

Justification for the selection of a substance for CoRAP inclusion

| | |
|--------------------------------------|---|
| Substance Name (Public Name): | Phenol, 4-methyl-, reaction products with dicyclopentadiene and isobutylene |
| Chemical Group: | |
| EC Number: | 271-867-2 |
| CAS Number: | 68610-51-5 |
| Submitted by: | ES CA for Environment (Ministry of Agriculture, Food and Environment). |
| Published: | 26/03/2014 |

Note

This document has been prepared by the evaluating Member State given in the CoRAP update.

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1 IDENTITY OF THE SUBSTANCE

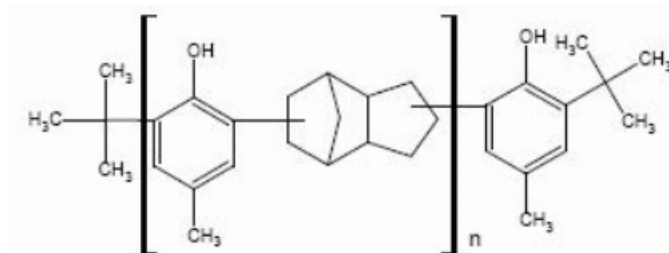
1.1 Other identifiers of the substance

Table 1: Substance identity

| | |
|---|---|
| EC name: | Phenol, 4-methyl-, reaction products with dicyclopentadiene and isobutylene |
| IUPAC name: | Phenol, 4-methyl-, reaction products with dicyclopentadiene and isobutylene |
| Index number in Annex VI of the CLP Regulation | - |
| Molecular formula: | $C_{32}H_{44}O_2$ |
| Molecular weight or molecular weight range: | 600.0 - 800.0 |
| Synonyms/Trade names: | 4-Methylphenol reaction products with dicyclopentadiene and isobutylene ; Butylated reaction product of p-cresol and dicyclopentadiene ; p-Cresol/dicyclopentadiene butylated reaction product ; isobutylene reaction products ; Polymeric sterically hindered phenol; SANTOWHITE ML ; VULKANOX SKF ; WINGSTAY L; WINGSTAY L-HLS; WINGSTAY LA; WTR Number 69; Lowinox CPL; Ralox LC; Ionol LC |

Type of substance Mono-constituent Multi-constituent UVCB

Structural formula:



1.2 Similar substances/grouping possibilities

None identified.

2 CLASSIFICATION AND LABELLING

2.1 Harmonised Classification in Annex VI of the CLP

Not listed.

2.2 Self classification

- In the registration

Hazard statements:

Aquatic Chronic 4 H413: May cause long lasting harmful effects to aquatic life.

Precautionary statements:

P273: Avoid release to the environment.

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

Depending on the notifiers, following hazard classes are provided :

| | |
|----------------------|--|
| Skin Irritant Cat. 2 | H315 Causes skin irritation |
| Skin Sens. 1B | H317 May cause an allergic skin reaction |
| Eye Irrit. 2 | H319 Causes serious eye irritation |
| STOT SE 3 | H335 May cause respiratory irritation |
| Not classified | |

2.3 Proposal for Harmonised Classification in Annex VI of the CLP

None.

3 INFORMATION ON AGGREGATED TONNAGE AND USES

| | | | |
|--|---|--|--|
| From ECHA dissemination site | | | |
| <input type="checkbox"/> 1 – 10 tpa | <input type="checkbox"/> 10 – 100 tpa | <input type="checkbox"/> 100 – 1000 tpa | |
| <input checked="" type="checkbox"/> 1000 – 10,000 tpa | <input type="checkbox"/> 10,000 – 100,000 tpa | <input type="checkbox"/> 100,000 – 1,000,000 tpa | |
| <input type="checkbox"/> 1,000,000 – 10,000,000 tpa | <input type="checkbox"/> 10,000,000 – 100,000,000 tpa | <input type="checkbox"/> > 100,000,000 tpa | |
| <input type="checkbox"/> <1 >+ tpa (e.g. 10+ ; 100+ ; 10,000+ tpa) | | <input type="checkbox"/> Confidential | |
| No more information is disseminated.. | | | |
| <input checked="" type="checkbox"/> Industrial use | <input checked="" type="checkbox"/> Professional use | <input checked="" type="checkbox"/> Consumer use | <input type="checkbox"/> Closed System |
| <p><i>Industrial use:</i> it is used in the manufacture of other substances at industrial sites, preparation of aqueous /dispersion emulsions, used in polymer preparations and compounds, production of solid rubber products, use in the production of latex gloves, condoms and rubber threads, production of impact modified plastic and thermoplastic articles, production of low/medium voltage crosslinked PE cables, production of carpets with latex rubber backing, production of coated paper, use in the production of solid rubber products, use in the production of articles based on rubber foams, manufacture of textiles, leather.</p> <p><i>Professional use:</i> use as laboratory reagent, scientific research and development, professional use of solid rubber.</p> <p><i>Consumer use:</i> Consumer use of solid rubber products, latex-based products, plastic parts, low- and medium-voltage cables, rubber foam-based products and paper, low/medium voltage crosslinked PE cables, carpets with latex rubber backing, Fabrics, textiles and apparel, and plastic articles.</p> | | | |

4 JUSTIFICATION FOR THE SELECTION OF THE CANDIDATE CoRAP SUBSTANCE

4.1 Legal basis for the proposal

- Article 44(2) (refined prioritisation criteria for substance evaluation)
- Article 45(5) (Member State priority)

4.2 Selection criteria met (why the substance qualifies for being in CoRAP)

- Fulfils criteria as CMR/ Suspected CMR
- Fulfils criteria as Sensitiser/ Suspected sensitiser
- Fulfils criteria as potential endocrine disrupter
- Fulfils criteria as PBT/vPvB / Suspected PBT/vPvB
- Fulfils criteria high (aggregated) tonnage (*tpa* > 1000)
- Fulfils exposure criteria
- Fulfils MS's (national) priorities

4.3 Initial grounds for concern to be clarified under Substance Evaluation

| | | |
|---|--|--|
| Hazard based concerns | | |
| CMR <input type="checkbox"/> C <input type="checkbox"/> M <input type="checkbox"/> R | Suspected CMR ¹ <input type="checkbox"/> C <input type="checkbox"/> M <input type="checkbox"/> R | <input type="checkbox"/> Potential endocrine disruptor |
| <input type="checkbox"/> Sensitiser | <input type="checkbox"/> Suspected Sensitiser ¹ | |
| <input type="checkbox"/> PBT/vPvB | <input checked="" type="checkbox"/> Suspected PBT/vPvB ¹ | <input type="checkbox"/> Other (please specify below) |
| Exposure/risk based concerns | | |
| <input checked="" type="checkbox"/> Wide dispersive use | <input type="checkbox"/> Consumer use | <input type="checkbox"/> Exposure of sensitive populations |
| <input checked="" type="checkbox"/> Exposure of environment | <input type="checkbox"/> Exposure of workers | <input type="checkbox"/> Cumulative exposure |
| <input type="checkbox"/> High RCR | <input type="checkbox"/> High (aggregated) tonnage | <input type="checkbox"/> Other (please specify below) |
| <p>Concerns on PBT properties should be assessed. According to the information provided:</p> <p>a) the substance is a low solubility substance and does not show acute toxicity at levels up to its water solubility, long-term toxicity is waived.</p> <p>b) it is not rapidly degradable</p> <p>c) it has a log Kow of ≥ 4 (mean value of 7.56 for the main component has been provided but a range between 6.08-11.95 is also indicated)</p> <p>d) bioaccumulation has been calculated by QSARs.</p> <p>Effects assessment will be checked. No long-term testing is proposed as it assumed that the substance will not cause any adverse effects to the aquatic organisms. PNECwater has been calculated with data above the water solubility. This aspect should be assessed.</p> <p>No quantitative RCR values for compartments of concern, i.e. sediment, could be calculated, due to the lack of a PNEC.</p> | | |

4.4 Other completed/ongoing regulatory processes that may affect suitability for substance evaluation

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

¹ CMR/Sensitiser: known carcinogenic and/or mutagenic and/or reprotoxic properties/known sensitising properties (according to CLP harmonized or registrant self-classification or CLP Inventory)

Suspected CMR/Suspected sensitiser: suspected carcinogenic and/or mutagenic and/or reprotoxic properties/suspected sensitising properties (not classified according to CLP harmonized or registrant self-classification)

Suspected PBT: Potentially Persistent, Bioaccumulative and Toxic

4.5 Preliminary indication of information that may need to be requested to clarify the concern

| | |
|--|---|
| <input type="checkbox"/> Information on toxicological properties | <input type="checkbox"/> Information on physico-chemical properties |
| <input checked="" type="checkbox"/> Information on fate and behaviour | <input checked="" type="checkbox"/> Information on exposure |
| <input checked="" type="checkbox"/> Information on ecotoxicological properties | <input type="checkbox"/> Information on uses |
| <input type="checkbox"/> Information ED potential | <input type="checkbox"/> Other (provide further details below) |

Some clarifications are needed, especially on the chronic aquatic environment as well as related exposure and PEC/PNEC ratios for the environmental compartments.

4.6 Potential follow-up and link to risk management

| | | | |
|---|--------------------------------------|--|--|
| <input type="checkbox"/> Harmonised C&L | <input type="checkbox"/> Restriction | <input type="checkbox"/> Authorisation | <input type="checkbox"/> Other (provide further details) |
|---|--------------------------------------|--|--|

Follow-up regulatory actions will be sent depending on the outcome of the evaluation. That is, further information is needed for the preparation of Annex XV dossier either for the authorization or restriction.