Toxicological profile for

Vinyl alcohol-vinyl acetate copolymer

This ingredient has been assessed to determine potential human health effects for the consumer. It was considered not to increase the inherent toxicity of the product and thus is acceptable under conditions of intended use.

1. Name of substance and physico-chemical properties

1.1. IUPAC systematic name

Acetic acid ethenyl ester, polymer with ethenol; Ethenol;ethenyl acetate (PubChem)

1.2. Synonyms

Vinyl acetate vinyl alcohol polymer; Acetic acid ethenyl ester, polymer with ethenol; Polyvinyl acetate polyvinyl alcohol copolymer, minimum number average molecular weight (in amu), 50,000 (ChemIDplus); Acetic acid, vinyl ester, polymer with vinyl alcohol; Vinyl acetate-vinyl alcohol copolymer

1.3. Molecular formula

(C4-H6-O2.C2-H4-O)x (ChemIDplus)

1.4. Structural Formula

(ChemIDplus)

1.5. Molecular weight (g/mol)

130.1418 (for the monomer) or “minimum average molecular weight (in amu) 50,000” (ChemIDplus)

1.6. CAS registration number

25213-24-5

1.7. Properties

1.7.1. Melting point

(°C): No data available to us at this time.

1.7.2. Boiling point

(°C): >100 [>212°F]; 72.7 (US Army Center for Health Promotion and Preventive Medicine, 2009).

1.7.3. Solubility

Insoluble (US Army Center for Health Promotion and Preventive Medicine, 2009).

1.7.4. pKa

No data available to us at this time.

1.7.5. Flashpoint

(°C): >93.3 [200°F]

1.7.6. Flammability limits (vol/vol%)

No data available to us at this time.

1.7.7. (Auto)ignition temperature

(°C): No data available to us at this time.

1.7.8. Decomposition temperature

(°C): No data available to us at this time.

1.7.9. Stability

Stable

1.7.10. Vapor pressure

90.2 mg Hg at 20°C (US Army Center for Health Promotion and Preventive Medicine, 2009).

1.7.11. log Kow

No data available to us at this time.

2. General information

2.1. Exposure

Vinyl alcohol - vinyl acetate copolymer (CAS RN 25213-24-5) is listed as an ingredient (at concentrations, where specified) in “old” auto products and home maintenance (at >3 to 51%) and inside the home (at 0.1–10%, includes “old” products) products by the CPID.

“Polyvinyl alcohol” (CAS RNs 9002-89-5/25213-24-5) is used as a film forming and viscosity controlling ingredient in cosmetics in the EU. As taken from CosIng, undated

“The purpose of this study was to identify, characterize, and assess data needs for ecological risk of household cleaning product polymers currently being used in the United States (US). Because of their range in properties and functions, polymers are used in a wide variety of household cleaning products, including fabric, dish, and hard surface cleaners. Understanding their potential environmental impact is essential for good ingredient and product stewardship. The household cleaning product polymers were first identified using several databases. Of the 185 polymers initially identified, 120 were eliminated from the list because they did not fit the definition of a polymer, were not well defined (e.g., no Chemical Abstracts Service [CAS] or trade name only), or were not in current use. Forty-seven of the remaining polymers had either adequate environmental fate and hazard data and/or sufficient data for conducting a comprehensive ecological risk assessment and were determined to be of low concern by either the United States Environmental Protection Agency (USEPA), the European Chemicals Agency (ECHA), and/or the Human and Environmental Risk Assessment (HERA) Project. The remaining 18 polymers were determined to need further review because of a lack of publicly available information for conducting ecological risk assessments. Additional data for these 18 polymers could be obtained by accessing privately held data, conducting laboratory tests on their fate and effects in aquatic environments, or by conducting

read-across of similar structured polymers. These steps can be utilized by industry to determine where best to dedicate future environmental stewardship efforts. Integr Environ Assess Manag 2019;15:621-632. © 2019 The Authors. Integrated Environmental Assessment and Management published by Wiley Periodicals, Inc. on behalf of Society of Environmental Toxicology & Chemistry (SETAC)..” As taken from Pecquet A et al. 2019. Integr. Environ. Assess. Manag. 15(4), 621-632. PubMed, 2020 available at https://pubmed.ncbi.nlm.nih.gov/30908881/

Used in food contact paper, dinnerware and take-out containers (Washington State Department of Ecology, 2021).

2.2. Combustion products

No data available to us at this time.

2.3. Ingredient(s) from which it originates

“Prepared by partial hydrolysis of polyvinyl acetate polymer and consists of methyl acetate, vinyl acetate monomer, polyvinyl alcohol and impurities” (US Army Center for Health Promotion and Preventive Medicine, 2009).

3. Status in legislation and other official guidance

‘Acetic acid ethenyl ester, polymer with ethenol’ (CAS RN 25213-24-5) is listed in the US EPA Toxic Substances Control Act (TSCA) inventory and is exempt from reporting under the US EPA 2020 CDR (Chemical Data Reporting) rule.

The TSCA inventory and 2020 CDR full exempt list are available at https://sor.epa.gov/sor_internet/registry/substreg/searchandretrieve/searchbylist/search.do

Polyvinyl acetate-polyvinyl alcohol copolymer (CAS RN 25213-24-5) is listed as an approved ingredient in food and non-food use pesticide products (US EPA InertFinder Database, 2021). For food use, it is regulated under 40 CFR Part 180.960 (Polymers; exemptions from the requirement of a tolerance) (US EPA, 2021).

“Vinyl acetate vinyl alcohol polymer” (CAS RN 25213-24-5) is included on the US EPA Safer Chemical Ingredients List (US EPA, 2022).

Acetic acid ethenyl ester, polymer with ethenol (CAS RN 25213-24-5) is pre-registered under REACH (“envisaged registration deadline 31 May 2018”) (ECHA).

“Acetic Acid Ethenyl Ester co-Polymer with Ethenol” (CAS RN 25213-24-5) is not classified for packaging and labelling under Regulation (EC) No. 1272/2008 (ECHA, 2022).

Acetic acid ethenyl ester, polymer with ethenol (CAS RN 25213-24-5) is listed in the New Zealand Inventory of Chemicals and may be used as a component in a product covered by a group standard but it is not approved for use as a chemical in its own right (NZ EPA, 2006).

Acetic acid ethenyl ester, polymer with ethenol (CAS RN 25213-24-5) is “poses no unreasonable risk to human health based on Tier I assessment under the NICNAS IMAP assessment framework” and has been “identified as low concern to human health by application of expert validated rules” by the Australian Department of Health (AICIS, 2012).

Acetic acid, ethenyl ester, polymer with ethenol (CAS 25213-24-5) is listed on Australian Inventory of Industrial Chemicals (AICIS, formerly NICNAS). As taken from AICIS, undated.

4. Metabolism/Pharmacokinetics

4.1. Metabolism/metabolites

No data available to us at this time.

4.2. Absorption, distribution and excretion

No data available to us at this time.

4.3. Interactions

No data available to us at this time.

5. Toxicity

5.1. Single dose toxicity

No data available to us at this time.

5.2. Repeated dose toxicity

No data available to us at this time.

5.3. Reproduction toxicity

No data available to us at this time.

5.4. Mutagenicity

No data available to us at this time.

5.5. Cytotoxicity

No data available to us at this time.

5.6. Carcinogenicity

No data available to us at this time.

5.7. Irritation/immunotoxicity

No data available to us at this time.

5.8. All other relevant types of toxicity

No data available to us at this time.

6. Functional effects on

6.1. Broncho/pulmonary system

No data available to us at this time.

6.2. Cardiovascular system

No data available to us at this time.

6.3. Nervous system

No data available to us at this time.

6.4. Other organ systems, dependent on the properties of the substance

No data available to us at this time.

7. Addiction

JTI is not aware of any information that demonstrates that this ingredient has any addictive effect.

8. Burnt ingredient toxicity

Endpoint	Tested level (ppm)	Reference
Smoke chemistry	-	JTI Internal Report
In vitro genotoxicity	-	JTI Internal Report
In vitro cytotoxicity	-	JTI Internal Report

In comparison with a CSC of a reference cigarette with sideseam adhesives/cigarette paper corresponding to representative specifications for the majority of commercial cigarettes no differences were observed either in the bacterial mutagenicity, cytotoxicity or mammalian cell genotoxicity of the smoke condensate prepared from cigarettes with sideseam adhesives/cigarette paper containing Acetic Acid Ethenyl Ester, Polymer with Ethanol at 0.1 mg/cig. The smoke chemistry data between test and reference cigarette revealed small changes towards both higher and lower yields per cigarette over all analytical groups. These differences were well within the variability of the analytical methods (JTI NTM Study Report(s)).

9. Heated/vapor emissions toxicity

Aerosol from heated tobacco stick(s) containing Vinyl acetate-vinyl alcohol copolymer was tested in aerosol chemistry and a battery of in vitro test(s). Under the test conditions and within the sensitivity and specificity of the bioassay(s), the activity of the total particulate matter (TPM) and/or gas vapor phase (GVP) were not increased by the addition of this ingredient when compared to TPM and/or GVP from reference combustible cigarettes. The table below provides the highest tested level(s) and specific endpoint(s):

Endpoint	Tested level (mg/stick)	Reference
Aerosol chemistry	2.55	Labstat International Inc. (2020a) Labstat International Inc. (2021a)
In vitro genotoxicity	2.55	Labstat International Inc. (2020b) Labstat International Inc. (2021b)

In vitro cytotoxicity	2.55	Labstat International Inc. (2020b) Labstat International Inc. (2021b)

10. Ecotoxicity

10.1. Environmental fate

The Ecological Categorization Results from the Canadian Domestic Substances List state that vinyl alcohol-vinyl acetate copolymer is persistent in the environment:

Media of concern leading to Categorization	Not Applicable
Experimental Biodegradation half-life (days)	Not Available
Comment (persistency)	90% in the Zahn Wellens Test (OECD 302B); the 28-day BODs with unacclimated cultures indicated essentially no degradation (RE)

Data accessed January 2015 on the OECD website: http://webnet.oecd.org/CCRWeb/Search.aspx

10.2. Aquatic toxicity

The Ecological Categorization Results from the Canadian Domestic Substances List state that vinyl alcohol-vinyl acetate copolymer is not inherently toxic to aquatic organisms:

Rational for iT	Monomer
Pivotal value for iT (mg/l)	14
Comment iT	HC GPE;

Data accessed January 2015 on the OECD website: http://webnet.oecd.org/CCRWeb/Search.aspx

10.3. Sediment toxicity

No data available to us at this time.

10.4. Terrestrial toxicity

No data available to us at this time.

10.5. All other relevant types of ecotoxicity

The Ecological Categorization Results from the Canadian Domestic Substances List simply state that vinyl alcohol-vinyl acetate copolymer is not bioaccumulative in the environment.

Data accessed January 2015 on the OECD website: http://webnet.oecd.org/CCRWeb/Search.aspx

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12. Other information

No data available to us at this time.

13. Last audited

May 2022

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

Version 8.10
Revision Date 24.09.2022
Print Date 07.11.2022
GENERIC EU MSDS - NO COUNTRY SPECIFIC DATA - NO OEL DATA

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifiers

Product name	:	Polyvinyl alcohol, partially hydrolyzed (Mw approx.70000) for synthesis
Product Number	:	8.43869
Catalogue No.	:	843869
Brand	:	Millipore
REACH No.	:	A registration number is not available for this substance as the substance or its uses are exempted from registration, the annual tonnage does not require a registration or the registration is envisaged for a later registration deadline.
CAS-No.	:	25213-24-5

1.2 Relevant identified uses of the substance or mixture and uses advised against

Identified uses	:	Chemical for synthesis

1.3 Details of the supplier of the safety data sheet

Company	:	Merck Life Science Sp.z.o.o. Szelągowska 30 PL-61-626 POZNAN
Telephone	:	+48 61 8290-100
Fax	:	+48 61 8290-120
E-mail address	:	TechnicalService@merckgroup.com

1.4 Emergency telephone

Emergency Phone #	:	+(48)-223988029 (CHEMTREC) 998 (Straz pozarna)

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Not a hazardous substance or mixture according to Regulation (EC) No 1272/2008.

2.2 Label elements

Not a hazardous substance or mixture according to Regulation (EC) No 1272/2008.

2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

SECTION 3: Composition/information on ingredients

3.1 Substances

CAS-No. : 25213-24-5

Component	Classification	Concentration
Methanol CAS-No. 67-56-1 EC-No. 200-659-6 Index-No. 603-001-00-X	Flam. Liq. 2; Acute Tox. 3; STOT SE 1; H225, H301, H331, H311, H370 Concentration limits: >= 10 %: STOT SE 1, H370; 3 - < 10 %: STOT SE 2, H371;	>= 1 - < 3 %

For the full text of the H-Statements mentioned in this Section, see Section 16.

SECTION 4: First aid measures

4.1 Description of first-aid measures

If inhaled
After inhalation: fresh air.

In case of skin contact
In case of skin contact: Take off immediately all contaminated clothing. Rinse skin with water/ shower.

In case of eye contact
After eye contact: rinse out with plenty of water. Remove contact lenses.

If swallowed
After swallowing: make victim drink water (two glasses at most). Consult doctor if feeling unwell.

4.2 Most important symptoms and effects, both acute and delayed

The most important known symptoms and effects are described in the labelling (see section 2.2) and/or in section 11

4.3 Indication of any immediate medical attention and special treatment needed

No data available

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media
Water Foam Carbon dioxide (CO2) Dry powder

Unsuitable extinguishing media
For this substance/mixture no limitations of extinguishing agents are given.

5.2 Special hazards arising from the substance or mixture
Combustible.
Risk of dust explosion.
Development of hazardous combustion gases or vapours possible in the event of fire.

5.3 Advice for firefighters
In the event of fire, wear self-contained breathing apparatus.

5.4 Further information
Prevent fire extinguishing water from contaminating surface water or the ground water system.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures
Advice for non-emergency personnel: Avoid inhalation of dusts. Ensure adequate ventilation. Evacuate the danger area, observe emergency procedures, consult an expert. For personal protection see section 8.

6.2 Environmental precautions
Do not let product enter drains.

6.3 Methods and materials for containment and cleaning up
Cover drains. Collect, bind, and pump off spills. Observe possible material restrictions (see sections 7 and 10). Take up dry. Dispose of properly. Clean up affected area. Avoid generation of dusts.

6.4 Reference to other sections
For disposal see section 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling
For precautions see section 2.2.

7.2 Conditions for safe storage, including any incompatibilities

Storage conditions
Tightly closed. Dry.

Recommended storage temperature see product label.

Storage class
Storage class (TRGS 510): 11: Combustible Solids

7.3 Specific end use(s)
Apart from the uses mentioned in section 1.2 no other specific uses are stipulated

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Ingredients with workplace control parameters

8.2 Exposure controls

Personal protective equipment

Eye/face protection
Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU). Safety glasses

Skin protection
This recommendation applies only to the product stated in the safety data sheet, supplied by us and for the designated use. When dissolving in or mixing with other substances and under conditions deviating from those stated in EN374 please contact the supplier of CE-approved gloves (e.g. KCL GmbH, D-36124 Eichenzell, Internet: www.kcl.de).
Full contact
Material: Nitrile rubber
Minimum layer thickness: 0,11 mm
Break through time: > 480 min
Material tested:KCL 741 Dermatril® L

This recommendation applies only to the product stated in the safety data sheet, supplied by us and for the designated use. When dissolving in or mixing with other substances and under conditions deviating from those stated in EN374 please contact the supplier of CE-approved gloves (e.g. KCL GmbH, D-36124 Eichenzell, Internet: www.kcl.de).
Splash contact
Material: Nitrile rubber
Minimum layer thickness: 0,11 mm
Break through time: > 480 min
Material tested:KCL 741 Dermatril® L

Respiratory protection
required when dusts are generated.
Our recommendations on filtering respiratory protection are based on the following standards: DIN EN 143, DIN 14387 and other accompanying standards relating to the used respiratory protection system.
Recommended Filter type: Filter type P2

The entrepeneur has to ensure that maintenance, cleaning and testing of respiratory protective devices are carried out according to the instructions of the producer. These measures have to be properly documented.

Control of environmental exposure
Do not let product enter drains.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

a)	Physical state	solid

b)	Color	colorless
c)	Odor	odorless
d)	Melting point/freezing point	Melting point: > 200 °C
e)	Initial boiling point and boiling range	Not applicable
f)	Flammability (solid, gas)	No data available
g)	Upper/lower flammability or explosive limits	No data available
h)	Flash point	No data available
i)	Autoignition temperature	No data available
j)	Decomposition temperature	> 300 °C -
k)	pH	No data available
l)	Viscosity	Viscosity, kinematic: No data available Viscosity, dynamic: No data available
m)	Water solubility	soluble in hot waterat 20 °C insoluble
n)	Partition coefficient: n-octanol/water	No data available
o)	Vapor pressure	No data available
p)	Density	ca.1,3 g/cm3 at 20 °C
	Relative density	No data available
q)	Relative vapor density	No data available
r)	Particle characteristics	No data available
s)	Explosive properties	Not classified as explosive.
t)	Oxidizing properties	none

9.2 Other safety information

Bulk density	400 - 600 kg/m3

SECTION 10: Stability and reactivity

10.1 Reactivity

The following applies in general to flammable organic substances and mixtures: in correspondingly fine distribution, when whirled up a dust explosion potential may generally be assumed.

10.2 Chemical stability

The product is chemically stable under standard ambient conditions (room temperature) .

10.3 Possibility of hazardous reactions
Violent reactions possible with:
Strong oxidizing agents

10.4 Conditions to avoid
Strong heating (decomposition).
no information available

10.5 Incompatible materials
No data available

10.6 Hazardous decomposition products
In the event of fire: see section 5

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute toxicity
Acute toxicity estimate Oral - > 2.000 mg/kg
(Calculation method)
Oral: No data available
Acute toxicity estimate Inhalation - 4 h - > 20 mg/l - vapor(Calculation method)

Acute toxicity estimate Dermal - > 2.000 mg/kg
(Calculation method)

Skin corrosion/irritation
No data available

Serious eye damage/eye irritation
No data available

Respiratory or skin sensitization
No data available

Germ cell mutagenicity
No data available

Carcinogenicity
No data available

Reproductive toxicity
No data available

Specific target organ toxicity - single exposure
No data available

Specific target organ toxicity - repeated exposure
No data available

Aspiration hazard
No data available (polymer of vinyl acetate and vinyl alcohol)

11.2 Additional Information

Endocrine disrupting properties

Product:

Assessment The substance/mixture does not contain

components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated. (polymer of vinyl acetate and vinyl alcohol)

SECTION 12: Ecological information

12.1 Toxicity
No data available

12.2 Persistence and degradability
No data available

12.3 Bioaccumulative potential
No data available

12.4 Mobility in soil
No data available (polymer of vinyl acetate and vinyl alcohol)

12.5 Results of PBT and vPvB assessment
This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

12.6 Endocrine disrupting properties
Product:

Assessment	:	The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

12.7 Other adverse effects
No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product
See www.retrologistik.com for processes regarding the return of chemicals and containers, or contact us there if you have further questions.

SECTION 14: Transport information

14.1 UN number
ADR/RID: - IMDG: - IATA: -

14.2 UN proper shipping name
ADR/RID: Not dangerous goods
IMDG: Not dangerous goods

IATA: Not dangerous goods

14.3 Transport hazard class(es)

ADR/RID: - IMDG: - IATA: -

14.4 Packaging group

ADR/RID: - IMDG: - IATA: -

14.5 Environmental hazards

ADR/RID: no IMDG Marine pollutant: no IATA: no

14.6 Special precautions for user

Further information

Not classified as dangerous in the meaning of transport regulations.

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

This material safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006.

Authorisations and/or restrictions on use

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII)	: methanol

15.2 Chemical Safety Assessment

For this product a chemical safety assessment was not carried out

SECTION 16: Other information

Full text of other abbreviations

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

Further information

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