

Justification for the selection of a candidate CoRAP substance

Substance Name (Public Name):	Alkanes, C16-20-iso
Chemical Group:	UVCB
EC Number:	292-461-1
CAS Number:	90622-59-6
Submitted by:	Norway
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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

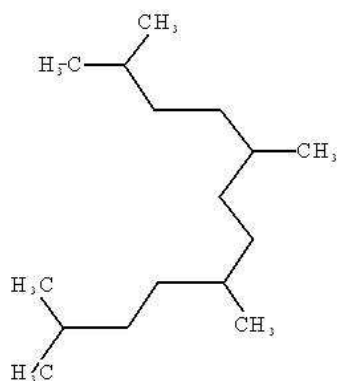
1.1 Name and other identifiers of the substance

Table 1: Substance identity

Public Name:	Alkanes, C16-20-iso-
EC number:	292-461-1
EC name:	Alkanes, C16-20-iso-
CAS number (in the EC inventory):	90622-59-6
CAS number:	90622-59-6
CAS name:	C16-(branched), C20-(branched) and C24-(branched)-alkanes
IUPAC name:	C16-(branched), C20-(branched) and C24-(branched)-alkanes
Index number in Annex VI of the CLP Regulation	-
Molecular formula:	Not applicable, UVCB
Molecular weight or molecular weight range:	>= 226.0
Synonyms:	Tetrabutane

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 yet included in Annex VI of the CLP Regulation

2.2 Proposal for Harmonised Classification in Annex VI of the CLP

No proposal available

2.3 Self classification

The registration data includes the following self classification:

According to CLP criteria:

- Aspiration Hazard, Asp. Tox. 1, H304 - May be fatal if swallowed and enters airways.

According to DSD criteria:

- Xn; R65 Harmful: may cause lung damage if swallowed.

The Classification and labelling inventory additionally includes the following classification:

- Hazardous to the aquatic environment – chronic, 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

<input 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 checked="" 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)	

Summary of the concern: Alkanes, C16-20-iso (tetrabutane) is potentially a PBT candidate. The available data are not sufficient to conclude on the definitive criteria therefore further information on PBT properties of the substance is needed. No exposure assessment has been included in the registration data, which is mandatory.

Persistence: There is very little information on abiotic and biotic degradation available, partly due to data waiving on hydrolysis, simulation test and biodegradation in soil. Further, no data on photo transformation, biodegradation in soil and sediment are available. The substance was tested for its biodegradation potential in a BODIS test according to ISO Draft (BOD Test for Insoluble Substances). Activated sludge from a domestic sewage treatment plant was used as inoculum. With a biodegradation value of 32.3 % of the corresponding Theoretical Oxygen Demand (ThOD) after 28 days, tetrabutane is not readily biodegradable, but can be considered as inherently biodegradable. From the degradation kinetics, the half-life value for tetrabutane can be calculated to 47.5 days. Based on the calculated half-life of > 40 days in freshwater the P criteria could be fulfilled. No information is available on the degradation products of tetrabutane.

All simulation tests are waived and the justification for simulation test in soil and sediment seems scientifically unjustified.

More information is needed to conclude on the biodegradability of the substance and its degradation products.

Bioaccumulation: The partition coefficient of tetrabutane was determined with Partition Coefficient (n-octanol/water), HPLC Method (OECD 117). A Log Kow of 9.5 – 10.1 was measured. A bioconcentration factor (BCF) of 400 was calculated by the BCFBAF subroutine (version 3.00) in the EPI Suite™ (2008) computer model. A log Koc of 7.715 and a BCF terrestrial of 400 was estimated by calculation using PCKOCWIN version 2.00, a subroutine within the computer program EPI Suite™ version 4.0. According to the PBT guideline measured values of log Kow above 8 must be carefully assessed for their reliability. Based on the current limited knowledge, both with respect to measured log Kow and BCFs, a calculated log Kow of 10 or above is taken as an indicator for showing reduced bioconcentration.

Aquatic BCF studies or terrestrial accumulation studies are needed to conclude on the bioaccumulation potential of the substance.

Toxicity: Due to low solubility of the substance in water (1.2 mg/l) the toxicity studies in the aquatic environment are difficult to perform. Few studies on aquatic toxicity on fish, invertebrates and algae are available, but toxicity tests on sediment organisms are missing. The substance was tested in a growth inhibition test with single cell green algae *Scenedesmus subspicatus* under static conditions according to the guideline EU Method C.3 (Algal growth inhibition test). The test was conducted as a limit test. In order to attain the solubility limit of the test substance, which is poorly soluble in water, 1 g tetrabutane, dest./L was stirred for 18 h and undissolved test substance was then removed by filtration. Since no relevant loss of test substance over the test period was recorded by analytical determination with gas chromatography, the concentration value given is therefore the initially measured value. No effects on growth rate were recorded, thus the NOEC Growth rate $\geq 21 \mu\text{g/L}$ and the EC50 Growth rate $> 21 \mu\text{g/L}$ constitutes the solubility limit of tetrabutane, under the conditions of the test. With a NOEC on growth rate of $\geq 0.02 \text{ mg/L}$ the T criterion is not fulfilled.

The substance has been tested for acute toxicity to earthworms (OECD 207) and for carbon transformation activity in soil microorganism. The available data indicate that tetrabutane is of low toxicity to soil macro and microorganisms and the NOECs are equal or greater than the test concentration of 1000 mg/kg soil dw.

Tetrabutane is probably strongly adsorptive to sediment and soil. Therefore more information is needed to conclude on the toxicity of the substance in sediment and chronic toxicity in soil. Further no PNECs have been calculated and a risk characterisation is missing.

Exposure: Industrial, professional and consumer use has been registered. Various use categories are registered indicating wide dispersive use and consumer exposure. No exposure assessment has been performed by the registrant, which is mandatory for this tonnage.

Substance identity: The substance is registered as an UVCB. The typical concentrations and concentration ranges of the known constituents are not given in the registration data.

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 checked="" type="checkbox"/> 1000 – 10,000 tpa	<input type="checkbox"/> 10,000 – 100,000 tpa		
<input type="checkbox"/> 100,000 – 1000,000 tpa	<input type="checkbox"/> > 1000,000 tpa		
<input type="checkbox"/> Confidential			
<i>Please provide further details</i>			
<input checked="" type="checkbox"/> Industrial use	<input checked="" type="checkbox"/> Professional use	<input checked="" type="checkbox"/> Consumer use	<input type="checkbox"/> Closed System
<p><u>Uses by workers in industrial settings</u></p> <ul style="list-style-type: none"> • Manufacture • Formulation and packaging of mixtures containing Tetrabutane • Use of Tetrabutane in Waste Water Treatment (industrial) • Use of Tetrabutane in fuels • Use of Tetrabutane in Special fluids • Use of Tetrabutane as Visco depressant for plastisols • Manufacture of Fine Chemicals • Use of small quantities of Tetrabutane within Laboratories <p><u>Uses by professional workers</u></p> <ul style="list-style-type: none"> • Use of Tetrabutane in waste water treatment (professional) • Use of Tetrabutane in fuels (professional) • Use of Tetrabutane in Special fluids (professional) • Use of Tetrabutane as Visco depressant for plastisols (professional) <p><u>Uses by consumers</u></p> <ul style="list-style-type: none"> • Consumer use of Tetrabutane in fuels • Tetrabutane as ingredient of Cosmetics 			

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

<input checked="" 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 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)	
<p>The information requested in the compliance check final decision regards the identity of the substance, to allow ECHA to establish and verify the composition and the name of the registered substance.</p>	

3.5 Information to be requested to clarify the suspected risk

<input type="checkbox"/> Information on toxicological properties	<input type="checkbox"/> Information on physico-chemical properties
<input checked="" type="checkbox"/> Information on fate and behaviour	<input checked="" type="checkbox"/> Information on exposure
<input checked="" type="checkbox"/> Information on ecotoxicological properties	<input type="checkbox"/> Information on uses
<input checked="" type="checkbox"/> Other (provide further details below)	
<p>Further degradation testing and information on degradation products</p> <p>Aquatic BCF studies or terrestrial accumulation studies</p> <p>Toxicity tests on sediment and soil</p> <p>Exposure assessment</p>	

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)
<p>The potential regulatory outcome of the clarification of the concern: Annex XV for SVHC identification. Restriction or authorisation.</p>			