

Justification for the selection of a candidate CoRAP substance

Substance Name (Public Name):	tert-butyl methyl ether
Chemical Group:	
EC Number:	216-653-1
CAS Number:	1634-04-4
Submitted by:	FRANCE
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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:	tert-butyl methyl ether
EC number:	216-653-1
EC name:	tert-butyl methyl ether
CAS number (in the EC inventory):	1634-04-4
CAS number:	1634-04-4
CAS name:	Propane, 2-methoxy-2-methyl-
IUPAC name:	tert-butyl methyl ether
Index number in Annex VI of the CLP Regulation	603-181-00-X
Molecular formula:	C ₅ H ₁₂ O
Molecular weight or molecular weight range:	88.1488
Synonyms:	<i>MTBE</i> Tert-butyl methyl ether (MTBE), grades A, B, V

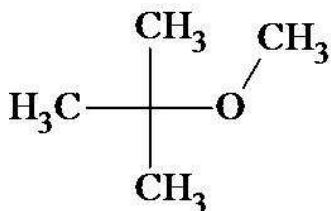
Type of substance:

 Mono-constituent

 Multi-constituent

 UVCB

Structural formula:



2 CLASSIFICATION AND LABELLING

2.1 Harmonised Classification in Annex VI of the CLP

Index No.: 603-181-00-X

According to CLP

Hazard Class and Category Code(s)	Hazard Statement Code(s)
Flam. Liq. 2 Skin Irrit. 2	H225 ; Highly flammable liquid and vapour H315 ; Causes skin irritation

According to DSD

Classification	Risk phrases
F; R11 Xi; R38	11 ; Highly flammable 38 ; Irritant; Irritating to skin.

2.2 Self classification

Classification in the registration is consistent with the harmonized classification.

In addition are the following classification(s) included in the Classification and Labelling Inventory:

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

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 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)	

Several studies suggest the endocrine disruptor's properties of MTBE.

Furthermore, according to DHI study (Petersen et al., 2007) on enhancing the ED priority list focus on LPV chemicals:

- The substance is not readily biodegradable and has a low potential for bioaccumulation (EUSES).
- A relatively low daily human intake is expected.
- and MTBE should be considered as:
 - HH: Cat 1 (At least one study providing evidence of endocrine disruption in an intact organism. Not a formal weight of evidence approach).
 - Wildlife: Cat 2 (Potential for endocrine disruption. In vitro data indicating potential for endocrine disruption in intact organisms. Also includes effects in-vivo that may, or may not, be ED-mediated. May include structural analyses and metabolic considerations).

Overall categorisation: Cat 1.

Finally, MTBE is widely dispersed in the environment.

3.3 Information on aggregated tonnage and uses

<input type="checkbox"/> 1 - 10 t	<input type="checkbox"/> 10 - 100 t	<input type="checkbox"/> 100 - 1000 t	<input type="checkbox"/> 1000 - 10,000 t	
<input type="checkbox"/> 10,000 - 100,000 t	<input checked="" type="checkbox"/> 100,000 - 1000,000 t	<input type="checkbox"/> > 1000,000 t	<input checked="" type="checkbox"/> 1,000,000 - 10,000,000 t	<input type="checkbox"/> Confidential

Two submissions with different tonnage bands.

<input checked="" type="checkbox"/> Industrial Use	<input checked="" type="checkbox"/> Professional Use	<input checked="" type="checkbox"/> Consumer Use	<input type="checkbox"/> Closed System
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3.4 Other completed/ongoing regulatory processes that may affect suitability for substance evaluation

<input type="checkbox"/> Compliance Check	<input type="checkbox"/> Annex VI (CLP)
<input type="checkbox"/> Testing Proposal(s)	<input type="checkbox"/> Annex XIV (Authorisation)
<input type="checkbox"/> Substance Identification Issues	<input type="checkbox"/> Annex XVII (Restriction)
<input checked="" type="checkbox"/> ESR Programme	<input type="checkbox"/> Other (provide further details below)
Risk Assessment report, priority list n° 3 (Finland RMS).	

3.5 Information to be requested to clarify the suspected risk

<input checked="" type="checkbox"/> Information on toxicological properties	<input type="checkbox"/> Information on exposure
<input type="checkbox"/> Information on fate and behaviour	<input type="checkbox"/> Information on uses
<input type="checkbox"/> Information on ecotoxicological properties	<input type="checkbox"/> Other (provide further details below)
<input type="checkbox"/> Information on physico-chemical properties	
Exact information required to be determined during the substance evaluation	

3.6 Potential follow-up and link to risk management

<input type="checkbox"/> Restriction	<input type="checkbox"/> Harmonised C&L
<input type="checkbox"/> Authorisation	<input type="checkbox"/> Other (provide further details below)
Depends on the outcome of substance evaluation	