

Biocidal Products Committee (BPC)

Opinion on the Union authorisation of
Teat disinfectants biocidal product family of Novadan

ECHA/BPC/215/2018

Adopted

18 October 2018

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:	Teat disinfectants biocidal product family of Novadan
Authorisation holder:	Novadan ApS
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 27 August 2015, recorded in R4BP3 under case number BC-YV019394-00, 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 11 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-27) and its Working Groups (WG IV 2018). Revisions agreed upon were presented and the draft PAR and the draft SPC were finalised accordingly.

Adoption of the BPC opinion

Rapporteur: Denmark

The BPC opinion on the Union authorisation of the biocidal product family was reached on 18 October 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 Teat disinfectants biocidal product family of Novadan 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

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

General

The biocidal product family "Teat disinfectants biocidal product family of Novadan" consists of products containing 0.714-3.57% of polyvinylpyrrolidone (PVP) iodine (corresponding to 0.15-0.75% available iodine) for post-milking disinfection of teats of milk producing animals (cow, buffalo, sheep, and goat). The products of the biocidal product family "Teat disinfectants biocidal product family of Novadan" do not contain co-formulants which can be considered as a substance of concern.

The biocidal product family (BPF) consists of 6 meta-SPC's, each containing 1 product. The products within the BPF consist of 1 soluble concentrate (SL) and 5 ready-to-use (RTU) products. The concentrate is to be diluted before use.

The structuring of the BPF into meta-SPCs was based on:

- Classification and labelling (no classification for meta-SPC 3 and 4, H412: Harmful to aquatic life with long lasting effects for meta-SPC 1, 2, 5 and 6, H290: May be corrosive to metals for meta-SPC 1);
- Application method (dipping or dipping/spraying);
- Type of formulation (SL (soluble concentrate), AL (any other liquid) or EW (emulsion, oil in water)).

The following uses have been assessed:

- Use 1.1: Post-milking manual dipping (This applies to meta-SPC 1 to meta-SPC 6)
- Use 1.2: Post-milking manual spraying using a trigger sprayer (This applies to meta-SPC 1, meta-SPC 4, meta-SPC 5 and meta-SPC 6)
- Use 1.3: Post-milking manual spraying using an electronic sprayer (This applies to meta-SPC 1, meta-SPC 4, meta-SPC 5 and meta-SPC 6)
- Use 1.4: Post-milking automated dipping (This applies to meta-SPC 1 to meta-SPC 6)
- Use 1.5: Post-milking automated spraying by robot (This applies to meta-SPC 1, meta-SPC 4, meta-SPC 5 and meta-SPC 6)

Physico-chemical properties

The products within the family have a rust brown colour with a very weak odour for iodine. The pH of the products within the family ranges from 4 to 5, the density is around 1.0 g/mL. The pH declines very little during storage, however stays in the range 4 to 6.

Although the products within the family are stabilised, the degradation of iodine exceeded 10 % in the accelerated stability studies and long term studies, which were provided to support stability of the products. Considering the accelerated storage stability studies the products should generally be protected from high temperatures (storage $\leq 30^{\circ}\text{C}$), frost and be kept away from sunlight in opaque containers to avoid degradation. Long term stability studies were considered acceptable for Meta-SPC 1, 2, 4, 5 and 6. The long term stability studies were not considered acceptable for meta-SPC 3, however stability was supported by efficacy studies performed with products after storage.

One of the products within the family in meta-SPC 1 should be classified with regard to physical and chemical properties as corrosive to metals, Category 1, H290 May be corrosive to metals. None of the other meta-SPCs within the family requires classification.

Efficacy

All tested products of the product family demonstrated a bactericidal and yeasticidal efficacy at the intended use concentration in the range of 0.15-0.3066% available iodine according to standard lab tests (EN 1656 and EN 1657) under test conditions defined for teat disinfection. In addition, the bactericidal activity was demonstrated according to the modified test method EN 16437 for porous surfaces using synthetic skin as surface carrier (phase 2, step 2). The results comply with the requirements for post-milking applications after 5 minutes contact time. 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 $\mu\text{g}/\text{day}$) and infants (200 $\mu\text{g}/\text{day}$). 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 (Jan. 2017) – "Exposure Assessment of Teat Disinfection Products

for Veterinary Hygiene (PT3)". As a first step, exposure assessments are performed for all individual scenarios which are relevant for post-milking teat disinfection considering the highest total iodine concentrations. In a second step, the exposure calculated for the individual work tasks are combined for the relevant individual treatments:

At 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, post-milking application (twice per day; same milker)

It is necessary to consider combined exposure to iodine from primary exposure during application of the BPF and total dietary intake (agreed at the human health WG IV, 2017).

When exposure arising from biocidal use and total dietary intake (3 application per day as worst case in the dietary exposure calculation while 2 times per day are used in the exposure assessment for the professional milker since an additional milker would be needed for milking >82 cows per day) are considered, acceptable risks are identified for post-milking application/disinfection without the use of PPE (gloves) for the following tasks

- manual dipping using a dip cup (concentrate and RTU products; meta-SPC 1 to meta-SPC 6);
- automated dipping (concentrate and RTU products; meta-SPC 1 to meta-SPC 6);
- automated spraying by robot (concentrate and RTU products; meta-SPC 1 and meta-SPC 4 to meta-SPC 6).

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 **only** identified for post-milking application **when PPE (gloves)** is used during application for **manual spraying with the concentrate and RTU products** (meta SPC 1 and meta-SPC 4 to meta-SPC 6) using a **trigger sprayer or electronic sprayer**.

Consumer risk assessment

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

For adults, the estimated daily iodine intake resulting from biocidal use is at maximum 17% of the UL. When adding background values for iodine in milk, daily iodine intake is at maximum 32% of the UL. Finally, the total dietary intake of iodine resulting from milk consumption and from other dietary sources is at maximum 63% of the UL. Based on a worst case assumption of three manual milking's per day the total dietary intake of iodine resulting from milk consumption and from other dietary sources is at maximum 63% of the UL.

For toddlers, the estimated daily iodine intake resulting from biocidal use is at maximum 52% of the UL. When adding background values for iodine in milk, daily iodine intake is at maximum 98% of the UL. Finally, the total dietary intake of iodine resulting from milk consumption and from other dietary sources is at maximum 146% of the UL. Based on a worst case assumption of three manual milking's per day the total dietary intake of iodine resulting from milk consumption and from other dietary sources is at maximum 146% of the UL.

Environment

The exposure of teat-disinfectants to the environment is via application of manure/slurry to agricultural land or by release from the facility drain to a sewage treatment plant and subsequent compartments.

The risk assessment follows the Emission Scenario Document for PT3 and is based on identified worst case for the biocidal product family, which is the use of a ready-to-use product containing 4.24 g/L total iodine. The use of the product applied post-milking for 3 milkings per day by dipping or spraying. An application volume of 4 mL has been assessed, but the conclusions are valid also for the worst case application volume of 15 mL.

The PEC/PNEC values for the compartments surface water and soil exceed 1 up to a factor of 14.4. However, iodine is found natural in the environment, and therefore the PEC values should be compared to the natural background level for iodine in the different environmental compartments. The calculated PEC values for surface water, soil and groundwater are all well within the natural background level. Hence, it can be concluded that there is no unacceptable risk for the environment from the proposed use of the teat disinfectant products.

Conclusion

Human health risk is acceptable for all milking applications based on estimated intakes, except for toddlers, where total daily intake considerably exceeds the UL in all scenarios (based on both the worst case assessments and the realistic worst case assessments for both adults and toddlers). Iodine from toddler dietary intake, arising from every other source except from iodine containing teat disinfection product residues, takes up almost the whole fraction of the UL if current EU data is used. It is considered important to obtain more reliable information on iodine background levels in food items in the EU, and consequently to update the data supporting the current UL.

Following the same approach as for the other iodine UA, which has been discussed at WG and BPC, the following has been taken into consideration for the proposed 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. It is further noted that WHO derived a value of 1000 µg/d for adults but no value for children was set. The UL for children is set by an extrapolation from adults. In the EFSA document 'Tolerable Upper Intake Levels for Vitamins and Minerals' published in 2006, the UL's for children were derived by adjustment of the adult UL on the basis of body surface area (body weight^{0.75}). This is not considered optimal considering the different activity of the thyroid gland between adults and toddlers. There are at present no alternative to the extrapolation due to lack of data from toddlers. At the moment, it is not possible to obtain a better setting of the UL due to gaps in knowledge.
- 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 toddlers are included in the CAR for iodine) also reports adapted UL values for older children. 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.
- Within Europe iodine deficiency is considered a major public health problem and iodine supplementation programs are on-going 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. It is recognised that both insufficient and excessive iodine intakes can cause diseases.

- 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. Furthermore, it was acknowledged that biocides are not the main contributor of the exposure level and more discussion was needed.

The BPC concludes that all available data have been provided to verify the outcome and conclusions, and permit authorisation of the biocidal product family. When 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 present an unacceptable risk to human and animal health nor the environment. It is considered important to obtain more reliable information on iodine background levels in food items in the EU, and consequently to update the data supporting the current UL. 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.

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 is described in the PAR. The description of the uses proposed to be authorised are available in the SPC.

d) 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 or unnecessary suffering and pain for vertebrates;
3. the biocidal product family has no immediate or delayed unacceptable effects itself, or as a result of its residues, on the health of humans, including that of vulnerable groups, or animals, directly or through drinking water, food, feed, air, or through other indirect effects;
4. the biocidal product family has no unacceptable effects itself, or as a result of its residues, on the environment, having particular regard to the following considerations:
 - the fate and distribution of the biocidal product 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/biocidal product family

It is proposed that the Teat disinfectants biocidal product family of Novadan BPF 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