

Justification for the selection of a substance for CoRAP inclusion

– UPDATE –

Substance Name (Public Name): Naphthalene

Chemical Group:

EC Number: 202-049-5

CAS Number: 91-20-3

Submitted by: UK

Published: 26/03/2014
update 17/03/2015

Note

This document has been prepared by the evaluating Member State given in the CoRAP update.

Contents

1	IDENTITY OF THE SUBSTANCE.....	3
1.1	Other identifiers of the substance	3
1.2	Similar substances/grouping possibilities	3
2	CLASSIFICATION AND LABELLING.....	4
2.1	Harmonised Classification in Annex VI of the CLP	4
2.2	Self classification	4
2.3	Proposal for Harmonised Classification in Annex VI of the CLP	5
3	INFORMATION ON AGGREGATED TONNAGE AND USES	5
4	OTHER COMPLETED/ONGOING REGULATORY PROCESSES THAT MAY AFFECT SUITABILITY FOR SUBSTANCE EVALUATION.....	5
5	JUSTIFICATION FOR THE SELECTION OF THE CANDIDATE CORAP SUBSTANCE ..	6
5.1	Legal basis for the proposal	6
5.2	Selection criteria met (why the substance qualifies for being in CoRAP)	6
5.3	Initial grounds for concern to be clarified under Substance Evaluation	6
5.4	Preliminary indication of information that may need to be requested to clarify the concern	7
5.5	Potential follow-up and link to risk management	7

1 IDENTITY OF THE SUBSTANCE

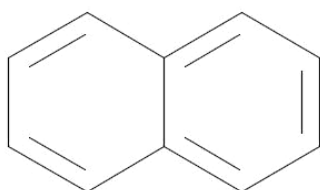
1.1 Other identifiers of the substance

Table 1: Substance identity

EC name:	Naphthalene
IUPAC name:	Naphthalene
Index number in Annex VI of the CLP Regulation	601-052-00-2
Molecular formula:	C ₁₀ H ₈
Molecular weight or molecular weight range:	128.17 g/mol
Synonyms/Trade names:	Albocarbon Dezodorator Moth flakes Naphthaline Tar camphor White tar NSC 37565 Naphthene

Type of substance Mono-constituent Multi-constituent UVCB

Structural formula:



1.2 Similar substances/grouping possibilities

None.

2 CLASSIFICATION AND LABELLING

2.1 Harmonised Classification in Annex VI of the CLP

Classification		Labelling		Specific Concentration limits, M-Factors
Hazard Class and Category Code(s)	Hazard Statement Code(s)	Hazard Statement Code(s)	Supplementary Hazard Statement Code(s)	
Acute Tox. 4 *	H302	H302		
Carc. 2	H351	H351		
Aquatic Acute 1	H400			
Aquatic Chronic 1	H410	H410		

Signal Words:

Warning

Pictograms:

GHS07

GHS09

GHS08

2.2 Self classification

- In the registration

The classification in the registrations is identical with the harmonized classification in Annex VI of CLP.

- The following hazard classes are in addition notified among the aggregated self classifications in the C&L Inventory:

Classification		Labelling		Specific Concentration limits, M-Factors
Hazard Class and Category Code(s)	Hazard Statement Code(s)	Hazard Statement Code(s)	Supplementary Hazard Statement Code(s)	
Flam. Sol. 2	H228	H228		M(Chronic)=1 M=1
Acute Tox. 2	H330	H330		
Asp. Tox. 1	H304	H304		
Eye Irrit. 2	H319	H319		
		H315		
		H372		
STOT RE 1	H373			
Aquatic Acute 1	H400	H400		
Aquatic Chronic 2	H411	H411		
Aquatic Chronic 3	H412	H412		
Carc. 2	H350	H350		
Not Classified				

Signal Words:

Danger

Pictograms:

GHS02

GHS06

2.3 Proposal for Harmonised Classification in Annex VI of the CLP

None

3 INFORMATION ON AGGREGATED TONNAGE AND USES

From ECHA dissemination site			
<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"/> 1,000,000 – 10,000,000 tpa	<input type="checkbox"/> 10,000,000 – 100,000,000 tpa	<input type="checkbox"/> > 100,000,000 tpa	
<input type="checkbox"/> <1 >+ tpa (e.g. 10+ ; 100+ ; 10,000+ tpa)		<input type="checkbox"/> Confidential	
<input type="checkbox"/> Industrial use	<input type="checkbox"/> Professional use	<input type="checkbox"/> Consumer use	<input type="checkbox"/> Closed System
Substance is used as fast sublimating substance in open/partly open systems. High level of inhalative exposure can occur.			

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 checked="" type="checkbox"/> Existing Substances Regulation 793/93/EEC
<input 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 ; Biocidal Product Regulation (Regulation (EU) 528/2012)
<input type="checkbox"/> Annex XIV (Authorisation)	<input checked="" type="checkbox"/> Other (provide further details below)
<input type="checkbox"/> Annex XVII (Restriction)	
SCOEL, German OEL. Risk assessment performed by UK under ESR programme. RA Report concluded in 2003.	

5 JUSTIFICATION FOR THE SELECTION OF THE CANDIDATE CoRAP SUBSTANCE

5.1 Legal basis for the proposal

- Article 44(2) (refined prioritisation criteria for substance evaluation)
- Article 45(5) (Member State priority)

5.2 Selection criteria met (why the substance qualifies for being in CoRAP)

- Fulfils criteria as CMR/ Suspected CMR
- Fulfils criteria as Sensitiser/ Suspected sensitiser
- Fulfils criteria as potential endocrine disruptor
- Fulfils criteria as PBT/vPvB / Suspected PBT/vPvB
- Fulfils criteria high (aggregated) tonnage (*tpa* > 1000)
- Fulfils exposure criteria
- Fulfils MS's (national) priorities

5.3 Initial grounds for concern to be clarified under Substance Evaluation

Hazard based concerns		
CMR <input type="checkbox"/> C <input type="checkbox"/> M <input type="checkbox"/> R	Suspected CMR ¹ <input type="checkbox"/> C <input type="checkbox"/> M <input type="checkbox"/> R	<input type="checkbox"/> Potential endocrine disruptor
<input type="checkbox"/> Sensitiser	<input type="checkbox"/> Suspected Sensitiser ¹	
<input type="checkbox"/> PBT/vPvB	<input type="checkbox"/> Suspected PBT/vPvB ¹	<input type="checkbox"/> Other (please specify below)
Exposure/risk based concerns		
<input type="checkbox"/> Wide dispersive use	<input type="checkbox"/> Consumer use	<input type="checkbox"/> Exposure of sensitive populations
<input type="checkbox"/> Exposure of environment	<input checked="" type="checkbox"/> Exposure of workers	<input type="checkbox"/> Cumulative exposure
<input checked="" type="checkbox"/> High RCR	<input checked="" type="checkbox"/> High (aggregated) tonnage	<input checked="" type="checkbox"/> Other (please specify below)
<p>Naphthalene has already been evaluated in 2003 in the existing chemicals program. The rapporteur was UK.</p> <p>An ongoing scientific debate has identified inflammatory reactions in the olfactory epithelium as the most critical effect. The derived value for this effect seems to be lower by a factor of 50 compared to the DNEL used in the registration dossiers.</p>		

¹ CMR/Sensitiser: known carcinogenic and/or mutagenic and/or reprotoxic properties/known sensitising properties (according to CLP harmonized or registrant self-classification or CLP Inventory)

Suspected CMR/Suspected sensitiser: suspected carcinogenic and/or mutagenic and/or reprotoxic properties/suspected sensitising properties (not classified according to CLP harmonized or registrant self-classification)

Suspected PBT: Potentially Persistent, Bioaccumulative and Toxic

Additionally, the German CA has received information, that the described exposure situation has changed a lot in the last ten years. For some of the high-risk applications a substitution to other substances is being/has been conducted. The aim of the substance evaluation is to investigate, if substitution (as indicated by the industry) has changed the exposure situation.

Since the existing (old) exposure data are significantly higher than the derived value, data on the new exposure situation are needed to evaluate whether or not a risk exists.

5.4 Preliminary indication of information that may need to be requested to clarify the concern

<input 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"/> Information ED potential	<input type="checkbox"/> Other (provide further details below)

In the light of the changed exposure situation (industrial information) actual information on exposure might be needed.

5.5 Potential follow-up and link to risk management

<input type="checkbox"/> Harmonised C&L	<input checked="" type="checkbox"/> Restriction	<input type="checkbox"/> Authorisation	<input type="checkbox"/> Other (provide further details)
---	---	--	--

If substitutes exist and RCR is >1, restriction(s) might be the best way to control the risks arising from the use of the substance.