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: Reaction mass of C18 (unsatd.) fatty acid amides/esters of diethanolamine, C16-18 (even-numbered) fatty amine (..)
EC Number (omit if confidential): 943-172-0
CAS Number (omit if confidential): NS

Date of considerations: 13 April 2016

- **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 available GLP studies on the substance or on read-across analogues suitable to fill the endpoint.
  - available non-GLP studies: there are no available non-GLP studies on the substance or on read-across analogues suitable to fill the endpoint
  - historical human data: there is no historical human data on the substance or on read-across analogues suitable to fill the endpoint
  - (Q)SAR: (Q)SAR analysis is not sufficient to fill the endpoint. The substance is a complex UVCB and there are no adequate models to address reproductive toxicity.
  - *in vitro* methods: there are no adequate *in vitro* methods allowing to address a complex endpoint such as reprotoxicity.
  - weight of evidence: there is not sufficient data on the substance or read-across analogues to be able to establish a weight of evidence argument.
  - grouping and read-across: there is not sufficient data on the substance or read-across analogues to be able to group or propose read-across.
  - 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): All possible adaptation possibilities were considered and none were applicable to this complex UVCB for which no reprotoxicity testing information is available. Exposure-based waiving could also not be used.

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Date of considerations: 13 April 2016

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

  Sub-chronic toxicity (90-day): oral 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 available GLP studies on the substance or on read-across analogues suitable to fill the endpoint.
  - available non-GLP studies: there are no available non-GLP studies on the substance or on read-across analogues suitable to fill the endpoint
  - historical human data: there is no historical human data on the substance or on read-across analogues suitable to fill the endpoint
  - (Q)SAR: (Q)SAR analysis is not sufficient to fill the endpoint. The substance is a complex UVCB and there are no adequate models to address repeated dose toxicity.
  - *in vitro* methods: there are no adequate *in vitro* methods allowing to address a complex endpoint such as repeated dose toxicity.
  - weight of evidence: there is not sufficient data on the substance or read-across analogues to be able to establish a weight of evidence argument.
  - grouping and read-across: there is not sufficient data on the substance or read-across analogues to be able to group or propose read-across.
  - 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): All possible adaptation possibilities were considered and none were applicable to this complex UVCB for which no longer term testing information is available. Exposure-based waiving could also not be used.

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CAS Number (omit if confidential): NS

Date of considerations: 13 April 2016

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

  Reproductive toxicity (pre-natal developmental toxicity) 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 available GLP studies on the substance or on read-across analogues suitable to fill the endpoint.
  - available non-GLP studies: there are no available non-GLP studies on the substance or on read-across analogues suitable to fill the endpoint
  - historical human data: there is no historical human data on the substance or on read-across analogues suitable to fill the endpoint
  - (Q)SAR: (Q)SAR analysis is not sufficient to fill the endpoint. The substance is a complex UVCB and there are no adequate models to address developmental toxicity.
  - *in vitro* methods: there are no adequate *in vitro* methods allowing to address a complex endpoint such as developmental toxicity.
  - weight of evidence: there is not sufficient data on the substance or read-across analogues to be able to establish a weight of evidence argument.
  - grouping and read-across: there is not sufficient data on the substance or read-across analogues to be able to group or propose read-across.
  - 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): All possible adaptation possibilities were considered and none were applicable to this complex UVCB for which no developmental toxicity testing information is available. Exposure-based waiving could also not be used.