

Justification for the selection of a candidate CoRAP substance

Substance Name (Public Name):	Dimethyl glutarate
Chemical Group:	Organic
EC Number:	214-277-2
CAS Number:	1119-40-0
Submitted by:	UK CA
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NOTE

This document has been prepared by United Kingdom Competent Authority but the evaluating Member State was changed to Poland in the CoRAP update for 2014-2016.

Contents

1	IDENTITY OF THE SUBSTANCE	
1.1	Name and other identifiers of the substance	3
2	CLASSIFICATION AND LABELLING	
2.1	Harmonised Classification in Annex VI of the CLP	4
2.2	Proposal for Harmonised Classification in Annex VI of the CLP	
2.3	Self classification	4
3	JUSTIFICATION FOR THE SELECTION OF THE CANDIDATE CoRAP SUBSTANCE	
3.1	Legal basis for the proposal	5
3.2	Grounds for concern	5
3.3	Information on aggregated tonnage and uses	5
3.4	Other completed/ongoing regulatory processes that may affect suitability for substance evaluation	7
3.5	Information to be requested to clarify the suspected risk	7
3.6	Potential follow-up and link to risk management	7

1 IDENTITY OF THE SUBSTANCE

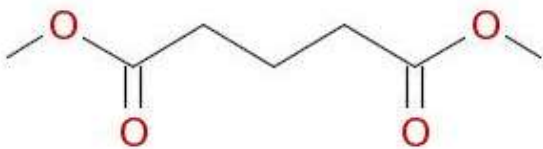
1.1 Name and other identifiers of the substance

Table 1: Substance identity

Public Name:	Dimethyl glutarate
EC number:	214-277-2
EC name:	Dimethyl glutarate
CAS number (in the EC inventory):	1119-40-0
CAS number:	1119-40-0
CAS name:	Pentanedioic acid, 1,5-dimethyl
IUPAC name:	Dimethyl glutarate
Index number in Annex VI of the CLP Regulation	Not applicable
Molecular formula:	C ₇ H ₁₂ O ₄
Molecular weight or molecular weight range:	160.16
Synonyms:	Glutaric acid, dimethyl ester Pentanedioic acid, dimethyl ester

Type of substance Mono-constituent Multi-constituent UVCB

Structural formula:



2 CLASSIFICATION AND LABELLING

2.1 Harmonised Classification in Annex VI of the CLP

Not applicable.

2.2 Proposal for Harmonised Classification in Annex VI of the CLP

Not applicable.

2.3 Self classification

No self classification on the dissemination site.

Classification and Labelling Inventory includes the following classifications;

Acute Tox. 4; H302: Harmful if swallowed.

STOT RE 2; H373: May cause damage to organs through prolonged or repeated exposure.

Skin Irrit. 2; H315: Causes skin irritation.

Eye Irrit. 2; H319: Causes serious eye irritation.

Acute Tox. 3; H331: Toxic if inhaled.

Acute Tox. 4; H312: Harmful in contact with skin.

Acute Tox. 4; H332: Harmful if inhaled.

STOT SE 3; H335: May cause respiratory irritation.

Aquatic Chronic 4; H413: May cause long lasting harmful effects to aquatic life.

3 JUSTIFICATION FOR THE SELECTION OF THE CANDIDATE CoRAP SUBSTANCE

3.1 Legal basis for the proposal

- Article 44(1) (refined prioritisation criteria for substance evaluation)
 Article 45(5) (Member State priority)

3.2 Grounds for concern

<input type="checkbox"/> (Suspected) CMR	<input checked="" type="checkbox"/> Wide dispersive use	<input type="checkbox"/> Cumulative exposure
<input type="checkbox"/> (Suspected) Sensitiser	<input checked="" type="checkbox"/> Consumer use	<input type="checkbox"/> High RCR
<input type="checkbox"/> (Suspected) PBT	<input type="checkbox"/> Exposure of sensitive populations	<input checked="" type="checkbox"/> Aggregated tonnage
<input checked="" type="checkbox"/> Suspected endocrine disruptor	<input type="checkbox"/> Other (provide further details below)	
<p>Human Health - In a 90-day rat inhalation study, a dose related decrease in testosterone and Luteinising hormone was observed raising concern the substance is an endocrine disruptor. Further evaluation is required to determine whether or not dimethyl glutarate is an endocrine disruptor.</p> <p>The human exposures and risk assessments (currently not a concern) may need to be reconsidered depending on the outcome of the evaluation of dimethyl glutarate's potential endocrine effects.</p>		

3.3 Information on aggregated tonnage and uses

<input type="checkbox"/> 1 - 10 tpa	<input type="checkbox"/> 10 - 100 tpa	<input type="checkbox"/> 100 - 1000 tpa
<input checked="" type="checkbox"/> 1000 - 10,000 tpa	<input type="checkbox"/> 10,000 - 100,000 tpa	
<input type="checkbox"/> 100,000 - 1000,000 tpa	<input type="checkbox"/> > 1000,000 tpa	
<input type="checkbox"/> Confidential		
Tonnage on dissemination site		
<input checked="" type="checkbox"/> Industrial use	<input checked="" type="checkbox"/> Professional use	<input checked="" type="checkbox"/> Consumer use
		<input type="checkbox"/> Closed System

Industrial Uses:

Manufacture of substance
Distribution of substance
Use as intermediate
Formulation & (re)packing of substances and mixtures
Uses in Coating
Use in Cleaning Agents
Use in Oil and Gas field drilling and production operations
Lubricants
Metal working fluids / rolling oils
Blowing agents
Use as binders and release agents
Use as a fuel
Functional Fluids
Use in laboratories
Polymer Production and processing
Rubber production and processing
Water treatment chemicals
Mining chemicals

Professional Uses:

Uses in Coating
Use in Cleaning Agents
Use in Oil and Gas field drilling and production operations
Lubricants
Metal working fluids / rolling oils
Use as binders and release agents
Use as a fuel
Functional Fluids
De-icing and anti-icing applications
Road and construction applications
Use in laboratories
Explosives manufacture & use
Polymer processing
Water treatment chemicals
Use in Agrochemicals

Consumer Uses:

Uses in Coating
Use in Cleaning Agents
Lubricants
Use in Agrochemicals
Use as a fuel
Functional Fluids
De-icing and anti-icing applications
Other Consumer Uses
Water treatment chemicals

3.4 Other completed/ongoing regulatory processes that may affect suitability for substance evaluation

<input type="checkbox"/> Compliance check	<input type="checkbox"/> Dangerous substances Directive 67/548/EEC
<input type="checkbox"/> Testing proposal	<input type="checkbox"/> Existing Substances Regulation 793/93/EEC
<input type="checkbox"/> Annex VI (CLP)	<input type="checkbox"/> Plant Protection Products Regulation 91/414/EEC
<input type="checkbox"/> Annex XV (SVHC)	<input type="checkbox"/> Biocidal Products Directive 98/8/EEC
<input type="checkbox"/> Annex XIV (Authorisation)	<input type="checkbox"/> Other (provide further details below)
<input type="checkbox"/> Annex XVII (Restriction)	
None known.	

3.5 Information to be requested to clarify the suspected risk

<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 type="checkbox"/> Information on exposure
<input type="checkbox"/> Information on ecotoxicological properties	<input type="checkbox"/> Information on uses
<input type="checkbox"/> Other (provide further details below)	
Human Health - In a 90-day rat inhalation study, a dose related decrease in testosterone and Luteinising hormone was observed raising concern the substance is an endocrine disruptor. Further investigation may be required to confirm whether or not the effects observed in the 90-day study are reproducible.	

3.6 Potential follow-up and link to risk management

<input checked="" type="checkbox"/> Restriction	<input type="checkbox"/> Harmonised C&L	<input checked="" type="checkbox"/> Authorisation	<input type="checkbox"/> Other (provide further details)
Will depend on the outcome of the evaluation.			