Biocidal Products Committee (BPC)

Opinion on the Union authorisation of

Iodine Teat Dip Products BPF based on Iodine

ECHA/BPC/217/2018

Adopted

14 December 2018

Annankatu 18, P.O. Box 400, FI-00121 Helsinki, Finland | Tel. +358 9 686180 | Fax +358 9 68618210 | echa.europa.eu

Opinion of the Biocidal Products Committee

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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: Iodine Teat Dip Products based on Iodine

Authorisation holder: GEA Farm Technologies (UK) Ltd

Active substance common name: Iodine

Product type: 3

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 20 August 2015, recorded in R4BP3 under case number BC-AL019223-55, the evaluating Competent Authority (the UK) submitted a draft product assessment report (PAR) containing the conclusions of its evaluation and the draft Summary of Product Characteristics (SPC) to ECHA on 6 June 2018. In order to review the draft PAR, the conclusions of the eCA and the draft SPC, the Agency organised consultations via the BPC (BPC-28) and its Working Groups (WG V 2018). Revisions agreed upon were presented and the draft PAR and the draft SPC were finalised accordingly.

Adoption of the BPC opinion

Rapporteur: United Kingdom

The BPC opinion on the Union authorisation of the biocidal product family was adopted on 14 December 2018.

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(s).

The biocidal product family may be expected to fulfil 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 Iodine Teat Dip Products BPF based on Iodine referred to in Article 22(2) of Regulation (EU) No 528/2012 (Annex I to this BPC opinion).

2. BPC Opinion

2.1 BPC Conclusions of the evaluation

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

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

General

The biocidal product family Iodine Teat Dip Products based on Iodione consists of products containing the active substance iodine for disinfection of teats. Iodine is formulated into the products as pure iodine (0.16% - 2.47 %).

The non-active coformulant C9-11 Alcohol Ethoxylate (CAS 68439-46-3) is classified as Eye Dam. 1 and was identified as a Substance of Concern for Meta SPC 1. The concentration of this coformulant triggers classification for Eye Damage Category 2 (H319), for meta SPC 1.

The biocidal product family (BPF), which is recommended for authorisation, consists of 2 meta SPCs, containing the following number of products:

- meta SPC 1: 4 products;
- meta SPC 2: 4 products;
- meta SPC 3: 1 product.

The structuring of the BPF into meta SPCs was based on:
- content of iodine;
- application method (dipping, spraying, foaming);
- formulation type (meta SPC 1: soluble concentrate; meta SPC 2 and 3: RTU liquid).

The applicant originally applied for 4 meta SPCs. Meta SPCs 1 and 4, as applied for by the applicant, have been recommended for autorisation. However, meta 4 has been split into 2 meta SPCs, which will be authorised as meta SPC 2 and meta SPC 3.

Meta SPC 3, as originally applied for by the applicant, could not be recommended for autorisation because it contained a Substance of Concern for the Environment. Meta SPC 2, as originally applied for by the applicant, could not be recommended for authorisation because a shelf life could not be supported for it, based on the available data.

The following uses have been assessed:

***meta* SPC 1 :**

- Use # 1.1 – Concentrates - Professional concentrates with 1:3, 1:4 and 1:7 dilution rates, for post milking - Dipping
- Use # 1.2 – Concentrates - Professional concentrates with 1:3, 1:4 and 1:7 dilution rates, for post milking - spraying
- Use # 1.3 – Concentrates - Professional concentrates with 1:3, 1:4 and 1:7 dilution rates, for post milking - foaming

***meta* SPC 2 & 3 :**

- Use # 2.1 & 3.1 - RTU Products - Professional RTU Liquid, for application pre-milking - dipping
- Use # 2.2 & 3.2 – RTU Products - Professional RTU Liquid, for application pre milking – spraying
- Use # 2.3 & 3.3 – RTU Products - Professional RTU Liquid, for application pre milking – foaming
- Use # 2.4 & 3.4 – RTU Products - Professional RTU Liquid, for application post milking – Dipping
- Use #2.5 & 3.5) – RTU Products - Professional RTU Liquid, for application post milking – spraying
- Use #2.6 & 3.6– RTU Products - Professional RTU Liquid, for application post milking – foaming
- Use #2.7 & 3.7) – RTU Products - Professional RTU Liquid, for application pre and post milking-Dipping
- Use #2.8 & 3.8– RTU Products - Professional RTU Liquid, for application pre and post milking- spraying
- Use # 2.9 & 3.9 – RTU Products - Professional RTU Liquid, for application pre and post milking - foaming

Physico-chemical properties

The physical, chemical and technical properties of Iodine Teat Dip Products product family are acceptable for the two formulation types, soluble concentrate and ready to use liquid.

The following shelf lives and maximum storage temperatures are supported:

Meta SPC 1: 12 months, maximum temperature 30 °C;
Meta SPC 2: 12 months, maximum temperature 30 °C;
Meta SPC 3: 12 months, maximum temperature 30 °C.

All other properties, such as, appearance, viscosity and dilution stability were acceptable before and after long term storage.

All products of the Iodine Teat Dip Products biocidal product family are classified as corrosive to metals; 'H290, may be corrosive to metals'.

Product labels should include the following:

- Protect from frost;
- Do not store at temperatures above 30 ºC;
- H290: may be corrosive to metals'.

Efficacy

The efficacy of the products in the family is demonstrated for use at concentrations of 0.158-2.47 % with a minimum contact time of 60 seconds for pre and post-milking.

To ensure sufficient contact time for post-milking application, care should be taken that the product is not removed after application (e.g. keep the cows standing at least 5 minutes).

The BPC considers that the following label claims have been supported:

Meta SPC 1

- For teat disinfection (kills bacteria and yeast) post-milking;
- Minimum contact time 60 seconds.

Meta SPC 2 & 3

- For teat disinfection (kills bacteria and yeast) pre-milking;
- For teat disinfection (kills bacteria and yeast) post-milking;
- Minimum contact time 60 seconds (for both pre and post milking applications).

Human health

For the purpose of the human health risk assessment, exposure to iodine arising from professional use of iodine products and via the diet was compared with the relevant upper limit (UL) values for iodine for adults (600 µg/day) and infants (200 µg/day). If the resulting exposure was below the iodine UL it was considered that the risks are acceptable.

The professional user is exposed during mixing and loading, application, and cleaning of the teats and the equipment. In addition, exposure from the biocidal use of these products can arise via the diet. The general public are also exposed via the diet through consumption of milk from treated cows following biocidal use. The human health exposure assessments are based on model calculations using models and default values from the HEAdhoc Recommendation no. 13 (January 2017). Pre, post and pre and post treatment, per milking event, for the product family are assessed.

However, at the BPC Human Health Working Group IV 2017, it was decided that the consumer risk assessment should not only consider the iodine exposure resulting from teat treatment with iodine-containing disinfectants, but also exposure to iodine from other sources. According to the European Food Safety Authority, milk and other dairy products are by far the main source of iodine in the human diet. However, it is noted that the level of iodine in milk varies greatly across Europe and is only partly due to teat treatment with iodine-containing disinfectants. The main non-biocidal factors influencing the level of iodine in milk are the dairy cattle diet (i.e. drinking water and grass), the use of iodine feed supplements, farming practices, seasonal variations and milk processing technologies. Other non-biocidal sources of iodine in the human diet include eggs, grain products, fish and iodized salt.

In order to undertake the consumer risk assessment, the Human Health Working Group, agreed harmonised values for background levels of iodine in milk and other dietary sources, as well as the approach to be taken for the consumer exposure assessment. The agreed background levels of iodine were 200 µg/L iodine from milk (EFSA monitoring data[1] and the O'Brien study, 2013[2]) and from sources other than milk, 185 µg/day for adults and 96

[1] EFSA Journal 2013;11(2):3101
[2] O'Brien et al. Iodine concentrations in milk. Irish Journal of Agricultural and Food Research 52: 209–216, 2013

µg/day for children (UK retail survey of iodine in UK produced dairy foods[3]).

It should be noted that the regulation of iodine exposure pathways that are not a consequence of biocidal use are outside the remit of the BPC. Where unacceptable risks are identified as a result of consideration of total dietary intake of iodine in addition to exposure arising from biocidal use, a risk management decision cannot be taken in isolation with respect to the biocides use only. It would be advisable that this issue is addressed at European level in order to ensure that all relevant regulatory bodies can be involved in agreeing a way forward.

Professional user risk assessment

It is necessary to consider combined exposure to iodine from primary exposure during application of the products and total dietary intake (agreed at the human health WG IV, 2017). When taking this into account, the following conclusions can be made:

For meta-SPC 1 applied post-milking only

- Acceptable combined exposure equivalent to 71% of the AEL for application via manual dipping is calculated without the use of PPE. Combined exposure equivalent to 84% of the AEL is calculated for application via spraying with the use of gloves, coated coveralls and chemical resistant boots.

For meta-SPC 2 & 3 applied pre –and/or post- milking, pre-milking or post-milking only

- Pre- and post- milking: Acceptable combined exposure equivalent to 71% of the AEL is calculated for application via dipping with the use of gloves. Combined exposure equivalent to 94% of the AEL is calculated for application via spraying with the use of gloves, coated coveralls and chemical resistant boots.
- Post-milking: Acceptable combined exposure equivalent to 87% of the AEL for application via manual dipping without the use of PPE. Combined exposure equivalent to 86% of the AEL is calculated for application via spraying with the use of gloves, coated coveralls and chemical resistant boots.
- Pre-milking: Acceptable combined exposure equivalent to 99% of the AEL for application via manual dipping without the use of PPE. Combined exposure equivalent to 98% of the AEL is calculated for application via spraying with the use of gloves.

Based on the exposure assessment and considering the hazard classification of each meta-SPC, the following PPE phrases are required:

Meta SPC 1 - concentrates	
Post- milking only	
Use 1.1 (post-milking, dipping)	Wear protective chemical resistant gloves and eye protection when handling the concentrate (glove material to be specified by the authorisation holder within the product information).
Use 1.2(post-milking, spraying)	Wear protective chemical resistant gloves and eye protection when handling the concentrate (glove material to be specified by the authorisation holder within the product information). Wear protective chemical resistant

[3] FSIS 02/08, 16 June 2008

	gloves and boots when applying the product by manual spraying (glove material to be specified by the authorisation holder within the product information). A protective coverall (at least type 6, EN 13034) shall be worn
Use 1.3 (post-milking, foaming)	Wear protective chemical resistant gloves and eye protection when handling the concentrate (glove material to be specified by the authorisation holder within the product information).
Meta SPC 2 & 3 – RTU liquids	
Pre-milking use only	
Use 2.1 & 3.1 (pre-milking, dipping)	-
Use 2.2 & 3.2 (pre-milking, spraying)	Wear protective chemical resistant gloves when applying the product by manual spraying (glove material to be specified by the authorisation holder within the product information)
Use 2.3 & 3.3 (pre-milking, foaming)	-
Post-milking use only	
Use 2.4 & 3.4 (post-milking, dipping)	-
Use 2.5 & 3.5 (post-milking, spraying)	Wear protective chemical resistant gloves and boots when applying the product by manual spraying (glove material to be specified by the authorisation holder within the product information). A protective coverall (at least type 6, EN 13034) shall be worn
Use 2.6 & 3.6 (post-milking, foaming)	-
Pre- and post- milking	
Use 2.7 & 3.7 (pre- and post-milking, dipping)	Wear protective chemical resistant gloves when applying the product by dipping (glove material to be specified by the authorisation holder within the product information).
Use 2.8 & 3.8 (pre- and post-milking, spraying)	Wear protective chemical resistant gloves and boots when applying the product by manual spraying (glove material to be specified by the authorisation holder within the product information). A protective coverall (at least type 6, EN 13034) shall be worn
Use 2.9 & 3.9 (pre- and post-milking, foaming)	Wear protective chemical resistant gloves when applying the product by foaming (glove material to be specified by the authorisation holder within the product information).

Consumer risk assessment

Dietary risk via iodine residues in milk and other dietary sources has been assessed for both adults and children.

When only exposures arising from the biocidal use are considered, acceptable risks are identified for both adults and toddlers following both pre-milking, post-milking and pre- and post-milking application.

However, when exposure arising from the biocidal use and total dietary intake are considered, an acceptable risk is identified for adults but an unacceptable risk is identified for toddlers following both pre-milking, post-milking and pre- and post-milking application.

It should be noted that the unacceptable risk identified for toddlers is mainly due to exposure to iodine from sources other than the biocidal use, accounting for 94% of the iodine UL.

A more elaborate discussion and proposal is included in the conclusions of this BPC opinion (see below).

Environment

With regards to the active substance iodine, the environmental exposure assessment confirms that there is no unacceptable risk in any relevant environmental compartment through the proposed uses of these iodine containing teat dips (Scenario 1). Whilst some PEC/PNEC ratios are in excess of 1, the BPC considers maximum PEC values to be below natural background levels of iodine in all instances. The iodine exposure calculations are based upon a worst case scenario of two milkings per day using a spray application of Ioklene concentrate pre and Intelliblend concentrate post milking- the exposure assessment covers the risk for iodine from all products within the product family (all meta SPC's) up to two milkings per day.

With the exception of Iodoshield Active (meta SPC 3, which has not been authorised), all products in all other meta SPC's within the product family show an acceptable risk to the environment up to two milkings per day.

Overall conclusion

Overall, when exposure arising from biocides use is considered in isolation, no unacceptable risks are identified for professional users if appropriate PPE is worn for the relevant uses or for the general public as a result of the consumer risk assessment.

Once exposure from biocides use is considered in conjunction with total dietary exposure of iodine, acceptable risks are still identified for professional users if appropriate risk mitigation measures are in place and for adults following exposure to iodine in the diet. However, an unacceptable risk is identified for toddlers which is mainly due to exposure from non-biocidal sources of iodine accounting for 94% of the UL for toddlers.

The regulation of iodine exposure pathways that are not a consequence of biocidal use are outside the remit of the BPC. Unacceptable risks have been identified as a result of consideration of total dietary intake of iodine in addition to exposure arising from biocidal use. Thus it is not considered appropriate to take risk management decisions in isolation with respect to the biocides use to address concerns that arise from the risk assessment. It would be advisable that this issue is addressed at European level in order to ensure that all relevant regulatory bodies can be involved in agreeing a way forward.

It is noted that the impact of taking into account total dietary exposure of iodine is not a new issue. In an EFSA scientific opinion intakes were reported to exceed the UL 2-fold for adults and 4-fold for toddlers with the current authorised maximum contents of total iodine in complete feed of 5 mg/kg. As a result of these exceedances, the FEEDAP Panel of EFSA recommended a reduction for iodine in feed of 2 mg/kg. However, even this reduced value would lead to exceedance of the iodine UL of the high consuming toddler (168% of the UL).

The following elements were taken into consideration for a decision on the authorisation of iodine teat disinfection products:

- The reference values for iodine of 600 µg/d for adults and 200 µg/d for children are not toxicological reference values but upper intake levels. These values have been derived with the aim of setting recommendations for intake and do not represent toxicological cut-off values for risk assessment. For trace elements like iodine, generally no toxicologically cut-off values are set. Therefore, it was agreed at Human Health Working Group II-2017 to use the upper intake levels as reference values. Furthermore, it is noted that effects that were taken into account for the derivation of the limit values were considered marginal and not associated with clinical effects. Moreover, the assessment factor taken into account is relatively high for a nutrient. It is further noted that WHO derived a value of 1000 µg/d for people in general but not for children specifically. Therefore, the limit values used in this assessment are considered conservative.

- The estimated intakes are based on theoretical worst case levels of iodine in milk and were calculated based on a chronic exposure, which was considered to be the most appropriate based on how the UL was derived. Furthermore, it is noted that the SCF (from which the UL for adult and toddler are included in the CAR for iodine) also reports adapted UL values for older children. As the estimated residue levels of iodine in milk are based on a worst case assessment and the data are based on short term consumption studies, then the intakes seen in reality may not be of concern if the lifelong exposures from varying sources of food were considered.

- Within Europe iodine deficiency is considered a major public health problem and iodine supplementation programs are ongoing nationally and internationally to improve the iodine intake and thereby to prevent consequences for public health, e.g. by the addition of iodine in food or salt (e.g. The Netherlands) or the advice to use iodine containing dietary supplements. Other EU countries (e.g. United Kingdom, Czech Republic) regulate adequate iodine intake through addition of iodine to cattle feed. Although it is recognised that both insufficient and excessive iodine intakes can cause diseases, it is generally considered that the benefits of the prevention of diseases from iodine deficiency far outweighs possible side-effects of oversupply.

- The actual amount of iodine intake in the EU is highly variable and difficult to estimate, as levels of iodine intake depend on the geographical location, the soil, people's diet, the season, farming practices, iodine fortification of feed for dairy animals, iodine supplementation programs and other factors. From iodine supplementation programs, monitoring data on iodine nutrition will become available and a clearer picture of the iodine status across Europe will emerge. It has been discussed in the CA-meeting whether the generation of additional data on residue levels from teat disinfection in milk should be requested from applicants for post-authorisation. However, in the September 2017 CA meeting it was agreed that such a requirement cannot be imposed to the applicants for product authorisation.

To summarise, taking all information into consideration and noting that:

- the assessment is based on worst case theoretical levels of iodine in milk, using a conservative limit value and using worst case short term exposure studies for long term exposure;
- 94% of UL for toddlers in the dietary assessment is due to used background in milk and other dietary sources;
- exceedance of the UL is reported based on dietary intake (without teat disinfection) and the biocidal use itself is not responsible for the exceedance of the UL for toddlers;
- the major contributor of iodine in milk is feed, due to natural sources and/or supplements;
- the authorized maximum iodine of 5 mg/kg content in feed leads to 400% of the UL for toddlers;
- within Europe iodine deficiency is considered a major public health problem and iodine supplementation programs are ongoing,

the BPC considers that using the products belonging to this biocidal product family according to the conditions as stated in the SPC, the products will be efficacious and will not by themselves present an unacceptable risk to human and animal health nor the environment.

b) Presentation of the biocidal product / 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 description of the uses proposed to be authorised are available in the SPC.

d) Comparative assessment

The active substance iodine 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 in accordance with Article 23 of the BPR 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 use(s) 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 uses, 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 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 products 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 products on non-target organisms,
    - the impact of the biocidal products on biodiversity and the ecosystem.

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

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

It is proposed that biocidal product family Iodine Teat Dip Products based on Iodine shall be authorised for the uses described under section 2.1 of this opinion, subject to compliance with the proposed SPC**.**

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Annex I: draft Summary of Product Characteristics