5 September 2018

Draft background document for 4,4'-bis(dimethylamino)-4''-(methylamino)trityl alcohol [with ≥ 0.1% of Michler's ketone (EC 202-027-5) or Michler's base (EC 202-959-2)]

Document developed in the context of ECHA's ninth 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.

Only for the purpose of easier reading, **trityl alcohol** is used throughout this document when referring to 4,4'-bis(dimethylamino)-4''-(methylamino)trityl alcohol with ≥ 0.1% of Michler's ketone (EC 202-027-5) or Michler's base (EC 202-959-2).

Information relevant for prioritisation and/or for proposing Annex XIV entries provided during the public consultation on the inclusion of trityl alcohol on the Authorisation List or in the registration dossiers (as of the last day of the public consultation, i.e. 5 December 2018) will be taken into consideration when finalising the recommendation and will be reflected in the final background document.

Contents

1. Identity of the substance

Identity of the substance as provided in the Candidate List[1]:

Name: 4,4'-bis(dimethylamino)-4''-(methylamino)trityl alcohol)[2]
EC Number: 209-218-2
CAS Number: 561-41-1

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 authorisation[3]. Results of the prioritisation of all substances included in the Candidate List by January 2018 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_sept_2018_en.pdf.

2.1. Intrinsic properties

Michler's ketone (4,4'-bis(dimethylamino)benzophenone; EC 202-027-5) is listed as Index number 606-073-00-0 in Regulation (EC) No 1272/2008 (the CLP Regulation) and classified in Annex VI, part 3, Table 3.1 (list of harmonised classification and labelling of hazardous substances) for carcinogenicity, Carc. 1B (H350: "May cause cancer").

Michler's base (N,N,N',N'-tetramethyl-4,4'-methylenedianiline; EC 202-959-2) is listed as Index number 612-201-00-6 in the CLP Regulation and classified in Annex VI, part 3, Table 3.1 for carcinogenicity, Carc. 1B (H350: "May cause cancer").

Where 4,4'-bis(dimethylamino)-4''-(methylamino)trityl alcohol) contains Michler's ketone or Michler's base ≥ 0.1%[4], it meets the criteria for classification as a carcinogen.

Therefore, 4,4'-bis(dimethylamino)-4''-(methylamino)trityl alcohol) *[with ≥ 0.1% of Michler's ketone (EC 202-027-5) or Michler's base (EC 202-959-2)]* (abbreviated throughout this background document as **trityl alcohol**) was identified as a Substance of Very High Concern (SVHC) according to Article 57 (a) of Regulation (EC) 1907/2006 (REACH) as it meets the criteria for classification as a carcinogen, Category 1B (H350: "May cause cancer") according to Regulation (EC) No 1272/2008 (CLP). It was therefore included in the Candidate List for authorisation on 18 June 2012, following ECHA's decision ED/87/2012.

[1] For further information please refer to the Candidate List and the respective support document at https://www.echa.europa.eu/candidate-list-table.
[2] The substance is an SVHC only where it contains Michler's ketone (EC Number: 202-027-5) or Michler's base (EC Number: 202-959-2) ≥ 0.1% (wt/wt).
[3] Document can be accessed at http://echa.europa.eu/documents/10162/13640/gen_approach_svhc_prior_in_recommendations_en.pdf
[4] There are no specific concentration limits for classification in Annex VI of the CLP Regulation with regard to Michler's ketone or Michler's base. Therefore, the generic concentration limit for carcinogens, Carc. 1B of ≥ 0.1% applies (see Table 3.6.2 in Part 3 of Annex I to the CLP Regulation).

2.2. Volume used in the scope of authorisation

The amount of trityl alcohol manufactured and/or imported into the EU is according to registration data in the range of 10-100 t/y (ECHA, 2018).

All tonnage appears to be in the scope of authorisation.

2.3. Wide-dispersiveness of uses

Registered uses of trityl alcohol in the scope of authorisation include uses at industrial sites (formulation and use of printing inks) and uses by professional workers (use of printing inks). The substance is also used in printed articles.

More detailed information on uses is provided in Annex I.

2.4. Further considerations for priority setting

None.

2.5. Conclusion

Verbal descriptions and scores			Total score
Inherent properties (IP)	Volume (V)	Wide dispersiveness of uses (WDU)	(= IP + V + WDU)
Trityl alcohol is classified as a carcinogen meeting the criteria of Article 57 (a) Score: 1	The amount of trityl alcohol used in the scope of authorisation is in the range 10-100 t/y. Score: 6	Trityl alcohol is used at industrial sites and by professional workers. Initial score: 10 Furthermore, the substance is used in printed articles in volumes > 10 t/y Refined score: 12	19

Conclusion

On the basis of the prioritisation criteria trityl alcohol receives priority among the substances on the Candidate List (see link to the prioritisation results above). Therefore, it is proposed to prioritise trityl alcohol for inclusion in Annex XIV.

3. Background information for the proposed Annex XIV entry

3.1. Latest application and sunset dates

ECHA proposes the following transitional arrangements:

Latest application date (LAD):	Date of inclusion in Annex XIV plus **18, 21 or 24 months**
Sunset date:	18 months after LAD

ECHA will make the final LAD allocation when finalising the recommendation and will use all available relevant information including that received in the public consultation. ECHA will apply the Annex XIV entries approach[5] and the criteria described in the implementation document[6]. According to these documents, substances for which the available information indicates a relatively high number of uses and/or complex supply chain(s) are allocated to the "later" LAD slots.

A summary of the information currently available is provided in Annex I.

The time needed to prepare an authorisation application of sufficient quality has been estimated to require 18 months in standard cases. When setting the LADs ECHA has also to take into account the anticipated workload of ECHA's Committees and Secretariat to process authorisation applications. This is done by allocating the substances proposed to be included in the final recommendation in slots, normally 3, and setting the application dates with 3 months intervals in between these slots (standard LAD slots: 18, 21 and 24 months).

For substances to be included in the 9th recommendation, ECHA sees currently no reason to deviate from these standard LAD slots.

3.2. Review period for certain uses

ECHA proposes not to include in Annex XIV any review period for trityl alcohol.

In general, ECHA does not propose any upfront specific review periods in its draft recommendations for inclusion in the Authorisation List. Setting review periods in Annex XIV for any uses would require that ECHA had access to adequate information on different aspects relevant for a decision on the review period. Such information is generally not available to ECHA at the recommendation step. It is to be stressed that, in the next step of the authorisation process, i.e. during the decision on whether authorisation is granted based on specific applications by manufacturers, importers or downstream users of the substance, all authorisation decisions will include specific review periods which will be based on concrete case-specific information provided in the applications for authorisation.

[5] General approach can be accessed at https://echa.europa.eu/documents/10162/13640/recom_general_approach_draft_axiv_entries.pdf
[6] Practical implementation document can be accessed at https://www.echa.europa.eu/documents/10162/13640/recom_general_approach_draft_axiv_entries_draft_implementation_en.pdf

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 trityl alcohol on the basis of Article 58 (1)(e) in combination with Article 58(2) of the REACH Regulation.

According to Article 58(2) of REACH it is possible to exempt from the authorisation requirement uses or categories of uses '*provided that, on the basis of the existing specific Community legislation imposing minimum requirements relating to the protection of human health or the environment for the use of the substance, the risk is properly controlled*'.

ECHA considers the following elements in deciding whether to recommend an exemption of a use of a substance:

- There is existing EU legislation (i.e., rules of law adopted by a European Union entity intended to produce binding effects) addressing the specific use (or categories of use) that is proposed to be exempted;

- The existing EU legislation properly controls the risks to human health and/or the environment from the use of the substance arising from the intrinsic properties of the substance that are specified in Annex XIV; generally, the legislation in question should specifically refer to the substance to be included in Annex XIV either by naming the substance or by referring to a group of substances that is clearly distinct from other substances;

- The existing EU legislation imposes minimum requirements for the control of risks of the use. The piece of legislation (i) has to define the minimum standard to be adopted in the interest of public health or the environment and (ii) allows EU Member States to impose more stringent requirements than the specific minimum requirements set out in the EU legislation in question. Legislation setting only a general framework of requirements or the aim of imposing measures or not clearly specifying the actual type and effectiveness of measures to be implemented is not regarded as sufficient to meet the requirements under Article 58(2). Furthermore, it can be implied from the REACH Regulation that attention should be paid as to whether and how the risks related to the life-cycle stages resulting from the uses in question (i.e. service-life of articles and waste stage(s), as relevant) are covered by the legislation.

Where interested parties are considering making a request for exemption from authorisation under Art. 58(2) for a particular use, it is strongly recommended that they take into account ECHA's previous responses to Art. 58(2) exemption requests[7]. It is noted that any Art. 58(2) request is assessed case-by-case.

Furthermore, it should be noted that if a use falls under the generic exemptions from authorisation[8], there is no need to propose an additional specific exemption.

[7] See analysis of most relevant pieces of legislation e.g. in sections C.2.8 – C.2.12 in https://echa.europa.eu/documents/10162/b80fccc0-c055-7cd7-4743-8d3c26956b15, or in section C.2 in https://echa.europa.eu/documents/10162/b1820209-b7f4-4f87-998a-a996729c7375

[8] https://echa.europa.eu/documents/10162/13640/generic_exemptions_authorisation_en.pdf/9291ab2a-fe2f-418d-9ce7-4c5abaaa04fc

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 trityl alcohol for PPORD.

So far, ECHA has not considered it appropriate to recommend specific exemptions for PPORD for any substance. ECHA notes that an operator may use a substance included in Annex XIV for a PPORD activity if that operator has obtained authorisation for that use of the substance in accordance with Articles 60 to 64 of the REACH Regulation.

No PPORD notifications have been submitted for trityl alcohol[9].

[9] As of 1 February 2018.

4. References

Annex XV SVHC report (2012): Proposal for identification of a substance as a CMR Cat 1A or 1B, PBT, vPvB or a substance of an equivalent level of concern. 4,4'-bis(dimethylamino)-4''-(methylamino)trityl alcohol with ≥ 0.1% of Michler's ketone (EC 202-027-5) or Michler's base (EC 202-959-2). Submitted by ECHA, February 2012.

https://echa.europa.eu/documents/10162/ccf43c6b-352e-4a4b-97b4-c799f1a56c3e

ECHA (2018): 4,4'-bis(dimethylamino)-4''-(methylamino)trityl alcohol with ≥ 0.1% of Michler's ketone (EC 202-027-5) or Michler's base (EC 202-959-2). ECHA's dissemination website on registered substances. Accessed on 1 February 2018.

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

RCOM (2012): "*Responses to comments*" document. Document compiled by ECHA from the commenting period 27/02/2012- 12/04/2012 on the proposal to identify 4,4'-bis(dimethylamino)-4''-(methylamino)trityl alcohol with ≥ 0.1% of Michler's ketone (EC 202-027-5) or Michler's base (EC 202-959-2) as a Substance of Very High Concern.

https://echa.europa.eu/documents/10162/cff120ad-ba8c-4324-a00a-0447570b6032

Annex I: Further information on uses

Further details on the type of applications

The Annex XV SVHC report (2012) states that some C&L notifiers indicated "Solvent Violet 8" as a synonym for trityl alcohol. However, the Colour Index International identifies "Solvent Violet 8" with the CAS numbers 52080-58-7 and 67989-22-4 as well with the EC number 268-006-8 which do not match the numerical identifiers of trityl alcohol. Information on "Solvent Violet 8" and its uses are therefore not considered relevant for trityl alcohol.

There are some other dye substances containing Michler's ketone or Michler's base ≥ 0.1% on the Candidate List, however based on the currently available information it seems not justified to group any of these substances with trityl alcohol (since the uses/applications seem different).

In preparation of the SVHC report, industry stakeholders were consulted. The individual EU companies consulted reported uses of trityl alcohol such as formulation and production of writing inks (Annex XV SVHC report, 2012). No further details are available.

Structure and complexity of supply chains

The following assumptions are made based on currently available information and will be used, together with any relevant information from public consultation, to allocate trityl alcohol to a specific LAD slot in the final recommendation.

Trityl alcohol is manufactured/imported by a limited number of registrants. No precise and up-to-date information is available on the number of industrial sites where the substance is currently used.

The supply chain can be characterised[10] by the following actors: formulators, users at industrial sites and professional workers. The substance is also used in articles (relevant life cycle stages: F, IS, PW, SL).

Trityl alcohol is used in inks and toners (relevant Product Category: PC18).

The sector relying on the substance appears to be printing and reproduction of recorded media (relevant Sector of Use: SU7).

Trityl alcohol ends up in paper articles (relevant Article Category: AC8)

Some categories mentioned are not explicitly listed as use descriptors in registrations but could be derived from the information on uses available in the registration dossiers and from the Annex XV SVHC report (2012).

[10] Categories listed here after (life cycle stage, SU, PC and AC) make reference to the use descriptor system described in ECHA's guidance on use description: https://echa.europa.eu/documents/10162/13632/information_requirements_r12_en.pdf