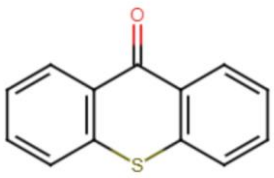
Assessment of regulatory needs

Authority: European Chemicals Agency (ECHA)

Date: 18.5.2022

Group Name: Thioxanthenones

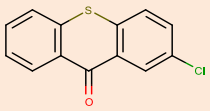
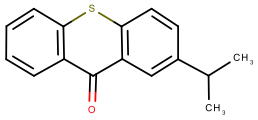
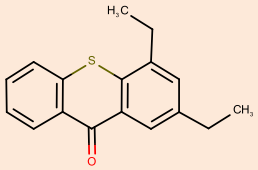
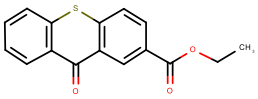
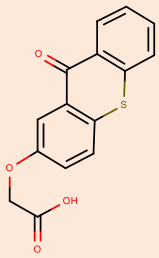
General structure:



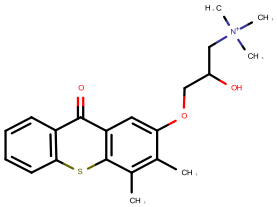
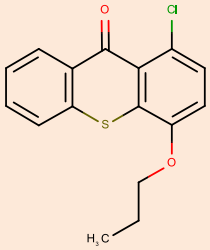
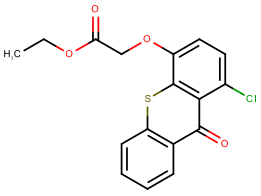
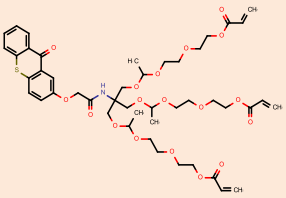
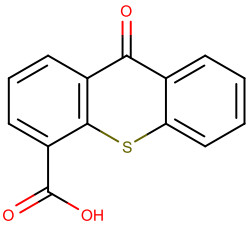
Revision history

Version	*Date*	*Description*
1.0	27.6.2022	

Substances within this group:

EC/List number	CAS number	Substance name	Chemical structures	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) [1]
201-667-2	86-39-5	2-chlorothioxanthen-9-one		OSII or TII
226-827-9	5495-84-1	2-isopropyl-9H-thioxanthen-9-one		Full, 10-100
280-041-0	82799-44-8	2,4-diethyl-9H-thioxanthen-9-one		Full, 10-100
280-960-7	83817-60-1	Ethyl 9-oxo-9H-thioxanthene-2-carboxylate		Full, 1-10
282-803-8	84434-05-9	[(9-oxo-9H-thioxanthen-2-yl)oxy]acetic acid		Full, 10-100

[1] Note that the total aggregated tonnage band may be available on ECHA's webpage at https://echa.europa.eu/information-on-chemicals/registered-substances

402-200-7	103430-24-6	(2-hydroxy-3-(3,4-dimethyl-9-oxo-10-thiaanthracen-2-yloxy)propyl)trimethylammonium chloride		NONS
415-890-1	142770-42-1	1-chloro-4-(n-propoxy)-5-thioxanthen-10-one		Full, ≥1
600-066-6	1003315-69-2	1-chloro-4-carboxymethoxy thioxanthone ethyl ester		OSII or TII
800-991-7	1427388-03-1	2-Propenoic acid, 1,1'-[7,13-dimethyl-10-(3-methyl-11-oxo-2,4,7,10-tetraoxatridec-12-en-1-yl)-10-[[2-[(9-oxo-9H-thioxanthen-2-yl)oxy]acetyl]amino]-3,6,8,12,14,17-hexaoxanonadecane-1,19-diyl] ester		Full, 1-10
849-175-2	51762-56-2	10-oxo-10H-dibenzo[b,e]thiopyran-4-carboxylic acid		Full, 1-10

This table does not contain group members that are only notified under the CLP Regulation. Should further regulatory risk management action on one or more substances in the group be considered, ECHA may make an additional search for related C&L notified substances to be included in the group and develop an assessment of regulatory needs for them.

Contents

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The author does not accept any liability with regard to the use that may be made of the information contained in this document. Usage of the information remains under the sole responsibility of the user. Statements made or information contained in the document are without prejudice to any further regulatory work that ECHA, the Member States or other regulatory agencies may initiate at a later stage. Assessment of regulatory needs and their conclusions are compiled on the basis of available information and may change in light of newly available information or further assessment.

Foreword

The purpose of the assessment of regulatory needs of a group of substances is to help authorities conclude on the most appropriate way to address the identified concerns for a group of substances or a single substance, i.e. the combination of the regulatory risk management instruments to be used and any intermediate steps, such as data generation, needed to initiate and introduce these regulatory measures.

An assessment of regulatory needs can conclude that regulatory risk management at EU level is required for a (group of) substance(s) (e.g. harmonised classification and labelling, Candidate List inclusion, restriction, other EU legislation) or that no regulatory action is required at EU level. While the assessment is done for a group of substances, the (no) need for regulatory action can be identified for the whole group, a subgroup or for single substance(s).

The assessment of regulatory needs is an important step under ECHA's Integrated Regulatory Strategy. However, it is not part of the formal processes defined in the legislation but aims to support them.

The assessment of regulatory needs can be applied to any group of substances or single substance, i.e., any type of hazards or uses and regardless of the previous regulatory history or lack of such. It can be done based on different level of information. A Member State or ECHA can carry out this case-by-case analysis. The starting point is available information in the REACH registrations and any other REACH and CLP information. However, more extensive set of information can be available, e.g., assessment done under REACH/CLP or other EU legislation, or can be generated in some cases (e.g., further hazard information under dossier evaluation). Uncertainties associated to the level of information used should be reflected in the documentation. It will be revisited when necessary. For example, after further information is generated and the hazard has been clarified or when new insights on uses are available. It can be revisited by the same or another authority.

The responsibility for the content of this assessment rests with the authority that developed it. It is possible that other authorities do not have the same view and may develop further assessment of regulatory needs. The assessment of regulatory needs does not yet initiate any regulatory process, but any authority can consequently do so and should indicate this by appropriate means, such as the Registry of Intentions.

For more information on Assessment of regulatory needs please consult ECHA website[2].

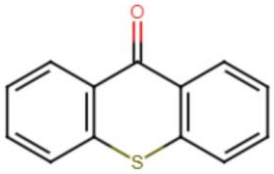
[2] https://echa.europa.eu/understanding-assessment-regulatory-needs

Glossary

ARN	Assessment of Regulatory Needs
CCH	Compliance Check
CLH	Harmonised classification and labelling
CMR	Carcinogenic, mutagenic and/or toxic to reproduction
DEv	Dossier evaluation
EAT	Estrogenic, Androgenic and Thyroid
ED	Endocrine disruptor
NONS	Notified new substances
OEL	Occupational exposure limit
OSH	Occupational Safety and Health
OSII or TII	On-site isolated intermediate or transported isolated intermediate
PBT/vPvB	Persistent, bioaccumulative and toxic/very persistent and very bioaccumulative
RMOA	Regulatory management options analysis
RRM	Regulatory risk management
SEv	Substance evaluation
STOT RE	Specific target organ toxicity, repeated exposure
SVHC	Substance of very high concern

1 Overview of the group

ECHA has grouped together 10 structurally similar substances based on the presence of the thioxanthenone moiety shown in the figure below.



All the substances in the group are identified as mono-constituent substances. There are 7 substances with full registrations. Four of these are manufactured in and/or imported to the European Economic Area at 1-10 t/y, and one at 10-100 t/y. EC 226-827-9 and 280-041-0 are registered with 10-100 t/y as highest registered tonnage band but are manufactured in and/or imported to the European Economic Area at 100-1000 t/y. Two substances are registered only as intermediate (TII/OSII) and 1 unclaimed NONS.

Based on information reported in the REACH registration dossiers, the substances in the group are typically used as photochemical or photoinitiator by industrial and/or professional workers in (UV curable) coatings and paints, inks and toners, and adhesives and sealants, e.g., for the treatment of paper articles, textiles, fibers and/or apparel, printed media, plastics or electronics. One substance is also registered for use in construction products. EC 226-827-9 and 280-041-0 are additionally indicated for use by consumers.

The reported uses suggest possible exposure of workers, consumers and the environment. Based on the technical functions, the potential for exposure of consumers and the environment is expected to be low but cannot be excluded. One of the substances in the group, EC 226-827-9 (2-isopropylthioxanthone, ITX), has been found in food and beverages, possibly from its use in UV curing inks on food packaging. Concentrations found ranged up to ~300µg/l depending on the food or beverages' composition, with a conservative average estimated at 250 µg/l for milk-based products and 125 µg/l for all other affected foods and beverages. In 2005, EFSA assessed these concentrations as safe for consumers[3]. These findings for ITX may suggest some migration from packaging to food and beverages, which may then also be suggested likely for ITXs' structural analogues that are part of this group.

For workers (in industrial and professional settings) the exposure potential may be expected to be higher than for consumers because they may work with the actual

[3] EFSA (2005) Opinion of the Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food; on a request from the Commission related to 2-Isopropyl thioxanthone (ITX) and 2-ethylhexyl[1]4-dimethylaminobenzoate (EHDAB) in food contact materials (Question numbers EFSA-Q-2005-240 & EFSA-Q[1]2005-241)
https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2005.293

unreacted substances whereas consumers may mainly be exposed to the unreacted residuals of the substances.

Similarity in structure and uses suggests the substances in this group might be used interchangeably.

Note on the scope of ECHA's assessment of regulatory needs

Regarding hazards, the focus of ECHA's assessment is on CMR (carcinogenic, mutagenic and/or toxic to reproduction), sensitiser, ED (endocrine disruptor), PBT/vPvB or equivalent (e.g. substances being persistent, mobile and toxic), aquatic toxicity hazard endpoints and therefore only those are reflected in the table in section 3. This does not mean that the substances do not have other known or potential hazards. In some specific cases, where ECHA identifies a need for regulatory risk management action at EU level for other hazards (e.g. neurotoxicity, STOT RE), such additional hazards may be addressed in the assessment. An overview of classification is presented in Annex 1.

On the exposure side, ECHA is mainly using the information on uses reported in the registration dossiers (IUCLID) as a proxy for assessing the potential for exposure to humans and releases to the environment. The potential for release / exposure is generally considered high for "widespread" uses, i.e. professional and consumer uses and uses in articles. For these uses, normally happening at many places, the expected level of control is *à priori* considered limited. The chemical safety reports are not necessarily consulted and no quantitative exposure assessment is performed at this stage.

2 Justification for the need for regulatory risk management action at EU level

Based on currently available information, there is a need for (further) EU regulatory risk management – Restriction for reproductive toxicity, mutagenicity, ED and/or PBT/vPvB due to the potential for release/exposure and/or the potential for interchangeability for EC/List 201-667-2, 226-827-9, 280-041-0, 282-803-8 and 800-991-7.

There is a potential for reproductive toxicity for all substances in the group based on information available on a number of substances (i.e. EC/List 226-827-9, 280-041-0, 282-803-8 and 800-991-7), self-classification as repr.2 (i.e. EC 226-827-9 and 282-803-8) and structural similarity. The potential for reproductive toxicity is supported by potential ED properties observed in *in vitro* test results showing anti-estrogenic and anti-androgenic activity for EC 226-827-9, and *in silico* modelling results with medium to high confidence suggesting i) additional thyroid effects for EC 226-827-9 and ii) anti-estrogenic and anti-androgenic activity for EC 201-667-2 and 280-041-0. A potential for similar toxic properties is further supported by metabolite predictions on EC 280-041-0 and 226-827-9, suggesting toxicodynamic activity from the ring structure as the actual driver of toxicity.

In addition, there is a potential for genotoxicity for two substances (i.e. EC 226-827-9 and 282-803-8) based on *in vitro* data, and for EC 280-041-0 based on read-across by the registrant to EC 226-827-9. Substance EC 201-667-2 does not show genotoxic/mutagenic properties, and for List 800-991-7 no conclusion can be drawn since there are equivocal/contradicting indications.

All substances in the group screen as persistent/very persistent, as information available for seven group members indicate that they are not readily biodegradable while higher-tier information on degradation is not available. Due to the high level structural similarity, i.e. presence of Thioxanthenone moiety, the same conclusion could be applied to the remaining three members of the group. Where available, relevant information on aquatic toxicity indicates that substances in the group are toxic to aquatic organisms (four of them are already self-classified in various aquatic hazard categories). Where available, information on log Kow (>4.5) and on the substance structure/dissociation constant indicates that the bioaccumulation potential cannot be ruled out for most members of the group, except List 800-991-7. For EC 201-667-2 and EC 600-066-6, absence of information on log Kow does not allow to predict the potential for bioaccumulation. There is a potential for endocrine disruptive effects for the environment for EC 280-041-0 and EC 226-827-9 based on the *in vitro* and *in silico* observations for ED for human health.

Regarding exposure, the reported uses suggest possible exposure of workers, consumers and the environment. The main use described in the registration dossiers is as photo-initiator in UV curable inks, coatings and/or adhesives, e.g. for the treatment of paper articles, textiles, fibers and/or apparel, printed media, plastics or electronics, or as intermediate in polymer preparations. A brief open literature search suggests that concentrations in mixtures may be <15% w/w[4], with limited, but likely, exposure expected from article service life due to any residual, non-reacted initiator.

Based on the technical functions, the potential for exposure of consumers and the environment as a consequence of article service life is expected to be low. A low potential for release to the environment is further supported by the registered environmental release categories suggesting primarily reactive uses in industrial and professional settings. Exposure of consumers and the environment cannot be excluded though. This is supported by the concentrations of EC 226-827-9 found in food and beverages and the fact that article service life is registered as relevant for EC 226-827-9 and 280-041-0. Based on similarity in chemical structure and technical function, article service life may be relevant also for the other substances in the group with uses in inks and toners, paper and board and textile dyes or impregnating products, and migration from packaging to food and beverages may similarly be expected for these.

For workers (in industrial and professional settings) the exposure potential is expected higher than for consumers as part of their work may involve the handling of unreacted substances and/or substances in mixtures.

ECHA proposes to generate further data on the genotoxicity, reproductive toxicity, ED and PBT/vPvB via CCH on EC 226-827-9, 280-041-0 and 282-803-8 to clarify potential hazards. EC 226-827-9 and 282-803-8 are currently self-classified as Repr. 2. For EC 280-041-0, no self-classification is yet in place, though read-across of the hazard data of EC 226-827-9 by the registrants would suggests similar classification.

The first step of the regulatory risk management action proposed, should the hazard exist, is the confirmation of hazard via harmonised classification (CLH) as

[4] E.g., Influence of Photoinitiator and Curing Conditionson Polymerization Kinetics and Gloss of UV-Cured Coatings; V. JANČOVIČOVÁ*, J. KINDERNAY, Z. JAKUBÍKOVÁ, and I. MRLLÁKOVÁ; DOI: 10.2478/s11696-007-0052-1;

Repr. 1B and Muta 1, and via SVHC identification and inclusion on the Candidate List as ED and PBT/vPvB.

Harmonised classification as Repr. 1B or Muta 1 will require company level risk management measures (RMM) under the OSH legislation for workers, to be in place, ii) will require that the necessary safety measures are in place for specific sensitive workers, i.e. pregnant women in accordance with Directive 92/85/EEC and young people in accordance with Directive 94/33/EC, and iii) is a prerequisite to restrict the presence of the substances in consumer mixtures, by means of the restriction entry 29 and 30. CLH is also a prerequisite to restrict the presence of the substances in clothing, other textiles, and footwear articles, by means of the restriction entry 72 of REACH Annex XVII (this would require addition of the relevant substances to Appendix 12 by the Commission through Article 68(2)).

SVHC identification is highly recommended for further restriction of substances with ED and PBT/vPvB hazards under REACH. In addition, SVHC identification brings immediate obligations for suppliers of the substances such as (i) supplying a safety data sheet and communicating on the safe use of the substances, (ii) responding to consumer requests within 45 days, (iii) notifying ECHA if the article they produce contains the substance above regulatory threshold, and (iv) requiring users and manufacturers to minimise emission where possible.

Restricting the use by workers and in consumer mixtures may be most relevant for EC 226-827-9 and 280-041-0 due to their high tonnage brought onto the EU market (i.e. 100-1000 t/y), registered consumer uses, and the relevance of article service life. For the other substance marketed at yearly tonnages <100 t or as OSII/TII, priority for restriction is much lower. However, their priority for restriction may change considering the suspected interchangeability of the substances in this group.

Should hazards be confirmed to be Repro 1B, Muta 1, ED and/or PBT/vPvB, ECHA therefore proposes further to consider similar regulatory action for List 800-991-7 based on its metabolization to EC 282-803-8, and for EC 201-667-2 based on high structural similarity to avoid regrettable substitution. With regard to List 800-991-7 which is a candidate for CCH, ECHA considers data generation is of low priority at the moment because it would not be able to significantly further inform on any need for EU RRM.

A relatively low priority for authorisation is suggested for all substances based on their specific uses (relevant for all substances; EC 201-667-2 is registered as OSII/TII), and particularly for List 800-991-7 also based on to its marketed tonnage.

Based on currently available information, there is no need for (further) EU regulatory risk management for EC/List 280-960-7, 402-200-7, 415-890-1, 600-066-6 and 849-175-2 in the group.

Due to the registration status of these substances being low tonnage (1-10 t/y), NONS or TII/OSII, it is not possible to clarify their potential hazards at the moment. Therefore, it is proposed that there is currently no need for EU RRM action on these substances. If the registration status changes, data generation and potential follow up actions will be re-considered when the assessment will be revisited.

Though there is a potential for reproductive toxicity also for these substances based on the presence of the ring structure as possible driver of toxicity, the information is not sufficient to classify, and there is no possibility to clarify this potential through CCH.

Similarly, all substances are considered potentially PBT/vPvB but their registration status does not allow clarifying these potential properties. As described above, all substances in the group screen as persistent/very persistent, either based on available data, or based on structural similarity, i.e. presence of the Thioxanthenone moiety. Also, bioaccumulation potential cannot be ruled out, except for List EC 600-066-6 where the absence of information on the log Kow does not allow to predict the potential for bioaccumulation. The classification (harmonised and self-classified, respectively) for EC 402-200-7 and 415-890-1 indicates that these are toxic to aquatic organisms.

List 849-175-2 has a potential for genotoxicity based on *in vitro* data. Substances EC 402-200-7 and 415-890-1 do not flag as genotoxic/mutagenic and for List 600-066-6 no conclusion can be drawn due to equivocal/ contradicting indications. For EC 280-960-7, there is no information available for this endpoint.

The modelling of ED activity through *in silico* methods resulted in a negative prediction with medium confidence on EAT activity for EC/List 280-960-7, 600-066-6 and 849-175-2, suggesting unlikely ED properties for the EAT modes of action for these substances. For EC 402-200-7 and 415-890-1, predictions came out as 'possible' (with low confidence), suggesting that ED properties for these substances are inconclusive.

CCH might clarify the potential for genotoxicity for List 849-175-2, but most likely only when supporting hazard information from EC 226-827-9, 280-041-0 and 282-803-8 would be available. ECHA therefore proposes to only open CCH when data generation on EC 226-827-9, 280-041-0 and 282-803-8 result in hazards possibly warranting a Muta 1 classification. Without this supporting information, priority for CCH for List 849-175-2 is low because of the low likeliness that data generation on the substance on its own would result in any further regulatory measures. Priority for CCH for EC 280-960-7 is also considered low for the similar reason that the data that can be generated would not significantly inform on any hazard and a possible consequent need for EU RRM for the substance.

Regarding exposure, none of the substances have consumer uses registered and hence low potential for exposure for consumers is suggested. Still consumer exposure may be possible for EC 280-960-7 via its use in inks and toners under the assumption that article service life is relevant for this use in a similar way as has been reported in the registration dossiers for EC 226-827-9 and 280-041-0.

For workers (in industrial and/or professional settings) there is potential for exposure for EC/List 415-890-1, 280-960-7 and 849-175-2 from uses in e.g. coatings, paints, inks, and/or adhesives. Exposure is considered not relevant for List 600-066-6, which is registered as on-site or transported intermediate, and for EC 402-200-7, which is an unclaimed NONs and has most likely ceased manufacture.

EC/List 280-960-7, 415-890-1 and 849-175-2 have overlapping use profiles and technical functions with those of EC 226-827-9 and 280-041-0, based on which a potential for interchangeability is suspected. The low registered tonnages for EC/List 280-960-7, 415-890-1 and 849-175-2, and relatively weak basis to suspect hazard in the absence of confirmed hazards for EC 226-827-9, 280-041-0 and 282-803-8 add to a low priority for pursuing possible hazards through SEv at this moment in time.

3 Conclusions and actions

The conclusions and actions proposed in the table below are based on the REACH and CLP information available at the time of the assessment by ECHA. The main source of information is the registration dossiers. Relevant public assessments may also be considered. When new information (e.g. on hazards through evaluation processes, or on uses) will become available, the document will be updated and conclusions and actions revisited.

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
201-667-2 226-827-9 280-041-0 282-803-8 800-991-7	Known or potential hazard for reproductive toxicity for all substances, and mutagenicity for EC 226-827-9, 280-041-0, 282-803-8 Known or potential hazard for ED for EC 201-667-2, 226-827-9, and 280-041-0 Inconclusive hazard for ED for EC/List 282-803-8 and 800-991-7	Known or potential hazard for PBT/vPvB and aquatic toxicity for EC 201-667-2, 226-827-9 and 280-041-0 Known or potential hazard for persistency and aquatic toxicity and possibly mobile in the environment for EC/List 282-803-8 and 800-991-7 Inconclusive hazard For ED for EC 280-041-0 and EC 226-827-9	Uses in polymer and polymer preparations and in adhesives, coatings or inks for various UV curing applications including paper and board and textile. Potential for exposure for consumers and the environment due to the type of use and technical function of the substances. Exposure of workers (industrial and professional) is expected higher. EC 201-667-2 is used as intermediate and	Need for EU RRM: Restriction Justification: Releases to the environment from consumer and professional uses cannot be avoided. CLH of Repr.1B and Muta 1 is a prerequisite to restrict the presence of the substances in consumer mixtures, by means of the restriction entry 29 and 30.	**First step:** CCH for EC 226-827-9, 280-041-0 and 282-803-8 **Next steps (if hazard confirmed):** CLH for Repr.1B or Muta 1 for possibly all substances, except List 800-991-7 which may confirm as Repr. but not as Muta. SVHC identification for ED or PBT/vPvB for EC 201-667-2, 226-827- 9 and 280-041-0

			might be used as substitute.	Professional uses are typically non-contained and non-automated leading to releases to the environment. Restriction of professional uses is preferred over authorisation as it is considered to be more efficient and effective to introduce controls at the level of placing on the market rather than at the level of uses.	
280-960-7 415-890-1 849-175-2	Known or potential hazard for reproductive toxicity for all substances Known or potential hazard for mutagenicity for List 849-175-2 Inconclusive hazard for mutagenicity for List 600-066-6	Known or potential hazard for PBT/vPvB and aquatic toxicity	Uses as photochemical in e.g. polymers, coatings, inks and adhesives with a potential for exposure for consumers, workers and the environment. Substances may act as substitute for EC 201-667-2, 226-827-9 or 280-041-0.	Currently no need for EU RRM Justification: CCH cannot clarify any priority hazards for EU RRM, and the low registered tonnages and/or registration status (intermediate, cease manufacture) result in low priority for SEv.	No action
402-200-7	Inconclusive hazard		Use as intermediate or ceased		

600-066-6	for ED for EC 402-200-7 and 415-890-1		manufacture for EC/List 600-066-6 and 402-200-7, respectively.	The need for EU RRM will be further investigated once the hazard properties will be clarified after data generation on several of their group members.	

Annex 1: Overview of classifications

Data extracted in February 2022

Table 1: Overview of classifications

EC/ List No	CAS No	Substance name	Harmonised classification	Classification in registrations	Classification in C&L notifications (*)
201-667-2	86-39-5	2-chlorothioxanthen-9-one	-	-	Flam. Solid 2 H228[2 out of 3]
226-827-9	5495-84-1	2-isopropyl-9H-thioxanthen-9-one	-	Repr. 2 H361, specific effect: fertility Aquatic Acute 1 H400 Aquatic Chronic 1 H410	Skin Sens. 1 H317[1 out of 36] Aquatic Chronic 4 H413[2 out of 36] STOT Rep. Exp. 2 H373, affected organs: liver[6 out of 36] Acute Tox. 4 H302[7 out of 36]
280-041-0	82799-44-8	2,4-diethyl-9H-thioxanthen-9-one	-	-	-
280-960-7	83817-60-1	ethyl 9-oxo-9H-thioxanthene-2-carboxylate	-	-	-
282-803-8	84434-05-9	[(9-oxo-9H-thioxanthen-2-yl)oxy]acetic acid	-	Aquatic Chronic 3 H412	-
402-200-7		(2-hydroxy-3-(3,4-dimethyl-9-oxo-10-thiaanthracen-2-yloxy)propyl)trimethylammonium chloride	Aquatic Chronic 3	-	-
415-890-1		1-chloro-4-(n-propoxy)-5-thioxanthen-10-one	-	Aquatic Acute 1 H400 Aquatic Chronic 2 H411	-
600-066-6	10033 15-69-2	ethyl [(1-chloro-10-oxo-10H-dibenzo[b,e]thiopyran-4-yl)oxy]acetate	-	-	-

800-991-7	1427388-03-1	7-methyl-10,10-bis(3-methyl-11-oxo-2,4,7,10-tetraoxatridec-12-en-1-yl)-12-oxo-13-[(10-oxo-10H-dibenzo[b,e]thiopyran-2-yl)oxy]-3,6,8-trioxa-11-azatridec-1-yl acrylate	-	Acute Tox. 4 H302 Skin Sens. 1 H317 Aquatic Chronic 2 H411	-
849-175-2	51762-56-2	10-oxo-10H-dibenzo[b,e]thiopyran-4-carboxylic acid			

(*) the number in brackets indicates the number of notifications received. Each notification can represent a group of notifiers, therefore the number may differ from the C&L inventory which displays number of notifiers.

Annex 2: Overview of uses based on information available in registration dossiers

Data extracted on 26-01-2022

Main types of applications structured by product or article types	201-667-2	226-827-9	280-041-0	280-960-7	282-803-8	415-890-1	600-066-6	800-991-7	849-175-2
PC 35: Washing and cleaning products		F, I, **P**,	F, I,						
PC 15: Non-metal-surface treatment products		F, I, **P**,							
PC 32: Polymer preparations and compounds		F, I, **P**,	F, I, **P**,	F, I, **P**,			I,		
PC 1: Adhesives, sealants		F, I, **P**,	F, I, **P**,	F, I, **P**,					**P**,
PC 9c: Finger paint		F,	F, I, **P**, **C**,						
PC 9b: Fillers, putties, plasters, modelling clay		F,	F, I, **P**, **C**,			F, I,			
PC 9a: Coatings and paints, thinners, paint removes		F, I, **P**,	F, I, **P**, **C**,	F, I, **P**,	F, **P**,	F, I,			I, **P**,
PC 18: Ink and toners		F, I, **P**, **C**, **A**,	F, I, **P**,	F, I, **P**,		F, I,		F, **P**,	I, **P**,
PC 26: Paper and board treatment products		F, I, **P**, **A**,	F, I, **P**, **A**,						
PC 34: Textile dyes, and impregnating products		**A**,							
PC 14: Metal surface treatment products			F, I, **P**,						
PC 21: Laboratory chemicals			I,	F, I,					
PC 19: Intermediate	I,		I,				I,		
PC 30: Photo-chemicals		I,				I,			

F: formulation, I: industrial use, P: professional use, C: consumer use, A: article service life; P, C and A are highlighted in red to indicate widespread use with potential for exposure/release

Annex 3: Overview of completed or ongoing regulatory risk management activities

Data extracted on 26-01-2022

EC/List number	RMOA	Authorisation		Restriction*	CLH	Actions not under REACH/ CLP
		Candidate list	Annex XIV	Annex XVII	Annex VI (CLP)	
226-827-9						EFSA (2005)

*Some of the broad restriction entries in the Annex XVII of REACH are not represented in the overview, e.g. when the scope of the restriction is defined by its classification or the substance identification is broad (e.g. entries 3, 28-30 and 40).

There are no relevant completed or ongoing regulatory risk management activities for any of the substances in REACH or CLP.

In 2005, EFSA assessed the substance ITX (226-827-9) as safe for use in inks used for food packaging material[3].