

2 March 2017

Draft background document for 2-(2H-benzotriazol-2-yl)-4-(tert-butyl)-6-(sec-butyl)phenol (UV-350)

Document developed in the context of ECHA's eighth recommendation for the inclusion of substances in Annex XIV

ECHA is required to regularly prioritise the substances from the Candidate List and to submit to the European Commission recommendations of substances that should be subject to authorisation. This document provides background information on the prioritisation of the substance, as well as on the determination of its draft entry in the Authorisation List (Annex XIV of the REACH Regulation). Information comprising confidential comments submitted during public consultation, or relating to content of registration dossiers which is of such nature that it may potentially harm the commercial interest of companies if it was disclosed, is provided in a confidential annex to this document.

Information relevant for prioritisation and/or for proposing Annex XIV entries provided during the public consultation on the inclusion of 2-(2H-benzotriazol-2-yl)-4-(tert-butyl)-6-(sec-butyl)phenol (UV-350) on the Authorisation List or in the registration dossiers (as of the last day of the public consultation, i.e. 2 June 2017) will be taken into consideration when finalising the recommendation and will be reflected in an update of the present document.

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1. Identity of the substance

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| Chemical name: | 2-(2H-Benzotriazol-2-yl)-4-(tert-butyl)-6-(sec-butyl)phenol (UV-350) |
| EC Number: | 253-037-1 |
| CAS Number: | 36437-37-3 |
| IUPAC Name: | 2-(2H-Benzotriazol-2-yl)-6-sec-butyl-4-tert-butylphenol |

2. Background information for prioritisation

Priority was assessed by using the General approach for prioritisation of SVHCs for inclusion in the list of substances subject to authorisation¹. Results of the prioritisation of all substances included in the Candidate List by December 2015 and not yet included or recommended in Annex XIV of the REACH Regulation is available at https://echa.europa.eu/documents/10162/13640/prioritisation_results_CL_substances_march_2017_en.pdf.

2.1. Intrinsic properties

2-(2H-Benzotriazol-2-yl)-4-(tert-butyl)-6-(sec-butyl)phenol (UV-350) was identified as a Substance of Very High Concern (SVHC) according to Article 57(e) as it meets the criteria of a vPvB substance and was therefore included in the Candidate List for authorisation on 17 December 2015, following ECHA's decision ED/079/2015.

2.2. Volume used in the scope of authorisation

There are currently no registrations for 2-(2H-benzotriazol-2-yl)-4-(tert-butyl)-6-(sec-butyl)phenol (UV-350) under Regulation (EC) No 1907/2006 (REACH)².

2.3. Wide-dispersiveness of uses

There are currently no registrations for 2-(2H-benzotriazol-2-yl)-4-(tert-butyl)-6-(sec-butyl)phenol (UV-350) under Regulation (EC) No 1907/2006 (REACH)².

More information is provided in Annex I.

2.4. Further considerations for priority setting

UV-328 is the only registered substance (ECHA, 2016) from the group of phenolic benzotriazoles including UV-320, UV-327 (substance in article notification available) and UV-350 prioritised in this recommendation. Due to structural similarities and similar physico-chemical properties it appears that the four phenolic benzotriazoles can be used as UV stabilisers in similar types of applications (e.g. in plastic articles or coatings) (Annex XV report, 2015) indicating the potential to substitute each other in (some of) their uses.

¹ Document can be accessed at http://echa.europa.eu/documents/10162/13640/gen_approach_svhc_prior_in_recommendations_en.pdf

² Number of registrations as of 25 October 2016. Substances (other than CMRs) manufactured or imported at volumes between 1 and 100 tonnes/year have to be registered by 1 June 2018.

2.5. Conclusion

On the basis of grouping considerations 2-(2H-benzotriazol-2-yl)-4-(tert-butyl)-6-(sec-butyl)phenol (UV-350) is proposed to be prioritised for inclusion in Annex XIV.

3. Background information for the proposed Annex XIV entry

Draft Annex XIV entries were determined on the basis of the General approach for preparation of draft Annex XIV entries for substances to be included in Annex XIV³ and as further specified in the practical implementation document⁴. The draft Annex XIV entries for all the substances included in this draft recommendation are available at https://echa.europa.eu/documents/10162/13640/8th_recom_draft_axiv_entries_en.pdf.

3.1. Latest application and sunset dates

ECHA proposes to recommend the following transitional arrangements:

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|--------------------------------|--|
| Latest application date (LAD): | Date of inclusion in Annex XIV plus 21 months |
| Sunset date: | 18 months after LAD |

The LAD slots are set in 3 months intervals (normally 18, 21 and 24 months after inclusion in Annex XIV).

Allocation of (group of) substances to LAD slots aims at an even workload for all parties during the opinion forming and decision making on the authorisation applications. All substances can therefore not be set at the same LAD. ECHA proposes to allocate those substances to the "later" LAD slots (21 months or more) for which the available information indicates a relatively higher complexity of supply chain.

Applying the criteria described in the implementation document⁴ the time required for the preparation of application(s) for authorisation for the group of phenolic benzotriazoles (UV-320, UV-327, UV-328 and UV-350) is assumed to be relatively longer than for other substances prioritised for this recommendation (NMP, karanal group⁵). For the phthalate, in comparison, the complexity of the supply chain seems to be slightly higher.

Therefore 2-(2H-benzotriazol-2-yl)-4-(tert-butyl)-6-(sec-butyl)phenol (UV-350) is assigned to the 2nd slot (LAD 21 months after inclusion in Annex XIV).

³ General approach can be accessed at http://echa.europa.eu/documents/10162/13640/recom_general_approach_draft_axiv_entries.pdf

⁴ Practical implementation document can be accessed at https://echa.europa.eu/documents/10162/13640/recom_general_approach_draft_axiv_entries_implementation_en.pdf

⁵ 5-sec-butyl-2-(2,4-dimethylcyclohex-3-en-1-yl)-5-methyl-1,3-dioxane [1], 5-sec-butyl-2-(4,6-dimethylcyclohex-3-en-1-yl)-5-methyl-1,3-dioxane [2] [covering any of the individual stereoisomers of [1] and [2] or any combination thereof]

3.2. Review period for certain uses

ECHA proposes not to include in Annex XIV any review period for 2-(2H-benzotriazol-2-yl)-4-(tert-butyl)-6-(sec-butyl)phenol (UV-350).

3.3. Uses or categories of uses exempted from authorisation requirement

3.3.1 Exemption under Article 58(2)

ECHA proposes not to recommend exemptions for uses of 2-(2H-benzotriazol-2-yl)-4-(tert-butyl)-6-(sec-butyl)phenol (UV-350) on the basis of Article 58 (1)(e) in combination with Article 58(2) of the REACH Regulation.

3.3.2 Exemption of product and process oriented research and development (PPORD)

ECHA proposes not to recommend to include in Annex XIV any exemption from authorisation for the use of 2-(2H-benzotriazol-2-yl)-4-(tert-butyl)-6-(sec-butyl)phenol (UV-350) for PPORD.

4. References

Annex XV report (2015): Proposal for identification of a substance as a CMR Cat 1A or 1B, PBT, vPvB or a substance of an equivalent level of concern. 2-(2H-benzotriazol-2-yl)-4-(tert-butyl)-6-(sec-butyl)phenol (UV-350) Submitted by Germany, August 2015.

<https://www.echa.europa.eu/documents/10162/0a09c8af-c7d2-4524-a880-6cb10ddcd1ac>

ECHA (2016): 2-(2H-Benzotriazol-2-yl)-4-(tert-butyl)-6-(sec-butyl)phenol (UV-350). ECHA's dissemination website on registered substances. Accessed on 25 October 2016.

<https://echa.europa.eu/search-for-chemicals>

ANNEX I: Further information on uses

UV-350 as well as other substances belonging to the chemical group of phenolic benzotriazoles (UV-320, UV-327, UV-328) are generally used as UV-stabilisers since they can absorb the full spectrum of UV light. It seems that this substance class is used as UV protection agent in plastics, rubber, resins and cosmetics as well as in coatings for e.g. cars and wood. The different phenolic benzotriazoles have different substitution pattern in ortho- and para-position to the hydroxyl group of the phenolic ring. This difference has effects on the solubility and the distinct coloration in different transparent plastic materials (Annex XV report, 2015).

According to the C&L Inventory, UV-350 has been notified by 146 companies (six aggregated notifications)⁶.

⁶ C&L Inventory can be found at <https://www.echa.europa.eu/web/guest/information-on-chemicals/cl-inventory-database>, accessed on 24 January 2017