

Justification Document for the Selection of a CoRAP Substance

Substance Name (public name): Ethylene dinitrate

EC Number: 211-063-0

CAS Number: 628-96-6

Authority: Italian 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):	Ethylene dinitrate
IUPAC name (public):	Ethane-1,2-diyl dinitrate
Index number in Annex VI of the CLP Regulation:	603-032-00-9
Molecular formula:	C ₂ H ₄ N ₂ O ₆
Molecular weight or molecular weight range:	152.06
Synonyms:	Ethylene nitrate; Dinitroglycol; Glycol dinitrate; 1,2-Ethenediol, dinitrate; Nitroglycol

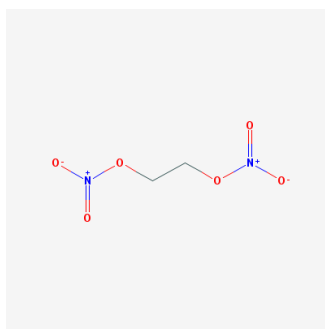
Type of substance

Mono-constituent

Multi-constituent

UVCB

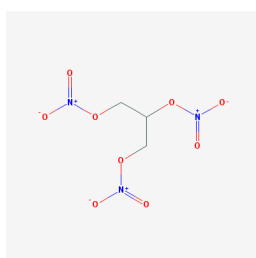
Structural formula:



1.2 Similar substances/grouping possibilities

The registrant has proposed to use data generated on Nitroglycerin (CAS No: 55-63-0)

Structural formula:



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 type="checkbox"/> Testing proposal
		<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 checked="" 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 checked="" type="checkbox"/> Other (provide further details below)	

Other legislation: Seveso Directive.

3 HAZARD INFORMATION (INCLUDING CLASSIFICATION)

3.1 Classification

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)		
603-032-00-9	Ethylene dinitrate	211-063-0	628-96-6	Unst. Expl. Acute Tox. 2 * Acute Tox. 1 Acute Tox. 2 * STOT RE 2	H200 H300 H310 H330 H373 **		

3.1.1 Self classification

- In the registration:

No deviations from harmonised classification.

- The following hazard classes are in addition notified among the aggregated self classifications in the C&L Inventory:

No additional classification notified.

3.1.2 Proposal for Harmonised Classification in Annex VI of the CLP

Not applicable.

4 INFORMATION ON (AGGREGATED) TONNAGE AND USES

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 checked="" 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 type="checkbox"/> <1 >+ tpa (e.g. 10+ ; 100+ ; 10,000+ tpa)		<input type="checkbox"/> Confidential
Further details: Joint submission		

4.2 Overview of uses

Table: Uses

Part 1:

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

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 ¹ <input type="checkbox"/> C <input type="checkbox"/> M <input checked="" type="checkbox"/> R	<input checked="" type="checkbox"/> Potential endocrine disruptor
<input type="checkbox"/> Sensitiser	<input checked="" type="checkbox"/> Suspected Sensitiser ¹	
<input type="checkbox"/> PBT/vPvB	<input checked="" type="checkbox"/> Suspected PBT/vPvB ¹	<input type="checkbox"/> Other (please specify below)
Exposure/risk based concerns		
<input checked="" type="checkbox"/> Wide dispersive use	<input type="checkbox"/> Consumer use	<input type="checkbox"/> Exposure of sensitive populations
<input type="checkbox"/> Exposure of environment	<input type="checkbox"/> Exposure of workers	<input type="checkbox"/> Cumulative exposure
<input type="checkbox"/> High RCR	<input checked="" type="checkbox"/> High (aggregated) tonnage	<input type="checkbox"/> Other (please specify below)

¹ 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

Suspected sensitising properties:

Read-across based on study for Nitroglycerin has been used in the documentation of skin sensitisation (moderate effect in guinea pig maximisation test). Some cases of skin sensitisation induced by Ethylene dinitrate in human was reported by Kanerva (1991). Within the SEv process, sensitisation concern should be further clarified.

Suspected reproductive toxicity / suspected ED properties:

Read-across based on study for Nitroglycerin has been used in the documentation of developmental toxicity (NOAEL: 0.6 mg/kg bw/day). Nitroglycerin has not been evaluated yet in any legal processes for chemicals in the EU, except C&L harmonisation (classification for reprotoxicity not harmonised, no self-classification notified). The study used in read-across has been published in 1978. As no self-classification has been proposed for reproductive toxicity and the only study presented is quite old, developmental toxicity concern should be further clarified within the SEv process. Additionally, substance activates DART alerts for developmental/ reproductive toxicity and ED concern should be further clarified within the SEv process.

Suspected PBT properties:

Toxic properties of the substance needs to be clarified regarding reproductive toxicity concern. Although estimated aquatic BCF is 8.9 L/kg (QSAR), the estimated (KOAWIN) Log K_{OA} is 5.78, this value has to be further clarified to assess bioaccumulation potential in air-breathing organisms. Read-across based on study for Nitroglycerin has been used in the documentation of persistency, DT_{50(water)} > 1 year.

The substance presents an high aggregate tonnage and the uses by professional workers are described by ERC 8f: Wide dispersive outdoor use resulting in inclusion into or onto a matrix.

Therefore, within the SEv process, PBT concern should be further clarified.

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

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)
Potential follow-up actions for the substance depend on the outcome of this substance evaluation.			