

Justification for the selection of a candidate CoRAP substance

Substance Name (Public Name):	2-methylpropan-2-ol
Chemical Group:	Organic
EC Number:	200-889-7
CAS Number:	75-65-0
Submitted by:	UK CA
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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

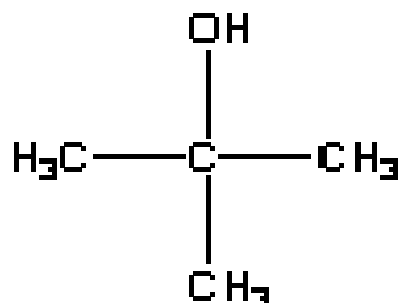
1.1 Name and other identifiers of the substance

Table 1: Substance identity

Public Name:	2-methylpropan-2-ol
EC number:	200-889-7
EC name:	2-methylpropan-2-ol
CAS number (in the EC inventory):	75-65-0
CAS number:	75-65-0
CAS name:	2-propanol, 2-methyl-
IUPAC name:	2-methyl-2-propanol
Index number in Annex VI of the CLP Regulation	603-005-00-1
Molecular formula:	C ₄ H ₁₀ O
Molecular weight or molecular weight range:	74.12
Synonyms:	2-propanol, 2-methyl-tert-butyl alcohol Trade names: TBA, TEBOL 88, TEBOL 90

Type of substance Mono-constituent Multi-constituent UVCB

Structural formula:



2 CLASSIFICATION AND LABELLING

2.1 Harmonised Classification in Annex VI of the CLP

Index Number: 603-005-00-1

According to CLP criteria:

Flam. Liq. 2; H225: Highly flammable liquid and vapour.

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

Acute Tox. 4*; H332: Harmful if inhaled.

STOT SE 3; May cause respiratory irritation.

According to DSD:

F; R11 Highly flammable.

Xn; R20 Harmful by inhalation.

Xi; R36/37 Irritating to eyes and respiratory system

2.2 Proposal for Harmonised Classification in Annex VI of the CLP

Not applicable

2.3 Self classification

The classifications in the registration data and notified to the Classification and Labelling Inventory are in accordance with the entry in Annex VI of CLP.

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 checked="" 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 checked="" type="checkbox"/> High RCR
<input type="checkbox"/> (Suspected) PBT	<input type="checkbox"/> Exposure of sensitive populations	<input checked="" type="checkbox"/> Aggregated tonnage
<input type="checkbox"/> Suspected endocrine disruptor	<input type="checkbox"/> Other (provide further details below)	

Carcinogenicity

Two carcinogenicity studies are available: one in rats and one in mice.

In the rat study, kidney toxicity (nephropathy, linear papillary mineralization and focal renal tubule hyperplasia) and an increase incidence in renal tumours were observed. It is suggested the kidney tumours were due to alpha-2u-g nephropathy and hyaline droplet formation was confirmed. However, kidney toxicity was also observed in females (nephropathy in all groups and hyperplasia in the top group). Evaluation of the existing information would confirm whether or not the tumours observed in male rats were a species specific effect.

The incidence of thyroid adenomas was increased in female and, to a lesser extent, male B6C3F1 mice. The relevance of these tumours has been investigated in a study investigating hepatotoxicity and thyroid hormone levels. An evaluation is required to determine whether this study allays our concerns for these tumours.

Genotoxicity

2-methylpropan-2-ol was negative in most *in vitro* and *in vivo* studies. However, a positive result was observed in the presence of metabolic activation for S.typhimurium strain TA 102 (in one study). A weight of evidence evaluation would determine whether this result was of concern and determine whether any further testing was required.

Exposure

The RCR values should be verified.

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 type="checkbox"/> 1000 – 10,000 tpa	<input type="checkbox"/> 10,000 – 100,000 tpa	
<input checked="" type="checkbox"/> 100,000 – 1,000,000 tpa	<input type="checkbox"/> > 1000,000 tpa	
<input type="checkbox"/> Confidential		
Tonnage band given on dissemination site 100,000 – 1,000,000 tpa		
<input checked="" type="checkbox"/> Industrial use	<input checked="" type="checkbox"/> Professional use	<input checked="" type="checkbox"/> Consumer use
		<input type="checkbox"/> Closed System
<p>Industrial uses:</p> <p>Manufacture of TBA and other substances using TBA Formulation & packing of preparations and mixtures containing TBA Use of TBA in Cleaning Agents Use of TBA in Coatings Use of TBA in Waste Water Treatment Use of small quantities of TBA within laboratory settings Use of TBA in fuels</p> <p>Professional uses:</p> <p>Use of TBA in Waste Water Treatment Use of TBA in Cleaning Agents Use of TBA in Coatings Use of small quantities of TBA within laboratory settings Use of TBA in fuels</p> <p>Consumer use:</p> <p>Consumer uses of cleaning products containing TBA Consumer use of TBA in adhesives and sealants Consumer use of TBA in coatings, paints, water based paints Consumer use of TBA in fuels</p>		

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

<input type="checkbox"/> Compliance check final decision	<input type="checkbox"/> Dangerous substances Directive 67/548/EEC
<input type="checkbox"/> Testing proposal	<input type="checkbox"/> Existing Substances Regulation 793/93/EEC
<input checked="" 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)	
Annex VI (CLP) see 2.1	

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 checked="" 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)	
<p>Further information may be required to confirm whether or not the thyroid tumours are relevant to humans.</p>	

3.6 Potential follow-up and link to risk management

<input type="checkbox"/> Restriction	<input checked="" type="checkbox"/> Harmonised C&L	<input type="checkbox"/> Authorisation	<input type="checkbox"/> Other (provide further details)
<p>If the tumours observed in the carcinogenicity studies are considered relevant to humans then a proposal for classification as a carcinogen could be made.</p>			