RISK MANAGEMENT OPTION ANALYSIS

CONCLUSION DOCUMENT

for

2-(2H-Benzotriazol-2-yl)-6-sec-butyl-4(2-methyl-2-propanyl)phenol (UV-350)

EC No 253-037-1

CAS No 36437-37-3

Member State(s): Germany

Dated: 12 June 2015

Disclaimer: Please note that this RMOA conclusion was compiled on the basis of available information and may change in the light of new information or further assessment.

Foreword

The purpose of Risk Management Option analysis (RMOA) is to help authorities decide whether further regulatory risk management activities are required for a substance and to identify the most appropriate instrument to address a concern.

RMOA is a voluntary step, i.e., it is not part of the processes as defined in the legislation. For authorities, documenting the RMOA allows the sharing of information and promoting early discussion, which helps lead to a common understanding on the action pursued. A Member State or ECHA (at the request of the Commission) can carry out this case-by-case analysis in order to conclude whether a substance is a 'relevant substance of very high concern (SVHC)' in the sense of the SVHC Roadmap to 2020[1].

An RMOA can conclude that regulatory risk management at EU level is required for a substance (e.g. harmonised classification and labelling, Candidate List inclusion, restriction, other EU legislation) or that no regulatory action is required at EU level. Any subsequent regulatory processes under the REACH Regulation include consultation of interested parties and appropriate decision making involving Member State Competent Authorities and the European Commission as defined in REACH.

This Conclusion document provides the outcome of the RMOA carried out by the author authority. In this conclusion document, the authority considers how the available information collected on the substance can be used to conclude whether regulatory risk management activities are required for a substance and which is the most appropriate instrument to address a concern. With this Conclusion document the Commission, the competent authorities of the other Member States and stakeholders are informed of the considerations of the author authority. In case the author authority proposes in this conclusion document further regulatory risk management measures, this shall not be considered initiating those other measures or processes. Since this document only reflects the views of the author authority, it does not preclude other Member States or the European Commission from considering or initiating regulatory risk management measures which they deem appropriate.

[1] For more information on the SVHC Roadmap: http://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern

1. OVERVIEW OF OTHER PROCESSES / EU LEGISLATION

Germany already submitted an SVHC-Dossier on UV-350 in 2013. However, "due to the need for further consideration of the documentation provided by the dossier submitter during the (MSC) meeting, the Member State Committee agreed that it is currently not possible to conclude on the identification of 2-(2H-benzotriazol-2-yl)-4-(tert-butyl)-6-(sec-butyl)phenol (UV-350) as a substance of very high concern." The RMOA of UV-350 was revised in May 2015 and a revised SVHC-Dossier will be submitted in August 2015. No other completed/ongoing processes (including RMOA) and EU legislation relevant for the substance are known.

2. CONCLUSION OF RMOA

This conclusion is based on the REACH and CLP data as well as other available relevant information taking into account the SVHC Roadmap to 2020, where appropriate.

Conclusions	**Tick box**
Need for follow up regulatory action at EU level	X
Harmonised classification and labelling	
Identification as SVHC (authorisation)	X
Restrictions	
Other EU-wide measures	
No need for regulatory follow-up action	

3. FOLLOW-UP AT EU LEVEL

3.1 Need for follow-up regulatory action at EU level

3.1.1 Identification as a substance of very high concern, SVHC (first step towards authorisation)

UV-350 may be used as a UV stabilizer for plastics, polyurethanes and rubber and in formulations used for coating of surfaces. It is unclear if UV-350 is used in the EU in relevant amounts. There are alternatives to UV-350, but so far it is uncertain if they are technically feasible for the same uses. At least some of these alternatives seem to have problematic properties by themselves.

UV-350 appears to fulfil the Art. 57 (e) criteria set out in Annex XIII according to the following data:

Persistence:

The persistence of UV-350 has been assessed by using a weight of evidence approach.

Conclusions of the weight of evidence approach:

- Results of the screening test on similar substances (UV-320, UV-327 and UV-328) along with the QSAR-results on UV-350 indicate a very low potential for biodegradation.
- 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)-4-hydroxyphenyl]-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-350 only with a minor different substitution group in position four and six of the phenolic ring. 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 (DT_{50}) 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, degradation half-lives ($DegT_{50}$-values) in turn have to be higher than the DT_{50}-values. Therefore they will have to exceed the vP-trigger for sediment as defined in Annex XIII. As the differing side chain of M1 will be degraded faster than that of UV-350, $DegT_{50}$-values for UV-350 have to be even higher.

- In a recent field study on dissipation in soil phenolic benzotriazoles were tested. The results indicate that the persistence of similar substances (UV-327, UV-328) has to be higher than the numerical vP-criterion of 180 days for the soil compartment as defined in Annex XIII.
- In a very recent water/sediment study according to OECD 308 (non-GLP), UV-350 rapidly and completely dissipated to sediment and was practically not degraded over 100 days (recovery 99 %).
- For 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.
- Thus, applying the weight of evidence approach, UV-350 seems to fulfil the P- and vP-criteria of REACH Annex XIII.

Bioaccumulation:

UV-350 was tested in a bioconcentration study according to OECD 305 C. Two different substance concentrations were tested in common carp (*Cyprinus carpio*) in the tests.

Table: BCF reported and BCF lipid normalised of UV-350 (values refer to whole body wet weight basis)

Test concentration in µg/L	$BCF_{reported}$	$BCF_{lipid\text{-}normalised}$
1.0	7700[1]	20263
0.1	13000[1]	34210

[1] Average lipid content of test fish 1.89 %

The data presented in the assessed studies suggest that UV-350 fulfils the B- and vB-criteria of REACH Annex XIII.

Consideration of authorisation:

As shown above UV-350 is considered a vPvB substance and thus can be identified as an SVHC. The objective for further risk management in this case is the identification of UV-350 as SVHC and in the long-term its substitution with substances or technologies of less concern.
Inclusion of UV-350 in the candidate list would trigger the obligation to inform downstream users as of REACH Article 33, if the substance is present in an article at a concentration > 0.1 %. Furthermore manufacturers and importers must notify ECHA if the substance is present in articles at concentrations > 0.1 % by weight (REACH

Article 7), if they are present in the articles at a tonnage level > 1 t/a and exposure of humans or the environment cannot be ruled out.

It is furthermore a strong signal to enterprises manufacturing, importing, and using these substances as such or in articles that the identified substances have properties of concern and should be substituted. This might then lead to the decision of a producer or downstream user to switch to a less hazardous alternative.

In conclusion, SVHC identification is necessary as a first regulatory step for, e.g., obtaining further information on uses of UV-350 and quantities put on the market, especially when dealing with imported articles. Up to now there is no complete picture of the (imported) articles containing the substances, so these obligations might trigger the need for further regulation.

In order to achieve the ultimate objective of substitution of UV-350 SVHC-identification may be followed by inclusion in Annex XIV, i.e. the authorisation procedure. A drawback of this option is that it would preclude later restrictions based on its SVHC properties (except for consumer products) as per article 58 (5). However, this regulatory management option achieves the risk reduction objective substitution as far as uses of the substance within the EU are concerned.

In conclusion the substitution target could be achieved both by an inclusion in Annex XIV or a restriction after an SVHC-identification. Currently there is not enough information on UV-350 in imported articles, so a combination of SVHC-identification followed by the authorisation process is considered to be the most appropriate combination of risk management options at this point in time.

3.1.2 Restriction

SVHC-identification might also be followed by a restriction. Advantages of this option are that imported articles can be covered and no regulatory follow-up process is triggered after an inclusion in Annex XVII. Furthermore, a restriction can selectively be imposed on substances as such, in mixtures and/or articles, i.e. a positive definition of restricted uses is possible, whereas under the authorisation procedure only exceptions to the general rule may be defined. However, based on the known uses there seems to be no need for a targeted restriction.

However, SVHC identification might yield further information on uses of UV-350 and quantities put on the market, especially with regard to imported articles. Up to now there is no complete picture of the (imported) articles containing the substance, so these obligations might trigger the need for further regulation, i.e. a restriction of imported articles.

4. TENTATIVE PLAN FOR FOLLOW-UP ACTIONS IF NECESSARY

Indication of a tentative plan is not a formal commitment by the authority. A commitment to prepare a REACH Annex XV dossier (SVHC, restrictions) and/or CLP Annex VI dossier should be made via the Registry of Intentions.

Follow-up action	Date for intention	Actor
Annex XV dossier for SVHC identification	August 2015	Germany