17 November 2014

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

Substance name: 2-(2H-benzotriazol-2-yl)-4,6-ditertpentylphenol (UV-328)
CAS number: 25973-55-1
EC number: 247-384-8

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
2	2014/10/15	Company Belgium	Full comments are provided in the attachments. Authorisation is not the appropriate route as certain risks suggested in the Annex XV cannot be controlled by the authorisation process. 2_2014-10-15 UV-328 consultation Cand List-non-confidential-public.pdf *Confidential attachment removed*	Thank you for your comments. **With regard to the best RMO-strategy** the RMO-assessment conducted by Germany came to a different conclusion than yours. Due to limited information we cannot conclude there is an existing risk according to article 69(4) of REACH. Furthermore, we also lack the detailed knowledge for assessing the availability of feasible alternatives, especially considering the specialised uses of these substances. As you yourself describe there are currently no feasible alternatives available. We therefore concluded that the phenolic benzotriazoles exhibiting SVHC-properties should be regulated via authorisation and be substituted in the long run (when feasible alternatives are available). This assessment is supported by relevant uses

				described in the registration dossier of the substance. It is possible that there are uses outside the scope of authorisation especially with regard to imported articles. This problem would have to be assessed after the inclusion of the substance in Annex XIV via the provisions of article 69(2). Considering the hazard assessment, please see our comments below.
6	2014/10/16	International NGO Health and Environment Alliance Belgium	We support the nomination of UV-328 to the Candidate List, and thank Germany for also including human biomonitoring data in this dossier.	Thank you for your support.
8	2014/10/16	International NGO ChemSec Sweden	*Confidential attachment removed*	Thank you for providing this extensive document.

Specific comments on the justification

No.	Date	Submitted by (name, Organisation/ MSCA)	Comment	Response
1	2014/10/14	Company Germany	We refer to page 50 (6.1.1.2. Bioaccumulation; vB criterion BCF>5000): < Written opinion > Having studied the Annex XV dossier of UV-328 (CAS No. 25973-55-1), we believe that it is necessary to conduct further verifications of the calculation method to normalize the Bioconcentration factor (BCF) with the lipid content and the calculation results reported in Table 22. We believe that the method to calculate the BCF normalized from BCF reported in Table 21 is not appropriate. Therefore, we do not agree with the conclusion "UV-328 fulfils the vB criterion (BCF>5000)" in chapter "6.1.1.2 bioaccumulation".	Please see our following comments. Given the available data provided by the registrant we think that our assessment is appropriate. For details please see below. Ciba 2000 only gives the lipid content for the test start but not for test end. We agree that the lipid content might have changed during the test. The information given in the registrant's dossier was missing. Thus it is only possible to use the lipid content for the test start for lipid normalisation. In addition, the non-normalised data already show BCF to be very high and in one case reaching the trigger value of 5000 at the low test concentration.

			In Table 21, the BCF reported in Ciba 2000 is described. In Table 22, the BCF normalized to 5% lipid content calculated with the BCF in Table 21 and 4.2% lipid content at the start of the test is described. However, paragraph 56 of the OECD test guideline 305(2012) requires the measurement of lipid content at least at the start and the end of the test to normalize BCF with the lipid content. Generally, the lipid content of fish does change during the test period of several weeks. The BCF values 940 and 620 – 1800, obtained from the bioaccumulation test performed by NITE, are described in Table 19. And the lipid content during this test is disclosed on the website of NITE (*1). According to this information, the lipid content was 3.75% at the start of the test and 4.62% at the end of the test. Therefore, the lipid content was increased by 1.23 times during this test. In addition, the BCF value 2400 is described in Table 19. However, the lipid content during this test cannot be found on the website of NITE. We investigated the lipid data of this test and found the lipid data of this test in the evaluation data for the Chemical Substances Control Law in Japan (*2). This lipid content was 2.38% at the start of the test and 4.14% at the end of the test. The lipid content was increased by 1.74 times. Looking to the facts above, as well as to the test result of Ciba 2000, we believe that there is a possibility of the lipid content having increased during the test. It is our strong opinion that it is very important to consider the lipid content at least at the start and at the end of the test, if normalizing the BCF is necessary. Therefore, we think that it is necessary to perform the bioaccumulation test again or to re-calculate the BCF	With regard to the Nite results: We agree with you that it is important to consider the lipid content. According to OECD 305 the BCF should be normalised based either for each test organism individually or on the lipid content at the end of test if a steady state BCF is used. However, no information on individual lipid content is given and apparently no steady state had been reached in the test. Thus, it is also invalid to use the lipid content at test end for normalisation as proposed by OECD 305. Instead we used the average of both values at test start and test end which are depicted in the footnotes of the table. Nevertheless, a comparison of non-lipid normalised and lipid normalised BCF shows that even without normalisation BCF is close to or above the trigger value of 2000 at the low test concentration. We are of the strong opinion that it is not necessary to test bioaccumulation anew. Though there are some deficiencies in available data there is already enough evidence to conclude that UV 328 is vB, especially when considering the available data on the bioaccumulation potential of similar phenolic benzotriazoles like UV-320, UV-327 and UV-350. For these substances BCF values of above 5.000 are found. In case of UV-320 for two of three available test concentrations BCF are even exceeding 10.000. As shown already in section 5.1.2.1.3 of the supporting document under "Rationale for Read Across

			with the normalization in order to identify UV-328 as PBT / vPvB, based on the OECD test guideline 305(2012), which requires the measurement of the lipid content at least at the start and the end of the test to normalize BCF with the lipid content. (*1) http://www.safe.nite.go.jp/jcheck/template.action?ano=21958&mno=5-3604&cno=25973-55-1&request_locale=ja (*2) https://www.env.go.jp/council/05hoken/y051-70b.html	Assessment" UV-320 is very similar to UV-328. In Table 6 the predicted log K_{OW} results are in the same range. As this is the screening criterion for bioaccumulation it is therefore shown that the BCF results from UV-328 and UV-328 should be similiar as well. This is a further argument that supports our assessment.
2	2014/10/15	Company Belgium	Full comments are provided in the attachments. Specific comments on the SVHC properties "persistence" and "bioaccumulation" are provided here (Part I, sections 3-6): 1. The Annex XV dossier does not constitute a balanced assessment of the PBT status of the substance. The lack of transparency and the selective use of data and of guidances by the MSCA-DE is demonstrated in this document. 2. More specifically, we question whether the MSCA-DE's conclusion on persistence accounts for the formation of NERs. It is clear that NERs are being formed, which according to the ECHA guidance R7B shall be considered as a removal pathway (not bio-available, not bio-accessible). 3. Reference is also made to two BCF studies. Only those test results are presented in the Annex XV dossier that fits the purpose of determining UV-328 as a PBT and vPvB, even though both studies are equally Klimisch rated as a K2. This is scientifically incorrect use of information. It would be scientifically correct to investigate the reason for the diverging test results on bioaccumulation, instead of drawing a conclusion on part of the data only. 2_2014-10-15 UV-328 consultation Cand List-	Thank you for your comments. We welcome the detailed feedback and suggestions for improvement but we strongly disagree on your criticism of being selective or not transparent. In the detailed comments no information or data is presented that is not already included in the dossier which shows that there is no assessment bias due to selective presentation of the data. We rather believe that you simply disagree with regard to our assessments. The lack of transparency is not further substantiated within your detailed comments. To the best of our knowledge we documented all data used and assessed within our dossier and its annexes thoroughly. As far as we understand your comments the main difference in our assessments concerns how NER are considered. This is of course still a topic of scientific and regulatory debate. We strongly believe that you misinterpret the assessment of NER as laid down in the guidance documents. While it is correct that the guidance documents state NER as a removal the guidance documents do not state that removal equals degradation. In contrast e.g. chapter R.11.1.3.1 Persistence assessment (P and vP) clearly states that "…With regard to persistence, it is insufficient to consider removal alone where this may simply represent the transfer of a substance from one environmental compartment to another (e.g. from the water phase to the sediment)." This clearly is the case for the benzotriazoles as shown in the water/sediment study and is to be expected for whatever simulation study offering sorbents is done. There are no means to differ

			non-confidential-public.pdf *Confidential attachment removed*	NER further into parent or metabolites and thus it remains unknown to which extent metabolites contribute to NER if at all. Hence, UBA developed a concept based on research to further explain the processes contributing to NER formation with the intention to enable a more realistic assessment of NER in the future. The concept basically divides NER into three fractions, covalently bound, biogenic (incorporated) and entrapped NER. It was presented and discussed at the ECETOC workshop on persistence in November 2012 where it was not challenged. However, neither our concept nor the concept on NER as proposed by ECETOC allows a more differentiated assessment of NER at present because it is still not possible to differentiate between NER fractions. This would provide a consensus on assignment of NER fractions to extraction techniques. Debate is still ongoing. In addition, it should be kept in mind that FOCUS gives very sophisticated advices on kinetic modeling of results of simulation tests on degradation of plant protection products with the purpose of predicting environmental concentrations, inter alia for groundwater. For this purpose it is correct to subsume NER to the processes which diminish the concentration in groundwater and to this effect to add the NER formation to the dissipation processes. However, it is not correct to do this in assessment of the degradation potential of a substance. This concern is mirrored by the requirements of REACH guidance as described above. With regard to your specific comments, please see below Chapter 2.1., Weight of Evidence Assessment: We believe that we presented all relevant data for our assessment and described why and how we came to the conclusion that UV-328 is very persistent and very bioaccumulative. A true Weight of Evidence approach (WoE) was only used for assessing the persistence. It is comprised of presenting the results of all types of studies on the end-point, regardless of whether the result itself can be directly numerically compared with the respective criterion, a discussion of the remaining uncertainties. This is done once on the level of the individual pieces of

				information and then on the overall uncertainty. In the case of bioaccumulation two different tests are available that are both assessed. Attempts to explain the differences are made and it is clearly stated why we believe that the second test shows that UV-328 is very bioaccumulative. This conclusion represents the application of the principle on how to use data from similar tests where results are different as presented in Section 3.1.5 of Annex I to REACH. 2.1.1.1.: Read Across First of all we do not share your evaluation that the WoE rests solely on the water-sediment-study. We rather believe that this test gives strong indication that 4,6-substituted phenolic benzotriazoles with complex side chains are slowly degraded in the environment. Furthermore, the Read Across is made on the degradation behavior and the rationale for this is given on page 17-20. It is not solely based on the expectation of similar relevant physico-chemical properties but on 1) a common functional group 2) common precursors and/or the likelihood of common breakdown products via physical and biological processes, which result in structurally similar chemicals 3) a constant pattern in the changing of the potency of the properties across the category As you requested we added physico-chemical data calculated with QSAR-models and also added a paragraph why we conclude that the difference in water solubility is no hinderance for comparing the DT50-values resulting of the water-sediment-study of EC 407-000-3 with what can be expected for UV-328 (and UV-320). Please also note the other elements of the WoE, especially the study by Lai et al. and the field data support this assessment. 2.1.1.2 OECD 308 Test As discussed above in our reply to your general comments the topic NER is still under debate. According to the UBA concept the term NER confines three different NER types which pose different risks to environment and thus would

				need to be considered differently in assessment. As you mentioned ECETOC developed a concept, too but at present there is no commonly accepted concept on NER assessment. In addition, there is no consensus on assignment of NER fractions to extraction techniques. This assignment is the prerequisite for a differentiation of NER fractions into covalently bound, biogenic (incorporated) or entrapped. Hence, the NER measured cannot be differentiated in the test system of EC 407-000-3, too. With regard to your question on the analytical procedure used in the study: There were several analytical steps performed which are standard procedure to determine the amount and nature of extractables. First acetonitrile, then a mixture of acetonitrile and water at ambient temperature was used for extraction. This was followed by a Soxhlet extraction using acetonitrile/water. The extracts were quantified by LSC and chromatographically profiled by TLC. NER were quantified by combustion and detection of $^{14}CO_2$. Because of the analytical procedure no M1 or other metabolites were identified in the NER. We assessed NER as removal pathway according to REACH guidance but removal does not equal degradation as already stated above. Consequently, we did not consider NER as part of degradation and NER did not contribute to $DegT_{50}$ but DT_{50}, only. This is in full compliance with REACH guidance. REACH explicitly demands to follow the precautionary principle. In cases where conflicting results from similar tests are available, which is the case here for the simulation degradation study, Section 3.1.5 of Annex I to REACH applies the precautionary principle by saying that it is required to use the results giving rise to the highest concern to draw the conclusion. Consequently, the pond system is decisive. With regard to the different results for the river and the pond system we would like to point you to the section "Summary on remaining uncertainty" in which we give an explanation for the different results: The amount of NER formed in the test systems differs. While in the river system 36.2% of NER are formed at day 100, in the pond system there is "only" 25.1%. Thus M1 disappears more rapidly into NER and consequently the DT50-values differ.

				In addition, further aspects confirm the conclusion that UV-328 is very persistent. As described in detail in the dossier the lack of mineralization and the low rate of metabolite formation fit to each other and to the conclusion drawn. NER formation increased in both systems under aerobic conditions but as discussed above the contribution of metabolites or parent remains unknown, NER fractions cannot be differentiated and thus NER has to be assessed as removal but not as degradation. NER formation is not helpful for degradation assessment. Furthermore, M1 is also very persistent under anaerobic conditions in the sediment phase. We partly agree that the OECD 308 or the OECD 307 may give results which are hard to interpret if highly adsorptive substances are tested. Nevertheless, these are the standard tests which represent the compartment of concern for adsorptive substances. We do not agree with the opinion that the OECD 308 lacks precision or accuracy more than other tests. It should be kept in mind that generally biotic test systems show a larger variability in results than e.g. those on physico-chemical properties. Tests on biodegradation often vary in results but this holds true for all test systems on biodegradation not only for the OECD 308. A reason is the inoculum that varies in microbial composition but cannot be standardized without rendering the tests useless for assessment. Nevertheless, there is general consent to use tests on biodegradation in assessment. We are aware of the scientific discussion and the research program initiated by ECETOC concerning OECD 308. It remains to be seen when the LRI project actually will end but it is not available and thus cannot be considered at present. However, we expect it to add valuable input for future discussions. 2.1.2 Biodegradation in soil The main criticism with regard to this subsection is that we did not especially have taken into account that presumably NER are formed and might be extracted and are contributed when calculating DT_{50}-values. This again

				ties in with your comment in the previous section where your regard NER as removal pathway. As we have stated in our comment above, this does not mean that NER do not have to be considered when assessing potential persistence. Therefore, we stand by our original assessment. 2.1.3: Field Data As correctly mentioned in your comments, there was and still is a municipal WWTP upstream of the (former) chemical production plant. It is also correctly stated that UV-327 and UV-328 were found in the sewage sludge of this WWTP, but not in the river water and sediment downstream of this municipal WWTP. Therefore we conclude in our dossier that potential emissions of the municipal WWTP apparently do not result in measurable concentrations of the compounds in the river. In contrast to this apparently well performing municipal WWTP the industrial WWTP of the former chemical manufacturing site was reported to perform badly, so high sediment concentrations of UV-327 and UV-328 are found downstream of the former industrial WWTP. Extraction methods for sediment samples used in the field studies cited in 3.1.3 are given below. With regard to the NER discussion see also our general comment above. For the analysis of the sediment samples **Lopez-Avila and Hites (1980) and Jungclaus et al. (1978)** allowed the freezed sediment samples to thaw at room temperature and then sieve-washed them through a 2-mm stainless steel screen. Excess water was decanted and the wet sediment was Soxhlet extracted for several hours with nanograde isopropyl alcohol. A further extraction with nanograde benzene was then necessary to isolate the PAH. The isopropanol extract was evaporated to dryness on a rotary evaporator at 30-40°C, the benzene extract was freed of elemental sulphur by passage through a column of colloidal copper. Some of the sediment samples were also liquid chromatograhically separated into hexane, benzene and methanol fractions on a column containing about 1 g of 5% water-deactivated silica gel.

				Hartmann et al., 2005 weighed ca. 10 g ww of the homogenized sample into a 60 mL Teflon centrifuge tube. Acetonitrile was then added to bring the total volume to 15 mL. The sample was hand agitated, and 10 mL of hexane was added. The centrifuge tube was then shaken vigorously by hand and then placed on the metabolic shaker for 1 h at 50 °C. After cooling to room temperature, 10 mL of Milli-Q water was added and then shaken vigorously. The sample was then centrifuged for 4 min to separate the hexane layer from the water/acetonitrile layer. The top hexane layer (8 mL) was drawn off with a Pasteur pipette. The sample was extracted two more times by adding 10mL of hexane, shaking, centrifugation, and drawing off the hexane layer. The combined hexane fraction (25 mL) was rotoevaporated down to 1 mL at which point 2 g of activated copper powder were added and allowed to stand overnight for the removal of elemental sulfur. A Pasteur pipette was used to draw off the hexane from the copper powder and then charge it onto a fully activated silica gel column. The copper powder was rinsed with an additional 1 mL of hexane, which was added to the column. The sample was then eluted in one fraction (20 mL of methylene chloride) into a 25mL graduated cylinder. The fraction was stored in the dark until analyzed. **Pruell and Quinn (1985):** 10-100 g ww sediment were placed in a flask along with a 5:1 (vol:weight) excess of methanol. This mixture was refluxed for 2 h, cooled and filtered through a class fibre filter. The filter was rinsed with petroleum ether and combined with the filtrate which was then added to distilled water in a separatory funnel. The water:methanol mixture was extracted 3 times with petroleum ether and the extracts were combined and reduced to ca. 1 ml using rotary evaporation under reduced pressure at 20 °C. The extracts were separated into 3 fractions by silica gel chromatography. **Reddy et al. (2000)** operationally defined the free fraction of phenolic benzotriazoles by the following extraction method. 15 mL of a 60/40 mixture of acetonitrile/hexane was added to a vial with ca. 0.5-5g wet sediment. The vial was shaken for 10 s and then placed in a boiling water bath for 30 min. After being cooled, the vial was centrifuged and the liquid layers were

				drawn off into a separatory funnel leaving the sediment residue in the vial. The funnel contained 50 mL of deionized water adjusted to a pH of 4, which would ensure that the phenolic hydroxyl groups would be protonated. The sediment residue was then extracted 4 more times in the same manner. The liquid layers were also added to the original separatory funnel. The hexane layer was removed from the separatory funnel and the remaining aqueous/acetonitrile solution was extracted with 25 mL of hexane two more times. All of the hexane extracts were combined, rotary evaporated to dryness and acetylated. The bound fraction was defined by the following procedure. The sediment residue from the above procedure was saponified in 2 N KOH in 90/10 methanol/water in a boiling water bath for 4 h. After being cooled, the pH of the mixture was adjusted to ca. 4 with 4 N HCl and the mixture was extracted 3 times with hexane. All hexane extracts were combined, rotary-evaporated and acetylated. 2.1.4 We still think that finding in biota is important but made it very clear in our dossier that Nakata is supporting evidence, only. Habitat and nutrition behaviour of finless porpoise fit well to the finding and give a plausible picture. The BAF value of 33 300 was directly taken from the Results and Discussion part of the publication of Nakata (Nakata H, Shinohara R, Murata S, Watanabe M. 2010 Aug. Detection of benzotriazole UV stabilizers in the blubber of marine mammals by gas chromatography-high resolution mass spectrometry (GC-HRMS). J Environ Monit(12):2088-2092). We did not perform any own calculation of BAF in this dossier. NITE 2012 gives results for two concentrations but there are two tests on the lower concentration. Thus there are three results. The additional information we got from NITE in 2012 clearly show a third concentration area. We researched the data again on http://www.safe.nite.go.jp/jcheck//template.action?ano=21958&mno=5-3604&cno=25973-55-1&request_locale=en on 2014-05-11 but found two test results, only. We have no explanation for this difference. Our BCF data vary showing higher values with lower test

				concentration one of which clearly shows a BCF above the trigger value without lipid normalization. For the two test results still listed on JCheck the BCF values vary between 570 and 1800 again without lipid normalization. Please note that these represent individual data values but not averaged ones as presented in our table. We presented and assessed all available data on bioaccumulation. There are two tests rated reliable with restriction. One shows that UV 328 is bioaccumulative and the other one that it is very bioaccumulative. REACH stipulates that a precautionary principle should be followed. Thus, in such cases it is necessary to assess a substance using the worst case. This was done here. Consequently, UV 328 is very bioaccumulative. Nevertheless, all data available was considered in the assessment process. Available information is sufficient to assess bioaccumulation of UV 328 and data do not justify another test on vertebrates. Furthermore, a dietary test on bioaccumulation would result in a BMF for which no trigger value exists at present. This would add only a value which is not clear-cut. Problems with highly adsorptive substances in aquatic tests systems do exist and it is possible that the organisms were exposed via the oral route, too. This might have led to an overestimation of the BCF. It is also possible that the substance may have been adhered to the glass walls but as well to dissolved carbon, e.g. faeces. Adsorption to dissolved carbon results in a lowered bioavailability. As mentioned in the dossier already this would lead to an underestimation of BCF because the active extraction normally used cannot detect it. Thus, there are two competing effects to be considered one over- and one underestimating the BCF. Adsorption to the glass wall and lowered test concentration should have been detected in the water extractions but it may be expected that it would have been corrected because one basic condition of the test system is a steady test concentration.

3	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 please 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 would like to refer to our RMO assessment: Due to limited information we cannot conclude there is an existing risk according to article 69(4) of REACH. Furthermore, we also lack the detailed knowledge for assessing the availability of feasible alternatives, especially considering the specialised uses of these substances. We therefore concluded that the phenolic benzotriazoles exhibiting SVHC-properties should be regulated via authorisation and be substituted in the long run (when feasible alternatives are available). This assessment is supported by relevant uses described in the registration dossier of the substance. It is possible that there are uses outside the scope of authorisation especially with regard to imported articles. This problem would have to be assessed after the inclusion of the substance in Annex XIV via the provisions of article 69(2).

4	2014/10/16	National NGO CHEM Trust United Kingdom	CHEM Trust supports the inclusion of (2H-Benzotriazol-2-yl)-4,6-ditertpentylphenol 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.
5	2014/10/16	Member State Norway	The Norwegian CA supports the proposal to identify 2-(2H-benzotriazol-2-yl)-4,6-ditertpentylphenol (UV-328) 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 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 on regulation of 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.
7	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
8	2014/10/16	International NGO ChemSec Sweden	Comments on the proposed SVHC property/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 based on the hazardous properties shown below:	Thank you for your support and the detailed assessment you provided in your own PBT-evaluation. Both evaluations agree in their assessment.

			This substance has persistent, bioaccumulative and toxic properties. It has been found in a variety of environmental samples and in different marine organisms. Estimated and experimental data show PBT properties. CAS 15571-58-1 is listed on the SIN List since October 2014 based on the information in the included confidential report. *Confidential attachment removed*	

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

Specific comments on uses, exposures, alternatives and risks

No.	Date	Submitted by (name, Organisation/MSCA)	Comment	Response
2	2014/10/15	Company Belgium	Full comments are provided in the attachments. The use of UV-328 by the submitter of the comments, a downstream user, does not constitute a wide dispersive use (limited number of sites, limited or no release). Even more, downstream there is very limited or no exposure. There are currently no suitable alternatives known. 2_2014-10-15 UV-328 consultation Cand List-non-confidential-public.pdf *Confidential attachment removed*	Thank you for your detailed comments. This information is valuable in the potential later stage of inclusion in the Annex XIV. With regard to the information on uses provided in the registration dossier apart from the use you describe there are relevant uses which are within the scope of authorization.
8	2014/10/16	International NGO ChemSec Sweden	*Confidential attachment removed*	Thank you for providing this document.