Helsinki, 25 January 2018

ECHA OPINION ON THE APPLICATION FOR AUTHORISATION OF THE SAME BIOCIDAL PRODUCT UNDER ARTICLE 6 OF COMMISSION IMPLEMENTING REGULATION (EU) NO 414/2013.

Opinion number: UBP-C-1177988-02-00/F

Name of the biocidal product family: PRODHYNET's iodine based products

Prospective authorisation holder: PRODHYNET SA, 11 avenue des châtelets, 22440, PLOUFRAGAN, France

Active substance(s): Iodine, including polyvinylpyrrolidone iodine

Product type(s): PT 3

The European Chemicals Agency ("ECHA"), in accordance with Article 6 of Commission Implementing Regulation (EU) No 414/2013, has evaluated the application for authorisation of the same biocidal product family 'PRODHYNET's iodine based products'.

The application for authorisation was submitted to ECHA on 3 August 2015 in accordance with Article 4 of Commission Implementing Regulation (EU) No 414/2013 and recorded in R4BP3 under case number BC-YK019030-42.

Following its acceptance by ECHA, the validation of the application was initiated on 12 August 2015.

ECHA requested further information from the applicant on 21 September 2015. Such information was received on 9 October 2015 - and was duly taken into account in the assessment.

The application was subsequently validated on 13 October 2015 following ECHA's conclusion that the information indicated in Article 2 of Commission Implementing Regulation (EU) No 414/2013 had been submitted.

The validation included a check that the proposed differences between the biocidal product family and the related reference biocidal product family ("related reference product") are limited to information which can be the subject of an administrative change in accordance with Implementing Regulation (EU) No 354/2013.

Following the adoption of the BPC opinion of the related reference product (including the draft SPC) on 12 December 2017 and the subsequent submission of a revised version of the draft SPC of the same biocidal product family, ECHA re-confirmed that all differences between these two families concern information which can be the subject of an administrative change.

In accordance with Article 6 of Commission Implementing Regulation (EU) No 414/2013, ECHA's opinion is set out below.

Detailed opinion and background

1. Overall conclusion

The overall conclusion of ECHA's opinion is that the biocidal product family 'PRODHYNET's iodine based products' is eligible for Union authorisation in accordance with Article 42(1) of Regulation (EU) No 528/2012 and that all differences between this biocidal product family and the related reference product are limited to information which can be the subject of an administrative change in accordance with Implementing Regulation (EU) No 354/2013.

The biocidal product family meets the definition in Article 3(1)(s) of Regulation (EU) No 528/2012, and may be expected to fulfil the conditions laid down in Article 19 of Regulation (EU) No 528/2012 and therefore may be authorised. The detailed grounds for the overall conclusion are described in the PAR of the related reference product.

A draft summary of biocidal product family characteristics ("SPC"), as referred to in Article 22(2) of Regulation (EU) No 528/2012, is attached as an annex to this opinion.

2. ECHA opinion

2.1. Conclusions of the assessment

The conclusions of the assessment supporting the intended uses in the application for the biocidal product family 'PRODHYNET's iodine based products' are based on the evaluation of the related reference product 'HYPRED's iodine based products' and described in BPC opinion ECHA/BPC/178/2017.

2.2. Presentation of the biocidal product family including classification and labelling

The description of the biocidal product family and the hazard and precautionary statements according to Regulation (EC) 1272/2008 are available in the SPC, see annex to this opinion.

2.3. Description of uses proposed to be authorised

The assessment supporting the intended uses in the application is described in the PAR of the related reference product 'HYPRED's iodine based products'.

The description of the uses proposed to be authorised is available in the SPC, see annex to this opinion.

2.4. Overall conclusion of the evaluation of the uses proposed to be authorised

For the uses proposed to be authorised, according to Article 19(1)(b) of Regulation (EU) No 528/2012, 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.

Therefore, it is proposed that the biocidal product family 'PRODHYNET's iodine based products' shall be authorised, for the uses referred to under section 2.3 of this opinion, subject to compliance with the proposed SPC.

Annex I: draft Summary of Product Characteristics