Helsinki, 8 December 2021

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-1544027-25-00/F

Name of the biocidal product family: QUARON SAS_H2O2 product family 1

Prospective authorisation holder: Covance Clinical Development S.A.

Active substance(s): Hydrogen peroxide

Product type(s): PT02, PT03, PT04

The European Chemicals Agency ("ECHA"), in accordance with Article 6 of Commission Implementing Regulation (EU) No 414/2013[1], has evaluated the application for Union authorisation of the biocidal product family "QUARON SAS_H2O2 product family 1".

The application for Union authorisation was submitted to ECHA on 31 January 2017 in accordance with Article 4 of Commission Implementing Regulation (EU) No 414/2013 and recorded in R4BP3 under case number BC-EJ029846-33.

Following its acceptance by ECHA, the validation of the application was initiated on 17 July 2017.

The application was subsequently validated on 11 December 2017 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 "QUARON SAS_H2O2 product family 1".and the related reference product family "Interox Biocidal Product Family 1" ("the related reference product family") are limited to information which can be the subject of an administrative change in accordance with Implementing Regulation (EU) No 354/2013[2].

Following the adoption of the BPC opinion of the related reference product family and the subsequent submission of a revised version of the draft SPC of the biocidal product family "QUARON SAS_H2O2 product family 1", ECHA confirmed again that all differences between the biocidal product family "QUARON SAS_H2O2 product family 1" and the related reference product family are limited to information which can be the subject of an administrative change in accordance with Implementing Regulation (EU) No 354/2013.

The evaluation was based on the information provided by the applicant in relation to the related reference product family.

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

[1] Commission Implementing Regulation (EU) No 414/2013 of 6 May 2013 specifying a procedure for authorisation of same biocidal products in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council

[2] Commission Implementing Regulation (EU) No 354/2013 of 18 April 2013 on changes of biocidal products authorised in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council.

Detailed opinion and background

1. Overall conclusion

The overall conclusion of ECHA's opinion is that the biocidal product family "QUARON SAS_H2O2 product family 1" is eligible for Union authorisation, and all reported differences between the biocidal product family "QUARON SAS_H2O2 product family 1" and the related reference product family 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 "QUARON SAS_H2O2 product family 1", as defined in Article 3(1)(s) of Regulation (EU) No 528/2012, meets the conditions laid down in Article 19(1) of that Regulation and therefore may be authorised for the uses specified in this opinion. The detailed grounds for the overall conclusion are described in the Product Assessment Report ("PAR") of the related reference product family.

A draft summary of biocidal product family characteristics ("SPC") of the biocidal product family "QUARON SAS_H2O2 product family 1", 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 evaluation

The conclusions of the risk assessment for the same biocidal product family "QUARON SAS_H2O2 product family 1" are based on the evaluation of the related reference product family and described in BPC opinion ECHA/BPC/295/2021 of 13 October 2021.

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

The description of the biocidal product family and its structure, 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 family "Interox Biocidal Product Family 1".

The description of the intended 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 the biocidal product family "QUARON SAS_H2O2 product family 1"

1. is sufficiently effective;

2. has no unacceptable effects on the target organisms, in particular unacceptable resistance, or cross-resistance, or unnecessary suffering and pain for vertebrates;

3. 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. 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.

Therefore, it is proposed that the biocidal product family "QUARON SAS_H2O2 product family 1" shall be authorised[3], for the uses described under section 2.3 of this opinion, subject to compliance with the proposed SPC.

Annex I: draft Summary of Product Characteristics

[3] This is without prejudice of any specific conditions that might apply in the territory of Member State(s) in accordance with Article 44(5) of Regulation (EU) No 528/2012.