PAR – Peracetic Acid Registration Group

TO WHOM IT MAY CONCERN

Information for product authorisation under the BPR

Brussels, 27 October 2016

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 them on the market. Until the inclusion of equilibrium and in-situ peracetic acid for each relevant product-type (PT) in the Union list of approved active substances, transitional national 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 equilibrium PAA in PT 1 to 6, the date of approval which is also the deadline for submission of product authorisation applications is set for 1 October 2017. Regulation (EU) 2016/672 approving peracetic acid as a biocidal active substance for PT 1 to 6 is accessible here.
- For equilibrium PAA in PT 11 and 12, the date of approval which is also the deadline for submission of product authorisation applications is likely to be set for 1 June 2018.
- For PAA generated in-situ from tetra-acetylethylenediamine (TAED) and sodium percarbonate for PT 2 to 4, the opinions of the Biocidal Products Committee are expected in December 2016. The date of approval is likely to be set two years after this (December 2018).

It has to be noted that for biocidal products containing more than one active substance, the deadline for submission of product authorisation applications is the date of approval of the last active substance to be approved.

In the transitional period, competent authorities of Member States may request for national product authorisation purposes the provision of specific data requirements on the active substances in the biocidal product. This implies data 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.

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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 purposes on behalf of a third party.

The members of the Cefic Peracetic Acid Registration Group (PAR) do not jointly intend to issue any letter of access for product authorisation purposes to the equilibrium peracetic acid BPR dossier. Letters of access should be requested from your direct supplier of peracetic acid.

Concerning in-situ peracetic acid, the PAR Secretariat may be contacted for discussions on access for product authorisation purposes to the dossier supporting the approval of in-situ PAA generated from sodium percabonate and TAED.

For more information, please contact the Cefic PAR secretariat.