



## **Committee for Risk Assessment**

### **RAC**

Annex 1

### **Background document**

to the 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 number: 425-220-8**  
**CAS number: 5945-33-5**

CLH-O-0000002129-76-03/A1

*The background document is a compilation of information considered relevant by the dossier submitter or by RAC for the proposed classification. It includes the proposal of the dossier submitter and the conclusion of RAC. It is based on the official CLH report submitted to public consultation. RAC has not changed the text of this CLH report but inserted text which is specifically marked as 'RAC evaluation'. Only the RAC text reflects the view of RAC.*

**Adopted**  
**28 November 2012**

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**Part A.**

**1 PROPOSAL FOR HARMONISED CLASSIFICATION AND LABELLING**

**1.1 Substance**

Table 1: Substance identity

|                               |   |
|-------------------------------|---|
| <b>Substance name:</b>        | <b>(1-methylethylidene)di-4,1-phenylene tetraphenyl diphosphate; BDP;BAPP</b> |
| <b>EC number:</b>             | <b>425-220-8</b>  |
| <b>CAS number:</b>            | <b>5945-33-5</b>  |
| <b>Annex VI Index number:</b> | <b>015-188-00-X</b>   |
| <b>Degree of purity:</b>      | <b>&gt;80%</b>  |
| <b>Impurities:</b>            | <b>Triphenyl phosphate</b>  |

**1.2 Harmonised classification and labelling proposal**

Table 2: The current Annex VI entry and the proposed harmonised classification

|   | <b>CLP Regulation</b>  | <b>Directive 67/548/EEC (Dangerous Substances Directive; DSD)</b>          |
|---|--|--|
| <b>Current entry in Annex VI, CLP Regulation</b>                                      | Hazard class:<br>Aquatic Chronic 4<br><br>Hazard statement code:<br><br>H413 | R53:<br><br>May cause long-term adverse effects in the aquatic environment |
| <b>Current proposal for consideration by RAC</b>                                      | Removal of Aquatic Chronic 4 classification.                                 | Removal of R53 classification.   |
| <b>Resulting harmonised classification (future entry in Annex VI, CLP Regulation)</b> | No classification  | No classification  |

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BISPHENOL A POLYPHOSPHATE

**1.3 Proposed harmonised classification and labelling based on CLP Regulation and/or DSD criteria**

Table 3: Proposed classification according to the CLP Regulation

| <b>CLP Annex I ref</b> | <b>Hazard class</b>  | <b>Proposed classification</b> | <b>Proposed SCLs and/or M-factors</b> | <b>Current classification<sup>1)</sup></b> | <b>Reason for no classification<sup>2)</sup></b> |
|------------------------|--|--------------------------------|---------------------------------------|--|--|
| <b>2.1.</b>            | Explosives   |                                |                                       |  |  |
| <b>2.2.</b>            | Flammable gases  |                                |                                       |  |  |
| <b>2.3.</b>            | Flammable aerosols   |                                |                                       |  |  |
| <b>2.4.</b>            | Oxidising gases  |                                |                                       |  |  |
| <b>2.5.</b>            | Gases under pressure   |                                |                                       |  |  |
| <b>2.6.</b>            | Flammable liquids  |                                |                                       |  |  |
| <b>2.7.</b>            | Flammable solids   |                                |                                       |  |  |
| <b>2.8.</b>            | Self-reactive substances and mixtures                                    |                                |                                       |  |  |
| <b>2.9.</b>            | Pyrophoric liquids   |                                |                                       |  |  |
| <b>2.10.</b>           | Pyrophoric solids  |                                |                                       |  |  |
| <b>2.11.</b>           | Self-heating substances and mixtures                                     |                                |                                       |  |  |
| <b>2.12.</b>           | Substances and mixtures which in contact with water emit flammable gases |                                |                                       |  |  |
| <b>2.13.</b>           | Oxidising liquids  |                                |                                       |  |  |
| <b>2.14.</b>           | Oxidising solids   |                                |                                       |  |  |
| <b>2.15.</b>           | Organic peroxides  |                                |                                       |  |  |
| <b>2.16.</b>           | Substance and mixtures corrosive to metals                               |                                |                                       |  |  |
| <b>3.1.</b>            | Acute toxicity - oral  |                                |                                       |  |  |
|                        | Acute toxicity - dermal  |                                |                                       |  |  |
|                        | Acute toxicity - inhalation  |                                |                                       |  |  |
| <b>3.2.</b>            | Skin corrosion / irritation  |                                |                                       |  |  |
| <b>3.3.</b>            | Serious eye damage / eye irritation                                      |                                |                                       |  |  |
| <b>3.4.</b>            | Respiratory sensitisation  |                                |                                       |  |  |
| <b>3.4.</b>            | Skin sensitisation   |                                |                                       |  |  |
| <b>3.5.</b>            | Germ cell mutagenicity   |                                |                                       |  |  |

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|              |  |                |   |               |  |
|--------------|--|----------------|---|---------------|--|
| <b>3.6.</b>  | Carcinogenicity                                    |                |   |               |  |
| <b>3.7.</b>  | Reproductive toxicity                              |                |   |               |  |
| <b>3.8.</b>  | Specific target organ toxicity –single exposure    |                |   |               |  |
| <b>3.9.</b>  | Specific target organ toxicity – repeated exposure |                |   |               |  |
| <b>3.10.</b> | Aspiration hazard                                  |                |   |               |  |
| <b>4.1.</b>  | Hazardous to the aquatic environment               | Not classified | - | Aq. Chronic 4 | Conclusive but not sufficient for classification |
| <b>5.1.</b>  | Hazardous to the ozone layer                       |                |   |               |  |

<sup>1)</sup> Including specific concentration limits (SCLs) and M-factors

<sup>2)</sup> Data lacking, inconclusive, or conclusive but not sufficient for classification

**Labelling:** Signal word: Not applicable  
Hazard statements: Not applicable  
Precautionary statements: Not applicable

**Proposed notes assigned to an entry:**

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Table 4: Proposed classification according to DSD

| Hazardous property   | Proposed classification | Proposed SCLs | Current classification <sup>1)</sup> | Reason for no classification <sup>2)</sup>       |
|--|-------------------------|---------------|--------------------------------------|--|
| Explosiveness  |                         |               |                                      |  |
| Oxidising properties   |                         |               |                                      |  |
| Flammability   |                         |               |                                      |  |
| Other physico-chemical properties<br><i>[Add rows when relevant]</i>     |                         |               |                                      |  |
| Thermal stability  |                         |               |                                      |  |
| Acute toxicity   |                         |               |                                      |  |
| Acute toxicity – irreversible damage after single exposure               |                         |               |                                      |  |
| Repeated dose toxicity   |                         |               |                                      |  |
| Irritation / Corrosion   |                         |               |                                      |  |
| Sensitisation  |                         |               |                                      |  |
| Carcinogenicity  |                         |               |                                      |  |
| Mutagenicity – Genetic toxicity  |                         |               |                                      |  |
| Toxicity to reproduction – fertility                                     |                         |               |                                      |  |
| Toxicity to reproduction – development                                   |                         |               |                                      |  |
| Toxicity to reproduction – breastfed babies. Effects on or via lactation |                         |               |                                      |  |
| Environment  | Not classified          | -             | R53                                  | Conclusive but not sufficient for classification |

<sup>1)</sup> Including SCLs

<sup>2)</sup> Data lacking, inconclusive, or conclusive but not sufficient for classification

**Labelling:** Indication of danger: Not applicable  
R-phrases: Not applicable  
S-phrases: Not applicable

## **2 BACKGROUND TO THE CLH PROPOSAL**

### **2.1 History of the previous classification and labelling**

The substance (1-methylethylidene)di-4,1-phenylene tetraphenyl diphosphate (bisphenol A diphosphate) (EC. No 425-220-8) is currently classified and labelled as R53 (Annex VI, Table 3.2 in the CLP regulation) and Aquatic Chronic 4 (Annex VI, Table 3.1 in the CLP regulation).

Based on the properties of the substance and the study data available on the substance a CLH proposal has been made for the removal of the R53 (Aquatic Chronic 4) classification.

This substance has previously been notified under the NONS scheme (Dir. 67/548/EEC) by a number of different registrants, some of whom have shared study data relating to the classification previously.

The classification of the substance has been reviewed by Member State Competent Authorities (UK and NL) under NONS. Additional study information has been provided to update registrations and agreements reached that the removal of the R53 (Aquatic Chronic 4) classification is valid.

For example, Great Lakes Chemical Corporation, the predecessor company to Chemtura had notified Reofos BAPP to the UK in 1998 (Notification Number 98-06-1163). On the basis of bioaccumulation data on an analogous product (AFR-1) provided to the UK in the course of their assessment of the substance, the UK sent a communication in 1999 indicating that they agreed with the removal of the R53 classification from the product (called CN-1985) at the time. This communication also states that a bioaccumulation study on CN-1985 (Noguchi S (1999)) was to be submitted and if the study indicated R53 should apply then the UK CA would revert their decision to remove R53. This study was subsequently submitted and the decision to remove the R53 was allowed to stand by the UK CA. This study has been evaluated as the key bioaccumulation study in this dossier.

More recently the Dutch CA (RIVM) has agreed that the R53 classification is not required (for Israel Chemicals Ltd-Industrial products (ICL-IP) notification based on the data available, such as results from further Daphnia Reproduction studies (Desjardin, D. et al (2002b)).

All the relevant study data for the removal of R53 (Aquatic Chronic 4) classification is evaluated in this dossier and a formal proposal to remove the classification put forward.

### **2.2 Short summary of the scientific justification for the CLH proposal**

This proposal has been prepared by Chemtura Corporation in accordance with Article 37(6) of CLP, and submitted by the UKCA.

The justification for the CLH proposal to remove the environmental classification of R53 (under DSD) and Chronic Category 4 (under CLP) is based upon relevant bioaccumulation study data (Noguchi S (1999) and Hori K (1996)), chronic toxicity in fish (Knight B (2003)) and Daphnia (Hargreaves TL & Clayton MA (2003) and Desjardin, D. et al (2002 a/b)) study data on the substance.

The experimental results show the BCF values are below the qualifying criteria for BCFs (>100 for DSD and >500 for CLP) and therefore that the substance does not show the potential to bioaccumulate in the aquatic environment. One result of <159 is not relevant to classification as 159 was the limit of detection in the study.



A chronic fish study (Early-Life Stage Test) and three chronic daphnia studies (Daphnia Reproduction studies) showed an absence of chronic toxicity effects at the solubility limits determined in the studies.

For full details on the justification for the removal of the classification please see the results section of this dossier and Section 5.6: Conclusions on classification and labelling for environmental hazards.

## **2.3 Current harmonised classification and labelling**

### **2.3.1 Current classification and labelling in Annex VI, Table 3.1 in the CLP Regulation**

Hazard Class and Category Code: Aquatic Chronic 4

Hazard Statement Code: H413

### **2.3.2 Current classification and labelling in Annex VI, Table 3.2 in the CLP Regulation**

Classification: R53

Risk phrase: R53

Safety phrase: S61

## **2.4 Current self-classification and labelling**

### **2.4.1 Current self-classification and labelling based on the CLP Regulation criteria**

Not classified by Chemtura and ICL-IP.

### **2.4.2 Current self-classification and labelling based on DSD criteria #**

Not classified by Chemtura and ICL-IP.

## **3 JUSTIFICATION THAT ACTION IS NEEDED AT COMMUNITY LEVEL**

There are data to indicate that the existing classification in Annex VI of CLP (i.e. R53 or Aquatic Chronic 4) is incorrect. As there are a number of suppliers of this substance in the EU, action is required at the Community level to amend the harmonised classification to ensure accurate communication of the (non) hazardous properties of the substance and therefore ensure adequate risk management throughout the Community. Failure to amend the classification could impact on the use of this substance in certain applications within the EU. A number of Member State Competent Authorities (Dutch CA and UK CA) have reviewed data on this substance and agreed in principle to the removal of the R53 (Aquatic Chronic 4) classification.

This proposal has been prepared by Chemtura Corporation in accordance with Article 37(6) of CLP, and submitted by the UKCA.

**Part B.**

**SCIENTIFIC EVALUATION OF THE DATA**

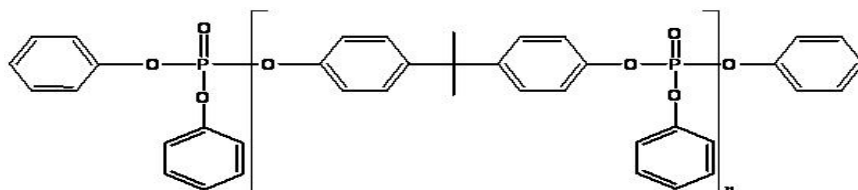
**1 IDENTITY OF THE SUBSTANCE**

**1.1 Name and other identifiers of the substance**

Table 5: Substance identity

|                                   |   |
|-----------------------------------|---|
| <b>EC number:</b>                 | 425-220-8   |
| <b>EC name:</b>                   | (1-methylethylidene)di-4,1-phenylene tetraphenyl diphosphate                  |
| <b>CAS number (EC inventory):</b> |   |
| <b>CAS number:</b>                | 5945-33-5   |
| <b>CAS name:</b>                  | Phosphoric acid, (1-methylethylidene)di-4,1-phenylene tetraphenyl ester (9CI) |
| <b>IUPAC name:</b>                | (1-methylethylidene)di-4,1-phenylene tetraphenyl diphosphate                  |
| <b>CLP Annex VI Index number:</b> | 015-188-00-X  |
| <b>Molecular formula:</b>         | C <sub>39</sub> H <sub>34</sub> O <sub>8</sub> P <sub>2</sub>                 |
| <b>Molecular weight range:</b>    | 692   |

**Structural formula:**



where  $n \sim 1.1$

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BISPHENOL A POLYPHOSPHATE

**1.2 Composition of the substance**

Table 6: Constituents (non-confidential information)

| Constituent  | Typical concentration | Concentration range | Remarks   |
|--|-----------------------|---------------------|---|
| (1-methylethylidene)di-4,1-phenylene tetraphenyl diphosphate | >80%                  | Confidential        | Concentration range is claimed as confidential and is not provided in this public document. The value is provided in the accompanying IUCLID dossier. The confidential information does not effect the classification proposal. |

Current Annex VI entry:

DSD: R53

CLP: Aquatic Chronic 4

**Table 7: Impurities (non-confidential information)**

| Impurity     | Typical concentration | Concentration range | Remarks |
|--------------|-----------------------|---------------------|---------|
| Confidential |                       |                     |         |

Current Annex VI entry: None.

The impurities are confidential and further information can be found in the technical dossier. These impurities have been taken into account in the proposal and are not considered to be of additional concern.

Table 8: Additives (non-confidential information)

| Additive | Function | Typical concentration | Concentration range | Remarks |
|----------|----------|-----------------------|---------------------|---------|
| None     |          |                       |                     |         |

Current Annex VI entry:

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BISPHENOL A POLYPHOSPHATE

**1.3 Physico-chemical properties**

Table 9: Summary of physico - chemical properties

| Property                                     | Value   | Reference  | Comment (e.g. measured or estimated)  |
|--|---|--|---|
| State of the substance at 20°C and 101,3 kPa | Liquid.   |  | Observation<br><br>Not evaluated further for the purposes of this dossier.    |
| Melting/freezing point                       | Pour point: 7°C   |  | Measured<br><br>Not evaluated further for the purposes of this dossier.       |
| Boiling point                                | Not determined – decomposes above 350°C without boiling   |  | Measured<br><br>Not evaluated further for the purposes of this dossier.       |
| Relative density                             | 1.26  |  | Measured<br><br>Not evaluated further for the purposes of this dossier.       |
| Vapour pressure                              | $1.3 \times 10^{-12}$ Pa at 25°C                          |  | Measured<br><br>Not evaluated further for the purposes of this dossier.       |
| Surface tension                              | 71.0 mN/m   |  | Measured<br><br>Not evaluated further for the purposes of this dossier.       |
| Water solubility                             | 1.88 mg/L ;<br>0.415 mg/L                                 | Sydney P (1998);<br>Hogg, AS & Bartlett, AJ (1997) | Measured values for substance from two different suppliers.<br>EEC A6 (Flask) |
| Partition coefficient n-octanol/water        | Log <sub>10</sub> Pow >4.9 ;<br>Log <sub>10</sub> Pow 4.5 | Sydney P (1998) ;<br>Kenneth W                     | Measured value for substance from two different suppliers.                    |

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|   |                                      | (2002) | EEC A6 (Shake Flask)  |
|---|--------------------------------------|--------|---|
| Flash point   | 281°C                                |        | Measured<br>Not evaluated further for the purposes of this dossier.   |
| Flammability  | Non-flammable                        |        | Not evaluated further for the purposes of this dossier.   |
| Explosive properties  | Not explosive                        |        | Measured<br>Not evaluated further for the purposes of this dossier.   |
| Self-ignition temperature   | None below 400°C                     |        | Measured<br>Not evaluated further for the purposes of this dossier.   |
| Oxidising properties  | No data available.                   |        | Observation due to experience in handling and use.<br>Not evaluated further for the purposes of this dossier. |
| Granulometry  | Not applicable.                      |        | Not evaluated for the purposes of this dossier.   |
| Stability in organic solvents and identity of relevant degradation products | No data available.                   |        | Not evaluated for the purposes of this dossier.   |
| Dissociation constant   | Not found to dissociate below pH 11. |        | Not evaluated for the purposes of this dossier.   |
| Viscosity   | No data available.                   |        | Not evaluated for the purposes of this dossier.   |

## **2 MANUFACTURE AND USES**

### **2.1 Manufacture**

The substance is manufactured in several member states.

### **2.2 Identified uses**

The substance is used as a flame retardant additive in thermoplastic resins for production of components used in electrical and electronic goods (e.g. housings for PCs, Televisions, etc).

### 3 CLASSIFICATION FOR PHYSICO-CHEMICAL PROPERTIES

Table 10: Summary table for relevant physico-chemical studies

| Method   | Results                    | Remarks            | Reference                      |
|--|----------------------------|--------------------|--------------------------------|
| Water solubility (OECD method No. 105 / EEC method No. A6) – Flask method                | 1.88 mg/l at 20°C          | Experimental value | Sydney P (1998)                |
| Water solubility (Method A6 of Commission Direction 92/69/EEC) – Flask method            | 0.415 mg/l at 20°C         | Experimental value | Hogg, AS & Bartlett, AJ (1997) |
| Partition coefficient (OECD method No. 107/117 / EEC method No. A8) – shake-flask method | Log <sub>10</sub> Pow >4.9 | Experimental value | Sydney P (1998)                |
| Partition coefficient (OECD method No. 117 / EEC method No. A8) – shake-flask method     | Log <sub>10</sub> Pow 4.5  | Experimental value | Kenneth W (2002)               |

#### 3.1.1 Summary and discussion of relevant physico-chemical studies.

##### Water solubility:

Experimental water solubility results are available for the substance from two different suppliers (notifications: Chemtura: 98-06-1163 and ICL-IP: 97-03-0400).

The water solubility of the test substance was found to be 1.88 mg/l at 20°C and 0.415 mg/l at 20°C in the respective studies.

Both water solubility studies were conducted to the EEC Method A6 (flask method). It has been considered that the flask method may not be the most suitable method to test a poorly soluble substance. The water solubility study (Hogg AS & Bartlett AJ 1997) gives the following discussion on the method used:

The preliminary water solubility test indicated that the column elution method should have been performed as the solubility was less than  $1 \times 10^{-2}$  g/l. However, due to the physical nature of the test material, it was not possible to use this method without blocking the column. Liquid test materials coated onto glass beads cause these beads to adhere together forming a plug within the column and thus preventing water circulation.

The difference in solubility results is presumed to be due to slight differences between the substances composition between suppliers, interlaboratory differences and slight test method differences. However, both products are considered to be identical and the proposal in this report to be valid for both suppliers results.

### **Partition coefficient:**

Experimental partition coefficient results are available for the substance from different suppliers (notifications: Chemtura: 98-06-1163 and ICL-IP: 97-03-0400).

The partition coefficient ( $\log_{10} Pow$ ) of the test substance was found to be >4.9 and 4.5 in the respective studies.

Both studies were conducted to EEC Method A8, OECD Method 107/117 (shake-flask method).

The difference in partition coefficient results is presumed to be due to slight differences between the substances composition between suppliers, interlaboratory differences and slight test method differences. However, both products are considered to be identical and the proposal in this report to be valid for both suppliers results.

### **3.1.2 Comparison with criteria**

Not applicable.

### **3.1.3 Conclusions on classification and labelling**

The substance is not classified for any physico-chemical properties.

For the purposes of this dossier (removal of R53 classification) the relevant physico-chemical results are the water solubility and the partition coefficient of the substance. No further physico-chemical results are evaluated in this dossier.

## **4 HUMAN HEALTH HAZARD ASSESSMENT**

Not evaluated for the purposes of this dossier.



## 5 ENVIRONMENTAL HAZARD ASSESSMENT

### 5.1 Degradation

Table 11: Summary of relevant information on degradation

| Method   | Results                               | Remarks                           | Reference                      |
|--|---------------------------------------|-----------------------------------|--------------------------------|
| equivalent or similar to OECD Guideline 301 C (Ready Biodegradability: Modified MITI Test (I)) | Average 0% degradation after 28 days. | See biodegradation section below. | Tsujimura (1998)               |
| Hydrolysis as a function of pH.  | Half life: >1 year at 25°C            | See stability section below.      | Hogg, As & Bartlett, AJ (1997) |

#### 5.1.1 Stability

##### Abiotic degradation:

##### Hydrolysis:

The test results are summarised in the following table:

Table 12. Overview of studies on hydrolysis

| Method   | Results  | Remarks   | Reference                      |
|--|--|---|--------------------------------|
| Method C.7 of directive 92/69/EEC - (Hydrolysis as a Function of pH) | Half-life (DT50):<br>t1/2 (pH 4): > 8760 h at 25 °C<br>t1/2 (pH 7): > 8760 h at 25 °C<br>t1/2 (pH 9): > 8760 h at 25 °C<br>Transformation products: no | 1 (reliable without restriction)<br>key study<br>experimental result<br><b>Test material (IUPAC name): (1-methylethylidene)di-4,1-phenylene tetraphenyl diphosphate</b> | Hogg, AS & Bartlett, AJ (1997) |

The hydrolysis of the substance was studied at test concentration of 0.25 mg/l at pH 4, 7 and 9. The tests were carried out in the dark at 50°C for a period of 5 days. The test solutions were analyzed using a HPLC technique.

Less than 10% hydrolysis was detected after 5-day period at 50°C, equivalent to a half life greater than 1 year at 25°C. Transformation products were not measured since no hydrolysis occurred.

As no hydrolysis occurred and the substance has a half life of greater than 1 year at 25°C, hence no degradants are rapidly formed, it is demonstrated that environmental classification should be based on the properties of the parent substance.

## 5.1.2 Biodegradation

### 5.1.2.1 Biodegradation estimation

No data available.

### 5.1.2.2 Screening tests

The test results are summarised in the following table:

**Table 13. Overview of screening tests for biodegradation in water**

| Method   | Results   | Remarks   | Reference                          |
|--|---|---|------------------------------------|
| Test type: ready biodegradability<br>activated sludge (adaptation not specified)<br>equivalent or similar to OECD Guideline 301 C (Ready Biodegradability: Modified MITI Test (I)) | not readily biodegradable<br><br>% Degradation of test substance:<br><br>0 after 28 d (Percentage biodegradation by BOD) (Average from 3 vessels)<br><br>0 after 28 d (Test mat. analysis (: Percentage biodegradation by HPLC)) (Average from 3 vessels) | 1 (reliable without restriction)<br><br>key study<br><br>experimental result<br><br><b>Test material (IUPAC name): (1-methylethylidene)di-4,1-phenylene tetraphenyl diphosphate</b> | Tsujimura (1998)                   |
| Test type: readily biodegradability<br>activated sludge (non-adapted).<br>According to OECD Guideline 301 C (Ready Biodegradability: Modified MITI Test (I))                       | not readily biodegradable.<br><br>% Degradation of test substance:<br><br>6% degradation after 28 d (based on O <sub>2</sub> depletion)<br><br>Mean 2.5% degradation after 28 d (based on residual test substance).                                       | 1 (reliable without restriction)<br><br>Supporting study<br><br>experimental result<br><br><b>Test material (IUPAC name): (1-methylethylidene)di-4,1-phenylene</b>                  | Mitsubishi-kasei Institute (1994). |

|  |  |                                |  |
|--|--|--------------------------------|--|
|  |  | <b>tetraphenyl diphosphate</b> |  |
|--|--|--------------------------------|--|

### 5.1.2.3 Simulation tests

No data available.

### 5.1.3 Summary and discussion of degradation

Experimental biodegradation results are available for the substance from two different suppliers (notifications: Chemtura: 98-06-1163 and ICL-IP: 97-03-0400).

#### Study Reference: Tsujimura (1998)

Ready biodegradation of the substance was tested by:

- 1) Measurement of biochemical oxygen demand (BOD) by means of a closed system oxygen consumption measuring apparatus.
- 2) Determination of test substance by means of HPLC.

After 28 days the average percentage degradation observed was 0%.

The test substance was not biodegraded by microorganisms under the test conditions and is not considered to be readily biodegradable.

#### Study Reference: Mitsubishi-kasei Institute (1994).

The substance is not readily biodegradable. After 28 days the mean degradation level was 2.5%.

## 5.2 Environmental distribution

### 5.2.1 Adsorption/Desorption

Not evaluated for the purposes of this dossier.

### 5.2.2 Volatilisation

Not evaluated for the purposes of this dossier.

### 5.2.3 Distribution modelling

Not evaluated for the purposes of this dossier.

## 5.3 Aquatic Bioaccumulation

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BISPHENOL A POLYPHOSPHATE

Table 14: Summary of relevant information on aquatic bioaccumulation

| Method   | Results   | Remarks                            | Reference                          |
|--|---|------------------------------------|------------------------------------|
| equivalent or similar to OECD Guideline 305 C (Bioaccumulation: Test for the Degree of Bioconcentration in Fish) | Study 1:<br>BCF range: $\leq 1.1 - \leq 159$<br>Study 2:<br>BCF range: 6.8 – 62 | See bioaccumulation section below. | Noguchi S (1999) and Hori K (1996) |

### 5.3.1 Aquatic bioaccumulation

The studies on aquatic bioaccumulation are summarised in the following table:

Table 15. Overview of studies on aquatic bioaccumulation

| Method  | Results  | Remarks   | Reference        |
|---|--|---|------------------|
| <i>Cyprinus carpio</i><br>aqueous (freshwater)<br>flow-through<br>Total uptake duration: 8 wk<br>equivalent or similar to OECD Guideline 305 C (Bioaccumulation: Test for the Degree of Bioconcentration in Fish) | BCF: $\leq 1.1$ (whole body d.w.) (Time of plateau: 8 wk)(steady state)<br>BCF: $\leq 2.7$ (whole body d.w.) (Time of plateau: 8 wk)(steady state)<br>BCF: $\leq 16$ (whole body d.w.) (Time of plateau: 8 wk)(steady state)<br>BCF: $\leq 11$ (whole body d.w.) (Time of plateau: 8 wk)(steady state)<br>BCF: $\leq 27$ (whole body d.w.) (Time of plateau: 8 wk)(steady state)<br>BCF: $\leq 159$ (whole body d.w.) (Time of plateau: 8 wk)(steady state)<br>Lipid content:<br>4.1 % (start of exposure) | 1 (reliable without restriction)<br>key study<br>experimental result<br><b>Test material (IUPAC name): (1-methylethylidene)di-4,1-phenylene tetraphenyl diphosphate</b> | Noguchi S (1999) |
| <i>Cyprinus carpio</i><br>aqueous (freshwater)<br>flow-through<br>Total uptake duration: 8 wk<br>equivalent or similar to OECD Guideline 305 C  | BCF: 6.8 – 40 (whole body d.w.) (Time of plateau: 8 wk)(steady state)<br>BCF: 22 – 62 (whole body d.w.) (Time of plateau: 8 wk)(steady state)<br>Lipid content:  | 1 (reliable without restriction)<br>supporting study<br>experimental result<br><b>Test material (IUPAC name):</b>   | Hori K (1996)    |

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BISPHENOL A POLYPHOSPHATE

|  |                           |   |  |
|--|---------------------------|---|--|
| (Bioaccumulation: Test for the Degree of Bioconcentration in Fish) | 3.9 % (start of exposure) | <b>(1-methylethylidene)di-4,1-phenylene tetraphenyl diphosphate</b> |  |
|--|---------------------------|---|--|

**5.3.1.1 Bioaccumulation estimation**

**5.3.1.2 Measured bioaccumulation data**

**5.3.2 Summary and discussion of aquatic bioaccumulation**

**Study 1:**

**Bioaccumulation test of CN-1985 in carp (Noguchi S (1999))**

**Results:**

**Acute toxicity test:**

48 -hour LC50 value: > 500 mg/L. No toxic effects were observed up to the water solubility limit.

**Bioaccumulation factors:**

The following factors have been taken into consideration for interpretation of the BCF results.

Preparation of test solution:

The test substance supplied and dispersant HCO-40 (Hydrogenated castor oil) (20 times amount of test substance) were dissolved with acetone. After the acetone was evaporated from the solution, ion-exchanged water was added to the mixture to prepare relevant stock solutions.

Analysis of test water and fish:

Three peaks were detected by HPLC analysis of the test substance. The peaks of the chromatogram were named peak 1, peak 2 and peak 3 in the elution order.

Determination limit of the test substance in test water:

The determination limits were calculated as:

|                    |                     |
|--------------------|---------------------|
| Level 1:           | Level 2:            |
| Peak 1: 0.031 mg/l | Peak 1: 0.0031 mg/l |
| Peak 2: 0.18 mg/l  | Peak 2: 0.018 mg/l  |
| Peak 3: 1.1 mg/l   | Peak 3: 0.11 mg/l   |

Determination limit of the test substance in test fish:

The determination limit of test substance in test fish was calculated as follows, assuming fish weight of 30g.

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BISPHENOL A POLYPHOSPHATE

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Peak 1: 1.9 µg/g

Peak 2: 4.9 µg/g

Peak 3: 29 µg/g

Calculation of bioconcentration factors (BCFs).

From the minimum determination limit of the test substance in fish, BCFs could be obtained for cases of a BCF exceeding the following values:

| Level 1     | Level 2     |
|-------------|-------------|
| Peak 1: 1.1 | Peak 1: 11  |
| Peak 2: 2.7 | Peak 2: 27  |
| Peak 3: 16  | Peak 3: 159 |

**Results:**

Concentrations of test substance in test water:

Each average concentration of the test substance in test water was maintained at 90% or more of the nominal concentration. It is therefore considered that it is acceptable to base the results on the nominal concentrations.

Bioconcentration Factors:

|        | Level 1 (2 mg/L) | Level 2 (0.2 mg/L) |
|--------|------------------|--------------------|
| Peak 1 | ≤ 1.1 -1.2       | ≤ 11               |
| Peak 2 | ≤ 2.7            | ≤ 27               |
| Peak 3 | ≤ 16             | ≤ 159              |

**Discussion:**

The BCF values obtained are less than or equal to values as these were the limits of detection for the BCK calculations i.e. no detectable test item was found in the fish so the BCF is lower than the limit of detection.

The wide range of BCF values is due to the different concentrations used for the two test levels, and are considered as valid.

The study results indicate that the test item does not bioaccumulate.

**Study 2:**

**Bioaccumulation test of AFR-1 in carp (Hori K (1996))**

**Results:**

**Acute toxicity test:**

48 -hrs LC50: 500 mg/L and over. No toxic effects were observed up to the water solubility limit.

**Bioaccumulation test:**

The following factors have been taken into consideration for interpretation of the BCF results.

Preparation of test solution:

The test substance supplied and dispersant HCO-40 (Hydrogenated castor oil) which was 20 times amount of test substance were dissolved with acetone and then the acetone was. The mixture was dissolved with deionised water.

Determination limit of the test substance in test water:

The minimum limit of determination was calculated as:

Level 1: 0.051 mg/l

Level 2: 0.0051 mg/l

Determination limit of the test substance in test fish:

The determination limit of test substance in test fish was calculated as 0.53 µg/g, assuming fish weight of 30g.

Calculation of bioconcentration factors (BCFs).

From the minimum determination limit of the test substance in fish, BCFs could be obtained for cases of a BCF exceeding the following values:

Level 1: 0.6

Level 2: 5.7

**Results:**

Concentrations of test substance in test water:

Each average exposure level was maintained at 90% and over of the nominated concentration levels.

Bioconcentration factors:

Level 1 (1.0 mg/L): 6.8 - 40

Level 2 (0.1 mg/L): 22 - 62

**Discussion:**

A different analytical method was used in this study to the Noguchi S (1999) study. The analytical method has not separated the test item into three test item peaks. This has resulted in some test item being seen in the fish (greater than the limit of detection) and so BCF values have been calculated.

The low and variable results are typical of a low bioaccumulating substance and suggest that the test item does not bioaccumulate.

**Summary:**

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BISPHENOL A POLYPHOSPHATE

Two bioconcentration studies have been conducted on the test substance (from two sources). Different analytical methods were used in the studies and both are considered valid. In one study (Noguchi S (1999)) the BCF values are reported to be less than or equal to the limits of detection determined i.e. no detectable test item was found in the fish. In the other study (Hori K (1996)) BCF values have been calculated and the low, variable results are typical of a low BCF substance.

Based on the two study results it is considered that the substance does not bioaccumulate.

## 5.4 Aquatic toxicity

Table 16: Summary of relevant information on aquatic toxicity

| Method   | Results                                 | Remarks  | Reference  |
|--|---|--|--|
| OECD Guideline 203 (Fish, Acute Toxicity Test),<br><br>OECD Guideline 202 (Daphnia sp. Acute Immobilisation Test)<br><br>OECD Guideline 201 (Alga, Growth Inhibition Test) | No toxicity at limit of solubility.     | LC50 and NOEC not identified.  | Jenkins CA (1998a).<br><br>Jenkins CA (1998b).<br><br>Jenkins CA (1998). |
| OECD Guideline 210 (Fish, Early-Life Stage Toxicity Test)  | NOELr: 5 mg/l                           | No observed effect loading result based on initial loading rate of 5 mg/l. | Knight B (2003).   |
| OECD Guideline 211 (Daphnia magna Reproduction Test)   | NOELr for reproduction: 5 mg/l (5 ppm). | No observed effect loading result based on initial loading rate of 5 mg/l. | Hargreaves TL & Clayton MA (2003).                                       |

### 5.4.1 Fish

#### 5.4.1.1 Short-term toxicity to fish

The results are summarised in the following table:

**Table 17. Overview of short-term effects on fish**

| Method                     | Results                              | Remarks             | Reference          |
|----------------------------|--------------------------------------|---------------------|--------------------|
| <i>Oncorhynchus mykiss</i> | LC50 (96 h): No toxicity at limit of | 1 (reliable without | Jenkins CA (1998a) |



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BISPHENOL A POLYPHOSPHATE

|  |             |   |  |  |
|--|-------------|---|--|--|
| freshwater<br>semi-static<br>OECD Guideline 203 (Fish, Acute Toxicity Test)<br>EU Method C.1 (Acute Toxicity for Fish) | solubility. | restriction)<br>key study<br>experimental result<br><b>Test material (IUPAC name): (1-methylethylidene)di-4,1-phenylene tetraphenyl diphosphate</b> |  |  |
|--|-------------|---|--|--|

**Discussion**

A study was performed to assess the acute toxicity of test substance to rainbow trout (*Oncorhynchus mykiss*) under semi-static conditions.

A group of ten juvenile fish were exposed to a single concentration of test substance, dispersed in water at nominally 10 mg/l; to aid dispersion acetone and ultrasound were employed. The test substance (1 g) was dissolved in acetone (10 ml) and an aliquot (1.1 ml) was added to warm diluent water (approximately 23°C) in a volumetric flask (2:l) to aid dissolution and/or dispersion. The contents of the flask were treated by ultrasound for fifteen minutes before being poured into a test vessel. The flask was refilled with cold diluent water (approximately 30°C) and the rinsings poured into the vessel; the volume was then adjusted to 11 litres by the further addition of cold water.

The selected exposure level intentionally exceeded the limit of aqueous solubility of test substance (stated value 1.9 mg/l) and was the highest concentration considered practical to prepare.

Measured concentrations of test substance ranged between 0.65l and 3.93 mg/l in unfiltered samples of medium, with an overall mean measured level of 1.44 mg/l. In filtered samples, the measured levels ranged from <0.1 to 0.141 mg/l. Although a stable concentration was not maintained, a condition of maximum attainable exposure is considered to have been employed.

No mortalities were noted during the test at a measured level of 1.44 mg/l; this value reflects the amount of test substance that remained suspended in the test medium during the test although, at most, only 0.141 mg/l was dissolved.

Sub-lethal effects were exhibited by some fish between 24 and 72 hours; these were attributed to the presence of aggressive fish in the test vessel and were not considered to be treatment-related.

Based on these findings, neither the 96-hour median lethal concentration (LC50) nor the no-observed effect concentration (NOEC) were identified.

In conclusion, the test substance was not found to be toxic to rainbow trout when dispersed in water at a concentration (1.44 mg/l) in excess of its limit of aqueous solubility under test conditions (at most, 0.141 mg/l).

#### 5.4.1.2 Long-term toxicity to fish

The results are summarised in the following table:

**Table 18. Overview of long-term effects on fish**

| Method  | Results  | Remarks  | Reference              |
|---|--|--|------------------------|
| <p><i>Pimephales promelas</i></p> <p>freshwater</p> <p>early-life stage: reproduction, (sub)lethal effects</p> <p>flow-through</p> <p>OECD Guideline 210 (Fish, Early-Life Stage Toxicity Test)</p> | <p>NOELr (28 d): 5 mg/L based on: number hatched (hatching success), mortality (larval survival), length (larval growth), weight (larval growth).</p> <p>No toxicity at limit of solubility.</p> | <p>1 (reliable without restriction)</p> <p>key study</p> <p>experimental result</p> <p><b>Test material (IUPAC name): (1-methylethylidene)di-4,1-phenylene tetraphenyl diphosphate</b></p> | <p>Knight B (2003)</p> |

#### Discussion

The effect of prolonged exposure to test substance on the early-life stages of the Fathead Minnow (*Pimephales promelas*) was assessed over embryo development, hatching and for 28 days post-hatch.

The test was conducted under continuous flow conditions, with embryos and larvae exposed to the following initial loading rates of test substance (prepared as water accommodated fraction (WAF)): 0.5 and 5 mg/l. A control (0 mg/l) was also included in the test. Duplicate tanks were tested at each loading rate, including control.

Individual WAF's were prepared by adding weighed amounts of test substance (24.9-25.3 and 249.7-250.4 mg respectively) to test water (50 litres) and stirring this for a period of ca 48 h. Following the period of stirring, the contents of the vessel were allowed to settle for 1 h after which ca 35-40 litres of solution (WAF) was removed via the tap at the base of the container, with the first ca 1 litre being discarded. This WAF was then connected to the flow-through system (via the stock tank) and delivered at the appropriate rate to the test and control tanks.

The hatching success of embryos in individual replicates ranged from 88 to 100%. Statistical analysis indicated no significant difference in hatching success at initial loading rates of 0.5 and 5 mg/l when compared to the control. The no observed effect loading (NOEL) would be regarded as 5 mg/l, based on initial loading rates.

Larval survival was found to be unaffected at initial loading rates of 0.5 and 5 mg/l when compared to the control. One larvae at 0.5 and one at 0 mg/l were dead by the end of the test period. The NOEL would be regarded as 5 mg/l, based on initial loading rates.

Larval growth (length measured at the end of the test) was found to be unaffected at initial loading rates of 0.5 and 5 mg/l when compared to the control. The NOEL would be regarded as 5 mg/l, based on initial loading rates.

Larval growth (weight measured at the end of the test) was found to be unaffected at initial loading rates of 0.5 and 5 mg/l when compared to the control. The NOEL would be regarded as 5 mg/l, based on initial loading rates.

#### Comments on Water Accommodated Fraction (WAF):

The test solutions used in the study were prepared as water accommodated fractions (WAFs) from specific loading rates of the test item, in view of the difficulties associated with the evaluation of aquatic toxicity of poorly water soluble test items. This modification to the standard method for the preparation of aqueous media was performed in line with the OECD Guidance Document on Aquatic Toxicity Testing of Difficult Substances and Mixtures (2000) No. 23.

Therefore, the results are considered to be highly reliable and suitable for the assessment of chronic effects and for the purposes of classification.

### 5.4.2 Aquatic invertebrates

#### 5.4.2.1 Short-term toxicity to aquatic invertebrates

The results are summarised in the following table:

**Table 19. Overview of short-term effects on aquatic invertebrates**

| Method   | Results  | Remarks   | Reference          |
|--|--|---|--------------------|
| <i>Daphnia magna</i><br>freshwater<br>static<br>OECD Guideline 202 ( <i>Daphnia</i> sp. Acute Immobilisation Test)<br>EU Method C.2 (Acute Toxicity for <i>Daphnia</i> )<br>EPA OTS 797.1300 (Aquatic Invertebrate Acute Toxicity Test, Freshwater Daphnids) | LC50 (48 h): No toxicity at limit of solubility. | 1 (reliable without restriction)<br><br>key study<br><br>experimental result<br><br><b>Test material (IUPAC name): (1-methylethylidene)di-4,1-phenylene tetraphenyl diphosphate</b> | Jenkins CA (1998b) |

#### Discussion

The acute toxicity of test substance to *Daphnia magna* was assessed under static exposure conditions.

A group of twenty *Daphnia*, less than 24 hours old, was exposed for 48 hours to a single concentration of test substance, dispersed in Elendt M4 medium at a nominal concentration of 10 mg/l; to aid dispersion, acetone and ultrasound treatment were employed. The test substance (100 mg) was dissolved in acetone (10 ml) and an aliquot (100 µl) was added to dilution water in a volumetric flask (1 l); to aid dissolution and/or dispersion, the contents of

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the flask were treated by ultrasound for ten minutes before aliquots (100 ml) were poured into the test vessels.

The selected exposure level intentionally exceeded the limit of aqueous solubility of test substance (stated value 1.9 mg/l) and was the highest concentration considered practicable to prepare.

Measured concentrations of CN- 1 985 in unfiltered samples of medium ranged from 2.82 mg/l at the start to 0.195 mg/l after 48 hours; in calculation of the test results, the worst estimate of 0.195 mg/l has been used. In filtered samples, the measured levels were below the limit of accurate quantification (<0.1 mg/l). Although a stable concentration was not maintained, a condition of maximum attainable exposure is considered to have been employed.

Observations of the Daphnia in each control and test vessel were made after 3, 24 and 48 hours. No immobilisation or effects on the Daphnia were noted at a measured concentration of 0.195 mg/l; this value reflects the amount of test substance that remained in suspension at the end of the test although <0.1 mg/l was dissolved.

Based on these findings, neither the 48-hour median effect concentration (EC50) nor the no-observed effect concentration (NOEC) were identified.

In conclusion, the test substance was not found to be toxic to Daphnia magna when dispersed in water at a concentration (0.195 mg/l) in excess of its limit of solubility under the test conditions (<0.1 mg/l).

#### 5.4.2.2 Long-term toxicity to aquatic invertebrates

The results are summarised in the following table:

**Table 20. Overview of long-term effects on aquatic invertebrates**

| Method  | Results  | Remarks   | Reference                         |
|---|--|---|-----------------------------------|
| <i>Daphnia magna</i><br>freshwater<br>semi-static<br>OECD Guideline 211 (Daphnia magna Reproduction Test) | EL50 (21 d): > 5 ppm<br>Initial loading rate (nominal) based on: reproduction<br><br>NOELR (21 d): 5 ppm<br>Initial loading rate (nominal) based on: reproduction<br><br>No toxicity at limit of solubility. | 1 (reliable without restriction)<br><br>key study<br><br>experimental result<br><br><b>Test material (IUPAC name): (1-methylethylidene)di-4,1-phenylene tetraphenyl diphosphate</b> | Hargreaves TL & Clayton MA (2003) |
| <i>Daphnia magna</i><br>freshwater  | NOEC (21 d): 1.8 mg/L test mat. (meas. (geom.  | 1 (reliable without   | Desjardin, D. et al (2002a)       |

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BISPHENOL A POLYPHOSPHATE

|  |  |  |                             |
|--|--|--|-----------------------------|
| flow-through<br>OECD Guideline 211 (Daphnia magna Reproduction Test)                                       | mean)) based on: immobilisation/mortality, reproduction, growth<br><br>No toxicity at limit of solubility.   | restriction)<br>supporting study<br><br>experimental result<br><br><b>Test material (IUPAC name): (1-methylethylidene)di-4,1-phenylene tetraphenyl diphosphate</b>                     |                             |
| <i>Daphnia magna</i><br>freshwater<br>flow-through<br>OECD Guideline 211 (Daphnia magna Reproduction Test) | NOEC (21 d): 1.2 mg/L test mat. (meas. (geom. mean)) based on: immobilisation/mortality, reproduction, growth<br><br>No toxicity at limit of solubility. | 1 (reliable without restriction)<br>supporting study<br><br>experimental result<br><br><b>Test material (IUPAC name): (1-methylethylidene)di-4,1-phenylene tetraphenyl diphosphate</b> | Desjardin, D. et al (2002b) |

## Discussion

### **Key study (Hargreaves TL & Clayton MA (2003)):**

This study was designed to determine the effects of the test substance on the reproductive capacity of the freshwater flea, *Daphnia magna* Straus.(Cladocera: Crustacea).

The method of preparation was selected to create conditions that maximised the solubility of the test item. Weighed amounts of test substance were added to known volumes of test medium (Elendt M4) and stirred for 48 h. After 48 h the solutions were allowed to settle for 1 h and a volume of the water was removed with a siphon. This mid water sample was considered to contain the water accommodated fraction of the test item (WAF), i.e. the soluble components of the test item at their highest achievable concentration under these conditions.

Following the results of a range finding test, a definitive test was conducted with WAF solutions at initial test substance loading rates of 5, 4, 3, 2 and 1 p.p.m., with an untreated control (Elendt M4). For each WAF or control solution 10 daphnia neonates (<24 h old) were individually placed into 100 ml glass beakers, i.e. one neonate per vessel, and their condition observed over a 21 day test period. Test solutions were renewed with freshly prepared WAF solutions ca. 3 times every 7 days. Neonates were fed daily with a green algae (*Chlorella vulgaris*) suspension, at a rate of 0.1 mg carbon/daphnid/day. The time taken for the daphnids

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to mature and produce their first brood of neonates was recorded, together with the number of neonates produced per day and cumulative production over the entire 21 day test period.

The concentrations of test substance found in solution were assessed by chemical analysis (using 2 indicator components), for freshly prepared (after stirring) and expired (72 h after renewal) WAF solutions. Test substance in solution was calculated to be many times less than the initial loading rates. Concentrations in freshly prepared WAF solutions were between 0.4 and 1.9% of nominal loading rates and between 0.3 and 1.3% in expired solutions.

For all initial loading rates of test substance tested there was no significant decrease in reproduction compared to the control after 21 days. Therefore the EL50 (reproduction) was greater than 5 p.p.m. and the No Observed Effect Loading rate (NOELr) for reproduction was at least 5 p. p. m., under the conditions of the test.

#### **Comments on Water Accommodated Fraction (WAF):**

The test solutions used in the study were prepared as water accommodated fractions (WAFs) from specific loading rates of the test item, in view of the difficulties associated with the evaluation of aquatic toxicity of poorly water soluble test items. This modification to the standard method for the preparation of aqueous media was performed in line with the OECD Guidance Document on Aquatic Toxicity Testing of Difficult Substances and Mixtures (2000) No. 23.

Therefore, the results are considered to be highly reliable and suitable for the purposes of classification.

#### **Additional studies:**

Two further Daphnia Reproduction study results are available. The studies were conducted using two different batches of the test material from the same supplier.

Results:

##### **1) Desjardin, D. et al (2002a)**

The objective of this study was to determine the effects of the test substance on the survival, growth and reproduction of the cladoceran, *Daphnia magna*, during a 21-day exposure period under flow through conditions.

Nominal concentrations used in this study were 0.19, 0.38, 0.75, 1.5 and 3.0 mg/l. A primary stock was prepared in DMF at a concentration of 36.0 mg/ml. The stock solution was sonicated for approximately 2 minutes and mixed by inversion (at least 20 times), and appeared clear and colourless. Proportional dilutions of the 36.0 mg/ml stock were made to prepare 500 mL each of 2.3, 4.5, 9.0 and 18 mg/l stock solutions. The stock solutions were delivered to the mixing chambers (at a rate of 12.50 µl/minute) where they were mixed with dilution water (at a rate of 150 ml/minute) to achieve the desired test concentrations of 0.19, 0.38, 0.75 and 3.0 mg/L.

The highest test concentration for this test was based on two times the functional water solubility (given in report as 1.5 mg/l). When measured concentrations of samples collected during the test were averaged, the mean test concentrations were 0.14, 0.26, 0.52, 1.1 and 1.8 mg/l, which represented 75, 67, 69, 74 and 61% of the nominal concentrations respectively. Mean measured concentrations were used to express to NOEC, LOEC and MATC. Concentrations were determined by HPLC.

*Daphnia magna* exposed to the test substance up to a concentration of 1.8 mg/l for 21 days showed no significant reductions in survival, reproduction or growth. Consequently, the no mortality/immobility concentration and NOEC were 1.8 mg/l, and the LOEC was >1.8 mg/l. The MATC (maximum acceptable toxicant concentration) was determined to be >1.8 mg/l. The 21-day EC50 was estimated to be >1.8 mg/l.

## **2) Desjardin, D. et al (2002b)**

The objective of this study was to determine the effects of the test substance on the survival, growth and reproduction of the cladoceran, *Daphnia magna*, during a 21-day exposure period under flow through conditions.

Nominal concentrations used in this study were 0.19, 0.38, 0.75, 1.5 and 3.0 mg/l. A primary stock was prepared in DMF at a concentration of 36.0 mg/ml. The stock solution was sonicated for approximately 2 minutes and mixed by inversion (at least 20 times), and appeared clear and colourless. Proportional dilutions of the 36.0 mg/ml stock were made to prepare 500 mL each of 2.3, 4.5, 9.0 and 18 mg/l stock solutions. The stock solutions were delivered to the mixing chambers (at a rate of 12.50 µl/minute) where they were mixed with dilution water (at a rate of 150 ml/minute) to achieve the desired test concentrations of 0.19, 0.38, 0.75 and 3.0 mg/L.

The highest test concentration for this test was based on two times the functional water solubility (given in report as 1.5 mg/l). When measured concentrations of samples collected during the test were averaged, the mean test concentrations were 0.15, 0.32, 0.52, 1.2 and 1.4 mg/l, which represented 81, 85, 70, 83 and 45% of the nominal concentrations respectively. Mean measured concentrations were used to express to NOEC, LOEC and MATC. Concentrations were determined by HPLC.

*Daphnia magna* exposed to the test substance up to a concentration of 1.4 mg/l for 21 days showed no significant reductions in reproduction or survival. However, a treatment related reduction in growth was apparent in the highest treatment level (1.4 mg/l). Consequently, the no mortality/immobility concentration and NOEC were 1.2 mg/l, and the LOEC was 1.4 mg/l. The MATC (maximum acceptable toxicant concentration) was determined to be 1.3 mg/l. The 21-day EC50 was estimated to be >1.4 mg/l.

### **Summary of *Daphnia* Reproduction Studies:**

Three studies have been conducted on the test substance from two suppliers. All three studies show no toxicity at the limit of solubility determined in the respective studies.

All studies were conducted to OECD Guideline 211, with one study (Hargreaves TL & Clayton MA (2003)) using test solutions prepared as water accommodated fractions (WAF), due to the difficulties associated with the evaluation of aquatic toxicity of poorly water soluble test items.

The use of WAF in one study ((Hargreaves TL & Clayton MA (2003)) and not in the remaining two studies (Desjardin, D. et al (2002a/b)) can be accounted for by the fact that the relevant studies were conducted at different testing facilities and sponsored by different companies who agreed different study protocols.

However, as all the studies were conducted to GLP and in compliance with agreed protocols, with no or minor deviations from standard test guidelines, it is therefore considered that the results are considered to be highly reliable and suitable for the assessment of chronic effects and for the purposes of classification.

### 5.4.3 Algae and aquatic plants

The results are summarised in the following table:

**Table 21. Overview of effects on algae and aquatic plants**

| Method   | Results   | Remarks  | Reference                   |
|--|---|--|-----------------------------|
| <p><i>Selenastrum capricornutum</i><br/>(new name:<br/><i>Pseudokirchnerella</i><br/><i>subcapitata</i>) (algae)</p> <p>freshwater</p> <p>static</p> <p>OECD Guideline 201 (Alga,<br/>Growth Inhibition Test)</p> <p>EU Method C.3 (Algal Inhibition<br/>test)</p> | <p>EC50 (96 h): No<br/>toxicity at limit of<br/>solubility.</p> | <p>1 (reliable<br/>without<br/>restriction)</p> <p>key study</p> <p>experimental<br/>result</p> <p><b>Test material<br/>(IUPAC name):<br/>(1-<br/>methylethylidene)di-4,1-<br/>phenylene<br/>tetraphenyl<br/>diphosphate</b></p> | <p>Jenkins C<br/>(1998)</p> |

## Discussion

### Effects on algae / cyanobacteria

The effect of the test substance on the growth of the unicellular green alga *Selenastrum capricornutum* was assessed under non-axenic conditions.

Six replicate algal cultures, with an initial cell density of  $1 \times 10^4$  cells/ml, were exposed to the test substance dispersed in algal nutrient medium at a nominal concentration of 10 mg/l; to aid dispersion, acetone was employed. The test substance (1 g) was dissolved in acetone (10 ml) and an aliquot (10 µl) was added directly to nutrient algal medium in the test vessels.

The selected exposure level intentionally exceeded the limit of aqueous solubility of test substance (stated value 1.9 mg/l) and was the highest concentration considered practicable to prepare.

Cultures were incubated in an orbital incubator under continuous illumination at temperatures ranging from 20.7 to 23.5°C for 96 hours.

The measured concentrations of test substance in unfiltered samples of the test culture, ranged between 1.61 and 2.93 mg/l, with an overall mean measured level of 2.17 mg/l. No test material was detected (<20 µg/l) in filtered samples of medium. These data were not unexpected in view of the low aqueous solubility of the test material. Although the concentration of dissolved test substance to which the algae were exposed was not identified, a condition of maximum attainable exposure is considered to have been employed.

Cell numbers were counted daily to monitor growth. The test results are expressed in terms of the area under the growth curve and growth rate. Compared to the solvent control cultures, neither the area under the growth curve nor the growth rate were significantly reduced at a



mean measured level of 2.17 mg/l; this concentration reflects the amount of test substance that remained suspended during the test, although less than 20 µg/l was dissolved.

Neither the 96-hour median effect concentrations (EbC50 and ErC50) nor the no-observed effect concentration of test substance were identified for inhibition of growth.

In conclusion, the test substance was not found to be inhibitory to *Selenastrum capricornutum* when dispersed in algal nutrient medium at a concentration (2.17 mg/l) in excess of its limit of aqueous solubility under test conditions (<20 µg/l).

#### **5.4.4 Other aquatic organisms (including sediment)**

Not evaluated for the purposes of this dossier.

#### **5.4.5 Overview of water solubility**

There is a difference in the measured water solubility of the substance measured in the water solubility studies and the solubility levels obtained in the ecotoxicity studies. These differences in solubility levels are attributed to slight differences in the test material, slightly differing methodologies in the studies and between testing laboratories. It is also considered that other factors may have some influence on the varying solubility levels, such as differences in test media used e.g demin-water in water solubility tests versus deep well water in *Daphnia* studies (Desjardin, D. et al (2002a/b)), and differences in laboratory water between testing laboratories.

It is considered that a condition of maximum attainable exposure has been employed in all the relevant studies and therefore that the all the results are suitable for assessing the toxicity of the test substance i.e. the slight differences in water solubility levels do not affect the assessment of the substance.

### **5.5 Comparison with criteria for environmental hazards (sections 5.1 – 5.4)**

#### *5.1 Degradation:*

The test substance is not considered to be readily biodegradable.

#### *5.2 Environmental distribution:*

Not relevant for the purpose of this dossier.

#### *5.3 Aquatic bioaccumulation:*

##### Study 1

Bioaccumulation test of CN-1985 in carp (Noguchi S (1999))

BCF range: <= 1.1 - <= 159

The BCF values obtained are less than or equal to values as these were the limits of detection for the BCK calculations i.e. no detectable test item was found in the fish so the BCF is lower than the limit of detection.

The wide range of BCF values is due to the different concentrations used for the two test levels, and are considered as valid.

The study results indicate that the test item does not bioaccumulate.

Study 2:

Bioaccumulation test of AFR-1 in carp (Hori K (1996))

BCF range: 6.8 – 62

The low and variable results are typical of a low bioaccumulating substance and suggest that the test item does not bioaccumulate.

The bioaccumulation criteria (BCF values) that indicate a potential to bioaccumulate are:

DSD: BCF >100

CLP: BCF >500

Two bioconcentration studies have been conducted on the test substance (from two sources). Different analytical methods were used in the studies and both are considered valid. In one study (Noguchi S (1999)) the BCF values are reported to be less than or equal to the limits of detection determined i.e. no detectable test item was found in the fish. In the other study (Hori K (1996)) BCF values have been calculated and the low, variable results are typical of a low BCF substance.

Based on the two study results it is considered that the substance does not bioaccumulate.

#### 5.4 Aquatic Toxicity

Acute toxicity studies:

No acute toxicity recorded up to levels of water solubility (LC50/EC50 values therefore not identified).

Chronic Toxicity studies:

Chronic toxicity studies in fish and daphnia showed an absence of chronic toxicity effects at the solubility limit and chronic toxicity NOEL/NOEC values were determined to be greater than the water solubility limit.

### 5.6 Conclusions on classification and labelling for environmental hazards (sections 5.1 – 5.4)

Based on the study results available the substance should not be classified for the environment under the DSD criteria or the CLP criteria, based on the arguments described below:

**DSD:**

The substance is currently classified as R53 (May cause long-term adverse effects in the aquatic environment) under the DSD (Dangerous Substances Directive 67/548/EEC)

Directive 67/548/EEC states the criteria for R53 classification as:

Substances not falling under the criteria listed in this Chapter (Chapter 5 –Classification on the Basis of Environmental Effects), but which on the basis of the available evidence concerning their persistence, potential to accumulate, and predicted or observed environmental fate and behaviour may nevertheless present a long-term and/or delayed danger to the structure and/or functioning of aquatic ecosystems.

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For example, poorly water soluble substances, i.e. substances with a solubility of less than 1 mg/l will be covered by this criterion if:

- a) they are not readily degradable; and
- b) the log Pow is greater than or equal to 3.0 (unless the experimentally determined BCF is less than 100).

This criterion applies to substances unless there exists additional scientific evidence concerning degradation and/or toxicity sufficient to provide an adequate assurance that neither the substance or its degradation products will constitute a potential long term and/or delayed danger to the aquatic environment.

Such additional scientific evidence should normally be based on studies required at Annex VIII and could include

- i) a proven potential to degrade rapidly in the aquatic environment.
- ii) An absence of chronic toxicity effects at the solubility limit e.g. a no observed effect concentration of greater than the solubility limit determined in a prolonged study with fish or daphnia.

**Basis for Proposed Removal of R53:**

Based on this criteria the substance meets the following criteria for R53:

- The substance can be considered to be poorly water solubility, based upon the limits of solubility found under test conditions (which are lower than the stated solubility level of 1.88 mg/l from the water solubility study).
- The substance is not readily biodegradable
- The substance has a log Pow >3.0.

However, the results of two bioaccumulation studies indicate the substance does not meet the R53 criteria as the experimentally determined BCF values are less than 100 (result of <159 is not relevant to classification as 159 was the limit of detection) and show the substance does not have potential to bioaccumulate.

Also, a chronic fish study (Early-Life Stage Test) and three chronic daphnia studies (Daphnia Reproduction studies) showed an absence of chronic toxicity effects at the solubility limits determined in the studies.

Therefore, the substance should not be classified as R53 based on the above criteria.

**CLP:**

The substance is currently classified under the CLP classification as Aquatic Chronic Category 4.

The criteria for classification as Chronic Category 4 states the classification is appropriate where:

poorly soluble substances for which no acute toxicity is recorded at levels up to the water solubility and which are not rapidly degradable and have an experimentally determined BCF  $\geq$  500 (or, if absent, a log Kow  $\geq$  4), indicating a potential to bioaccumulate, will be classified in this category unless other scientific evidence exists showing classification to be unnecessary.

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Such evidence includes chronic toxicity NOECs > water solubility or > 1 mg/l, or evidence of rapid degradation in the environment.

**Basis of Proposal Removal of Chronic Category 4:**

Based on the criteria above the substance should not be classified in this category as:

- the results of two bioaccumulation studies show the BCF values to be substantially less than 500.
- Chronic toxicity studies in fish and *Daphnia* showed an absence of chronic toxicity effects at the solubility limits determined in the studies. The determined NOEL/NOECs were equal to or greater than the level of water solubility in the relevant studies.

Therefore, the substance should not be classified as Aquatic Chronic Category 4.

**Summary of classification:**

Based on study data from bioaccumulation studies and chronic toxicity studies (in fish and *Daphnia*) the substance does not fulfil the criteria required for classification as R53 (under the DSD regulation) or as Aquatic Chronic Category 4 (under the CLP regulation) and as such a proposal has been made to remove the classifications from the substance.

**RAC evaluation of Hazards to the Aquatic Environment.**

**(a) Summary of 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  $1 \times 10^{-2}$  g/l). They argue that due to the physical nature of the test material, it was not technically possible to use this

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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   |
|---|---|--|
| <b>Fish</b>   | No toxicity up to the limit of solubility | No toxicity up to the limit of solubility (Water Accommodated Fraction)  |
| <b>Aquatic invertebrates (<i>Daphnia magna</i>)</b> | No toxicity up to the limit of solubility | <ol style="list-style-type: none"> <li>1. No toxicity up to the limit of solubility (Water Accommodated Fraction)</li> <li>2. NOEC of 1.8 mg/l and LOEC of ≥ 1.8 mg/l</li> <li>3. NOEC of 1.2 mg/l (based on some growth reduction) and LOEC 1.4 mg/l</li> </ol> |
| <b>Aquatic algae and plants</b>                     | 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 by the dossier

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submitter 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.

**(b) 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.

**(c) Any key elements not included in the original CLH report but used to formulate the opinion**

The dossier submitter submitted additional clarification regarding the bioaccumulation data which has been included in Annex 1 to the RCOM.

**(d) RAC assessment and comparison with 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

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values range between  $\leq 1.1$  and  $\leq 159$  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  $\geq 500$  according to CLP and most likely below the  $\geq 100$  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 ( $\geq 500$  according to CLP and  $\geq 100$  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.

## **6 OTHER INFORMATION**

None applicable.

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