Justification for the selection of a candidate CoRAP substance

Substance Name (Public name):	Diisodecyl azelate
EC Number:	249-044-4
CAS Number:	28472-97-1
Submitted by:	Ministry of Health – Italy
Published:	20/03/2013

Note

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

CONTENTS

1 IDENTITY OF THE SUBSTANCE

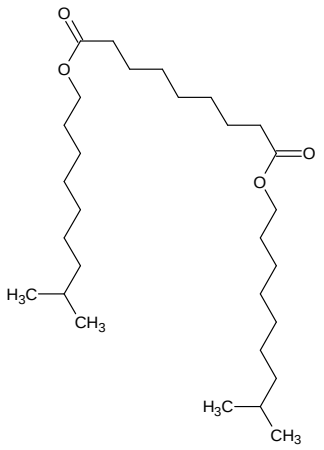
1.1 Name and other identifiers of the substance

Table 1: Substance identity

EC number:	249-044-4
EC name:	Diisodecyl azelate
CAS number (in the EC inventory):	28472-97-1
CAS number:	
CAS name:	
IUPAC name:	Not available because not a single isomer. The product consists of isomers with different branching patterns.
Index number in Annex VI of the CLP Regulation	
Molecular formula:	C29H56O4
Molecular weight or molecular weight range:	468.7525 g/mol
Synonyms:	

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 classified.

2.2 Proposal for Harmonised Classification in Annex VI of the CLP

None proposed.

2.3 Self-classification

Not classified in the registration.

No other notifications to the Classification and Labelling Inventory than "Not classified".

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

☐ (Suspected) CMR	☒ Wide dispersive use	☐ Cumulative exposure
☐ (Suspected) Sensitiser	☒ Consumer use	☐ High RCR
☒ (Suspected) PBT	☐ Exposure of sensitive populations	☒ Aggregated tonnage
☐ Suspected endocrine disruptor	☐ Other (provide further details below)	

The substance was selected on the basis of structural similarities to a known PBT substance (dichlorodioctylstannane, CAS 3542-36-7).

Vapour pressure: 9.71E-10 Pa at 20°C (SPARC calculation)

Water solubility: <0.05 mg/L at 20°C (and pH=6.8)

Log Kow (calculated) : 11.55

Log Koc: 6.3 – 7.1 (calculated KoCWin v2.00)

Regarding biodegradation the information available is a read across to Bis(2-ethylhexyl) azelate (CAS 103-24-2) which indicates that the substance is readily biodegradable (73.2 – 89.3% degradation after 29 days in a OECD 301B test. In addition there is a test with a reliability 3 performed with the substance of concern which indicates 60% degradation after 7 days (remaining hydrocarbons). This test was conducted according to the Coordinating European Council (CEC) Guideline (1982) "Development of performance tests for lubricants and engine fuels, tentative test method. Biodegradability of two-stroke cycle outboard engine oils in water". Due to methodological deficiencies, biodegradation values could only be obtained up to day 7 (planned study period 21 days) and therefore the study was classified as not reliable. No more information is given on the study.

Only acute data on fish is available where no effects were seen at the highest tested concentration (LC50 (96h)>10g/L). Acute data on invertebrates and algae are available on the analogue substance Bis(2-ethylhexyl) azelate (CAS 103-24-2) for which no effects were seen (use of WAF). Long term testing has been waived.

The uses are clearly wide dispersive as the substance is a lubricant used for vehicles and machineries in industrial settings but also by professionals and consumers.

The whole chemical safety report is based on the fact that the substance is readily biodegradable and not toxic. However the read across would need to be checked and due to the low solubility of the substance long term testing should have been investigated.

From a hazard point of view this substance is of potential concern for the environment, in addition the tonnage is high and the uses are wide dispersive. In conclusion it is proposed to investigate further this substance under substance evaluation.

3.3 Information on aggregated tonnage and uses

☐ 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 tpa	
☐ <1 . . . . . >+ tpa	☐ Confidential	
Please provide further details if appropriate		

☒ Industrial use	☒ Professional use	☒ Consumer use	☐ Closed System

Diisodecyl azelate is used as a lubricant or additive in lubricants in vehicles and machineries in industrial settings but is also used by professionals as well as consumers (ERC 8a, b, d and e as well as ERC 9a and b).

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

☐ Compliance check	☐ Dangerous substances Directive 67/548/EEC
☐ Testing proposal	☐ Existing Substances Regulation 793/93/EEC
☐ Annex VI (CLP)	☐ Plant Protection Products Regulation 91/414/EEC
☐ Annex XV (SVHC)	☐ Biocidal Products Directive 98/8/EEC
☐ Annex XIV (Authorisation)	☐ Other (provide further details below)
☐ Annex XVII (Restriction)	
Please provide further details	

3.5 Information to be requested to clarify the suspected risk

☐ Information on toxicological properties	☐ Information on physico-chemical properties
☐ Information on fate and behaviour	☐ Information on exposure
☐ Information on ecotoxicological properties	☐ Information on uses
☐ Other (provide further details below)	
Please provide further details	

3.6 Potential follow-up and link to risk management

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

Depending on the outcome of substance evaluation.