[Possibility for MSCA Logo]

Risk Management Option Analysis Conclusion Document

Substance Name: Lead stabilisers used in PVC

EC Number: -

CAS Number: -

Authority: ECHA

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Foreword

The purpose of Risk Management Option analysis (RMOA) is to help authorities decide whether further regulatory risk management activities are required for a substance and to identify the most appropriate instrument to address a concern.

RMOA is a voluntary step, i.e., it is not part of the processes as defined in the legislation. For authorities, documenting the RMOA allows the sharing of information and promoting early discussion, which helps lead to a common understanding on the action pursued. A Member State or ECHA (at the request of the Commission) can carry out this case-by-case analysis in order to conclude whether a substance is a 'relevant substance of very high concern (SVHC)' in the sense of the SVHC Roadmap to 2020[1].

An RMOA can conclude that regulatory risk management at EU level is required for a substance (e.g. harmonised classification and labelling, Candidate List inclusion, restriction, other EU legislation) or that no regulatory action is required at EU level. Any subsequent regulatory processes under the REACH Regulation include consultation of interested parties and appropriate decision making involving Member State Competent Authorities and the European Commission as defined in REACH.

This Conclusion document provides the outcome of the RMOA carried out by the author authority. In this conclusion document, the authority considers how the available information collected on the substance can be used to conclude whether regulatory risk management activities are required for a substance and which is the most appropriate instrument to address a concern. With this Conclusion document the Commission, the competent authorities of the other Member States and stakeholders are informed of the considerations of the author authority. In case the author authority proposes in this conclusion document further regulatory risk management measures, this shall not be considered initiating those other measures or processes. Since this document only reflects the views of the author authority, it does not preclude Member States or the European Commission from considering or initiating regulatory risk management measures which they deem appropriate.

[1] For more information on the SVHC Roadmap: http://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern/svhc-roadmap-to-2020-implementation

1. OVERVIEW OF OTHER PROCESSES / EU LEGISLATION

PVC is used in a variety of applications (such as window profiles, cable insulation, pipes, roofing and flooring) in tonnages greater than 1 million tons per year in Europe. Certain lead compounds are used as stabilisers for PVC products (see Annex I for an indicative list) with long service life and that are required to endure longer fabrication (heating) time (or protection against light). Use of lead stabilisers has been decreasing as a result of Industry's Vinyl 2010 substitution commitment and its successor VinylPlus[3].

Lead is highly regulated in the EU and internationally. Restrictions or total bans have been implemented for a range of uses and in several sectors in EU. A few of the most relevant are indicated here:

Occupational health legislation

There is a binding occupational exposure limit value for lead and inorganic lead compounds in the Chemical Agents Directive (98/24/EC) of 0.15 mg/m³ and a biological limit value and health surveillance measures for lead and its ionic compounds. Specific measures are also in place for protecting young workers and pregnant women under current EU legislation.

Classification and labelling

Lead[4] and lead compounds are classified as toxic to reproduction (fertility and development), toxic following prolonged and repeated exposure (adverse effects on several organs) and hazardous to the aquatic environment (acute and long-term effects).

There are several harmonised classifications for lead compounds in Annex VI of CLP, the relevant classification for the substances in question being:

Index No	International Chemical Identification	EC/CAS No	Classification		Spec. Conc. Limits, M-factors	Notes
			Hazard Class and Category Code(s)	Hazard statement code(s)		
082-001-00-6	lead compounds with the exception of those specified elsewhere in Annex VI	-	Repr. 1A Acute Tox. 4* Acute Tox. 4* STOT RE 2* Aquatic Acute 1 Aquatic Chronic 1	H360-Df H332 H302 H373** H400 H410	STOT RE 2; H373: C≥0,5%	A 1

Restrictions

Annex XVII of the REACH regulation has restrictions on:

- Entry 16 and entry 17: Lead carbonates and lead sulphates, as substances or in mixtures for their use in paints.
- Entry 30: Substances classified as CMR may not be sold to the public (lead compounds are Toxic to Reproduction Category 1A and lead hydrogen arsenate is also a Carcinogen Category 1A).
- Entry 63: Lead and lead compounds shall not be placed on the market or used in concentration of more than 0.05% by weight (i) in jewellery articles

[3] ESPA and EuPC are committed to replacing lead-based stabilisers across the EU-28 by the end of 2015: http://www.vinylplus.eu/

[4] A proposal for a harmonised classification of metallic lead as Repr 1A was adopted by the Risk Assessment Committee (RAC) in 2013. The relevant entry in Annex VI of CLP has not yet been adopted.

(paragraphs 1-5), and (ii) in articles supplied to the general public (or accessible parts thereof) that children can place in their during normal or reasonably foreseeable conditions of use.

SVHC identification/Authorisation

There are currently 31 lead compounds included on the candidate list (of which 9 are potential lead stabilisers) and 2 of the potential lead stabilisers were included in the draft 7th recommendation for Annex XIV (see Annex I).

Three lead compounds are currently included in Annex XIV to REACH (Lead chromate EC No: 231-846-0 CAS No: 7758-97-6; Lead sulfochromate yellow (C.I. Pigment Yellow 34) EC No: 215-693-7 CAS No: 1344-37-2; Lead chromate molybdate sulphate red (C.I. Pigment Red 104) EC No: 235-759-9 CAS No: 12656-85-8). However, these substances are not identified as being used as lead stabilisers.

Water Framework Directive

Lead is regulated under the Water Framework Directive 2000/60/EC establishing a framework for Community action in the field of water policy, as well as Directive 2008/105/EC on environmental quality standards in the field of water policy, and Directive 2006/118/EC on the protection of groundwater against pollution and deterioration.

In relation to surface water, lead and its compounds are listed as priority substances in Annex X of the WFD and an annual average environmental quality standard of 7.2 µg/l has been set. In relation to groundwater, lead is listed in the minimum list of pollutants and their indicators for which Member States have to consider establishing threshold values.

Waste legislation

Lead is regulated under Directive 2010/75/EU on industrial emissions, Directive 2008/98/EC on waste and Decision 2000/532/EC establishing a list of wastes.

Total air emission limit values for certain metals and metal compounds (including lead) of 0.5 mg/Nm^3 have been set. Emission limit value for lead and its compounds in discharges of waste water from the cleaning of waste gases of 0.2 mg/l (expressed as lead).

Other

In addition to the regulatory action taken, several previous RMO analyses have also been carried out on lead and lead compounds and are on the PACT:

- The Swedish Chemicals Agency submitted an RMO analysis on lead and lead compounds in articles intended for consumer use (23/9/2014). No conclusion on further action has yet been reached (http://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern/pact/-/substance-rev/2001/del/50/col/synonymDynamicField_3413/type/desc/pre/6/view).
- 2014, Denmark submitted an RMO analysis on lead and lead compounds concluding possible risk management measures were needed regarding lead exposure via drinking water and food but these would not be addressed under REACH (http://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern/pact/-/substance-rev/1943/del/50/col/synonymDynamicField_3413/type/desc/pre/6/view).

2. CONCLUSION OF RMOA

This conclusion is based on the REACH and CLP data as well as other available relevant information taking into account the SVHC Roadmap to 2020, where appropriate.

Conclusions	**Tick box**
Need for follow-up regulatory action at EU level:	
Harmonised classification and labelling	
Identification as SVHC (authorisation)	
Restriction under REACH	✓
Other EU-wide regulatory measures	
Need for action other than EU regulatory action	
No action needed at this time	

3. NEED FOR FOLLOW-UP REGULATORY ACTION AT EU LEVEL

3.1 Restriction under REACH

Lead in PVC

Uses

Formulated lead stabiliser products usually contain a blend of various inorganic lead compounds, plus other additives. In the manufacturing of PVC-articles, lead-stabilisers are added during the compounding phase to the PVC-matrix prior to the extrusion process to provide protection of the final PVC-product against the influence of temperature and light. Lead-containing PVC products are used primarily in construction applications where long product life and durability are required. PVC-products most often sold in the EU27 were profiles (28%), pipes and fitting (23%), rigid films (9%), cables (7%) and flooring (6%)[5]. According to VinylPlus (2015)[6], in the 2007-2014 period, the use of lead stabilisers decreased by over 86K tonnes (- 86%) in the EU-28, while use of calcium-based stabilisers increased by over 29K tonnes. The main compounds used as lead stabilisers are set out in Annex I.

Hazards and risks

Related to human health, lead can cause effects on the blood, as well as the nervous, immune, renal and cardiovascular systems. Exposure to high amounts of lead can cause gastrointestinal symptoms, severely damage the brain and kidneys, and may cause reproductive effects (US-EPA, 2011). In humans, the most critical health effects in

[5] Vinyl 2010 progress report: http://www.plasticseurope.org/documents/document/20110422155920-vinyl2010__progress_report_2011.pdf

[6] VinylPlus 2015 progress report, http://www.vinylplus.eu/documents/35/57/Progress-Report-2015

children of lead are its neurodevelopmental effects which cause impaired brain function. The critical effects in adults are its haematological effects (increased blood pressure) and adverse effects on the kidneys. A recent evaluation made by the European Food Safety Authority (EFSA) in 2010 concluded that a no-effect-level for lead could not be identified.

In the environment, lead accumulates in soils and sediments and is toxic to plants, animals and micro-organisms. Ecosystems near point sources of lead demonstrate a wide range of adverse effects including losses in biodiversity, changes in community composition, decreased growth and reproductive rates in plants and animals, and neurological effects in vertebrates[7].

According to the Voluntary Risk Assessment carried out by Industry in 2008[8], the main health concern for the use of lead stabilisers is predominantly occupational in PVC processing and the environmental concern is for sediment related to Pb stabiliser production. However, several MS had concerns regarding the voluntary risk assessment so the issues raised should only be viewed as indicative. In addition, the need for further information was also indicated.

Alternatives

The vinylplus website states that calcium-based stabilisers (including Ca/Zn) can be used as an alternative to lead-based stabilisers. They are currently used in wires and pipes, in window and technical profiles (also foamed ones) and in any type of pipes (such as soil and sewer pipes, foam core pipes, pressure pipes, corrugated pipes, land drainage pipes and cable ducting) as well as the corresponding fittings.

These calcium/zinc stabilisers are in general more complex and expensive than the traditional soaps, mainly because of the specialised co-stabilisers (polyols, epoxydised soya bean oil, antioxidants and organic phosphites). Nevertheless it is possible to switch from lead to calcium-based stabilisation without making major changes to processing machinery such as extrusion screws and tools.

Other stabilisers are generally based on metal carboxylates and will sometimes incorporate other elements such as aluminium or magnesium to boost performance.

Calcium/zinc stabiliser systems incorporating the proven range of co-stabilisers have low toxicity according to industry[9].

Initial contacts with EU lead industry have indicated the cost difference between the lead stabilisers and the available alternatives is very low.

Recycling

A study was carried out for Vinyl Plus on the effects of EU regulations on lead recycling[10]. This study showed that a general concentration limit of 0.1% of lead in PVC (and no exemptions for recycling) would have a negative impact on recycling (with a consequential loss of jobs and increase in costs). However, if an exemption was given for recycling of PVC for use in construction products with a concentration limit of 1%, this would reduce any impacts to almost the same level as the Business as normal scenario.

7 US-EPA, http://epa.gov/air/lead/health.html
8 VRAR; LDAI, 2008 (2008)
9 http://www.pvc.org/en/p/calcium-zinc-stabilisers
10 Tauw (2013) *Impact of lead restrictions on the recycling of PVC*

Conclusion

The potential scope of any restriction could include the use of lead stabilisers in PVC and in PVC articles. The potential scope would need further investigation as, for example, some consumer articles (including PVC articles containing virgin and recycled PVC) will be covered by the new restriction on lead in consumer articles that can be mouthed by children (e.g. garden hoses). In addition it should be considered if all lead compounds are covered or just certain identified compounds (such as set out in Annex I).

There are likely to be potential benefits to health and the environment from such a restriction, given the hazard profile of the relevant lead compounds. This proposal would contribute to reducing the amount of lead circulating in society and help to reduce risks to human health via the environment. The costs of the restriction are likely to be low given alternative stabilisers are available and in use, and in addition that the use of the substances is decreasing in the EU. However, issues such as recycling will need to be further considered in any final proposal with the possible inclusion of a suitable exemption. A another benefit of a restriction on lead stabilisers used in PVC would be to reinforce the current voluntary agreement and cover any EU companies that haven't signed up to VinylPlus as well as imports.

4. TENTATIVE PLAN FOR FOLLOW-UP ACTIONS IF NECESSARY

Follow-up action	Date for follow-up	Actor
Annex XV dossier for restrictions, if requested by Commission	06 / 2016 (Dossier Submission)	ECHA

Annex I: most common lead stabilisers in PVC (non-exhaustive list)[11]

Substance name*	CAS No.	EC No.	Registered for use as stabiliser	Registration band (tonnes per year)	SVHC status	Other regulatory action
Lead distearate (Neutral lead stearate)	1072-35-1	214-005-2	x	Not registered at present (Pre-registration envisaged deadline 30/11/2010)		
Dioxobis(stearato)dilead (Dibasic lead stearate)	56189-09-4	260-043-8	x	Not registered at present (Pre-registration envisaged deadline 30/11/2010)		
2-Butenedioic acid (E)-, lead(2+) salt, basic (Polybasic lead fumarate)	90268-59-0	290-862-6	x	Not registered at present (Pre-registration envisaged deadline 30/11/2010)		
Trilead bis(carbonate) dihydroxide (Basic lead carbonate)	1319-46-6	215-290-6	x	10 – 100	Candidate list (Repr)	
Tetralead trioxide sulphate (Tribasic lead sulphate)	12202-17-4	235-380-9	✓	1 000 000 – 10 000 000	Candidate list (Repr) Draft 7th recommendation	
Pentalead tetraoxide sulphate (Tetrabasic lead sulphate)	12065-90-6	235-067-7	✓	10 000-100 000	Candidate list (Repr) Draft 7th recommendation	
[Phthalato(2-)] dioxotrilead	69011-	273-	✓ (PVC	100 - 1000	Candidate list (Repr)	Compliance check

[11] Table compiled using information gathered from draft 6th Recommendation and European Stabiliser Producers Association (ESPA) website (http://www.stabilisers.org/stabilisers-types/lead-stabilisers).

Substance name*	CAS No.	EC No.	Registered for use as stabiliser	Registration band (tonnes per year)	SVHC status	Other regulatory action
(Dibasic lead phthalate)	06-9	688-5	Processing)			
Lead oxide sulfate (Basic lead sulphate)	12036-76-9	234-853-7	✓	0 - 10	Candidate list (Repr)	
Dioxobis(stearato)trilead	235-702-8	235-702-8	✓	10 000 – 100 000	Candidate list (Repr)	
Trilead dioxide phosphonate (Dibasic lead phosphite)	12141-20-7	235-252-2	✓	10 000-100 000	Candidate list (Repr)	
Sulfurous acid, lead salt, dibasic	62229-08-7	263-467-1	✓	100 - 1000	Candidate list (Repr)	
Fatty acids, C16-18, lead salts	91031-62-8	292-966-7	✓	10 000 – 100 000	Candidate list (Repr)	