

1 October 2019

Background document for tetraethyllead

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.

Information relevant for prioritisation and/or for proposing Annex XIV entries provided during the public consultation on the inclusion of tetraethyllead 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

1. Identity of the substance

Identity of the substance as provided in the Candidate List³:

Name: Tetraethyllead
EC Number: 201-075-4
CAS Number: 78-00-2

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 authorisation⁴. 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

Tetraethyllead 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 3.1 (the list of harmonised classification and labelling of hazardous substances) of Regulation (EC) No 1272/2008 as Toxic for Reproduction, Category 1A, H360D ("May damage the unborn child")⁵, and was therefore included in the Candidate List for authorisation on 19 December 2012, following ECHA's decision ED/169/2012.

2.2. Volume used in the scope of authorisation

The amount of tetraethyllead manufactured and/or imported into the EU is according to registration data (ECHA, 2018) in the range of 1,000 - 10,000 t/y.

All tonnage is formulated into fuel additive within the EU. According to registration information, this fuel additive is used exclusively in aviation fuel in the EU. Therefore, the volume in the scope of authorisation is estimated to be in the range of 1,000 - <10,000 t/y.

More detailed information is provided in Annex I.

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 Document can be accessed at http://echa.europa.eu/documents/10162/13640/gen_approach_svhc_prior_in_recommendations_en.pdf

⁵ The full hazard statement of the Annex VI (CLP) entry for lead alkyls (index number 082-002-00-1) is H360Df ("May damage the unborn child. Suspected of damaging fertility."). The entry has a specific concentration limit for Repr.1A; H360D of C \geq 0.1%.

2.3. Wide-dispersiveness of uses

Registered uses of tetraethyllead in the scope of authorisation include uses at industrial sites (formulation of fuel additives and formulation of fuels with additives).

The use of the additised fuel by industrial and professional workers as well as by consumers is registered specifying the tetraethyllead content to be below the specific concentration limit for classification as toxic to reproduction of 0.1% (see footnote 5). Furthermore, the use of the substance or the fuel additive (containing 61.5 % tetraethyllead) by professional workers or consumers is advised against.

Therefore, the use of the additised fuel is considered to be outside the scope of authorisation.

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)	
Tetraethyllead is classified as toxic for reproduction 1A meeting the criteria of Article 57 (c) Score: 1	The amount of tetraethyllead used in the scope of authorisation is in the range of 1,000 - <10,000 t/y Score: 12	Tetraethyllead is used at industrial sites Score: 5	18

Conclusion

On the basis of the prioritisation criteria, tetraethyllead receives priority among the substances on the Candidate List (see link to the prioritisation results above). Therefore, tetraethyllead 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 XIV⁶ and as further specified in the practical implementation document⁷. The draft Annex XIV entries for all the substances that underwent public consultation are available at

⁶ General approach can be accessed at https://echa.europa.eu/documents/10162/13640/recom_general_approach_draft_axiv_entries.pdf

⁷ Practical implementation document can be accessed 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 recommends the following transitional arrangements for tetraethyllead:

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.

During the public consultation comments were received asking for long LADs due to e.g. uncertainties related to UK’s possible exit from the EU, the need for actors in the supply chain to get organised or awaiting results of the research programme for alternatives.

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 tetraethyllead.

During the public consultation, comments were received arguing for the need to have long review periods if no viable lead-free alternatives for the majority of piston engines can be produced. However, the setting of upfront review periods requires detailed use-specific information which should be provided in applications for authorisation. Furthermore, all authorisation decisions include review periods that are set case-by-case for each use applied for (see also RCOM, 2019).

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

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

During the public consultation ECHA received some requests for exemptions (ComRef, 2019). Those were referring to other existing Community legislation, such as EU aviation law (e.g. EASA Basic Regulation EU 2018/1139), or the PIC regulation (EU 649/2012). Also REACH Art. 56(4) was referred to as basis for possible exemptions.

In its opinion MSC expresses the view that there appears to be no grounds for an exemption under Article 58(2). MSC further supported ECHA's intention to invite COM to assess the exemption possibilities.

ECHA has carefully assessed all the requests made (see detailed assessment in Section C, in particular C.2, of the response document (RCOM, 2019)). ECHA concluded that there is currently no sufficient basis to propose Article 58(2) exemptions for a use or a category of uses of tetraethyllead, and therefore does not recommend exemptions for uses of tetraethyllead on the basis of Article 58 (1)(e) in combination with Article 58(2) of the REACH Regulation.

The European Commission is however invited to make its assessment of the exemption possibilities.

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 tetraethyllead 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 tetraethyllead for PPORD from authorisation.

4. References

ComRef (2019): "Comments and references to responses" document. Document compiling comments and references to respective answers from commenting period 05/09/2018 – 05/12/2018 on ECHA's proposal to include tetraethyllead 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_tetraethyllead_en.rtf

ECHA (2018): Tetraethyllead. 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 03/09/2012-18/10/2012 on the proposal to identify tetraethyllead as a Substance of Very High Concern.

<https://echa.europa.eu/documents/10162/07e61c3c-175f-488d-a4d7-749b4566fd0c>

RCOM (2019): "Responses to comments" document. Document compiling the responses to comments from commenting period 05/09/2018 – 05/12/2018 on ECHA's proposal to include tetraethyllead 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_tetraethyllead_en.pdf

Annex I: Further information on uses

1. Further details on the type of applications and main (sector of) uses

The use of motor fuels regulated under Directive 98/70/EC is exempted from the authorisation requirement under REACH (Article 56(4)(c)). According to registration information as well as comments received (RCOM, 2019), tetraethyllead is in the EU exclusively used in aviation fuels which are not covered by Directive 98/70/EC. Consequently, the formulation of tetraethyllead-containing fuel additives and their use in the formulation of aviation gasoline fall within the scope of authorisation.

Tetraethyllead functions as antiknock additive in aviation gasoline ("Avgas"). Avgas is used in small aircrafts equipped with spark ignition piston engines. Those aircrafts are used in the private and professional sector (including pilot training). Avgas is available in various grades and there are different standards describing its specifications, e.g. ASTM D910 or UK Def. Stan 91-90 (ComRef, 2019; RCOM, 2012; RCOM, 2019).

According to the Substances in Preparations in Nordic Countries (SPIN) database⁸, the substance was used in 2015 in four preparations at about 1 t/y (data from three countries claimed confidential) for air transport and manufacture of coke and refined petroleum products in the product category fuels and other (no further information provided).

Some comments (ComRef, 2019) state that ASTM standards allow for a tetraethyllead concentration in aviation fuel above the specific concentration limit (SCL) for classification as toxic to reproduction of 0.1%. However, the registrations specify a tetraethyllead content below the SCL and ECHA has not received any downstream user reports⁹ covering this use of tetraethyllead. According to the prioritisation approach ECHA bases its priority assessment on the registration information as the main source of information (see also RCOM, 2019). Therefore, the use of the additised fuel is considered to be outside the scope of authorisation.

2. Structure and complexity of supply chains

The following assumptions were made to allocate the substance to a specific LAD slot.

Tetraethyllead is registered by a limited number of registrants. According to RCOM (2012) and ComRef (2019), there is one formulator supplying tetraethyllead containing fuel additives to a limited number of industrial oil refineries and fuel blenders. The further formulation to the additised fuel – to the extent it happens in the EU – takes place at a limited number of sites (ComRef, 2019).

The supply chain can be characterised¹⁰ by the following actors: formulators (multi-layered formulation) (relevant life cycle stage: F).

The substance is used in products categorised as fuels (relevant product category: PC13).

Manufacturers of bulk and large scale chemicals, including petroleum products (relevant sector of use category: SU8) seem to rely on the substance.

⁸ SPIN database can be found at <http://spin2000.net/>

⁹ acc. to Article 38 of the REACH regulation

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

Some categories mentioned are not explicitly listed as use descriptors in registrations but could be derived from information on uses available in registration dossiers.