7 February 2024

Draft background document for s-(tricyclo(5.2.1.$0^{2,6}$)deca-3-en-8(or 9)-yl O-(isopropyl or isobutyl or 2-ethylhexyl) O-(isopropyl or isobutyl or 2-ethylhexyl) phosphorodithioate

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 s-(tricyclo(5.2.1.$0^{2,6}$)deca-3-en-8(or 9)-yl O-(isopropyl or isobutyl or 2-ethylhexyl) O-(isopropyl or isobutyl or 2-ethylhexyl) phosphorodithioate 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. Identity of the substance 2

2. Background information for prioritisation 2

2.1. Intrinsic properties 2

2.2. Volume used in the scope of authorisation 2

2.3. Wide-dispersiveness of uses 2

2.4. Further considerations for priority setting 2

2.5. Conclusion 3

3. Background information for the proposed Annex XIV entry 3

3.1. Latest application and sunset dates 3

3.2. Review period for certain uses 4

3.3. Uses or categories of uses exempted from authorisation requirement 4

4. References 6

Annex I: Further information on uses 7

1. Identity of the substance

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

Name:	S-(tricyclo[5.2.1.0^{2,6}]deca-3-en-8(or 9)-yl) O-(isopropyl or isobutyl or 2-ethylhexyl) O-(isopropyl or isobutyl or 2-ethylhexyl) phosphorodithioate
EC Number:	401-850-9
CAS Number:	255881-94-8

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 (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).

2.1. Intrinsic properties

S-(tricyclo[5.2.1.0^{2,6}]deca-3-en-8(or 9)-yl) O-(isopropyl or isobutyl or 2-ethylhexyl) O-(isopropyl or isobutyl or 2-ethylhexyl) phosphorodithioate was identified as a Substance of Very High Concern (SVHC) according to Article 57(d) as it meets the criteria of a PBT substance and was therefore included in the Candidate List for authorisation on 17 January 2022, following ECHA's decision D(2021)10043-DC.

2.2. Volume used in the scope of authorisation

The amount of s-(tricyclo[5.2.1.0 ^{2,6}]deca-3-en-8(or 9)-yl) O-(isopropyl or isobutyl or 2-ethylhexyl) O-(isopropyl or isobutyl or 2-ethylhexyl) phosphorodithioate manufactured and/or imported into the EU is according to registration data in the range of 100 - 1,000 t/y. All tonnage appears to be in the scope of authorisation. Therefore, in conclusion, the volume used in the EU in the scope of authorisation is estimated to be in the range of 100 – <1,000 t/y. (ECHA, 2023)

2.3. Wide-dispersiveness of uses

Registered uses of s-(tricyclo[5.2.1.0 ^{2,6}]deca-3-en-8(or 9)-yl) O-(isopropyl or isobutyl or 2-ethylhexyl) O-(isopropyl or isobutyl or 2-ethylhexyl) phosphorodithioate in the scope of authorisation include uses at industrial sites (e.g. use of lubricants and greases), and/or uses by professional workers (e.g. use of lubricants and greases in vehicles or machinery).

More detailed information on uses is provided in Annex I.

2.4. Further considerations for priority setting

None.

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

2.5. Conclusion

Verbal descriptions and scores			Total score (= IP + V + WDU)
Inherent properties (IP)	Volume (V)	Wide dispersiveness of uses (WDU)	
S-(tricyclo[5.2.1.0 ^{2,6}]deca-3-en-8(or 9)-yl) O-(isopropyl or isobutyl or 2-ethylhexyl) O-(isopropyl or isobutyl or 2-ethylhexyl) phosphorodithioate is identified as PBT meeting the criteria of Article 57 (d) Score: 13	The amount of s-(tricyclo[5.2.1.0 ^{2,6}]deca-3-en-8(or 9)-yl) O-(isopropyl or isobutyl or 2-ethylhexyl) O-(isopropyl or isobutyl or 2-ethylhexyl) phosphorodithioate in the scope of authorisation in the range of 100 - 1,000 t/y. Score: 9	S-(tricyclo[5.2.1.0 ^{2,6}]deca-3-en-8(or 9)-yl) O-(isopropyl or isobutyl or 2-ethylhexyl) O-(isopropyl or isobutyl or 2-ethylhexyl) phosphorodithioate at industrial sites and by professional uses. Score: 10	32

Conclusion

On the basis of the prioritisation criteria, s-(tricyclo(5.2.1.0^{2,6})deca-3-en-8(or 9)-yl O-(isopropyl or isobutyl or 2-ethylhexyl) O-(isopropyl or isobutyl or 2-ethylhexyl) phosphorodithioate receives priority among the substances on the Candidate List (see link to the prioritisation results above). Therefore, it is proposed to prioritise s-(tricyclo(5.2.1.0^{2,6})deca-3-en-8(or 9)-yl O-(isopropyl or isobutyl or 2-ethylhexyl) O-(isopropyl or isobutyl or 2-ethylhexyl) phosphorodithioate 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 (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.

3.2. Review period for certain uses

ECHA proposes not to include in Annex XIV any review period for s-(tricyclo(5.2.1.0^{2,6})deca-3-en-8(or 9)-yl O-(isopropyl or isobutyl or 2-ethylhexyl) O-(isopropyl or isobutyl or 2-ethylhexyl) phosphorodithioate.

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.

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 s-(tricyclo(5.2.1.0^{2,6})deca-3-en-8(or 9)-yl O-(isopropyl or isobutyl or 2-ethylhexyl) O-(isopropyl or isobutyl or 2-ethylhexyl) phosphorodithioate] 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 s-(tricyclo(5.2.1.$0^{2,6}$)deca-3-en-8(or 9)-yl O-(isopropyl or isobutyl or 2-ethylhexyl) O-(isopropyl or isobutyl or 2-ethylhexyl) phosphorodithioate 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 s-(tricyclo(5.2.1.$0^{2,6}$)deca-3-en-8(or 9)-yl O-(isopropyl or isobutyl or 2-ethylhexyl) O-(isopropyl or isobutyl or 2-ethylhexyl) phosphorodithioate[2].

[2] As of 20 July 2023.

4. 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.

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.

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 (2023): Substance s-(tricyclo(5.2.1.0'2,6)deca-3-en-8(or 9)-yl O-(isopropyl or isobutyl or 2-ethylhexyl) O-(isopropyl or isobutyl or 2-ethylhexyl) phosphorodithioate (EC 401-850-9). ECHA's dissemination website on registered substances. Accessed on 20 July 2023. https://echa.europa.eu/search-for-chemicals

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

Annex I: Further information on uses

1. Information on uses

The substance is reported to be used in hydraulic fluids (PC 17), lubricants, greases, release products (PC 24) mainly in vehicles and machinery. The substance is used in the industrial formulation of lubricant additives, lubricants and greases. In industrial and professional settings, the substance is used in lubricants and greases in open systems. Lubricants containing the substance are for example applied to work pieces or equipment.

Based on the uses described in registrations (uses in lubricants and functional fluids) it is unclear whether the substance ends-up in articles. Substances in these types of uses may in some cases become an integral part of an article. However, at the moment registrants did not report any article service-life.

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. No precise and up-to-date information is available on the number of industrial sites where the substances is currently used.

The supply chain can be characterised (according to ECHA, 2015) by the following actors: formulators, users at industrial sites, professional workers, consumer, articles producers, articles 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: hydraulic fluids and lubricants, greases, release products (relevant product categories: PC 17 and PC 24).

A number of sectors is relying on the substance in some of their uses including manufacturers of vehicles and machinery (relevant sector of use category: SU 17).

Uses of substance/substance group in the scope of authorisation seem to be relevant for the production of a number of article types such as vehicles and machinery (relevant article categories: AC 1, AC 2).

Some of the categories mentioned are not explicitly reported in registrations but could be derived from information on uses available in registration dossiers.