

Justification Document for the Selection of a CoRAP Substance

Substance Name (public name): 3,5,5-trimethylhexanoic acid

EC Number: 221-975-0

CAS Number: 3302-10-1

Authority: UK MSCA

Date: 22/03/2016

Note

This document has been prepared by the evaluating Member State given in the CoRAP update.

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1 IDENTITY OF THE SUBSTANCE

1.1 Other identifiers of the substance

Table: Other Substance identifiers

EC name (public):	3,5,5-trimethylhexanoic acid
IUPAC name (public):	3,5,5-trimethylhexanoic acid
Index number in Annex VI of the CLP Regulation:	NA
Molecular formula:	C ₉ H ₁₈ O ₂
Molecular weight or molecular weight range:	158.24
Synonyms:	

Type of substance Mono-constituent Multi-constituent UVCB

Structural formula:



1.2 Similar substances/grouping possibilities

Not applicable

2 OVERVIEW OF OTHER PROCESSES / EU LEGISLATION

Table: Completed or ongoing processes

RMOA	<input type="checkbox"/> Risk Management Option Analysis (RMOA)	
REACH Processes	Evaluation	<input type="checkbox"/> Compliance check, Final decision
		<input checked="" type="checkbox"/> Testing proposal – complete – dossier updated
		<input type="checkbox"/> CoRAP and Substance Evaluation
	Authorisation	<input type="checkbox"/> Candidate List
		<input type="checkbox"/> Annex XIV
Restriction	<input type="checkbox"/> Annex XVII	
Harmonised C&L	<input type="checkbox"/> Annex VI (CLP) (see section 3.1)	
Processes under other EU legislation	<input type="checkbox"/> Plant Protection Products Regulation Regulation (EC) No 1107/2009	
	<input type="checkbox"/> Biocidal Product Regulation Regulation (EU) 528/2012 and amendments	
Previous legislation	<input type="checkbox"/> Dangerous substances Directive Directive 67/548/EEC (NONS)	
	<input type="checkbox"/> Existing Substances Regulation Regulation 793/93/EEC (RAR/RRS)	
(UNEP) Stockholm convention (POPs Protocol)	<input type="checkbox"/> Assessment	
	<input type="checkbox"/> In relevant Annex	
Other processes / EU legislation	<input type="checkbox"/> Other (provide further details below)	

3 HAZARD INFORMATION (INCLUDING CLASSIFICATION)

3.1 Classification

3.1.1 Harmonised Classification in Annex VI of the CLP

No harmonised classification is available for the substance.

3.1.2 Self classification

- In the registration:
 - Acute tox 4, H302 Harmful if swallowed
 - Skin irrit 2, H315 Causes skin irritation
 - Eye damage 1, H318 Causes serious eye damage
- The following hazard classes are in addition notified among the aggregated self classifications in the C&L Inventory:
 - Eye irrit 2, H319 Causes serious eye irritation
 - STOT SE 3, H335 (resp system, inhalation) May cause respiratory irritation
 - Unclassified

3.1.3 Proposal for Harmonised Classification in Annex VI of the CLP

Not applicable

4 INFORMATION ON (AGGREGATED) TONNAGE AND USES¹

4.1 Tonnage and registration status

Table: Tonnage and registration status

From ECHA dissemination site		
<input checked="" type="checkbox"/> Full registration(s) (Art. 10)	<input type="checkbox"/> Intermediate registration(s) (Art. 17 and/or 18)	
Tonnage band (as per dissemination site)		
<input type="checkbox"/> 1 - 10 tpa	<input type="checkbox"/> 10 - 100 tpa	<input type="checkbox"/> 100 - 1000 tpa
<input type="checkbox"/> 1000 - 10,000 tpa	<input type="checkbox"/> 10,000 - 100,000 tpa	<input type="checkbox"/> 100,000 - 1,000,000 tpa
<input type="checkbox"/> 1,000,000 - 10,000,000 tpa	<input type="checkbox"/> 10,000,000 - 100,000,000 tpa	<input type="checkbox"/> > 100,000,000 tpa
<input checked="" type="checkbox"/> <10,000>+ tpa (e.g. 10+ ; 100+ ; 10,000+ tpa)		<input type="checkbox"/> Confidential
Joint submission		

4.2 Overview of uses

Part 1:

<input checked="" type="checkbox"/> Manufacture	<input checked="" type="checkbox"/> Formulation	<input checked="" type="checkbox"/> Industrial use	<input checked="" type="checkbox"/> Professional use	<input type="checkbox"/> Consumer use	<input type="checkbox"/> Article service life	<input type="checkbox"/> Closed system
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Part 2:

	Use(s)
Uses as intermediate	At industrial sites. Not SCC.
Formulation	Preparations
Uses at industrial sites	laboratory use metal working fluids / rolling oils lubricants functional fluids use as intermediate (non SCC)

¹ Date when the dissemination site was accessed – May 2015

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Uses by professional workers	functional fluids laboratory use lubricants metal working fluids / rolling oils
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5. JUSTIFICATION FOR THE SELECTION OF THE CANDIDATE CoRAP SUBSTANCE

5.1. Legal basis for the proposal

- Article 44(2) (refined prioritisation criteria for substance evaluation)
- Article 45(5) (Member State priority)

5.2. Selection criteria met (why the substance qualifies for being in CoRAP)

- Fulfils criteria as CMR/ Suspected CMR
- Fulfils criteria as Sensitiser/ Suspected sensitiser
- Fulfils criteria as potential endocrine disrupter
- Fulfils criteria as PBT/vPvB / Suspected PBT/vPvB
- Fulfils criteria high (aggregated) tonnage (*tpa > 1000*)
- Fulfils exposure criteria
- Fulfils MS's (national) priorities

5.3 Initial grounds for concern to be clarified under Substance Evaluation

Hazard based concerns		
CMR <input type="checkbox"/> C <input type="checkbox"/> M <input type="checkbox"/> R	Suspected CMR ² <input type="checkbox"/> C <input type="checkbox"/> M <input checked="" type="checkbox"/> R	<input type="checkbox"/> Potential endocrine disruptor
<input type="checkbox"/> Sensitiser	<input type="checkbox"/> Suspected Sensitiser ²	
<input type="checkbox"/> PBT/vPvB	<input type="checkbox"/> Suspected PBT/vPvB ²	<input type="checkbox"/> Other (please specify below)
Exposure/risk based concerns		
<input type="checkbox"/> Wide dispersive use	<input type="checkbox"/> Consumer use	<input type="checkbox"/> Exposure of sensitive populations
<input type="checkbox"/> Exposure of environment	<input checked="" type="checkbox"/> Exposure of workers	<input type="checkbox"/> Cumulative exposure
<input type="checkbox"/> High RCR	<input type="checkbox"/> High (aggregated) tonnage	<input type="checkbox"/> Other (please specify below)

² CMR/Sensitiser: known carcinogenic and/or mutagenic and/or reprotoxic properties/known sensitising properties (according to CLP harmonized or registrant self-classification or CLP Inventory)
Suspected CMR/Suspected sensitiser: suspected carcinogenic and/or mutagenic and/or reprotoxic properties/suspected sensitising properties (not classified according to CLP harmonized or registrant self-classification)
Suspected PBT: Potentially Persistent, Bioaccumulative and Toxic

A developmental toxicity study in rats has been conducted according to OECD test guideline 414. In this study morphological changes indicative of delayed development, such as supernumerary and wavy ribs and delayed ossification, were reported at the top dose, together with severely altered rib cages that were reported to result in malformations. This was in the presence of maternal toxicity. From the information available in the dossier it is not clear whether the findings reported are malformations or are the result of variations/delayed development.

Also reported is a yellow discolouration of the foetal livers. This finding was seen in all dose groups in the absence of maternal toxicity and showed a dose-response relationship. There were no underlying morphological changes or histopathology to explain the finding. A one generation range/screening study according to OECD guideline 415 was available, but this did not include histopathology on the pups so provided no information on the persistence of the discolouration post-partum. However, the study reported no effects on the pups in terms of either survival or clinical signs, other than in the presence of maternal toxicity.

These effects raise concern that the substance might be a developmental toxicant in rats. No developmental study in a second species is available. Further consideration is needed of this endpoint.

3,5,5-trimethylhexanoic acid is registered at high tonnages (> 1000 tpa) and, for some exposure scenarios, there is the potential for direct human contact (for example, through the use of metal-working fluids).

5.4 Preliminary indication of information that may need to be requested to clarify the concern

<input checked="" type="checkbox"/> Information on toxicological properties	<input type="checkbox"/> Information on physico-chemical properties
<input type="checkbox"/> Information on fate and behaviour	<input checked="" type="checkbox"/> Information on exposure
<input type="checkbox"/> Information on ecotoxicological properties	<input type="checkbox"/> Information on uses
<input type="checkbox"/> Information ED potential	<input type="checkbox"/> Other (provide further details below)

During substance evaluation details of the effects reported in the developmental study should be requested. Further information or studies might be needed to clarify the concern

5.5 Potential follow-up and link to risk management

<input type="checkbox"/> Harmonised C&L	<input type="checkbox"/> Restriction	<input type="checkbox"/> Authorisation	<input type="checkbox"/> Other (provide further details)
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Further action and risk management measures will depend upon the outcome of the evaluation.