



**Ministry of Environment
and Food of Denmark**
Environmental
Protection Agency

Justification Document for the Selection of a CoRAP Substance

Substance Name (public name): 2-furaldehyde

EC Number: 202-627-7

CAS Number: 98-01-1

Authority: Danish Environmental Protection
Agency

Date: 21/03/2017

Cover Note

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

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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:	C ₅ H ₄ O ₂
Molecular weight or molecular weight range:	96.08
Synonyms:	Furfural 2-Furancarboxaldehyde 2- Furaldehyde 2-Formylfuran 2-Furaldehyde 2-Furanaldehyde 2-Furancarbal 2-Furancarboxaldehyde 2-Furfural 2-Furyl-methanal 2-Furylaldehyde alpha-Furole artificial ant oil Artificial oil of ants Fural Furaldehyde Furale Furan-2-carbaldehyde Furfural Furfuraldehyde Furfurane carboxylic aldehyde Furfurol Furfurole Furole Pyromucic aldehyde

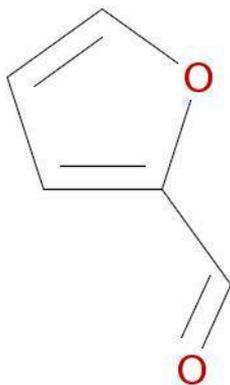
Type of substance

Mono-constituent

Multi-constituent

UVCB

Structural formula:



2 OVERVIEW OF OTHER PROCESSES / EU LEGISLATION

Table: Completed or ongoing processes

RMOA	<input type="checkbox"/> Risk Management Option Analysis (RMOA)	
REACH Processes	Evaluation	<input type="checkbox"/> Compliance check, Final decision
		<input type="checkbox"/> Testing proposal
		<input type="checkbox"/> CoRAP and Substance Evaluation
	Authorisation	<input type="checkbox"/> Candidate List
		<input type="checkbox"/> Annex XIV
	Restriction	<input type="checkbox"/> Annex XVII
Harmonised C&L	<input checked="" type="checkbox"/> Annex VI (CLP) (see section 3.1)	

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Processes under other EU legislation	<input type="checkbox"/> Plant Protection Products Regulation Regulation (EC) No 1107/2009
	<input type="checkbox"/> Biocidal Product Regulation Regulation (EU) 528/2012 and amendments
Previous legislation	<input type="checkbox"/> Dangerous substances Directive Directive 67/548/EEC (NONS)
	<input checked="" type="checkbox"/> Existing Substances Regulation Regulation 793/93/EEC (RAR/RRS)
(UNEP) Stockholm convention (POPs Protocol)	<input type="checkbox"/> Assessment
	<input type="checkbox"/> In relevant Annex
Other processes / EU legislation	<input type="checkbox"/> Other (provide further details below)
Further details	

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	None	None

3.1.2 Self classification

- In the registration:

In addition to the harmonised classification the substance is self-classified as:

Flam. Liquid 3: H226

Acute Tox. 2: H330

Aquatic Chronic 3: H412

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

Flam. Lig. 3: H226

Acute Tox. 1: H330

Acute Tox. 2: H330

Aquatic Chronic 2: H411

Aquatic Chronic 3: H412

3.1.3 Proposal for Harmonised Classification in Annex VI of the CLP

N.A.

4 INFORMATION ON (AGGREGATED) TONNAGE AND USES¹

4.1 Tonnage and registration status

Table: Tonnage and registration status

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

¹ Information compiled in May 2016

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 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 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:

<input checked="" type="checkbox"/> Manufacture	<input checked="" type="checkbox"/> Formulation	<input checked="" type="checkbox"/> Industrial use	<input checked="" type="checkbox"/> Professional use	<input type="checkbox"/> Consumer use	<input type="checkbox"/> Article service life	<input type="checkbox"/> Closed system
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Part 2:

	Use(s)
Uses as intermediate	2-furaldehyde is used as intermediate in e.g. pesticide production, and manufacturing 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 wide 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)

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	from/to vessels/large containers at non-dedicated facilities PROC 10: Roller application or brushing PROC 11: Non industrial spraying
Consumer Uses	Not reported
Article service life	Not reported

5. JUSTIFICATION FOR THE SELECTION OF THE CANDIDATE CoRAP SUBSTANCE

5.1. Legal basis for the proposal

Article 44(2) (refined prioritisation criteria for substance evaluation)

Article 45(5) (Member State priority)

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 <input type="checkbox"/> C <input type="checkbox"/> M <input type="checkbox"/> R	Suspected CMR ¹ <input checked="" type="checkbox"/> C <input checked="" type="checkbox"/> M <input type="checkbox"/> R	<input type="checkbox"/> Potential endocrine disruptor
<input type="checkbox"/> Sensitiser	<input type="checkbox"/> Suspected Sensitiser ²	
<input type="checkbox"/> PBT/vPvB	<input type="checkbox"/> Suspected PBT/vPvB ¹	<input type="checkbox"/> Other (please specify below)
Exposure/risk based concerns		
<input checked="" type="checkbox"/> Wide dispersive use	<input type="checkbox"/> Consumer use	<input type="checkbox"/> Exposure of sensitive populations
<input type="checkbox"/> Exposure of environment	<input checked="" type="checkbox"/> Exposure of workers	<input type="checkbox"/> Cumulative exposure
<input type="checkbox"/> High RCR	<input checked="" type="checkbox"/> High (aggregated) tonnage	<input type="checkbox"/> Other (please specify below)

² 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

Several *in vitro* studies (DNA synthesis inhibition, mammalian chromosome aberration (CA), mammalian cell gene mutation assay, sister chromatid exchange (SCE), etc.) shows genotoxic effects. This has been followed up by some *in vivo* studies. A *Drosophila* SLRL test and chromosome breakagetest in germ cells and wind spot test in somatic cells also in *Drosophila* showed positive responses. SCE, unscheduled DNA synthesis (UDS), a pre-guideline TGR assay and Chromosome Aberration study showed negative responses.

However, a comet assay study in mice from 2000³ (which is not included in the chemical safety report or in the EU Risk Assessment report) for 2-furaldehyde, reports positive responses in the stomach, colon, liver, kidney, urin bladder, lung/respiratory track, brain and bone marrow.

The substance has a harmonised classification as Carc. 2. However, based on the above there is a concern for a genotoxic mode of action and that the substance might be a Carcinogen in category 1b. In addition the substance might also be classified as mutagenic.

Based on the concerns for genotoxicity 2-furaldehyde has been selected for CoRAP inclusion. During the substance evaluation, it will be evaluated if the pre-guideline TGR study is adequately robust to conclude definitively on (lack of) in-vivo mutagenicity in light of the positive findings in the COMET assay.

Furthermore, a combination of high tonnage and a registered wide dispersive 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

<input checked="" type="checkbox"/> Information on toxicological properties	<input type="checkbox"/> Information on physico-chemical properties
<input type="checkbox"/> Information on fate and behaviour	<input type="checkbox"/> Information on exposure
<input type="checkbox"/> Information on ecotoxicological properties	<input type="checkbox"/> Information on uses
<input type="checkbox"/> Information ED potential	<input type="checkbox"/> Other (provide further details below)
Based on the evaluation it may be necessary to request further information on genotoxicity of the registered substance.	

³ *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*".

5.5. Potential follow-up and link to risk management

<input checked="" type="checkbox"/> Harmonised C&L	<input type="checkbox"/> Restriction	<input type="checkbox"/> Authorisation	<input type="checkbox"/> Other (provide further details)
<p>If the substance is concluded to meet the criteria for classification as MUT or CARC in category 1.B a proposal for harmonized classification will be submitted.</p>			