Committee for Risk Assessment

RAC

Opinion

proposing harmonised classification and labelling
at EU level of

4,4'-sulfonylbisphenol, polymer with ammonium chloride (NH_4Cl), pentachlorophosphorane and phenol

EC Number: 439-270-3
CAS Number: 260408-02-4

CLH-O-0000001412-86-153/F

Adopted

9 June 2017

Annankatu 18, P.O. Box 400, FI-00121 Helsinki, Finland | Tel. +358 9 686180 | Fax +358 9 68618210 | echa.europa.eu

9 June 2017

CLH-O-0000001412-86-153/F

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

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

Chemical name: **4,4'-sulfonylbisphenol, polymer with ammonium chloride (NH_4Cl), pentachlorophosphorane and phenol**

EC Number: **439-270-3**

CAS Number: **260408-02-4**

The proposal was submitted by **Germany** and received by RAC on **7 June 2016.**

In this opinion, all classification and labelling elements are given in accordance with the CLP Regulation.

PROCESS FOR ADOPTION OF THE OPINION

Germany has submitted a CLH dossier containing a proposal together with the justification and background information documented in a CLH report. The CLH report was made publicly available in accordance with the requirements of the CLP Regulation at ***http://echa.europa.eu/harmonised-classification-and-labelling-consultation/*** on **19 July 2016**. Concerned parties and Member State Competent Authorities (MSCA) were invited to submit comments and contributions by **2 September 2016**.

ADOPTION OF THE OPINION OF RAC

Rapporteur, appointed by RAC: **Katalin GRUIZ**

The opinion takes into account the comments provided by MSCAs and concerned parties in accordance with Article 37(4) of the CLP Regulation and the comments received are compiled in Annex 2.

The RAC opinion on the proposed harmonised classification and labelling was adopted on **9 June 2017** by **consensus**.

Classification and labelling in accordance with the CLP Regulation (Regulation (EC) 1272/2008)

	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard state-ment Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	604-083-00-X	4,4'-sulfonylbisphenol, polymer with ammonium chloride (NH_4Cl), pentachlorophosphorane and phenol	439-270-3	260408-02-4	Aquatic Chronic 4	H413		H413			
Dossier submitters proposal	604-083-00-X	4,4'-sulfonylbisphenol, polymer with ammonium chloride (NH_4Cl), pentachlorophosphorane and phenol	439-270-3	260408-02-4	**Remove** Aquatic Chronic 4	**Remove** H413		**Remove** H413			
RAC opinion	604-083-00-X	4,4'-sulfonylbisphenol, polymer with ammonium chloride (NH_4Cl), pentachlorophosphorane and phenol	439-270-3	260408-02-4	**Remove** Aquatic Chronic 4	**Remove** H413		**Remove** H413			
Resulting Annex VI entry if agreed by COM	604-083-00-X	4,4'-sulfonylbisphenol, polymer with ammonium chloride (NH_4Cl), pentachlorophosphorane and phenol	439-270-3	260408-02-4							

GROUNDS FOR ADOPTION OF THE OPINION

RAC general comment

The substance phenol, 4,4'-sulfonylbis-, polymer with ammonium chloride ($(NH_4)Cl$), pentachlorophosphorane and phenol, is also known also as SPS-100 and this name is used throughout the current opinion. It is used as a halogen-free flame-retardant and fire preventing agent and is used as an additive for thermoplastic and/or thermosetting polymers.

ENVIRONMENTAL HAZARD EVALUATION

RAC evaluation of aquatic hazards (acute and chronic)

Summary of the Dossier Submitter's proposal

Currently, SPS-100 has an harmonised classification in Annex VI of CLP as Aquatic Chronic 4. The Dossier Submitter proposed to remove the current classification based on new data available after the current harmonised classification was agreed.

Water Solubility: The substance is constituted by 3 components, which give 3 peaks in the HPLC: Peak 1: < 4 µg/L, Peak 2: < 28 µg/L, Peak 3: < 44 µg/L; the water solubility was estimated based on the limit of detection of the components (Brekelmans, 2001a).

Log K_{OW}: The partition coefficient Log $K_{OW,}$ > 6.2, was measured using the HPLC method (Brekelmans, 2001b).

Degradation: The substance's degradation was investigated in a screening test (ready biodegradability – Japanese Industrial Standard) performed in 1998 and considered to be in accordance with OECD TG 301C. The test was performed at 25°C, without a toxicity control.

After 28 days, a degradation of 2% and 0% was observed, measured by O_2 consumption and test material analysis (HPLC), respectively. As the test was performed significantly above the water solubility of the substance, the lack of degradation might reflect limited bioavailability/dissolution.

The test quality was given as 2 (reliable with restrictions) – Haruguchi, 1998 and the Dossier Submitter concluded that the substance was not readily degradable.

Aquatic Bioaccumulation

The substances bioaccumulation potential was measured using a Japanese standard method equivalent to OECD TG 305 (Maihara, 2000).

Cyprinus carpio were exposed to the test item at nominal concentrations of 0.1 and 1 mg/L, achieved via dispersion with the emulsifier HCO-40, using a flow-through system, with a total uptake duration of 56 d. No depuration phase was took place in the study. The effects of growth dilution are unknown. The steady state concentration in fish from both low and high concentration solutions after 56 d was measured via HPLC. Only peak 1 was detected to be < 2 µg/g, however it is not clear from the report to which of the 3 components this peak corresponds to.

Results: **BCF: < 21.3** (whole body d.w.) with 0.1 mg/L (nominal) (steady state)

BCF: < 2.1 (whole body d.w.) with 1 mg/L (nominal) (steady state)

According to the Dossier Submitter, the study should be considered unreliable: the report does not contain any information on the concentration of the truly dissolved test substance (the nominal concentration in water of both solutions (100 and 1000 µg/L) exceeds the solubility limit of the 3 components which have different solubilities (< 4 µg/L, < 28 µg/L and < 44 µg/L respectively)). Additionally, in fish, the concentration of peak 1 was always < 2 µg/g, irrespective of the nominal concentration. Relevant details on test conditions (e.g. photoperiod, mortality in control and treated fish) were not reported and the documentation of the analytical method and results are considered poor.

Aquatic Toxicity

The Dossier Submitter included studies for all thropic levels for both acute and chronic toxicity conduceted using SPS-100.

1. Acute fish test with *Oryzias latipes* (ricefish) – Method 71 of JIS K0102, which is equivalent or similar to OECD TG 305C "Bioconcentration: Flow-Through Fish Test; 305C, Modified MITI Test". The ricefish were exposed for 96h to 5 concentrations up to 100 mg/L, which were analytically confirmed. A dispersant (HCO-40) was used to reach the concentrations over water solubility.

Result: LC_{50} (96h) >100 mg/L based on mortality (nominal test material concentration).

The study (Maihara, 1999) is considered to be reliable with restrictions (Klimisch score 2) because the recoveries of the analytical method were not reported and the final dispersant (HCO-40) concentrations were above the maximum mentioned in the OECD TG 203.

2. Chronic fish test with *Pimephales promelas* – OECD TG 210 (Fish, Early-Life Stage Toxicity Test), EPA OPPTS 850.1400 (Fish Early-life Stage Toxicity Test). The study (Migchielsen, 2014) is considered reliable without restriction (1).

Result: NOEC (33d) Maximum soluble test substance (based on: embryo development, number hatched, time to hatch and larval development). Since no effects were observed in a water soluble fraction (WSF) prepared at a loading rate of 10 mg/L, the NOEC is considered to be equal to the maximum soluble test substance concentration in test medium.

Maximum soluble concentration of the test substance: Analytical measurements showed that concentrations in the WSF were variable and ranged between 6.7 and 178 µg/L for day 0 until day 9 (the embryonic and early larval stage which are the most sensitive life stages of the fathead minnow) and ranged between < LOD (< 2.3 µg/L) and 29.1 µg/L from day 14 until day 33 (later larval stages).

3. Acute invertebrate test with *Daphnia sp.* based on immobilisation according to OECD TG 202. *Result:* EC_{50} (48h) No acute toxicity up to solubility limit based on mobility was observed. The test (Migchielsen, 2001a) is considered reliable (Klimisch score 1), without restriction.

4. Chronic invertebrate test with *D. magna* based on reproduction OECD TG 211

Result: NOEC (21d) No inhibition of reproduction, growth or survival up to solubility limit, based on: parental body length, reproduction, growth, survival. The Migchielsen study (2012) is considered relaible without restriction (1).

5. Algae, growth inhibition test with *Pseudokirchnerella subcapitata*, OECD TG 201

- *Acute result:* EC_{50} (72h) No acute toxicity up to solubility limit, based on growth rate;

- *Chronic result:* NOEC (72h) No acute toxicity up to solubility limit based on growth rate. The Migchielsen study (2001b) is considered reliable without restriction (1).

6. Respiration inhibition test with activated sludge, OECD TG 209

Result: EC_{50} (30 min): >100 mg/L (nominal test material concentration) based on respiration rate (Desmares-Koopmans, 2001).

Comments received during public consultation

Two Member States Competent Authorities (MSCA) commented, one of them agreed, the other disagreed with the classification proposed by the Dossier Submitter. The MS opposing the proposal of the Dossier Submitter sent in two comments:

1. "*The substance fulfils the criteria of classification Aquatic Chronic 4; H413, ...moreover it is potentially toxic for environmental organisms*" – evidence was not provided to support these statements.

2. The "*fish tests (short and long term) are not reliable*" – Contrary to this statement the chronic fish test is classified in the CLH dossier as reliable without restriction (1) and the acute fish test as reliable with restriction (2). The commenter's view of the test results as not being reliable was thus not considered to be justified.

The commenting MS added that: "..*only nominal concentrations are reported*" to which the Dossier Submitter replied that this statement is correct, but does not influence the evidence, because the results are not given in concentrations – the criterion for no classification in this case is the solubility limit, which was reported as follows: "*the NOEC is greater than the water solubility of the substance*". RAC considers the reporting as sufficient and the interpretation of the Dossier Submitter to be correct.

Assessment and comparison with the classification criteria

***Water solubility*:** was measured with HPLC and determined to be very low for all three components which have different solubility ranging from < 4 µg/L and < 44 µg/L.

Degradability: A ready biodegradability study of SPS-100 was performed for 28 days using a method similar to MITI (I) (OECD TG 301C). At the end of the test period the average biodegradation was 2%. Thus, the criterion for ready biodegradability (at least 60% biodegradation) was not met. The study is considered to be reliable with restrictions since a toxicity control was not included.

Bioaccumulation: the test result is considered unreliable. The OECD TG 305 (bioconcentration test in fish) indicates that for substances with very low solubility in the aquatic environment, exposure via water may be of limited importance in comparison to the dietary route. In addition, other experimental shortcomings were reported in the study, as discussed by the Dossier Submitter (see above).

A worst case interpretation of the data suggests a BCF at or below 1000 L/kg. Both this predicted BCF and the high Kow indicate that SPS-100 may have the potential to bioaccumulate. Nevertheless the decision-making pathways in CLP Annex I, Table 4.1.0 allows to exclude bioaccumulative substances from classification, on the ground that it has no acute or chronic toxicity on the aquatic ecosystem.

Aquatic toxicity: All acute and chronic test results show that no acute and no chronic toxicity occured up to solubility limit.

According to the CLP regulation, Aquatic Chronic category 4 is appropriate when (i) poorly soluble substances for which no acute toxicity is recorded at levels up to the water solubility, and (ii) which are not rapidly degradable and (iii) have an experimentally determined BCF ≥ 500 (or, if absent, a log Kow ≥ 4), unless other scientific evidence exists showing classification to be unnecessary. Such evidence includes chronic toxicity NOECs >water solubility or >1 mg/L.

SPS-100 fulfills criteria (i) to (iii), however the removal of the environmental classification is supported by newly performed long-term test results, which confirmed that classification is unnecessary since chronic toxicity NOECs to fish, daphnia and algae are greater than the water solubility of the test substance – in accordance with the 2nd ATP to Regulation (EC) No 1272/2008 (CLP).

In conclusion, RAC agrees with the Dossier Submitter proposal to **remove the classification as Aquatic Chronic 4**; H413 of phenol, 4,4'-sulfonylbis-, polymer with ammonium chloride ($(NH_4)Cl$), pentachlorophosphorane and phenol.

ANNEXES:

Annex 1 The Background Document (BD) gives the detailed scientific grounds for the opinion. The BD is based on the CLH report prepared by the Dossier Submitter; the evaluation performed by RAC is contained in 'RAC boxes'.

Annex 2 Comments received on the CLH report, response to comments provided by the Dossier Submitter and RAC (excluding confidential information).