MINISTERIO
DE SANIDAD, CONSUMO
Y BIENESTAR SOCIAL

Justification Document for the Selection of a CoRAP Substance

-Update-

Substance Name (public name):	3,5,5-trimethylhexanoic acid
EC Number:	221-975-0
CAS Number:	3302-10-1
Authority:	Ministry of Health, Consumer Affairs and Social Welfare, Spain
Date:	22/03/2016 (UK) 20/03/2018 (1. Update) (UK) 19/03/2019 (2. Update) (ES)

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

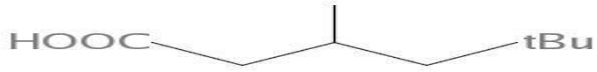
1.1 Other identifiers of the substance

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:	C9H18O2
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	☐ Risk Management Option Analysis (RMOA)	
REACH Processes	Evaluation	☐ Compliance check, Final decision
		☒ Testing proposal – complete – dossier updated
		☐ CoRAP and Substance Evaluation
	Authori-sation	☐ Candidate List
		☐ Annex XIV
	Restri-ction	☐ Annex XVII
Harmonised C&L	☐ Annex VI (CLP) (see section 3.1)	
Processes under other EU legislation	☐ Plant Protection Products Regulation Regulation (EC) No 1107/2009	
	☐ Biocidal Product Regulation Regulation (EU) 528/2012 and amendments	
Previous legislation	☐ Dangerous substances Directive Directive 67/548/EEC (NONS)	
	☐ Existing Substances Regulation Regulation 793/93/EEC (RAR/RRS)	
(UNEP) Stockholm convention (POPs Protocol)	☐ Assessment	
	☐ In relevant Annex	
Other processes / EU legislation	☐ 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 USES[1]

4.1 Tonnage and registration status

Table: Tonnage and registration status

From ECHA dissemination site*		
☒ Full registration(s) (Art. 10)	☐ Intermediate registration(s) (Art. 17 and/or 18)	
Tonnage band (as per dissemination site)		
☐ 1 – 10 tpa	☐ 10 – 100 tpa	☐ 100 – 1000 tpa
☐ 1000 – 10,000 tpa	☐ 10,000 – 100,000 tpa	☐ 100,000 – 1,000,000 tpa
☐ 1,000,000 – 10,000,000 tpa	☐ 10,000,000 – 100,000,000 tpa	☐ > 100,000,000 tpa
☒ 10,000+ tpa		☐ Confidential
Joint submission		

*the total tonnage band has been calculated by excluding the intermediate uses, for details see the Manual for Dissemination and Confidentiality under REACH Regulation (section 2.6.11): https://echa.europa.eu/documents/10162/22308542/manual_dissemination_en.pdf/7e0b87c2-2681-4380-8389-cd655569d9f0

4.2 Overview of uses

Part 1:

☒ Manufacture	☒ Formulation	☒ Industrial use	☒ Professional use	☐ Consumer use	☐ Article service life	☐ Closed system

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

[1] *The dissemination site was accessed November 2018*

	functional fluids use as intermediate (non SCC)
Uses by professional workers	functional fluids laboratory use lubricants metal working fluids / rolling oils

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 ☐ C ☐ M ☐ R	Suspected CMR[2] ☐ C ☐ M ☒ R	☐ Potential endocrine disruptor
☐ Sensitiser	☐ Suspected Sensitiser[2]	
☐ PBT/vPvB	☐ Suspected PBT/vPvB[2]	☐ Other (please specify below)

Exposure/risk based concerns		
☐ Wide dispersive use	☐ Consumer use	☐ Exposure of sensitive populations
☐ Exposure of environment	☒ Exposure of workers	☐ Cumulative exposure
☐ High RCR	☐ High (aggregated) tonnage	☐ 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 ofeither 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 t clarify the concern

☒ Information on toxicological properties	☐ Information on physico-chemical properties
☐ Information on fate and behaviour	☒ Information on exposure
☐ Information on ecotoxicological properties	☐ Information on uses
☐ Information ED potential	☐ 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

☐ Harmonised C&L	☐ Restriction	☐ Authorisation	☐ Other (provide further details)

Further action and risk management measures will depend upon the outcome of the evaluation.