Active Substance Support for Didecyldimethylammonium Chloride (DDAC)

Didecyldimethylammonium Chloride (DDAC) [CAS No. 7173-51-5] is a quaternary ammonium compound supported by Lonza under the European Union Biocidal Products Regulation (BPR, EU (No) 528/2012) for use in Product Type (PT) 1, 2, 3, 4, 6, 8, 10, 11 & 12.

1. Purpose

The purpose of this document is to provide Lonza's customers with a summary of the supporting information that Lonza can make available on DDAC, which is sold under the Bardac® brand name. This information will be essential for the preparation of Biocidal Product Authorisation Dossiers under the European Union Biocidal Products Regulation (BPR, EU (No) 528/2012).

2. Supported Use Patterns for Product Types 1 - 4

The Active Substance Review of DDAC in Product Types 1 – 4 remains on-going. However, to allow forward planning, a list of the 'Hygiene' use patterns which Lonza actively supports and plans to continue supporting under the BPR has been compiled. It should be noted that use patterns and efficacy claims not listed in the document may be supported by customers subject to an assessment of the final end use biocidal product which takes into account efficacy data, product stewardship considerations and a suitable Risk Assessment in addition to any other factors which may be relevant.

DDAC supported uses can be shared with customers under provision of a Confidentiality Agreement (CDA).

3. Analytical Method for the Determination of DDAC by HPLC- ELSD

A method is provided that Lonza's customers can adapt to identify and quantify the DDAC level in formulated products using HPLC-ELSD. This method was submitted in the DDAC Active Substance dossier and will be used by Competent Authorities for enforcement. Certified secondary laboratory standards can also be made available for use in this analysis.

The analytical method can be made available to customers after signing a supply agreement.

4. End Points

A list of End Points for Active Substances will be required in the preparation of Human Health and Environmental Risk Assessments required as part of the Biocidal Product Authorisation dossier. The following documents are available for DDAC:

- Phys-Chem End Points Document covering:
  - Active Substance Classification according to CLP[1]
  - Active Substance Identity
  - Physical and Chemical Properties
  - Analytical Methods

Human Health End Points Document covering:

- Relevant CLP Classification
- Local Effects
- Systemic Effects
- Maximum Residue Limit (MRL)

Ecotox End Points Document covering:

- Relevant CLP Classification
- Eco-Toxicity (PNECs)
- Fate and Behaviour in the Environment

Summaries of relevant End Points for DDAC can be made available to customers after signing a supply agreement.

[1] CLP is the European Regulation on the Classification, Labelling and Packaging of Substances and Mixtures (EC (No) 1272/2008).

5. Mode of Action and Occurrence of Resistance

The Biocidal Products Committee (BPC) issued a conclusion on the 'Mode of Action' and 'Occurrence of Resistance' during the assessment of DDAC for PT8. Lonza recommends that applicants seeking Product Authorisation use the same wording in their Biocidal Product applications.

A summary of the wording can be made available to customers under provision of a Confidentiality Agreement (CDA).

For further guidance and support, please contact your nearest Lonza sales representative or office.

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