhouses | Professional user:  
- coarse spraying or foaming  
- brushing or pouring+wiping  
- dipping | Meta SPC 7 use # 7.3  
Meta SPC 8 use # 8.3  
Meta SPC 9 use # 9.3  
Meta SPC 10 use # 10.2 |
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<td>- continuous dosing in closed system</td>
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Physico-chemical properties

The chemical identity, quantity and technical equivalence requirements for the active substance in the BPF ‘Active Chlorine based products BPF – CID LINES NV’ are met. The determined physical, chemical and technical properties of biocidal products in the BPF, as shown by the available test reports, are acceptable for soluble concentrates (meta SPC 1, 4-15) and other liquids to be applied undiluted (meta SPC 2 and 3). The required validated analytical methods are available.

The pH of all biocidal products (BP) in the BPF is upwards of 12, influencing their classification for human health. BP in Meta SPC 2 and Meta SPC 4 to Meta SPC 15 are classified as ‘corrosive to metals’. The BP in the BPF are considered to be non-explosive, non-flammable and non-oxidising liquids.

Due to the rapid decrease in active chlorine content over time, shelf-life was determined through efficacy assessment of aged products for all meta SPCs. BP in all meta SPCs are stable under cold storage conditions. However, they must be stored below 30 °C and protected from sunlight. Furthermore, chlorate is known to be a degradation product of active chlorine; its content was determined at ‘end-of-shelf life’ for representative products.

The meta-SPCs 1, 3 – 11 and 13 – 15 include few non-active compounds having a chemical group potentially associated with self-reactive properties. The precise chemical structure considerations (stable oxidation state) and very low concentration of these compounds (5% for the worst case) are good indications of the absence of self-reactive properties of the concerned products. Moreover, none of the compounds with potentially alerting chemical groups are considered as explosive. In addition, a screening has been performed (REACH dossier and harmonized C&L when available) and no indication of self-reactivity for these compounds has been found.

Based on the eCA evaluation no classification with self-reactivity hazard is necessary. It can be concluded that the conditions of Art 19.1.(d) are fulfilled. To confirm the absence of self-reactivity for the meta-SPCs 1, 3-11 and 13-15 the SADT for a 50 kg packaging of heat of decomposition is to be provided as post-authorization requirement, within 1 year.

It can be concluded that data on the physical, chemical and technical properties of the products in the BPF are sufficient for authorization of the BPF.

Efficacy

Target organisms include bacteria, fungi and yeasts and viruses, relevant to the products’ areas of use and in-use conditions. Detailed function, field of use (including areas) and application rates of the products is described in the Efficacy part of the PAR and in the section # 2.1.4.” Authorized use(s)”.

It can be concluded that all products in the family are efficacious, when used in accordance with the use instructions proposed in the SPC.

Human health

All meta-SPCs (PT 2,3 and 4 surface disinfection, PT 5 animal drinking water disinfection) are intended for professional use. MetaSPC 2 (PT2 surface disinfection) and 3 (PT 2 toilet disinfection) additionally contain non-professional uses.

All of the BP in the BPF are classified for skin and eye corrosion due to the high pH of all formulations (Skin corrosion category 1, serious eye damage category 1). For the same reason, in-use dilutions also have to be classified as corrosive to skin and eyes. MetaSPCs containing spraying applications are classified as corrosive to the respiratory tract (EUH071,
meta SPC 1, 2, 7-10 and 12). Due to the presence of the active substance, Meta SPC 9 to 12 carry the supplemental hazard phrase EUH031 (Contact with acids liberates toxic gas); Meta SPC 3 carries the phrase EUH206 (Warning! Do not use together with other products. May release dangerous gases (chlorine)). Due to the corrosive properties of the BP, only a local risk assessment was performed for relevant routes of exposure.

Professionals – CIP/closed systems

No adverse health effects are expected for professionals using BP from meta SPC 4 to 6, meta SPC 9, and meta SPC 11 to 15 during the application phase for CIP in PT2 and PT4 uses, for CIP in milking parlours, ware washers, disinfection of water distribution systems and animal drinking water disinfection. All of these uses are in closed systems where exposure of professionals is unlikely, and personal protective equipment (PPE) is not required.

No adverse health effects are expected for professionals using the above BP, performing mixing and loading and post-application tasks, when using PPE appropriate for handling corrosive mixtures (chemical resistant gloves, eye/face protection, protective clothing and closed footwear). Apart from BP in meta SPC 12, for post-application/maintenance and repair, appropriate respiratory protection is needed when there is potential exposure to pressurized systems (APF10 mask). Professional bystanders are to use the same protective measures when exposed via inhalation.

Professionals – surface disinfection

No adverse health effects are expected for professionals using BP from meta SPC 1, meta SPC 2, meta SPC 12 and meta SPC 7 to meta SPC 10, performing mixing and loading, surface disinfection and post-application tasks, when using PPE appropriate for handling corrosive mixtures (chemical resistant gloves, eye/face protection, protective clothing and closed footwear). For some spraying/foaming applications (meta SPC 1 and meta SPC 7 to 10) this includes appropriate respiratory protection.

Professional bystanders are to use the same protective measures when exposed via inhalation.

- APF10 mask for trigger spraying/foaming meta SPC 1;
- APF40 full face mask for coarse spraying/foaming meta SPC 1, 7-10

In order to reduce inhalatory exposure, additional risk mitigation measures (RMMs) to limit spraying/foaming applications to coarse droplet size are proposed:

- Meta SPC 1 trigger spray/foam: In order to reduce inhalatory exposure products may only be applied by trigger spraying device delivering coarse droplets (MMAD > 100). Please refer to device supplier for technical details.
- Meta SPC 1, 7-10 Coarse spray/foam: In order to reduce inhalatory exposure product may only be applied by coarse spraying. + Please refer to device supplier for technical details.
- For brushing, pouring + wiping, dipping applications: in order to reduce dermal exposure, an additional RMM is put in place: Do not immerse hands in the solution.

Professionals – additional RMM for ventilation

For some professional uses, an additional RMM for ventilation is suggested:

*meta-SPC 1-2, 4-11, 13-15: Ensure adequate ventilation during the application.*
Professionals and non-professionals – toilet disinfection

Adverse health effects are not expected for the professional and non-professional user using BP from meta SPC 3 for toilet disinfection (pouring under rim using plug bottle), even when no PPE are used. The following RMM are required on the label: "Wash hands thoroughly after handling", "Apply only into the rim of the toilet to avoid skin contact. Avoid splashing.", "Avoid contact with skin and eyes", "Do not brush the product in toilet bowl." and "Flush toilet after contact time."

Non-professionals – surface disinfection

Adverse health effects are expected for the non-professional user using BP from meta SPC 2 for surface disinfection due to the corrosive properties of the BP. BP for non-professional surface disinfection (meta SPC 2 use # 2.1) will therefore not be authorized.

General public

No adverse health effects are expected for the general public when BP from meta SPC 1 to meta SPC 15 are applied according to the use instructions. However, for the general public re-entering areas treated by coarse spraying or foaming applications of meta SPC1, appropriate risk mitigation measures are required to avoid exposure to chlorine air concentrations at or above 0.5 mg/m^3: After disinfection by coarse spraying or foaming, the treated area can be re-entered only when the ambient air concentration of chlorine is ensured to be below 0.5 mg/m^3. If no appropriate method to determine the chlorine air concentration after use is available, contact the supplier. Moreover, for areas where professional surface treatment is taking place, access of the general public during treatment and until surfaces are dried should be prevented: "No access of the general public during treatment and until surfaces are dried." and "Keep away from pets/keep out of reach of pets.”

Consumers: residues in food

No unacceptable risks for consumers via residues in food have been identified when BP are applied according to the use instructions.

No risks were identified for consumers via PT3 animal housing disinfection, PT4 disinfectants for CIP use in food industry, drinking water systems, surfaces which come into contact with food, PT4 use in ware washers and for exposure to substances of concern, provided that a rinsing step is applied after disinfection. The following RMM is to be added:

After disinfection, treated surfaces should be thoroughly rinsed with water of drinking water quality.

PT2 surface disinfection BP should carry the following RMM:

- Do not (use/apply) directly on or near food, feed or drinks, or on surfaces or utensils likely to be in direct contact with food, feed, drinks and livestock.
- Do not apply directly to surfaces on which food or feed is stored, prepared or eaten.

Exposure to sodium chlorate

The formation of sodium chlorate does not impact the classification of the metaSPCs if the shelf life is respected. The labels should carry the following RMM:

Sodium chlorate may be formed during storage. To avoid increasing formation of this degradation product, do not exceed the established shelf life of the biocidal product.

No concern was identified for exposure of consumers to the degradation product chlorate
when taking into account the following RMM:

- After disinfection, treated surfaces should be thoroughly rinsed with water of drinking water quality.
- For PT3, PT4 and PT5 uses: For food commodities, ensure that the concentration of chlorate present in food does not exceed the MRL values set in Regulation 2020/749.

Substances of concern

The BPF contains 4 co-formulants which are considered as substances of concern. However, any risk derived from the presence of these substances is covered by the qualitative risk assessment and by the risk mitigation measures imposed above.

Disinfection by-products (DBP)

Currently, insufficient data on DBP formation and no harmonised toxicological reference values are available. For the intended uses of this BPF no guidance is available for DBP risk assessment. At present, a full DBP evaluation cannot be carried out.

Animal health

No unacceptable risks for animal health were identified from PT 5 disinfection of animal drinking water applications. Risks for animal health are acceptable for PT 3 animal housing disinfection for all animal species included in the evaluation.

**It can be concluded that the BPF has no unacceptable effects on human health when applied according to the use instructions. However, meta SPC 2’s non-professional surface disinfection applications will not be authorized. No unacceptable risks are identified for animal health from the use of PT3 and PT5 BP in the BPF.**

Environment

Except for meta SPC 2, all meta SPCs are classified as hazardous to the aquatic environment — Acute Hazard, Category 1, Chronic Hazard, Category 2. Meta SPC 2 is classified as hazardous to the aquatic environment — Chronic Hazard, Category 3. This classification is due to the presence of the active substance. The substance “amines, C12-C14 (even numbered)-alkyldimethyl, N-oxides” is to be considered a substance of concern for environment in a limited number of meta SPCs.

No concerns were identified for exposure of the environment to active chlorine released from hypochlorite as a result of appropriate use of the products in ‘Active Chlorine based products BPF - CID LINES NV’, either via the atmosphere, sewage treatment plant, aquatic compartment or the terrestrial compartment including groundwater.

Risks are also considered acceptable for exposure to the substance of concern Amines, C12-C14 (even numbered)-alkyldimethyl, N-oxides in all environmental compartments.

No concern was identified for exposure of the environment to the degradation product chlorate via the compartments: atmosphere, sewage treatment plant, and the aquatic and terrestrial compartments.

**DBP risk assessment: Due to insufficient data at present the full DBP evaluation cannot be carried out. Available guidance does not allow any harmonized DBP assessment.**

**It can be concluded that use of the products in the BPF according to the use instructions does not result in unacceptable risks to the environment.**
Overall conclusion

According to the assessment performed for Active chlorine based products BPF – CID LINES NV, the overall conclusion for the following uses considering the appropriate instruction of uses and risk mitigation measures as indicated in the SPC, is as follows:

<table>
<thead>
<tr>
<th>PT</th>
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<th>User category &amp; application methods</th>
<th>metaSPC / use #</th>
<th>Justification</th>
</tr>
</thead>
</table>
| 2  | Disinfectants for surfaces | Professional user:  
- coarse spraying or foaming  
- brushing or pouring+wiping  | Meta SPC 1 Use # 1.1  
Meta SPC 7 use # 7.1  
Meta SPC 8 use # 8.1  
Meta SPC 9 use # 9.1  
Meta SPC 10 use # 10.1  
Meta SPC 12 use # 12.1  | authorized |
|    |               | Professional user:  
- coarse spraying or foaming  
- brushing or pouring+wiping  | Meta SPC 1 Use # 1.1  
Meta SPC 7 use # 7.1  
Meta SPC 8 use # 8.1  
Meta SPC 9 use # 9.1  
Meta SPC 10 use # 10.1  
Meta SPC 12 use # 12.1  | authorized |
|    |               | Professional user:  
- coarse spraying or foaming  
- brushing or pouring+wiping  | Meta SPC 1 Use # 1.1  
Meta SPC 2 use # 2.1  | Not authorized  
Justification: corrosive properties of the BP |
| 2  | Disinfectants for toilets (inside) | Professional and non-professional user:  
- pouring under rim  
- trigger spraying or foaming  | Meta SPC 3 use # 3.1  | authorized |
| 2  | CIP use in industries (non food) | Professional user:  
- CIP dosing in closed system  | Meta SPC 4 Use # 4.1  
Meta SPC 5 use # 5.1  
Meta SPC 6 use # 6.1  
Meta SPC 9 use # 9.2  
Meta SPC 11 use # 11.1  
Meta SPC 12 use # 12.2  
Meta SPC 13 use # 13.1  
Meta SPC 15 use # 15.1  | authorized |
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<td>- dosing in closed system</td>
<td>Meta SPC 5 use # 5.3</td>
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<td>Meta SPC 15 use # 15.3</td>
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### Uses assessed

<table>
<thead>
<tr>
<th>PT</th>
<th>Uses assessed</th>
<th>User category &amp; application methods</th>
<th>metaSPC / use #</th>
</tr>
</thead>
<tbody>
<tr>
<td>4</td>
<td>Disinfection of human drinking water systems</td>
<td>Professional user: - dosing in closed system</td>
<td>Meta SPC 4 Use # 4.5</td>
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<td>Meta SPC 15 use # 15.5</td>
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<tr>
<td>4</td>
<td>Disinfection of veterinary water distribution systems</td>
<td>Professional user: - dosing in closed system</td>
<td>Meta SPC 4 Use # 4.6</td>
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<td>Meta SPC 15 use # 15.6</td>
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<td>Animal drinking water disinfection</td>
<td>Professional user: - continuous dosing in closed system</td>
<td>Meta SPC 12 use # 12.6</td>
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<td>authorized</td>
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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/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 use, storage and transportation of the biocidal product.

For the proposed authorised use(s), 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, in particular unacceptable resistance or cross-resistance;
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 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 the biocidal product family shall be authorised\(^1\) for the use(s) described under section 2.1 of this opinion, subject to compliance with the proposed SPC.

To fulfill the post-authorisation requirements related to the non-classification as self-reactive mixture for meta SPCs 1, 3-11, and 13-15, the authorisation holder shall complete, within the stated timeframe, the action set out in the table below:

<table>
<thead>
<tr>
<th>Description</th>
<th>Due date</th>
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<tbody>
<tr>
<td>Provide the SADT for meta SPCs 1, 3-11, and 13-15.</td>
<td>Not later than 1 year after the authorisation date.</td>
</tr>
</tbody>
</table>

It is noted that for the product family ‘Active chlorine based products BPF – CID LINES NV’ 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.

\(^{1}\) 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.