

Committee for Risk Assessment
RAC

Opinion

proposing harmonised classification and labelling
at EU level of

**(1-methylethylidene)di-4,1-phenylene
tetraphenyl diphosphate; Bisphenol A
Diphosphate; Bisphenol A Polyphosphate**

EC No.: 425-220-8

CAS No.: 5945-33-5

ECHA/RAC/CLH-O-0000002129-76-03/F

Adopted

28 November 2012

**OPINION OF THE COMMITTEE FOR RISK ASSESSMENT
ON A DOSSIER PROPOSING HARMONISED CLASSIFICATION AND
LABELLING AT EU LEVEL**

In accordance with Article 37 (4) of (EC) No 1272/2008, the Classification, Labelling and Packaging (CLP) Regulation, the Committee for Risk Assessment (RAC) has adopted an opinion on the proposal for harmonised classification and labelling (CLH) of:

Chemical names: (1-methylethylidene)di-4,1-phenylene tetraphenyl diphosphate; Bisphenol A Diphosphate; Bisphenol A Polyphosphate

EC No.: 425-220-8

CAS No.: 5945-33-5

The proposal was submitted by the **United Kingdom** and received by the RAC on **25/11/2011**.

In this opinion, all classifications are given firstly in the form of CLP hazard classes and/or categories, the majority of which are consistent with the Globally Harmonised System (GHS) and secondly, according to the notation of 67/548/EEC, the Dangerous Substances Directive (DSD).

The proposed harmonised classification

	CLP	DSD
Current entry in Annex VI of CLP Regulation (EC) No 1272/2008	Hazard class: Aquatic Chronic 4 Hazard statement code: H413	R53: May cause long-term adverse effects in the aquatic environment
Original proposal by dossier submitter for consideration by RAC	Removal of Aquatic Chronic 4 classification.	Removal of R53 classification.
Resulting harmonised classification (future entry in Annex VI of CLP Regulation) as proposed by dossier submitter	No classification	No classification

PROCESS FOR ADOPTION OF THE OPINION

The **United Kingdom** has submitted a CLH dossier containing a proposal together with the justification and background information documented in a CLH report. The CLH report was made publicly available in accordance with the requirements of the CLP Regulation at <http://echa.europa.eu/harmonised-classification-and-labelling-consultation> on **25/11/2011**. Concerned parties and Member State Competent Authorities (MSCA) were invited to submit comments and contributions by **09/01/2012**.

ADOPTION OF THE OPINION OF RAC

Rapporteur, appointed by RAC: **Yvonne Mullooly**
Co-rapporteur, appointed by RAC: **Hans-Christian Stolzenberg**

The opinion takes into account the comments provided by MSCAs and concerned parties in accordance with Article 37(4) of the CLP Regulation.

The RAC opinion on the proposed harmonised classification and labelling was adopted on **28 November 2012** and the comments received are compiled in Annex 2.

The RAC Opinion was adopted by **consensus**.

OPINION OF THE RAC

The RAC adopted the opinion that **(1-methylethylidene)di-4,1-phenylene tetraphenyl diphosphate; Bisphenol A Diphosphate; Bisphenol A Polyphosphate** should be classified and labelled as follows:

Classification & Labelling in accordance with CLP:

Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
				Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
015-188-00-X	(1-methylethylidene)di-4,1-phenylenetetraphenyl diphosphate*	425-220-8	5945-33-5	Aquatic Chronic 4	H413	—	H413			

Classification & Labelling in accordance with DSD:

Index No	International Chemical Identification	EC No	CAS No	Classification	Labelling	Concentration Limits	Notes
015-188-00-X	(1-methylethylidene)di-4,1-phenylenetetraphenyl diphosphate	425-220-8	5945-33-5	R53	R: 53 S: 61		

*Text in the above table which has been struck through indicates the proposed removal of that part of the classification

SCIENTIFIC GROUNDS FOR THE OPINION

Environmental hazards

Hazards to the Aquatic Environment

Summary of the Dossier submitter's proposal

(1-methylethylidene)di-4,1-phenylene tetraphenyl diphosphate (Bisphenol A Diphosphate) was classified as Aquatic Chronic 4 according to Regulation EC 1272/2008 (Annex VI Table 3.1 in the CLP) and R53 according to Directive 67/548 (DSD) (Annex VI Table 3.2 in the CLP). The substance is considered to be mono-constituent with a typical concentration range of 80% to 85%.

This substance was reviewed by Member State Competent Authorities (MSCA's) under the DSD legislation and was classified based on the low water solubility, the lack of ready biodegradability and a Log Kow >3. While the acute toxicity data of the substance showed no toxicity up to the maximum water solubility, the test results did not adequately justify removing the Aquatic Chronic 4 (H413) classification (CLP) and its corresponding R53 classification according to the DSD criteria.

Further relevant information on bioaccumulation and chronic toxicity in fish and *Daphnia magna* was submitted at a later stage. However, this information was not part of the original dossier and therefore not implemented in Annex I of the previous legislation.

In accordance with the CLP Regulation, the Dossier Submitter (DS) proposes the removal of the classification Aquatic Chronic 4 (H413) and the corresponding R53 classification according to the DSD. The proposed removal is based on the evidence that the DS has provided in the CLH report and subsequent clarifications following the Public Consultation that the substance is not bioaccumulative. The removal of the classification is based on BCF values <500 and the lack of chronic toxicity in fish (*Pimephales promelas*) and invertebrates (*Daphnia magna*).

Water solubility: two studies were conducted according to the EEC Method A6 (flask method). The water solubility of the substance tested was found to be 1.88 mg/l at 20°C and 0.415 mg/l at 20°C in the respective studies. While the dossier submitter considers that the flask method may not be the most suitable method to test a poorly soluble substance and outlines that, based on the preliminary water solubility test, the column elution method should have been performed (as the solubility was less than 1×10^{-2} g/l). They argue that due to the physical nature of the test material, it was not technically possible to use this method without blocking the column. The difference in solubility results is presumed to be due to slight differences in substance composition between suppliers, inter-laboratory differences and slight test method differences.

Degradability: Bisphenol A Diphosphate is considered not to undergo abiotic or biotic degradation. Hydrolysis results at pH 4, 7 and 9 showed less than 10% hydrolysis after 5 days at 50°C, equivalent to a half-life greater than 1 year at 25°C. The substance is considered not readily biodegradable with two screening studies (conducted according to OECD 301C – Modified MITI test) which reported mean degradation levels of 0% and 2.5% after 28 days.

Bioaccumulation: The log n-octanol-water partition coefficient was measured in two different experimental studies. The Log Kow of the test substance was found to be > 4.9 at 20°C (pH 7.29-7.37) and 4.5 at 25°C (pH 5.65) indicating a potential for bioaccumulation.

In addition two separate bioaccumulation studies are reported where *Cyprinus carpio* were exposed to the substance for an 8 week uptake period. In these bioaccumulation studies different analytical methods were used: in one study the main component and the related impurities in both fish and water were analytically separated. BCF values for each component were analysed separately and the observed BCF values for each

component were ≤ 1.1 to ≤ 159 . These values reflect those samples where measurements were above or equal to the limit of detection. No detectable test item was found in the fish indicating low bioaccumulation. The dossier submitter considered the result of ≤ 159 as not relevant to classification, as 159 was the limit of detection.

In a second study the BCF values were found to be between 6.2 and 62. In this study the substance and its impurities was not separated but again the measured values were greater than the limit of detection resulting in low BCF values.

Based on these two studies, the dossier submitter considered that the substance does not bioaccumulate.

Ecotoxicity: The ecotoxicity results from both short term and long term studies were as follows:

Trophic level	Short-term result	Long-term result
Fish	No toxicity up to the limit of solubility	No toxicity up to the limit of solubility (Water Accommodated Fraction)
Aquatic invertebrates (<i>Daphnia magna</i>)	No toxicity up to the limit of solubility	<ol style="list-style-type: none"> 1. No toxicity up to the limit of solubility (Water Accommodated Fraction) 2. NOEC of 1.8 mg/l and LOEC of ≥ 1.8 mg/l 3. NOEC of 1.2 mg/l (based on some growth reduction) and LOEC 1.4 mg/l
Aquatic algae and plants	No toxicity up to the limit of solubility	N/A

No toxicity was found at the limit of solubility in the acute studies for fish, daphnia or algae. Bisphenol A Polyphosphate is not acutely toxic across all taxonomic groups, with no effects seen up to the limit of water solubility under the test conditions (provided in the Annex I in the description of the acute aquatic toxicity studies).

Four long term studies are available for the substance, one 28 day Fish Early Life Stage study (FELS) and three *Daphnia magna* reproduction studies. In the FELS study the test solutions used in the study were prepared as Water Accommodated Fractions (WAF). The determined NOELr of 5 mg/l (based on initial loading rates) was found to be equal to the maximum water solubility tested. One study with *Daphnia magna* was also conducted using the WAF technique, with concentrations selected to exceed the limit of aqueous solubility. No effects were seen at the highest measured concentration of 5 ppm.

Two additional long term *Daphnia magna* reproduction studies are available with mean measured concentrations of 0.14, 0.26, 0.52, 1.1 and 1.8 mg/l, and 0.15, 0.32, 0.52, 1.2 and 1.4 mg/l. One study resulted in a NOEC (21 d) of 1.8 mg/l and a LOEC of > 1.8 mg/l, as no effects were observed in any treatment level. In the second study a reduction in growth was apparent in the highest treatment level (1.4 mg/l), thus resulting in a NOEC (21 d) of 1.2 mg/l and a LOEC of 1.4 mg/l. No effects were determined for reproduction or survival at the highest tested concentration of 1.4mg/l.

The dossier submitter explains the different results for the chronic aquatic toxicity studies based on the use of the WAF technique, the different ratio of constituents and the fact that studies were carried out by different laboratories.

Because of the low BCF values (< 100) and the absence of chronic toxicity effects at the water solubility limits, the dossier submitter concludes that the classification as Aquatic Chronic 4 and DSD R53, should both be removed.

Comments received during public consultation

Five comments were received during the public consultation and while MS commentators in general did not object to the removal of the classification proposed by the dossier submitter, requests for additional technical clarifications were made.

Two comments were made regarding the stated purity of the substance and the level of impurities present. Comments were also submitted by two MS and one industry seeking clarification on the reported BCF values.

One MS requested clarification on the reporting of actual measured concentrations in the aquatic toxicity studies and the use of the Water Accommodated Fraction (WAF) in two long term studies.

A comment from one MS suggested classifying as Aquatic Chronic 2 based on unclear results showing adverse effects measured at its water solubility.

The RAC assessment and comparison with the classification criteria

Solubility: the RAC agrees with the dossier submitter in considering Bisphenol A Diphosphate as a poorly soluble substance. While the test method employed is not considered to be the most appropriate, the explanation provided for not using the column elution method is acceptable.

Degradation: the RAC agrees with the dossier submitter in considering Bisphenol A Diphosphate as not undergoing any significant abiotic or biotic degradation when compared to the criteria.

Bioaccumulation: two BCF studies are available for the substance. The determined BCF values range between ≤ 1.1 and ≤ 159 and 6.8 and 62 , i.e. below the level of detection in both studies. Following clarification by the DS it has been confirmed that the values in both studies are reported relative to wet weight and not dry weight as indicated in the CLH report. Moreover, the determined BCF values have not been lipid normalised (lipid content 4.1% and 3.9, respectively).

Nonetheless, based on the low values of the experimentally determined BCF (below the level of detection in two studies), they are well below the cut-off values of ≥ 500 according to CLP and most likely below the ≥ 100 value according to DSD and therefore the RAC agrees with the dossier submitter that the substance should not be considered as bioaccumulative.

Toxicity: studies are available for both acute and chronic aquatic toxicity. Actual concentrations were measured in all the acute and long term aquatic toxicity studies. However, no toxicity was reported up to the maximum attainable exposure concentration. The actual measured concentrations in the acute toxicity testing with fish, daphnia and algae ranged between 0.141 and 3.93 mg/l (in filtered and unfiltered samples of the test medium). In the long term toxicity testing with fish conducted using the WAF technique the chemical analysis (HPLC) of test substance was below the limit of quantification (0.0007 to 0.0019 mg/l and 0.003 to 0.009 mg/l, respectively). Also in the reproduction study with daphnia where the test solutions were prepared as water accommodated fractions of 1, 2, 3, and 5ppm, the test substance concentration was less than the initial loading rates (between 0.4 and 1.9% nominal in fresh solutions).

Conclusion on classification

Bisphenol A Polyphosphate is considered not readily (or rapidly) degradable. The results of the available BCF studies do not exceed the cut-off values for bioaccumulation (≥ 500

according to CLP and ≥ 100 according to DSD, respectively), showing that the application of the safety net classification is no longer necessary, as the substance is not likely to bioaccumulate. As the criteria have not been met, the RAC agrees with the dossier submitter that classification for chronic effects is not warranted.

Since no toxicity was found at the limit of water solubility in the acute studies for fish, daphnia or algae, the RAC agrees with the DS that no acute classification for the environment is warranted.

ANNEXES:

- Annex 1 Background Document (BD) gives the detailed scientific grounds for the opinion. The BD is based on the CLH report prepared by the dossier submitter; the evaluation performed by RAC is contained in RAC boxes.
- Annex 2 Comments received on the CLH report, response to comments provided by the dossier submitter and RAC (excl. confidential information)