Committee for Risk Assessment

RAC

Annex 2

Response to comments document (RCOM)

to the Opinion proposing harmonised classification and labelling at EU level of

4,4'-sulfonylbisphenol, polymer with ammonium chloride (NH4Cl), pentachlorophosphorane and phenol

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

CLH-O-0000001412-86-153/F

Adopted
9 June 2017

ANNEX 2 - COMMENTS AND RESPONSE TO COMMENTS ON CLH PROPOSAL ON 4,4-SULFONYLBISPHENOL, POLYMER WITH AMMONIUM CHLORIDE (NH4CL), PENTACHLOROPHOSPHORANE AND PHENOL

COMMENTS AND RESPONSE TO COMMENTS ON CLH: PROPOSAL AND JUSTIFICATION

Comments provided during public consultation are made available in the table below as submitted through the web form. Any attachments received are referred to in this table and listed underneath, or have been copied directly into the table.

All comments and attachments including confidential information received during the public consultation have been provided in full to the dossier submitter (Member State Competent Authority), the Committees and to the European Commission. Non-confidential attachments that have not been copied into the table directly are published after the public consultation and are also published together with the opinion (after adoption) on ECHA's website. Dossier submitters who are manufacturers, importers or downstream users, will only receive the comments and non-confidential attachments, and not the confidential information received from other parties.

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Substance name: 4,4-sulfonylbisphenol, polymer with ammonium chloride (NH4Cl), pentachlorophosphorane and phenol
CAS number: 260408-02-4
EC number: 439-270-3
Dossier submitter: Germany

GENERAL COMMENTS

Date	Country	Organisation	Type of Organisation	Comment number
31.08.2016	France		MemberState	1
Comment received				
We disagree with the proposal to remove classification of 4,4'-sulfonylbisphenol, polymer with ammonium chloride (NH4Cl), pentachlorophosphorane and phenol (n° CAS: 260408-02-4) as Aquatic Chronic 4, H413. The substance fulfils the criteria of classification Aquatic Chronic 4, H413. Moreover, the substance is potentially toxic for environmental organisms; especially for those in the sediment and soil compartments and it exhibits potential PBT/vPvB properties.				
Dossier Submitter's Response				
For response see comment number 2.				
RAC's response				
Unfortunately France did not provide arguments for the statement of "The substance fulfils the criteria of classification" – so Rapp cannot give a specific response, only the argument for no classification, – and that is the measured chronic toxicity data: NOECs > WATER SOLUBILITY. Safety net COULD BE applied, and SPS-100 classified as Aquatic chronic 4 without the evidence on NOEC> water solubility, as it is defined by the CLP Guidance (Annex I: 4.1.2.6.): "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 ≥ 500 (or, if absent, a log Kow ≥ 4), indicating a potential to bioaccumulate" BUT the same paragraph says – "UNLESS other scientific evidence exists showing classification to be unnecessary. Such evidence includes chronic toxicity NOECs ABOVE WATER SOLUBILITY" – This is our case. The newly performed chronic toxicity test results confirmed that classification is unnecessary since NOECs to fish, daphnia and algae are greater than the water solubility of the test substance – in accordance with the 2nd ATP of Regulation (EC) No 1272/2008 (CLP). The reason for former classification was the lack of chronic fish and Daphnia toxicity data, and the condition for the abolition of classification the acquirement of these lacking data has been given, which has been fulfilled now.				

(Rapp. does not agree with aquatic classification of a substance that did not show aquatic toxicity (up to its water solubility) in any of the tests applied.)

OTHER HAZARDS AND ENDPOINTS – Hazardous to the Aquatic Environment

Date	Country	Organisation	Type of Organisation	Comment number
31.08.2016	France		MemberState	2

Comment received

We don't support the proposal to remove classification of 4,4'-sulfonylbisphenol, polymer with ammonium chloride (NH4Cl), pentachlorophosphorane and phenol (n° CAS: 260408-02-4) from the actual entry Aquatic Chronic 4, H413.

According to data presented in the dossier (page 10), the substance exhibits a poor water solubility of <4µg/L, 28µg/L, 44µg/L and is not ready biodegradable, only 2% of biodegradation was reported after 28 days (OECD 301C). Furthermore, the partition coefficient n-octanol/water (log Kow) is very high (>6.2), thus the substance is potentially bioaccumulable. The only test of bioaccumulation presented in the dossier (page 18) is not considered as reliable because the concentrations tested were above of solubility limit and there is also missing information.

Concerning aquatic ecotoxicity tests, we agree that fish tests (short and long term) are not reliable. However, data presented for Daphnia magna test (short term) must be taken with caution because the report does not contain enough information (page 30) about the preparation of the substance tested (start concentration tested, justification about filtration, WAF conditions) and only nominal concentrations are reported. There is also missing information with respect to the long term test (page 31) about the stability of the substance over exposure time. Regarding to algae test (page 32) concentrations tested are only expressed as nominal and not information about measured concentrations are presented in the report.

It is important to remind that according to regulation (EC) No 1272/2008, the 'Safety net' classification Category Chronic 4 is used when the substance exhibits some grounds for concern. This includes for example: poorly soluble substances for which no acute toxicity is recorded at levels up to the water solubility, they are not rapidly degradable and have an experimentally determined BCF ≥ 500 (or, if absent, a log K ow ≥ 4), indicating a potential to bioaccumulate. Thus, the substance 4,4'-sulfonylbisphenol, polymer with ammonium chloride (NH4Cl), pentachlorophosphorane and phenol (n° CAS: 260408-02-4) fulfils the criteria of classification "Aquatic Chronic 4, H413".

Moreover, to our point of view, according to physical-chemical properties, the substance is also potentially toxic for organisms; especially for those living in the sediment and soil compartments and could exhibit PBT/vPvB properties. Therefore, we are of the opinion that the classification "Aquatic Chronic 4" should be kept

Dossier Submitter's Response

Thank you for your comment.
We agree that the substance is not readily biodegradable and potentially bioaccumulative. Nevertheless, no acute and chronic toxic effects were observed up to the water solubility.

Concerning aquatic ecotoxicity tests: In contrast to your remarks, the fish tests are reliable (acute: reliability 2; long-term: reliability 1). The results for the acute *Daphnia magna* test are based on nominal concentrations. As no effect occurred in the highest test concentration, which is comparable to a WAF approach (direct solution without dilution), the results are reliable although only based on nominal concentrations. The same approach was used for the algae toxicity test. Therefore, for all three trophic levels reliable long-term toxicity data is available, which does not reveal any effect.

The CLP regulation reflects only hazardous to the aquatic environment. Toxicity to e.g. soil organisms is not considered.
RAC's response
The shortcomings of the dossier, e.g. not mentioning some important details of the tests, really exist, – the dossier submitter should have provided more information on test solution preparation methods for all relevant tests, including test material components and their actual concentrations during the tests, – BUT, the information processed by DS originate from studies qualified as reliable (except one, all of them without restriction) and also used in other legal procedures – the dossier have been accepted, because Rapp. and Sec. judged the information enough to obtain a conclusion. Chronic fish test of Migchielsen (2014) is classified as (1) – reliable without restriction, the studies of Migchielsen (2001a); Migchielsen (2012) and Migchielsen (2001b) are considered reliable without restriction (1). The acute fish study of (Maihara, 1999) is considered to be reliable with restrictions (Kilimsch 2) because the recoveries of the analytical method were not reported and the final dispersant (HCO-40) concentrations were above the maximum mentioned by OECD TG 203. France disagrees with this classification, saying that the studies are not reliable, – if they have some evidence on this statement, it would be necessary to share it! The section cited from the regulation on safety net is not complete. The CLP Guidance (Annex I: 4.1.2.6.) clarifies that: "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 ≥ 500 (or, if absent, a log Kow ≥ 4), indicating a potential to bioaccumulate; – UNLESS other scientific evidence exists showing classification to be unnecessary. Such evidence includes chronic toxicity NOECs ABOVE WATER SOLUBILITY". This is the point in the Guidance on which the dossier submitter's proposal is based: new chronic evidence appeared, which may confirm the exclusion of SPS-100 from Aquatic acute 4 classification. All in all, based on the information has been provided, the substance does not appear to have any short- or long-term aquatic effects up to its water solubility limit, so does not require hazard classification for the environment.

Date	Country	Organisation	Type of Organisation	Comment number
02.09.2016	Sweden		MemberState	3
Comment received				
The Swedish CA supports the removal of the classification of Phenol, 4,4'-sulfonylbis-, polymer with ammonium chloride ((NH4)Cl), pentachlorophosphorane and phenol (CAS No. 260408-02-4) in Aquatic Chronic 4 (H413) as specified in the proposal. This conclusion is based on new data available on long-term testing of Daphnia magna. The substance is not readily biodegradable and has a log Kow >6.2 indicating a potential to bioaccumulate. However, since the chronic NOECs of Daphnia magna, fish and algae are above the water solubility limit of the substance no classification for environmental hazard is warranted. Minor comment: It would have been helpful if the reliability of the studies were indicated in Table 17.				
Dossier Submitter's Response				
Thank you for your support.				
RAC's response				
Thank you for your comment and I agree to present the information about the studies quality, as it has been done in the ODD: The study (Migchielsen, 2014) is considered reliable without restriction (1). The test (Migchielsen (2001a) is considered reliable (1), without restriction. The Migchielsen (2012) study is considered relaible without restriction (1). The Migchielsen study (2001b) is considered reliable without restriction (1).				

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