

## **Justification for the selection of a candidate CoRAP substance**

**Substance Name (Public Name):** Tetrahydrofuran

**Chemical Group:**

**EC Number:** 203-726-8

**CAS Number:** 109-99-9

**Submitted by:** Germany

**Published:** 20/03/2013

### **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

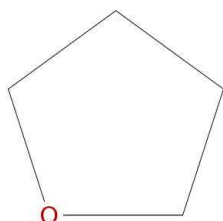
### 1.1 Name and other identifiers of the substance

Table 1: Substance identity

<b>Public Name:</b>	tetrahydrofuran
<b>EC number:</b>	203-726-8
<b>EC name:</b>	tetrahydrofuran
<b>CAS number (in the EC inventory):</b>	
<b>CAS number:</b>	109-99-9
<b>CAS name:</b>	furan, tetrahydro-
<b>IUPAC name:</b>	tetrahydrofuran
<b>Index number in Annex VI of the CLP Regulation</b>	603-025-00-0
<b>Molecular formula:</b>	C <sub>4</sub> H <sub>8</sub> O
<b>Molecular weight or molecular weight range:</b>	72.1057 g/mol
<b>Synonyms:</b>	THF

**Type of substance**     Mono-constituent     Multi-constituent     UVCB

**Structural formula:**



## 2 CLASSIFICATION AND LABELLING

### 2.1 Harmonised Classification in Annex VI of the CLP

Table 2: Classification according to part 3 of Annex VI, Table 3.1 (List of harmonised classification and labelling of hazardous substances) of Regulation (EC) No 1272/2008

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)	Suppl. Hazard statement Code(s)	
Flam. Liq. 2 Eye Irrit. 2 STOT SE 3	H225 H319 H335	GHS02 GHS07 Dgr	H225 H319 H335	EUH019	Eye Irrit. 2; H319: C ≥ 25 % STOT SE 3; H335: C ≥ 25 %

Table 3: Classification according to part 3 of Annex VI, Table 3.2 (list of harmonized classification and labelling of hazardous substances from Annex I of Council Directive 67/548/EEC) of Regulation (EC) No 1272/2008

Index No	Classification	Labelling	Concentration Limits
603-025-00-0	F; R11-19 Xi; R36/37	F; Xi R: 11-19-36/37 S: (2-)16-29-33	Xi; R36/37: C ≥ 25%

Tetrahydrofuran is included in the 3rd ATP to CLP, Commission Regulation (EU) No 618/2012, with an amended entry where classification as

**Carc. Cat. 2, H351 Suspected of causing cancer** is added.

(According to DSD: Cat. 3, R40 Limited evidence of a carcinogenic effect.)

### 2.2 Proposal for Harmonised Classification in Annex VI of the CLP

The proposal to classify THF as Carc. Cat. 2, H351 (under CLP Regulation) or Carc. Cat. 3, R40 (in accordance with the Directive 67/548/EEC) is adopted.

### 2.3 Self classification

Additionally to the Harmonised Classification in Annex VI of the CLP the following information is given by the registrants:

#### GHS

STOT Single Exp. 3 H336: May cause drowsiness and dizziness.

Affected organs: Central Nervous System

Route of exposure: Inhalation

#### Specific concentration limits

STOT SE3 / H336 : Concentration range (%) ≥ 25.0

#### DSD-DPD

R67 - vapours may cause drowsiness and dizziness

### 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 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)	

(a) Relevance for humans of carcinogenic properties of THF

The potential carcinogenicity of THF results from evidence of carcinogenic activity in male F344/N rats in a standard 2-species carcinogenicity study.<sup>1</sup> Based on increased incidents of renal tumours in the male rats following long-term inhalation exposure THF was proposed to be classified as Carc. Cat. 2, H351 (under CLP Regulation) or Carc. Cat. 3, R40 (in accordance with the Directive 67/548/EEC).<sup>2</sup> This proposal is now adopted (see 2.1). However, possible mechanisms of the kidney tumour formation had not been identified clearly, and so there remains uncertainty about extrapolation to humans.<sup>3</sup> From the available studies it was not possible to give a final judgment on the relevance to humans of all experimental tumour findings.

(b) Wide and dispersive use, consumer use and high workers exposure

THF has a wide dispersive use (worker/professional and consumer uses). In consumer uses THF is present in various products such as paints, glues, adhesives, varnishes, inks and cleaning agents often in high concentrations.

(c) High aggregated tonnage

THF is a high production volume chemical.

The intention is to scrutinize the CSA regarding relevant uses and exposure scenarios (worker, professional and consumer) and to evaluate the exposure assessments as well as the practiced risk management measures to conclude whether further risk management will be needed.

<sup>1</sup> European Chemicals Agency, Information on Registered Substances, 2007-2011: <http://apps.echa.europa.eu/registered/registered-sub.aspx#search>

<sup>2</sup> Harmonising classification and labelling - previous consultations <http://echa.europa.eu/harmonised-classification-and-labelling-previous-consultations/-/substance/970/search/+/del/20/col/SUBSTANCENAME/type/desc/pre/1/view>

<sup>3</sup> Opinions of the Committee for Risk Assessment on proposals for harmonised classification and labelling <http://echa.europa.eu/opinions-of-the-committee-for-risk-assessment-on-proposals-for-harmonised-classification-and-labelling/-/substance/972/search/+/del/20/col/SUBSTANCENAME/type/desc/pre/1/view>

### 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			
THF is a high production volume chemical.			
<input checked="" type="checkbox"/> Industrial use	<input checked="" type="checkbox"/> Professional use	<input checked="" type="checkbox"/> Consumer use	<input type="checkbox"/> Closed System
<p>THF has wide and dispersive uses by workers/professionals and consumers.</p> <p>The substance is used for the production of pyrrolidine, in processing as solvent for the synthesis of polymers and as solvent in paint strippers, adhesive agents and printing inks (GESTIS-database on hazardous substances, 2011).<sup>4</sup></p> <p>According to the information on ECHAs registration data dissemination website, THF is present also in various consumer products; it is registered for the following consumer uses:                  PC 35: Washing and cleaning products (including solvent based products)                  PC 1: Adhesives, sealants                  PC 9a: Coatings and paints, thinners, paint removes                  PC 0: Other:                  PC9: Coatings and paints, fillers, putties, thinners                  PC 4: Anti-freeze and de-icing products                  PC 9b: Fillers, putties, plasters, modelling clay                  PC 9c: Finger paints                  PC 0: Other:                  PC5,PC10                  PC 18: Ink and toners                  PC 23: Leather tanning, dye, finishing, impregnation and care products                  PC 24: Lubricants, greases, release products                  PC 31: Polishes and wax blends</p> <p>In its function as solvent, it is often used in high concentration.</p>			

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

<input type="checkbox"/> Compliance check final	<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)	

<sup>4</sup> GESTIS-database on hazardous substances, 2011: <http://gestis-en.itrust.de/>

THF is included in Annex VI (CLP) and the entry was amended by the 3<sup>rd</sup> ATP to CLP (Commission Regulation (EU) No 618/2012) to include classification as Carc. Cat. 2, H351 (under CLP Regulation) or Carc. Cat. 3, R40 (in accordance with the Directive 67/548/EEC).

RAC opinion on the proposal:

Harmonising classification and labelling – RAC opinion

<http://echa.europa.eu/documents/10162/2415df29-6d80-4e96-ae25-7da19e92c3aa>

### 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 checked="" type="checkbox"/> Information on uses
<input type="checkbox"/> Other (provide further details below)	

Investigation of the possible mechanism of kidney tumour formation in male rats might be one approach to eliminate doubts about the relevance of the carcinogenic responses to humans.

Information related to the identified uses (especially consumer uses) and of exposure scenarios as well as information needed to refine exposure assessments and risk management measures.

### 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 checked="" type="checkbox"/> Other (provide further details)
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In case the suspected risk is confirmed after receiving further information and finalisation of the evaluation:

1. Adherent to classification and labeling, further administrative measures could be envisaged following RMO analysis (e.g. concentration limits in consumer products or other restrictions)