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-piperazin-1-ylethylamine
EC Number (omit if confidential): 205-411-0
CAS Number (omit if confidential): 140-31-8

Date of considerations: 21 July 2017

- ☐ Hazard endpoint for which vertebrate testing was proposed:

  Reproductive toxicity (extended one-generation reproductive toxicity study) with the registered substance 2-piperazin-1-ylethylamine.

- ☐ 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 or non-GLP studies or historical human data

    - ☐ There are no pre-existing data available (GLP or non-GLP) that can satisfy the data requirements of an extended one-generation reproductive toxicity study. There are no Historical human data that could be used in place of an extended one-generation reproductive toxicity study.

  - ☐ (Q)SAR

    - ☐ There are no accepted QSAR approaches for predicting pre- and postnatal effects of this class of substances on development nor a thorough evaluation of systemic toxicity in pregnant and lactating females and young and adult offspring.

  - ☐ in vitro methods

    - ☐ There are no accepted in vitro approaches for predicting pre- and postnatal effects of chemicals on development nor a thorough evaluation of systemic toxicity in pregnant and lactating females and young and adult offspring.

  - ☐ weight of evidence

    - ☐ There are no data from which to generate a weight of evidence

- grouping and read-across
  - Higher ethyleneamines could be used for as analogues for read across purposes; however, these analogues differ in their ability to chelate essential nutrients from the body and hence interfere with reproduction through an indirect mechanism. Therefore, a read across approach is not possible for this endpoint
- substance-tailored exposure driven testing [if applicable]
  - An exposure based waiver for this substance is not deemed appropriate. It is almost impossible to formulate a sufficiently robust case for exposure based waiving due to the need to demonstrate 'No' exposure, or use a risk assessment. This substance is corrosive and risk management measures for it's use have been instituted to mitigate any local effects. Potential exposure to the substance would be dose limited since DNELS protective for local effects would also be protective of systemic toxicity bserved at higher exposure concentrations.
- [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):

Adaptation options as defined in Annexes VI to X were not appllicable for this substance and this endpoint.