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Background document for 4,4'-bis(dimethylamino)-4''-(methylamino)trityl alcohol [with \geq 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 \geq 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 dossiers¹ as well as the MSC opinion² were taken into consideration when finalising the recommendation and are reflected in the present document.

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¹ As of the last day of the public consultation, i.e. 5 December 2018

² Opinion of the Member State Committee on the draft ninth recommendation of the priority substances to be included in Annex XIV, adopted on 26 June 2019

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1. Identity of the substance

Identity of the substance as provided in the Candidate List³:

Name: 4,4'-bis(dimethylamino)-4''-(methylamino)trityl alcohol)⁴
 [with $\geq 0.1\%$ of Michler's ketone (EC 202-027-5) or Michler's base (EC 202-959-2)]
 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 authorisation⁵. 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 are available at

https://echa.europa.eu/documents/10162/13640/prioritisation_results_cl_substances_sept_2018_en.pdf.

The prioritisation results of the substances included in the draft 9th recommendation have been updated as necessary after the public consultation. The updated results are available at https://echa.europa.eu/documents/10162/13640/prioritisation_results_draft9threc_substances_October2019_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 $\geq 0.1\%$ ⁶, it meets the criteria for classification as a carcinogen.

Therefore, 4,4'-bis(dimethylamino)-4''-(methylamino)trityl alcohol [with $\geq 0.1\%$ 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.

³ For further information please refer to the Candidate List and the respective support document at <https://www.echa.europa.eu/candidate-list-table>.

⁴ 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) $\geq 0.1\%$ (wt/wt).

⁵ Document can be accessed at

http://echa.europa.eu/documents/10162/13640/gen_approach_svhc_prior_in_recommendations_en.pdf

⁶ 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 $\geq 0.1\%$ 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).

Article service life was removed from registrations, however given the use in printing inks, the substance is expected to end up in articles, e.g. 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 (= IP + V + WDU)
Inherent properties (IP)	Volume (V)	Wide dispersiveness of uses (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, trityl alcohol is recommended 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 XIV⁷ and as further specified in the practical implementation document⁸. The draft Annex XIV entries for all the substances that underwent public consultation are available at

https://www.echa.europa.eu/documents/10162/13640/9th_recom_draft_axiv_entries_en.pdf.

The final draft Annex XIV entries that ECHA recommends are available at

https://echa.europa.eu/documents/10162/13640/9th_axiv_recommendation_October2019_en.pdf.

3.1. Latest application and sunset dates

ECHA proposes the following transitional arrangements for trityl alcohol:

Latest application date (LAD): Date of inclusion in Annex XIV plus 18 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 (groups 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. Groups of substances are considered together.

ECHA made the final LAD allocation using all available relevant information including that received in the public consultation.

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

3.2. Review period for certain uses

In its draft recommendation ECHA had seen no ground to include in Annex XIV any review period for trityl alcohol.

During the public consultation ECHA did not receive comments requesting upfront review period for specific uses.

ECHA therefore does not recommend to include in Annex XIV any review periods for uses of trityl alcohol.

⁷ General approach can be accessed at

https://echa.europa.eu/documents/10162/13640/recom_general_approach_draft_axiv_entries.pdf

⁸ Practical implementation document can be accessed at

https://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)

In its draft recommendation ECHA had not proposed any exemptions for (categories of) uses of trityl alcohol on the basis of Article 58(1)(e) in combination with Article 58(2) of the REACH Regulation.

During the public consultation ECHA did not receive any requests for exemptions for the substance.

ECHA therefore does not 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.

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

In its draft recommendation ECHA had not proposed to include in Annex XIV any exemption from authorisation for the use of trityl alcohol for PPORD.

During the public consultation ECHA did not receive any requests for exemptions from the authorisation requirement for PPORD for the substance.

No PPORD notifications had been submitted by the end of public consultation.

ECHA therefore does not recommend exempting any use of trityl alcohol for PPORD from authorisation.

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 $\geq 0.1\%$ 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>

ComRef (2019): "Comments and references to responses" document. Document compiling comments and references to respective answers from commenting period 5/09/2018 – 5/12/2018 on ECHA's proposal to include 4,4'-bis(dimethylamino)-4''-(methylamino)trityl alcohol with $\geq 0.1\%$ of Michler's ketone (EC 202-027-5) or Michler's base (EC 202-959-2) in its 9th recommendation of priority substances for inclusion in the list of substances subject to authorisation (Annex XIV).

https://echa.europa.eu/documents/10162/13640/9th_recom_comref_trityl_alcohol_en.rtf

ECHA (2018): 4,4'-bis(dimethylamino)-4''-(methylamino)trityl alcohol with $\geq 0.1\%$ 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 5 December 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 $\geq 0.1\%$ 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>

RCOM (2019): "Responses to comments" document. Document compiling the responses to comments from commenting period 5/09/2018 – 5/12/2018 on ECHA's proposal to include 4,4'-bis(dimethylamino)-4''-(methylamino)trityl alcohol with $\geq 0.1\%$ of Michler's ketone (EC 202-027-5) or Michler's base (EC 202-959-2) in its 9th recommendation of priority substances for inclusion in the list of substances subject to authorisation (Annex XIV).

https://echa.europa.eu/documents/10162/13640/9th_recom_respdoc_trityl_alcohol_en.pdf

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 $\geq 0.1\%$ 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 were made to allocate the substance to a specific LAD slot.

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 characterised⁹ by the following actors: formulators, users at industrial sites and professional workers. The substance is also expected to end up 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 is assumed to end 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).

⁹ 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