

RESPONSES INTO THE PUBLIC CONSULTATION ON ECHA'S DRAFT 9TH ANNEX XIV RECOMMENDATION: Trilead dioxide phosphonate

About the Lead REACH Consortium

The Pb REACH Consortium is a voluntary initiative managed by the International Lead Association (ILA). It represents the interests of 92 Consortium members and acts on behalf of the Lead Registrants for several Pb substances – including six of those included in the draft 9th Annex XIV recommendation: dioxobis(stearato)trilead; fatty acids, C16-18, lead salts; trilead dioxide phosphonate; sulfurous acid, lead salt, dibasic; [phthalato(2-)]dioxotrilead, and lead oxide sulfate.

Pb REACH Consortium members are listed in Annex 1.

Comments on the prioritisation results and general issues:

We would question the relevance and effectiveness of including this substance in the 9th recommendation and in REACH Annex XIV.

The major use of trilead dioxide phosphonate (EC 235-252-2, CAS 12141-20-7), historically, was as a stabiliser for PVC; minor uses also identified in the REACH Registration dossier are in industrial formulation and application of mirror backing, and in industrial rubber production.

As noted in the draft background report, the stabiliser sector made a voluntary commitment to replace Pb-based stabilisers in all formulations sold on the EU market by the end of 2015. According to Vinylplus progress reports 2016 and 2017, Industry completed the replacement of according to foreseen timelines.

Furthermore, in April 2018, ECHA sent a combined RAC and SEAC opinion to the Commission in favour of a REACH Restriction on the use of lead compounds in PVC articles and the placing on the market of PVC articles containing lead compounds such as this substance. With such a Restriction and the voluntary commitment in place, the only recognised EU use of this substance in the context of PVC stabilisers would be formulation for export-only.

According to the Chemical Safety Report, the specialist industrial use of this substance in mirror backing is carried out by a very limited number of workers using either lead oxide sulfate and/or trilead dioxide phosphonate. The CSR reports 12 workers involved in the application of the lead-based mirror backing for the period 2010-2011; the 90th percentile blood lead level reported in the CSR was less than 8 µg/dL.

The other specialist industrial use of trilead dioxide phosphonate, i.e. in rubber production, is also carried out by a limited number of workers: the CSR reports 33 workers involved in the use for the period 2009-2012. Again, the 90th percentile blood lead level reported in the CSR was less than 8 µg/dL. Furthermore, during the Consortium's 2009-2012 blood lead survey, the rubber sector reported that some companies had ceased using lead compounds entirely by virtue of substitution. Therefore, this niche use of trilead dioxide phosphonate should be noted as in decline.

In light of ECHA's draft 9th recommendation, a number of registrants have recently deactivated their registrations of the lead compounds included in the list in order to indicate cease manufacture/import

and to facilitate an update to the total registered tonnage band. As Secretariat to the Consortium, ILA has also recently advised active registrants to update their dossiers to clarify volumes manufactured, volumes directly exported, and volumes used in EU uses, i.e. formulation for export, rubber production, and mirror backing – only the EU uses would be in scope of Authorisation – given the Vinylplus voluntary replacement initiative and the impending REACH Restriction.

As such, we contest the volume estimated by ECHA to be in scope of Authorisation and we disagree with the volume score of 15 and the total score of 23 as reported in the current draft background document. According to registration from the Registered Substances Database (ECHA, 2018), as at 30 October **the total tonnage range is 1,000-10,000 tpy, not 10,000-100,000 tpy as reported in the current draft background document.** Furthermore, the volume score should be based on EU uses, taken from registration dossiers, rather than total registered tonnage. We note that at least two of the six active registrants have submitted dossier updates during 2018. Therefore, **we would request ECHA to re-evaluate the volume score based on the latest registration information, which would reduce it to no more than 12**, per the “Prioritisation of substances of very high concern (SVHCs) for inclusion in the Authorisation List (Annex XIV)” (ECHA, 2014).

As EU use of this substance is restricted to the workplace, we propose that a review of existing EU binding occupational and biological limit values for lead and compounds would be a more proportionate risk management option than REACH Authorisation. We would request that ECHA and MSC consider any precedent that might be established in this regard for other lead compounds that have previously been included in ECHA recommendations for SVHCs to be added to the Authorisation List.

Comments on the proposed Latest Application (LAD) and Sunset dates:

If this substance were to be included in Annex XIV, the standard LAD slots would not appear to be inappropriate.

Comments on uses (or categories of uses) that should be exempted from Authorisation

We note that, in the draft background document, ECHA proposes not to recommend exemptions for uses of this substance on the basis of Article 58 (2) of the REACH Regulation (Section 3.3.1).

However, we would highlight that the Commission has discretion for granting a REACH Article 58 (2) exemption for uses in the EU that are restricted to industrial processing, such as formulation for export-only, given the framework of existing legislation established to address risk in and from the workplace.

Should this substance be included in Annex XIV without relevant (Article 58 (2)) exemptions, there is a strong case for the use of a Simplified Authorisation Process for of trilead dioxide phosphonate, given the two small-volume, specialist end uses involving a very limited number of workers with demonstrably low exposure to Pb.

Annex 1: List of members of the Lead REACH Consortium

5N Plus Belgium SA	Jenox Akumulatory Sp. z o.o
Akkumulatorenfabrik Moll GmbH	Johnson Controls Autobatterie GmbH & Co. KGaA
Anton Schneider Sohne GmbH	Johnson Controls Autobaterias SA (Spain)
Asua Products SA	Johnson Controls Autobatterie spol (Czech)
Aurubis GA	Johnson Controls Recycling GmbH
Azor Ambiental SA	Johnson Controls Sachsen-Batterien GmbH
BAE Batterien GmbH	KCM 2000 SA SC
Baerlocher GmbH	KGHM Polska Miedz SA
Banner GmbH	Kovohute Pribram Nastupnicka a.s
BASF SE	Le Plomb Francais Sarl
Berzelius Stolberg GmbH	Loxa Sp. Z.o.o.
BMG Metall und Recycling GmbH	Metal Processors Limited
Boliden Bergsoe AB	Metalblanc
Boliden Mineral	Metallo Belgium NV
Britannia Refined Metals Ltd	Metalurgica de Medina SA
BSB Recycling GmbH	Midac SpA
Campine Recycling NV	ML Operations Ltd
Chemson Polymer-Additive AG	Monbat Recycling EAD
Colorobbia Italia spa	MPI Reciklaza d.o.o
COPLOSA, Sociedad Anonima	Muldenhutten Recycling und Umwelttechnik GmbH
Eco-Bat SpA	New Meca Srl
Ecological Scrap Industry SpA	Nizi International SA
Ecometal Ltd	Nyrstar
EnerSys AD	Penox GmbH
EnerSys Newport	Piombifera Italiana Spa
EnerSys SARL	Piombologhe Srl
EnerSys Sp. Zoo	Portovesme Srl
EnviroWales	PPUH Autopart Jacek BAK Sp z o.o
Exide Technologies GmbH (Deutsche Exide)	RECOBAT
Exide Technologies Lda (SPAT)	SC Rombat SA
Exide Technologies Recycling II Lda (So-nalur)	SIA Industria Accumulatori Spa
Exide Technologies Recycling SL (Oxivolt)	STCM-APSM
Exide Technologies SA (Centra)	Sunlight SA
Exide Technologies SA (Tudor)	TAB dd
Exide Technologies SAS (CEAC)	Teck Resources Ltd.
Exide Technologies Srl (Exide Italia)	Traxys Europe SA
Fenix Metals Sp. z o.o.	Umicore
FIAMM Energy Technology S.p.A	Uzimet

Glencore Import BV	Vellonton LLP
Glencore International Import BV	Vipiemme SpA
H J Enthoven Ltd	Weser-Metall GmbH
Hakurnas	Wilhelm Grillo Handelsgesellschaft mbH
Hammond Lead Products	Yuasa Battery UK Ltd
Hawker GmbH	Zap Sznajder Batterien s.a
Hoppecke Batterien GmbH & Co KG	ZM Silesia SA – Grupa Impexmetal
Huta Cynku “Maisteczko Slaskie”	
IKA Innovative Kunststoffaufbereitung GmbH & Co.KG	Associate Member: AFEMS