Justification Document for the Selection of a CoRAP Substance

– UPDATE –

Substance Name (public name):	2-furaldehyde
EC Number:	202-627-7
CAS Number:	98-01-1
Authority:	Danish Environmental Protection Agency
Date:	15/03/2017 22/03/2022 (1. update)

Cover Note

This document has been prepared by the evaluating Member State given in the CoRAP update.

1 IDENTITY OF THE SUBSTANCE

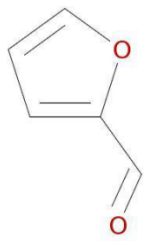
1.1 Other identifiers of the substance

Table: Other Substance identifiers

EC name (public):	2-furaldehyde
IUPAC name (public):	2-furaldehyde
Index number in Annex VI of the CLP Regulation:	605-010-00-4
Molecular formula:	C5H4O2
Molecular weight or molecular weight range:	96.08
Synonyms:	Furfural 2-Furfural 2-Furanaldehyde Furaldehyde Furfuraldehyde 2-Furancarboxaldehyde Furan-2-carbaldehyde Furfurane carboxylic aldehyde 2-Formylfuran 2-Furancarbonal 2-Furyl-methanal 2-Furylaldehyde alpha-Furole artificial ant oil Artificial oil of ants Fural Furale Furfurol Furfurole Furole Pyromucic aldehyde

Type of substance ☒ Mono-constituent ☐ Multi-constituent ☐ UVCB

Structural formula:



1.2 Similar substances/grouping possibilities

Not relevant

2 OVERVIEW OF OTHER PROCESSES / EU LEGISLATION

Table: Completed or ongoing processes

RMOA	☐ Risk Management Option Analysis (RMOA)	
REACH Processes	Evaluation	☒ Compliance check
		☐ Testing proposal
		☐ CoRAP and Substance Evaluation
	Authorisation	☐ Candidate List
		☐ Annex XIV
	Restriction	☐ Annex XVII[1]
CLH	☒ Annex VI (CLP) (see section 3.1)	
Processes under other EU legislation	☐ Plant Protection Products Regulation Regulation (EC) No 1107/2009	
	☐ Biocidal Product Regulation Regulation (EU) 528/2012 and amendments	
Previous legislation	☐ Dangerous substances Directive 67/548/EEC (NONS)	
	☒ Existing Substances Regulation 793/93/EEC (RAR/RRS)	
(UNEP) Stockholm convention (POPs Protocol)	☐ Assessment	
	☐ In relevant Annex	
Other processes/ EU legislation	☐ Other (provide further details below)	
Further details		

[1] Please specify the relevant entry.

3 HAZARD INFORMATION (INCLUDING CLASSIFICATION)

3.1 Classification

3.1.1 Harmonised Classification in Annex VI of the CLP

Table: Harmonised classification

Index No	International Chemical Identification	EC No	CAS No	Classification		Spec. Conc. Limits, M-factors	Notes
				Hazard Class and Category Code(s)	Hazard statement code(s)		
605-010-00-4	2-furaldehyde	202-627-7	98-01-1	Acute Tox. 3 Acute Tox. 4 Skin Irrit. 2 Eye Irrit. 2 Acute Tox. 3 STOT SE 3 Carc. 2	H301 H312 H315 H319 H331 H335 H351	-	-

3.1.2 Self classification

- In the registration:

  In addition to the harmonised classification the substance is self-classified by the registrant(s) as:

  Flam. Liquid 3: H226

  Acute Tox. 2: H330

  Aquatic Chronic 3: H412

- The following hazard classes are notified in addition among the aggregated self classifications in the C&L Inventory:

  Acute Tox. 1: H330

  Aquatic Chronic 2: H411

  Further 35 aggregated notifications include some of the following self classifications in addition to the harmonised classifications:

Table: Self classification

Index No	International Chemical Identification	EC No	CAS No	Classification		Spec. Conc. Limits, M-factors
				Hazard Class and Category Code(s)	Hazard statement code(s)	
				Flam. Lig. 3 **Acute Tox. 1 or 2** **Aquatic Chronic 2** **Aquatic Chronic 3**	**H226** **H330** **H411** **H412**	

3.1.3 Proposal for Harmonised Classification in Annex VI of the CLP

Table: Proposed classification harmonisation

Index No	International Chemical Identification	EC No	CAS No	Classification		Spec. Conc. Limits, M-factors	Notes
				Hazard Class and Category Code(s)	Hazard statement code(s)		

Not relevant.

4 INFORMATION ON (AGGREGATED) TONNAGE AND USES[2]

4.1 Tonnage and registration status

Table: Tonnage and registration status

From ECHA dissemination site *		
☒ Full registration(s) (Art. 10)	☒ Intermediate registration(s) (Art. 17 and/or 18)	
Tonnage band (as per dissemination site)		
☐ 1 – 10 tpa	☐ 10 – 100 tpa	☐ 100 – 1000 tpa
☐ 1000 – 10,000 tpa	☒ 10,000 – 100,000 tpa	☐ 100,000 – 1,000,000 tpa
☐ 1,000,000 – 10,000,000 tpa	☐ 10,000,000 – 100,000,000 tpa	☐ > 100,000,000 tpa
☐ <1 . . . . . >+ tpa (e.g. 10+ ; 100+ ; 10,000+ tpa)		☐ Confidential

*the total tonnage band has been calculated by excluding the intermediate uses, for details see the Manual for Dissemination and Confidentiality under REACH Regulation (section 2.6.11): https://echa.europa.eu/documents/10162/22308542/manual_dissemination_en.pdf/7e0b87c2-2681-4380-8389-cd655569d9f0

4.2 Overview of uses

This substance is manufactured and/or imported in the European Economic Area in 10 000 - 100 000 tonnes per year.

This substance is used in the following products: polymers, fertilisers, coating products and extraction agents. This substance has wide spread use by professional workers and an industrial use resulting in manufacture of another substance (use of intermediates).

This substance is used in the following areas: agriculture, forestry and fishing.

Release to the environment of this substance is likely to occur from industrial use: as an intermediate step in further manufacturing of another substance (use of intermediates), for thermoplastic manufacture, formulation of mixtures, in

[2] *Date of assessment: November 15 2021.*

processing aids at industrial sites, manufacturing of the substance and in the production of articles. Other release to the environment of this substance is likely to occur from: indoor use (e.g. machine wash liquids/detergents, automotive care products, paints and coating or adhesives, fragrances and air fresheners) and outdoor use as reactive substance.

ECHA has no registered data indicating the type of article into which the substance has been processed.

Table: Uses

Part 1:

☒ Manufacture	☒ Formulation	☒ Industrial use	☒ Professional use	☐ Consumer use	☐ Article service life	☐ Closed system

Part 2:

	Use(s)
Uses as intermediate	2-furaldehyde is used as intermediate in e.g. pesticide production, and manufactoring of furan derivatives.
Formulation	Most of the process categories (PROC) indicate only limited or no potential for exposure.
Uses at industrial sites	2-Furaldehyde is used in a wide variety of industrial sites and for different purposes such as manufacturing of polymers, manufacturing of polymers, extraction agent in the petroleum refining industry and for manufacturing of furan derivatives. Most of the process categories (PROC) indicate only limited or no potential for exposure.
Uses by professional workers	Used in vide variety of uses by industrial workers. Several process categories indicate potential for exposure, such as: PROC 4: Use in batch and other process (synthesis) where opportunity for exposure arises PROC 5: Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact) PROC 8a: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities PROC 10: Roller application or brushing PROC 11: Non industrial spraying
Consumer Uses	None reported
Article service life	None reported.

5. JUSTIFICATION FOR THE SELECTION OF THE CANDIDATE CoRAP SUBSTANCE

5.1. Legal basis for the proposal

☒ Article 44(2)

☐ Article 45(5)

5.2. Selection criteria met (why the substance qualifies for being in CoRAP)

☒ Fulfils criteria as CMR/ Suspected CMR

☐ Fulfils criteria as Sensitiser/ Suspected sensitiser

☐ Fulfils criteria as potential endocrine disrupter

☐ Fulfils criteria as PBT/vPvB / Suspected PBT/vPvB

☒ Fulfils criteria high (aggregated) tonnage (*tpa > 1000*)

☒ Fulfils exposure criteria

☐ Fulfils MS's (national) priorities

5.3. Initial grounds for concern to be clarified under Substance Evaluation

Hazard based concerns		
CMR ☐ C ☐ M ☐ R	Suspected CMR[1] ☒ C ☒ M ☐ R	☐ Potential endocrine disruptor
☐ Sensitiser	☐ Suspected Sensitiser[3]	
☐ PBT/vPvB	☐ Suspected PBT/vPvB[1]	☐ Other (please specify below)
Exposure/risk based concerns		
☒ Wide dispersive use	☐ Consumer use	☐ Exposure of sensitive populations
☐ Exposure of environment	☒ Exposure of workers	☐ Cumulative exposure
☐ High RCR	☒ High (aggregated) tonnage	☐ Other (please specify below)
Several *in vitro* studies (DNA synthesis inhibition, mammalian chromosome aberration (CA), mammalian cell gene mutation assay, sister chromatid exchance (SCE), etc.) shows genotoxic effects of 2-furaldehyd. This has been followed up by		

[3] CMR/Sensitiser: known carcinogenic and/or mutagenic and/or reprotoxic properties/known sensitising properties (according to CLP harmonized or registrant self-classification or CLP Inventory)
Suspected CMR/Suspected sensitiser: suspected carcinogenic and/or mutagenic and/or reprotoxic properties/suspected sensitising properties (not classified according to CLP harmonized or registrant self-classification)
Suspected PBT: Potentially Persistent, Bioaccumulative and Toxic

some *in vivo* studies. A Drosophila SLRL test and chromosome breakage test in germ cells, a wind spot test in somatic cells also in Drosophila showed positive responses. A sister chromatid exchanges (SCE) test in bone marrow cells, a unscheduled DNA synthesis (UDS) test and a pre-guideline TGR assay in the liver were concluded to be negative by the registrant.

On the other hand, a comet assay study in mice from 2000[4] (which is not included in the chemical safety report or in the EU Risk Assessment report), reports positive responses in the stomach, colon, liver, kidney, urine bladder, lung/respiratory track, brain and bone marrow.

The available *in vivo* studies are not conducted according to the OECD test guidelines and/or are not performed in all relevant tissues. Therefore, a thorough analysis of the methodology and results of the studies in a weight of evidence analysis is necessary to clarify the concern for both gene mutations and chromosomal aberrations in somatic tissue and germ cells raised by the available positive results from the available *in vitro* and *in vivo* tests.

In September 2017 ECHA issued decision on a compliance check requesting an *in vivo* micronucleus test (OECD TG 474), an *in vivo* mammalian bone marrow chromosomal aberration test (OECD TG 475) or an *in vivo* mammalian alkaline comet assay (OECD TG 489) in the following tissues: liver, glandular stomach and duodenum. Following that decision, the registrant provided further information, which was considered by ECHA as meeting the standard information requirements. However the information is not considered sufficient by the evaluating MSCA to address the above-mentioned concerns for mutagenicity in somatic tissues and the germ cells.

The substance has a harmonized classification as Carc. 2. However, based on the available data, the need for a classification as Carcinogen in category 1b cannot be excluded. In addition, the substance might also be classified as mutagenic.

Based on the concerns for mutagenicity and carcinogenicity, 2-furaldehyde has been selected for CoRAP inclusion. Furthermore, the high tonnage and a registered wide spread use raises concerns in relation to high potential for exposure of at least the working population and adds up to the overall concerns contributing to why the substance is selected for CoRAP inclusion.

5.4. Preliminary indication of information that may need to be requested to clarify the concern

☒ Information on toxicological properties	☐ Information on physico-chemical properties
☐ Information on fate and behaviour	☐ Information on exposure
☐ Information on ecotoxicological properties	☐ Information on uses
☐ Information ED potential	☐ Other (provide further details below)

[4] Critical Reviews in Toxicology, 30(6):629-799 (2000). The Comet Assay with Multiple Mouse Organs: Comparison of Comet Assay Results and Carcinogenicity with 208 Chemicals Selected from the IARC Monographs and U.S. NTP Carcinogenicity Database".

Based on the evaluation it may be necessary to request further information on genotoxicity of the registered substance.

5.5. Potential follow-up and link to risk management

☒ Harmonised C&L	☐ Restriction	☐ Authorisation	☐ Other (provide further details)
If the substance is concluded to meet the criteria for classification as MUT cat.1B and/or CARC cat. 1B a proposal for harmonised classification will be submitted.			