

Biocidal Products Committee (BPC)

Opinion on the Union authorisation of:

Boumatic Iodine product family

ECHA/BPC/220/2019

Adopted

27 February 2019

Opinion of the Biocidal Products Committee

on the Union authorisation of the Boumatic Iodine 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: Boumatic Iodine product family

Authorisation holder: Boumatic

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 21 August 2015, recorded in R4BP3 under case number BC-PG019260-52, 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 10 April 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-29) and its Working Groups (WG-VII-2018). Revisions agreed upon were presented and the draft PAR and the draft SPC were finalised accordingly.

Adoption of the BPC opinion

Rapporteur: The Netherlands

The BPC opinion on the Union authorisation of the biocidal product family was reached on 27 February 2019.

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 the Boumatic Iodine product family 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.

General

The Boumatic Iodine product family consists of products containing the active substance iodine (0.26-0.5%) for disinfection of teats. Fatty alcohol ethoxylated is identified as a substance of concern due to its classification for certain human endpoints. The biocidal product family (BPF) consists of 3 meta SPCs, each containing 1 or 2 products.

The following uses have been assessed:

meta SPC 1:

- Use 1.1: Manual dip treatment, pre- or post-milking teat disinfectants;
- Use 1.2: Manual spraying treatment, pre- or post-milking teat disinfectants;
- Use 1.3: Automated dip treatment, pre- or post-milking teat disinfectants;
- Use 1.4: Automated spraying treatment, pre- or post-milking teat disinfectants;

meta SPC 2:

- Use 2.1: Manual dip treatment, post milking teat disinfectants;
- Use 2.2: Manual spraying treatment, post milking teat disinfectants;
- Use 2.3: Automated dip treatment, post milking teat disinfectants;
- Use 2.4: Automated spraying treatment, post milking teat disinfectants;

meta SPC 3:

- Use 3.1: Manual dip treatment, post milking teat disinfectants;
- Use 3.2: Manual spraying treatment, post milking teat disinfectants;
- Use 3.3: Automated dip treatment, post milking teat disinfectants;
- Use 3.4: Automated spraying treatment, post milking teat disinfectants.

Physico-chemical properties

The products within the family are ready to use (yellow to) brown liquids, with a characteristic iodine odour. All products in meta-SPC 1 and 3 are stable at ambient temperature during 24 months in HDPE packaging. The shelf life for products in meta-SPC 2 is 12 months in HDPE packaging. pH-measurements on all 4 products of the 3 meta-SPCs were performed. Given the ranges of ingredient concentrations in the meta SPC's, the pH level will remain between 4 and 6. Values between these limits will not require any additional considerations. The provided data are considered to cover the complete family including non-existing theoretical products.

None of the products within the family need to be classified with regard to physical and chemical properties.

Efficacy

The biocidal products in this family have bactericidal and yeasticidal activity. This has been demonstrated for the worst case product for these meta SPCs, according to the international guidelines EN 1656 and EN 1657. In addition, as a standard simulated-use test is not available, a modified EN 16437 has been used to demonstrate efficacy against bacteria attached to skin. 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). 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 is 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). For the professional user risk assessment either pre- (meta SPC 1) or post-milking (meta SPC 1-3) is evaluated, as the dietary risk assessment shows that pre- and post-milking would result in exceeding the UL for toddlers (see below at consumer risk assessment). For meta SPC1 intended for pre-treatment, the following is reflected in the risk mitigation measures (RMM) section of the SPC: In case a combination of pre- and post-milking disinfection is necessary, using another biocidal product not containing iodine has to be considered for post-milking disinfection. For meta SPCs intended for post-treatment, the following is reflected in the risk mitigation measures (RMM) section of the SPC: in case a combination of pre- and post-milking disinfection is necessary, using another biocidal product not containing iodine has to be considered for pre-milking disinfection. This RMM has been agreed upon previously by the BPC when discussing other UAs on iodine-based products for teat disinfection.

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

Meta SPC1 is the only meta SPC which includes pre-milking application (by manual dipping or spraying).

When only exposures arising from the biocidal use are considered, acceptable risks are identified for pre-milking disinfection by manual dipping or by automated dipping/spraying applications without PPE and for manual spraying using a trigger sprayer or electronic sprayer when appropriate PPE is worn (chemical resistant gloves). For pre-milking disinfection by automated dipping/spraying application no PPE is necessary for safe use.

When exposure arising from biocidal use and total dietary intake are considered, for pre-milking disinfection by manual dipping chemical resistant gloves are needed for safe use (75 % of the iodine UL for meta SPC1). For pre-milking disinfection by manual spraying application using a trigger sprayer or electronic sprayer, chemical resistant gloves, protective clothing and chemical resistant boots are needed for safe use (92 % of the iodine UL for meta SPC1). For pre-milking disinfection by automated dipping/spraying application no PPE is necessary for safe use (90 % of the iodine UL for meta SPC1).

Professional use, post-milking application

When only exposures arising from the biocidal use are considered, acceptable risks are identified for post-milking disinfection by manual dipping without PPE and for manual spraying using a trigger sprayer or electronic sprayer when appropriate PPE is worn (chemical resistant gloves) for calculations with the worst case of 0.5% total iodine. For post-milking disinfection by automated dipping/spraying application no PPE is necessary for safe use.

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

When exposure arising from biocidal use and total dietary intake are considered, acceptable risks are identified for post-milking disinfection by manual dipping or automated dipping/spraying with products included in meta SPC 2 without the need for PPE (as the max. total iodine concentration is below 0.41% which is the limit for safe use without gloves) or when appropriate PPE is worn (chemical resistant gloves, meta SPC 1 and 3 max. 79% of the UL for both meta SPCs). Acceptable risks are identified for post-milking disinfection by spraying with trigger sprayer or electronic sprayer with products included in meta SPC 1-3 with appropriate PPE (chemical resistant gloves for meta SPC2, max 100 % of the iodine UL when the maximum concentration in metaSPC2 is reduced to 0.36% total iodine or chemical resistant gloves, coveralls and chemical resistant boots for meta SPC 1 and 3, max. 94% of the iodine UL).

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 or post-milking.

Although the intended use includes either pre- or post-milking, products could be combined and therefore this is assessed. Combined pre- and post-milking teat disinfection results in 161% UL for toddlers by exposure to residues due to treatment. Therefore, the combination of pre- and post-milking is considered not safe therefore, the following risk mitigation measure needs to be included in paragraph 5.2 of the SPC: In case a combination of pre- and post-milking disinfection is necessary, using another biocidal product not containing iodine has to be considered for pre- or post-milking disinfection.

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

For all metaSPCs the UL for toddlers is exceeded when taken into account teat disinfection and dietary intake.

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

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 levels up to 2.30 µg/L iodine in surface water adjacent to agricultural soils due to runoff, resulting in PEC:PNEC ratios up to 3.90. In addition concentrations in groundwater above the 0.1 µg/L threshold are indicated (14-23 µg iodine/L) However, the calculated concentrations for iodine are within the natural background range of 0.5–20 µg/L for surface water and 1-70 µg/L for groundwater. Because iodine is a natural 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), the background concentration has been accepted as a threshold which cannot be exceeded. 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 appropriate PPE is worn 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 (160% 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 background levels in milk and other dietary sources not related to biocidal use;
- 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 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 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 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;
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

It is proposed that biocidal product family Boumatic Iodine product 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