~~Confidential~~

Helsinki, 08 November 2021

Addressees
Registrants of Hexene_HOPA listed in the last Appendix of this decision

Date of submission of the dossier subject of a decision
26/07/2018

Registered substance subject to this decision, hereafter 'the Substance'
Substance name: Hexene
EC number: 246-768-2
CAS number: 25264-93-1

Decision number: Please refer to the REACH-IT message which delivered this communication (in format TPE-D-XXXXXXXXXX-XX-XX/F)

DECISION ON TESTING PROPOSAL(S)

Based on Article 40(3)(d) of Regulation (EC) No 1907/2006 (REACH), the testing proposals listed below are rejected:

A. Testing proposals under Annex VIII to REACH

1. Pre-natal developmental toxicity study in rabbits (EU B.31./OECD TG 414)
2. Extended one-generation reproductive toxicity study (EU B.56./OECD TG 443)

Reasons for the rejection(s) are explained in Appendix A.

Appeal

This decision can be appealed to the Board of Appeal of ECHA within three months of its notification. An appeal, together with the grounds thereof, has to be submitted to ECHA in writing. An appeal has suspensive effect and is subject to a fee. Further details are described under: http://echa.europa.eu/regulations/appeals.

Approved[1] under the authority of Christel Schilliger-Musset, Director of Hazard Assessment

[1] As this is an electronic document, it is not physically signed. This communication has been approved according to ECHA's internal decision-approval process.

Appendix A: Reasons to reject testing proposals under Annex VIII to REACH

This decision is based on the examination of the testing proposals you submitted.

1. Pre-natal developmental toxicity study

A pre-natal developmental toxicity (PNDT) study may be proposed in case of serious concerns about the potential for adverse effects on development under Annex VIII to REACH instead of a screening study (Section 8.7.1., column 2).

1.1. Information provided

You have submitted testing proposals for PNDT studies in a second species (rabbit) according to OECD TG 414, to be performed on the following substances:

- hex-1-ene (EC No. 209-753-1)
- octadec-1-ene (EC No. 204-012-9)
- octadecene (EC No. 248-205-6)
- Alkenes, C8-10, C9-rich (EC No. 271-212-0)
- Nonene, branched (EC No. 306-492-6)

You refer to a read-across strategy and provided a read-across category justification document in IUCLID section 13.

You have not provided any justification why there is a need to perform these studies to address the information requirements of your Substance.

In particular, you have not identified any indication of serious concerns about the potential for adverse effects on development for your Substance in the testing proposals or in the category justification document. On the contrary, you consider that the proposed test substances are '*unlikely to cause developmental toxicity*'.

Therefore these studies are not needed.

ECHA requested your considerations for alternative methods to fulfil the information requirement for Developmental toxicity. You provided your considerations and you applied read-across to fulfil the respective information requirement, and no other alternative methods were available. ECHA has taken these considerations into account.

ECHA considers that, in the absence of indications of serious concerns about the potential for adverse effects on development, PNDT studies are not necessary at this tonnage band.

1.2. Outcome

Under Article 40(3)(d) of REACH, the proposed tests are rejected.

In the testing proposal examination, ECHA has only assessed the need for the tests. This assessment resulted in the rejection of the testing proposals. Therefore, no assessment of the adequacy of studies/test materials proposed was performed.

2. Extended one-generation reproductive toxicity study

An Extended one-generation reproductive toxicity (EOGRT) study may be proposed in case of serious concerns about the potential for adverse effects on fertility under Annex VIII to REACH instead of a screening study (Section 8.7.1., column 2).

2.1 Information provided

You have submitted testing proposals for EOGRT studies according to OECD TG 443 to be performed on the following substances:

- hex-1-ene (EC No. 209-753-1)
- octadec-1-ene (EC No. 204-012-9)
- hexadecene (EC No. 248-131-4)
- Alkenes, C8-10, C9-rich (EC No. 271-212-0)
- Nonene, branched (EC No. 306-492-6)

You refer to a read-across strategy and provided a read-across category justification document in IUCLID section 13.

You have not provided any justification why there is a need to perform these studies to address the information requirements of your Substance.

In particular, you have not identified any indication of serious concerns about the potential for adverse effects on fertility for your Substance in the testing proposals or in the category justification document.

Therefore these studies are not needed.

ECHA requested your considerations for alternative methods to fulfil the information requirement for Toxicity to reproduction. You provided your considerations and you applied read-across to fulfil the respective information requirement, and no other alternative methods were available. ECHA has taken these considerations into account.

ECHA considers that, in the absence of indications of serious concerns about the potential for adverse effects on fertility, EOGRT studies are not necessary at this tonnage band.

2.2 Outcome

Under Article 40(3)(d) of REACH, the proposed tests are rejected.

In the testing proposal examination, ECHA has only assessed the need for the tests. This assessment resulted in the rejection of the testing proposals. Therefore, no assessment of the adequacy of study/test material proposed was performed.

Appendix B: Procedure

ECHA started the testing proposal evaluation in accordance with Article 40(1) on 1 July 2020.

ECHA held a third party consultation for the testing proposal(s) from 23 November 2020 until 7 January 2021. ECHA did not receive information from third parties.

ECHA followed the procedure detailed in Articles 50 and 51 of REACH.

ECHA notified you of the draft decision and invited you to provide comments.

ECHA did not receive any comments within the commenting period.

ECHA notified the draft decision to the competent authorities of the Member States for proposals for amendment.

As no amendments were proposed, ECHA adopted the decision under Article 51(3) of REACH.

Appendix C: Addressees of this decision and the corresponding information requirements applicable to them

You must provide the information requested in this decision for all REACH Annexes applicable to you.

Registrant Name	Registration number	Highest REACH Annex applicable to you
[redacted]	[redacted]	[redacted]

Where applicable, the name of a third party representative (TPR) may be displayed in the list of recipients whereas ECHA will send the decision to the actual registrant.