

Active chlorine released from hypochlorous acid: Advice on information requirements for technical equivalence applications under Article 54 of the BPR

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In February 2021 Commission implementing regulations (EU) 2021/347 and 2021/365 approving 'Active chlorine released from hypochlorous acid' as an active substance for use in biocidal products of product-types 1, 2, 3, 4 and 5 were published. Applicants who wish ECHA to assess technical equivalence of an alternative source of this active substance can now submit applications to the Agency through R4BP 3. The purpose of this document is to provide useful information for prospective applicants when preparing their applications.

In general, the advice described in *Guidance on applications for technical equivalence* (TE Guidance) applies to 'Active chlorine released from hypochlorous acid'. In order to facilitate the preparation of the applications and taking into account the particular nature of the active substance, the Agency provides in this document targeted advice regarding the analytical information to be submitted. Applicants are advised to provide the following information on 'Active chlorine released from hypochlorous acid':

- 5-batch analysis: Applicants shall submit a 5-batch analysis performed under GLP including results for the following parameters:
 - Active chlorine
 - Chlorate
 - Sodium
 - Chloride
 - Chlorite (if applicable)
 - Perchlorate (if applicable)
 - pH

In addition, any other impurities expected to be present in concentrations $\geq 0.1\%$ (w/w), based on dry weight, should be identified and quantified. Impurities in concentrations $< 0.1\%$ (w/w) should be identified and quantified if they are regarded as (eco)toxicologically relevant.

For the determination of active chlorine content, analytical methods of official status, such as ISO 7393 or the method described in EN 901:2013 can, for example, be used.

For the calculation of the specification (see below) active chlorine shall be recalculated to hypochlorous acid using conversion factor 0.74. For more information on the conversion factor from active chlorine to hypochlorous acid, please see p. 5 of the public assessment report.

The final results of the 5-batch analysis need to be provided in the unit of %w/w.

- Absorption spectra data is not necessary for this substance and does not have to be submitted.

- Proposed specification: A proposed specification for the minimum purity of the active substance and maximum concentrations of the impurities needs to be submitted in the technical equivalence application. In the current case this needs to include a specification for the substance as manufactured (i.e. in aqueous solution), and also a dry weight specification (see p. 26-27 of the TE Guidance, and the reference mentioned on p. 27).

In the case where 'Active chlorine released from hypochlorous acid' is manufactured from sodium chloride and sodium chloride remains in a large excess in the aqueous solution compared to active chlorine, the sodium chloride needs to be excluded (together with water) from the dry weight calculation to obtain a meaningful result. Therefore, as a general rule, sodium chloride should be excluded from the dry weight calculation.

The proposed specifications need to be provided in the unit of %w/w.

For applications where a Tier II assessment of toxicological and ecotoxicological data is needed, the application and self-assessment need to be prepared according to the instructions in the TE Guidance, section 6.

For more information, applicants can also consult the public version of the assessment reports for 'Active chlorine released from hypochlorous acid', which are available at the ECHA website: <https://echa.europa.eu/information-on-chemicals/biocidal-active-substances>

For general information about the technical equivalence applications and the information to be provided please see:

- Guidance on applications for technical equivalence (Volume V)
- Guidance on the BPR: Volume I Identity/physico-chemical properties/analytical methodology (Parts A+B+C)
- Biocides Submission Manual: How to submit an application for technical equivalence and chemical similarity check

These documents are available using the following links:

<https://echa.europa.eu/guidance-documents/guidance-on-biocides-legislation>

https://echa.europa.eu/documents/10162/14938692/bsm_05_technical_equivalence_en.pdf

If you have specific questions concerning the preparation of your technical equivalence case, you can also contact the ECHA helpdesk <https://echa.europa.eu/contact/bpr>