Justification for the selection of a candidate CoRAP substance

Substance Name (Public Name): 4,4’-sulphonyldiphenol

Chemical Group:

EC Number: 201-250-5
CAS Number: 80-09-1
Submitted by: BE CA
Published: 20/03/2013

NOTE
This document has been prepared by the evaluating Member State given in the CoRAP update.
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1 IDENTIFICATION OF THE SUBSTANCE

1.1 Name and other identifiers of the substance

Table 1: Substance identity

<table>
<thead>
<tr>
<th>Public Name:</th>
<th>4,4’-sulphonyldiphenol</th>
</tr>
</thead>
<tbody>
<tr>
<td>EC number:</td>
<td>201-250-5</td>
</tr>
<tr>
<td>EC name:</td>
<td>4,4’-sulphonyldiphenol</td>
</tr>
<tr>
<td>CAS number (in the EC inventory):</td>
<td>80-09-1</td>
</tr>
<tr>
<td>CAS number:</td>
<td>80-09-1</td>
</tr>
<tr>
<td>CAS name:</td>
<td>Phenol, 4,4’-sulfonylbis-</td>
</tr>
<tr>
<td>IUPAC name:</td>
<td>4,4’-sulphonyldiphenol</td>
</tr>
<tr>
<td>Index number in Annex VI of the CLP Regulation</td>
<td>Not applicable.</td>
</tr>
<tr>
<td>Molecular formula:</td>
<td>C₁₂H₁₀O₄S</td>
</tr>
<tr>
<td>Molecular weight or molecular weight range:</td>
<td>250.27</td>
</tr>
<tr>
<td>Synonyms:</td>
<td>Phenol, 4,4’-sulfonylbis- (9CI) , Phenol, 4,4’-sulfonyldi- (6CI, 8CI), 1,1’-Sulfonylbis[4-hydroxybenzene], 4,4’-Bisphenol S, 4,4’-Dihydroxydiphenyl sulphone, 0lfone, 4,4’-Sulfonylbisphenol, 4-Hydroxyphenyl sulfone, Bis(4-hydroxyphenyl) sulfone, Bis(p-hydroxyphenyl) sulfone, Bisphenol S, BPS 1, Diphone C, p,p’-Dihydroxydiphenyl sulfone, Phenol, sulfonylbis, Bis(hydroxyphenyl)sulphone, Dihydroxydiphenyl sulphone, Phenol, sulphonyldi-, Sulfonyldiphenol-</td>
</tr>
</tbody>
</table>

Type of substance ☒ Mono-constituent ☐ Multi-constituent ☐ UVCB
2 CLASSIFICATION AND LABELLING

2.1 Harmonised Classification in Annex VI of the CLP
Not applicable.

2.2 Proposal for Harmonised Classification in Annex VI of the CLP
Not applicable.

2.3 Self classification
The registration data includes no self classification.

In addition are the following classification(s) included in the Classification and labeling inventory:

- Hazardous to the aquatic environment chronic, Aquatic Chronic 3, H412 – Harmful to aquatic life with long lasting effects.
- Serious Eye Damage/Eye Irritation, Eye Irrit. 2, H319 – Causes serious eye irritation.
3 JUSTIFICATION FOR THE SELECTION OF THE CANDIDATE CoRAP SUBSTANCE

3.1 Legal basis for the proposal

☐ Article 44(1) (refined prioritisation criteria for substance evaluation)
☐ Article 45(5) (Member State priority)

3.2 Grounds for concern

☐ (Suspected) CMR ☐ Wide dispersive use ☐ Cumulative exposure
☐ (Suspected) Sensitiser ☐ Consumer use ☐ High RCR
☐ Suspected PBT ☐ Exposure of sensitive populations ☑ Aggregated tonnage
☑ Suspected endocrine disruptor ☑ Other (provide further details below)

QSAR toolbox profiler ERBA: Strong potential for ER binding
Predicted ERBA TIMES: Active High Reliability
FDA Endocrine Screening Database: Potential for Androgen Receptor Binding; Species: Rat; Structure: Phenol; Assay: AR Binding (Receptor Binding Assay)

There are some indications for possible effects on reproduction. This should be verified more in detail.

This substance may be used as an alternative to bisphenol A.

3.3 Information on aggregated tonnage and uses

☐ 1 – 10 tpa ☐ 10 – 100 tpa ☐ 100 – 1000 tpa
☐ 1000 – 10,000 tpa ☐ 10,000 – 100,000 tpa
☐ 100,000 – 1000,000 tpa ☐ > 1000,000 tpa
☐ Confidential

Please provide further details

☑ Industrial use ☐ Professional use ☐ Consumer use ☐ Closed System

Industrial manufacture of polymer:
PROCs 1,8a,8b,9 and 15

Industrial manufacture of paper:
PROCs 1 and 8b
3.4 Other completed/ongoing regulatory processes that may affect suitability for substance evaluation

<table>
<thead>
<tr>
<th>Compliance check final decision</th>
<th>Dangerous substances Directive 67/548/EEC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Testing proposal</td>
<td>Existing Substances Regulation 793/93/EEC</td>
</tr>
<tr>
<td>Annex VI (CLP)</td>
<td>Plant Protection Products Regulation 91/414/EEC</td>
</tr>
<tr>
<td>Annex XIV (Authorisation)</td>
<td>Other (provide further details below)</td>
</tr>
<tr>
<td>Annex XVII (Restriction)</td>
<td></td>
</tr>
</tbody>
</table>

A testing proposal examination regarding sub-chronic toxicity (90-day, oral) was finalized and an update of the registration data is expected as a result of this examination.

3.5 Information to be requested to clarify the suspected risk

<table>
<thead>
<tr>
<th>Information on toxicological properties</th>
<th>Information on physico-chemical properties</th>
</tr>
</thead>
<tbody>
<tr>
<td>Information on fate and behaviour</td>
<td>Information on exposure</td>
</tr>
<tr>
<td>Information on ecotoxicological properties</td>
<td>Information on uses</td>
</tr>
<tr>
<td>Other (provide further details below)</td>
<td></td>
</tr>
</tbody>
</table>

During the more detailed evaluation other items might come up that need clarification. The above only reflects the most probable information to be requested to clarify the suspected risk, other options are however still open.

3.6 Potential follow-up and link to risk management

<table>
<thead>
<tr>
<th>Restriction</th>
<th>Harmonised C&amp;L</th>
<th>Authorisation</th>
<th>Other (provide further details)</th>
</tr>
</thead>
</table>

Depending on the outcome of the evaluation any of the above mentioned risk management measures could be initiated if warranted.