Annex XV report

PROPOSAL FOR IDENTIFICATION OF A SUBSTANCE OF VERY HIGH CONCERN ON THE BASIS OF THE CRITERIA SET OUT IN REACH ARTICLE 57

Substance Name(s):	**2-ethylhexyl 10-ethyl-4,4-dioctyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate (DOTE)**
EC Number(s):	**239-622-4**
CAS Number(s):	**15571-58-1**

Submitted by: Environment Agency Austria on behalf of the Austrian Competent Authority (Austrian Federal Ministry of Agriculture, Forestry, Environment and Water Management)

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TABLES

ABBREVIATIONs

AC	Article Category
ATP	Adaptation to Technical Progress
CAS	Chemical Abstract Service
CMR	Carcinogenic, Mutagenic or Toxic for reproduction
DK	Denmark
DNEL	Derived No Effect Level
DOT	Dioctyltin
DOTE	2-ethylhexyl 10-ethyl-4,4-dioctyl-7-oxo-8-oxa-3,5-dithia-4-stannatetra-decanoate
EC	European Community
ECHA	European Chemicals Agency
ECTOC TRA	European Centre for Ecotoxicology and Toxicology of Chemicals Targeted Risk Assessment Tool
ERC	Environmental Release Category
ESIS	European Chemical Substances Information System
ESPA	European Stabiliser Producers Association
ERPA	European Rigid Film Producers Association
ETINSA	European Tin Stabilisers Association
EU	European Union
FIN	Finland
HCl	Hydrogen Chloride
HPV	High Production Volume
IUPAC	International Unit of Pure and Applied Chemistry
MAK	Maximale Arbeitsplatzkonzentration
MOT	Monooctyltin
MOTE	2-ethylhexyl 10-ethyl-4-[[2-[(2-ethylhexyl)oxy]-2-oxoethyl]thio]-4-octyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate
MSC	Member State Committee
MSDS	Material Safety Data Sheet
MSCA	Member State Competent Authority
NO	Norway
OECD	Organisation for Economic Co-operation and Development
OEL	Occupational Exposure Limit
PBT	Persistent, Bioaccumulative and Toxic
PE	Polyethylene
PROC	Process Category
PVC	Polyvinylchloride
PPE	Personal protective equipment
RCR	Risk Characterisation Ratio
REACH	Registration, Evaluation, Authorisation and Restriction of Chemical substances
SE	Sweden
SU	Sector of Use
SML	Specific Migration Limit
SPIN	Substances in Preparations in the Nordic countries
SVHC	Substances of Very High Concern
vPvB	very Persistent and very Bioaccumulative

PROPOSAL FOR IDENTIFICATION OF A SUBSTANCE OF VERY HIGH CONCERN ON THE BASIS OF THE CRITERIA SET OUT IN REACH ARTICLE 57

Substance Name:

2-ethylhexyl 10-ethyl-4,4-dioctyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate (DOTE)

EC Number: 239-622-4

CAS number: 15571-58-1

- 2-ethylhexyl 10-ethyl-4,4-dioctyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate (DOTE) is proposed to be identified as substance meeting the criteria of Article 57 (c) of Regulation (EC) 1907/2006 (REACH) owing to its classification as toxic for reproduction category 1B.

Summary of how the substance meets the criteria set out in Article 57 of the REACH Regulation

Pursuant to Annex III of Commission Regulation (EU) No 944/2013 as of 2 October 2013 DOTE will be listed in Table 3.1 (List of harmonised classification and labelling of hazardous substances) of Annex VI, part 3, of Regulation (EC) No 1272/2008 as toxic for reproduction Repr. 1B, H360D (May damage the unborn child).

Therefore, this classification of the substance in Commission Regulation (EC) No 944/2013 shows that the substance meets the criteria for classification in the hazard class:

- Reproductive toxicity category 1B in accordance with Article 57 (c) of REACH.

Registration dossiers submitted for the substance? YES

PART I

Justification

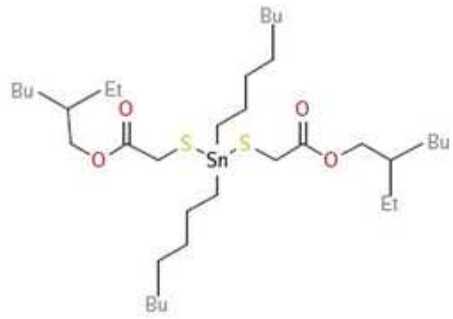
1. Identity of the substance and physical and chemical properties

1.1. Name and other identifiers of the substance

Table 1: Substance identity

EC number:	239-622-4
EC name:	2-ethylhexyl 10-ethyl-4,4-dioctyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate
CAS number (in the EC inventory):	15571-58-1
CAS number:	15571-58-1 CAS numbers deleted: 52433-96-2 64685-79-6 71061-19-3 85873-44-5
CAS name:	8-Oxa-3,5-dithia-4-stannatetradecanoic acid, 10-ethyl-4,4-dioctyl-7-oxo-, 2-ethylhexyl ester
IUPAC name:	2-ethylhexyl 10-ethyl-4,4-dioctyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate
Index number to be used in Annex VI of the CLP Regulation	050-027-00-7
Molecular formula:	$C_{36}H_{72}O_4S_2Sn$
Molecular weight range:	751.79
Synonyms:	DOTE, DOT(EHMA)2, Dioctyltin bis(2-ethylhexyl mercaptoacetate), Dioctyltin bis(2-ethylhexyl) mercaptoacetate, Advastab 17MOL, 17MOK, Advastab 17 MOK, Acetic acid, 2,2'-((dioctylstannylene)-bis(thio))bis-, di-2-ethylhexyl ester, Bis(2-ethylhexyl thioglycolato)dioctyltin, Bis(2-ethylhexyl) ((dioctylstannylene)dithio)diacetate, Bis(carboxymethylthio)dioctylstannylene, di(2-ethylhexyl) ester, Di-n-octyltin bis(2-ethylhexyl mercaptoacetate), Di-n-octyltin-dithioglycolic acid 2-ethylhexyl ester, Dioctyltin bis(2-ethylhexyl thioglycolate), Dioctyltin bis(2-ethylhexylmercaptoacetate)

Structural formula:



It is noted that DOTE contains chiral carbon atoms in the ethylhexyl residue of the acetic ester group. The indicated CAS number does not reflect any specific stereoisomeric forms. No specification on the stereoisomers of DOTE is provided in the registrations. The SVHC dossier covers the substance including all possible stereoisomers.

1.2. Composition of the substance

Name: 2-ethylhexyl 10-ethyl-4,4-dioctyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate (DOTE)

Description: Well-defined substance comprising DOTE, including all possible stereoisomers, as main constituents

Degree of purity: See confidential Annex II

DOTE is present in a reaction mass (multi-constituent substance), with the corresponding monooctyltin (MOT) compound 2-ethylhexyl 10-ethyl-4-[[2-[(2-ethylhexyl)oxy]-2-oxoethyl]thio]-4-octyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate (MOTE) (CAS number: 27107-89-7, EC number: 248-227-6). The concentration ratio between DOTE and MOTE in the reaction mass can differ depending on the manufacture of the mixture and the technical needs. The registrants have made use of the option allowing the registration of individual constituents for multi-constituent substances and have submitted registration dossiers for DOTE and MOTE as individual substances. DOTE is the toxicologically relevant substance of concern and the DOTE registration contains all relevant exposure scenarios (taking pure DOTE as a generic worst case). Therefore, the present Annex XV SVHC dossier is submitted for the substance DOTE. In addition, a separate Annex XV SVHC dossier is submitted for the reaction mass DOTE:MOTE.

1.3. Identity and composition of degradation products/metabolites relevant for the SVHC assessment

Not relevant for the dossier.

1.4. Identity and composition of structurally related substances (used in a grouping or read-across approach)

Not relevant for the dossier.

1.5. Physicochemical properties

Not relevant for the dossier.

2. Harmonised classification and labelling

Pursuant to Annex III of Commission Regulation (EU) No 944/2013[1] as of 2 October 2013 DOTE will be listed in Table 3.1 (List of harmonised classification and labelling of hazardous substances) of Annex VI, part 3, of Regulation (EC) No 1272/2008[2] as toxic for reproduction Repr. 1B, H360D (May damage the unborn child).

Therefore, this classification of the substance in Commission Regulation (EC) No 944/2013 shows that the substance meets the criteria for classification as toxic for reproduction in accordance with Article 57 (c) of REACH.

Table 2: Harmonised classification according to Regulation (EC) No 944/2013

Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Spec. Conc. Limits, M-factors	Notes
				Hazard Class and Category Code(s)	Hazard statement code(s)	Pictogram, Signal Word Code(s)	Hazard statement code(s)	Suppl. Hazard statement code(s)		
050-027-00-7	2-ethylhexyl 10-ethyl-4,4-dioctyl-7-oxo-8-oxa-3,5-dithia-4-stannate-tradecanoate	239-622-4	15571-58-1	Repr. 1B	H360D	GHS08 Dgr	H360D	--	--	--

[1] Commission Regulation (EU) No 944/2013 of 2 October 2013 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures

[2] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006

3. Environmental fate properties

Not relevant for the dossier.

4. Human health hazard assessment

See information given in Chapter 2 (Harmonised classification and labelling).

4.1. Toxicokinetics (absorption, metabolism, distribution and elimination)

Not relevant for this dossier.

4.2. Acute toxicity

Not relevant for this dossier.

4.3. Irritation

Not relevant for this dossier.

4.4. Corrosivity

Not relevant for this dossier.

4.5. Sensitisation

Not relevant for this dossier.

4.6. Repeated dose toxicity

Not relevant for this dossier.

4.7. Mutagenicity

Not relevant for this dossier.

4.8. Carcinogenicity

Not relevant for this dossier.

4.9. Toxicity for reproduction

Brief information is provided in Annex I.

4.10. Other effects

Not relevant for this dossier.

5. Environmental hazard assessment

Not relevant for this dossier.

6. Conclusions on the SVHC Properties

6.1. CMR assessment

Pursuant to Annex III of Commission Regulation (EU) No 944/2013 as of 2 October 2013 DOTE will be listed in Table 3.1 (List of harmonised classification and labelling of hazardous substances) of Annex VI, part 3, of Regulation (EC) No 1272/2008 as toxic for reproduction Repr. 1B, H360D (May damage the unborn child).

Therefore, this classification of the substance in Commission Regulation (EC) No 944/2013 shows that the substance meets the criteria for classification as toxic for reproduction in accordance with Article 57 (c) of REACH.

6.2. PBT and vPvB assessment

Not relevant for this dossier.

6.3. Equivalent level of concern assessment

Not relevant for this dossier.

Part II

7. Manufacture, import and export

DOTE has been registered in a tonnage band of 1,000-10,000 t/yr.

Following four companies have registered the substance:

- ARKEMA B.V. headquarters, Postbus 6030, 3196 XH, Vondelingenplaat Rotterdam, Netherlands

- Baerlocher Italia SPA, Via San Colombano, 62/A, 26900, Lodi, Italy

- Galata Chemicals GmbH, Chemiestrasse 22 1760, 68623, Lampertheim 06, Germany

- REAGENS SPA, Via Codronchi, 4, 40016, San Giorgio Di Piano (BO), Italy

According to the information of registrants, DOTE is manufactured and marketed as multi-constituent substance, consisting of DOTE and of the corresponding monooctyltin substance MOTE. The registrants have made use of the option allowing the registration of individual constituents for multi-constituent substances and have submitted registration dossiers for DOTE and MOTE as individual substances. DOTE is the toxicologically relevant substance and the DOTE registration contains all relevant exposure scenarios (taking pure DOTE as a generic worst case). Detailed information on production figures of DOTE and MOTE is given in Annex III (confidential data on manufacture, import and export). The registrants provided information on detailed production figures of different compositions of DOTE:MOTE reaction mass. Those data are also depicted in Annex III.

Commercial DOTE:MOTE reaction mass is produced from the corresponding mixture of dioctyltin/monooctyltin chlorides, 2-ethylhexyl mercaptoacetate, and a base. The reaction is carried out in water and the organotin stabiliser is isolated by phase separation and if considered relevant filtered or stripped to remove solids or volatile components (CLH, 2011). The concentration ratio between DOTE and MOTE can differ depending on the manufacture of the mixture (CLH, 2011). For technical reasons the ratio varies to create suitable stabilisers with best performances for different process technologies and polyvinylchloride (PVC) end-use applications.

7.1. Imports and exports of the substance into and from the EU

Available information is provided in the confidential Annex III.

7.2. Recent and future trends

Data on production volumes of DOTE and MOTE over several years as indicated in the registrations are provided in the confidential Annex III.

Different heat stabilisers are used in the production of PVC (for further details see Chapter 10). Tin stabilisers account for 8% of the total stabiliser demand and are used mainly for the production of un-plasticised PVC (e.g., rigid films and sheets, bottles) (ESPA, 2013). Data indicate that the demand for tin stabilisers is constant (personal communication, ESPA).

8. Information on uses of the substance

8.1. Overview of uses

General function

The reaction mass DOTE:MOTE is used in the production of PVC as heat stabiliser. PVC is thermally unstable. Heating results in elimination of hydrogen chloride (HCl), the formation of polyene sequences, and rapid discoloration. Heat stabilisers are used to prevent elimination of HCl during the heating of PVC to 170-180°C. Decomposition (release of HCl) leads to unstable structures, which further accelerate HCl elimination. Stabilisers (metal compounds) are used to prevent chain reaction of decomposition.

Heat stabilisers are rated according to several criteria. The criteria are based on efficiency as heat stabilisers, such as versatility (use with mass, suspension, and emulsion PVC), effect on melt rheology of PVC, lubricant action, migration, plate-out, compatibility with other additives and pigments, effect on transparency, light fastness, electrical insulation, and fogging (especially for automotive interior parts). Furthermore, approval as indirect food additives and easy handling and costs are factors, which have an impact on the choice of the most suitable heat stabiliser (Wolf and Kaul, 2000).

PVC is a versatile thermoplastic material and is used in numerous consumer products to which humans are exposed in everyday life (e.g., bags, bottles, toys, electric articles, textiles, flooring, art, sports equipment).

There are two main types of tin stabilisers used in the production of PVC, which have a very good stabilising performance (Baerlocher, 2013):
(a) thioacid half esters such as thio-glycolates (known as thio-tins or mercaptides (tin-sulphur bond))
(b) carboxylic half esters, often referred to as maleates or carboxylates (tin-oxygen bond)

DOTE:MOTE belongs to the group of mercaptides, which are very efficient and can be employed without co-stabilisers. The general formula of the mercaptide stabilisers can be depicted as:

$(R1)_nSn(SR2)_{4-n}$

where n = 1 or 2; R1 = methyl, n-butyl, n-octyl, or n-dodecyl; and R2 is, for example, $-CH_2COO$-alkyl, $-CH_2CH_2COO$-alkyl, or $-CH_2CH_2OOC$-alkyl.

The alkyl group is often isooctyl (Wolf and Kaul, 2000).

The most frequently used organotins in rigid or flexible PVC are octyltins (appr. 61%), followed by butyltins (appr. 31%) and methyltins (appr. 7,9%). Furthermore, octyltins are mainly used in rigid PVC (up to 97%) and to a lesser extent in flexible PVC (WHO, 2006, RPA, 2007).

The application of DOTE:MOTE allows the production of clear, rigid vinyl commodities even under demanding processing conditions, and thereby exhibiting also moderate light stability (RPA, 2007). Depending on the type of PVC and the end-use application the ratio of mono- and dioctyl can vary.

Identified uses

DOTE is used in industrial settings (manufacture and distribution, formulation of DOTE

into dry blends, processing of polymers containing DOTE), but also by professionals (processing of polymers containing DOTE).

In the registration "service life of manufactured articles" is identified as potential source of human and environmental exposure. For details see following Chapters 8.2 and 8.3.

8.2. Substance use as indicated in the registration

8.2.1. Description of use (including use type)

According to the registrants the reaction mass DOTE:MOTE is used as heat stabiliser in the production of rigid and to a minor extent of plasticised PVC.

DOTE is used in the industrial setting (manufacture and distribution, formulation of DOTE, processing of polymers containing DOTE) (Table 3), but also by professionals (processing of polymers containing DOTE) (Table 4).

DOTE:MOTE reaction mass is present in various different consumer products. It is applied for the production of rigid PVC films and sheets. This kind of PVC is used for packaging material (e.g. food and pharmaceutical packaging material), credit cards and rigid construction sheets. The reaction mass is also applied in PVCs used in the production of bottles (containing shampoos, shower gels and detergents rather than beverages) (RPA, 2005). Furthermore, DOTE:MOTE is applied in the production of pipes (e.g., drinking water), fittings and profiles (e.g., window and furniture profiles) (for further details see Confidential Annex IV).

The registrants indicate that for DOTE wide dispersive outdoor and indoor use of long-life articles and materials occur with low release (Table 5 and Table 6).

The registrant advice against the use as substances and constituents of mixtures when acting as biocides in free association paint or as biocides to prevent the fouling by micro-organisms, plants or animals and of preparations intended for use in the treatment of industrial waters (REACH Regulation, Annex XVII, group 20: organostannic compounds, Nr. 1, 2, 3).

Furthermore, after 1 January 2012 the use in certain articles is restricted if the concentration in the article, or part thereof, is greater than the equivalent of 0.1 % by weight of tin. This restriction applies to the following articles: textile articles intended to come into contact with the skin, gloves, footwear or part of footwear intended to come into contact with the skin, wall and floor coverings, childcare articles, female hygiene products, nappies, two-component room temperature vulcanisation moulding kits (RTV-2 moulding kits) (REACH Regulation, Annex XVII, group 20: organostannic compounds, Nr. 6). It is further laid down in this entry that these articles shall not be placed on the market after 1 January 2012, except articles that were already in use in the Community before that date.

Table 3: Uses by workers in industrial settings (summary of all registration(s))

Identified use name	**Sector of end use**
Manufacture and distribution of substance	-
Formulation of substance in dry-blend formulations	-
Production of dry-blend substance	-
Processing of polymers containing substance as stabiliser through calendering, extrusion, injection moulding and low energy manipulation	**SU 12**: Manufacture of plastics products, including compounding and conversion

Table 4: Uses by professional workers (summary of all registration(s))

Identified use name	Sector of end use
Processing of polymer containing substance as a stabiliser through low energy manipulation of plastic articles	SU 12: Manufacture of plastics products, including compounding and conversion
Processing of polymers containing substance as a stabiliser through calendering, extrusion, injection and low energy manipulation of plastic articles	SU 12: Manufacture of plastics products, including compounding and conversion

Table 5: Uses by consumers (summary of all registration(s))

Identified use name	Article category	Environmental release category
Service life of articles containing substance	AC 13: Plastic articles	ERC 10a: Wide dispersive outdoor use of long-life articles and materials with low release ERC 11a: Wide dispersive indoor use of long-life articles and materials with low release

Table 6: Article service life (summary of all registration(s))

Identified use name	Article category	Environmental release category
Processing of polymers containing DOTE as stabiliser through calendering, extrusion, injection moulding and low energy manipulation	AC 13: Plastic articles	ERC 5: Industrial use resulting in inclusion into or onto a matrix ERC 10a: Wide dispersive outdoor use of long-life articles and materials with low release ERC 11a: Wide dispersive indoor use of long-life articles and materials with low release

8.2.1. Locations and quantities used

According to registration data in total four companies are manufacturing the reaction mass DOTE:MOTE in the European Union in a tonnage band of 1,000-10,000 t/yr.

A considerable higher number of PVC manufacturers and downstream users (professional workers handling PVC) are involved in further processes (see also confidential Annex IV).

8.2.2. Recent and future trends

No information on recent and future trends has been provided in the registration. Data indicate that the demand on tin stabilisers is constant (personal communication, ESPA) and that tin stabiliser account for 8% of the total stabiliser demand.

8.2.3. Structure of supply chain

After manufacture, the substance is used in the PVC production process, in which a higher number of industries are involved. ETINSA provided information on the number of PVC converters, which use tin stabilisers and probably DOTE:MOTE reaction mass (details see Annex IV).

No detailed information on the supply chain can be provided for the time being.

8.3. Substance use in products and articles

Use information from the Nordic countries

The SPIN database[3] summarizes information on DOTE in products on the national markets of Norway, Sweden, Finland and Denmark.

For detailed information on the number of mixtures in which DOTE is used and on the tonnage bands see Table 7.

Table 7: DOTE in products according to SPIN*

Year	SE Nr. of prep [tons]	FIN Nr. of prep [tons]	DK Nr. of prep [tons]	NO Nr. of prep [tons]
	DOTE			
2011	9 [27]	conf.	7 [0.6]	conf.
2010	conf.	conf.	6 [0.0]	conf.
2009	conf.	n.e.	7 [0.2]	conf.
2008	8 [4]	n.e.	6 [0.0]	conf.
2007	8 [3]	n.e.	6 [0.0]	conf.
2006	10 [7]	conf.	5 [0.0]	conf.
2005	11 [18]	conf.	5 [0.0]	conf.

conf.; confidential, n.e.; no entry
* total quantities and the total number of products have not been reported to SPIN if the substance is contained in less than 4 products and is registered by less than 3 companies.

According to SPIN DOTE has been registered for the years 2005-2011 for the manufacture of rubber and plastic products, and the manufacture of chemicals and chemical products. DOTE is used according to information from SPIN database mainly as stabiliser, but also as colouring agent. No trend towards lower tonnages of use can be derived from these data.

According to the statistics of the Swedish chemicals agency (KEMI) the use of DOTE in Sweden compared to the late 90ties has decreased in more recent years (from 53.5 t/yr to 21.7 t/yr).[4]

Further information obtained from registrants

A questionnaire has been sent to registrants in order to obtain additional information on uses and exposure of DOTE. A detailed description received on current uses in different consumer articles is given in Annex IV (confidential data on uses).

The typical content for the most used reaction mass DOTE:MOTE (70:30 % w/w) in the production of PVC is 1-2.5% (ETINSA, 2014).

Only a minor amount of the stabiliser present in the PVC compound does react during the process of conversion in articles. Hence, the concentration of DOTE:MOTE in the articles remains close to its initial concentration of around 1-2.5% (ETINSA, 2014).

DOTE:MOTE is mainly used in the production of rigid PVC, however, there are also some niche applications for which substances are used in the production of plasticised PVC. Rigid films, obtained by extrusion-calendering, are one of the major applications. It

[3]Substances in Preparations in the Nordic countries (SPIN); link: http://195.215.251.229/-DotNetNuke/default.aspx (accessed 11th December 2014)
[4] KEMI-STAT; link: http://apps.kemi.se/kemistat/start.aspx?sprak=e (accessed 21th July 2014)

includes films used for food-contact and pharmaceuticals. According to ETINSA, DOTE is listed for specific applications (pharmaceutical films) in the European pharmacopoeia.

8.4. Imports and exports of articles into and from the EU

8.4.1. Information from consultation

No detail on import and exports of articles into and from the EU is provided for the time being.

8.4.2. Information from literature and trade statistics

No relevant information on import and export data has been identified at present.

9. Release and exposure from uses

9.1. Introduction

The information provided in the following section is based on the exposure scenarios for different uses described in the registration dossier as well as additional information provided by the registrants via a questionnaire (ETINSA, 2014).

Data and information regarded as relevant but confidential are depicted in Annex V (confidential data on releases and exposure).

Information analysed and summarised in previous risk assessments (RPA, 2003, RPA, 2005) was considered as well.

9.2. Industrial and professional uses

The most likely route of exposure of workers in the industrial and professional setting is through inhalation and/or dermal route.

The registrants carried out occupational exposure assessment with ECTOC Targeted Risk Assessment Tool (ECETOC TRA) applying specific default values and correction factors. According to the registrants most manufacturing steps are carried out in closed systems and the exposure to workers is considered to be low.

Following exposure scenarios in the occupational setting have been identified by the registrants:

I) Manufacture and distribution of DOTE

II) Formulation of DOTE in dry blend formulations

III) Processing of polymers containing DOTE as a stabiliser through calendering, extrusion, injection and low energy manipulation of plastic articles

The handling of the substance during individual working processes and the resulting human exposure scenarios and values are described in more detail in Annex III.

9.3. Consumer uses

9.3.1. Direct exposure: consumer articles

Beside the consumer exposure assessment carried out by the registrants (details are provided in Annex IV), profound risk assessments on organotin substances in consumer products, including DOT compounds used as heat stabilisers in the production of PVC, have been carried out on behalf of DG Enterprise and Industry (RPA, 2003, RPA, 2005, SCHER, 2006).

In the report carried out in 2005 (in the following referred to RPA report 2005) different DOT exposure sources were identified. The sources as well as the data (exposure of adults and children to DOT compounds) are presented in Table 8.

Table 8: Consumer exposure to DOT compounds (as Sn) (RPA, 2005)

Exposure source	**DOT (µg Sn/kg bw/day)**	**DOT (µg Sn/kg bw/day)**
	ADULTS	**Children**
Household dust (worst case)	0.004	0.013
T-shirts (worst case)	0.023	0.171
Drinking water pipes (worst case)	<0.001	<0.001
Rigid film (worst case)	0.002	-
Female hygiene products (worst case)	0.062	-
PVC food packaging (median)	0.004	0.005
PVC food packaging (high)	0.022	0.054
PVC squash bottle (worst case)	-	0.015

It is noted that with the exception of female hygiene products, the exposure values reported in 2005 are equal or below the respective values from the 2003 report.

In the meantime the exposure values might have further decreased due to the regulatory measures introduced (see Table 12, REACH Annex XVII entry). Especially, exposure to articles, which come into direct contact with the skin, should have decreased.

In the RPA 2005 report risk sources of DOT exposure have been identified, which are likely to contribute significantly to the overall risk for consumers (RPA, 2005). A concern has been raised, since risks to consumers may arise from the use of a wide range of products containing DOT compounds. Thus, it was evident that cumulative exposure to different risk sources might lead to unacceptable exposure levels and therefore warrants certain risk reduction measures. On this basis, specific restrictions on the use of DOT compounds in consumer products, which might come in contact to the skin, have been laid down in REACH Regulation Annex XVII (see Chapter 11). Restrictions are in place for the following articles: textile articles intended to come into contact with the skin, gloves, footwear or part of footwear intended to come into contact with the skin, wall and floor coverings, childcare articles, female hygiene products, nappies, two-component room temperature vulcanisation moulding kits (RTV-2 moulding kits). It is noted, that in the RPA 2005 report most consumer products containing DOTE which are still on the market have been assessed and no risk regarding single exposure sources has been identified.

9.3.2. Indirect exposure of consumers/man via the environment

The registrant considers exposure of consumers via the environment and the risk of secondary poisoning as negligible. In the RPA 2005 report, however, it is indicated that humans might be indirectly exposed to DOT compounds via the environment.

It is stated in the RPA 2005 report, that DOT compounds used in the production of PVC comprises mainly DOTE. This has been confirmed by ETINSA also for recent production figures (personal communication). The exposure estimations for DOT from the report (thus representing DOTE) are listed in Table 9.

Table 9: Exposure of consumers to DOT compounds via the environment

Exposure source	**DOT (µg Sn/kg bw/day)**	**DOT (µg Sn/kg bw/day)**
	ADULTS	**Children**
Via environment (regional)	0.001	0.005
Via environment (worst case)	0.411	1.644

The RPA 2005 report provides a worst case scenario for the aggregated maximum local daily intake of DOT of about 0.4 µg/kg bw/day (as Sn) for adults, and 1.6 µg/kg bw/day for children and the authors conclude that local DOT emissions from organotin production and PVC processing may potentially lead to a significant total exposure.

It is noted, that these estimates are based on modelling of worst-case local exposure routes (close to PVC processing sites) and assumptions on the DOT leaf-air partition coefficient, which are quite uncertain. Moreover, the worst case scenario is not representative for the majority population since in this scenario the regional intake via the environment is about 400 (300) fold lower for adults (children) than the maximum local intake close to a point source.

In the RPA 2005 report the authors compared the DOT exposure values with a group TDI for organic tin compounds of 0.1 µg/kg bw (as Sn). The exposure values for the worst case scenario (see Table 9) exceed the TDI and thus the authors of the RPA study concluded that a risk for persons living near hot spots cannot be excluded.

A comparison of these exposure values (worst case – man via the environment) with the oral DNEL for DOTE derived by the registrant, would lead to RCRs slightly above 1. However, in view of the potential overestimation of exposure in the RPA study it is not possible to imply an unacceptable risk on the basis of available data. However, there is clear health concern from indirect consumer exposure documented in the RPA study.

9.4. Releases from use of articles

The typical content for the most used reaction mass DOTE:MOTE (70/30 % w/w) in the production of PVC is 1-2.5% (ETINSA, 2014). Based on information of registrants only a minor amount of the stabiliser present in the PVC compound does react during the process of conversion in articles. Hence the concentration of DOTE:MOTE in the articles remains close to its initial concentration of around 1-2.5%.

According to ETINSA (2014) stabilisers are designed to have inherently low leaching rates in order to continue to stabilise the articles throughout its life-cycle. This is the case for octyltins which have very low water solubility (high Octanol/Water partition coefficient).

Food contact material

DOTE:MOTE reaction mass is used in rigid PVC films for food-contact and needs to comply with the applicable SML of 6 µg/kg food (as Sn), which confirms the low leaching rate in aqueous media. Like all additives, leaching in contact with water is limited to a thin diffusion layer and does almost not affect the bulk of the material (ETINSA, 2014).

Migration tests have been undertaken by Fabes (2005) using 12 different PVC samples stabilised with DOTE:MOTE reaction mass. It has been concluded by the author, that the polyethylene (PE) layer has no barrier properties for the transfer of DOTE:MOTE into the food. Thus, it could be demonstrated within the study, that migration was governed by the food simulant and not by the nature of PVC and whether or not it was laminated. A higher migration rate was measured for fatty than for aqueous simultants.

Furthermore, a comprehensive analysis has been undertaken by the UK Central science laboratory on behalf of industry across a wide range of food stuffs (CSL, 2005, cited in RPA, 2005) in order to determine the overall intake of DOT for consumers. According to the analysis adults are exposed to 0.004 µg Sn/kg bw/day (median intake) and 0.0022 µg Sn/kg bw/day (97.5% intake) and children to 0.005 µg Sn/kg bw/day (median intake) and 0.054 µg Sn/kg bw/day (97.5% intake). The analysis does not consider drinks, however, it is reported that the vast majority of plastic bottles are polyethylene

terephthalate (PET) or high density polyethylene (HDPE). PVC bottles are used mainly in the domestic products such as shampoo and cleaners.

Skin contact: thin rigid films and credit cards

Layers of rigid PVC film containing DOTE:MOTE reaction mass are extensively used for credit (or similar) cards. Furthermore, another source of dermal exposure are PVC packed products. A short exposure time to such products is assumed for the general public (2 hrs/week). However, some people, for example warehouse workers or retails workers might be exposed for a longer time.

In general the contact area to the cards is assumed to be small (3 cm^2), for PVC packaging products contact area of 400 cm^2 (both hands) is assumed. A migration rate of 0.2 ng Sn/cm^2/hr has been assumed in the RPA report (RPA, 2005).

Based on these assumptions a daily uptake for adults of 0.002 µg Sn/kg bw/day (thin film, credit cards) was estimated (RPA, 2005).

9.5. Releases from the waste stage

The registrant(s) have addressed the waste stage arising from each exposure scenario (confidential Annex V).

According to the RPA 2005 report numerous studies report on presence of octyltin compounds in sewage sludge resulting from waste water treatment and monitoring data report on its presence in landfill sites.

A maximum concentration in sewage sludge of 0.56 mg DOTC/kg (a hydrolysis product of DOTE) was measured in the study of Summer et al. (1996). KemI (2000) reports on concentrations of octyltins in sewage sludge found at Swedish and Danish waste water plants (WWTP), in the concentration range of up to 0.14 mg/kg DOT and up to 0.49 mg/kg MOT.

A study carried out for the European Commission (Argus et al., 2000) examined the behaviour of PVC products in landfills. With respect to organotins, it was concluded that the landfill emissions cannot be directly attributed to the presence of PVC.

In a monitoring study carried out by Mersiowsky et al. (2001) dioctyl (DOT) compounds have been detected in actual EU landfill sites. The maximal concentration reported is 0.25 µg Sn/l. It is noted by the authors, that the concentrations found in leachate do not present the concentrations that would be actually found in the environment, since the leachate might be treated (e.g., disposed to municipal sewer) or is diluted upon entering the environment. Thus, the concentrations found in the environment are likely to be significantly lower.

9.6. Summary of releases

During industrial working steps the exposure to DOTE:MOTE reaction mass is controlled and exposure levels are below toxicological reference values.

A concern has been raised for professional workers, which further process the PVC products (low energy manipulation: e.g., cutting, welding of sheets). It can be reasonably assumed that in these processing steps a higher number of workers is involved as compared to the manufacturing process.

Release of DOTE:MOTE reaction mass from consumer articles after being embedded in PVC matrix is low. However, since the substance is present in various consumer articles

different exposure sources are possible. Thus, based on earlier risk assessments, DOT compounds have been restricted in specific consumer articles intended to come in close contact with the skin. Furthermore, these risk assessments conclude that DOT production sites and PVC processing sites are a potential source for indirect exposure of man via the environment.

10. Current knowledge on alternatives

10.1. Introduction

In the production of PVC, different heat stabiliser systems are used depending on intrinsic characteristics and technical demands. The actual market share of stabilisers in the EU and a comparison of production data from 2007 and 2012 are indicated in Table 10 (Vinylplus, 2013). It is shown that more than 12,000 t/yr of tin stabilisers are produced in the European Union.

Table 10: Comparison of production data of stabiliser systems in the year 2007 and 2012 (Vinylplus, 2013)

Stabiliser systems	**2007 t/yr**	**2012 t/yr**
Formulated lead stabiliser	99,991	23,627
Formulated calcium stabiliser	62,082	91,552
Tin stabiliser	16,628	12,193
Liquid stabiliser (Ba/Zn or Ca/Zn)	19,000	14,611

The following diagram depicts the market share of stabilisers used in the production of PVC.

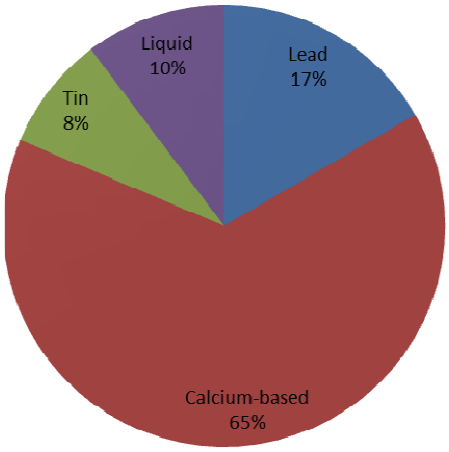


Figure 1: Overview of stabiliser consumption in the year 2012 (adopted from ESPA, 2013)

A comprehensive assessment of alternatives for organotin compounds has been undertaken by RPA, 2007, in their "Impact Assessment of Potential Restrictions on the Marketing and Use of Certain Organotin Compounds" prepared for the European Commission. In the following section a short summary of this analysis and the main conclusions regarding possible alternatives to DOTE:MOTE are presented.

10.2. Literature review

Five main alternative stabiliser systems have been identified by RPA, 2007:

I) lead-based stabilisers
II) cadmium-based stabilisers
III) calcium-organic stabilisers

IV) liquid mixed metal stabilisers
V) other organotins (in particular, methyltins).

The assessment recognises that the selection of the appropriate stabiliser system requires considerable knowledge and expertise of process equipment, polymer choice, final application, regulatory approval requirements and cost. Also, depending on the stabiliser selected, it is possible to obtain a selection of properties including good clarity, good weatherability, good colour hold, good long-term stability, suitability for white pigmented applications, low migration, low odour and low volatility. Some products are specifically designed to meet just a few of these criteria but others can achieve a good compromise of all the features mentioned above.

The use of cadmium PVC stabilisers was phased out due to restrictions laid down in Annex XVII of the REACH Regulation as well as part of the Vinyl 2010 voluntary agreement[5], with some specific exemptions.

Because of health concerns, a phasing out of lead-based stabilisers is on-going, these being substituted by calcium-organic systems rather than organotin-based stabilisers. A potential comeback of lead stabilisers as substitutes for the organotins is not expected as organotin stabilisers allow for the production of very clear rigid calendering films, a result which cannot be technically achieved with lead.

Calcium-organic stabilisers were originally known as calcium/zinc systems; however, during the development of alternatives to cadmium- and lead-based systems, the newer stabilisers sometimes required less or no zinc component, and hence the new name 'calcium-organic stabilisers' was introduced. The term calcium-organic stabilisers includes (traditional) calcium/zinc stabilisers and those stabilisers which, on occasion, are called organic based stabilisers (OBS). The Calcium-organic stabilisers are important substitutes in the former applications of lead-based stabilisers and their versatility is a primary reason for their general extensive use in the processing of PVC.

Concerning possible environmental and health effects of calcium-organic stabilisers, a review of various Material Safety Data Sheets (MSDS) (undertaken in the frame of the RPA 2007 report) provided by manufacturers and available in the open literature does not indicate any major concerns relating to any human and environmental effects. There is, however, the possibility that other substances used in these stabilisers may have some undesirable effects. For instance, one MSDS sheet refers to their calcium-organic stabiliser as a "solid blend based on Ca and Zn metal soaps, inorganic complexes based on Na, Mg, Ca and Al, phenolic antioxidants, beta-diketones and polyols".

The European Plastics Converters (EuPC) provided RPA with a study they commissioned to investigate the human health and environmental hazards of calcium/zinc stabiliser systems. This study considered seven major ingredients of a commercially available calcium/zinc stabiliser system (which for reasons of commercial confidentiality could not be named). The study concluded the following:

• for human health: using a database of variable detail for each component, the hazard from these to systemic toxicity was considered to be generally low, on the basis of available information. No specific hazard due to systemic toxicity was identified from the ingredients; however, data gaps would be identified under REACH for three of these. Further, the structure of the ingredients suggests that the probability of untoward findings is low but cannot be excluded. The insoluble ingredients however may pose a risk by inhalation when formulating the stabiliser mixture or adding the stabiliser to the PVC; and

• for environment: again, using a database of variable detail, several data gaps were identified and for two of the ingredients the hazard to the environment could not be sufficiently evaluated due to the lack of data. One of the components might be

[5] http://www.vinylplus.eu/

considered as posing a hazard to the environment linked to its persistence in the environment while another component showed aquatic toxicity with possible acute and long-term effects not excluded.

Liquid mixed metal stabilisers include barium/zinc systems, potassium/zinc systems, or less commonly calcium/zinc stabilisers and are used only in plasticised PVC. As this application accounts only for a small part of the applications of DOTE/MOTE this group is considered of minor importance in the discussion of suitable alternatives.

Methyltin stabilisers may be suitable as alternatives to octyltin stabilisers. They are sold for rigid packaging films, profiles and pipes, although its non-EU sales are more important than EU sales. Two specific substances of this group are mentioned in the RPA report: MMTC (Methyltin trichloride, CAS No 993-16-8) and DMTC (Dimethyltin dichloride, CAS No 753-73-1), their classification is as follows:

Table 11: Harmonised and additional classification of selected alternatives

	Harmonised classification	**Additional classification from C&L inventory (summary)**
MMTC CAS 993-16-8	Repr 2; - H361d	Flam. Sol. 2 Acute Tox. 3 - H311 Acute Tox. 3 - H331 Skin Corr. 1B Skin Sens. 1 Muta. 2 Aquatic Acute 1 Aquatic Chronic 1
DMTC CAS 753-73-1	*) Acute Tox. 3 - H301 Acute Tox. 3 - H311 Acute Tox. 2 - H330 Skin Corr. 1B - H314 Repr. 2 - H361d STOT RE1 - H372 (nervous system)	Acute Tox. 3 - H331 Acute Tox. 4 – H312 STOT RE1 STOT SE 3 - H335 (lungs) Eye Dam. 1 Aquatic Acute 1 Aquatic Chronic 3

Conclusions of the assessment by RPA, 2007:
The key alternative to organotin stabilisers is calcium-organic stabilisers for rigid PVC applications. In plasticised PVC applications, organotins find continuously decreasing use and where they are currently used, industry intends to soon replace them by liquid mixed metal (barium/zinc) stabilisers which already dominate the plasticised PVC market. Concerns have been raised in respect to the clarity/transparency of PVC articles stabilised with calcium-organic stabilisers as well as the processability of these products as opposed to organotin-stabilised PVC. However, several sources (including industry associations) suggest that desired clarity can be achieved with calciumorganic stabilisers. Evidently, the requirement for clarity is not an issue for window profiles and pipes, as compared with rigid films and sheets.

The substitution support portal SUBSPORT describes a case story on "Environmentally friendly PVC-stabilisation using synthetic hydrotalcites"[6]: Hydrotalcite is a double-layered inorganic complex. In its natural form, it is hydrated magnesium-aluminum hydroxycarbonate with the formula: Mg_6Al_2 16(OH) CO_3 x $4H_2O$, which can be commercially produced. Hydrotalcite is confirmed to be environmentally safe and an effective costabiliser for rigid PVC: static thermal stability (through oven testing) and dynamic thermal stability (via torque rheometry). PVC compounds are modified by their presence. The extent of change is determined by the primary stabiliser type and the

[6] http://www.subsport.eu/case-stories/294-en?lang=de (accessed 12 June 2014)

grade of the hydrotalcite (Wernicke and Großman, 2009).The substitution capacity of hydrotalcite is described for lead and cadmium based stabilisers, however no specific information on the substitution of dioctyltin stabilisers is given.

Finally, it has to be noted that apart from alternative compounds, there are materials which could be used in the place of PVC. RPA, 2007, provides a list of alternative materials that may be used for packaging applications that are currently made from PVC. Furthermore, also construction and consumer goods are mentioned for which alternative materials exist.

10.3. Information from consultation

According to information submitted by ETINSA DOTE:MOTE stabilisers are used for demanding applications and there are no "drop-in" replacement for DOTE:MOTE which could meet all the regulatory, technical and commercial aspects for the existing applications. Non-organotin based stabilisers are currently not providing the same level of quality, efficiency and process safety in the production of PVC articles. Organotins are liquids and changing to solid formulations would imply for the downstream users to invest in equipment for large-scale handling of solid stabilisers (ETINSA, 2014).

10.4. Conclusions on alternatives

From available literature it seems that substitution of DOTE:MOTE as stabilisers for PVC is technically feasible. Substitution in soft PVC has already taken place to a large extent. The remaining uses will probably be substituted by industry in the near future. For rigid PVC, Ca-organic stabilisers seem to be a promising alternative. Additional efforts by industry will be necessary to achieve the required level of quality, efficiency and process safety. However, Ca-organic stabilisers have not yet undergone an extensive and comprehensive testing. There are some indications in literature that human health or environmental concerns may not be significant. Given the relative low health concerns currently attributed to MOTE an obvious option would be to lower the content of DOTE as much as technically possible aiming to use largely purified MOTE.

11. Existing EU legislation

An overview of current relevant legislation for DOTE is given in Table 12. DOT compounds (including DOTE) are listed in Annex XVII, group 20, No. 6 of REACH[7]. DOTE is also included in Annex XVII group 30. This provision means that DOTE shall not be placed on the market, or used for supply to the general public as substance or in mixtures. Under Regulation (EC) No 10/2011 on plastic materials and articles intended to come into contact with food DOTE is listed in the Union List (Annex I)[8]. The specific migration limit (SML) is 0.006 mg/kg (expressed as Sn), which must not be exceeded.

Table 12: Relevant EU legislations for DOTE

Legal instrument	EU/national	Status of DOTE
REACH Regulation	Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)	Registration of production and use. Tonnage band: 1,000 - 10,000 t/yr.
REACH Regulation	Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)	DOT compounds are listed in Annex XVII in group 20 (organostannic compounds) No 6; they shall not be used after 1 January 2012 in the following articles for supply to, or use by, the general public, where the concentration in the article, or part thereof, is greater that the equivalent of 0.1 % by weight of tin: textile articles intended to come into contact with the skin, gloves, footwear or part of footwear intended to come into contact with the skin, wall and floor coverings, childcare articles, female hygiene products, nappies, two-component room temperature vulcanisation moulding kits (RTV-2 moulding kits)
REACH Regulation	Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)	DOTE is included in Annex XVII, Group 30, resulting that DOTE is not allowed to be placed on the market, or used for supply to the general public as substance or in mixtures.
CLP Regulation	Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures	DOTE will be included in Annex VI with a harmonised classification as Repr. 1B, H360D following Regulation (EC) No 944/213 (5th ATP to CLP Regulation).
Food Contact Material -Regulation	Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food.	DOTE is listed in the Union list. The specific migration limit (SML) is 0.006 mg/kg expressed as tin.

[7] Commission Regulation (EU) No 276/2010of 31 March 2010 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards Annex XVII (dichloromethane, lamp oils and grill lighter fluids and organostannic compounds)

[8] Commission Regulation (EU) No 10/2011of 14 January 2011 on plastic materials and articles intended to come into contact with food.

12. Previous assessments

Risk assessments and risk management option assessments for organotin compounds (including DOT compounds used as heat stabiliser for PVC production) have been carried out previously on behalf of DG Enterprise and Industry. In 2003 a risk assessment was carried out (RPA, 2003), which has been further refined in 2005 (RPA, 2005). Thereafter an impact analysis on different risk management option was conducted (RPA, 2007). The use of organotin compounds in different applications and, more specifically, the use of DOT compounds as additives in the production of PVC were analysed in-depth.

The authors of the RPA 2005 report concluded that single exposure sources do not lead to an unacceptable risk, however, also a cumulative exposure was considered. Risk sources for di-substituted tin exposure have been identified, which are likely to contribute significantly to the overall cumulative risks (e.g. exposure levels are in the range of 20-100% of the TDI[9]).

As a follow-up, an impact assessment on the potential restrictions on the marketing and use of certain organotin compounds was conducted on behalf of the European Commission (DG Enterprise and Industry) in 2007. It has been concluded by the authors, that based on the aforementioned risk assessments (RPA, 2003, RPA, 2005) risk management measures are needed. The authors have proposed different relevant restriction measures for organotin compounds of concern, amongst others the restriction on use of DOT compounds as stabiliser in consumer products. A restriction has been laid down under REACH Regulation (see Chapter 11).

Furthermore, the WHO within the international programme on chemical safety (IPCS) has evolved a concise international chemical assessment document (CICAD) on mono-substituted methyltin, butyltin, and octyltin compounds. The document summarizes relevant scientific information concerning the effects of organotins upon human health and/or environment (WHO, 2006).The Scientific panel on Contaminants in the Food Chain of the European Food Safety Agency (EFSA) assessed possible health risks from the consumption of food containing organotin compounds. A group TDI of 0.1 µg/kg bw (as Sn) has been established, since the toxic organotin compounds exhibit immunotoxic effects by similar mode of action (EFSA, 2004). Few data on DOT concentration in food have been available, which were always below the limit of determination. The main sources of organotins in food (e.g., fish and fishery products) were tri-substituted compounds and tri-phenyltin, which have been used in antifouling paints for boats and as pesticides (EFSA, 2004).

[9] A group tolerable daily intake (TDI) for organotins of 0.1 µg/kg bw/day (expressed as Sn) was considered

13. Executive summary of information on manufacture, use, exposure and alternatives

13.1. Manufacture, imports and exports

DOTE is registered in a tonnage band of 1,000 – 10,000 t/yr. It is manufactured as reaction mass together with the corresponding monooctyltin compound MOTE. Detailed information on the production volumes is provided in the confidential Annex III.

Data on imports and exports provided by the registrants are given in the confidential Annex III. No further information on export/import data of the substance has been identified.

13.2. Uses

DOTE:MOTE reaction mass is used as a heat stabiliser in the production of PVC to prevent the elimination of HCl. Hereby, DOTE:MOTE is predominantly used in the production of un-plasticised PVC. It is present in various different types of consumer articles, such as packaging material (food and pharmaceutical packaging) and credit cards. Furthermore, the reaction mass is used for window profiles, pipes (e.g. drinking pipes) and bottles used to keep shampoos, shower gels and detergents. Exposure scenarios are described for industrial and professional workers and for consumers.

13.3. Releases from manufacture and use

During industrial working steps the exposure to DOTE:MOTE reaction mass is controlled and exposure levels are below toxicological reference values. A concern was raised for professional workers who process the PVC products (low energy manipulation: e.g., cutting, welding of sheets). It is assumed that these processing steps are carried out by a high number of workers.

Release of DOTE:MOTE reaction mass from consumer articles after being embedded in PVC matrix is generally considered to be low. However, given the wide dispersive outdoor use of long-life articles and materials, an exposure for consumers has been considered and estimated by the registrants. Thus, exposure for consumers at low concentration levels cannot be excluded.

13.4. Current knowledge of alternatives

Based on the available information it can be assumed that suitable alternatives for DOTE:MOTE reaction mass are presently available or could be developed within the next decade.

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Annexes

Annex I - Additional information on human health

DOTE is self-classified by 118 notifiers[10] indicated in the C&L inventory. In addition to the reproductive toxicity, further hazard endpoints are addressed. A summary is given in Table 13.

Table 13: Self-classification of DOTE in addition to its adverse developmental effects

Hazard Class and Category Code(s)	Hazard Statement Code(s)
Acute Tox. 4	H302 (Harmful if swallowed)
Skin Irrit. 2	H315 (Causes skin irritation)
Skin Sens. 1	H317 (May cause an allergic skin reaction)
STOT RE 1	H372 (Causes damage to thymus through prolonged or repeated exposure via the oral route)
STOT RE 2	H373 (May cause damage to organs through prolonged or repeated exposure)
Aquatic Acute 1	H400 (Very toxic to aquatic life.)
Aquatic Chronic 1	H410 (Very toxic to aquatic life with long lasting effects)

DOTE is (according to the information of registrants) manufactured and marketed as a multi-constituent substance, consisting of DOTE and of the corresponding monooctyl substance MOTE. Based on the currently available data it can be assumed that the monooctyl tin compound MOTE has no adverse effect on the reproductive system (MAK, 2012, Arkema, 2009). No harmonised classification exists for MOTE. The self-classification as indicated in the C&L inventory is shown in Table 14.

Table 14: Self-classification of MOTE

Hazard Class and Category Code(s)	Hazard Statement Code(s)
Repr. 2*	H361 (Suspected of damaging the fertility or the unborn child)
Skin Irrit. 2	H315 (Causes skin irritation)
Skin Sens. 1B	H317 (May cause an allergic skin reaction)
STOT RE 1	H372 (Causes damage to thymus through prolonged or repeated exposure via the oral route)
STOT RE 2	H373 (May cause damage to organs through prolonged or repeated exposure)
Aquatic Acute 1	H400 (Very toxic to aquatic life)
Aquatic Chronic 1	H410 (Very toxic to aquatic life with long lasting effects)

*it is assumed that the classification for reproductive toxicity is based on the impurity DOTE and the use of MOTE as multi-constituent substance MOTE:DOTE.

Reproductive toxicity

The dioctyltin compound DOTE has been identified as Repr. 1B substance based on criteria laid down in Regulation (EC) No 1272/2008. A CLH dossier has been submitted by industry suggesting to classify DOTE as Repr. 2 (H361d: suspected of damaging the unborn child) (CLH Report, 2011). The Committee for Risk Assessment (RAC) decided on the basis of available data that DOTE should be classified as Repr. 1B (RAC, 2012). According to RAC the observed developmental toxicity effects are not considered to be secondary non-specific consequences of the thymus toxicity but are due to adverse effects on the developmental toxicity parameters. The studies showed clear evidence of

[10] C&L Inventory database, http://echa.europa.eu/web/guest/information-on-chemicals/cl-inventory-database (accessed 02 January 2014)

developmental toxicity in three different species, and there is no information available that these might not be relevant for humans.

Available data indicate that MOT compounds do not have adverse effects on the reproductive system, thus the adverse effects of the reaction mass DOTE:MOTE is related to the presence of DOTE (MAK, 2012).

In a recently conducted developmental screening assay, in which pure MOTE (97.9%) was applied in concentrations up to 1250 mg/kg bw/day orally to Wistar rats, no adverse effects on fertility or on the development were observed (Arkema, 2009), confirming the previous conclusion. A testing proposal for a reproductive toxicity (pre-natal developmental toxicity) study according to OECD test guideline 414 with MOTE has been submitted by the registrant(s).

Annex II – VI

Confidential data