Note for the attention of Tim Bowmer, Chairman of the Committee for Risk Assessment

Ref: Request to the Committee for Risk Assessment for an opinion on repeated dose toxicity of two phenolic benzotriazoles (UV-320 and UV-328) proposed by Germany for SVHC identification

The Committee for Risk Assessment (RAC) is requested to draw up an opinion on whether **2-benzotriazol-2-yl)-4,6-di-tert-butylphenol** (UV-320) and **2-(2H-benzotriazol-2-yl)-4,6-ditertpentylphenol** (UV-328) meet the criteria for repeated dose toxicity (STOT RE).

1. Background

The German Member State Competent Authority has submitted a proposal to ECHA for discussion with a view to include UV-320 and UV-328 on the candidate list of Substances of Very High Concern (SVHC) by reason of their identification as PBT.

Sections 1.1.3. and 3.2.3 of Annex XIII of the REACH Regulation provide that the toxicity criterion (T) for PBT identification is fulfilled i.a where the substance meets the criteria for classification for specific target organ toxicity after repeated exposure (STOT RE category 1 or 2).

According to the submitted SVHC Annex XV dossiers, the assessment of repeated dose toxicity of the two substances is based on a 28-day repeated dose toxicity study in rats (further information is available in IUCLID 5) for UV-320 and on a brief summary of a 90-day repeated dose toxicity study in Wistar rats for UV-328.

2. Terms of Reference

To allow the Member State Committee (MSC) to assess whether the proposed substances fulfil the criteria of Annex XIII of REACH for a Persistent, Bioaccumulative and Toxic (PBT) substance, recognising that UV-320 and UV-328 currently have no entry in Annex VI of the CLP Regulation which would cover repeated dose toxicity and that the Committee for Risk Assessment is tasked under the CLP Regulation with the responsibility for developing opinions on harmonised classification and labelling, pursuant to Art. 77(3)(c) of REACH, the Executive Director of ECHA therefore requests the RAC to develop an opinion on the repeated dose toxicity of these two substances as follows:

a) Assess whether the information provided in the SVHC Annex XV dossiers is sufficient to develop an opinion of a similar robustness to a CLH opinion,

b) Assess whether the information provided shows that the substance meets the criteria for classification for specific target organ toxicity after repeated exposure (STOT RE category 1 or 2) under CLP.

It should be noted that this request is not intended as a request for an opinion on harmonised classification and labelling as such; it is solely intended to provide advice to the MSC in this specific case. This request specifically does not cover the assessment of 'P' and 'B' or 'vP' and 'vB' criteria as this is the competence of the MSC.

3. Timescale for the RAC opinion

The SVHC Annex XV dossiers as prepared by the German Competent Authority are subject to a 45-day public consultation which has been launched on 4 March 2013. The comments provided in this public consultation on the 'T' hazard should be taken into account when RAC opinion is developed.

Therefeore, the opinion of the RAC is requested at the latest at its 25th plenary meeting from 3 to 7 June 2013 and preferably before this date (by written procedure) in order to allow the MSC to meet their legal deadline for dealing with these substances.

4. Remuneration

The task for RAC following from this request is not considered to fulfil any of the requirements of a transfer of funds to the competent authorities of the Member States pursuant to Article 14(1) of Regulation (EC) 340/2008 and therefore no remuneration will be paid by the Agency.

[signed]
Geert Dancet
Executive Director

Cc: Jukka Malm, Jack de Bruijn