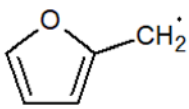
# Assessment of regulatory needs

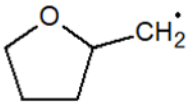
**Authority: European Chemicals Agency (ECHA)**

**Date: 8.6.2022**

## Group Name: (Tetrahydro)furan primary alcohol derivatives and their oxidation products

## General structure:

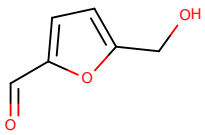
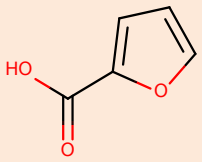
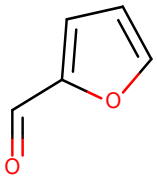
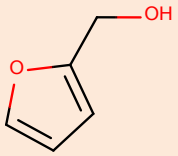


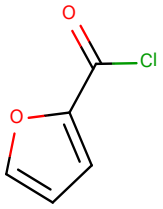
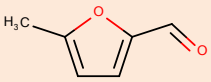
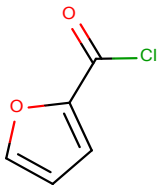
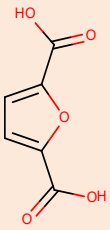
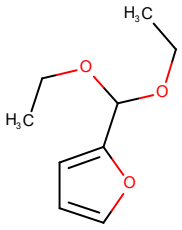

**Revision history**

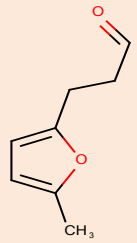
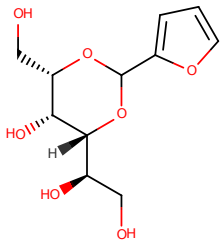
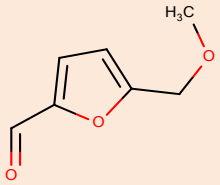
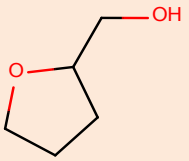
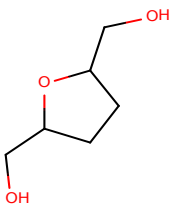
| *Version* | *Date* | *Description* |
|---|---|---|
| **1.0** | 09.09.2022 | |
| | | |
| | | |

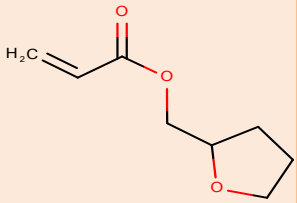
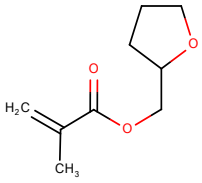
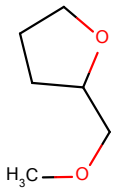
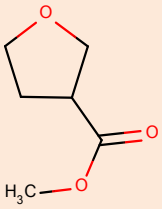
**Substances within this group:**

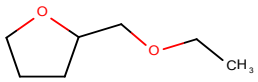
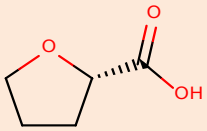
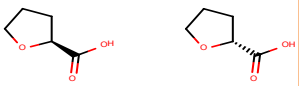
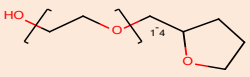
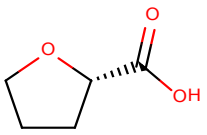
| EC / List number | CAS number | Substance name<br><br>[and / or Substance name acronyms] | Chemical structures | Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y)[1] |
|---|---|---|---|---|
| **Subgroup 1: Substances containing Furfuryl Substructure** | | | | |
| **200-654-9** | 67-47-0 | 5-(hydroxymethyl)-2-furaldehyde |  | Full, 1-10 |
| **201-803-0** | 88-14-2 | 2-furoic acid |  | Full, not (publicly) available |
| **202-627-7** | 98-01-1 | 2-furaldehyde |  | Full, >1000 |
| **202-626-1** | 98-00-0 | Furfuryl alcohol |  | Full, >1000 |

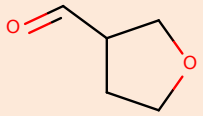
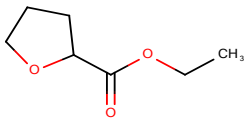
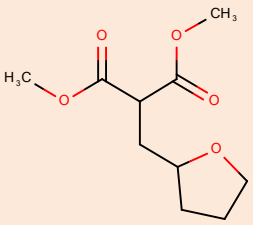
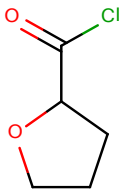
[1] Note that the total aggregated tonnage band may be available on ECHA's webpage at https://echa.europa.eu/information-on-chemicals/registered-substances

| EC/List number | CAS number | Substance name<br><br>[and/ or Substance name acronyms] | Chemical structures | Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y)[1] |
|---|---|---|---|---|
| **208-422-9*** | 527-69-5 | 2-furoyl chloride |  | OSII or TII |
| **210-622-6** | 620-02-0 | 5-methylfurfural |  | C&L notification |
| **215-082-5*** | 1300-32-9 | Furoyl chloride |  | OSII or TII |
| **221-800-8** | 3238-40-2 | Furan-2,5-dicarboxylic acid |  | Full, not (publicly) available |
| **236-872-6** | 13529-27-6 | 2-furaldehyde-diethylacetal |  | OSII or TII |

| EC/List number | CAS number | Substance name<br><br>[and/ or Substance name acronyms] | Chemical structures | Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y)[1] |
|---|---|---|---|---|
| **252-190-1** | 34756-16-6 | 5-methylfuran-2-propionaldehyde |  | OSII or TII |
| **422-440-6** | 7089-59-0 | 2S-(2-furyl)-5R-hydroxy-4R-(1R,2-dihydroxy)ethyl-6S-hydroxymethyl-1,3-dioxane |  | NONS |
| **700-511-5** | 1917-64-2 | 5-(methoxymethyl)-2-furaldehyde |  | OSII or TII |
| **Subgroup 2: Substances containing tetrahydrofuran substructure** | | | | |
| **202-625-6** | 97-99-4 | Tetrahydrofurfuryl alcohol |  | Full, 100-1000 |
| **203-239-0** | 104-80-3 | 2,5-anhydro-3,4-dideoxyhexitol |  | C&L notification |

| EC/List number | CAS number | Substance name<br><br>[and/ or Substance name acronyms] | Chemical structures | Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y)[1] |
|---|---|---|---|---|
| **219-268-7** | 2399-48-6 | Tetrahydrofurfuryl acrylate |  | Full, 100-1000 |
| **219-529-5** | 2455-24-5 | Tetrahydrofurfuryl methacrylate |  | Full, 10-100 |
| **227-407-8** | 5831-59-4 | 2-[(tetrahydrofurfuryl)oxy]ethanol |  | Not registered |
| **242-986-7** | 19354-27-9 | Methyl tetrahydrofurfuryl ether |  | C&L notification |
| **420-670-1** | 37443-42-8 | Methyl tetrahydro-2-furancarboxylate |  | NONS |

| EC/List number | CAS number | Substance name<br><br>[and/ or Substance name acronyms] | Chemical structures | Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y)[1] |
|---|---|---|---|---|
| **423-630-1** | 62435-71-6 | Furan, 2-(ethoxymethyl)tetrahydro- |  | Full, not (publicly) available |
| **433-770-5** | - | (S)-(-)-tetrahydro-2-furoic acid |  | NONS |
| **605-530-1** | 16874-33-2 | 2-Furancarboxylic acid, tetrahydro- |  | OSII or TII |
| **608-659-1** | 31692-85-0 | 2-(oxolan-2-ylmethoxy)ethanol |  | Full, not (publicly) available |
| **618-003-6** | 87392-07-2 | (2S)-oxolane-2-carboxylic acid |  | C&L notification |

| EC/List number | CAS number | Substance name<br><br>[and/ or Substance name acronyms] | Chemical structures | Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y)[1] |
|---|---|---|---|---|
| **629-664-5** | 79710-86-4 | 3-Furancarboxaldehyde, tetrahydro- |  | OSII or TII |
| **807-745-8** | 16874-34-3 | 2-Furancarboxylic acid, tetrahydro-, ethyl ester |  | Full, not (publicly) available |
| **811-744-8** | 1134802-45-1 | 2-[(Tetrahydro-2-furanyl)methyl]-propanedioic acid, 1,3-dimethyl ester |  | OSII or TII |
| **922-279-6** | 52449-98-6 | 2-Furancarbonyl chloride, tetrahydro- |  | OSII or TII |

* In this Group the following are considered duplicate entries: EC 208-422-9 and EC 215-082-5.

This table contains also group members that are only notified under the CLP Regulation. However, the list is not necessarily exhaustive. 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



## DISCLAIMER

# 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 a 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, a 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].

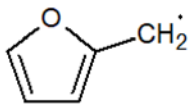
[2] https://echa.europa.eu/understanding-assessment-regulatory-needs

# Glossary

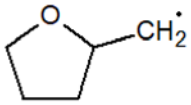
| | |
|---|---|
| ARN | Assessment of Regulatory Needs |
| CCH | Compliance Check |
| CLH | Harmonised classification and labelling |
| CMR | Carcinogenic, mutagenic and/or toxic to reproduction |
| DEv | Dossier evaluation |
| ED | Endocrine disruptor |
| NONS | Notified new substances |
| OEL | Occupational 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 furfuryl and tetrahydro-furfuryl moieties shown in the figure below:




furfuryl




tetrahydro-furfuryl

Furfuryl alcohols, esters, furfurals, furoic acids and furoic acid halides and furfuryl alcohol ethers are included in the group boundaries, according to the following chemistry considerations:

- furfuryl alcohol is rapidly oxidized to 2-furaldehyde;
- 2-furaldehyde can be converted to furoic acid by oxidative metabolism;
- halide acids and esters can be converted to respective carboxylic acid.

Substances with furfuryl and tetrahydro-furfuryl moieties with additional chemical functional groups than the ones described above were excluded from the current group.

Because the furfuryl and the tetrahydro-furfuryl moieties give rise to different hazard profiles (as explained in section 2 of this report) the two following subgroups (SG) are proposed:

- SG1: Substances containing Furfuryl substructure;
- SG2: Substances containing Tetrahydrofuran (THF) substructure.

The group consists of 27 substances, of which 11 have full registrations, 10 are registered as intermediates only, 1 is NONS, 4 are only notified under the CLP Regulation and 1 is neither registered nor notified.

Based on information reported in the REACH registration dossiers, the uses and potential for exposure of the substances in this group can be summarised as follows:

- the substances of SG1 (containing the Furfuryl substructure) are predominantly used in industrial settings as intermediate in the manufacturing of other chemicals, as binding agents, odour agents and flavoring agents in polymers, coatings and paints, inks and toners and adhesives. Overall, the substances of Subgroup 1 have limited potential for exposure and release, with the exception of furfuryl alcohol (EC 202-626-1) and 2-furaldehyde (EC 202-627-7) which have also widespread professional uses as additives in coatings and paints (pre-polymers), biocidal products, fertilisers, and as laboratory chemicals, with potential for worker exposure and release in the environment;
- the substances of SG2 (containing the tetrahydrofuran substructure) have professional and consumer uses giving rise to the potential for exposure or

release, professional uses as adhesives and sealants and fertilisers, as well as consumer uses in plant protection products (EC 202-625-6), professional uses in washing and cleaning agents and article service life uses in coatings and paints and ink toners (EC 219-268-7), professional uses in adhesives, sealants, and coatings and paints (EC 219-529-5) as well as functioning as an odour agent with consumer and professional uses as washing and cleaning agents, biocidal products, air care and polishes and waxes (EC 807-745-8). Two substances in this Subgroup (EC 423-630-1 and EC 608-659-1), have only industrial uses.

Furfuryl alcohol (EC 202-626-1) has harmonised classification Carc. 2 and following SEV process the Polish Competent Authority[3] concluded that such classification is appropriate according to the data. In addition, furfuryl alcohol has been considered to fulfil the criteria to be classified as skin sensitiser 1B, thus flagged for CLH.

Furfural (EC 202-627-7) has been assessed under the Existing Substances Regulation (ESR) and an EU Risk Assessment Report[4] is available for this substance. It is also currently undergoing substance evaluation to clarify mutagenicity and carcinogenicity.

[3] Substance evaluation conclusion_furfuryl alcohol

[4] Link to EU RAR furfural

**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 action - restriction** for reproductive toxicity hazards due to the potential for release/ exposure of the substances in Subgroup 2 (Substances containing tetrahydrofuran substructure).

Based on ECHA's assessment of hazard information currently available in the registration dossiers and considerations of structural similarity and presence of common functional moiety all the substances in the subgroup have (potential) toxicity to reproduction.

Tetrahydrofurfuryl alcohol (THFA - EC 202-625-6) and tetrahydrofurfuryl alcohol esters (EC 219-268-7 and EC 219-529-5) which may hydrolyse to form THFA all have reproductive toxicity properties and either have a harmonised classification as Repr. 1B (EC 202-625-6) or are subject to a proposed CLH as Repr. 1B (EC 219-529-5). These substances may cause developmental toxicity and affect spermatogenesis. The (potential) formation of THFA is the underlying hypothesis for the extrapolation of the reproductive toxicity hazards to the substances such as esters and ethers included in the subgroup 2.

Furthermore, this reproductive toxicity hazard is preliminary extrapolated to the alcohol (EC 203-239-0) and the aldehyde (EC 629-664-5) which are structurally related to THFA but for which hazard information is not (yet) available.

Evidence of reproductive toxicity consistent with the effects on spermatogenesis observed with THFA have been detected in a study performed with the methyl ester of tetrahydrofuroic acid (EC 420-670-1) suggesting that tetrahydrofuroic acid may also carry reproductive toxicity properties. Therefore, for the purpose of this screening, the substances leading to exposure to tetrahydrofuroic acid such as esters of this acid or halides of this acid are considered to have potential reproductive toxicity hazards.

No hazard for mutagenicity, carcinogenicity and endocrine disruption based on the available data has been identified. Two substances are self-classified as Skin Sensitisers (EC 219-268-7 and EC 219-529-5).

Based on ECHA's assessment of hazard information currently available in the registration dossiers and considerations of structural similarity and presence of common functional moiety all the substances in Subgroup 2 have no or unlikely aquatic toxicity except for ECs 219-268-7 and 219-529-5. However, due to a lack of long-term toxicity data the following representative substances of this subgroup are proposed for compliance check to clarify the aquatic toxicity: ECs 202-625-6, 423-630-1 and 219-268-7.

The first step of the regulatory risk management action proposed, is the confirmation of hazard via harmonised classification (CLH) as Repr. 1B for all subgroup members.

When preparing the CLH proposals, it may be considered what would be the best way to develop them, for instance whether to make a proposal for the group of substances, to submit them individually or jointly.

CLH will require i) company level risk management measures (RMM) in workplaces to be implemented, ii) is needed or highly recommended for further regulatory processes under REACH and iii) is a prerequisite to restrict the presence of the substances in consumer mixtures, by means of the restriction entry, 30.

CLH will also support regulatory action under other regulations. For instance, in this specific case harmonised classification as Repr. 1B

- will trigger regulatory action under the Cosmetic products regulation (EC) No 1223/2009, since CMR cat. 1 are restricted by this regulation;
- will trigger regulatory action under the biocidal product regulation (EU) 528/2012, which does not allow the use by the general public of a product containing substances above the concentration limit leading to classification of the mixture as CMR cat. 1;
- would render the substances unacceptable co-formulants in plant protection products.

The professional uses reported for the substances of Subgroup 2 (uses in coatings and paints, thinners, paint removers, plant protection products and fertilisers, washing and cleaning) are expected to be widespread (at many sites and by many users). Professional use is often widespread with relatively low levels of operational controls and risk management measures but with often frequent exposures with a long duration. In addition, professional users may be self-employed and therefore not covered by occupational safety and health (OSH) legislation.

Consumers may be co-exposed to the substances used by professionals (e.g. house painters).

Therefore, after or in parallel (to avoid unnecessary delay) to the proposed CLH as Repr. 1B a **restriction of the substance as such or in mixtures (concentration limit in mixtures) used by professionals** is suggested to be initiated.

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.

In addition, the use of the most harmful substances by professional workers has been recognised as an area of concern under the European Commission's Chemicals Strategy for Sustainability[5] which aims to extend to professional users under REACH the level of protection granted to consumers.

Moreover, **restricting substances in articles** used by professionals or consumers (EC 219-268-7 in plastic articles containing inks and coatings) should be considered in the context of the restriction of professional uses as potential exposure from articles needs further investigation first.

Substances with intermediate registrations only, or for which there is absence of professional or consumer uses, do not give rise to concern due exposure potential and releases in the environment. However, due to structural similarity, potential for substitution with other substances of the group can be assumed and therefore the same regulatory action is proposed for these substances.

**Based on currently available information, there is no need for (further) EU regulatory risk management** for all substances in the Subgroup 1 (Substances containing Furfuryl Substructure).

Based on ECHA's assessment of hazard information currently available in the registration dossiers and considerations of structural similarity and presence of common functional moiety all the substances in the subgroup have potentially carcinogenic hazards except EC 442-440-6 and EC 221-800-8.

Furfuryl alcohol (EC 202-626-1) and furfural (EC 202-627-7) have carcinogenicity (liver) as their leading health effect (harmonised classified as Carc. 2). While no information is available on the actual mode of action behind the observed carcinogenicity of these substances, according to the available assessments both are considered as non-threshold carcinogens.

Furfuryl alcohol is rapidly oxidized to furfural which in turn is converted by oxidative metabolism to furoic acid and excreted in urine. It is not known whether the carcinogenicity of furfuryl alcohol is caused by the alcohol itself or whether its oxidation to furfural contributes to the findings observed after exposure to furfuryl alcohol. For the purpose of this assessment, in the absence of data showing otherwise, the carcinogenic properties of furfuryl alcohol and furfural are extrapolated to all the substances having the potential to form furfuryl alcohol, furfural, a structurally similar aldehydes to furfural either in their native form or as

[5] European Commission, *Chemical Strategy for Sustainability Towards a Toxic-Free Environment*, available at https://ec.europa.eu/environment/pdf/chemicals/2020/10/Strategy.pdf

a result of metabolism.

Similarly, in the absence of conclusive information on the systemic toxicity of the substance EC 201-803-0 (furoic acid), this substance is considered as likely carcinogenic, noting that this conclusion carries a particularly high uncertainty: it is not established that the acid, formed as a result of the oxidation of the carcinogenic aldehyde, also has carcinogenic properties. Since the halides 2-fuoryl chloride (EC 208-422-9 and 215-082-5) are expected to form the acid in contact with water, the conclusions on the properties of the acid and the related uncertainty equally apply to these halides.

Data from repeated dose toxicity studies on EC 442-440-6 and EC 221-800-8 did not detect pre-neoplastic effects in the liver. This conclusion is further supported by the anticipated unlikely formation of furfuryl alcohol or furfural from these substances based on their chemical structures.

The substances of Subgroup 1 have overall intermediate industrial uses with limited potential for exposure and release. Furfuryl alcohol (EC 202-626-1) and furfural (EC 202-627-7) have potential for exposure and release in the environment due to widespread professional uses in coatings and paints, biocidal products, fertilisers, and as laboratory chemicals. Nevertheless, for industrial and professional uses of these substances, it is expected that based on the harmonised classification as Carc. 2 and/or self-classification as Skin sens. registrants have recommended necessary RMMs to ensure safe use at the workplace. In addition, 4 substances of this Subgroup (EC 200-654-9, 201-803-9, 202-627-7, 202-626-1) are amongst furfuryl derivatives listed in the Annex I to the Commission Implementing Regulation (EU) No 872/2012 adopting the list of flavouring substances provided for by Regulation (EC) No 2232/96. For these substances EFSA concluded that no safety concern exists at estimated levels of intake as flavouring substances[6]. Therefore, it is proposed that there is currently no need for EU-wide regulatory risk management.

Uncertainties:

Furfural (EC 202-627-7) is currently undergoing a SEV process to clarify mutagenicity and carcinogenicity. The outcome of the re-examination of the entire data set may lead to the changes to the harmonised classification of the substance (currently as Carc. 2).
While awaiting the outcome of this SEV, the conclusions from the previous international assessments (EU risk assessment under Existing Substances Regulation 793/93/EEC) are regarded as valid and the substances in the subgroup are considered as unlikely to have genotoxic properties.
Since the properties of a number of substances included in this subgroup are extrapolated from those of furfural, the assessment for this subgroup may need to be revised based on the conclusions of this substance evaluation, balancing the weight of all available reliable information on the individual substances in the subgroup.

[6] Scientific Opinion on Flavouring Group Evaluation 66, Revision 1 (FGE.66Rev1): Consideration of Furfuryl Alcohol and Related Flavouring Substances Evaluated by JECFA (55th meeting). EFSA Journal 2011; 9(9):2314. [44 pp.]. doi:10.2903/j.efsa.2011.2314. Available at www.efsa.europa.eu/efsajournal.htm

Based on ECHA's assessment of hazard information currently available in the registration dossiers and considerations of structural similarity and presence of common functional moiety all the substances in Subgroup 1 have known or potential aquatic toxicity except for EC 201-803-0 and EC 221-800-8. However, due to lack of long-term toxicity data the following representative substances of this subgroup are proposed for Compliance check to clarify (no)hazard hypothesis for aquatic toxicity: ECs 202-626-1, 201-803-0, 221-800-8.

It is expected that following data generation for aquatic toxicity registrants would adequately self-classify the substances and implement necessary RMMs to ensure safe use. Therefore, it is proposed that there is currently no need for EU-wide regulatory risk management.

For the reasons above, no action is currently foreseen for the substances in Subgroup 1.

# 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 | Human Health Hazard | Environmental Hazard | Relevant use(s) & exposure potential | Last foreseen action | Action |
|---|---|---|---|---|---|
| **Subgroup 2 (Substances containing tetrahydrofuran substructure)**<br>**202-625-6**<br>**203-239-0**<br>**219-268-7**<br>**219-529-5**<br>**227-407-8**<br>**242-986-7**<br>**420-670-1**<br>**423-630-1**<br>**433-770-5** | Known or potential hazard<br>for reproductive toxicity<br><br>for skin sensitisation (only for ECs 219-268-7 and 219-529-5) | Known or potential hazard<br>for aquatic toxicity for EC 219-268-7 (t.b.c.) and EC 219-529-5<br><br>No hazard or unlikely hazard<br>for aquatic toxicity for the other members of the subgroup (to be confirmed for EC 423-630-1) | Industrial, widespread professional and consumer uses giving rise to the potential for exposure or release. Professional uses as adhesives and sealants, coatings and paints as well as fertilisers, plant protection products (PPP), washing and cleaning agents. Consumer uses and article service life in coatings and paints and ink toners. | **Need for EU RRM: Restriction**<br><br><u>Justification</u>:<br>The harmonised classification as Repr. 1B would trigger the restriction entry 30 and by that ensure that the substances are not included in consumer mixtures above the limits specified in that entry.<br><br>The reported professional uses are widespread (at many sites and many users) with relatively low levels of operational | **First step:**<br>CCH<br>(for EC 202-625-6, EC 423-630-1 and EC 219-268-7)<br><br>**Next steps:**<br>CLH and in parallel restriction |

| Subgroup name, EC number | Human Health Hazard | Environmental Hazard | Relevant use(s) & exposure potential | Last foreseen action | Action |
|---|---|---|---|---|---|
| **605-530-1**<br>**608-659-1**<br>**618-003-6**<br>**629-664-5**<br>**807-745-8**<br>**811-744-8**<br>**922-279-6** | | | | controls and risk management measures but with often frequent exposures with a long duration.<br>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.<br>Potential exposure from articles needs further investigation, restriction for use in articles to be considered together with the restriction of professional uses. | |
| **Subgroup 1 (Substances** | Known or potential hazard for carcinogenicity | Known or potential hazard for aquatic toxicity | Mainly used in industrial settings as intermediate with | **Currently no need for EU RRM** | CCH for EC 202-626-1, EC 201-803-0 and |

| Subgroup name, EC number | Human Health Hazard | Environmental Hazard | Relevant use(s) & exposure potential | Last foreseen action | Action |
|---|---|---|---|---|---|
| **containing Furfuryl Substructure)**<br><br>**200-654-9**<br><br>**201-803-0**<br><br>**202-627-7**<br><br>**202-626-1**<br><br>**208-422-9 and 215-082-5**<br><br>**210-622-6**<br><br>**236-872-6**<br><br>**252-190-1**<br><br>**700-511-5** | for skin sensitisation (only for ECs 200-654-9 and 202-626-1) | (to be confirmed for EC 202-626-1)<br><br>No hazard or unlikely hazard for aquatic toxicity<br><br>for ECs, 201-803-0, 208-422-9 and 215-082-5, 236-872-6 252-190-1 | limited potential for exposure and release, with the exception of professional use biocides, fertilisers, coatings and paints and as laboratory chemicals only for ECs 202-627-7 and 202-626-1 with potential for worker exposure and release in the environment. | Justification:<br>Harmonised/self-classification as Carc. 2 and/or Skin sens. followed by implementation of necessary RMMs should be sufficient to ensure safe use by workers at industrial and professional settings. | EC 221-800-8; await ongoing SEV on EC 202-627-7 |
| **Subgroup 1 (Substances containing Furfuryl Substructure)**<br><br>**221-800-8**<br><br>**422-440-6** | No hazard or unlikely hazard | No hazard or unlikely hazard | | **Currently no need for EU RRM**<br><br>Justification:<br>Overall, no or unlikely hazard that would lead to concern for the reported uses. | |

# Annex 1: Overview of classifications

Data extracted on 26 April 2022

| EC / List No | CAS number | Substance name | Harmonised classification | Classification in registrations[7] |
|---|---|---|---|---|
| **Subgroup 1: Substances containing Furfuryl Substructure** | | | | |
| **200-654-9** | 67-47-0 | 5-(hydroxymethyl)-2-furaldehyde | n.a. | Aquatic Chronic 3 H412<br>STOT Single Exp. 3 H335, affected organs: lungs<br>Skin Irrit. 2 H315<br>Eye Irrit. 2 H319<br>Skin Sens. 1A H317<br>STOT Single Exp. 3 H335, affected organs: respiratory tract |
| **201-803-0** | 88-14-2 | 2-furoic acid | - | Skin Irrit. 2 H315<br>STOT Single Exp. 3 H335, affected organs: Respiratory tract<br>Eye Irrit. 2 H319 |
| **202-626-1** | 98-00-0 | furfuryl alcohol | Carc. 2<br>Acute Tox. 3 *<br>Acute Tox. 4 *<br>Acute Tox. 4 *<br>STOT SE 3<br>STOT RE 2 *<br>Eye Irrit. 2 | STOT Single Exp. 3 H335, affected organs: respiratory tract<br>Acute Tox. 4 H312<br>STOT Rep. Exp. 2 H373, affected organs: respiratory tract<br>Acute Tox. 4 H302<br>Carc. 2 H351<br>Acute Tox. 3 H301<br>Acute Tox. 3 H311<br>Acute Tox. 3 H331<br>Acute Tox. 4 H332<br>Skin Irrit. 2 H315<br>Eye Irrit. 2 H319<br>STOT Rep. Exp. 2 H373<br>STOT Single Exp. 3 H335 |

[7] The column gives the classifications in registrations received under REACH. Additional classifications in intermediate and in inactive registrations (if any) are annotated and displayed last. For each classification the table includes information on the hazard category, the hazard statement and any available information on specific effects (relevant for reproductive toxicity), specific concentration limits, M-Factors and affected organs. Two classifications differing in any of these aspects are considered different and are repeated in the table. The columns "Classifications in registrations" and "Classifications in C&L notifications" are empty if there are no Registrations/C&L notifications (hazard is unknown). The value '-' is displayed on the same columns when there are (relevant) submissions but they do not contain self-classifications (substance is not hazardous).

| EC / List No | CAS number | Substance name | Harmonised classification | Classification in registrations[7] |
|---|---|---|---|---|
| **202-627-7** | 98-01-1 | 2-furaldehyde | Carc. 2<br>Acute Tox. 3 *<br>Acute Tox. 3 *<br>Acute Tox. 4 *<br>STOT SE 3<br>Skin Irrit. 2<br>Eye Irrit. 2 | Aquatic Chronic 3 H412<br>Acute Tox. 3 H331<br>STOT Single Exp. 3 H335, affected organs: respiratory<br>Carc. 2 H351<br>Flam. Liquid 3 H226<br>Acute Tox. 3 H301<br>Acute Tox. 4 H312<br>Acute Tox. 2 H330<br>Skin Irrit. 2 H315<br>Eye Irrit. 2 H319<br>STOT Single Exp. 3 H335 |
| **208-422-9** | 527-69-5 | 2-furoyl chloride | - | Acute Tox. 4 H302<br>Acute Tox. 4 H312<br>Skin Corr. 1B H314<br>Acute Tox. 4 H332 |
| **215-082-5** | 1300-32-9 | furoyl chloride | - | Acute Tox. 4 H302<br>Acute Tox. 4 H312<br>Acute Tox. 4 H332<br>Skin Corr. 1B H314 |
| **210-622-6** | 620-02-0 | 5-methylfurfural | - | - |
| **221-800-8** | 3238-40-2 | furan-2,5-dicarboxylic acid | - | Eye Irrit. 2 H319 |
| **236-872-6** | 13529-27-6 | 2-furaldehyde-diethylacetal | - | Skin Irrit. 2 H315<br>Eye Irrit. 2 H319<br>STOT Single Exp. 3 H335 |
| **252-190-1** | 34756-16-6 | 5-methylfuran-2-propionaldehyde | - | - |
| **422-440-6** | | 2S-(2-furyl)-5R-hydroxy-4R-(1R,2-dihydroxy)ethyl-6S-hydroxymethyl-1,3-dioxane | - | - |
| **700-511-5** | 1917-64-2 | 5-(methoxymethyl)-2-furaldehyde | - | Aquatic Chronic 2 H411<br>Skin Irrit. 2 H315<br>Skin Sens. 1B H317 |

| EC / List No | CAS number | Substance name | Harmonised classification | Classification in registrations[7] |
|---|---|---|---|---|
| **Subgroup 2: Substances containing tetrahydrofuran substructure** | | | | |
| **203-239-0** | 104-80-3 | 2,5-anhydro-3,4-dideoxyhexitol | STOT SE 3<br>Skin Irrit. 2<br>Eye Irrit. 2 | - |
| **202-625-6** | 97-99-4 | tetrahydrofurfuryl alcohol | Repr. 1B<br>Eye Irrit. 2 | Repr. 1B H360<br>Eye Irrit. 2 H319 |
| **219-268-7** | 2399-48-6 | tetrahydrofurfuryl acrylate | - | Aquatic Chronic 2 H411<br>Repr. 1B H360, specific effect:H360Df: May damage the unborn child and Suspected of damaging fertility<br>Acute Tox. 4 H302<br>Skin Corr. 1C H314<br>Eye Damage 1 H318<br>Skin Sens. 1B H317 |
| **219-529-5** | 2455-24-5 | tetrahydrofurfuryl methacrylate | - | Aquatic Chronic 3 H412<br>Repr. 1B H360, specific effect:H360D (May damage the unborn child)<br>Skin Sens. 1 H317 |
| **420-670-1** | 37443-42-8 | methyl tetrahydro-2-furancarboxylate | Eye Dam. 1 | Eye Damage 1 H318 |
| **423-630-1** | | | - | Repr. 2 H361<br>Skin Corr. 1B H314 |
| **433-770-5** | | | - | - |
| **605-530-1** | 16874-33-2 | Tetrahydro-2-furancarboxylic acid | - | Skin Corr. 1B H314<br>Eye Damage 1 H318<br>Acute Tox. 4 H302<br>Met. Corr. 1 H290 |
| **608-659-1** | 31692-85-0 | | - | Repr. 1B H360<br>Eye Irrit. 2 H319 |
| **629-664-5** | 79710-86-4 | tetrahydrofuran-3-carbaldehyde | - | Acute Tox. 4 H302<br>Eye Damage 1 H318 |
| **807-745-8** | 16874-34-3 | ethyl tetrahydrofuran-2-carboxylate | - | Skin Corr. 1B H314<br>Eye Damage 1 H318 |

| EC / List No | CAS number | Substance name | Harmonised classification | Classification in registrations[7] |
|---|---|---|---|---|
| **811-744-8** | 1134802-45-1 | | - | - |
| **922-279-6** | 52449-98-6 | tetrahydrofuran-2-carbonyl chloride | - | Skin Corr. 1B H314<br>Acute Tox. 4 H302<br>Acute Tox. 4 H332<br>Eye Damage 1 H318<br>STOT Single Exp. 3 H335, affected organs: repiratory system<br>Met. Corr. 1 H290 |

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

Data extracted on 16.03.2022

| | Subgroup 1: Substances containing Furfuryl Substructure | | | | | Subgroup 2: Substances containing tetrahydrofuran substructure | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Main types of applications structured by product or article types** | **EC/ List 200-654-9** | **EC/ List 201-803-0** | **EC/ List 202-626-1** | **EC/ List 202-627-7** | **EC/ List 221-800-8** | **EC/ List 202-625-6** | **EC/ List 219-268-7** | **EC/ List 219-529-5** | **EC/ List 423-630-1** | **EC/ List 608-659-1** | **EC/ List 807-745-8** |
| **PC 20: Products such as ph-regulators, flocculants, precipitants, neutralisation agents** | | | | I, **P** | | I, **P** | | | | | |
| **PC 12: Fertilisers** | | | | **P** | | F, **P** | | | | | |
| **PC 27: Plant protection products** | | | | | | F, **P**, **C** | | | | | |
| **PC 35: Washing and cleaning products** | | | | | | F, I | F, I, **P** | | | | I, **P**, **C** |
| **PC 8: Biocidal products (e.g. disinfectants, pest control)** | | | I | **P** | | F | | | | | **C** |
| **PC 28: Perfumes, fragrances** | | I | | | | | | | | | **C** |
| **PC 3: Air care products** | | | | | | | | | | | **C** |
| **PC 39: Cosmetics, personal care products** | | I | | | | | | | | | **C** |
| **PC 29: Pharmaceuticals** | | | | | | I | | | | F, I | |
| **PC 31: Polishes and wax blends** | | | | | | | | | | | **P**, **C** |

| | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **PC 15: Non-metal-surface treatment products** | | | | | | | F, I, **P** | | | | |
| **PC 13: Fuels** | | | | | | **P** | | | | | |
| **PC 32: Polymer preparations and compounds** | I | | F, I | F, I | I | F, I, **P** | F, I, **P** | | I | | |
| **PC 1: Adhesives, sealants** | I | | | | | F, I, **P** | F, I | I, **P** | | | |
| **PC 9a: Coatings and paints, thinners, paint removes** | I | | F, I, **P** | **P** | | F | F, I, **A** | F, I, **P** | | | |
| **PC 18: Ink and toners** | | | | I | | F | F, I, **P**, **A** | F | | | |
| **PC 26: Paper and board treatment products** | | | | | | | F, I, **P** | | | | |
| **PC 21: Laboratory chemicals** | | I | F, I | I, **P** | | I, **P** | | | | | |
| **PC 19: Intermediate** | I | F, I | | I | I | I | | I | | | |
| **PC 40: Extraction agents** | | | | 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 24.03.2022

| EC / List number | RMOA | Authorisation | | Restriction* | CLH | Actions not under REACH / CLP |
|---|---|---|---|---|---|---|
| | | Candidate list | Annex XIV | Annex XVII | Annex VI (CLP) | |
| **202-625-6** | YES | | | | YES | |
| **203-239-0** | | | | | YES | |
| **219-529-5** | | | | | YES | |
| **420-670-1** | | | | | | NONS |
| **422-440-6** | | | | | | NONS |
| **433-770-5** | | | | | | NONS |

*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 other substances.