Justification for the selection of a substance for CoRAP inclusion

Substance Name (Public Name):	tert-butyl-4-methoxyphenol
Chemical Group:	
EC Number:	246-563-8
CAS Number:	25013-16-5
Submitted by:	FRANCE
Date:	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

1.1 Other identifiers of the substance

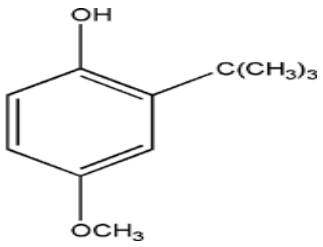
Table 1: Substance identity

EC name:	tert-butyl-4-methoxyphenol
IUPAC name:	2-tert-butyl-4-methoxyphenol
Index number in Annex VI of the CLP Regulation	none
Molecular formula:	$C_{11}H_{16}O_2$
Molecular weight or molecular weight range:	180,2 g/mol
Synonyms/Trade names:	tert-butyl-hydroxyanisole; Butylated hydroxyanisole BHA E 320

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

BHA consists of a mixture of two isomers: 3-tert-butyl-4-hydroxyanisole (3-BHA) and 2-tert-butyl-4-hydroxyanisole (2-BHA).

Structural formula:



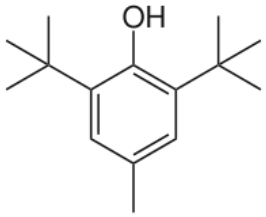
1.2 Similar substances/grouping possibilities

Table: Substance identity of BHT

EC name:	204-881-4
IUPAC name:	2,6-bis(1,1-dimethylethyl)-4-methylphenol
Index number in Annex VI of the CLP Regulation	none
Molecular formula:	$C_{15}H_{24}O$
Molecular weight or molecular weight range:	
Synonyms/Trade names:	2,6-di-*tert*-butyl-4-methylphenol, 2,6-di-*tert*-butyl-*p*-cresol (DBPC), 3,5-di-*tert*-butyl-4-hydroxytoluene, BHT E321

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: Harmonised classification

Index No	International Chemical Identification	EC No	CAS No	Classification		Spec. Conc. Limits, M-factors	Notes
				Hazard Class and Category Code(s)	Hazard statement code(s)		
No current entry							

2.2 Self classification

- In the registration:

  Skin Irrit. 2; H315: Causes skin irritation.

  Eye Irrit. 2; H319: Causes serious eye irritation.

  Carc. 2; H351: Suspected of causing cancer <state route of exposure if it is conclusively proven that no other routs of exposure cause the hazard>. Route of exposure: Oral.

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

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

  Acute Tox. 4; H302: Harmful if swallowed.

  Acute Tox. 4; H312: Harmful in contact with skin.

  Acute Tox. 4; H332: Harmful if inhaled.

  STOT SE 3; H335: May cause respiratory irritation.

  Aquatic Chronic 4; H410: very toxic to aquatic life with long lasting effects.

  Eye Dam. 1; H318: Causes serious eye damage.

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

  STOT SE 3; H336: may cause drowsiness or dizziness.

  Repr. 2; H361: Suspected of damaging fertility or the unborn child.

  Aquatic Chronic 1; H410: Very 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		
☐ 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

☒ Industrial use	☐ Professional use	☒ Consumer use	☐ Closed System

Main uses: antioxidant in cosmetics, pesticides, rubber and petroleum products, and as antioxidant and preservative in food & food packaging.

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

☐ Compliance check, Final decision	☐ Dangerous substances Directive 67/548/EEC
☐ Testing proposal	☐ Existing Substances Regulation 793/93/EEC
☐ Annex VI (CLP)	☐ Plant Protection Products Regulation 91/414/EEC
☐ Annex XV (SVHC)	☐ Biocidal Products Directive 98/8/EEC ; Biocidal Product Regulation (Regulation (EU) 528/2012)
☐ Annex XIV (Authorisation)	☐ Other (provide further details below)
☐ Annex XVII (Restriction)	

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[1]	
☐ 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)

[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

Several public agencies such as USEPA have identified BHA as a priority for evaluation, in particular for evaluating if it displays any ED effects. Several international and European assessments have been carried out on the BHA.

Endocrine disruption

- The European Commission on Endocrine Disruption (EDC Database) listed BHA as a Category 1 priority substance, based on evidence that it interferes with hormone function.
- SIN List: BHA is included as endocrine disruptor with oestrogenic, thyroid and antiandrogen activity, affecting several body functions including development and reproduction.
- World Wildlife Fund 1996 lists BHA as a suspected endocrine disruptor.
- European Commission priority list 2007: BHA is in category 1 on the priority list of substances for further evaluation of their role in endocrine disruption.
- OCDE, 2010 : BHA is in the 2010 list of the high concern substances with evidence or potential evidence of ED effects, which are already regulated or being addressed under existing legislation (Dir 2002/72/EC on food Contact Materials and Dir 95/2/EC on food additives other than colours and sweeteners)

Substance evaluation has been proposed as the outcome of a French Risk management Option Analysis after an assessment of the toxicological data in the dossier and following a discussion with other experts of the ED-expert group of ECHA.

Further studies shall also clarify if BHA alters thyroid pathway as the effects described in various studies and models seems incoherent with the fact that no carcinogenic effects are described in thyroid in longer studies.

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)
Based on reprotoxicity adverse effects and various data showing potential thyroid and oestrogenic effect of BHA, this substance is suspected to be an ED as defined by the WHO definition. In order to investigate the ED potential for the environmental species and persistence within environment, information on fate and behavior is necessary.	

5.5 Potential follow-up and link to risk management

☒ Harmonised C&L	☐ Restriction	☐ Authorisation	☒ Other (provide further details)
In order to speed up management options and in order to ease further SVHC identification as 57(f), it may be proposed to carry on harmonized classification proposal depending on the evaluation outcome.			