Justification Document for the Selection of a CoRAP Substance

Substance Name (public name):	2,4,6-tri-tert-butylphenol
EC Number:	211-989-5
CAS Number:	732-26-3
Authority:	BE CA
Date:	21/03/2017

Cover 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

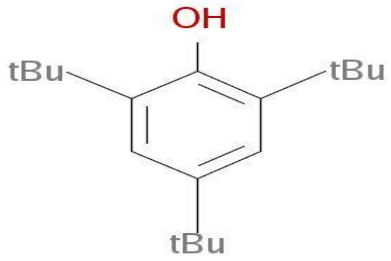
1.1 Other identifiers of the substance

Table: Other Substance identifiers

EC name (public):	2,4,6-tri-tert-butylphenol
IUPAC name (public):	2,4,6-tri-tert-butylphenol
Index number in Annex VI of the CLP Regulation:	/
Molecular formula:	$C_{18}H_{30}O$
Molecular weight or molecular weight range:	262.4302
Synonyms:	/

Type of substance ☒ Mono-constituent ☐ Multi-constituent ☐ UVCB

Structural formula:



1.2 Similar substances/grouping possibilities

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2 OVERVIEW OF OTHER PROCESSES / EU LEGISLATION

Table: Completed or ongoing processes

RMOA	☐ Risk Management Option Analysis (RMOA)	
REACH Processes	Evaluation	☐ Compliance check, Final decision
		☐ Testing proposal
		☐ CoRAP and Substance Evaluation
	Authorisation	☐ Candidate List
		☐ Annex XIV
	Restric-tion	☐ Annex XVII[1]
Harmonised C&L	☐ Annex VI (CLP) (see section 3.1)	
Processes under other EU legislation	☐ Plant Protection Products Regulation Regulation (EC) No 1107/2009	
	☐ Biocidal Product Regulation Regulation (EU) 528/2012 and amendments	
Previous legislation	☐ Dangerous substances Directive Directive 67/548/EEC (NONS)	
	☐ Existing Substances Regulation Regulation 793/93/EEC (RAR/RRS)	
(UNEP) Stockholm convention (POPs Protocol)	☐ Assessment	
	☐ In relevant Annex	
Other processes / EU legislation	☐ Other (provide further details below)	

[1] Please specify the relevant entry.

Further details	*Please provide further details and more particularly specify where relevant if the process is ongoing or completed. Give only publicly available information.*

3 HAZARD INFORMATION (INCLUDING CLASSIFICATION)

3.1 Classification

3.1.1 Harmonised Classification in Annex VI of the CLP

NA

3.1.2 Self classification

Skin Sens. 1B; H317: May cause an allergic skin reaction

STOT Rep. Exp. 1 (liver); H372: Causes damage to organs through prolonged or repeated exposure

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

Notified classification and labelling on ECHA dissemination website:

Acute tox 4; H302

Eye Irrit. 2; H319

Skin Irrit. 2; H315

STOT SE 3; H335

Aquatic chronic 1; H410

3.1.3 Proposal for Harmonised Classification in Annex VI of the CLP

NA

4 INFORMATION ON (AGGREGATED) TONNAGE AND USES[2]

4.1 Tonnage and registration status

Table: Tonnage and registration status

From ECHA dissemination site		
☒ Full registration(s) (Art. 10)	☐ Intermediate registration(s) (Art. 17 and/or 18)	
Tonnage band (as per dissemination site)		
☐ 1 – 10 tpa	☒ 10 – 100 tpa	☐ 100 – 1000 tpa
☐ 1000 – 10,000 tpa	☐ 10,000 – 100,000 tpa	☐ 100,000 – 1,000,000 tpa
☐ 1,000,000 – 10,000,000 tpa	☐ 10,000,000 – 100,000,000 tpa	☐ > 100,000,000 tpa
☐ <1 . . . . . >+ tpa (e.g. 10+ ; 100+ ; 10,000+ tpa)		☐ Confidential

[2] *Dissemination site was accessed 17 August 2016.*

4.2 Overview of uses

Table: Uses

Part 1:

☐ Manufacture	☒ Formulation	☒ Industrial use	☒ Professional use	☐ Consumer use	☐ Article service life	☐ Closed system

Part 2:

	Use(s)
Uses as intermediate	
Formulation	Formulation of preparations; Product categories fuels and intermediates
Uses at industrial sites	Industrial use resulting in manufacture of another substance and industrial use of substances in closed systems
Uses by professional workers	Professional use of fuel additives and additised fuels
Consumer Uses	/
Article service life	/

The registrant(s) states that the substance is treated as being a PBT/vPvB substanc. Therefore, it is claimed that risk management measures are in place to prevent release of the substance to the environment during all processes.

The BE CA however notes that there is a potential for exposure as it seems doubtful that there would be no emission to the environment given the use of the substance as fuel additive.

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 ☐ C ☐ M ☐ R	Suspected CMR[1] ☐ C ☐ M ☐ R	☐ Potential endocrine disruptor
☐ Sensitiser	☐ Suspected Sensitiser[3]	
☐ PBT/vPvB	☒ Suspected PBT/vPvB[1]	☐ Other (please specify below)
Exposure/risk based concerns		
☐ Wide dispersive use	☐ Consumer use	☐ Exposure of sensitive populations
☒ Exposure of environment	☐ Exposure of workers	☐ Cumulative exposure
☐ High RCR	☐ High (aggregated) tonnage	☐ Other (please specify below)

[3] 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

Persistency:

The substance is not readily biodegradable (USEPA QSAR data).

The substance is not inherently biodegradable (13% biodegradation after 28 days in an OECD 302(C) test (Sewell, 1992) => the substance is potentially P or vP.

This OECD 302C test was performed at a concentration of 30 mg/L TTBP. It should be noted that given the low water solubility of the substance (0.063 mg/L) and the high adsorption potential of the substance (Log Koc = 5.3), it is difficult to conclude on the P/vP status based on this inherently biodegradability test. In order to remove any doubt about the fulfillment of the P/vP criterion (comparison to Annex XIII criteria), a biodegradation half-life should be determined.

Bioaccumulation:

Measured log Kow = 7.1 => screening criterion for P is fulfilled

A fish bioconcentration study is available: BCF values between 4320 and 23200 L/kg (0.001 ppm) and between 4830 and 16000 L/kg (0.01 ppm) (Anon, 1982)

⇨ The vB criterion is fulfilled

Toxicity:

Environment: All L/EC50 values are greater than the limit of solubility => the T criterion is potentially fulfilled.

Human Health: The substance is classified as STOT RE Category 1 => the T criterion is fulfilled according to Annex XIII of REACH.

The registrant(s) states that the substance is treated as being a PBT/vPvB substance. Therefore, it is claimed that risk management measures are in place to prevent release of the substance to the environment during all processes.

The BE CA however notes that there is a potential for exposure as it seems doubtful that there would be no emission to the environment given the use of the substance as fuel additive.

Based on the available data, it seems that the B/vB criterion and the T criterion are fulfilled (according to the Annex XIII criteria) and that exposure to the environment cannot be excluded. Not enough data are available to conclude on the fulfillment of the definite P/vP criterion, but the screening criterion for P is fulfilled.

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

☐ Information on toxicological properties	☐ Information on physico-chemical properties
☒ Information on fate and behaviour	☐ Information on exposure

☐ Information on ecotoxicological properties	☐ Information on uses
☐ Information ED potential	☐ Other (provide further details below)
A degradation half-life will provide the needed information to decide whether the P/vP criterion is fulfilled (according to Annex XIII criteria) => A degradation simulation study may be requested for this substance.	

5.5. Potential follow-up and link to risk management

☐ Harmonised C&L	☐ Restriction	☒ Authorisation	☐ Other (provide further details)
Identification as SVHC (PBT/vPvB) according to article 57(d)/(e) if considered appropriate.			