Justification for the selection of a candidate CoRAP substance

Substance Name (Public Name):	methylcyclohexane
Chemical Group:	the substance belongs to a category detailed for isoheptane (CAS 31394-54-4)
EC Number:	203-624-3
CAS Number:	108-87-2
Submitted by:	Finnish Safety and Chemicals Agency, Finland
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

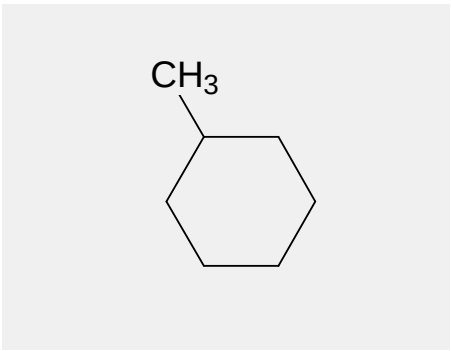
1.1 Name and other identifiers of the substance

Table 1: Substance identity

Public Name:	methylcyclohexane
EC number:	203-624-3
EC name:	methylcyclohexane
CAS number (in the EC inventory):	108-87-2
CAS number:	108-87-2
CAS name:	methylcyclohexane
IUPAC name:	methylcyclohexane
Index number in Annex VI of the CLP Regulation	601-018-00-7
Molecular formula:	C7H14
Molecular weight or molecular weight range:	98.1861 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

According to CLP

Classification		Labelling		Specific Conc. Limits, M-factors
Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	
Flam.Liquid 2 Skin Irrit.2 Asp. Tox. 1 STOT Single Exp. 3 Aquatic Chronic 2	H225 H315 H304 H336 H411	GHS07 GHS02 GHS09 GHS08 Dgr	H225 H315 H304 H336 H411	

H225: Highly flammable liquid and vapour
H315: Causes skin irritation
H304: May be fatal if swallowed and enters airways
H336: May cause drowsiness or dizziness
H411: Toxic to aquatic life with long lasting effects

According to DSD;

F; R11 Highly flammable; Highly flammable.

Xn; R65 Harmful; Harmful: may cause lung damage if swallowed.

R67 Vapours may cause drowsiness and dizziness.

Xi; R38 Irritant; Irritating to skin.

2.2 Proposal for Harmonised Classification in Annex VI of the CLP

None proposed.

2.3 Self classification

Classification by the lead registrant is consistent with harmonised classification.

In addition to the harmonised classification, the following classifications or classification for other endpoint are notified to the Classification and Labelling Inventory:

Eye Irrit. 2 H319: Causes serious eye irritation

Aquatic Acute 1 H400: Very toxic to aquatic life

Aquatic Chronic 1 H410: Very toxic to aquatic life with long lasting effects

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 screened as a potential PBT with wide dispersive uses (industrial, professional and consumer uses as solvent in cleaning agents and coatings). Closer investigation indicates that the substance does not fulfill P and B screening criteria. However, the concern remains due to the lack of experimental data combined with the wide dispersive uses and significant use volume. It is proposed to investigate further the reasoning, rationale and applicability of the used category approach, read across and QSARs. In addition the classification as compared to the classification of another member of the same category, isoheptane, should be evaluated.

The registration dossier is based on the use of category approach, read across and QSAR (petrorisk) estimates. Most of the physico-chemical properties, hazard and fate properties of the substance are based on QSAR (petrorisk) estimates as well as read across to "C6-C7 n-alkanes, isoalkanes, cyclics, < 5 % n-hexane".

Regarding biodegradation, read across to "C6-C7 n-alkanes, isoalkanes, cyclics, < 5 % n-hexane" indicates that the substance is readily biodegradable. The calculated biodegradation half-life of 7.31 days (Episuite, BioHCwin version 1.01) indicates that primary biodegradation is relatively fast.

The log Kow estimated is 3.88 (handbook). The estimated BCF-value is 105 L/kg (Episuite, BCFBAF v. 3.00).

Based on the available information, it can be concluded that methylcyclohexane does not fulfil screening criteria for P or B properties.

The assessment of aquatic toxicity is also based on QSAR (petrorisk) estimates and read across. The ecotoxicity test results are based on nominal concentrations of the water-accomodated fraction (WAF). The substance is classified in Annex VI of the CLP as Aquatic chronic 2 (H411)(R51/53).

The substance should be linked to another substance (isoheptane, CAS: 31394-54-4). The information on this substance is based on a read across to "C7-C9 isoalkanes cyclics" and the use of petrorisk estimates. Isoheptane has been classified in Annex VI to CLP as aquatic acute 1; aquatic chronic 1. Taking into account that both methylcyclohexane and isoheptane belong to the same category of non-polar narcotic chemicals the difference between the classifications is not clear. Under substance evaluation the reasoning for the differing classification of these two substances belonging to the same category can be assessed.

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 – 1000,000 tpa	☐ > 1000,000 tpa	
☐ Confidential		
Please provide further details		

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

Methylcyclohexane is used as a solvent for example in cleaning agents and coatings in industrial settings but also in cleaning agents and coatings used by professionals as well as consumers (wide dispersive indoor and outdoor use).

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), see section 2.1	☐ 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)
Please provide further details			