Biocidal Products Committee (BPC)

Opinion on the Union authorisation of

Deosan Activate BPF based on Iodine

ECHA/BPC/207/2018

Adopted

28 June 2018

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Opinion of the Biocidal Products Committee

on the Union authorisation of Deosan Activate BPF based on Iodine

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: Deosan Activate BPF based on Iodine

Authorisation holder: Diversey Europe Operations B.V.

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 7 July 2015, recorded in R4BP3 under case number BC-JN018376-30, 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 20 December 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-26) and its Working Groups (WG II 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 28 June 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 DEOSAN ACTIVATE 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 Deosan Activate BPF based on Iodione consists of products containing the active substance iodine for disinfection of teats. Iodine is formulated into the products as pure iodine (0.3-1.6%). No substances of concern were identified in the formulation.

The biocidal product family (BPF) consists of 3 meta SPCs containing the following number of products:

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

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

- content of iodine;
- application method (manual or automated dipping, spraying, foaming);
- formulation type (meta SPC 1: soluble concentrate; meta SPC 2: RTU liquid; meta SPC 3: RTU gel).

The following uses have been assessed:

***meta* SPC 1 :**

- Use # 1 – Pre-milking disinfection, Manual dipping (concentrate)
- Use # 2 – Pre-milking disinfection, Manual foaming (concentrate)
- Use # 3 – Pre-milking disinfection, Manual spraying (concentrate)
- Use # 4 – Post-milking disinfection, Manual dipping (concentrate)

- Use # 5 – Post-milking disinfection, Manual foaming (concentrate)
- Use # 6 – Post-milking disinfection, Manual spraying (concentrate)
- Use # 7 – Post-milking disinfection, Automatic spraying (not to be combined with a pre-milking disinfection (concentrate)
- Use # 8 – Post-milking disinfection, Semi-automatic dipping (concentrate)
- Use # 9 Pre and post-milking disinfection, Manual dipping (concentrate)
- Use # 10 Pre and post-milking disinfection, Manual foaming (concentrate)
- Use # 11 Pre and post-milking disinfection, Manual spraying (concentrate)

***meta* SPC 2 :**

- Use # 12 Pre-milking disinfection, Manual dipping (RTU liquid)
- Use # 13 – Pre-milking disinfection, Manual foaming (RTU liquid)
- Use # 14 Pre-milking disinfection, Manual spraying (RTU liquid)
- Use # 15 – Post-milking disinfection, Manual dipping (RTU liquid)
- Use # 16 – Post-milking disinfection, Manual foaming (RTU liquid)
- Use # 17 – Post-milking disinfection, Manual spraying (RTU liquid)
- Use # 18 – Post-milking disinfection, Automatic spraying (not to be combined with a pre-milking disinfection (RTU liquid)
- Use # 19 – Post-milking disinfection, Semi-automatic dipping (RTU liquid)
- Use # 20 – Pre and post milking disinfection, manual dipping (RTU liquid)
- Use # 21 – Pre and post milking disinfection, manual foaming (RTU liquid)
- Use # 22 – Pre and post milking disinfection, manual spraying (RTU liquid)

***meta* SPC 3 :**

- Use # 23 – Pre-milking disinfection, Manual dipping (RTU gel)
- Use # 24 – Post-milking disinfection, Manual dipping (RTU gel)
- Use # 25 – Post-milking disinfection, Semi-automatic dipping (RTU gel)
- Use # 26 – Pre and post-milking disinfection, manual dipping (RTU gel)

Physico-chemical properties

The physical, chemical and technical properties of the Deosan Activate product family are acceptable for the three formulation types, soluble concentrate, ready to use liquid and water soluble gel (ready to use), and therefore each meta SPC. For a number of properties, data for the ready to use liquids can be read across from the concentrated products. Therefore the data provided are sufficient to support the BPF requested (see confidential annex of the PAR for details).

Accelerated storage data for both the concentrated products were acceptable, therefore long term storage data were only collected for one product – Deosan Activate Pre AG106. These data can be used to support the storage stability for the other concentrate product and therefore the whole meta SPC.

Long term storage stability data were provided for product Deosan Activate PVP Plus AG215 supporting a shelf life of 24 months. These data can be extrapolated to support all products in meta SPC 2.

Data were provided for the ready to use gel for both accelerated and long term storage. After 24 months the iodine content decreased by 24 %. Based on the storage stability data alone, a shelf life of 6 months is supported. It is noted that the applicant has

provided efficacy studies which support a longer shelf life (18 months) for the product. Please see the efficacy section (section 2.2.5 of the PAR) for the outcome for the evaluation of the relevant studies.

Where the active substance content decreases by > 10 % during the storage stability study, it is required to investigate, in addition to whether the product is still efficacious, whether any compounds are formed that may influence the risk assessment e.g. hazardous metabolites. Iodine is a common oxidising agent. Generally iodine oxidises a compound to form iodide and an oxidised compound. The oxidised compounds would be expected to be hard to identify, and unlikely to pose a significant risk. Iodide would also not cause a significant risk. Therefore, no additional work is necessary to further identify the breakdown products.

There were no observations of degradation for the HDPE packaging in all cases. The following shelf lives and maximum storage temperatures are therefore supported:

- Meta SPC 1: 24 months, maximum temperature 40 °C;
- Meta SPC 2: 24 months, maximum temperature 30 °C;
- Meta SPC 3: 18 months, maximum temperature 30 °C.

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

None of the products of the Deosan Activate biocidal product family are classified for physical hazards. Therefore, a non-classification for each product of the BPF is acceptable.

Efficacy

The efficacy of the products in the family is demonstrated for use at concentrations of 0.3-0.32 % with a minimum contact time of 30 seconds for pre-milking and 5 minutes for post-milking

The minimum contact time for pre-milking applications is 30 seconds and for post-milking application is 5 minutes. 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).

Based on the efficacy results, the label claims for the product family are: effective against bacteria and yeasts being relevant for teat disinfection.

In addition to bacterial and yeasticidal efficacy claims, the applicant also applied for use against viruses. However, it was concluded that the data do not support the virucidal efficacy claims.

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 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 Deosan Activate BPF and total dietary intake (agreed at the human health WG IV, 2017). For adults, a total dietary intake of iodine resulting from other dietary sources, the baseline milk value and the estimated iodine resulting from the proposed biocidal product use is 0.409 mg for pre- and post- milking, 0.337 mg for pre-milking and 0.347 mg for post- milking. These values are equivalent to 68% of UL for pre- and post- milking, 56% of the UL for pre- milking only and 58% of the adult UL for post-milking. . For detailed dietary exposure calculations, please refer to 'Risk for consumers via residues in food' section below. When taking into account primary exposure from application of the Deosan Active BPF and total dietary intake, the following conclusions can be made:

[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

For meta SPC 1

- Pre-milking: Acceptable combined exposure equivalent to 86% of the AEL is calculated for application via dipping without the use of PPE. Combined exposure equivalent to 96% of the AEL is calculated for application via spraying with the use of gloves.
- Post-milking: Acceptable combined exposure equivalent to 63% of the AEL for application via manual dipping is calculated without the use of PPE (this estimate forms a risk envelope semi-automated dipping). Combined exposure equivalent to 95% of the AEL is calculated for application via spraying with the use of gloves.
- Pre- and post- milking: Acceptable combined exposure equivalent to 98% of the AEL is calculated for application via dipping without the use of PPE. Combined exposure equivalent to 102% of the AEL is calculated for application via spraying with the use of gloves, boots and coated coveralls.

For meta SPC 2

- Pre-milking: Acceptable combined exposure equivalent to 100% of the AEL is calculated for application via dipping without the use of PPE. Combined exposure equivalent to 97% of the AEL is calculated for application via spraying with the use of gloves.
- Post-milking: Acceptable combined exposure equivalent to 76% of the AEL for application via manual dipping without the use of PPE (this estimate also forms a risk envelope for semi-automated dipping). Combined exposure equivalent to 96% of the AEL is calculated for application via spraying with the use of gloves.
- Pre- and post- milking: Acceptable combined exposure equivalent to 73% of the AEL is calculated for application via dipping with the use of gloves. Combined exposure equivalent to 103% of the AEL is calculated for application via spraying with the use of gloves, boots and coated coveralls.

For meta SPC 3

- Pre-milking: Acceptable combined exposure equivalent to 100% of the AEL is calculated for application via dipping without the use of PPE.
- Post-milking: Acceptable combined exposure equivalent to 76% of the AEL for application via manual dipping without the use of gloves (this estimate also forms a risk envelope for semi-automated dipping).
- Pre- and post- milking: Acceptable combined exposure equivalent to 73% of the AEL is calculated for application via dipping with the use of gloves.

On the basis of the risk assessment and considering that Deosan Activate BPF is not classified with respect to human health, the following PPE phrases are required:

Meta SPC 1 - concentrates	
Use 1 (pre-milking, manual dipping)	-
Use 2 (pre-milking, manual foaming)	-
Use 3 (pre-milking, manual spraying)	Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information)
Use 4 (post-milking, manual dipping)	-
Use 5 (post-milking, manual foaming)	-
Use 6 (post-milking, manual spraying)	Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information)
Use 7 (post-milking, automatic spraying)	-
Use 8 (post-milking, semi-automatic dipping)	-
Use 9 (pre- and post- milking, manual dipping)	-
Use 10 (pre- and post- milking, manual foaming)	-
Use 11 (pre- and post- milking, manual spraying)	Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information) Wear suitable protective footwear (EN 13832) when applying the product. A protective coverall (at least type 6, EN 13034) shall be worn
Meta SPC 2 – RTU liquid	
Use 12 (pre-milking, manual dipping)	-
Use 13 (pre-milking, manual foaming)	-
Use 14 (pre-milking, manual spraying)	Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information)
Use 15 (post-milking, manual dipping)	-
Use 16 (post-milking, manual	-

foaming)	
Use 17 (post-milking, manual spraying)	Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information)
Use 18 (post-milking, automatic spraying)	-
Use 19 (post-milking, semi-automatic dipping)	-
Use 20 (pre- and post- milking, manual dipping)	Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information)
Use 21 (pre- and post- milking, manual foaming)	Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information)
Use 22 (pre- and post- milking, manual spraying)	Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information Wear suitable protective footwear (EN 13832) when applying the product. A protective coverall (at least type 6, EN 13034) shall be worn
Meta SPC 3 – RTU gel	
Use 23 (pre-milking, manual dipping)	-
Use 24 (post-milking, manual dipping)	-
Use 25 (post-milking, semi-automatic dipping)	-
Use 26 (pre- and post- milking, manual dipping)	Wear protective chemical resistant gloves during product handling phase (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

The Deosan Activate product family is made up of teat disinfectant products consisting of ready to use formulations and concentrate formulations that are diluted prior to use. All products within the product family are used at the same in use concentration; concentrate products are diluted prior to use to match the concentration in the RTU products. The in use concentration is 0.439 % total iodine (sum of available iodine and iodide from sodium iodide). The use of the product applied both pre and post-milking, by foaming, dipping or spraying (max 15 mL/cow/application) at a herd average of 3 milkings per day has been assessed. This results in a total application of 90 mL of diluted product/cow/day. In line with the consideration in the CAR on iodine (2013) the assessment is performed for iodine, iodide and iodate (expressed as total iodine).

In the risk assessment, PEC/PNEC values less than 1.00 indicate an acceptable risk. The individual PEC/PNEC ratio for the STP scenario 1a for iodine is below the trigger value of 1. However, as iodine is a naturally occurring substance PEC/PNEC values above 1 are acceptable, if the PEC-values are within the natural occurring background concentrations (for more details see CAR on iodine 2013).

The PEC/PNEC ratios for the terrestrial environment and surface water are above 1.0. Therefore a comparison has been made against the naturally occurring levels in these compartments:

- The maximum surface water PEC is 6.09 µg iodine/L, which is within the natural background concentration of iodine in freshwater (river and lake) of 0.5-20 µg/L.
- The PEC values for iodine/iodide and iodate in soil are in the range of 0.32 – 0.44 mg/kgwwt which are below the lower limit of the background concentrations for iodine in soil of 0.4 -18.0 mg/kgwwt soil.
- The maximum estimated levels in groundwater are 61.12 µg/L for iodine/iodide and 84.47 µg/L iodate. These values are below the maximum natural background concentration of 70 µg iodine/L.

Therefore, it is concluded that there is no unacceptable environmental risk from the proposed use of the Deosan Activate teat disinfectant products.

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 Deosan Activate BPF based on Iodine shall be authorised, for the use(s) described under section 2.1 of this opinion, subject to compliance with the proposed SPC and the following conditions**.**

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Annex I: draft Summary of Product Characteristics