



## **Justification Document for the Selection of a CoRAP Substance**

**Substance Name (public name):** Vinyl acetate

**EC Number:** 203-545-4

**CAS Number:** 108-05-4

**Authority:** LV MSCA

**Date:** 22/03/2016

### **Note**

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

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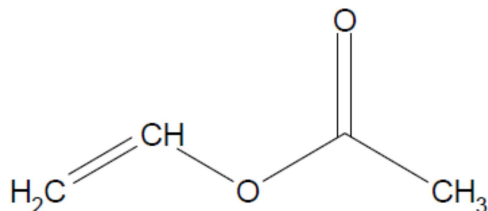
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**1 IDENTITY OF THE SUBSTANCE****1.1 Other identifiers of the substance****Table: Other Substance identifiers**

<b>EC name (public):</b>	Vinyl acetate
<b>IUPAC name (public):</b>	Vinyl acetate
<b>Index number in Annex VI of the CLP Regulation:</b>	607-023-00-0
<b>Molecular formula:</b>	C <sub>4</sub> H <sub>6</sub> O <sub>2</sub>
<b>Molecular weight or molecular weight range:</b>	86.1 g/mol
<b>Synonyms:</b>	Ethenyl acetate Ethenyl ethanoate Ethenyl ester acetic acid Acetic acid vinyl ester

**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	<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
Restri- -ction	<input type="checkbox"/> Annex XVII	
Harmonised C&L	<input checked="" type="checkbox"/> Annex VI (CLP) (see section 3.1)	
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 checked="" type="checkbox"/> Other (provide further details below)	

	Seveso Directive substance Directive 2012/18/EU (Seveso-III) which repeals the Seveso II Directive 96/82/EC; Category P5a, P5b, P5c
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### 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)		
607-023-00-0	vinyl acetate	203-545-4	108-05-4	Flam. Liq. 2 Acute Tox. 4 STOT SE 3 Carc. 2	H225 H332* H335** H351***		Note D

\* Harmful if inhaled.

\*\* May cause respiratory irritation. Affected organs: respiratory tract. Route of exposure: Inhalation.

\*\*\* Suspected of causing cancer. Route of exposure: Oral.

##### 3.1.2 Self classification

In the registration:

- The harmonised classification of Vinyl acetate has been updated according to the 5th ATP ((EU) No 944/2013). The classification is the same as harmonised classification (3.1.1) but supplemented with environmental hazard classification:
  - Aquatic Chronic 3 H412: Harmful to aquatic life with long lasting effects.

In the notifications:

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

Hazard Class and Category Code(s)	Hazard Statement Code(s)
Aquatic Chronic 3	H412
Skin Sens. 1	H317
Eye Irrit. 2	H319
STOT RE 2	H373 (respiratory tract)
STOT SE 2	H371 (liver) (inhalation)
Not classified	-

**4 INFORMATION ON (AGGREGATED) TONNAGE AND USES**  
(AUGUST 20<sup>TH</sup>, 2015)

**4.1 Tonnage and registration status**

**Table: Tonnage and registration status**

<b>From ECHA dissemination site</b>		
<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 type="checkbox"/> 10,000 - 100,000 tpa	<input type="checkbox"/> 100,000 - 1,000,000 tpa
<input checked="" 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

## 4.2 Overview of uses

Vinyl acetate is a monomer that is manufactured for production of polymeric thermoplastics (polyvinyl acetate (PVAc) and mixed vinyl acetate polymers). These are widely used in paints, adhesives and paper coating materials. Other chemical product categories include textile dyes, finishing and impregnating products, bleaches and other processing aids, cosmetics and personal care products.

**Table: Uses**

**Part 1:**

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

	<b>Use(s)</b>
<b>Formulation</b>	Polymer production Use of polymers (textile dyes, impregnation etc.) Formulation of oral care products
<b>Uses at industrial sites</b>	Polymer production Monomer to produce polymer Use in the production of oral care products Use as glue
<b>Consumer Uses</b>	Use as oral care product
<b>Article service life</b>	Other (non intended to be released): Hobby articles

## 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)

### 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 <sup>1</sup> <input type="checkbox"/> C <input type="checkbox"/> M <input checked="" type="checkbox"/> R	<input checked="" type="checkbox"/> Potential endocrine disruptor
<input type="checkbox"/> Sensitiser	<input checked="" type="checkbox"/> Suspected Sensitiser <sup>1</sup>	
<input type="checkbox"/> PBT/vPvB	<input type="checkbox"/> Suspected PBT/vPvB <sup>1</sup>	<input type="checkbox"/> Other (please specify below)
Exposure/risk based concerns		
<input checked="" type="checkbox"/> Wide dispersive use	<input checked="" type="checkbox"/> Consumer use	<input type="checkbox"/> Exposure of sensitive populations
<input type="checkbox"/> Exposure of environment	<input 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)

<sup>1</sup> 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



Vinyl acetate was selected for CoRAP for the following reasons:

- 1) the substance is included in the TEDX list (The Endocrine Disruption Exchange Database, <http://endocrinedisruption.org/endocrine-disruption/tedx-list-of-potential-endocrine-disruptors/chemicalsearch>),
- 2) the substance is classified as Carc. 2 and
- 3) the substance is predicted to be developmental or reproductive toxicant with DART profiler (Reproductive or Developmental Toxic (DART) chemicals in the QSAR Toolbox v3.3).

General properties:

Vinyl acetate is water soluble (20 - 24 g/l and rather volatile (Henry's law constant 49 Pa\*m<sup>3</sup>/mol). The hydrolytic half-life is 17 d and it is initially enzymatically hydrolysed to acetate and acetaldehyde.

PBT/vPvB -properties:

Vinyl acetate does not screen as a PBT/vPvB substance. It is readily biodegradable and not bioaccumulable (log Kow is 0.73). Vinyl acetate has been shown to be subject to microbial degradation in the environment. The lowest available environmental NOEC for fish (long-term early life-stage study) is 0.551 mg/l.

Toxicological properties:

Vinyl acetate has a self classification Skin Sens. 1; H317. Registration dossier contains a reliable negative LLNA test result and a positive Buehler test result with some shortcomings on the test protocol description. Therefore Vinyl acetate is considered as a suspected skin sensitiser.

Vinyl acetate is not classified for reproductive toxicity. A reliable 2-generation reproductive toxicity study (OECD TG 416) showed several changes in reproductive parameters (decrease in fertility in F1, decrease in male mating performance in F1 in cross-mating trial and decrease in F1 pup weight) at the highest dose level tested. NOAEL is 1000 ppm equivalent to 100 mg/kg bw/day. However, the study was conducted according to the old test guideline and not all reproductive parameters (parental sperm parameters and estrous cycle) were included. Therefore, a definitive conclusion about the reproductive toxicity can not be made based on the study.

A supporting non-guideline study regarding testicular genotoxic effects of Vinyl acetate and acetaldehyde was conducted on mice. The study showed significant increase in the frequency of sperm abnormalities, a dose-dependent decrease in sperm production and reduced testicular weight.

Based on the available data, conclusions about the reproductive toxicity, especially toxicity to male fertility, cannot be made. More information is needed to clarify the concern.

Potential ED:

- 1) TEDX inclusion is based on a 2-years chronic toxicity study with rats (Lijinsky and Reuber 1983) that showed adenoma or carcinoma of the thyroid and carcinoma of the uterus in some of the test animals receiving higher doses of the test substance.
- 2) Harmonised classification Carc. 2.
- 3) DART profiler prediction is in line the available experimental data, which showed some developmental and reproductive effects (NOAEL of 100 mg/kg bw/d in a 2-gen. reproduction toxicity study via oral route with rats and NOAEC of 205 mg/kg bw/d for maternal and developmental toxicity of developmental toxicity study via inhalation route with pregnant rats).

EU commission priority list (2000):

Vinyl acetate has been identified for further evaluation of ED properties (Annex 1, list of 553 substances). The ranking was Group III: No evidence of ED activity or no data available. Further evaluation (Annex 12, 146 substance) concluded: Wildlife - No evident scientific basis for inclusion in the list; Mammalian - Three chronic toxicity studies on rodents available: no overall evidence for an endocrine disrupting potential.

DHI (2007) conducted a study for enhancing the ED priority list and ranked Vinyl acetate as: CAT3b Substances with no or insufficient data gathered.

EU Risk assessment report has been prepared for Vinyl acetate in accordance with Council Regulation (EEC) 793/931 in 2008. Regarding toxicity, it was concluded i.a. that 1) Carcinogenicity is thought to act via a secondary mechanism, 2) Distinct reproduction related adverse effects were not evidenced from a 2-gen. study with rats (drinking water, up to and including 1000 ppm) and 3) No embryo/fetotoxic or teratogenic effects were observed for the oral route (drinking water, up to and including 5000 ppm); fetotoxic effects (inhalation) were confined to high dose levels only, where severe maternal toxicity was observed.

Tonnage and identified uses:

Vinyl acetate is produced in high volumes at a number of sites mostly as a monomer for polymer production. Consumer uses (in glues, paints, dental care products) have also been identified indicating widespread use. The chemical safety report gives RCRs below 1 for the environment and workers.

Conclusion:

Potential ED activity has been identified for Vinyl acetate in earlier EU screening studies, but with conclusion of insufficient data for final judgement. Here a concern was identified regarding suspected ED, reprotox and sensitising properties combined with significant tonnage and wide dispersive uses including consumer use. Thus it is proposed to investigate further the suspected potential for endocrine disruption and reprotox properties as well as the sensitising properties in a substance evaluation process.

**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 checked="" type="checkbox"/> Information ED potential	<input type="checkbox"/> Other (provide further details below)

More information is needed to clarify the concern regarding reprotoxic properties, ED potential and skin sensitizing properties.

**5.5 Potential follow-up and link to risk management**

<input checked="" type="checkbox"/> Harmonised C&L	<input checked="" type="checkbox"/> Restriction	<input checked="" type="checkbox"/> Authorisation	<input type="checkbox"/> Other (provide further details)
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Follow up actions will be considered taking into account the evaluated information. The above ticked follow-up processes are only indicative.