

# SUBSTANCE EVALUATION CONCLUSION as required by REACH Article 48 and EVALUATION REPORT

for

Isoheptane EC No 250-610-8 CAS No 31394-54-4

**Evaluating Member State(s):** Latvia

Dated: September 2015

# **Evaluating Member State Competent Authority**

# Latvian Environment, Geology and Meteorology Centre

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# Year of evaluation in CoRAP: 2012

Before concluding the substance evaluation a Decision to request further information was issued on: 20.06,2013.

# Further information on registered substances here:

http://echa.europa.eu/web/guest/information-on-chemicals/registered-substances

#### **DISCLAIMER**

This document has been prepared by the evaluating Member State as a part of the substance evaluation process under the REACH Regulation (EC) No 1907/2006. The information and views set out in this document are those of the author and do not necessarily reflect the position or opinion of the European Chemicals Agency or other Member States. The Agency does not guarantee the accuracy of the information included in the document. Neither the Agency nor the evaluating Member State nor any person acting on either of their behalves may be held liable for the use which may be made of the information contained therein. Statements made or information contained in the document are without prejudice to any further regulatory work that the Agency or Member States may initiate at a later stage.

# **Foreword**

Substance evaluation is an evaluation process under REACH Regulation (EC) No. 1907/2006. Under this process the Member States perform the evaluation and ECHA secretariat coordinates the work. The Community rolling action plan (CoRAP) of substances subject to evaluation, is updated and published annually on the ECHA web site<sup>1</sup>.

Substance evaluation is a concern driven process, which aims to clarify whether a substance constitutes a risk to human health or the environment. Member States evaluate assigned substances in the CoRAP with the objective to clarify the potential concern and, if necessary, to request further information from the Registrant(s) concerning the substance. If the evaluating Member State concludes that no further information needs to be requested, the substance evaluation is completed. If additional information is required, this is sought by the evaluating Member State. The evaluating Member State then draws conclusions on how to use the existing and obtained information for the safe use of the substance.

This Conclusion document, as required by Article 48 of the REACH Regulation, provides the final outcome of the Substance Evaluation carried out by the evaluating Member State. The document consists of two parts i.e. A) the conclusion and B) the evaluation report. In the conclusion part A, the evaluating Member State considers how the information on the substance can be used for the purposes of regulatory risk management such as identification of substances of very high concern (SVHC), restriction and/or classification and labelling. In the evaluation report part B the document provides explanation how the evaluating Member State assessed and drew the conclusions from the information available.

With this Conclusion document the substance evaluation process is finished and the Commission, the Registrant(s) of the substance and the Competent Authorities of the other Member States are informed of the considerations of the evaluating Member State. In case the evaluating Member State proposes further regulatory risk management measures, this document shall not be considered initiating those other measures or processes. Further analyses may need to be performed which may change the proposed regulatory measures in this document. Since this document only reflects the views of the evaluating Member State, it does not preclude other Member States or the European Commission from initiating regulatory risk management measures which they deem appropriate.

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<sup>&</sup>lt;sup>1</sup> http://echa.europa.eu/regulations/reach/evaluation/substance-evaluation/community-rolling-action-plan

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# Part A. Conclusion

# 1. CONCERN(S) SUBJECT TO EVALUATION

Isoheptane was originally selected for substance evaluation in order to clarify suspected risks about:

- Suspected PBT/vPvB;
- Exposure/Wide dispersive use (workers, professional and industrial users), high tonnage.

# 2. OVERVIEW OF OTHER PROCESSES / EU LEGISLATION

Not applicable.

# 3. CONCLUSION OF SUBSTANCE EVALUATION

The evaluation of the available information on the substance has led the evaluating Member State to the following conclusions, as summarised in the table below.

Table 1

CONCLUSION OF SUBSTANCE EVALUATION	
Conclusions	Tick box
Need for follow-up regulatory action at EU level	
Harmonised Classification and Labelling	
Identification as SVHC (authorisation)	
Restrictions	
Other EU-wide measures	
No need for regulatory follow-up action	Х

# 4. FOLLOW-UP AT EU LEVEL

# 4.1. Need for follow-up regulatory action at EU level

Not applicable.

#### 4.1.1. Harmonised Classification and Labelling

Not applicable.

# 4.1.2. Identification as a substance of very high concern, SVHC (first step towards authorisation)

Not applicable.

#### 4.1.3. Restriction

Not applicable.

# 4.1.4. Other EU-wide regulatory risk management measures

Not applicable.

# 5. CURRENTLY NO FOLLOW-UP FORESEEN AT EU LEVEL

# 5.1. No need for regulatory follow-up at EU level

#### Table 2

REASON FOR REMOVED CONCERN	
The concern could be removed because	Tick box
Clarification of hazard properties/exposure*	Х
Actions by the registrants to ensure safety, as reflected in the registration dossiers** (e.g. change in supported uses, applied risk management measures, etc.)	
*This conclusion can be reached e.g. if the outcome of a test on hazardous properties clarified that substance is not hazardous, the exposure data shows no risk. This can be due to the fact that the data was originally available in the registration dossiers or was obtained due to a substance evaluation decision.	

Taking into consideration the PBT and vPvB criteria detailed in Annex XIII of REACH, the information submitted by the Registrant and based on expert judgment, isoheptane does

st\*This conclusion can be reached if registrants changed their registrations e.g. the supported uses, applied risk

The exposure assessment for workers, professional and industrial use was done. According to exposure assessment the evaluating Member State Competent Authority (eMSCA) concludes that the estimated exposure presented by the Registrant based on modelling seems plausible.

not meet the criteria for persistence (P and vP) and for bioaccumulation (B or vB).

The long term Risk Characterization Ratio for combined routes (inhalation + dermal) value is < 1. The eMSCA notes that the risk for workers, professional and industrial users are controlled, taking into account Risk management measures (RMMs) and Occupational conditions (OCs) proposed by the Registrant.

#### 5.2. Other actions

No need for other follow-up actions based on this substance evaluation.

# 6. TENTATIVE PLAN FOR FOLLOW-UP ACTIONS (IF NECESSARY)

Not applicable.

# Part B. Substance evaluation

# 7. EVALUATION REPORT

# 7.1. Overview of the substance evaluation performed

Isoheptane was originally selected for substance evaluation in order to clarify suspected risks about:

- Suspected PBT/vPvB;
- Exposure/Wide dispersive use (workers, professional and industrial), high tonnage.

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Table 3

EVALUATED ENDPOINTS	
Endpoint evaluated	Outcome/conclusion
PBT/vPvB	Concern not substantiated. No further action.
Exposure assessment and risk characterisation for workers, professional and industrial users	Acceptable. No further action.

### 7.2. Procedure

On the basis of an opinion of the ECHA Member State Committee and due to initial grounds for concern relating to exposure to workers, professional and industrial users and possible PBT/vPvB properties isoheptane CAS No 31394-54-4 (EC No 250-610-8) was included in the Community rolling action plan (CoRAP) for substance evaluation according to Article 44(2) of the REACH Regulation, to be evaluated in 2012. The CoRAP was published on the ECHA website on 29 February 2012 and the Competent Authority of Latvia was appointed as the evaluating Member State Competent Authority (eMSCA).

According to Article 45(4) of the REACH Regulation eMSCA has initiated substance evaluation for isoheptane, based on a registration submitted by the concerned Registrant and prepared the decision in accordance with Article 46(1) of the REACH Regulation.

Based on the evaluation of the available data, the eMSCA concluded that there was a need to request further information to clarify the substance identity, in order to be able to clarify the initial concerns. Taking into account the registration submitted by the Registrant the eMSCA prepared a draft decision pursuant to Article 46(1) of the REACH Regulation, to request further information.

Following a unanimous agreement of the Member State Committee reached on 9 September 2013 ECHA issued on 20 December 2013 a decision pursuant to Article 51(6) of the REACH Regulation, requesting information on:

- 1. Name or other identifier of each substance,
- 2. Composition of the substance,
- 3. Spectral data,
- Description of analytical methods or the appropriate bibliographical references for identification of the substance and, where appropriate, for the identification of impurities and additives.

The Registrant submitted the requested information on 19 March 2014. The eMSCA assessed the submitted information and concluded that the information is sufficient to clarify the concerns.

eMSCA consulted with PBT Expert Group regarding the evaluation of PBT properties for isoheptane.

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# **7.3. Identity of the substance**

# Table 4

SUBSTANCE IDENTITY		
Public name:	Isoheptane	
EC number:	250-610-8	
CAS number:	31394-54-4	
Index number in Annex VI of the CLP Regulation:	601-008-00-2	
Molecular formula:	C <sub>7</sub> H <sub>16</sub>	
Molecular weight range:	100.2 g/mol	
Synonyms:	2-methylhexane	

Type of substance	☐ Mono-constituent	☐ Multi-constituent	⊠ UVCB
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# Structural formula:

# **Composition of the substance**

Name: Isoheptane

**Description:** Composition of substance is presented as hydrocarbon with C7 carbon atoms containing some linear and cyclic saturated alkanes (isomers of isoheptane). The information on composition is in line with the analytical methods provided by Registrant. For identification of Registrant substance following methods were used and described: Ultraviolet-Visible Spectroscopy (UV-VIS), Infrared Spectroscopy (IR), Proton-Nuclear Magnetic resonance spectroscopy (1H NMR), Gas Chromatography (GC) and Gas Chromatography – Mass Spectroscopy (GC-Mass Spec).

The substance is considered as a substance of Unknown or Variable composition, Complex reaction products or Biological materials (UVCB) - substances for which the number of constituents is high, or the composition is to a significant extent unknown, or the variability of composition is large or unpredictable. In these cases a straightforward identification is not possible because the substance cannot be sufficiently identified by the chemical composition [Guidance in a Nutshell Identification and naming of substances under REACH and CLP, 2011, ECHA].

#### **UVCB** substance

#### Table 5

Constituents	Typical concentration	Concentration range
2-methylhexane EC No.: 209-730-6	Confidential	Confidential
3-methylhexane EC No.: 209-643-3	Confidential	Confidential
2,3-dimethylpentane EC No.: 209-280-0	Confidential	Confidential
3,3-dimethylpentane EC No.: 209-230-8	Confidential	Confidential
2,4-dimethylpentane EC No.: 209-230-8	Confidential	Confidential
2,2-dimethylpentane EC No.: 209-230-8	Confidential	Confidential
cis-1,3- dimethylcyclopentane EC No.: 219-793-1	Confidential	Confidential
n-hexane EC No.: 203-777-6	Confidential	Confidential
heptane EC No.: 205-563-8	Confidential	Confidential
C6-C7 cycloalkanes EC No.: none	Confidential	Confidential

C6-C7 isoalkanes EC No.: none  Confidential Confidential	
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# **7.4. Physico-chemical properties**

# Table 6

OVERVIEW OF PHYSICOCHEMICAL PROPERTIES			
Property	Value	Remarks	
Physical state at 20°C and 101.3 kPa	Liquid	The substance is a colourless liquid.	
Melting/freezing point	Study scientifically unjustified	In accordance with column 2 of REACH Annex VII, the study does not need to be conducted below a lower limit of - 20 °C.	
Boiling point	89.3 – 91.3 °C at 100 kPa	Experimental data according to ASTM D 1078 method.	
Relative Density	0.69 g/cm³ at 15 °C	Experimental data according to DIN 51757.	
Vapour pressure	8.9 kPa at 20 °C	Data was estimated by a QSAR, the Petrotox computer model (v 3.04).	
Surface tension	20 mN/m at 25 °C	Experimental data according to DIN 53914 using Wilhelmy plate.	
Water solubility	2.5 mg/L at 25 °C	Data from handbook.	
Partition coefficient n- octanol/water (Log K <sub>ow</sub> )	3.7	Data is calculated based on KOWWIN programme v1.67, Estimation Programs Interface Suite™ for Microsoft® Windows v 4.00. US EPA, United States Environmental Protection Agency, Washington, DC, USA.	
Flash point	< 0 °C at 1 atm (closed cup)	Experimental data according to ASTM D56.	
Flammability	Study scientifically unjustified	In accordance with REACH Annex XI, point 1.1.1 testing does not appear scientifically necessary. Data generated in accordance with CLP. The substance has a flash point below 23 °C and an initial boiling point higher than 35 °C. Based on CLP, Section 2.6 substance is considered as Flammable liquid (Category 2).	

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Explosive properties	Study scientifically unjustified	In accordance with column 2 of REACH Annex VII, the study is not required, no chemical groups associated with explosive properties present in the molecule.
Oxidising properties	Study scientifically unjustified	In accordance with column 2 of REACH Annex VII, the study is not required, on the basis on chemicals structure: no halogen atoms chemically bonded to oxygen or nitrogen.
Granulometry	Study scientifically unjustified	In accordance with column 2 of REACH Annex VII, the study is not required: the substance is marketed or used in a non solid or granular form.
Stability in organic solvents and identity of relevant degradation products	Study scientifically unjustified	In accordance with column 1 of REACH Annex IX, the study is not required, as the stability of the substance is not considered to be critical.
Dissociation constant	Study scientifically unjustified	According to Guidance for implementation of REACH, document on Guidance on information requirements and CSA, Chapter R.7a: Endpoint Specific Guidance (2008), the study is not required, if the substance cannot dissociate due to a lack of relevant functional groups. The dissociation constant is irrelevant.

# 7.5. Manufacture and uses

# 7.5.1. Quantities

Tonnage band: 1000-10 000 tonnes per annum.

# 7.5.2. Overview of uses

# Table 8

USES	
	Use(s)
Manufacture	01 - Manufacture of Substance
Formulation	02 - Formulation & (Re)packing of Substances and Mixtures
Uses at industrial sites	01b - Distribution of Substance 04a - Use in Cleaning Agents: Industrial 03a - Uses in Coatings: Industrial

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Uses by professional workers	04b - Use in Cleaning Agents: Professional 11a - Use in Agrochemicals: Professional 03b - Uses in Coatings: Professional
Consumer Uses	03c - Uses in Coatings: Consumer 04c - Use in Cleaning Agents: Consumer

# 7.6. Classification and Labelling

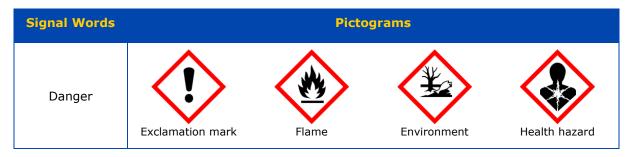
# 7.6.1. Harmonised Classification (Annex VI of CLP)

Isoheptane is listed by Index number 601-008-00-2 in Annex VI of the CLP Regulation. The following table shows the CLP classification in Annex VI, Table 3.1 of isoheptane.

Table 9

HARMONISED CLASSIFICATION ACCORDING TO ANNEX VI OF CLP REGULATION (REGULATION (EC) 1272/2008)						
Classification		Labelling			Cunnifin	
Hazard Class and Category Code(s)	Hazard statement code(s)	Hazard Class and Category Code(s)	Supplementary Hazard Statement Code(s)	Pictograms, Signal Word Code(s)	Specific Concentration limits, M- Factors	Notes
Flam. Liq. 2 Asp. Tox. 1 Skin Irrit. 2 STOT SE 3 Aquatic Acute 1 Aquatic Chronic 1	H225 H304 H315 H336 H400	H225 H304 H315 H336		GHS07 GHS02 GHS09 GHS08 Dgr		Note C

Table 10



# 7.6.2. Self-classification

Not applicable.

# 7.7. Environmental fate properties

#### 7.7.1. Degradation

With respect to **abiotic degradation** through hydrolysis, isoheptane and other constituent chemicals of the C7-C9 aliphatic hydrocarbon solvents category are composed of carbon and hydrogen and are not subject to hydrolysis because of their molecular structure and lack of the chemical reaction required for this type of transformation. Hydrolysis of an organic molecule only occurs when a molecule (R-X) reacts with water ( $H_2O$ ) to form a new carbon-oxygen bond after the carbon-X bond is cleaved what is not the case with isoheptane.

Concerning **phototransformation in air**, isoheptane has the potential to volatilize to air based on a relatively high vapour pressure where it is subject to atmospheric oxidation by means of hydroxyl radicals (OH-). The estimated Half-life (DT $_{50}$ ) for isoheptane is 1.56 days based on assumption of 12-hour day (Experimental study. APOWIN calculation 2010; Experimental study. Kocwin calculation, 2010; Experimental study. BCFAF calculation, 2010).

Data on phototransformation in water or soil are not available.

**Biodegradation** tests **in water were** performed according to OECD Guideline 301 F or with methods equivalent to OECD Guideline 301 F in the activated sludge used for domestic wastewater treatment. As the test substance the C7-C9 isoalkanes were used. Again, read-across approach to isoheptane should be used owing to structural similarities of these hydrocarbons.

Degradation of test substance summarized from the two studies was the following: 10.5 - 26.83 % after 11-15 days, 51.3 % after 28 days, 49 - 60.3 % after 42 - 43 days, 60.2 % after 60 days, 61.81 - 64.06 % after 70 - 75 days (Experimental study. Ready Biodegradability, 1998).

According to CLP criteria, substances are considered rapidly degradable in the environment if the substance can be degraded (biotically and/or abiotically) in the aquatic environment to a level > 70 % within a 28-day period.

The data show that C7-C9 isoalkanes are not so readily biodegradable, but can demonstrate high extents of biodegradability when test durations are extended. So, it is considered that isoheptane is not expected to persist in the environment.

According to REACH legislation, Annex IX, 9.2, column 2, studies on further biotic degradation do not need to be conducted if direct and indirect exposure of the water, sediment and soil compartments is unlikely. Risk assessment shows that the modelled RCRs values by application of aquatic PNECs values from which the other PNECs are derived are very low in all other environmental compartments.

#### 7.7.2. Bioaccumulation

With regard to bioaccumulation no experimental data are available in relation to isoheptane. In this case read-across approach from other members in the C7-C9 aliphatic hydrocarbons` group could be applied taking into account similarity in their molecular structure. For the n-octane in the mussel *Mytilus edulis* the measured aquatic bioconcentration factor (BCF) value is reported to be 199 (log BCF = 2.3) (Publ., 1989).

In addition, calculated BCF is obtained particularly for isoheptane, too, and the respective value is 129 (log BCF = 2.11). For these calculations the software BCFBAF version 3.00, a subroutine of the computer program EPI Suite $^{\text{TM}}$ , 2000 was used (Experimental study. APOWIN calculation 2010; Experimental study. Kocwin calculation, 2010; Experimental study. BCFAF calculation, 2010)).

No information available on terrestrial bioaccumulation.

According to criteria of REACH Annex XIII, a substance fulfils the bioaccumulation criterion when the BCF is higher than 2000.

Following, isoheptane is not recognized as bioaccumulative substance based on simulated data as well as on read-across approach from n-octane, similar member in the C7-C9 aliphatic hydrocarbons` group.

# 7.8. Environmental hazard assessment

According to Annex XIII of REACH, in order to fulfil the toxicity criterion concerning environmental toxicity, the long-term no-observed effect concentration (NOEC) or  $EC_{10}$  for marine or freshwater organisms must be less than 0.01 mg/l. The applicant has provided one key study related to the long-term toxicity to fish (*Oncorhynchus mykiss*) caused by isoheptane. 28-day NOELR (No Observed Effect Loading Rate) value was

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calculated using the Petrotox computer model (v. 3.04). The estimated 28-day NOELR value is 2.426 mg/l based on growth.

In addition, long-term effects on aquatic invertebrates (*Daphnia magna*) are studied by application of hydrocarbons solvents (C7-C9 hydrocarbons - n-alkanes, isoalkanes, cyclics. As no studies are available on the chronic toxicity to aquatic invertebrates for isoheptane read-across to C7-C9 hydrocarbons was used. In this key study performed acc. to OECD 211 guideline chronic toxicity to *Daphnia* at 1.6 mg/l is detected based on nominal loadings of the test substance in water. A NOELR was determined to be 1 mg/l.

Following, isoheptane is not classified in relation to aquatic environment.

#### 7.9. Human Health hazard assessment

Not evaluated further as the eMSCA concluded that the substance is not P and not B.

#### 7.10. PBT and vPvB assessment

Based on the evaluated information, and considerations described in section 7.7, the eMSCA concludes that isoheptane can be considered to be non-persistent in the environment, not bioaccumulative and therefore does not meet the PBT/vPvB criteria.

# 7.11. Exposure assessment

# 7.11.1. Exposure assessment for workers, professional and industrial users

The eMSCA assessed exposure to workers and derived exposure values. Based on the information submitted by the Registrant regarding exposure conditions, described RMMs and OCs, the eMSCA concludes that the estimated exposure seems plausible.

#### 7.12. Risk characterisation

# **7.12.1.** Risk characterisation for workers, professional and industrial users

Based on the evaluated information, the eMSCA concludes that the long term Risk Characterization Ratio for combined routes (inhalation + dermal) value is < 1 and the risk for workers, professional and industrial users appears to be controlled taking into account RMMs and OCs proposed by the Registrant. The eMSCA notes that Registrant also proposed and considered the RMMs and OCs for controlling and reducing a risk for workers, professional and industrial users.

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