Justification Document for the Selection of a CoRAP Substance

Substance Name (public name):	Methylethylketone peroxide trimer (Trigonox 301)
EC Number:	429-320-2
CAS Number:	24748-23-0
Authority:	NL-CA
Date:	19/03/2019

Cover 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

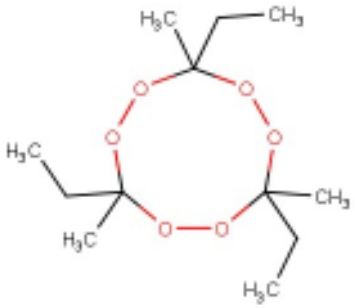
1.1 Other identifiers of the substance

Table: Other Substance identifiers

EC name (public):	Methylethylketone peroxide trimer
IUPAC name (public):	3,6,9-triethyl-3,6,9-trimethyl-1,2,4,5,7,8-hexaoxonane
Index number in Annex VI of the CLP Regulation:	617-021-00-1
Molecular formula:	C12H24O6
Molecular weight or molecular weight range:	ca. 264.32
Synonyms:	• TRIGONOX 301 • INITIATOR D-129 (R&D-NAME) • 1,2,4,5,7,8-Hexoxonane, 3,6,9-triethyl-3,6,9-trimethyl- • methylethylketone peroxide trimer (upper limit: 42% w/w; typical concentration: 41% w/w)

Type of substance ☒ Mono-constituent ☐ Multi-constituent ☐ UVCB

Structural formula:



2 OVERVIEW OF OTHER PROCESSES / EU LEGISLATION

Table: Completed or ongoing processes

RMOA	☐ Risk Management Option Analysis (RMOA)	
REACH Processes	Evaluation	☐ Compliance check
		☐ Testing proposal
		☐ CoRAP and Substance Evaluation
	Authorisation	☐ Candidate List
		☐ Annex XIV
	Restriction	☐ Annex XVII[1]
CLH	☒ 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 67/548/EEC (NONS)	
	☐ Existing Substances Regulation 793/93/EEC (RAR/RRS)	
(UNEP) Stockholm convention (POPs Protocol)	☐ Assessment	
	☐ In relevant Annex	
Other processes/ EU legislation	☐ Other (provide further details below)	
Further details		

[1] Please specify the relevant entry.

3 HAZARD INFORMATION (INCLUDING CLASSIFICATION)

3.1 Classification

3.1.1 Harmonised Classification in Annex VI of the CLP

Table: Harmonised classification

Index No	International Chemical Identification	EC No	CAS No	Classification		Spec. Conc. Limits, M-factors	Notes
				Hazard Class and Category Code(s)	Hazard statement code(s)		
617-021-00-1	**Methylethyl-ketone peroxide trimer**	429-320-2	24748-23-0	Org. Perox. B Skin Irrit. 2 Skin Sens. 1 Asp. Tox. 1	H241 H315 H317 H304		

3.1.2 Self classification

- In the registration:

The registration dossier follows the Harmonised Classification in Annex VI of the CLP, but specifies the Skin Sens. as category 1B instead of category 1.

Table: Self classification

Index No	International Chemical Identification	EC No	CAS No	Classification		Spec. Conc. Limits, M-factors	Notes
				Hazard Class and Category Code(s)	Hazard statement code(s)		
617-021-00-1	**Methylethyl-ketone peroxide trimer**	429-320-2	24748-23-0	Org. Perox. A Asp. Tox. 1 Skin Irrit. 2 Skin Sens. 1 Org. Perox. B Asp. Tox. 1 Skin Irrit. 2 Skin Sens. 1B	H240 H304 H315 H317 H241 H304 H315 H317		

4 INFORMATION ON (AGGREGATED) TONNAGE AND USES[2]

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
☐ <1 . . . . . >+ tpa (e.g. 10+ ; 100+ ; 10,000+ tpa)		☐ Confidential

*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

Table: Uses

Part 1:

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

Technical function of the substance: process regulators used in vulcanisation or polymerisation processes

[2] *The dissemination site was accessed August 2018.*

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 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[1] ☐ C ☐ M ☐ R	☐ Potential endocrine disruptor
☐ Sensitiser	☐ Suspected Sensitiser[3]	
☐ PBT/vPvB	☒ Suspected PBT/vPvB[1]	☐ 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)

[3] 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

Justification for the concerns:

Trigonox 301 had been previously notified under Directive 67/548/ EEC (NONS) and a bioaccumulation study in fish (OECD 305) was requested by the NL-CA in 2007. The REG updated its dossier in 2016 waiving the requested test. The NL-CA assessed all data provided and concluded the evaluation of the substance according to transitional measures described in Article 48, 135(2) of the REACH Regulation.
The proposal for re-inclusion to a CoRAP update is indicated based on Article 47 REACH with reference to new information provided by the REG and the subsequent chance of circumstances.

Since the production of Trigonox 301 has stopped in Europe, a bioaccumulation study (as requested in the former NONS framework) is no longer needed to assess the risk for secondary poisoning. The only (remaining) concern is whether or not the substance fulfils the PBT criteria. In that respect we have to follow the testing strategy according to the REACH guidance, starting with the P assessment first. In case the substance does not fulfill the P criteria, a bioaccumulation study would not be needed. It is foreseen that the tests conducted upon request of the US EPA: OECD302A (inherent biodegradability) and OECD303A (waste water treatment simulation), will not be appropriate to conclude on the P criteria and therefore we would like to start a SEV requesting a more appropriate biodegradation simulation test.

The substance is not readily biodegradable (3% oxygen consumption after 28 days), but stated by the registrant to be inherently biodegradable according to the result of the extended ready biodegradability test (65% oxygen consumption after 140 days). No further information on biodegradability is present in the registration dossier. The claimed inherent biodegradability is questioned due to the extremely long extension of the OECD301 test duration, and it does not give any indication that the P-criterion in the environment (half-live of 40 days in fresh water) will not be met. The logical first test to investigate the persistence of the substance would be an OECD309 degradation simulation test in fresh water. Possibly this could turn out to be an OECD308 if fate modelling indicates that fresh water sediment is the compartment of concern. This could be investigated in a Substance Evaluation, which would also take into account any further information (monitoring data for organic peroxides, any other persistence testing information, indications of bioaccumulative behaviour from read across with comparable organic peroxides e.g. EC no.: 229-782-3; CAS no.: 6731-36-8).

A Substance evaluation of Trigonox301 could be part of a grouping approach to evaluation of organic peroxides with similar properties / uses. As NL already is involved in substance evaluaton (SEv) of some organic peroxides (like EC no. 246-678-3, currently in NL-SEv) NL would like to follow up with this structured grouping approach to SEv.

5.4. Preliminary indication of information that may need to be requested to 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)
The logical first test to investigate the persistence of the substance would be an OECD309 degradation simulation test in fresh water. Possibly this could turn out to be an OECD308 if fate modelling indicates that fresh water sediment is the compartment of concern.	

5.5. Potential follow-up and link to risk management

☐ Harmonised C&L	☐ Restriction	☐ Authorisation	☒ Other (provide further details)
Identification as SVHC/ Candidate list entry			