

## RISK MANAGEMENT OPTIONS ANALYSIS

### CONCLUSION DOCUMENT

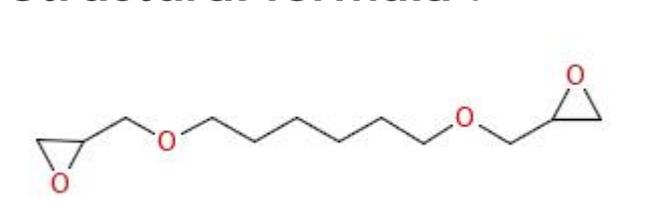
for

## 1,6 HEXANDIOLDIGLYCIDYLETHER (HDDGE)

EC number: 240-260-4

CAS number: 16096-31-4

Structural formula :



Member State(s): Denmark

Dated: August 2014, Final version

*Disclaimer: Please note that this RMOA conclusion was compiled on the basis of available information and may change in the light of new information or further assessment.*

DRAFT

## 1. OVERVIEW OF OTHER REGULATORY PROCESSES / EU LEGISLATION

This RMOA on 1,6-hexandioldiglycidylether (HDDGE) and the underlying surveys are a part of the review of the substances on the Danish List of undesirable substances (LOUS-review).

HDDGE is a diluent in epoxy systems. The substance is registered under REACH in the 1000 – 10.000 ton/year tonnage band. It is included on the Danish EPA “List of Undesirable Substances” (Danish EPA, 2009) due to its use tonnage in Denmark above 100 tonnes and QSAR modelling of the substance showing it to be a potential carcinogen. The substance was reviewed by the Danish EPA under the LOUS 2012-15 review project, resulting in the report: “Survey of 1,6 hexandioldiglycidyl ether, part of the LOUS-review” (Danish EPA 2013). This report has identified data gaps on carcinogenic potential of HDDGE.

The current status of HDDGE pertaining to relevant community legislation is summarised in the table below.

Table 1: Relevant legislation pertaining to the manufacture and use of BHT

| Legal instrument                      | EU/national  | Status of HDDGE  |
|---------------------------------------|--|--|
| REACH regulation                      | Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) | Registration of production and use. Tonnage band: 1,000 – 10,000 tonnes per year. A joint registration covering 6 registrants and one individual registrant.   |
| CLP regulation                        | Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures                       | No EU harmonised classification is available.<br>Industry self-classification is reported to the ECHA C&L inventory database. Self-classification as skin and eye irritant, skin sensitizer and aquatic chronic toxicant are seen in 3 out of 4 notifications. |
| Directive on Chemicals Agents at Work | Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work   | No SCOEL recommendation regarding indicative OEL values is available   |

## 2. CONCLUSION OF RMOA

| Conclusions   | Tick box |
|---|----------|
| Need for follow up regulatory action at EU level<br><i>[if a specific regulatory action is already identified then, please, select one or more of the specific follow up actions mentioned below]</i> |          |
| Harmonised classification and labelling   |          |
| Identification as SVHC (authorisation)  |          |
| Restrictions  |          |
| Other EU-wide measures  |          |
| No need for regulatory follow-up action   | X        |

The Danish EPA has identified a possible data gap in the registration report for HDDGE, i.e. for the end-points of mutagenicity and carcinogenicity, based on results of QSAR modelling and uncertainty related to the suitability of the available tests. The existing registration report does not address this concern. A substance evaluation procedure would address the concern. If the genotoxic carcinogenic effect is confirmed, it would mean that there is a possible concern for human health.

Exposure of workers is in Denmark reduced by working environment regulation of epoxides. Based on retrieved information demonstrating reduced consumption in Denmark, and new surveys from Denmark indicating that the general public are only scarcely exposed to the substance, the risk of exposure, and thus the risk for human health from HDDGE is low in Denmark. Therefore, Denmark will not prioritise HDDGE for substance evaluation.