

AGREEMENT OF THE MEMBER STATE COMMITTEE

ON THE IDENTIFICATION OF

2-BENZOTRIAZOL-2-YL-4,6-DI-TERT-BUTYLPHENOL (UV-320)

AS A SUBSTANCE OF VERY HIGH CONCERN

According to Articles 57 and 59 of Regulation (EC) 1907/2006¹

Adopted on 27 November 2014

This agreement concerns

Substance name: 2-benzotriazol-2-yl-4,6-di-tert-butylphenol (UV-320)

EC number: 223-346-6

CAS number: 3846-71-7

Molecular formula: C20H25N3O

Structural formula:

OH N

¹ Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC

Germany presented a proposal in accordance with Article 59(3) and Annex XV of the REACH Regulation (26 August 2014, submission number DU001625-32) on identification of 2-benzotriazol-2-yl-4,6-di-tert-butylphenol (UV-320) as a substance of very high concern due to its persistence, bioaccumulation and toxic properties.

The Annex XV dossier was circulated to Member States on 1 September 2014 and the Annex XV report was made available to interested parties on the ECHA website on the same day according to Articles 59(3) and 59(4).

Comments were received from both Member States and interested parties on the proposal.

The dossier was referred to the Member State Committee on 17 November 2014 and agreed in the written procedure of the Member State Committee with closing date of 27 November 2014.

Agreement of the Member State Committee in accordance with Article 59(8):

2-benzotriazol-2-yl-4,6-di-tert-butylphenol (UV-320) is identified as a substance of very high concern because

- it meets the criteria of Article 57 (d) of Regulation (EC) 1907/2006 (REACH) as a substance which is persistent, bioaccumulative and toxic, and
- it meets the criteria of Article 57 (e) of Regulation (EC) 1907/2006 (REACH) as a substance which is very persistent and very bioaccumulative,

in accordance with the criteria and provisions set out in Annex XIII of Regulation (EC) 1907/2006 (REACH).

UNDERLYING ARGUMENTATION FOR IDENTIFICATION OF SUBSTANCE OF VERY HIGH CONCERN

Persistence:

The persistence of UV-320 has been assessed by using a weight of evidence approach.

Conclusions of the weight of evidence approach:

- ready biodegradation test of UV-320 suggest the substance is not subject to biological degradation (0% after 28 days);
- There are no simulation tests on UV-320 for water and sediment. The degradation of the substance EC 407-000-3 (Reaction mass of branched and linear C7-C9-alkyl-3-[3-(2-H-benzotriazol-2-yl)-5-(1,1-dimethyl)-4hydroxyphenyl]-propionates) was studied in several simulation tests. In these studies, a major degradation product M1 was analyzed. This metabolite is structurally very similar to UV-320 only with a minor different substitution group in position 4 of the phenolic ring and was therefore used in a read-across assessment for UV-320. M1 was formed in the water phase, and dissipated rapidly in a few days to the sediment compartment. In the sediment, M1 is persistent with calculated disappearance half-lives up to 238 and 248 days depending on the sediment type. As the disappearance in this case has to be faster than the degradation of M1, DegT50-values in turn have to be higher than the DT50-values. The differing side chain of M1 will be faster degraded than that of UV-320. Therefore, and assuming that the fate properties of UV-320 and M1 are very similar in a degradation simulation test, the results on M1 may be expected to be a best case representative on the disappearance and degradation of UV-320;
- In recent field study dissipation in soil using the structural very similar substance UV-328 was tested. Using the results of this test, a DT50 of up to 223 days was calculated. As the disappearance has to be shorter or as long as the degradation, the respective DegT50-values will have to exceed the numerical vP-criterion of 180 days for the soil compartment as defined in Annex XIII as well. These results were taken as a read-across on UV-320;

 For the very similar substances UV-327 and UV-328 available monitoring studies indicate presence of the substances in sediments decades after environmental releases had stopped. Model calculations indicate that these findings can only be explained if the half-life for degradation is exceeding the Annex XIII trigger of 180 days. These results on UV-327 and UV-328 were taken as a read-across on UV-320;

Thus, applying the weight of evidence approach, UV-320 clearly fulfils the P- and vP-criteria of REACH Annex XIII as defined under Sections 1.1.1. and 1.2.1.

Bioaccumulation:

In a BCF study on fish according to the OECD Guideline 305 C lipid normalized BCF values of 5905 and 12041 were found in two of the three test concentrations. Therefore UV-320 fulfils the B (BCF >2000) and vB criterion (BCF >5000) of REACH Annex XIII as defined under Sections 1.1.2. and 1.2.2.

Toxicity:

There is evidence based on the RAC opinion² on UV-320 that indicates that the substance meets the criteria for classification as STOT RE 2 as defined in the CLP Regulation (EC) 1272/2008. As a consequence, the toxicity criterion of REACH Annex XIII is fulfilled.

Conclusion:

In conclusion, UV-320 meets the criteria for a PBT/vPvB-substance according to Article 57 (d) and Article 57 (e) of REACH.

Reference:

Support Document 2-benzotriazol-2-yl-4,6-di-tert-butylphenol (UV-320) (Member State Committee, 27 November 2014)

² http://echa.europa.eu/documents/10162/13641/rac opinion uv-320-328 en.pdf