Justification for the selection of a candidate CoRAP substance

Substance Name (Public Name):	2-ethylhexan-1-ol
Chemical Group:	Organic; alcohol
EC Number:	203-234-3
CAS Number:	104-76-7
Submitted by:	UK CA
Published:	20/03/2013

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

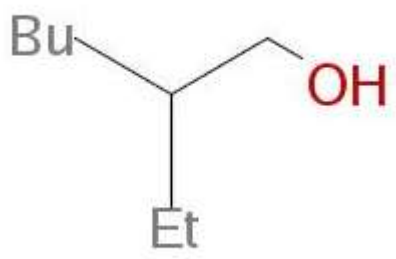
1.1 Name and other identifiers of the substance

Table 1: Substance identity

Public Name:	2-ethylhexan-1-ol
EC number:	203-234-3
EC name:	2-ethylhexan-1-ol
CAS number (in the EC inventory):	104-76-7
CAS number:	104-76-7
CAS name:	1-Hexanol, 2-ethyl
IUPAC name:	2-ethylhexan-1-ol
Index number in Annex VI of the CLP Regulation	Not applicable
Molecular formula:	$C_8H_{18}O$
Molecular weight or molecular weight range:	130
Synonyms:	1-Hexanol, 2-ethyl

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

Classification given in registration on the dissemination site:

CLP:

Acute Tox 4. ; H332: Harmful if swallowed.

Skin Irrit. 2 ; H315: Causes skin irritation

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

STOT SE 3; H335: May cause respiratory irritation

According to DSD:

Xn; R20 Harmful by inhalation.

Xi; R36/37/38 Irritating to eyes, respiratory system and skin.

In the Classification and Labelling Inventory the following classifications are included in addition:

Flam. Liq. 3; H226: Flammable liquid and vapour.

Acute Tox. 4; H302: Harmful if swallowed.

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

Eye Dam. 1; H318: Causes serious eye damage.

STOT SE 3; H336: May cause drowsiness or dizziness

Aquatic Chronic 3; H412: Harmful to aquatic life with long lasting effects.

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

☒ (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)	

Exposure - RCRs for some scenarios are close to 1. Further assessment is required to confirm the risks are adequately managed for all scenarios.

Human Health – Developmental effects were observed in the pre-natal developmental toxicity studies. A full evaluation of the available information is required to assess whether the observed developmental effects are the result of maternal toxicity.

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	☐ > 1000,000 tpa	

☐ Confidential

Tonnage band given on the on the dissemination site is 100,000 – 1,000,000 tpa.

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

Industrial use:

manufacture
distribution
formulation
in coatings
in laboratories
in functional fluids
in oil and gas field drilling
as intermediate under non strictly controlled conditions
use as intermediate in wet and dry processes

Professional use:

in coatings
dilution of a concentrate
in functional fluids
in cleaning products

Consumer use:

Dilution of a concentrate

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

☐ Compliance check final decision	☐ 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)	

Not that we are aware of.

Note: The substance was identified as an existing active substance under BPD but was not notified.

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)	

The study reports for the developmental studies will be required to determine whether or not the developmental effects were a secondary non-specific consequence of maternal toxicity.

Further details of tasks giving rise to high RCRs will be required to determine if the conditions required to achieve an RCR < 1 will be met during use.

3.6 Potential follow-up and link to risk management

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

A harmonised C&L proposal may be required if we consider the substance to be a developmental toxicant.

The registrant may be asked to update the registration with a refined exposure assessment and possibly adaptations of the risk management measures recommended in their exposure scenarios.