Estimating the number of applications expected for five substances added to the Authorisation List in April 2022

April 2022

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Forecasting the number of applications for authorisation under REACH is important for ECHA as it allows the Agency to adequately plan its use of staff resources and to ensure capacity for processing applications in its committees for risk assessment (RAC) and socio-economic analysis (SEAC).

On 8 April 2022, the European Commission added five substances of very high concern (SVHCs) to the Authorisation List (Annex XIV of REACH Regulation). These substances are listed in Table 1.

To estimate the number of applications for authorisation that might be received for these substances, ECHA carried out an online survey which was sent to more than 450 stakeholders (registrants of the five substances and companies that submitted classification and labelling notifications for the concerned substances). As a follow up to the survey, ECHA also directly contacted a limited number of stakeholders, namely trade associations and registrants.

Through the research it was discovered that – as reported in Table 1 – ECHA should expect to receive 12-23 applications for the five substances in 2023[1].

Table 1: Substances added to the Authorisation List

Substance	EC number/CAS	Number of applications expected
Tetraethyllead (TEL)[2]	EC 201-075-4 CAS 78-00-2	1-3
4,4'-bis(dimethylamino)-4''-(methylamino)trityl alcohol [with ≥ 0.1% w/w of Michler's ketone (EC No. 202-027-5) or Michler's base (EC No. 202-959-2)][3]	EC 209-218-2 CAS 561-41-1	0-4
Reaction products of 1,3,4-thiadiazolidine-2,5-dithione, formaldehyde and 4-heptylphenol, branched and linear (RP-HP) [with ≥ 0.1% w/w 4-heptylphenol, branched and linear (4-HPbl)][4]	-	0
2-ethylhexyl 10-ethyl-4,4-dioctyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate (DOTE)[5]	EC 239-622-4 CAS 15571-58-1	10-15
Reaction mass of 2-ethylhexyl 10-ethyl-4,4-dioctyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate and 2-ethylhexyl 10-ethyl-4-[[2-[(2-ethylhexyl)oxy]-2-oxoethyl]thio]-4-octyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate (reaction mass of DOTE and MOTE)[6]	-	1
Total		**12-23**

In addition to the survey, ECHA also performed internet-based research to identify potential alternatives to the five substances for uses that fall into the scope of the Authorisation title. Based on this study, some potential alternatives appear to be available for most of the uses identified.

[1] Assuming the applications will be submitted by the latest application date. ECHA may however also receive applications in 2024 if applicants submit applications after the latest application date.
[2] https://echa.europa.eu/candidate-list-table/-/dislist/details/0b0236e1807de06e
[3] Candidate List of substances of very high concern for Authorisation - ECHA (europa.eu)
[4] https://echa.europa.eu/candidate-list-table/-/dislist/details/0b0236e181f38c8a
[5] Candidate List of substances of very high concern for Authorisation - ECHA (europa.eu)
[6] Candidate List of substances of very high concern for Authorisation - ECHA (europa.eu)

However, information is lacking to fully understand the technical and economic feasibility of the potential alternatives identified. Also, no investigation of the risk profile of the identified alternatives was carried out as part of this study.

1. Introduction

The Authorisation process – described in Title VII of the REACH Regulation – aims to ensure that substances of very high concern (SVHCs) are progressively replaced by less dangerous substances or technologies where technically and economically feasible alternatives are available.

Substances included in the Candidate List are regularly assessed by ECHA to determine which should be recommended for inclusion in the Authorisation List (Annex XIV to REACH) as a priority. ECHA's recommendations are then submitted to the European Commission, which decides on the substances to be included in the Authorisation List and on the final entries (sunset date, latest application date, exemptions).

The five substances which are discussed in this report were included in ECHA's ninth recommendation in 2019[7] and added to the Authorisation List on 8 April 2022[8], meaning that companies wanting to use the substances or place them on the market for use after their sunset date need to apply for an authorisation. Table 2 summarises the intrinsic properties as well as the final entries for the five substances.

Table 2: Substances added to the Authorisation List, latest application dates and sunset dates

Substance	Intrinsic properties referred to in Article 57	Latest application date	Sunset date
Tetraethyllead (TEL) EC 201-075-4, CAS 78-00-2	Toxic for reproduction (category 1A)	1 November 2023	1 May 2025
4,4'-bis(dimethylamino)-4''-(methylamino)trityl alcohol [with ≥ 0.1% w/w of Michler's ketone (EC No. 202-027-5) or Michler's base (EC No. 202-959-2)] EC 209-218-2 CAS 561-41-1	Carcinogenic[9] (category 1B)	1 November 2023	1 May 2025
Reaction products of 1,3,4-thiadiazolidine-2,5-dithione, formaldehyde and 4-heptylphenol, branched and linear (RP-HP) [with ≥ 0.1% w/w 4-heptylphenol, branched and linear (4-HPbl) - EC - CAS -	Endocrine disrupting properties – environment	1 November 2023	1 May 2025
2-ethylhexyl 10-ethyl-4,4-dioctyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate (DOTE) EC 239-622-4 CAS 15571-58-1	Toxic for reproduction (category 1B)	1 November 2023	1 May 2025

[7] https://echa.europa.eu/documents/10162/17232/9th_axiv_recommendation_October2019_en.pdf
[8] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32022R0586&qid=1649642172564
[9] A majority of data submitters agree this substance is persistent, bioaccumulative and toxic (PBT).

Reaction mass of 2-ethylhexyl 10-ethyl-4,4-dioctyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate and 2-ethylhexyl 10-ethyl-4-[[2-[(2-ethylhexyl)oxy]-2-oxoethyl]thio]-4-octyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate (reaction mass of DOTE and MOTE) EC - CAS -	Toxic for reproduction (category 1B)	1 November 2023	1 May 2025

Source: European Commission (2022)

In 2019, ECHA performed a similar survey for 11 substances added to the Authorisation List in February 2020 – commissioning the work to an external consultant. This is the second time that ECHA engages with relevant stakeholders to assess their interest in applying for authorisation. The following steps were taken.

Firstly, ECHA carried out initial research based on the information provided in the registration dossiers and ECHA's background documents. This initial work was instrumental for obtaining information on the uses that fall into the scope of authorisation and on the substances' functions in those uses.

Secondly, ECHA sent an online survey to relevant stakeholders requesting them to provide information on whether:

- they manufacture, import, formulate, distribute, or use any of the five substances within the EU;
- they have an intention to apply for authorisation to continue using any of the substances;
- they have an intention to apply for authorisation alone or through an upstream applicant; and
- they have an intention to apply for authorisation on behalf of downstream users[10].

As a follow-up, ECHA also contacted relevant associations and registrants, when there was a need to corroborate certain findings from the survey.

Finally, ECHA also investigated whether potential alternatives to the above substances are available.

To find the relevant information on alternatives, a review of the stakeholders' comments to the ninth recommendation for inclusion of substances of very high concern in Annex XIV was performed. This analysis was crucial for gaining an understanding of the availability of alternatives to the five substances and uses where substitution could be more challenging.

Additional research (primarily internet-based) was performed to collect more information on alternatives, and specific questions on alternatives were also included as part of the online survey on the likely number of applications for authorisation.

[10] Relevant only if the respondent is the manufacturer or importer of the substance.

2. Information on the uses and alternatives

2.1 Overview of the uses of the five substances and their technical functions

Table 3 summarises the information obtained on the uses of the five substances. This is based mainly on the information retrieved from registration dossiers and ECHA's background documents developed in the context of ECHA's ninth recommendation for inclusion of substances in Annex XIV.

Table 3: Summary of substance uses

Substance	Registered (Yes/No)	Number of registrants/suppliers	Registered tonnage	Use summary and substance function	Relevant associations
Tetraethyllead (TEL)[11] EC 201-075-4 CAS 78-00-2	Yes[12]	3 -Innospec Performance Chemicals France SAS (Only Rep 2) -Total Raffinage France and -Warter Fuels Spółka Akcyjna	≥ 100 to < 1 000 tonnes	Anti-knock agent in aviation gasoline (avgas)	European Union Aviation Safety Agency (EASA)
4,4'-bis(dimethylamino)-4''-(methylamino)trityl alcohol[13] [with ≥ 0.1% w/w of Michler's ketone (EC No. 202-027-5) or Michler's base (EC No. 202-959-2)] EC 209-218-2 CAS 561-41-1	Yes[14]	4 Dokumental GmbH & Co KG -Global Product Compliance (Europe) AB (3 OR registrations)	≥ 10 to < 100 tonnes	The substance appears to be used in the formulation of inks	CEPE (European Council of the Paint, Printing Ink and Artists' Colours (CEPE), EuPIA – European Printing Ink Association
Reaction products of 1,3,4-thiadiazolidine-2,5-dithione, formaldehyde and 4-heptylphenol, branched and linear (RP-HP) [with ≥ 0,1% w/w 4-heptylphenol, branched and linear (4-HPbl)][15] EC - CAS -	Yes[16]	Confidential[17]	≥ 10 to < 100 tonnes	The substance is used as corrosion inhibitor in lubricant additives	ATIEL (Representative body for European lubricants industry)
2-ethylhexyl 10-ethyl-4,4-dioctyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate (DOTE)[18] EC 239-622-4 CAS 15571-58-1	Yes[19]	5 -Baerlocher Italia SPA -BNT Chemicals GmbH -Galata Chemicals GmbH -Pmcvlissingenbv -REAGENS SPA	≥ 1 000 to < 10 000 tonnes	The substance is used as heat stabiliser in the production of PVC applications	European Stabiliser Producers Association (ESPA), European Plastic Converters (EuPC)

[11] svhc_supdoc_tetraethyllead_en (europa.eu)
[12] https://echa.europa.eu/registration-dossier/-/registered-dossier/23838/1/2
[13] https://echa.europa.eu/documents/10162/4300b1a0-79ae-4d90-bcac-07a34691c435
[14] Registration Dossier - ECHA (europa.eu)
[15] Annex XV report (europa.eu)
[16] Only the substance 'Formaldehyde, reaction products with phenol heptyl derivs. and 1,3,4-thiadiazolidine-2,5-dithione' with CAS number 1471311-26-8 and List number 939-460-0 is registered: https://echa.europa.eu/registration-dossier/-/registered-dossier/12316
[17] https://echa.europa.eu/registration-dossier/-/registered-dossier/12316/1/2
[18] support_document_dote_20141209 (europa.eu)
[19] Registration Dossier - ECHA (europa.eu)

Reaction mass of 2-ethylhexyl 10-ethyl-4,4-dioctyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate and 2-ethylhexyl 10-ethyl-4-[[2-[(2-ethylhexyl)oxy]-2-oxoethyl]thio]-4-octyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate (reaction mass of DOTE and MOTE)[20] EC - CAS -	No	n/a	n/a	The substance is used as heat stabiliser in the production of PVC applications	European Stabiliser Producers Association (ESPA), European Plastic Converters (EuPC)

2.2 Overview of potential alternatives to five substances included in the Authorisation List

ECHA conducted internet-based research to identify potential chemical alternatives to the five substances for the uses that fall into the scope of authorisation under REACH. The findings are summarised in Table 4 and discussed in this section.

The search was focused on identifying alternatives which may be suitable to replace the technical functions provided by the five substances. Some general considerations have been made on their economic feasibility when the relevant information was available.

However, an assessment of potential risks associated with the use of the considered alternatives was not in the scope of this study. Therefore, the reader should consider with caution the following list of alternatives and be aware that some of the alternatives listed below may not be suitable from a risk profile perspective.

[20] https://echa.europa.eu/documents/10162/a410b50c-11f9-49ca-9e8f-54f2a674b032

Table 4: Potential alternatives to five substances

Substance	Possible alternatives
Tetraethyllead (TEL) EC 201-075-4 CAS 78-00-2	• Toluene • Mesitylene • Methyl tert-butyl ether (MTBE) • Ethyl tert-butyl ether (ETBE) • Aniline • m-toluidine • Methylcyclopentadienyl manganese tricarbonyl (MMT) • tert-amyl methyl ether (TAME) • Ferrocene • N-methyl-p-toluidine
4,4'-bis(dimethylamino)-4''-(methylamino)trityl alcohol [with ≥ 0.1% w/w of Michler's ketone (EC No. 202-027-5) or Michler's base (EC No. 202-959-2)] EC 209-218-2 CAS 561-41-1	• 4,4’-bis(dimethylamino)-4’’-(methylamino)trityl alcohol not containing Michler’s ketone or Michler’s base at or above the CMR threshold
Reaction products of 1,3,4-thiadiazolidine-2,5-dithione, formaldehyde and 4-heptylphenol, branched and linear (RP-HP) [with ≥ 0,1% w/w 4-heptylphenol, branched and linear (4-HPbl)] EC No - CAS No -	<u>Organic inhibitors</u> • Compounds containing nitrogen • Compounds containing nitrogen and sulphur • Compounds containing nitrogen and oxygen <u>Inorganic inhibitors</u> • Sodium molybdate • Calcium nitrite • Rare earth metal salts • Siloxane-based sol-gel coatings • Zinc phosphate • Chromates • Lanthanide compounds
2-ethylhexyl 10-ethyl-4,4-dioctyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate (DOTE) EC 239-622-4 CAS 15571-58-1	• Calcium organic-based stabilisers (calcium/zinc stabilisers and organic-based stabilisers (OBS)) • Liquid mixed metal stabilisers • Other organotin compounds (in particular, methyltins)
Reaction mass of 2-ethylhexyl 10-ethyl-4,4-dioctyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate and 2-ethylhexyl10-ethyl-4-[[2-[(2-ethylhexyl)oxy]-2-oxoethyl]thio]-4-octyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate (reaction mass of DOTE and MOTE) EC - CAS -	• Calcium organic-based stabilisers (calcium/zinc stabilisers and organic-based stabilisers (OBS)) • Liquid mixed metal stabilisers • Other organotin compounds (in particular, methyltins)

2.2.1 Tetraethyllead

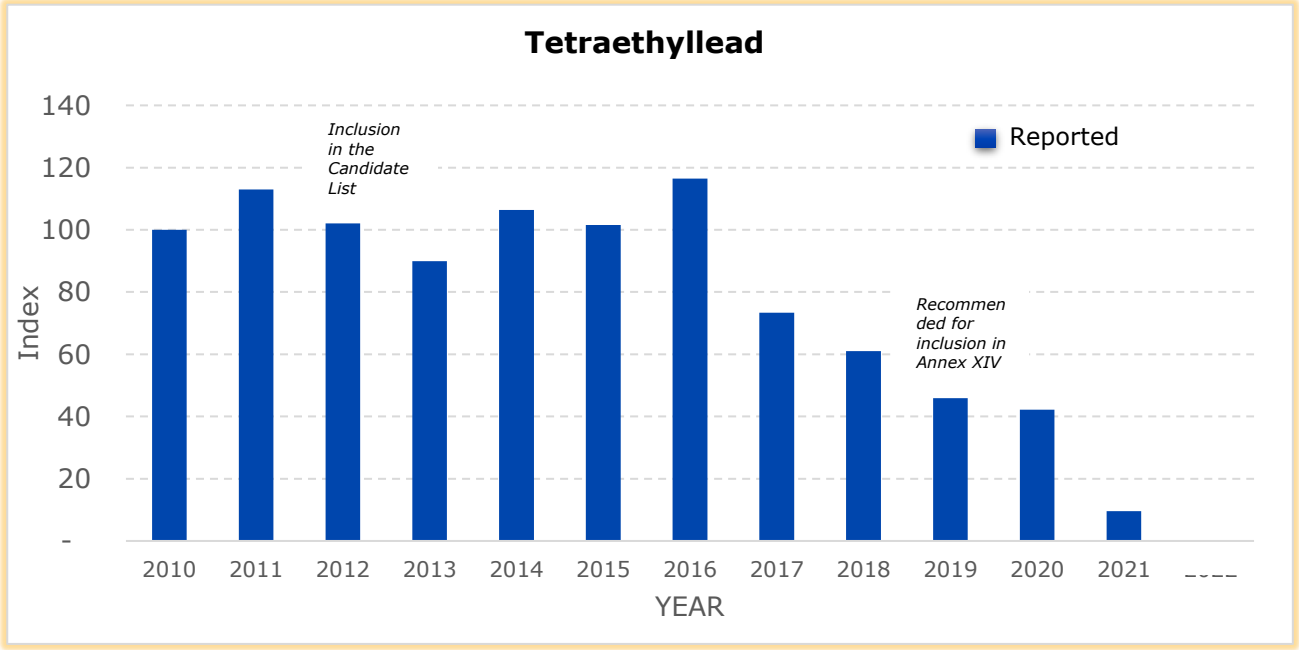
Tetraethyllead (TEL) is used as an anti-knock agent in aviation gasoline (avgas). It helps raise the octane rating, which is the ability of a fuel to resist detonation[21] or "knock"[22]. A higher-octane rating means that the fuel is more stable.[23]

Tetraethyllead is added in small amounts to avgas to boost the octane number. Avgas must have an octane number of 100 to protect high-powered engines from detonation.[24]

The substance was included in the Candidate List in 2012 and recommended for inclusion in REACH Annex XIV on 1 October 2019[25].

In terms of volumes, the chart below shows that between 2016 and 2021[26] the consumption in the EU (reported values) decreased by 92 %.

Charts 1: Tetraethyllead (TEL), volumes consumed in the EU (2010-2022)



Source: *Registration dossiers (i.e., intermediate registrations are excluded). The annual consumed tonnes have been normalised with 2010 set as the base year.*

[21] https://faa.gov/newsroom/leaded-aviation-fuel-and-environment
[22] https://exxon.com/en/octane-rating
[23] https://eia.gov/energyexplained/gasoline/octane-in-depth.php
[24] https://flyingmag.com/aircraft/modifications-maintenance/avgas-alternatives/
[25] https://echa.europa.eu/fi/recommendations-for-inclusion-in-the-authorisation-list/-/dislist/details/0b0236e1828a5e98
[26] UK is the only country in the world where the substance is produced. After Brexit, the volumes reported in the chart reflect only the volumes imported to the EU.

Table 5 reports the potential alternatives to tetraethyllead which have been considered by the Piston Aviation Fuels Initiative, PAFI (EASA report)[27].

Table 5: Potential alternatives

Alternative	Examples of alternatives	Specifications	EC no.	CAS no.	Hazard properties[28]
ALTERNATIVE 1 – Aromatics	Toluene[29]	ASTM D7719[30]	203-625-9	108-88-3	Suspected to be Toxic to Reproduction[31]
	Mesitylene[32]	ASTM D7719	203-604-4	108-67-8	Not classified as CMR, ED, PBT, and/or vPvB[33]
ALTERNATIVE 2– Oxygenates	Methyl tert-butyl ether (MTBE)[34]	ASTMD7618[35] ASTM D7618 ASTM D4814[36]	216-653-1	1634-04-4	Under assessment as ED and PBT[37]
	Ethyl tert-butyl ether (ETBE)[38]	ASTM D7618 ASTM D4814	211-309-7	637-92-3	Not classified as CMR, ED, PBT, and/or vPvB[39]
	tert-amyl methyl ether (TAME)[40]		213-611-4	994-05-8	Not classified as CMR, ED, PBT, and/or vPvB[41]
ALTERNATIVE 3- Aromatic Amines	Aniline[42]	ASTM D7960[43]	203-583-1	108-44-1	Skin sensitising, suspected to be Carcinogenic[44]
	m-toluidine[45]	ASTM D7960	203-583-1	108-44-1	Not classified as CMR, ED, PBT, and/or vPvB[46]
	N-methyl-p-toluidine[47]		210-769-6	623-08-5	Not classified as CMR, ED, PBT, and/or vPvB[48]
ALTERNATIVE 4 – Organometallics	Methylcyclopentadienyl manganese tricarbonyl	ASTM WK6928[51]	235-166-5	12108-13-3	Not classified as CMR, ED, PBT,

[27] EASA report: "Art. 87.2 Information (REACH)"
[28] All information under that heading is taken from ECHA's Dissemination Portal.
[29] https://worldofchemicals.com/428/chemistry-articles/toluene-additive-for-racing-fuels-fuel-octane-booster.html
[30] https://astm.org/d7719-21a.html
[31] https://echa.europa.eu/substance-information/-/substanceinfo/100.003.297
[32] https://patents.google.com/patent/US20110088311A1/en
[33] https://echa.europa.eu/substance-information/-/substanceinfo/100.003.278
[34] https://sciencedirect.com/science/article/pii/S0360128516300570
[35] https://astm.org/d7618-13r21.html
[36] https://astm.org/d4814-21c.html
[37] https://echa.europa.eu/substance-information/-/substanceinfo/100.015.140
[38] https://petrochemistry.eu/wp-content/uploads/2018/01/ETBE-Product-Bulletin-Jun-2006.pdf
[39] https://echa.europa.eu/substance-information/-/substanceinfo/100.010.282
[40] https://sciencedirect.com/science/article/pii/S0360128516300570
[41] https://echa.europa.eu/substance-information/-/substanceinfo/100.012.374
[42] https://sae.org/publications/technical-papers/content/2016-01-2273/
[43] https://normstream.com/en/ASTM/144611687/ASTM-D7960
[44] https://echa.europa.eu/substance-information/-/substanceinfo/100.000.491
[45] https://sciencedirect.com/science/article/pii/S0016236121013971
[46] https://echa.europa.eu/substance-information/-/substanceinfo/100.003.258
[47] https://pubs.acs.org/doi/10.1021/acs.energyfuels.1c00912
[48] https://echa.europa.eu/substance-information/-/substanceinfo/100.009.791
[51] https://astm.org/get-involved/technical-committees.html

	(MMT)[49] [50]	Item 6 ASTM D910[52]			and/or vPvB[53]
	Ferrocene[54]		203-039-3	102-54-5	Most data submitters agree this substance is Toxic to Reproduction. However, no harmonised classification yet[55]

Source: EASA report: "Article 87.2 Information (REACH)" and literature review

According to the EASA report, mid-octane unleaded aviation gasoline, such as UL91 pr 91/96 UL, is available in several European countries. However, due to its lower anti-knock performance without the TEL additive, it cannot be used in all engines and so considered as a suitable alternative. Furthermore, automotive fuels are not suitable for 100LL engines, because even those considered premium do not meet the 100LL Motor Octane Number (MON) requirement of 99.6 (EASA report).

Alternatives are currently under development in the United States. The development of an unleaded high-octane fuel was initiated by the US aviation authority FAA – "*Piston Aviation Fuels Initiative*" (PAFI). PAFI[56] program forms a key component of the recently announced US EPA/FAA[57] "*Eliminate Aviation Gasoline Lead Emissions*" initiative to transition to a new aviation gasoline without tetraethyllead by the end of 2030.

Toluene, MTBE, ETBE, aniline, m-toluidine and MMT are among the candidates considered for unleaded high-octane avgas by PAFI.

ATERNATIVE 1 – Aromatics

- ***Toluene***

Toluene's low sensitivity makes it an excellent fuel for a heavily loaded engine (World of Chemicals, 2022). Furthermore, the same article published on WOC (World of Chemicals, 2022) describes toluene as a good anti-knock agent, considering that this substance is denser than ordinary gasoline and contains more energy per unit volume. Thus, the combustion of toluene leads to the release of more energy and can generate more power. This also means that a smaller amount of this substance is needed to obtain the same octane boost compared to 100 octane running gas.

[49] https://saemobilus.sae.org/content/2016-01-9073/
[50] https://pubs.acs.org/doi/10.1021/acs.energyfuels.1c00912
[52] Standard Specification for Leaded Aviation Gasolines (astm.org)
[53] https://echa.europa.eu/substance-information/-/substanceinfo/100.031.957
[54] https://researchgate.net/publication/41114077_OPPORTUNITIES_FOR_GASOLINE_OCTANE_INCREASE_BY_USE_OF_IRON_CONTAINING_OCTANE_BOOSTER
[55] https://echa.europa.eu/substance-information/-/substanceinfo/100.002.764
[56] https://faa.gov/about/initiatives/avgas
[57] Federal Aviation Administration

- ***Mesitylene***

According to Bower et al. (2011), the use of mesitylene (1,3,5-trimethylbenzene) in gasoline blending produces a fuel blend with higher RON and MON that increases the octane number of the final blend.

ALTERNATIVE 2–Oxygenates

- ***Methyl tert-butyl ether (MTBE)***

In terms of its technical properties, the literature refers to methyl tert-butyl ether's (MTBE) remarkably high RON of 117, achieved through the highly branched tertiary butyl group attached to the ether group (Boot et al., 2017). MTBE has higher energy compared to alcohols, higher octane than aromatics and low water affinity (Lyondell Basell, 2015).

- ***Ethyl tert-butyl ether (ETBE)***

Ethyl tert-butyl ether (ETBE) has an impressive anti-knock quality due to the highly branched tertiary butyl group attached to the ether group (Boot et al., 2017). Moreover, this substance manifests other relevant properties, such as high octane – 118 (Boot et al., 2017) –, low boiling point and low vapour pressure (EFOA[58], 2006). These characteristics make ETBE a very versatile gasoline blending component, that can be used to upgrade naphtha to gasoline or to upgrade low octane gasoline grades to higher ones, while meeting increasingly stringent environmental specifications (EFOA, 2006).

Although, from an EU point of view, this substance shows a promising path, there are technical problems that require further investigation – reduced energy content, higher required fuel flow, achievable octane level and water tolerance (EASA report). For instance, it is relevant to mention the possible difficulty in achieving a 100 MON fuel by using only ETBE as an octane booster and limiting the aromatic content to a reasonable level. In this case, it may be necessary to use another octane booster, like MMT, to achieve the MON requirement (EASA report).

- ***tert-amyl methyl ether (TAME)***

Tert-amyl methyl ether (TAME) has a high RON of 112 and a molecular structure similar to the other two oxygenate substances (Boot et al., 2017).

In general, all these three oxygenate substances present more or less the same advantages as octane boosters (AMF, 2016): maintenance of high-octane numbers in fuels with reduced content of aromatics (including benzene) (McGregor, 2007), reduction in the fuel vapour pressure (McGregor, 2007) and low solubility in water (AMF, 2016).

ALTERNATIVE 3-Aromatic Amines

- ***Aniline***

Aromatic amines, particularly anilines, *"have been examined as anti-knock agents, and they*

[58] European Fuel Oxygenates Association

have been found to be generally more efficient in increasing the octane number than oxygenate additives" (Viayna et al., 2021). Their efficiency as anti-knock agents is related to the abstraction of the amino hydrogen atom by a reactive radical species (Viayna et al., 2021). However, their applicability is limited by the higher price compared to oxygenated compounds and their potential toxicity (Viayna et al., 2021). In the field of aviation, aniline "*has been known to be aggressive*" to materials present in the fuel systems since the 1950s (EASA report).

- ***m-toluidine***

m-Toluidine is reported to have excellent chemical stability (Ershov et al. 2021). The same authors carried out experimental studies, where they concluded that this substance has a greater anti-knock performance in high-octane base fuel mixtures when compared to other aromatic amines.

- ***N-methyl-p-toluidine***

It has been experimentally demonstrated that this substance is an excellent anti-knock agent in low-octane base fuel mixtures (Ershov et al., 2021). Recently, an unleaded 100-octane fuel (containing N-methyl-p-toluidine) has been approved in the US[59] to be used in certain types of engines.

ALTERNATIVE 4 – Organometallics

- ***Methylcyclopentadienyl manganese tricarbonyl (MMT)***

Davis (1998) stated that Methylcyclopentadienyl manganese tricarbonyl (MMT) was "*developed (…) to increase the octane level of gasoline and thereby enhance the anti-knock properties of the fuel. It also was marketed to improve the combustion of fuel oil and turbine fuel*". Although it has been successfully approved for use in EN228 automotive gasoline, for aviation gasoline it would be necessary to add a much larger amount of MMT to obtain the required octane level of about 100 MON. Regarding its chemical properties, MTT displays low water solubility and low vapour pressure (Hoekman and Broch, 2016).

- ***Ferrocene***

Ferrocenes emerged as cheaper alternatives to MMT to boost octane numbers (Badia et al., 2021). Experimental studies conducted by Chandra and Madhu (2016) showed that ferrocene not only improves the efficient combustion of fuel, but also decreases the knocking tendency due to the presence of aromatic molecules. Another study, carried out by Stratiev and Kirilov (2009), confirmed that the addition of ferrocene to gasoline with RON rating of 78.6–95.9, can increase the octane number by 0.7-1.9 points. It is also important to note that experimental results showed that ferrocene "*can effectively increase the combustion rate and reduce kindling temperature by 50°C"* (Chandra and Madhu, 2016).

[59] https://avweb.com/aviation-news/gami-awarded-long-awaited-stc-for-unleaded-100-octane-avgas/

2.2.2 4,4'-bis(dimethylamino)-4''-(methylamino)trityl alcohol

4,4'-bis(dimethylamino)-4''-(methylamino)trityl alcohol is a substance of the triphenylmethane dyes group. The substance appears to be used at industrial sites in the formulation of inks and toners[60]. In providing comments to ECHA's ninth draft recommendation for inclusion of 4,4'-bis(dimethylamino)-4''-(methylamino)trityl alcohol with ≥ 0.1 % of Michler's ketone (EC 202-027-5) or Michler's base (EC 202-959-2) to Annex XIV, the registrants specified that the substance is used in formulation of inks, which are used in the production of ballpoint pens and permanent markers[61].

No detailed information appears to be available on the substance's technical function for the uses in the scope of authorisation. However, it is plausible that the substance is used as a dyeing agent.

When preparing the Annex XV report for the identification of 4,4'-bis(dimethylamino)-4''-(methylamino)trityl alcohol with ≥ 0.1% of Michler's ketone (EC 202-027-5) or Michler's base (EC 202-959-2) as an SVHC in 2012, the dossier submitter stated that according to the information submitted during the public consultation on alternatives, some research on substitutes had been done in the past but without success, due to technical and economic factors[62]. However, no specific information was provided on the technical and economic suitability of the potential alternatives.

Also, based on inputs provided during the public consultation, it seems that trityl alcohol which does not contain Michler's ketone or Michler's base above the 0.1 % threshold is available on the market. Based on this information, the dossier submitter concluded that grades of 4,4'-bis(dimethylamino)-4''-(methylamino)trityl alcohol not containing Michler's ketone or Michler's base at or above the CMR threshold might be a possible alternative.

No information on the availability of alternatives was provided during the consultation on the ninth draft recommendation of priority substances for inclusion in the list of substances subject to authorisation (Annex XIV).

The relevant EU association indicated that – based on their knowledge – the European printing ink industry is not using the substance.

2.2.3 RP-HP

RP-HP (Reaction products of 1,3,4-thiadiazolidine-2,5-dithione, formaldehyde and 4-heptylphenol, branched and linear) is used to improve the anti-corrosive ability of lubricants (Annex XV Report, 2017). A literature search suggests the existence of two types of corrosion inhibitors – organic and inorganic – which may be considered potential alternatives to RP-HP (Brycki et al., 2017; El Ibrahimi, 2021). Table 6 shows the main corrosion inhibitors organised by group.

[60] PC 18: Ink and toners (Registration Dossier - ECHA (europa.eu))
[61] Submitted recommendations - ECHA (europa.eu)
[62] Registry of SVHC intentions until outcome - ECHA (europa.eu)

Table 6: Potential alternatives (organic and inorganic corrosion inhibitors)

ALTERNATIVE 1 – Organic corrosion inhibitors	Compounds containing nitrogen: amines, pyridine derivatives, quaternary ammonium salts, triazole derivatives, Schiff bases, amino acids, indazole and imidazole derivatives
	Compounds containing nitrogen and sulphur: thiadiazole derivatives and thiazole derivatives
	Compounds containing sulphur: thiourea derivatives and sulfonates
	Compounds containing nitrogen and oxygen: oxazole derivatives, phthalimide and plant extracts
ALTERNATIVE 2 – Inorganic corrosion inhibitors	Sodium molybdate
	Calcium nitrite
	Rare earth metal salts
	Siloxane based sol-gel coatings
	Zinc phosphate
	Chromates
	Lanthanide compounds
ALTERNATIVE 3 - Green corrosion inhibitors	Green inhibitors contain natural products which, in turn, include alkaloids (e.g. quinine, nicotine), carboxylic acids, polyphenols, terpenes and other functional groups that have elements such as C, N, O and S.

Source: table compiled by authors based on literature review

ALTERNATIVE 1 (GROUP) – Organic corrosion inhibitors

Organic corrosion inhibitors are popularly used by industries due to their characteristics, namely (Brycki et al., 2017):

- effectiveness at a wide range of temperatures;
- compatibility with protected materials;
- good solubility in water; and
- low cost.

Based on information retrieved from literature, the most effective organic inhibitors are those containing single electron pairs of nitrogen, oxygen, sulphur and/or phosphorus (Brycki et al., 2017; Grassino et al., 2021; Meng et al., 2017; Obot et al., 2015).

The sequence O < N < S < P must be followed for inhibition competence (Sharma et al., 2021). This means that when there are free pairs of phosphorus electrons the retarding of corrosive processes is more effective than when there are free oxygen electrons.

Organic inhibitors prove to be quite effective due to the aforementioned properties – namely, effectiveness at a wide range of temperatures, compatibility with protected materials and good solubility in water.

According to some studies, this group of inhibitors can be considered economically viable. However, further research is needed to obtain the concrete and real costs of each inhibitor (Brycki et al., 2017).

ALTERNATIVE 2 (GROUP) – Inorganic corrosion inhibitors

Inorganic corrosion inhibitors are those inhibitors in which the active substance is an inorganic compound (Lipiar et al., 2018). Unlike organic inhibitors that reveal both anodic and cathodic action simultaneously, inorganic inhibitors show only one type of action (Faisal et al., 2018). Therefore, inorganic inhibitors are relatively less efficient than organic ones (Faisal et al., 2018; Vishnudevan and Thangavel, 2007).

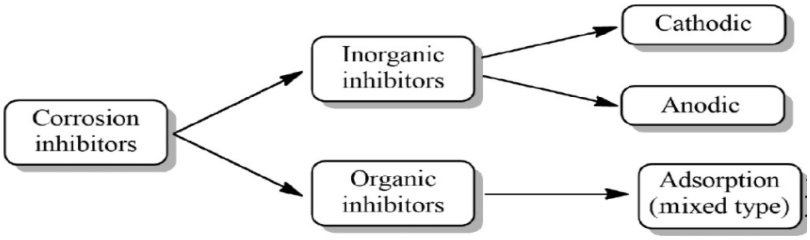


Figure 1: Types of corrosion inhibitors

According to the literature, the applications of the inorganic compounds are limited because of the "*high maintenance cost and reduced safety levels accompanied with their use*" (Abo El-Enin and Amin, 2015).

The use of many inorganic inhibitors, particularly those containing phosphate, chromate, and other heavy metals, is now being gradually restricted or has been already banned by various environmental regulations because of their toxicity and the difficulties faced in their disposal, especially in the marine industry, where aquatic life is at threat (Chigondo, 2016).

ALTERNATIVE 3 (GROUP) – Green corrosion inhibitors

Green inhibitors contain natural products which, in turn, include alkaloids (e.g. quinine, nicotine), carboxylic acids, polyphenols, terpenes and other functional groups that have elements such as C, N, O and S (Grassino et al., 2021; Payal and Jain, 2021). They work as anti-corrosive agents, as they form a thin layer on the metal surface by adsorption (Payal and Jain, 2021).

Regarding technical feasibility, in general, the vast literature points to green corrosion inhibitors as effective alternatives with a simple manufacture process and easy availability (Grassino et al., 2021; Sharma et al., 2021). In addition, it is interesting to note the various applications where this type of inhibitors can be used (Figure 2).

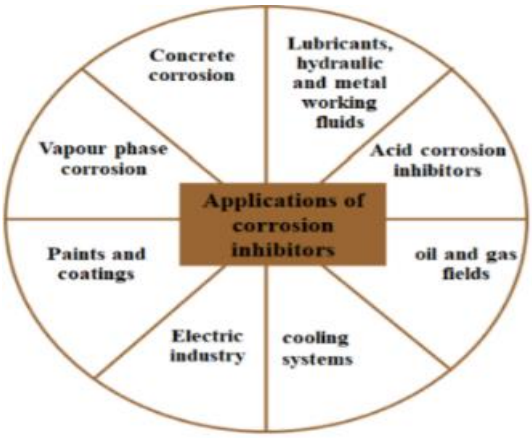


Figure 2: Applications of green corrosion inhibitors in various industries

However, it was noticed that such effectiveness may have some limitations according to environmental conditions. In scientific research conducted by Grassino et al. (2021), numerous plant extracts were prepared from various plant parts, including leaf, root, stem, bark, pulp and fruit, and investigated as green corrosion inhibitors for many metal surfaces. It was concluded that, since phytochemicals are extracted from various parts of plants, the proportion of constituents responsible for the anti-corrosive performance

differs among them. For example, plant extracts and oils obtained from the leaf appear to be an effective type of corrosion inhibitor and can be used successfully on an industrial level, due to the high inhibition efficiency (up to 88 %). However, they do not resist high temperatures and are not efficient in extremely aggressive environments. Another drawback reported has to do with their longevity. As these inhibitors are generally highly biodegradable, it is difficult to store them for a long time (Kundu et al., 2021).

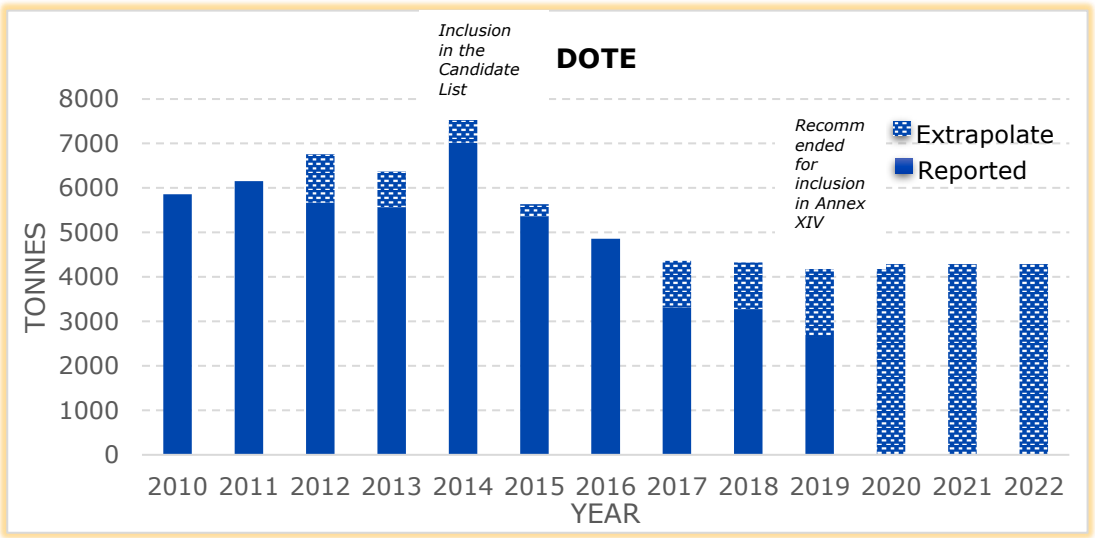
With regard to their economic profile, several articles describe them as very cheap inhibitors (Kundu et al., 2021; Payal and Jain, 2021; Ramesh and Rajeshkumar, 2021; Sharma et al., 2021).

2.2.4 DOTE and reaction mass DOTE:MOTE

DOTE and the reaction mass DOTE:MOTE are used in the production of PVC as heat stabilisers. Since PVC is thermally unstable at processing temperatures, it degrades at high temperatures and produces hydrochloric acid gas (HCl)[63], which in turn can deteriorate mechanical, thermal and physical properties of the polymer. Without the use of heat stabilisers, the final characteristics of the plastic products would be severally impacted. Heat stabilisers, such as DOTE and reaction mass DOTE:MOTE, are used to prevent elimination of HCl during the heating of PVC to 170-180°C.

The use of DOTE and reaction mass of DOTE:MOTE[64] allows the manufacturing of clear, rigid vinyl commodities under demanding processing conditions. DOTE and reaction mass of DOTE:MOTE are mainly used in rigid PVC applications.[65] In terms of volumes consumed in the EU, Chart 2 shows a 62 % decrease between 2016 and 2021.

Charts 2: DOTE, volumes consumed in the EU, 2010-2022



Source: *Registration dossiers of full dossiers (i.e. intermediate registrations are excluded), with linear extrapolation between those years where registrants did not report tons placed on the EU market.*

[63] https://echa.europa.eu/documents/10162/21732369/annex_xv_svhc_dote_mote_reaction_mass_en.pdf
[64] Impact Assessment of Potential Restrictions on the Marketing and Use of Certain Organotin Compounds (RPA 2007)
[65] Impact Assessment of Potential Restrictions on the Marketing and Use of Certain Organotin Compounds (RPA 2007)

Heat stabilisers are evaluated according to several criteria, which are also linked to the technical requirements of the final plastic materials. To evaluate the technical performance of the heat stabilisers, the stabilised PVC needs to be assessed through the following tests:

- A dynamic mechanical analysis (DMA)[66], which provides information on the viscoelastic behaviour[67] of polymers.
- Colour measurement test, during which the index that measures the physical deterioration of the PVC ("*yellowness index value*") is calculated over a certain number of processing cycles.
- Flexural property test that measures the flexural strength of the PVC and so its ability to resist deformation.

For a heat stabiliser to be technically suitable, it needs to successfully pass all the above tests. For each of the above tests, quantitative parameters are generally used for concluding on the technical suitability of a thermal stabiliser.

The information on the possible alternatives has been retrieved from the following sources:

- RPA report 2007 (Impact Assessment of Potential Restrictions on the Marketing and Use of Certain Organotin Compounds);
- Annex XV report for the identification of the reaction mass DOTE:MOTE as an SVHC;
- Comments on ECHA's ninth draft recommendation for DOTE and Reaction mass of DOTE and MOTE;
- Literature available online;
- Information provided (on the internet) by suppliers of heat stabilisers.

In the above sources, the following substances have been identified as potential alternatives to DOTE and reaction mass DOTE:MOTE:

- calcium organic-based stabilisers (calcium/zinc stabilisers and organic-based stabilisers (OBS));
- liquid mixed metal stabilisers;
- other organotin compounds (in particular, methyltins).

ALTERNATIVE 1 – calcium/zinc-based stabilisers

Calcium organic stabilisers were originally known as calcium/zinc systems. However, since the use of zinc in the formulations has been decreasing, the new term: "*calcium organic stabilisers"* was introduced. This term includes:

- Traditional calcium/zinc stabilisers; and
- Organic-based stabilisers (OBSs)

Calcium/zinc-based stabilisers are mainly used in food contact and medical applications and as an alternative to lead-based stabilisers[68]. They might be considered as potential alternatives to DOTE and reaction mass DOTE:MOTE. However, this might not be true for applications where DOTE and reaction mass DOTE:MOTE are currently used.

[66] https://sciencedirect.com/topics/engineering/dynamic-mechanical-analysis
[67] https://sciencedirect.com/topics/engineering/viscoelastic-behavior
[68] Page 11, https://stabilisers.eu/wp-content/uploads/2016/01/ESPA-stabilisers_update_January-20161.pdf

From an economic perspective, calcium/zinc-based stabilisers are available on the market[69] and might be considered economically feasible.

Organic-based stabilisers (OBSs) are considered in the literature as a new technology providing environmentally friendly heat stabilisers for PVC (Asawakosinchai, 2015)[70]. Two of the examples of OBSs reported in literature are:

- 1,3-dimethyl-6-amino-uracil (DAU) (EC 229-662-0); and
- Eugenol (EC 202-589-1).

According to a study, "*DAU and eugenol showed high potential to be used as an organic heat stabilizer for PVC because of their non-toxic and good heat resistance properties*", (Asawakosinchai, 2017)[71]. In another study, the efficiency of several organic-based stabilisers (uracil derivatives) was tested specifically in rigid PVC, through the discoloration test. According to this study, uracil derivatives exhibit great stabilising efficiency when compared to calcium/zinc stabilisers (Xu et al., 2012)[72]

ALTERNATIVE 2 – Liquid mixed metal stabilisers

This category includes barium/zinc systems and potassium/zinc systems and are mainly used in plasticised PVC.

ALTERNATIVE 3 – Other organotin compounds (in particular, methyltins)

Other organotin stabilisers may also be considered among potential substitutes to DOTE and reaction mass DOTE:MOTE. They are used, for example, in rigid packaging films, profiles and pipes. Two substances in this group seem to be the most relevant ones according to the RPA report (2007):

- MMTC (Methyltin trichloride, EC 213-608-8); and
- DMTC (Dimethyltin dichloride, EC 212-039-2).

Therefore, stabilisers (based on MMTC and DMTC) might also be considered as potential alternatives to DOTE and reaction mass DOTE:MOTE-based stabilisers.

ALTERNATIVES – findings from the survey

In response to the survey on the likely number of authorisation applications, some information was provided on the availability of alternatives to DOTE and reaction mass DOTE:MOTE. The following summarises the information submitted by stakeholders:

- In some applications, stearates[73] can replace DOTE.
- In some applications, solid calcium-based PVC stabilisers may potentially substitute DOTE.
- The substitution of DOTE-containing stabilisers may not be possible in several applications, including clear film, pipe fittings, CPVC.

[69] https://polymer-additives.specialchem.com/selectors/ap-pvc/c-additives-heat-stabilizers/z-western-europe?src=pa-selectionguide
[70] https://scientific.net/KEM.659.321
[71] Organic Heat Stabilizers for Polyvinyl Chloride (PVC): A Synergistic Behavior of Eugenol and Uracil Derivative | springerprofessional.de
[72] Synthesis and application of uracil derivatives as novel thermal stabilizers for rigid poly(vinyl chloride) - ScienceDirect
[73] Salts or esters of stearic acid

- The substitution of DOTE-containing stabilisers seems not to be possible in medical devices and pharmaceutical packaging.
- Compared with other commercially available heat stabilisers, DOTE-containing stabilisers seem to be able to impart a unique combination of the following performance attributes to PVC compounds: low volatility, excellent balance of external and internal lubrication, high stabilising efficiency, suitability for use in clear films and in compounds intended to come in contact with food.
- There are some concerns among stakeholders that, as a result of the inclusion of DOTE in the Authorisation List, manufacturing of other octyltin stabilisers as well as PVC articles would be moved outside of Europe.
- It seems that there might be some applications where the substitution might not be possible. For example, it seems that COS cannot provide equivalent transparency while MOTE appears unable to provide equivalent thermal stability.
- It has also been reported that methyltin compounds cannot provide equivalent processability, as they are much more volatile and, therefore, not suitable for open systems like calendaring.
- Some stakeholders have also discarded MOTE[74], MMTE[75] and DMTE[76] as there are concerns regarding their future regulatory status.

3. Stakeholder consultation – findings from the survey

As it is not possible to conclude from classification and labelling notifications whether any of the notifiers still use the substance and intend to apply for authorisation, ECHA sent a dedicated survey to notifiers and industry associations to gather their interest in applying for authorisation.

The survey was sent to substances' registrants, classification and labelling notifiers and relevant trade associations. In total, more than 450 stakeholders were asked to respond to the survey. 20 responses were received giving a response rate of 4 %. As a follow up to the survey, ECHA also directly contacted a limited number of stakeholders, namely trade associations and registrants.

Regarding tetraethyllead, the lead EU registrant informed ECHA that they are planning to submit an authorisation application, which would possibly cover the downstream users of TEL.

Regarding, 4,4'-bis(dimethylamino)-4''-(methylamino)trityl alcohol, no company responded to the online survey. However, ECHA contacted the registrants of this substance. At the time of preparing this report, the registrants were still evaluating whether to apply for authorisation.

With regard to RP-HP, ECHA contacted ATIEL[77], ATC[78] and the registrant. The registrant indicated that, considering the status of their ongoing R&D activities, they intend to switch to an alternative by the anticipated sunset date.

Regarding DOTE and reaction mass of DOTE:MOTE, all five registrants for DOTE responded to the survey and some of them indicated that they may apply for an authorisation. ECHA has further contacted the registrants and industry associations. Based on the findings from the

[74] The substance has been identified as potential endocrine disruptor to be evaluated by Netherlands in 2024 13898cd4-e4ce-4448-fe7a-0e5027156043 (europa.eu).
[75] Substance Information - ECHA (europa.eu)
[76] Substance evaluation - CoRAP - ECHA (europa.eu)
[77] The Technical Association of the European Lubricants Industry
[78] Technical Committee of Petroleum Additive Manufacturers in Europe

survey and information from the EU association of plastic converters, ECHA can expect to receive a number of applications for authorisation for these substances, in the range of 10-15.

Table 7 indicates the number of likely applications to be submitted for each substance.

Table 7: Number of expected applications for authorisation for the five substances

Substance name	EC number	CAS number	Predicted number of AfAs to be received[79]	Predicted type of application
Tetraethyllead (TEL)	201-075-4	78-00-2	1-3	Applicant probably covers all downstream users
4,4'-bis(dimethylamino)-4''-(methylamino)trityl alcohol [with ≥ 0.1% w/w of Michler's ketone (EC No. 202-027-5) or Michler's base (EC No. 202-959-2)]	209-218-2	561-41-1	0-4[80]	Not available.
Reaction products of 1,3,4-thiadiazolidine-2,5-dithione, formaldehyde and 4-heptylphenol, branched and linear (RP-HP) [with ≥ 0,1% w/w 4-heptylphenol, branched and linear (4-HPbl)]	-	-	0	Not applicable
2-ethylhexyl 10-ethyl-4,4-dioctyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate (DOTE)	239-622-4	15571-58-1	10-15[81]	Downstream
Reaction mass of 2-ethylhexyl 10-ethyl-4,4-dioctyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate and 2-ethylhexyl 10-ethyl-4-[[2-[(2-ethylhexyl)oxy]-2-oxoethyl]thio]-4-octyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate (reaction mass of DOTE and MOTE)	-	-	1	Downstream
Total			**12-23**	

[79] It is assumed one 1 application for 1 use.
[80] Please note that at the time of preparing this report, the registrants were still evaluating whether to apply for authorisation.
[81] 10 responses to the survey were received (4 will apply, 4 not sure yet, 2 will not apply)

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