

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: 2,2'-[OXYBIS(METHYLENE)]BIS[2-ETHYLPROPANE-1,3-DIOL]

EC Number (omit if confidential): 245-509-0

CAS Number (omit if confidential): 23235-61-2

Date of considerations: 11 April 2016

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

Reproductive toxicity (pre-natal developmental toxicity) with the registered substance ~~[name of analogue substance if public];~~

2,2'-[OXYBIS(METHYLENE)]BIS[2-ETHYLPROPANE-1,3-DIOL]

- **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; no data available for this endpoint
 - available non-GLP studies; no data available for this endpoint
 - historical human data; no data available for this endpoint
 - (Q)SAR; not applicable for this endpoint
 - *in vitro* methods; no invitro methods available for this endpoint
 - weight of evidence; not applicable for this endpoint
 - grouping and read-across; no substance similar enough
 - substance-tailored exposure driven testing [if applicable]; not applicable
 - [approaches in addition to above [if applicable]; not applicable
 - other reasons [if applicable]; not applicable
- **Considerations that the specific adaptation possibilities of Annexes VI to X (and column 2 thereof) were not applicable** (instruction: free text):

Based on the data requirements in Annex VI to X, tonnage band and the final decision, TPE-D-0000001722-79-05/F on 2,2'-[OXYBIS(METHYLENE)]BIS[2-ETHYLPROPANE-1,3-DIOL], Perstorp Specialty Chemicals AB could not see any other possibilities including considerations that are listed in Annex XI to fulfil the legal

requirement.

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EC Number (omit if confidential): 245-509-0

CAS Number (omit if confidential): 23235-61-2

Date of considerations: 11 April 2016

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

Sub-chronic toxicity (90-day): oral with the registered substance ~~[name of analogue substance if public];~~

2,2'-[OXYBIS(METHYLENE)]BIS[2-ETHYLPROPANE-1,3-DIOL]

- **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; no data available for this endpoint
 - available non-GLP studies; no data available for this endpoint
 - historical human data; no data available for this endpoint
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 - *in vitro* methods; no invitro methods available for this endpoint
 - weight of evidence; not applicable for this endpoint
 - grouping and read-across; no substances similar enough
 - substance-tailored exposure driven testing [if applicable]; not applicable
 - [approaches in addition to above [if applicable]; not applicable
 - other reasons [if applicable]; not applicable
- **Considerations that the specific adaptation possibilities of Annexes VI to X (and column 2 thereof) were not applicable** (instruction: free text):

Based on the data requirements in Annex VI to X, tonnage band and the draft decision, TPE-D-2114312528-52-01/D on 2,2'-[OXYBIS(METHYLENE)]BIS[2-ETHYLPROPANE-1,3-DIOL], Perstorp Specialty Chemicals AB could not see any other possibilities including considerations that are listed in Annex XI to fulfil the legal

requirement.