Helsinki, 30 March 2020

Propan-1-ol and propan-2-ol:
Procedure and requirements for accelerated technical equivalence applications for these active substances under Article 54 of the BPR

Scope of the document

Due to the current COVID-19 situation, there is a need to ensure adequate supply of the active substances propan-1-ol and propan-2-ol for use in biocidal products for disinfection purposes. The most effective way to address the needs to have more biocidal products on the market is that MSCAs use Article 55(1) of the BPR to permit the making available on the market and use of biocidal products under derogation from Articles 17 and 19 and in particular derogation from the technical equivalence requirement in Article 19(1)(c).

An alternative for biocidal products already authorised under the the BPR is for product manufacturers who want to use new sources of propan-1-ol or propan-2-ol to submit a request for technical equivalence (TE) assessment of the new source to ECHA.

In order to accelerate both the preparation of the applications by the companies and their assessment by ECHA, ECHA has defined reduced information requirements and will apply, as a temporary measure, a modified procedure in order to start working immediately on the assessment and issue a draft decision even if the fee has not yet been paid by the applicant.

The present document outlines ECHA's procedure for handling these specific TE applications for the active substances propan-1-ol and propan-2-ol and describes the related information requirements.

Application procedure

The following procedure applies until further notice for technical equivalence applications for propan-1-ol and propan-2-ol:

1. Pre-submission discussion with ECHA is strongly recommended to ensure rapid assessment of the case. Companies that plan to submit a TE application for propan-1-ol or propan-2-ol are advised to contact the ECHA Helpdesk (https://echa.europa.eu/contact/bpr) before submission to arrange a discussion on how to prepare their application.

2. The information requirements for the applications are reduced to facilitate rapid preparation of the application. See section below on information requirements.

3. Applications are to be submitted via R4BP and need to include an IUCLID dossier and a supporting document. Applicants can turn to ECHA if they need support with any IT problems related to the submission.

4. The normal fees described in the Implementing Regulation (EU) No 564/2013 apply. The applicant will receive an invoice to be paid within 30 days. However, ECHA will start the assessment as soon as the invoice is issued.

5. If there is no need to request additional information from the applicant, ECHA will normally provide the draft decision to the applicant within a few working days from acceptance of the application. The applicant will be given the possibility to provide comments on the draft decision.

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6. If ECHA cannot conclude on technical equivalence without requesting additional information from the applicant, ECHA will send a formal request for additional information with an indicated deadline. If the applicant is able to provide the missing information rapidly, ECHA aims to finalise the assessment as soon as possible.

7. The final decision will be issued after comments have been received from the applicant (if any) and once the fee has been paid.

Please note that the procedure is limited to Tier I applications. If the applicant anticipates that a Tier II assessment is needed, the standard procedure for Tier II applications should be followed. However, also in this case ECHA aims to complete the assessment as soon as possible.

Information requirements

The standard technical equivalence requirements described in the *Guidance on applications for technical equivalence* (TE Guidance) apply, with the following exceptions:

- The 5-batch analysis performed with validated analytical methods can be replaced by Certificates of Analysis (CoA) for five representative batches of the active substance. The CoAs need to include information about the composition of the active substance as follows, and in line with the TE Guidance:
    - Obligatory: Purity of the active substance
    - Obligatory: Impurities and their contents (significant and relevant impurities)
    - Recommended: results of Ph. Eur. tests specified in the Recommendations document[1], carried out in accordance with the specific tests of European Pharmacopoeia (Ph. Eur.) monographs for Propanol or Isopropyl alcohol
    - Recommended: results of other tests carried out in accordance with the specific tests of European Pharmacopoeia (Ph. Eur.) monographs for Propanol or Isopropyl alcohol
    - Obligatory: Descriptions of the analytical methods used. This information shall be sufficient for the methods to be reproduced and shall therefore include details of the experimental protocol followed and any calculations made. For Ph. Eur. test methods used without modifications, is sufficient to provide a reference to the specific test.

  For further information regarding Certificates of analysis, please see below.

- The requirement for spectral data can be waived.

General support information

Information on how to prepare and submit an application:

- Biocides Submission Manual: How to submit an application for Technical Equivalence or Chemical Similarity

- Biocides Submission Manual: How to prepare a biocides dossier

Both documents are available here: https://www.echa.europa.eu/web/guest/support/dossier-submission-tools/r4bp/biocides-submission-manuals

Supporting document to be included in R4BP 3 on submission (TE-APP): https://www.echa.europa.eu/web/guest/support/dossier-submission-tools/r4bp/supporting-

[1] *Recommended requirements for the active substances Propan-1-ol and Propan-2-ol, for the purpose of derogations under Article 55(1) of the BPR*; Available here: https://echa.europa.eu/-/speeding-up-the-supply-of-disinfectants

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documents

General information about the technical equivalence applications and the information to be provided:

- Guidance on applications for technical equivalence
- Guidance on the BPR: Volume I Identity/physico-chemical properties/analytical methodology (Parts A+B+C)

Both documents are available here: https://echa.europa.eu/guidance-documents/guidance-on-biocides-legislation

For further information about Certificates of analysis please see below and the document:

- Technical Agreements for Biocides

The document is available here: https://echa.europa.eu/about-us/who-we-are/biocidal-products-committee/working-groups

Certificates of analysis

Please note that a certificate of analysis should in general include the following information:

The administrative information shall include:

- Header (Certificate of analysis)
- Name and address of the supplier or manufacturer
- Name and address of the manufacturer
- Name and address of the manufacture location/site
- Name and address of the testing laboratory
- Date, printed names and signature(s) of analysts
- Date, printed names and signature(s) of approver
- Date of analyses
- Lot/Batch number and size
- Date of Manufacture
- Product code or number
- Expiration date of the analysed substance

The technical information shall include:

- IUPAC-, CAS-, ISO- (if available) and general name of the substance analysed
- EC- and CAS-number of the substance analysed
- Appearance of the test material (e.g. powder including particle size)
- Stability and storage statement
- Name of the test, used analytical instruments and method applied (including analytical, physical and physico-chemical tests)
- Test result (which should include the chemical composition of the substance, at least the content of the active substance, and the significant and relevant impurities)
- Acceptance criteria (e.g. product specification)