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'-dimethyl-2,2'-azodipropiononitrile
EC Number (omit if confidential): 201-132-3
CAS Number (omit if confidential): 78-67-1

Date of considerations: 17 December 2015

Hazard endpoint for which vertebrate testing was proposed:

Reproductive toxicity (pre-natal developmental toxicity) in a non-rodent sepcies (second species) 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
  None

- available non-GLP studies
  None

- historical human data
  None

- (Q)SAR
  According to ECHA guidance (see Chapter R.7.a, Version 4.1, October 2015, R 7.6.4.1.2 , Page 382): "*QSAR approaches are currently not well fitted-for-purpose for reproductive toxicity and not all necessary aspects can be covered by a QSAR prediction*".

- *in vitro* methods
  In vitro studies are not available on the registered substance.

  Some in vitro methods and methodology are reported, however, according to ECHA guidance (see Chapter R.7.a, October 2015, R.7.6.4.1, page 381) *:"the regulatory acceptance of these in vitro studies and approaches to replace the animal testing for reproductive toxicity has not been achieved as they do not provide equivalent information" .*

- weight of evidence
  No data is available on the second species for the registered substance or for a comparable substance.

  According to ECHA Guidance R.7a, for the evaluation of developmental toxicity, testing in a second species should be performed in case this type of study is not available. Weight of evidence using available studies in the first tested species is not relevant and applicable for assessment in the second species.

- grouping and read-across
  No information is available from comparable substance.

- substance-tailored exposure driven testing [if applicable]
  Not applicable

- [approaches in addition to above [if applicable]
  Not applicable

- other reasons[if applicable]
  None

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

Test proposal is fully compliant with ECHA guidance (R.7.a-Octobre 2015, R.7.6.2.3.2, Page 373):

> If a study on a second species is found to be necessary by the registrant, a testing proposal needs to be submitted. Testing in a second species should be performed in a non-rodent species (rabbit) if the first species was a rodent species (rat) and vice versa. Further considerations on the species selection are provided in Section R.7.6.4.2.2 of this Guidance.

The specific adaptation possibilities for waiving the developmental second species test mentioned in colomn 2 in Annex X section 7.8.2 are not applicable for the test susbstance:

1**-Results from existing studies (prenatal developmental toxicity test or repeated-dose studies) are sufficient to support classification to category 1 B for effects on developmental toxicity and/or sexual function and fertility:* ***not applicable
2**-Substance is a genotoxic carcinogen and appropriate risk management measure are implemented:* ***not applicable
3**-Substance is known to be a germ cell mutagene and appropriate risk management are implemented:* ***not applicable
4**-Substance is of low toxicological activity, no systemic absorption occurs via relevant route of exposure:* ***not applicable