Peroxygens Sector Group

TO WHOM IT MAY CONCERN

Hydrogen peroxide and the European Biocides Regulation EU/528/2012

29 June 2017

Dear Madam, Sir,

The Biocidal Products Regulation (BPR) (EU/528/2012) was adopted in 2012 and came into effect on 1st September 2013. The BPR aims to improve the functioning of the internal market through the harmonisation of the rules on the making available on the market and the use of biocidal products, while ensuring a high level of protection of both human and animal health and the environment. The BPR replaced the Biocidal Products Directive (BPD) 98/8/EC previously in force since 2000.

More information on the BPR is available on the website of the European Chemicals Agency (ECHA): http://echa.europa.eu/regulations/biocidal-products-regulation.

You can find below general information on the BPR scheme with regards to Hydrogen Peroxide. For additional questions, please contact the Cefic Hydrogen Peroxide Subgroup Secretariat.

Kind regards,
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I. Inclusion of Hydrogen Peroxide in the European Biocides Scheme (Biocidal Products Regulation EU/528/2012)

The members of the Cefic Hydrogen Peroxide Subgroup notified hydrogen peroxide (CAS 7722-84-1; EC 231-765-0) as an active substance for the following product types as provided in the BPD:

- PT 01: Human hygiene biocidal products,
- PT 02: Private area and public health area disinfectants and other biocidal products,
- PT 03: Veterinary hygiene biocidal products,
- PT 04: Food and feed area disinfectants,
- PT 05: Drinking water disinfectants,
- PT 06: In-can preservatives,
- PT 11: Preservatives for liquid-cooling and processing systems, and
- PT 12: Slimicides.

A complete registration dossier was submitted in July 2007 for PT 1-6 to the competent evaluating authority of Finland. The dossier for PT 11-12 was submitted in October 2008.

The evaluation of the dossier for PT 1-6 is complete. The opinions of the Biocidal Products Committee on the approval of hydrogen peroxide for PT 1-6 were published in February 2015. The date of approval, which is also the deadline for submission of product authorisation applications, was set for 1 February 2017. You can access Regulation (EU) 2015/1730 approving hydrogen peroxide as a biocidal active substance for PT 1-6 here.

The dossier for PT 11-12 is still under evaluation with the Rapporteur Member State. The BPC opinions are expected in April 2018 for PT 11-12. The date of approval which is also the deadline for submission of product authorisation applications is likely to be set two years after this.

The Members of the Cefic Hydrogen Peroxide Subgroup are:

1. Arkema France
2. Akzo Nobel Pulp and Performance Chemicals AB
3. Belinka Perkemija d.o.o.
4. Ercros SA
5. Evonik Resource Efficiency GmbH
6. Kemira Oyj
7. Peroxychem Spain s.l.u.
8. Solvay SA.

For more information, please contact the Cefic Hydrogen Peroxide Subgroup Secretariat.

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II. Information for manufacturers and importers (suppliers) of hydrogen peroxide as a biocidal active substance in view of compliance with Article 95 of the BPR

Article 95 of the Biocidal Products Regulation (BPR) (EU/528/2012) establishes the list of approved suppliers of active substances. Since 1st September 2015, a biocidal product cannot be placed on the market unless the supplier of the active substance on its own or in biocidal products or the supplier of the biocidal product is included in this list.

For this purpose, three options are listed in Article 95 which requires suppliers to submit to the European Chemicals Agency (ECHA) either:

- A full dossier for the approval of an active substance (data requirements as specified in Annex II of the BPR)
- A letter of access (LoA) to a full active substance dossier; or
- A reference to a full dossier for which data protection has expired.

Since 1st September 2015, only biocidal products formulated with active substances from a supplier on this list have been allowed on the EU market. The list of approved suppliers contains the names of the participants in the review programme for existing active substances.

The Cefic Hydrogen Peroxide Subgroup is supporting under the review programme the approval of hydrogen peroxide (CAS 7722-84-1; EC 231-765-0) for product-types 1, 2, 3, 4, 5, 6, 11 & 12.

In view of Article 95 of the BPR, two options are available as concerns the Hydrogen Peroxide Subgroup:

- Joining the group as a full member, gaining full co-ownership rights on the studies and the BPR dossier.
- Purchasing a letter of access (LoA) to the BPR dossier for hydrogen peroxide, granting the right to refer to this dossier.

The members of the Cefic Hydrogen Peroxide Subgroup are open to a discussion on new membership or the issuing of a LoA.

If your company is a supplier of the active substance and would like more information, please contact the Cefic Hydrogen Peroxide Subgroup Secretariat.

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III. Information for product authorisation purposes under the transitional period and under the BPR

The Biocidal Products Regulation (BPR) (EU/528/2012) requires persons responsible for the placing on the market of a biocidal product to obtain an authorisation for such product prior to placing it on the market. Until the inclusion of hydrogen peroxide for each relevant product-type in the Union list of approved active substances, transitional measures will be applicable in EU Member States, Iceland, Liechtenstein and Norway.

Product authorisation according to the principles of the BPR will be needed according to the following timelines:
- For product-types 1 to 6, the date of approval which is also the deadline for submission of product authorisation applications is set for 1 February 2017.
- For product-types 11-12, the BPC opinions are expected in October 2017. The date of approval which is also the deadline for submission of product authorisation applications is likely to be set two years after this.

In the transitional period, competent authorities of Member States may request for product authorisation purposes the provision of specific data requirements on the active substances in the biocidal product. This could take the form of a letter of access for each active substance contained in the product.

For product authorisation purposes under the BPR, applicants for authorisation of a biocidal product will need either a dossier or a letter of access for each active substance contained in the product.

In both situations, a letter of access will allow the Member State Competent Authority or the European Chemicals Agency to access the data in the active substance dossier for biocidal product authorisation on behalf of a third party.

The members of the Cefic Hydrogen Peroxide Subgroup do not jointly intend to issue any letter of access to the hydrogen peroxide BPR dossier for product authorisation. Letters of access should be requested from your direct supplier of hydrogen peroxide.

For more information, please contact the Cefic Hydrogen Peroxide Subgroup secretariat.