Information gathering in addition to the draft recommendation of priority substances for inclusion in Annex 14 of UK REACH 2025

Supporting document for 4,4'-bis(dimethylamino)-4''-(methylamino)trityl alcohol [with ≥ 0.1% of Michler's ketone (EC No. 202-027-5) or Michler's base (EC No. 202-959-2)]

- EC: 209-218-2
- CAS: 561-41-1

October 2025

Contents

1 Introduction

HSE is seeking GB specific information on 4,4'-bis(dimethylamino)-4''-(methylamino)trityl alcohol [with ≥ 0.1% of Michler's ketone (EC No. 202-027-5) or Michler's base (EC No. 202-959-2)], to assist with future prioritisation work for recommendations to the Authorisation List (Annex 14) of UK REACH. This document outlines the information currently available to HSE, and interested parties are invited to provide information to refine this assessment. In particular, GB specific data on uses and associated tonnages is sought to verify the information and conclusions presented.

Background and context for seeking this information is provided in the document entitled "Technical rationale for the development of the recommendation 2025"[1].

[1] "Technical rationale for the development of the recommendation 2025", available from here: https://www.hse.gov.uk/reach/assets/docs/recommendations.xlsx

2 Background information for prioritisation in GB

2.1 Substance Identity

Identity of the substance in the UK REACH Candidate List:

Name: 4,4'-bis(dimethylamino)-4''-(methylamino)trityl alcohol [with ≥ 0.1% of Michler's ketone (EC No. 202-027-5) or Michler's base (EC No. 202-959-2)]

EC Number: 209-218-2

CAS Number: 561-41-1

2.2 Intrinsic properties

Michler's ketone ((4,4'-bis(dimethylamino)benzophenone; EC No. 202-027-5) and Michler's base (N,N,N',N'-tetramethyl-4,4'-methylenedianiline; EC No. 202-959-2) are classified for carcinogenicity, Carc. 1B (H350: "May cause cancer") and included in the GB Mandatory Classification and Labelling (MCL) list under index numbers 606-073-00-0 and 612-201-00-6 respectively.

4,4'-bis(dimethylamino)-4''-(methylamino)trityl alcohol does not have a mandatory classification. However, if the substance contains Michler's ketone or Michler's base as impurities at concentrations ≥ 0.1% w/w, the alcohol also meets the criteria for classification as Carc. 1B (H350: "May cause cancer"). Therefore, 4,4'-bis(dimethylamino)-4''-(methylamino)trityl alcohol **[with ≥ 0.1% of Michler's ketone (EC No. 202-027-5) or Michler's base (EC No. 202-959-2)]** meets the criteria under Article 57(a) of UK REACH.

4,4'-bis(dimethylamino)-4''-(methylamino)trityl alcohol [with ≥ 0.1% of Michler's ketone (EC No. 202-027-5) or Michler's base (EC No. 202-959-2)] was included in the UK REACH candidate list on 1st January 2021 in accordance with Article 59(1A).

Both Michler's ketone and Michler's base are also included individually on the UK REACH Candidate List.

4,4'-BIS(DIMETHYLAMINO)- 4''-(METHYLAMINO)TRITYL ALCOHOL [WITH ≥ 0.1% OF MICHLER'S KETONE (EC NO. 202-027-5) OR MICHLER'S BASE (EC NO. 202-959-2)]

2.3 Volume used in the scope of authorisation

No registrations for 4,4'-bis(dimethylamino)-4''-(methylamino)trityl alcohol have been submitted under UK REACH.

There are 3 Downstream User Import Notifications (DUINs)[2] for 4,4'-bis(dimethylamino)-4''-(methylamino)trityl alcohol (submitted for CAS No. 561-41-1). However, there is significant uncertainty[3] in the DUIN database and this does not provide direct evidence of the substance being imported into GB from the EU. Further, if the alcohol is imported into GB, there is no information in this database regarding the level of impurities. It is noted that, whilst the substance has been added to Annex 14 of EU REACH, no applications for authorisation have been published on the European Chemicals Agency (ECHA) website. This could indicate that substitution has occurred in the EU or, the impurities are below 0.1%.

Overall, HSE does not have accurate information on the tonnages that may actually be placed on the GB market. However, available information suggests this would likely be low, if at all.

2.4 Wide-dispersiveness of uses

Based on information provided in ECHA, 2019, the substance is or has been used as a dye and may be present in printing/writing inks. These inks may be used to produce finished (printed) articles.

2.5 Further considerations for priority setting

It is noted that where a substances is listed on Annex 14, and meets the SVHC criteria due to classification as a carcinogen, it is in scope of authorisation when it is present at concentrations of 0.1 % w/w or more. However, if that classification (and SVHC

[2] GB-based companies who imported substances from EU-based suppliers before UK REACH became law on 1 January 2021 had no EU REACH registration obligations as they were classed as Downstream Users (DUs). As they are now importers from outside of GB, they may have registration obligations under UK REACH. However, a transitional measure allows former DUs to suspend the registration until one of three deadlines (depending on tonnage and hazard). Where the identity of these imported substances was known, they could be included in a DUIN submitted to HSE.

[3] DUINs could be submitted for substances imported from the EU-27 into GB at any point within the two years prior to EU exit. They represent an approximate snapshot of substances on the GB market in the period before EU exit. As DUIN submission was a simple process and free of charge, companies may have under or over-reported substances (potentially erring on the side of caution to be compliant). Consequently, the DUIN data needs to be treated with caution. Many former DUs will not (currently) have full information on the identity of the substances they import from the EU. This is because most substances are placed on the market as mixtures and the full composition of those mixtures is not always given on a Safety Data Sheet (SDS) or a SDS may not be required. In addition, substances could be imported by multiple importers in lower volumes (i.e. below 1 tonne/year/importer); in these cases, the substances did not need to be included in a DUIN submission as there would be no registration duty under UK REACH for each importer.

identification) is due to the presence of an impurity or impurities, the actual substance(s) of concern could be present at concentrations well below 0.1% w/w, which would not ordinarily trigger the authorisation requirement. For example, if 4,4'-bis(dimethylamino)-4''-(methylamino)trityl alcohol [with ≥ 0.1% of Michler's ketone (EC No. 202-027-5) or Michler's base (EC No. 202-959-2)] was present in a mixture or another substance at 0.1% w/w, this would be within scope of authorisation. However, in this case, the actual concentration of Michler’s ketone or base would be well below 0.1% w/w which would not otherwise trigger authorisation.

4,4'-BIS(DIMETHYLAMINO)- 4''-(METHYLAMINO)TRITYL ALCOHOL [WITH ≥ 0.1% OF MICHLER'S KETONE (EC NO. 202-027-5) OR MICHLER'S BASE (EC NO. 202-959-2)]

3 Other factors and considerations

In addition to the above, HSE notes the 'Defra rationale for prioritising substances in the UK REACH work programme; 2025-2026'[4], which states:

"The Appropriate Authorities will consider the criteria set out in the UK REACH Regulations, alongside a range of relevant factors including those identified in the '*New approach to ensure regulators and regulation support growth*'[5] UK Government Action Plan. In taking forward this strategic approach, the Appropriate Authorities will consider drawing from the regulatory decisions that the EU has made in this area (where appropriate)."

Recognising this, information is provided below to support the Appropriate Authorities consideration of regulatory consistency with decisions made by the EU.

3.1 EU prioritisation activity

4,4'-bis(dimethylamino)- 4''-(methylamino)trityl alcohol [with ≥ 0.1% of Michler's ketone (EC No. 202-027-5) or Michler's base (EC No. 202-959-2)] was added to the EU Candidate List on 18th June 2012, following ECHA's decision ED/87/2012 (ECHA, 2012) .

Both Michler's ketone and Michler's base are included individually on the EU Candidate List.

4,4'-bis(dimethylamino)-4''-(methylamino)trityl alcohol [with ≥ 0.1% of Michler's ketone (EC No. 202-027-5) or Michler's base (EC No. 202-959-2)] was prioritised by the European Chemicals Agency (ECHA) and included in its 9th recommendation (ECHA, 2019a). The following points were noted in the Annex 14 background document (ECHA, 2019b) at that time:

- The substance was registered under EU REACH with a combined tonnage of ≥ 10 to < 100 tonnes per year, with all tonnage considered to be within scope of authorisation.

[4] Defra rationale for prioritising substances in the UK REACH work programme; 2025-2026, available at: https://www.gov.uk/government/publications/uk-reach-rationale-for-priorities-2025-to-2026/rationale-for-prioritising-substances-in-the-uk-reach-work-programme-2025-to-2026

[5] '*New approach to ensure regulators and regulation support growth, available at* 'https://www.gov.uk/government/publications/a-new-approach-to-ensure-regulators-and-regulation-support-growth

- Uses in scope of authorisation included use at industrial sites (formulation of printing inks) and use by professional workers (use of printing inks). It was also noted that the substance is expected to end up in printed articles.

It is noted that, at the time of drafting this document, the most recent data show that the substance is still registered under EU REACH within the same tonnage band[6].

The substance was added to Annex 14 of EU REACH on the 8th April 2022 (Commission Regulation (EU) 2022/586).

3.2 EU authorisations

4,4'-bis(dimethylamino)-4''-(methylamino)trityl alcohol [with ≥ 0.1% of Michler's ketone (EC No. 202-027-5) or Michler's base (EC No. 202-959-2)] was added to Annex 14 of EU REACH with a sunset date of 1st May 2025 and latest application date of 1st November 2023. No applications for authorisation have been published on the ECHA website.

3.3 Consideration of regulatory decisions in the EU

HSE is not aware of any applications for authorisation having been submitted to ECHA for this substance. It may be that there is no ongoing use of the substance in the EU, or that it is being used but with the level of the relevant impurities below 0.1 % w/w. It is not possible for HSE to confirm.

3.4 Conclusions based on current information held by HSE.

HSE does not expect the use profile for the substance in GB to differ to that in the EU. As noted in Section 3.3, the available data suggest that the impurities may be present at <0.1% or the use of the substance has been substituted. As such, we would not expect to receive any applications for authorisation if the substance (with the impurities) was added to Annex 14 of UK REACH.

Adding the substance to Annex 14 may not be the most effective way to manage a concern that is driven by the potential impurities. However, including it would provide consistency in decision making and could lead to clarity for those who trade with the EU. This would include, for example, reducing the administrative workload of companies in the chemicals sector or those using chemicals and therefore having positive socio-economic benefits.

[6] [6] ECHA CHEM; ECHA's public chemicals database (https://chem.echa.europa.eu/).

4,4'-BIS(DIMETHYLAMINO)- 4''-(METHYLAMINO)TRITYL ALCOHOL [WITH ≥ 0.1% OF MICHLER'S KETONE (EC NO. 202-027-5) OR MICHLER'S BASE (EC NO. 202-959-2)]

HSE is seeking further information on 4,4'-bis(dimethylamino)-4''-(methylamino)trityl alcohol [with ≥ 0.1% of Michler's ketone (EC No. 202-027-5) or Michler's base (EC No. 202-959-2)]. In particular, this includes GB-specific data on the uses and associated tonnages to help refine this assessment.

4,4'-BIS(DIMETHYLAMINO)- 4''-(METHYLAMINO)TRITYL ALCOHOL [WITH ≥ 0.1% OF MICHLER'S KETONE (EC NO. 202-027-5) OR MICHLER'S BASE (EC NO. 202-959-2)]

4 References

Commission Regulation (EU) 2022/586 of 8 April 2022 amending Annex XIV to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH). Available at https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv%3AOJ.L_.2022.112.01.0006.01.ENG&toc=OJ%3AL%3A2022%3A112%3ATOC

Defra (2025). Defra rationale for prioritising substances in the UK REACH work programme: 2025 to 2026 – July 2025. Available at: https://www.gov.uk/government/publications/uk-reach-rationale-for-priorities-2025-to-2026/rationale-for-prioritising-substances-in-the-uk-reach-work-programme-2025-to-2026

ECHA (2012). ECHA decision ED/87/2012, Inclusion of substances of very high concern on the candidate list – June 2012. Available at: https://echa.europa.eu/documents/10162/bcf29e5e-c152-4f88-8df9-1f9515582e3e

ECHA (2019a). Recommendation of the European Chemicals Agency of 1 October 2019 for the inclusion of substances in Annex XIV to REACH. Available at: https://echa.europa.eu/recommendations-for-inclusion-in-the-authorisation-list/-/dislist/details/0b0236e1828a5e98

ECHA (2019b). 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. October 2019. Available at: https://echa.europa.eu/documents/10162/7c581cb3-35b7-b61b-dcb7-b901bd304317

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5 Declarations

Within this document we have provided links to documents and information found on ECHA's website: https://echa.europa.eu/

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For the avoidance of doubt, no part of this document has been endorsed by ECHA.

Further information

This publication is available on the HSE website at;
https://www.hse.gov.uk/reach/assets/docs/recommendations.xlsx

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