Assessment of regulatory needs

Authority: European Chemicals Agency (ECHA)

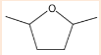
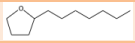
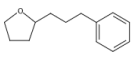
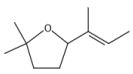
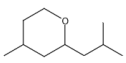
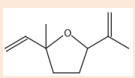
Date: 7 December 2021

Group Name: Cyclic ethers

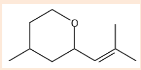
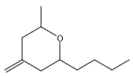
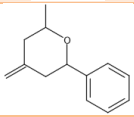
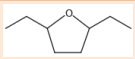
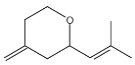
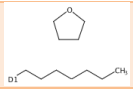
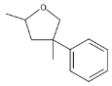
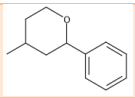
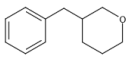
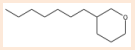
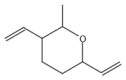
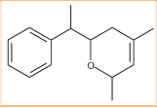
Revision history

Version	*Date*	*Description*
1.0	7 December 2021	

Substances within this group:

EC/List number	CAS number	Substance name/Substance name acronyms	Chemical structures	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) [1]
202-507-4	96-47-9	tetrahydro-2-methylfuran		Full, >1000
203-726-8	109-99-9	tetrahydrofuran		Full, >1000
203-810-4	110-87-2	3,4-dihydro-2H-pyran		Full, 1-10
204-661-8	123-91-1	1,4-dioxane		Full, >1000
205-552-8	142-68-7	tetrahydropyran		C&L notified
207-964-3	503-30-0	oxetane		C&L notified
209-777-2	592-90-5	oxepane		C&L notified
212-957-3	887-15-0	2,2-diphenyltetrahydrofuran		C&L notified
213-707-6	1003-38-9	tetrahydro-2,5-dimethylfuran		C&L notified
216-898-4	1693-74-9	[2H4]tetrahydro[2H4]furan		C&L notified
219-423-9	2435-16-7	2-heptyltetrahydrofuran		C&L notified
221-715-6	3208-40-0	2-(3-phenylpropyl)tetrahydrofuran		C&L notified
225-207-5	4717-96-8	tetrahydro-4-methyl-2H-pyran		Full, not (publicly) available
231-028-3	7416-35-5	2,2-dimethyl-5-(1-methylpropenyl)tetrahydrofuran		C&L notified
236-537-4	13423-15-9	tetrahydro-3-methylfuran		Full, 100-1000
236-770-1	13477-62-8	tetrahydro-2-isobutyl-4-methyl-2H-pyran		Full, not (publicly) available
237-184-9	13679-86-2	tetrahydro-5-isopropenyl-2-methyl-2-vinylfuran		C&L notified
237-550-8	13837-56-4	(±)-tetrahydro-2,6,6-trimethyl-2-vinyl-2H-pyran		C&L notified
237-551-3	13837-60-0	2-ethynyltetrahydro-2,6,6-trimethyl-2H-pyran		OSII or TII, not (publicly) available

[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

EC/List number	CAS number	Substance name/Substance name acronyms	Chemical structures	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) [1]
239-117-9	15045-43-9	tetrahydro-2,2,5,5-tetramethylfuran		C&L notified
240-457-5	16409-43-1	tetrahydro-4-methyl-2-(2-methylprop-1-enyl)pyran		Full, 100-1000
246-101-5	24237-02-3	2-butyltetrahydro-6-methyl-4-methylene-2H-pyran		C&L notified
247-455-3	26093-63-0	tetrahydro-3-methyl-2H-pyran		C&L notified
250-124-6	30310-41-9	tetrahydro-2-methyl-4-methylene-6-phenyl-2H-pyran		C&L notified
255-274-6	41239-48-9	2,5-diethyltetrahydrofuran		C&L notified
262-475-2	60857-05-8	tetrahydro-4-methylene-2-(2-methyl-1-propenyl)-2H-pyran		OSII or TII, not (publicly) available
275-801-3	71662-35-6	heptyltetrahydrofuran		C&L notified
279-967-8	82461-14-1	2,4-dimethyl-4-phenyltetrahydrofuran		Full, not (publicly) available
303-662-1	94201-73-7	tetrahydro-4-methyl-2-phenyl-2H-pyran		Full, not (publicly) available
458-610-1	60466-73-1	2H-Pyran, tetrahydro-3-(phenylmethyl)-		NONS, not (publicly) available
462-530-2	854737-09-0	3-heptyl-tetrahydro-pyran		NONS, not (publicly) available
653-633-5	29539-04-6	3,6-divynil-2-methyltetrahydropyran		C&L notified
700-263-8	89686-69-1	2,2-di(tetrahydrofuryl)propane		Full, 10-100
851-325-7	35270-87-2	2,2-dimethyloxane		C&L notified
948-409-1	1945993-03-2	4,6-dimethyl-2-(1-phenylethyl)-3,6-dihydro-2H-pyran		Full, not (publicly) available

This table contains also group members that are only notified under the CLP Regulation. However, the list is currently non-exhaustive. Should further regulatory risk management action on one or more substances in the group be considered, ECHA will 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

CCH	Compliance Check
CLH	Harmonised classification and labelling
CMR	Carcinogenic, mutagenic and/or toxic to reproduction
DEv	Dossier evaluation
ED	Endocrine disruptor
NONS	Notified new substances
OEL	Occupational exposure limit
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 structurally similar substances based on the presence of the cyclic ether functionality with other varied structures e.g. alkyl chains or cyclic or aromatic ring.

The group consists of 35 mono- and multi-constituent substances. Two substances of the group have a harmonised classification for carcinogenicity (EC 203-726-8 as Carc. 2 and EC 204-661-8 as Carc. 1B) and several have self-classifications, most notably for Repr. 2 (EC 240-457-5) and Skin Sens. 1B (EC 203-810-4, 700-263-8, 948-409-1).

Based on information reported in the REACH registration dossiers, the main uses and relevant potential for exposure can be summarised as follows:

- EC 202-507-4, 203-810-4, 204-661-8, 225-207-5 have industrial use in chemical synthesis. Exposure and release are assumed as properly controlled, although they cannot be excluded.

- EC 236-770-1, 240-457-5, 279-967-8, 458-610-1, 462-530-2, 948-409-1, have industrial, widespread professional and consumer uses as fragrances in a variety of products including cleaning products, perfumes, cosmetics. There is high exposure potential for professional workers and consumers as well as high potential for release to the environment. Release and exposure in industrial settings, although unlikely, cannot be excluded.

- EC 203-726-8 has many reported uses (several of which are widespread) such as use in chemical synthesis, laboratories, cleaning products, polymer production, coatings, inks, fuel/fuel additives, functional/metalworking fluids and batteries. There is exposure potential for both workers and consumers as well as potential release to the environment.

  - EC 700-263-8 has industrial use in production of rubber products, although tyre manufacturing is mentioned under the sector of use, exposure resulting from article service life is unlikely.

All other substances either have no reported uses, are registered as intermediate and expected to be handled under strictly controlled conditions or are not registered.

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 known carcinogenicity and P/vP, mobile and toxic properties due to potential for exposure and release to the environment of the substance EC 204-661-8.

The last foreseen regulatory action for 1,4-dioxane (EC 204-661-8) is based on the conclusions developed by Germany in its RMOA[3].

Available monitoring data suggest that it is a contaminant of drinking water. The main use is as a solvent/processing aid in chemical synthesis where there is a potential for release as a result of industrial use (e.g. via wastewater) and formulation. An additional source of emission is likely from the presence of 1,4-dioxane as a constituent/impurity in other substances with high release potential (e.g. surfactants). Although the residual concentrations are usually quite low (<0.1%), in sum they result in relevant emissions.

For such risks affecting the environment, Germany argued that emissions of the substance into the environment might be best controlled with a restriction in order to also address uses of substances containing 1,4-dioxane; additionally, a targeted restriction would also impact importers and manufacturers of articles.

The assessment done as part of this report further corroborates the conclusions derived by Germany and therefore restriction is proposed to address the

[3] RMOA entry on ECHA website (public)

environmental exposure (including from the import and use of articles) and hazardous properties of 1,4 dioxane.

1,4-dioxane was identified as SVHC and included in the Candidate List in July 2021 based on its carcinogenicity (Carc.1B) and equivalent level of concern resulting from the combination of its properties causing higher concern to the environment and human health (man via environment). The combined intrinsic properties which demonstrate scientific evidence of probable serious effects to human health and the environment and which give rise to an equivalent level of concern are the following: very high persistence, high mobility in water, potential for being transported in the water phase over long distances, difficulty of remediation and water purification. The observed probable serious effects for human health and the environment are carcinogenicity and yet unknown environmental effects. Together, these elements lead to a very high potential for irreversible effects.

Furthermore, for risks related to carcinogenic properties of the substance, Germany has proposed in their RMOA to set a binding occupational exposure limit value (BOELV) in order to limit exposure to workers. ECHA at the request of the Commission is currently assessing the option of setting a binding occupational exposure limit (OEL) under the Carcinogens and Mutagens Directive (Directive 2004/37/EC)[4]. The OEL in addition to the CLH for Carc. 1B are considered adequate risk management measures for limiting exposure to workers; measures for the protection of consumers have not been considered as no consumer uses are reported.

Based on currently available information, there is a need for (further) EU regulatory risk management– CLH for reproductive toxicity due to the potential for exposure for substances EC 240-457-5, 202-507-4.

Substance EC 240-457-5 has potential reproductive toxicity and is self-classified as Repr. 2. The substance is used as a fragrance in various products by both professionals and consumers where the potential for exposure is high. The last foreseen action is CLH to confirm the hazard and trigger company-level risk management. CLH as Repr. 2 will i) trigger prohibition under the Cosmetic Products Regulation (EC) No 1223/2009 unless an exemption is granted upon assessment of safe use of the substances in cosmetic products by the Scientific Committee on Consumer Safety (SCCS), ii) trigger additional safety measures 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. Coherently, information on adequate protective measures is expected to be communicated to workers.

Substance EC 202-507-4 has potential reproductive toxicity due to effects observed in a repeated dose toxicity study. Testing proposals have been submitted to clarify the hazard. Exposure as a result of industrial use as a solvent in chemical synthesis and as a laboratory chemical cannot be excluded. CLH is recommended to ensure adequate risk management measures are put in place at workplaces; however, it is proposed to first wait for the results of the ongoing data generation rather than proceeding to CLH directly.

Based on currently available information, there is no need for (further) EU regulatory risk management for persistent and mobile properties for the substances EC 203-810-4, 225-207-5, 205-552-8, 247-455-3.

These substances potentially have persistent and mobile properties similarly to 1,4-dioxane; however, there are no human health hazards expected, including

[4] Consultation on OEL recommendation

carcinogenicity, nor any other toxicity which could fulfil the T criteria. Two of these substances (EC 203-810-4, 225-207-5) are used in chemical synthesis either as an intermediate or as a solvent respectively, the latter one of which is also used as a laboratory chemical. The remaining two (EC 205-552-8, 247-455-3) are not registered and therefore have no reported uses.

There is currently no additional evidence (e.g. monitoring information) to identify these substances as being of equivalent level of concern according to article 57(f) and therefore to propose those for SVHC identification. Furthermore, although one of these substances is used similarly to 1,4-dioxane where a similar level of release may be suspected, the others are either not registered or used in a controlled setting where exposure is expected to be low. Therefore, despite some potential for release to the environment, it is proposed for the time being that for these substances no further regulatory action is needed. Nevertheless, it is worth noting that there may be a concern related to persistent and mobile substances used in a manner potentially leading to environmental emissions.

In view of the planned restriction for 1,4-dioxane, it may be worth investigating whether these substances could be considered as potential substitutes. It is worth noting that both registered substances are used in chemical synthesis and have similar physico-chemical properties (i.e. boiling point, vapour pressure and density).

Based on currently available information, there is no need for (further) EU regulatory risk management for carcinogenicity for substance EC 203-726-8.

The substance EC 203-726-8 has a harmonised classification for Carc. 2. There is also indication of mutagenic properties however the available data are inconclusive. It has many reported uses including use in chemical synthesis, laboratories, cleaning products, polymer production, coatings (e.g. adhesives, sealants, paints, PVC primer), inks, fuel/fuel additives, functional/metalworking fluids and batteries. Many of the uses are widespread and there is exposure potential for both industrial and professional workers as well as consumers. Exposure as a result of article service life from the reported battery use cannot be excluded.

The harmonised classification has been applied by the registrant(s) and should trigger company-level risk management measures to sufficiently control risks for both workers and consumers. It is not proposed to further investigate the mutagenic properties, because from a regulatory perspective clarification and confirmation of mutagenicity would not bring any added value as the existing CLH is considered adequate.

Furthermore, a substance evaluation conclusion published by Germany in 2017[5] also proposed that no further follow-up regulatory action at EU level would be warranted. They clarified that the registrant(s) provided information on exposure scenarios demonstrating that risks were properly controlled for workers. For consumers, they concluded that despite some remaining unclarity regarding exposure scenarios covering consumer applications, they would not propose further EU level action; instead, they mention that verification of exposure data is sought through a national project.

Based on currently available information, there is no need for (further) EU regulatory risk management for skin sensitisation properties for substances List 948-409-1, 700-263-8.

[5] Substance evaluation conclusion

Both substances have a self-classification for Skin Sens. 1B. The uses vary between substance:

- EC 948-409-1 is used as a fragrance in various products by both consumers and professionals with a high potential for exposure. The main concern is related to the reported consumer use.

- EC 700-263-8 is used as a process regulator/ rubber modifier in the production of rubber products (e.g. tyres). Based on the information available in the registration dossier potential for exposure as a result of article service life is expected to be low.

For industrial and professional uses, sufficient and consistent self-classification by registrants should trigger adequate risk management measures according to workplace legislation. Adequate product labelling should in principle provide consumers with sufficient information to manage risks arising from the use of mixtures containing these substances. However, there is a concern related to skin sensitisers present in consumer mixtures and the need to further investigate whether further regulatory actions are needed and what would be the best options to address this concern. Such concern has already been identified in other groups of substances and was brought for further discussion to Member States. Work is ongoing on this generic issue by both Member States and ECHA which may affect the regulatory actions on substances in this group.

Based on currently available information, there is no need for (further) EU regulatory risk management for all not registered substances [EC/List 209-777-2, 212-957-3, 213-707-6, 216-898-4, 219-423-9, 221-715-6, 231-028-3, 237-184-9, 237-550-8, 239-117-9, 246-101-5, 250-124-6, 255-274-6, 275-801-3, 653-633-5, 851-325-7].

None of these substances are registered and the available data is too limited to clarify the hazards. However, based on similarities to other group members, it is expected that human health hazard potential is low whereas for environmental hazards it remains uncertain. As there is no means to generate data under REACH for substances which are not registered, it is proposed that no further EU regulatory action is needed at this stage. If the registration status changes, data generation and actions will be re-considered when the assessment will be revisited.

Based on currently available information, there is no need for (further) EU regulatory risk management for low (potential) toxicological and environmental hazard of the substances [EC 236-770-1, 236-537-4, 237-551-3, 303-662-1, 262-475-2, 458-610-1, 462-530-2, 279-967-8, 207-964-3].

Most of these substances don’t need further EU regulatory risk management actions at the moment due to low (potential) toxicological and environmental hazard.

Exceptionally, it is noted that EC 236-537-4 has potential for carcinogenicity and is inconclusive for mutagenicity; however, according to the available information, the substance is imported as reacted monomer in an imported polymer. Consequently, as a result of low exposure potential, this substance is also proposed for no further

EU regulatory risk management at the moment. However, if the use profile changes for this substance, actions will be re-considered.

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/List number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
204-661-8, 1,4-dioxane	Known or potential hazard for carcinogenicity Inconclusive hazard for mutagenicity	Known or potential hazard other[6]	Used as solvent in chemical synthesis. Potential for exposure for workers. Potential for release: • as a result of industrial use (e.g. via wastewater) • emission due the presence as constituent/impurity in other substances with high release potential (e.g. surfactants).	**Need for EU RRM: Restriction and EU-wide exposure limit through OSH or REACH** <u>Justification:</u> Emissions of the substance into the environment might be best controlled with a restriction in order to also address uses of substances containing 1,4-dioxane and presence of the substance in articles (including the imported ones). Worker exposure (to Carc. 1B	**First step:** Restriction

[6] equivalent level of concern resulting from the combination of its properties causing higher concern to the environment and human health (man via environment)

Subgroup name, EC/List number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
				substance) in industrial settings will be addressed by the ongoing work for setting an OEL through OSH.	
240-457-5, tetrahydro-4-methyl-2-(2-methylprop-1-enyl)pyran 202-507-4, tetrahydro-2-methylfuran	Known or potential hazard for reproductive toxicity	No hazard or unlikely hazard for PBT/vPvB Known or potential hazard for aquatic toxicity	EC 240-457-5 is used as fragrance in e.g. cleaning products, perfumes, air care products with potential for exposure for workers and consumers. EC 202-507-4 is used in industrial settings as solvent in chemical synthesis. Exposure cannot be excluded.	**Need for EU RRM: CLH** <u>Justification:</u> CLH for reproductive toxicity • for EC 240-457-5 would trigger obligations under the cosmetic products regulation • for EC 202-507-4 should ensure adequate risk management measures are put in place at workplaces.	**First step:** wait for TPE results for EC 202-507-4 **Next steps (if hazard confirmed):** potentially followed by CLH

Subgroup name, EC/List number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
203-810-4, 3,4-dihydro-2H-pyran 225-207-5, tetrahydro-4-methyl-2H-pyran 205-552-8, Tetrahydropyran (not registered) 247-455-3, Tetrahydro-3-methyl-2H-pyran (not registered)	No hazard or unlikely hazard	Known or potential hazard other	Used as solvent in chemical synthesis. Low potential for worker exposure. Potential for release to the environment.	**Currently no need for EU RRM** <u>Justification:</u> Not sufficient evidence to conclude on persistency and mobility (equivalent level of concern to PBT/vPvB) and low potential for exposure to workers	No action
203-726-8, tetrahydrofuran	Known or potential hazard for carcinogenicity Inconclusive hazard for mutagenicity	No hazard or unlikely hazard for PBT/vPvB Known or potential hazard for aquatic toxicity	Several widespread uses including in cleaning products, coatings, adhesives, sealants, functional/metalworking fluids, production of batteries. Potential for exposure for workers and consumers	**Currently no need for EU RRM** <u>Justification:</u> The harmonised classification for carcinogenicity should trigger company-level risk management measures to sufficiently control risks for both workers and consumers.	No action

Subgroup name, EC/List number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
948-409-1, 4,6-dimethyl-2-(1-phenylethyl)-3,6-dihydro-2H-pyran 700-263-8, 2,2-di(tetrahydrofuryl)propane	Known or potential hazard for skin sensitisation	No hazard or unlikely hazard for PBT/vPvB Known or potential hazard for aquatic toxicity	List 948-409-1 is used as fragrance in e.g. cleaning products, perfumes, air care products with potential for exposure for workers and consumers List 700-236-8 is used as processing aid/rubber modifier in the production of rubber products e.g. tyres with limited exposure for workers and release to the environment	**Currently no need for EU RRM** Justification: The concern related to skin sensitisers present in consumer mixtures is being discussed within the ongoing generic initiatives to restrict skin sensitisers.	No action
209-777-2, Oxepane (not registered) 212-957-3, 2,2-diphenyltetrahydrofuran (not registered)213-707-6, Tetrahydro-2,5-dimethylfuran (not registered) 216-898-4, [2H4]tetrahydro[2H4]furan (not registered)	No hazard or unlikely hazard	Inconclusive hazard for PBT/vPvB Known or potential hazard for aquatic toxicity	*not registered*	**Currently no need for EU RRM** Justification: Not registered, too limited available data to conclude.	No action

Subgroup name, EC/List number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
219-423-9, 2-heptyltetrahydrofuran (not registered)221-715-6, 2-(3-phenylpropyl)tetrahydrofuran (not registered) 231-028-3, 2,2-dimethyl-5-(1-methylpropenyl)tetrahydrofuran (not registered) 237-184-9, Tetrahydro-5-isopropenyl-2-methyl-2-vinylfuran (not registered) 237-550-8, (±)-tetrahydro-2,6,6-trimethyl-2-vinyl-2H-pyran (not registered) 239-117-9, Tetrahydro-2,2,5,5-tetramethylfuran (not registered) 246-101-5, 2-butyltetrahydro-6-methyl-4-methylene-2H-pyran (not registered) 250-124-6, Tetrahydro-2-methyl-4-methylene-6-phenyl-2H-pyran (not registered)					

Subgroup name, EC/List number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
255-274-6, 2,5-diethyltetrahydrofuran (not registered) 275-801-3, Heptyltetrahydrofuran (not registered) 653-633-5, 3,6-divynil-2-methyltetrahydropyran (not registered) 851-325-7, 2,2-dimethyloxane (not registered)					
236-770-1, tetrahydro-3-methylfuran 236-537-4, Tetrahydro-2-isobutyl-4-methyl-2H-pyran 237-551-3, Tetrahydro-2-isobutyl-4-methyl-2H-pyran 303-662-1, tetrahydro-4-methyl-2-phenyl-2H-pyran 262-475-2, tetrahydro-4-methylene-2-(2-methyl-1-propenyl)-2H-pyran	No hazard or unlikely hazard	No hazard or unlikely hazard for PBT/vPvB Known or potential hazard for aquatic toxicity	EC 236-770-1, 279-967-8, 458-610-1, and 462-530-2 are used as fragrance in e.g. cleaning products, perfumes, air care products with potential for exposure for workers and consumers EC 236-537-4 and 303-662-1, are imported as reacted monomer in an imported polymer, with no potential for exposure	**Currently no need for EU RRM** <u>Justification:</u> low (potential) toxicological and environmental hazard	No action

Subgroup name, EC/List number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
458-610-1, 2H-Pyran, tetrahydro-3-(phenylmethyl)- 462-530-2, 3-heptyl-tetrahydro-pyran 279-967-8, 2,4-dimethyl-4-phenyltetrahydrofuran 207-964-3, oxetane			EC 237-551-3 and 262-475-2, intermediate registration only (SCC)		

Annex 1: Harmonised and self-classifications

Data extracted on 30/10/2020

EC/ List No	Substance name	Harmonised classification	Classification in registrations	Classification in C&L notifications
202-507-4	Tetrahydro-2-methylfuran		Flam. Liquid 2, H225 Acute Tox. 4, H302 Eye Damage 1, H318 Skin Irrit. 2, H315	Eye Irrit. 2, H319 STOT SE3, H336 STOT SE 3, H335*
203-726-8	Tetrahydro-furan	Flam. Liq. 2 H225, Eye Irrit. 2 H319 (C>=25%), STOT SE 3 H335 (resp irrit) (C>=25%), Carc.2 H351**	Acute Tox. 4, H302	Acute Tox. 4, H302 Acute Tox. 4, H332 Eye Irrit. 2A, H319 Eye Dam. 1 Skin Corr. 1B, H314 STOT SE3, H336 STOT SE3, H371
203-810-4	3,4-dihydro-2H-pyran		Flam. Liquid 2, H225 Eye Irrit. 2 H319 Skin Irrit. 2, H315 Skin Sens. 1B, H 317 Aquatic Chronic 3 H412	Skin Sens. 1, H 317 STOT SE 3, H335*
204-661-8	1,4-dioxane	Flam. Liq. 2 H225, Eye Irrit. 2 H319, STOT SE 3 H335 (resp irrit), Carc. 1B H350 *, **		STOT RE 1, H372 (central nerve) STOT RE 2, H373 (kidneys, liver, eyes, respiratory tract) STOT SE 3, H336 (drowsiness) Skin Irrit. 2, H315 Eye Irrit. 2A, H319 Acute Tox 3, H331
205-552-8	Tetrahydro-pyran		-	Flam. Liquid 2, H225 Eye Irrit. 2 H319 Skin Irrit. 2, H315 STOT SE3, H335*
207-964-3	Oxetane	Flam. Liq. 2 H225, Acute Tox 4 H302/H312/H332	-	-

EC/ List No	Substance name	Harmonised classification	Classification in registrations	Classification in C&L notifications
209-777-2	Oxepane		-	Flam. Liquid 2, H225
212-957-3	2,2-diphenyltetra-hydrofuran		-	Acute Tox. 4, H302
213-707-6	Tetrahydro-2,5-dimethylfuran		-	Flam. Liquid 2, H225 Flam. Liquid 3, H227 *
216-898-4	[2H4]tetra-hydro[2H4]-furan		-	Flam. Liquid 2, H225 Flam. Liquid 1, H224 Acute Tox. 4, H302 Eye Irrit. 2 H319 Skin Irrit. 2, H315 STOT SE3, H335 STOT SE2, H371 STOT RE1, H372 Carc. 2, H351*
219-423-9	2-heptyltetra-hydrofuran		-	Skin Irrit. 2, H315
221-715-6	2-(3-phenylpropyl) tetrahydro-furan		-	Acute Tox. 4, H302
225-207-5	Tetrahydro-4-methyl-2H-pyran		Flam. Liquid 2, H225 Eye Damage 1, H318 Skin Corr. 1, H314	Acute Tox. 4, H302 Skin Irrit. 2, H315 STOT SE3, H335
231-028-3	2,2-dimethyl-5-(1-methyl-propenyl) tetrahydro-furan		-	Flam. Liquid 3, H226
236-537-4	Tetrahydro-3-methylfuran		Flam. Liquid 2, H225 Eye Damage 1, H318 Skin Corr. 1C, H314 STOT SE3, H336 (drowsiness)	STOT SE3, H336 Eye Irrit. 2 H319 Skin Irrit. 2, H315*
236-770-1	Tetrahydro-2-isobutyl-4-methyl-2H-pyran (Reaction mass of 2H-Pyran, tetrahydro-4-		Skin Irrit. 2, H315 Aquatic Chronic 3, H412	Flam. Liquid 3, H226

EC/ List No	Substance name	Harmonised classification	Classification in registrations	Classification in C&L notifications
	methyl-2-(2-methylpropyl) -, (2R,4R)-rel- and 2H-Pyran, tetrahydro-4-methyl-2-(2-methylpropyl) -, (2R,4S)-rel-)			
237-184-9	Tetrahydro-5-isopropenyl-2-methyl-2-vinylfuran		-	Flam. Liquid 3, H226 Eye Irrit. 2 H319 Skin Irrit. 2, H315
237-550-8	(±)-tetrahydro-2,6,6-trimethyl-2-vinyl-2H-pyran		-	Flam. Liquid 3, H226 Eye Irrit. 2 H319 Aquatic Chronic 3 H412
237-551-3	2-ethynyl-tetrahydro-2,6,6-trimethyl-2H-pyran		Flam. Liquid 3, H226	-
239-117-9	Tetrahydro-2,2,5,5-tetramethyl-furan		-	Flam. Liquid 2, H225 Acute Tox. 4, H302
240-457-5	Tetrahydro-4-methyl-2-(2-methylprop-1-enyl)pyran		Eye Irrit. 2 H319 Skin Irrit. 2, H315 Repr. 2, H361 (f)	Repr. 2, H360 Aquatic Chronic 3 H412
246-101-5	2-butyltetra-hydro-6-methyl-4-methylene-2H-pyran		-	Not classified
247-455-3	Tetrahydro-3-methyl-2H-pyran		-	Flam. Liquid 2, H225 Eye Irrit. 2 H319 Skin Irrit. 2, H315 STOT SE3, H335 (respiratory irritation)*
250-124-6	Tetrahydro-2-methyl-4-methylene-6-phenyl-2H-pyran		-	Eye Irrit. 2, H319 Aquatic Chronic 3, H412

EC/ List No	Substance name	Harmonised classification	Classification in registrations	Classification in C&L notifications
255-274-6	2,5-diethyltetra-hydrofuran		-	Flam. Liquid 2, H225
262-475-2	Tetrahydro-4-methylene-2-(2-methyl-1-propenyl)-2H-pyran		Eye Irrit. 2 H319 Skin Irrit. 2, H315 Aquatic Chronic 3, H412	-
275-801-3	Heptyltetra-hydrofuran		-	Skin Irrit. 2, H315
279-967-8	2,4-dimethyl-4-phenyltetra-hydrofuran		Aquatic Chronic 3, H412	Skin Irrit. 2, H315
303-662-1	Tetrahydro-4-methyl-2-phenyl-2H-pyran		Skin Irrit. 2, H315 Aquatic Chronic 3, H412	Skin Sens. 1B, H317 Skin Sens. 1, H317 Eye Irrit. 2 H319
458-610-1	Tetrahydro-3-(phenylmethyl)-2H-Pyran		-	-
462-530-2	3-heptyl-tetrahydro-pyran		(NONS, Xi – irritant, Competent Authority classification proposal)	-
653-633-5	3,6-divinyl-2-methyltetrahydropyran		-	Acute Tox. 4, H302
700-263-8	2,2-di(tetrahydro-furyl)propane		Acute Tox. 4, H302 Eye Irrit. 2 H319 Skin Sens. 1B, H317	Flam. Liquid 3, H226 Skin Sens. 1, H317 Acute Tox. 4, H312, H332 Eye Dam. 1, H318 Aquatic Chronic 2 H411
851-325-7	2,2-dimethyloxane		-	Flam. Liquid 2, H225 Eye Irrit. 2A H319 Skin Irrit. 2, H315 STOT SE3, H335 (respiratory irritation)

EC/ List No	Substance name	Harmonised classification	Classification in registrations	Classification in C&L notifications
948-409-1	4,6-dimethyl-2-(1-phenylethyl)-3,6-dihydro-2H-pyran		Skin Irrit. 2, H315 Skin Sens. 1B, H 317 Aquatic Chronic 2, H411	-

* EUH019: May form explosible peroxides
** EUH066: Repeated exposure may cause skin dryness or cracking

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

Data extracted on 30/10/2020

Main types of applications structured by product or article types	202-507-4	203-726-8	203-810-4	204-661-8	225-207-5	236-770-1	240-457-5	279-967-8	458-610-1	462-530-2	700-263-8	948-409-1
Use in synthesis of other chemicals (e.g. fine chemicals, agrochemicals, pharmaceuticals)	I	F, I	I	F, I	F, I							
Use in laboratories	I	F, I		F, I	F, I							
Use in perfumes, cosmetics, personal care products, air care products, biocidal products						F, I, **C**	F, I, **C**	F, I, **C**	F, I, **C**	F, I, **C**		F, I, **C**
Use in cleaning products		F, I, **P, C**				F, I, **P, C**	F, I, **P, C**	F, I, **P, C**	F, I, **P, C**	F, I, **P, C**		F, I, **P, C**
Use in polymer production		F, I										
Use in coatings (e.g. adhesives, sealants, paints, PVC primer)		F, I, **P, C**										
Use in inks		F, I, **P, C**										
Use in functional/ metalworking fluids		F, I, **P**										
Use in fuel/fuel additives		F, I, **P, C**										
Use in production of batteries		F, I, **A**										
Use in production of rubber products (e.g. tyres)											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 **20/07/2020**

EC/List number	RMOA	Authorisation		Restriction	CLH	Actions not under REACH/ CLP
		Candidate list	Annex XIV	Annex XVII	Annex VI (CLP)	
202-507-4						
203-726-8	YES				YES	IOELV, Cosmetics (prohibited)
204-661-8	YES	YES			YES	IOELV, Cosmetics (prohibited), ESR

No relevant completed or ongoing regulatory risk management activities for the other substances.