

Biocidal Products Committee (BPC)

Opinion on the Union authorisation of Ecolab Iodine PT3 Family

ECHA/BPC/177/2017

Adopted

12 December 2017

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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 application for Union authorisation of:

Name of the biocidal product family: Ecolab Iodine PT3 Family

Authorisation holder: Ecolab Deutschland GmbH

Active substance common name: Iodine, including polyvinylpyrrolidone 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 23 July 2015, it was recorded in R4BP3 under case number BC-VG018734-32. The evaluating Competent Authority (The Netherlands) 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 2017. In order to review the draft PAR, the conclusions of the eCA and the draft SPC, the Agency organised consultations via the BPC (BPC-23) and its Working Groups (WG-IV-2017). 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 was adopted on 12 December 2017.

The BPC opinion was adopted by consensus. The opinion is published on ECHA webpage.

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 referred to in Article 22(2) of Regulation (EU) No 528/2012 for the Ecolab Iodine PT3 Family (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.

General

The biocidal product family 'Ecolab Iodine PT3 Family' consists of products containing 1% to 3% of the Polyvinylpyrrolidone-iodine (PVP-iodine) for disinfection of teats of milk producing animals like dairy cows, buffaloes, sheep and goats. The biocidal product family consists of 6 meta SPCs, each containing 1 or 2 products. The structuring of the BPF into meta SPCs was based on:

- The hazard and precautionary statements (no product is classified in meta SPCs 1,2, 4-6, H412 applies for meta SPC 3);
- Application method (manual or automated dipping, spraying);
- Target organisms (bacteria, yeast or enveloped viruses);
- The shelf-life: 18 months for meta SPC 5 and 24 months for meta SPC 1-4 and 6.

The following uses have been assessed:

- meta SPC 1 : Dipping, post-milking
 - Use 1.1: Teat dips for post-milking disinfection
- meta SPC 2 : Dipping, post-milking, virucidal
 - Use 2.1: Teat dips for post-milking disinfection
- meta SPC 3 : Dipping or spraying, pre- or post-milking
 - Use 3.1: Teat dips or sprays for post-milking disinfection, including virucidal activity
 - Use 3.2: Teat dips or sprays for pre-milking disinfection
- meta SPC 4 : Dipping or spraying, post-milking, including virucidal activity
 - Use 4.1: Teat dips or sprays for post-milking disinfection
- meta SPC 5 : Dipping, post-milking, virucidal activity
 - Use 5.1: Teat dips for post-milking disinfection
- meta SPC 6: Dipping or spraying, post-milking, including virucidal activity
 - Use 6.1: Teat dips or sprays for post-milking disinfection

Physico-chemical properties

The products within the family typically have the characteristic dark brown to amber colour and odour of iodine dispersions. The pH of the products within the family ranges from approximately 2.4 to 6 and the density is around 1.0 g/mL.

Although the products within the family are stabilised, the degradation of iodine exceeded 10% in some studies. Efficacy trials showed products can generally be adequately used after 24 months storage (meta SPCs 1 to 4 and 6), with the exception of meta SPC 5, which has a shelf-life of 18 months. Products should generally be protected from high temperatures, but are resistant to low temperatures. The storage conditions prescribe storage at 5 to 25°C, away from direct sunlight. With regard to classification and labelling, none of the products needs to be classified with regard to physical and chemical hazards.

Efficacy

All tested products of the iodine product family demonstrated a bactericidal and yeasticidal efficacy at the intended use concentrations of 1% to 3% PVP-iodine according to standard lab tests (EN 1656, EN 1657) under test conditions defined for teat disinfection. Furthermore, as a standard simulated-use test is not available, a modified EN 1500 has been used to demonstrate efficacy against microbes attached to skin.

The virucidal efficacy against Vaccinia virus, as a representative species for enveloped viruses, has been proven according to EN 14476 (phase 2, step 1) version EN 14476:2013/FprA1:2014 modified to meet veterinary conditions. The activity against enveloped viruses is claimed in products for post milking teat disinfection only.

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

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). Acceptable risks were identified if exposure was below the iodine UL.

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 (Jan. 2017). Either pre- or post-treatment per milking event for the product family is assessed, since products included in the product family can only be used for pre- or post-application. This is also reflected in the instruction included in the section for general risk mitigation measures (RMM) of the SPC.

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 data¹ and the O'Brien study, 2013²) and from sources other than milk, 185 µg/day for adults and 96 µg/day for children (UK retail survey of iodine in UK produced dairy foods³).

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

Professional use, pre-milking application - BPF first level

When only exposures arising from the biocidal use are considered, acceptable risks are identified for pre-milking disinfection by manual dipping without PPE and for pre-milking disinfection by manual spraying using a trigger or electronic sprayer when appropriate PPE is worn (chemical resistant gloves).

When exposure arising from biocidal use and total dietary intake are considered, acceptable risks are identified for pre-milking disinfection by manual dipping assuming appropriate PPE is worn (chemical resistant gloves; 62% of the UL). For pre-milking disinfection by manual spraying using a trigger or electronic sprayer, the UL is exceeded, even when PPE is worn (110% and 108% of the UL, respectively).

It is noted that the evaluation of meta SPC 3 (see below) shows a safe use for a professional user wearing chemical resistant gloves when the concentration of total iodine is 0.44% in products used for pre-milking application trigger sprayer or electronic sprayer. Thus, while a possible risk mitigation measure would be to reduce the maximum concentration of total iodine in the BPF to 0.44%, this would be biocides acting in isolation especially given the contribution of non-biocidal sources of iodine to the unacceptable risk.

Professional use, pre-milking application - meta SPC level: meta SPC 3

When only exposures arising from the biocidal use are considered, acceptable risks are identified for manual dipping without PPE and for manual spraying using a trigger or electronic sprayer when appropriate PPE is worn (chemical resistant gloves).

When exposure arising from biocidal use and total dietary intake are considered, acceptable risks are identified for pre-milking disinfection by manual dipping with products included in meta SPC 3 without the need for PPE (100 % of the iodine UL). For pre-milking disinfection by manual spraying using a trigger sprayer or electronic sprayer, acceptable risks are identified assuming appropriate PPE is worn (chemical resistant gloves; 98% and 96% of the UL, respectively).

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

³ FSIS 02/08, 16 June 2008

Professional use, post-milking application - BPF first level

When only exposures arising from the biocidal use are considered, acceptable risks are identified for post-milking disinfection by manual dipping and automated spraying without the need for PPE and for post-milking disinfection by manual spraying using a trigger or electronic sprayer when appropriate PPE is worn (chemical resistant gloves).

When exposure arising from biocidal use and total dietary intake are considered, acceptable risks are identified for post-milking disinfection by manual dipping and automated spraying without the need for PPE (83% and 64 % of the iodine UL, respectively). For post-milking disinfection by manual spraying using a trigger or electronic sprayer, unacceptable risks are identified, even when PPE is worn (109% and 106 % of the UL, respectively).

It is noted that the evaluation of meta SPC 3 (see below) shows a safe use for a professional user wearing chemical resistant gloves when the total concentration of iodine is 0.44% in products used for post-milking application by manual spraying by trigger sprayer or electronic sprayer. Thus, while a possible risk mitigation measure would be to reduce, the maximum concentration of total iodine in the BPF to 0.44%, this would be biocides acting in isolation especially given the contribution of non-biocidal sources of iodine to the unacceptable risk.

Professional use, post-milking application- meta SPC level

As post-milking disinfection by manual dipping and automated spraying at a concentration of 0.58% total iodine showed acceptable risks (see BPF above) when both biocide only use and biocide use and total dietary intake were considered, these application methods are also considered to show acceptable risks for the meta SPC's 1 to 5 where the maximum concentration of total iodine is 0.44 %.

For post-milking disinfection by manual spraying using a trigger or electronic sprayer, an acceptable risk is identified for both biocide only use and biocide use and total dietary intake, at the highest concentration of total iodine of 0.44% in the meta SPC's when appropriate PPE is worn (chemical resistant gloves).

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 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 and post-milking application. As a result the assessment was also performed at meta SPC level and the same conclusions were found.

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 draft BPC opinion (see below).

Environment

Teat disinfectants are released to the environment due to spillage during application, cleaning of the applied equipment, and dripping from animal's teats and udders. As most dairy farms are not connected to the public sewer, residues are predominantly discharged to the manure storage and eventually to soils when manure is applied as a fertiliser. Iodine is not volatile and is persistent as it does not degrade biologically or abiotically. Depending on the redox conditions and acidity, iodine will be transformed into iodide or iodate. Both species exist in water, but iodate is the dominant species in soils.

When residues are released to the municipal sewer, no unacceptable risks are identified for micro-organisms in the sewage treatment plant, and aquatic organisms in surface water and sediment as all predicted environmental concentrations (PECs) are well below the predicted no-effect concentrations (PNECs). Although the iodine concentrations in soils after distribution of sewage sludge on land does result in an exceeding of the PNEC, no unacceptable risks are expected as soils are aerobic and therefore iodine is transformed into iodate for which the PEC is well below the PNEC. However, emission to individual waste water treatment systems may result in malfunctioning of the installation as such systems are vulnerable for high loads of biocides due to their size. Diluted residues and waste water must be discharged to the sewer where legally allowed or to the manure storage.

Release via manure results in unacceptable risks for surface water adjacent agricultural soils (PEC:PNEC ratios up to 8.05) due to runoff and concentrations in groundwater (30-50 µg iodine/L) that are well above the 0.1 µg/L threshold and acceptable human intake limits. However, the calculated concentrations are within the natural background range (0.5-70 µg/L). Because iodine is a naturally occurring compound and many uncertainties exist in the applied methodology as appropriate models for runoff to surface water and leaching to groundwater are not available for inorganic substances like iodine, background concentration has been accepted as standard. From an environmental perspective the application of iodine-based teat disinfectants is therefore acceptable. No risk mitigation measures are necessary.

Overall conclusion

Overall, when exposure arising from biocides use is considered in isolation, no unacceptable risks are identified for professional users if PPE is worn as appropriate 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 lead 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 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 are 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 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 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 individual biocidal products.

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;
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

It is proposed that biocidal product family Ecolab Iodine PT3 Family 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