

## RISK MANAGEMENT OPTIONS ANALYSIS

### CONCLUSION DOCUMENT

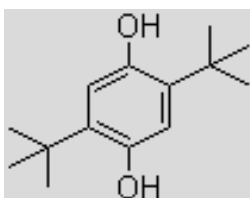
for

### 2,5-DI-TERT-BUTYLHYDROQUINONE (DTBHQ)

EC number: 201-841-8

CAS number: 88-58-4

Structural formula:



Member State(s): Denmark

Dated: August 2014, Final version

*Disclaimer: Please note that this RMOA conclusion was compiled on the basis of available information and may change in the light of new information or further assessment.*

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## 1. OVERVIEW OF OTHER REGULATORY PROCESSES / EU LEGISLATION

The RMO and the underlying surveys are a part of the review of the substances on the Danish List of undesirable substances (LOUS-review).

The Danish Environmental Protection Agency's List of Undesirable Substances (LOUS) (Danish EPA, 2011) consists of 40 substances/groups of substances selected for their problematic effects according to criteria defined by the Danish EPA. The aim of the list is to urge enterprises to reduce or substitute the use of the substances on the list.

The Danish EPA is currently conducting a survey of all substances on LOUS. Access to the surveys carried out so far can be found at the following link:

[http://www.mst.dk/English/Chemicals/assessment\\_of\\_chemicals/LOUS\\_2012\\_2015/](http://www.mst.dk/English/Chemicals/assessment_of_chemicals/LOUS_2012_2015/)

The substance 2,5-di-tert-butylhydroquinone (DTBHQ) was included in the LOUS due to a use tonnage in Denmark larger than 100 tonnes and based on an evaluation founded on QSAR modeling that the substance should be classified as N; R50/53, leading to concern for a potential risk for the environment from the substance.

The survey carried out for DTBHQ provides an overview of the use and the environmental and human health aspects of the substance. The results of the survey have been used as the main background information for this RMO.

The current status of DTBHQ pertaining to relevant community legislation is summarised in Table 1 below.

**Table 1 Relevant legislation pertaining to the manufacture and use of DTBHQ**

Legal instrument	EU/national	Status of DTBHQ
REACH regulation	Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)	Not registered
CLP regulation	Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances	No EU harmonised classification is available. Industry self-classification is reported to the ECHA C&L inventory database.

Legal instrument	EU/national	Status of DTBHQ
	and mixtures	
Waste Framework Directive	Directive 2008/98/EC the European Parliament and of the Council of 19 November 2008 on waste	According to the Directive waste containing a concentration of DTBHQ triggering classification of a mixture according to the CLP Directive is considered to be hazardous waste.
Water Framework Directive	Directive 2000/60/EC the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy.	No EQS value has been established for DTBHQ.
Biocide Regulation	Regulation (EU) No 528/2012 of the European Parliament and the Council of 22 May 2012 concerning the making available on the market and use of biocidal products	DTBHQ is not notified as a biocide and may thus not be marketed as a biocide.
Cosmetics regulation	Regulation (EC) No 1223/2009 on cosmetic products	DTBHQ is not mentioned in the regulation. However, the substance is listed on the Cosing list with the function antioxidant indicating a possible use as cosmetic ingredient
Food contact materials regulation	EU regulation 10/2011 on plastic materials and articles intended to come into contact with food.	DTBHQ is not listed on the positive list for food contact materials of plastic.  However, DTBHQ is listed on FDA's list of substance permitted in glue and coatings in food contact materials.

## 2. CONCLUSION OF RMOA

Conclusions	Tick box
Need for follow up regulatory action at EU level <i>[if a specific regulatory action is already identified then, please, select one or more of the specific follow up actions mentioned below]</i>	
Harmonised classification and labelling	
Identification as SVHC (authorisation)	
Restrictions	
Other EU-wide measures	
No need for regulatory follow-up action	X

DTBHQ is not yet registered under REACH due to low tonnage. Due to the

very few data available on DTBHQ, it is not possible to perform a risk characterization or to identify specific risk management options at this point in time.

Further information would be needed in order to confirm or revoke the concern of a possible risk to human health and to the environment. Information from the Danish product register indicates a significant decrease in the use of the substance. The Danish EPA has performed surveys on the possible use of the substance in cosmetics, in paint and in food contact materials.

Based on the strong decrease leading to a very low consumption level reported from the Danish product register over the past 5 years, results from surveys performed by the Danish EPA of the occurrence in products in Denmark showing only very scarce use in chemicals mixtures and an possible use in drinking water tanks and the scarce use shown in Sweden in the Nordic SPIN database, the risks to human health and to the environment from DTBHQ are considered to be low.

Therefore, the Danish EPA proposes that no further regulatory action is initiated on DTBHQ.

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