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: SODIUM 1H-BENZOTRIAZOLIDE
EC Number (omit if confidential): 239-269-6
CAS Number (omit if confidential): 15217-42-2

Date of considerations: 14 June 2016

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

  Reproductive toxicity (pre-natal developmental toxicity) with the analogue substance Benzotriazole (CAS# 95-14-7);

- **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

    For Benzotriazole a well-conducted in vivo study (that adheres to OECD Guideline 421) is available showing a NOAEL of 200 mg/kg bw for the reproductive and developmental dose toxicity. The study was designed as screening study and no higher doses were tested in this study.

  - available non-GLP studies

    No non GLP-compliant developmental toxicity/teratogenicity studies are available.

  - historical human data

    No historical human data that could address the current data gap are available.

  - (Q)SAR

    (Q)SAR tools sufficiently addressing the endpoint developmental toxicity/teratogenicity are currently not available.

  - *in vitro* methods

    In vitro tools sufficiently addressing the endpoint developmental toxicity/teratogenicity are currently not available.

- weight of evidence

  There is not sufficient data available that could be used in a weight of evidence approach.

- grouping and read-across

  No specific information on similar substances is available. Mutual read across from sodium 1H-benzotriazolide to 1H-Benzotriazole was already chosen to avoid unnecessary animal testing. This is explained further below.

- substance-tailored exposure driven testing [if applicable]

  Not applicable

- [approaches in addition to above [if applicable]

  Not applicable

- other reasons [if applicable]

  In accordance with EC 1907/2006 Annex XI 1.5 sodium benzotriazole is registered in a category approach covering 1H-Benzotriazole and Tolyltriazole as well as the conjugated sodium salts of these two substances.

  The substances 1H-Benzotriazole, Methyl-1H-Benzotriazole, Sodium 1H-Benzotriazolate (sodium benzotriazole) and Sodium Methyl-1H-Benzotriazolate were identified as a category and Read Across for certain (eco)toxicological endpoints was performed.

  For the proposed test, one substance i.e. 1H-Benzotriazole of this category is intended to be tested and read across to the other three substances may be performed to meet the information requirements for all four substances.

  This pre-natal developmental toxicity study (OECD Guideline 414/EU B.31) for 1H-Benzotriazole (CAS# 95-14-7) has been proposed by the REACH lead registrant (Connect Chemicals GmbH) for the substance (CAS# 95 -14 -7). The results from this study will be included in the registration dossier for sodium 1H-benzotriazolide once the study on 1H-Benzotriazole has been completed by the lead registrant for CAS# 95-14-7. As sodium benzotriazole is registered in a category approach covering 1H-Benzotriazole and Tolyltriazole as well as the conjugated sodium salts further testing with other category members is considered to be not necessary.

- **Considerations that the specific adaptation possibilities of Annexes VI to X (and column 2 thereof) were not applicable** (instruction: free text):

Annex IX 8.7.2. Pre-natal developmental toxicity study, one species, most appropriate route of administration, having regard to the likely route of human exposure (B.31 of the Commission Regulation on test methods as specified in Article 13(3) or OECD 414).

Column 2: 8.7.2. The study shall be initially performed on one species. A decision on the need to perform a study at this tonnage level or the next on a second species should be based on the outcome of the first test and all other relevant available data.

The proposed study [to be conducted by the REACH lead registrant (Connect Chemicals GmbH) for the read-across substance 1H-Benzotriazole (CAS# 95-14-7)] is a standard information requirement at 100-1000 tonnes, which is the registration tonnage band for sodium 1H-benzotriazolide. No adaptation possibilities are stated in Annex IX Column 2: 8.7.2.