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-1546434-18-00/F

Name of the biocidal product: Manorapid express GEL

Prospective authorisation holder: Lysoform Dr. Hans Rosemann GmbH

Active substance(s): Propan-1-ol, Propan-2-ol

Product type: PT01

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 single biocidal product "Manorapid express GEL".

The application for Union authorisation was submitted to ECHA on 23 April 2019 in accordance with Article 4 of Commission Implementing Regulation (EU) No 414/2013 and recorded in R4BP3 under case number BC-SV051112-22.

Following its acceptance by ECHA, the validation of the application was initiated 14 May 2019.

The application was subsequently validated on 27 June 2019 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 single biocidal product "Manorapid express GEL" and the related reference biocidal product family "Knieler & Team Propanol ("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[2].

Following the adoption of the BPC opinion of the related reference product and the subsequent submission of a revised version of the draft SPC of the single biocidal product "Manorapid express GEL", ECHA confirmed again that all differences between the single biocidal product "Manorapid express GEL" 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 evaluation was based on the information provided by the applicant in relation to the related reference product.

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

[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.

The overall conclusion of ECHA's opinion is that the single biocidal product "Manorapid express GEL" is eligible for Union authorisation and all reported differences between the single biocidal product "Manorapid express GEL" 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 single biocidal product "Manorapid express GEL", as defined in Article 3(1)(r) 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.

A draft summary of biocidal products characteristics ("SPC") of the single biocidal product "Manorapid express GEL", 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. Conlusions of the evaluation

The conclusions of the risk assessment for the single biocidal product "Manorapid express GEL" are based on the evaluation of the related reference product and described in BPC opinion ECHA/BPC/292/2021 of 7 October 2021.

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

The description of the single biocidal product "Manorapid express GEL" 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 "Knieler & Team Propanol Family".

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 single biocidal product "Manorapid express GEL":

1. is sufficiently effective;

2. has no unacceptable effects on the target organisms;

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 single biocidal product "Manorapid express GEL" 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.