

Justification for the selection of a candidate CoRAP substance

– UPDATE –

Substance Name (Public Name): Tetrapropylenebenzene
Chemical Group: Branched alkylbenzenes
EC Number: 246-772-4
CAS Number: 25265-78-5

Submitted by: RIVM, the Netherlands
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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

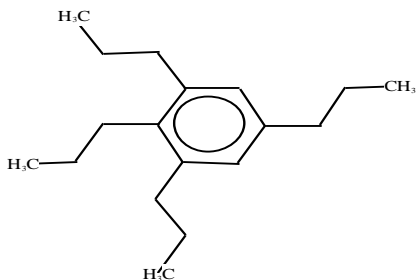
1.1 Name and other identifiers of the substance

Table 1: Substance identity

EC number:	246-772-4
EC name:	tetrapropylenebenzene
IUPAC name:	Benzene, reaction product with propylene tetramer
Index number in Annex VI of the CLP Regulation	
Molecular formula:	C ₁₈ H ₃₀
Molecular weight or molecular weight range:	>= 237.0 <= 247.0
Synonyms:	<i>Dodecylbenzene</i> <i>Benzene, tetrapropylene-</i> <i>Branched alkyl benzene</i>

Type of substance Mono-constituent Multi-constituent UVCB

Structural formula:



1.2 Similar substances/grouping possibilities

A read-across has been performed in a separate document (Rebondy, 2010), based on data on LAB of various substituent size. These compounds have been subject, notably, to ECB (1997) and OECD (2002) risk assessment dossiers, which are reliable data sources. As BAB is C9-15-substituted and contains a majority of C12- substituted components, the following analogues containing >40% of C12 were considered to be the closest ones among those assessed in these published dossiers:

Table 5: Substances used in the grouping approach

Number	Chemical name	CAS
1	Tetrapropylene benzene	25265-78-5
2	Dodecylbenzene	123-01-3
3	Benzene C10-C13 alkyl derivatives	67774-74-7
4	Benzene C14-C24 branched and linear alkyl derivatives	115733-08-9
5	Benzenes, C6-C12 alkyl derivatives	68608-80-0
6	Benzene, poly(propene) derivatives	68081-77-6
7	Nonylbenzene	1081-77-2
8	Benzene, 1,2-dimethyl-, mono-C10-14-branched alkyl derivatives., C12-rich	90171-16-7
9	Benzene, mono-C10-14-alkyl derivatives.	68442-69-3
10	Benzene, mono-C10-13-alkyl derivatives, distn. residues	84961-70-6
11	Benzene, mono-C10-14-alkyl derivatives, fractionation bottoms	85117-41-5
12	Benzene, (tetrapropenyl) derivatives	68512-02-7
13	Benzene, mono-C15-36-branched alkyl derivatives, C24-rich	90171-05-4
14	Benzene, mono-C12-18-branched alkyl derivatives	94094-94-7
15	Benzene, mono-C10-12-alkyl derivs., fractionation bottoms, light ends	68515-35-5
16	Benzene, mono-C10-12-alkyl derivs., fractionation bottoms, heavy ends	68515-33-3
17	Benzene, mono-C8-10-branched alkyl derivs.	90171-02-1

2 CLASSIFICATION AND LABELLING

2.1 Harmonised Classification in Annex VI of the CLP

Not listed

2.2 Self classification

In the registration: Asp Tox 1, H304: May be fatal if swallowed and enters airways.

Repr. 2, H361: Suspected of damaging fertility or the unborn child <state specific effect if known> <state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard>.

Aquatic Chronic 4: H413: May cause long lasting harmful effects to aquatic life.

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

Eye Irrit. 2: H319: causes serious eye irritation.

Aquatic Chronic 2: H411: Toxic to aquatic life with long lasting effects.

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 checked="" type="checkbox"/> 1000 – 10,000 tpa	<input type="checkbox"/> 10,000 – 50,000 tpa	<input type="checkbox"/> 50,000 – 100,000 tpa	
<input type="checkbox"/> 100,000 – 500,000 tpa	<input type="checkbox"/> 500,000 – 1000,000 tpa	<input type="checkbox"/> > 1000,000 tpa	
<input type="checkbox"/> Confidential			
<input checked="" type="checkbox"/> Industrial use	<input type="checkbox"/> Professional use	<input type="checkbox"/> Consumer use	<input type="checkbox"/> Closed System
The substance is used as intermediate and for formulation. The sector of end use includes manufacture of basic metals and manufacture of fabricated metal products.			

4 OTHER COMPLETED/ONGOING REGULATORY PROCESSES THAT MAY AFFECT SUITABILITY FOR SUBSTANCE EVALUATION

<input type="checkbox"/> Compliance check	<input type="checkbox"/> Dangerous substances Directive 67/548/EEC
<input checked="" 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)	
Testing proposal Final decision (TPE-D-0000002548-68-06/F) requesting subchronis toxicity study (90 day) in rats, oral route (Annex IX, 8.6.2; test method: EU B.26/OECD 408). The study protocol shall be modified with additional sperm parameters and histopathological evaluations to evaluate effects on reproductive organs; specially as described in OECD 416 adopted 22 nd January 2001, paragraph 29-39, 41-45. Deadline 11 September 2014.	

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 disrupter
 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 checked="" 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 checked="" 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 type="checkbox"/> Exposure of workers	<input type="checkbox"/> Cumulative exposure
<input type="checkbox"/> High RCR	<input checked="" type="checkbox"/> High (aggregated) tonnage	<input type="checkbox"/> Other (please specify below)

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

PBT

Two good quality screening studies determined the 28-day biodegradation of branched alkylbenzene as 18% and 58.8%, respectively. In a USGS study, frozen sediment cores were analyzed for tetrapropylene alkylbenzenes (TAB) which revealed that these compounds were recalcitrant with -8.8% and 1.8% biodegradation over an eleven year period. However, these data were compiled on frozen sediment samples and may not be reflective of in situ conditions. Biodegradation tests were not completed on soil or simulation tests in water. Based on the biodegradation data provided in this report, tetrapropylene benzene appears to be potentially "P".

The summary of a cited summary of similar compounds (linear alkylated benzenes) underwent direct photolysis within 14 days so, by extrapolation, the registrant concludes that BAB will also undergo photolysis. No empirical data were available for hydrolysis.

The Kow was measured at 8.58 which indicates a strong probability of bioaccumulation. As it exceeds the EU "B" criterion of 4.5, this compound may be identified as potentially "B".

One study was found on the bioaccumulation of tetrapropylene benzene that resulted in a BCF of 443 for immature rainbow trout (whole body) exposed to an average concentration of 0.00032 mg/L over 28 days. However, this study only used one concentration and there was no indication as to the data reliability.

CMR

Tetrapropylenebenzene was not considered mutagenic in good quality in vitro and in vivo studies by Robinson and Nair (1992) and the Italian Ministry of Public Health. No data for carcinogenicity was found. A linear alkyl benzene mixture had a NOEL of 125 mg/kg for developmental and reproductive toxicity due to reduced survival and weight gain of the offspring and fetal ossification changes. Therefore, this substance is considered potential "T".

ECHA evaluated the newly submitted sub-chronic toxicity study, which confirmed concerns on effects on reproductive organs and sperm already observed in a sub-acute study in rats. No NOAEL could be derived, the LOAEL of 25 mg/kg bw/d is based on the critical effect of reduced sperm motility. The substance is considered to be a potential candidate for Repro cat. 1B. The scope of the substance evaluation is therefore expanded with human health. ECHA also notes indications of potential immunotoxic properties, which will also be taken in to consideration in the substance evaluation. The NL-CA determines the indication as doubtful, but will check this in more detail during the substance evaluation which is foreseen in 2016.

Tonnage

The tonnage level is between 1000 and 10000 tpa.

5.4 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 checked="" type="checkbox"/> Information on fate and behaviour	<input type="checkbox"/> Information on exposure
<input checked="" type="checkbox"/> Information on ecotoxicological properties	<input type="checkbox"/> Information on uses
<input type="checkbox"/> Other (provide further details below)	
<p>Since the substance is determined to be potentially, P, B and T, additional information in the form of testing for P (biodegradation tests and/or simulation tests), B (BCF-study) and T (both human toxicological tests or ecotoxicological tests) can be required. In addition, the concern for reprotoxicity will be investigated in more detail and additional testing may be required.</p>	

5.5 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)
Non-conclusive at this stage.			