

7 February 2024

Draft background document for diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide

Document developed in the context of ECHA's twelfth 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 the 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.

Information relevant for prioritisation and/or for proposing Annex XIV entries provided during the consultation on the inclusion of diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide in the Authorisation List or in the registration dossiers (as of the last day of the consultation, i.e. 7 May 2024) will be taken into consideration when finalising the recommendation and will be reflected in the final background document.

Contents

1. Background information for prioritisation	2
1.1. Intrinsic properties	2
1.2. Volume used in the scope of authorisation.....	2
1.3. Wide-dispersiveness of uses	2
1.4. Further considerations for priority setting.....	2
1.5. Conclusion.....	3
2. Background information for the proposed Annex XIV entry	3
2.1. Latest application and sunset dates	3
2.2. Review period for certain uses	4
2.3. Uses or categories of uses exempted from authorisation requirement	4
3. References	6
Annex I: Further information on uses.....	7

1. 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 (ECHA, 2020a). Results of the prioritisation of all substances included in the Candidate List by July 2023 and not yet recommended or included in Annex XIV of the REACH Regulation is available in ECHA (2024a).

1.1. Intrinsic properties

Diphenyl(2,4,6-trimethylbenzoyl)phosphine was identified as a Substance of Very High Concern (SVHC) according to Article 57(c) as it is classified in Annex VI, part 3, Table 3 (the list of harmonised classification and labelling of hazardous substances) of Regulation (EC) No 1272/2008 as Toxic for Reproduction, Category 1B, H360Fd ("May damage fertility. Suspected of damaging the unborn child."), and was therefore included in the Candidate List for authorisation on 14 June 2023, following ECHA's decision D(2023)3788-DC.

1.2. Volume used in the scope of authorisation

The amount of diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide manufactured and/or imported into the EU is according to registration data in the range 1,000 - < 10,000 t/y (ECHA, 2023a). All tonnage used in EU appear to be in the scope of authorisation. Therefore, in conclusion, the volume in the scope of authorisation is estimated to be in the range of 1,000 - <10,000 t/y.

1.3. Wide-dispersiveness of uses

Registered uses of diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide in the scope of authorisation include uses at industrial sites (such as formulation of inks, toners, coatings and adhesives, use as photoinitiator in UV-curable inks, coatings and adhesives, as process regulator for polymerisation processes in production of resins, rubbers, polymers) and uses by professional workers (application of inks, coatings and adhesives).

Consumer uses e.g. in ink bottles are also registered. The substance was recently included in the Annex VI, part 3, Table 3 of Regulation (EC) No 1272/2008 with a harmonised classification as Repr. 1B. Once the substance is included in the appendix to entry 30 of REACH Annex XVII, the generic restriction on Reprotoxic substances sold to the general public will apply. Consumer uses of the substance above the specific concentration limit should not take place anymore and are therefore not considered for the priority assessment.

According to registrations, the substance is used in 3D printed articles, ink-printed paper articles or textiles. Release from articles is not expected as substance is assumed to have reacted.

More detailed information on uses is provided in Annex I.

1.4. Further considerations for priority setting

Grouping with EC 400-600-6 (2-methyl-1-(4-methylthiophenyl)-2-morpholinopropan-1-one) and EC 404-360-3 (2-benzyl-2-dimethylamino-4'-morpholinobutyrophenone) already recommended (11th Recommendation) is considered.

1.5. Conclusion

Verbal descriptions and scores			Total score (= IP + V + WDU)	Further considerations
Inherent properties (IP)	Volume (V)	Wide dispersiveness of uses (WDU)		
Diphenyl(2,4,6-trimethylbenzoyl) phosphine oxide is classified as toxic for reproduction 1B meeting the criteria of Article 57 (c) Score: 1	The amount of diphenyl(2,4,6-trimethylbenzoyl) phosphine oxide used in the scope of authorisation is in the range of 1,000 - <10,000 t/y Score: 12	Diphenyl(2,4,6-trimethylbenzoyl) oxide is used at industrial sites and by professional workers. Score: 10	23	Grouping with EC 400-600-6 (2-methyl-1-(4-methylthiophenyl)-2-morpholinopropan-1-one) and EC 404-360-3 (2-benzyl-2-dimethylamino-4'-morpholinobutyrophe none) already recommended (11th Recommendation)

Conclusion

On the basis of the prioritisation criteria further strengthened by grouping considerations, diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide receives priority among the substances on the Candidate List (see link to the prioritisation results above). Therefore, it is proposed to prioritise diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide for inclusion in Annex XIV.

2. Background information for the proposed Annex XIV entry

2.1. Latest application and sunset dates

ECHA proposes the following transitional arrangements (ECHA, 2024b):

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 consultation. ECHA will apply the Annex XIV entries approach (ECHA, 2020b) and the criteria described in the implementation document (ECHA, 2020c). 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 12th recommendation, ECHA sees currently no reason to deviate from these standard LAD slots.

2.2. Review period for certain uses

ECHA proposes not to include in Annex XIV any review period for diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide.

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.

2.3. 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 diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide 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 general responses to Art. 58(2) exemption requests (ECHA, 2020d). 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 (ECHA, 2024c), there is no need to propose an additional specific exemption.

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 diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide 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 diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide¹.

¹ As of 20 July 2023.

3. References

Note: Documents supporting the draft Annex XIV recommendations are available under [Recommendations for inclusion in the Authorisation List - ECHA \(europa.eu\)](#) (filter by the substance name or EC number). Further information relevant for the consultation can be accessed at [Consultation on draft recommendation for inclusion in the Authorisation List - ECHA \(europa.eu\)](#). In absence of specific links in the references listed below, the above links are relevant.

Annex XV SVHC report (2023): Annex XV report. Proposal for identification of a substance of very high concern on the basis of the criteria set out in REACH Article 57. Substance name: diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide, EC Number: 278-355-8, CAS Number: 75980-60-8. Submitted by Sweden, January 2023. [Registry of SVHC intentions until outcome - ECHA \(europa.eu\)](#).

ECHA (2015): ECHA's guidance on use description:
https://echa.europa.eu/documents/10162/13632/information_requirements_r12_en.pdf

ECHA (2020a): Prioritisation of substances of very high concern (SVHCs) for inclusion in the Authorisation List (Annex XIV). Prioritisation approach.

ECHA (2020b): Preparation of draft Annex XIV entries for substances recommended to be included in Annex XIV. General approach.

ECHA (2020c): Setting Latest Application Dates. Practical implementation document for the Annex XIV entries approach.

ECHA (2020d): ECHA's general responses on issues commonly raised in consultations on draft recommendations.

ECHA (2023a): Substance diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide (EC 278-355-8). ECHA's dissemination website on registered substances. Accessed on 20 July 2023.
<https://echa.europa.eu/search-for-chemicals>

ECHA (2023b): [Assessment of regulatory needs list - ECHA \(europa.eu\)](#), filter by substance diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide (EC 278-355-8)

ECHA (2024a): Prioritisation assessment results of the Candidate List substances assessed - Substances included in the Candidate List by July 2023 and not yet recommended for inclusion in Annex XIV. ECHA's 12th draft recommendation. 7 February 2024.

ECHA (2024b): Draft 12th Recommendation of Priority Substances to be included in Annex XIV of the REACH Regulation (List of Substances Subject to Authorisation). 7 February 2024.

ECHA (2024c): Generic exemptions from the authorisation requirement. 7 February 2024.

Annex I: Further information on uses

1. Detailed information on uses

Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide is used in photo-chemicals, inks and toners, coating products, adhesives and sealants, polymers and fillers, putties, plasters, and modelling clay. The substance can also be found in materials based on fabrics, textiles and apparels (e.g. clothing, mattresses, curtains, carpets, or textile toys), paper (e.g., tissues, feminine hygiene products, nappies, books, magazines, or wallpaper) and plastics (e.g., food packaging and storage, toys, or mobile phones) (ECHA, 2023a).

According to the SVHC report, data available in the Nordic product register database (SPIN) from 2019, shows the technical uses of the preparations include activator, catalyst, surfactant, pigment, UV-absorbent and "unspecified function". The industrial use of diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide includes: manufacture of chemicals and chemical products; manufacture of wood and of products of wood and cork, except furniture; manufacture of articles of straw and plaiting materials; printing, publishing and reproduction of recorded media (ECHA 2023a).

Article service life (ASL) is reported in registrations mainly due to the use of the substance in printing (3D printed articles, ink-printed paper articles and ink-printed textiles). Release from articles is not expected or intended during use due to reactivity of the substance. Limited information is available on residual concentration on unreacted substance in articles.

Based on similar function as photoinitiator with a benzoyl radical releasing mode of action it appears that diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide might be used as a substitute for the two photoinitiators already recommended for inclusion in Annex XIV. There are indications on the potential for using the substances in the same types of application (Annex XV SVHC report (2023), ECHA, 2023b).

2. Structure and complexity of supply chains

The following assumptions on the structure and complexity of supply chains associated to uses in the scope of authorisation are made. There are based on currently available information and will be used, together with any relevant information from consultation, to allocate the substance to a specific LAD slot in the final recommendation.

The substance is manufactured and/or imported by a limited number of registrants. According to registration information, the substance is used at more than 100 industrial sites (ECHA, 2023a).

The supply chain can be characterised (according to ECHA, 2015) by the following actors: formulators, users at industrial sites, professional workers, consumers, articles producers and assemblers (multi-layer assembling chain) (relevant life cycle stages: F, IS, PW, C, SL (multi-layer)). The substance seems to be used in the following product categories: adhesives, sealants, coatings and paints, thinners, paint removers, fillers, putties, plasters, modelling clay, non-metal-surface treatment products, inks and toners, paper and board treatment products, photo-chemicals, polymer preparations and compounds, washing and cleaning products (relevant product categories: PC 1, PC 9a, PC 9b, PC 15, PC 18, PC 26, PC 30, PC 32, PC 35).

A number of sectors is relying on the substance in some of their uses including printing and reproduction of recorded media, manufacturers of plastic products (relevant sector of use

categories: SU 7, SU 9, SU 12).

Uses of the substance in the scope of authorisation seem to be relevant for the production of a number of article types such as fabrics, textiles and apparel, paper and plastic articles (relevant article categories: AC 5, AC 8, AC 13). Some of the categories mentioned are not explicitly reported in registrations but could be derived from information on uses available in registration dossiers, the Annex XV SVHC report (2023) and/or the SPIN database.