13 November 2014

COMMENTS ON AN ANNEX XV DOSSIER FOR IDENTIFICATION OF A SUBSTANCE AS SVHC AND RESPONSES TO THESE COMMENTS

Substance name: 2-benzotriazol-2-yl-4,6-di-tert-butylphenol (UV-320)
CAS number: 3846-71-7
EC number: 223-346-6

The substance is proposed to be identified as meeting the following SVHC criteria set out in Article 57 of the REACH Regulation: PBT (Article 57 (d)); vPvB (Article 57 (e))

Disclaimer: Comments provided during public consultation are made available as submitted by the commenting parties. It was in the commenting parties own responsibility to ensure that their comments do not contain confidential information. The Response to Comments table has been prepared by the competent authority of the Member State preparing the proposal for identification of a Substance of Very High Concern. RCOM has not been agreed by the Member State Committee nor has the document been modified as result of the MSC discussions.

PART I: Comments and responses to comments on the SVHC proposal and its justification

General comments on the SVHC proposal

No.	Date	Submitted by (name, Organisation/ MSCA)	Comment	Response
5	2014/10/16	International NGO Health and Environment Alliance Belgium	We support the nomination of UV 320 to the Candidate list and thank Germany for submitting it and including data related to its presence in house dust.	Thank you for your support.

Specific comments on the justification

No.	Date	Submitted by (name, Organisation/ MSCA)	Comment	Response
1	2014/10/15	Member State France	We first thank Germany for preparing this document. We support the German proposal that UV320 and UV328 should be added to the candidate list as SVHC according to REACH article 57(d) and (e). We are of the opinion that sufficient evidence for defining UV320 and UV328 as PBT/vPvB substance are given, based on the results available. The vB criterion is fulfilled for the 2 substances. Moreover, Germany has shown with a weight of evidence approach that there is strong evidence of high persistence in soil and sediment for both substances. The proposed read across is considered as robust. Minor revision for UV320: - P16. "Screening test". Please could you add (Nite, 2012) study in annex. Due to the low water solubility of the substance, we think that more details of this study could be given such as the use of a solvent in the test, the use of a suitable positive reference for poorly soluble substance such as diisooctylphtalate or anthraquinone for example. - Typical error: P16. "see also 3.1.2.1.1" but there is nothing in this paragraph… We supposed that it was 3.1.2.1.2 ? - Typical error: P17. "Valif". Replace by "valid". - P20. "The concentration of EC 407-000-3 in the 308 test is 3 µg/L". Could you please indicate if this value is below the water solubility?	Thank you for the support and the detailed feedback. We amended your individual points as indicated below. Where applicable this was done for UV-320 and UV-328 -P16 "Screening test":The information you asked for would be very helpful for interpretation indeed. Unfortunately our efforts to find a description of the actual test conditions in English were unsuccessful. As the majority of data is in Japanese we only can assume that a solubiliser was used because experience shows that this was not unusual in this test system. However, we do not believe that poorly soluble test substances were tested because this is not even common now - P16, Typo: This is actually a wrong reference to an older version of the document and was therefore deleted. -P.17, Typo: corrected -P20: A sentence was added concerning the concentration which is below the water solubility of EC 407-000-3 (18 µg/L).

			- Typical error: P26. "Figure 10 gives a subsumption of data observed in and trends modelled for the river and the pond system under aerobic conditions". Please replace aerobic by anaerobic.	-P26, Typo: corrected
			- P29. Please add the limit of quantification of UV327 and UV328 for an easier assessment of soil contamination in the figures 13 and 14.	-P29, Limit of quantification: The limits of quantification are given in the Supporting Information of the article. For UV-327 it is 9.23 ng/g and for UV-328 3.76 ng/g. We added this in the dossier and in the discussion of uncertainties.
			- P30. In the Lai study, it is mentioned that 4 replicates of measured concentrations were carried out. We wonder if any standard errors could be calculated and reported on Figures 13 and 14. Are they too small to be seen? If yes, please add some indications in the figures captions.	-P30: The standard errors are available in the Supporting Information of the article. In case of T1 they lie between 0.4 and 1.7% and in case of T2 between 2 and 10.4%. As this errors are quite small compared to the concentration we simply added the information in the caption as you suggested.
			- P34. "The core concentrations of the compounds in the sediment were condensed into a single number". This sentence does not seem clear. Could you please give more explanation about the number of sample for each site in Table 11 and which samples were combined?	-P34, Core concentrations: 8 sediment cores were taken by divers at 3 locations in the Pawtuxet River. Additional sediment cores were taken at 4 locations in the Pawtuxet Cove and 13 stations in the Providence River and Narragansett Bay. Sediment cores were taken with a 6 cm i.d. x 80 cm stainless steel sampler or 24 x 16 x 8 cm bottomless cans. The sediment cores taken with the 6-cm sampler were sectioned into 3- or 4-cm layers, the cores taken with the bottomless cans were sectioned into 6-8 cm layers. The different layers were analysed, but "the core concentrations of the compounds in the sediment have been abstracted and are summarized" in Table 11. The authors stress that although there is some uncertainty resulting from condensing core profiles into a single number, they feel the values given in Table 11 are representative of the sediment concentrations and are useful in getting an overall picture.
			- P34. "With regard to the study discussed in the following, the dossier submitters were asked to include	-P34, Phthalates: In a former comment one MS criticised that there were no reference substances

			information on phthalates". The relation between the phthalate and the UV320 is not so clear. Could you please better explain why the reference to DEHP RAR is mentioned?	to provide information about the actual persistence observed and asked us to include data on phthalates, which were also monitored in the respective study. The MS argued that some phthalates are known to be readily biodegradable and that it would be helpful to include these results to provide some context to the UV-327/8 data. We included the requested information although we didn't find it helpful. Next time we would include it in the response to comments, only.
			- Typical error: P37. "The results of this comparison are summarized in Table"... The number of the table is missing.	-P37, Typo: "Table 14" was inserted
			- P38. The table and its caption are quite confusing. Concentration corrected by a DegT50 of 180 days are not indicated in the table but mentioned in the caption. We think that a row reporting the concentration "c at that layer based on DegT50" is missing to harmonize the table with the caption.	-P38: The caption was changed to "Comparison of concentrations from literature after and during the respective production periods" which reflects its content
			- Typical error: P40. "The DT50-result for the aerobic pond is certainly is influenced". Delete "is".	-P40, Typo: Deleted
			- P44.You mentioned that "For example it might be that the actual water solubility was overestimated and the test concentrations were therefore above it." Nevertheless there is not discussion about the water solubility in the physico-chemical part. If there are some concerns about water solubility estimation we are of the opinion that this point should be discussed in details in the relevant part of the SVHC dossier.	-P44, solubility: We only intended to give a possible explanation for the trend of higher BCF values with lower test concentrations seen but we have no concerns about the water solubility as given in chapter 1.4.
			- P44. "Maximum BCF values represent the worst case and the BCF at test end represent a best case for the high and medium concentration, because probably some elimination had already started". FR disagrees with the end of the sentence. Indeed, we wonder why elimination would be efficient only at the end of the test. We think	-P44, Max BCF: You are certainly right that elimination may occur already early in a bioaccumulation test. However, it seems that the elimination rate exceeded the uptake rate and BCF declined after the maximum had been reached. As the phrase is speculative

			that the elimination process occurs from the beginning of the exposure. Therefore, the end of the sentence should be deleted or rephrased.	anyway we followed your proposal and deleted it.
2	2014/10/16	Member State Finland	We welcome the proposal by DE and note that the dossier has been further improved as compared to the dossier discussed at the MSC-30 meeting in June 2013. Further information has been added (Field study by Lai et al. (2014)). Data on the dissipation and degradation of substance EC 407-000-3 to an analogue substance (M1) have been re-evaluated in order to strengthen the weight of evidence conclusion on persistency. In addition, a chapter on uncertainties related to the assessment of biodegradation has been elaborated. We propose the following amendments to the dossier: Page 18. Please add in Table 6 information on physico-chemical properties in order to strengthen the used read- across. Where measured data are not available, please include QSAR predictions. Page 41 (Chapter 3.1.4 "summary of uncertainties"). Regarding the case studies in Pawtuxet River and Narrangansett Bay, please include in the summary of uncertainties a discussion on microbial viability (or lack of viability) in the sediments. As the studied sediments were anaerobic and apparently heavily contaminated, it is possible that conditions for the degradation of phenolic benzotriazoles were quite adverse. Based on the provided information, and acknowledging the uncertainties related to the information, we agree that the substance meets the criteria as SVHC according to Article 57 d and e. The Finnish CA considers that after inclusion of the substance in the candidate list (for eventual inclusion in the Annex XIV) it still needs to be further considered which risk management measures would be the most appropriate.	Thank you for your assessment of the dossier. With regard to your specific comments see below: Page 18: The requested information in Table 18 was added and also some explanation of its explanatory power. Page 41: A short comment on the possible lack of microbial viability was added. Thank you for your overall assessment. With regard to later regulatory steps we concluded in our RMO assessment that the phenolic benzotriazoles exhibiting SVHC-properties should be regulated via authorisation and be substituted in the long run (when feasible alternatives are available).

3	2014/10/16	National NGO CHEM Trust United Kingdom	CHEM Trust supports the inclusion of 2-Benzotriazol-2-yl-4,6-di-tert-butylphenol in the REACH candidate list according to REACH article 57 d) and e). The evidence is very well presented and convincingly demonstrates the PBT and vPvB properties in accordance with Annex XIII.	Thank you for your support.
4	2014/10/16	Member State Norway	The Norwegian CA supports the proposal to identify 2-benzotriazol-2-yl-4,6-di-tert-butylphenol (UV-320) as a substance of very high concern and should be included in the Candidate List. Concerning monitoring data a new screening report from Norway has recently been published, which includes findings of several UV filters in the environment (benzotriazoles UV 328 and the very similar substances 327 and 329). http://www.miljodirektoratet.no/Documents/publikasjoner/M176/M176.pdf UV-327, UV-328 were shown to accumulate in marine and freshwater sediments receiving treated wastewater. Further, the results show the occurrence of UV-328 and UV-237 in selected biota samples (prawn, cod) in the Oslo fjord, supporting these substances' potential to bioaccumulate in organisms. These results may be useful supporting information proving the persistency and bioaccumulative properties of the substances. While supporting the inclusion of UV 328 and UV 320 in the candidate list we would propose that further effort should be put on regulating the structurally similar benzotriazoles with similar hazardous properties like UV 327 and 329.	Thanks, information from the study has been included in Annex 4 of the support document.
6	2014/10/16	Member State Netherlands	NL supports the proposal to include 2-(2H-benzotriazol-2-yl)-4,6-ditertpentylphenol (UV-328) in the candidate list of substances of very high concern, based on its intrinsic PBT/vPvB properties.	Thank you for your support

7	2014/10/16	International NGO ChemSec Sweden	Comments on the proposed SVHC properties summarised on page 6-7 of the Annex XV SVHC report: We fully support the inclusion of this substance on the REACH candidate list. This substance both contains the same for hazardous properties important structural element as, and has structural similarity to the SIN-listed substance CAS 25973-55-1 according to the new SINimilarity tool. This indicates an increased probability for similar hazards. References: http://sinlist.chemsec.org/	Thank you for your support, we also see a strong similarity of the two compounds.

PART II: Comments and responses to comments on uses, exposures, alternatives and risks

No specific comments on uses, exposures, alternatives and risks