

CONSIDERATIONS OF ALTERNATIVE METHODS ON TESTING PROPOSALS IN YOUR REGISTRATION

Please complete this form and provide information for each of the points below.

If you have more than one testing proposal, please copy and paste the three bullet points within the same document and complete the details as appropriate for each testing proposal.

This document will be published on ECHA website along with the third party consultation on the testing proposal(s).

Public substance name: Amines, polyethylenepoly-, triethylenetetramine fraction
EC Number (omit if confidential): 292-588-2
CAS Number (omit if confidential): 90640-67-8

Date of considerations: 26 July 2017

- **Hazard endpoint for which vertebrate testing was proposed:**

- **Reproductive toxicity (extended one-generation reproductive toxicity study) with the registered substance;**

- **Considerations that the general adaptation possibilities of Annex XI of the REACH Regulation were not adequate to generate the necessary information** (instruction: please address all points below):
 - available GLP studies: There are no GLP-compliant studies available on reproductive toxicity with the registered substance.
 - available non-GLP studies: There are no non-GLP studies available on reproductive toxicity with the registered substance.
 - historical human data: There are no appropriate historical human data available addressing the endpoint reproductive toxicity.
 - (Q)SAR: (Q)SAR tools sufficiently addressing the endpoint reproductive toxicity are currently not available.
 - *in vitro* methods: No validated or regulatory accepted alternative methods are available for replacing animal testing with respect to reproductive toxicity.
 - weight of evidence: There are no studies available on repeated dose toxicity with the registered substance which could be used in a weight of evidence approach.
 - grouping and read-across: There are no read-across data available on toxicity to reproduction
- **Considerations that the specific adaptation possibilities of Annexes VI to X (and column 2 thereof) were not applicable** (instruction: free text):

- There is no data available on reproductive toxicity with Amines, polyethylenepoly-, triethylenetetramine fraction (CAS 90640-67-8). Validated or regulatory accepted

alternative methods are not available for replacing animal testing with respect to reproductive toxicity. Furthermore, although appropriate read-across substances are available (N,N'-bis(2-aminoethyl)ethane-1,2-diamine tetrahydrochloride / CAS 4961-40-4 / EC 225-604-3; N,N'-bis(2-aminoethyl)ethane-1,2-diamine dihydrochloride / CAS 38260-01-4 / EC 253-854-3) for none of these substances a reproductive toxicity study is available so far.

In order to fulfil the standard information requirements, a GLP-compliant reproductive toxicity study in the rat via the oral route following OECD 443 was proposed, according to Annex IX, Column I, 8.7.2.