according to Regulation (EC) No. 1907/2006 (REACH), amended by 2020/878/EU



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Acetic acid ROTIPURAN® Supra 100 %

article number: **HN55** Version: **5.0 en** Replaces version of: 2023-03-23 Version: (4)

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

1.1 Product identifier

Identification of the substance

Article number

Registration number (REACH)

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607-002-00-6

200-580-7

64-19-7

It is not required to list the identified uses because the substance is not subject to registration according to REACH (< 1 t/a).

Index number in CLP Annex VI

EC number

CAS number

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

Relevant identified uses:

Uses advised against:

Laboratory chemical Laboratory and analytical use

Do not use for squirting or spraying. Do not use for products which come into direct contact with the skin. Do not use for private purposes (household). Food, drink and animal feedingstuffs.

1.3 Details of the supplier of the safety data sheet

Carl Roth GmbH + Co. KG Schoemperlenstr. 3-5 D-76185 Karlsruhe Germany

Telephone:+49 (0) 721 - 56 06 0 **Telefax:** +49 (0) 721 - 56 06 149 **e-mail:** sicherheit@carlroth.de **Website:** www.carlroth.de

Competent person responsible for the safety data Department Health, Safety and Environment sheet:

e-mail (competent person):

sicherheit@carlroth.de

1.4 Emergency telephone number

Name	Street	Postal code/city	Telephone	Website
National Poisons Information Centre Beaumont Hospital	Beaumont Road	Dublin 9	+353 1 809 2166	https:// www.poisons.ie/

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SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008 (CLP)

Section	tion Hazard class		Hazard class and category	Hazard statement
2.6	Flammable liquid	3	Flam. Liq. 3	H226
3.2	Skin corrosion/irritation	1A	Skin Corr. 1A	H314
3.3	Serious eye damage/eye irritation	1	Eye Dam. 1	H318

For full text of abbreviations: see SECTION 16

The most important adverse physicochemical, human health and environmental effects

Skin corrosion produces an irreversible damage to the skin; namely, visible necrosis through the epidermis and into the dermis. The product is combustible and can be ignited by potential ignition sources.

2.2 Label elements

Labelling according to Regulation (EC) No 1272/2008 (CLP)

Pictograms

GHS02, GHS05



Hazard statements

H226	Flammable liquid and vapour
H314	Causes severe skin burns and eye damage

Precautionary statements

Precautionary statements - prevention

P210	Keep away from heat, hot surfaces, sparks, open flames and other ignition
	sources. No smoking
P280	Wear protective gloves/protective clothing/eye protection/face protection

Precautionary statements - response

P301+P330+P331 P303+P361+P353	IF SWALLOWED: rinse mouth. Do NOT induce vomiting IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin
P305+P351+P338	with water [or shower] IF IN EYES: Rinse cautiously with water for several minutes. Remove contact
P310	lenses, if present and easy to do. Continue rinsing Immediately call a POISON CENTER/doctor

Labelling of packages where the contents do not exceed 125 ml

Signal word: Danger

according to Regulation (EC) No. 1907/2006 (REACH), amended by 2020/878/EU

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H314

Causes severe skin burns and eye damage.

P280 Wear protective gloves/protective clothing/eye protection/face protection. P301+P330+P331 IF SWALLOWED: rinse mouth. Do NOT induce vomiting. P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water or shower. P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P310

Immediately call a POISON CENTER/doctor.

2.3 **Other hazards**

Endocrine disrupting properties

Does not contain an endocrine disruptor (ED) at a concentration of $\geq 0,1\%$.

SECTION 3: Composition/information on ingredients

3.1 **Substances**

Name of substance	Acetic acid
Molecular formula	$C_2H_4O_2$
Molar mass	60,05 ^g / _{mol}
CAS No	64-19-7
EC No	200-580-7
Index No	607-002-00-6

Substance, Specific Conc. Limits, M-factors, ATE						
Specific Conc. Limits	M-Factors	ATE	Exposure route			
Skin Corr. 1A; H314: C ≥ 90 % Skin Corr. 1B; H314: 25 % ≤ C < 90 % Skin Irrit. 2; H315: 10 % ≤ C < 25 % Eye Dam. 1; H318: C ≥ 25 % Eye Irrit. 2; H319: 10 % ≤ C < 25 %	-	-				

SECTION 4: First aid measures

4.1 **Description of first aid measures**



General notes

Take off immediately all contaminated clothing. Self-protection of the first aider.

Following inhalation

Provide fresh air. In all cases of doubt, or when symptoms persist, seek medical advice.

Following skin contact

After contact with skin, wash immediately with plenty of water. Immediate medical treatment required because corrosive injuries that are not treated are hard to cure.



according to Regulation (EC) No. 1907/2006 (REACH), amended by 2020/878/EU

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Following eye contact

In case of contact with eyes flush immediately with plenty of flowing water for 10 to 15 minutes holding eyelids apart and consult an ophthalmologist. Protect uninjured eye.

Following ingestion

Rinse mouth immediately and drink plenty of water. Call a physician immediately. If swallowed danger of perforation of the esophagus and the stomach (strong corrosive effects).

4.2 Most important symptoms and effects, both acute and delayed

Following inhalation: Irritant effects, Cough, pain, choking, and breathing difficulties, Following skin contact: Causes severe burns, Causes poorly healing wounds, After eye contact: Risk of serious damage to eyes, Risk of blindness, Following ingestion: Corrosion, Gastric perforation

4.3 Indication of any immediate medical attention and special treatment needed

none

SECTION 5: Firefighting measures

5.1 Extinguishing media



Suitable extinguishing media

co-ordinate firefighting measures to the fire surroundings! water spray, alcohol resistant foam, dry extinguishing powder, BC-powder, carbon dioxide (CO₂)

Unsuitable extinguishing media

water jet

5.2 Special hazards arising from the substance or mixture

Combustible. In case of insufficient ventilation and/or in use, may form flammable/explosive vapourair mixture. Solvent vapours are heavier than air and may spread along floors. Places which are not ventilated, e.g. unventilated below ground level areas such as trenches, conduits and shafts, are particularly prone to the presence of flammable substances or mixtures. Vapours are heavier than air, spread along floors and form explosive mixtures with air. Vapours may form explosive mixtures with air.

Hazardous combustion products

In case of fire may be liberated: Carbon monoxide (CO), Carbon dioxide (CO₂)

5.3 Advice for firefighters

In case of fire and/or explosion do not breathe fumes. Fight fire with normal precautions from a reasonable distance. Wear self-contained breathing apparatus. Wear full chemical protective clothing.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures



For non-emergency personnel

Use personal protective equipment as required. Avoid contact with skin, eyes and clothes. Do not breathe vapour/spray. Avoidance of ignition sources.

according to Regulation (EC) No. 1907/2006 (REACH), amended by 2020/878/EU



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6.2 Environmental precautions

Keep away from drains, surface and ground water. Retain contaminated washing water and dispose of it.

6.3 Methods and material for containment and cleaning up

Advice on how to contain a spill

Covering of drains.

Advice on how to clean up a spill

Absorb with liquid-binding material (sand, diatomaceous earth, acid- or universal binding agents).

Other information relating to spills and releases

Place in appropriate containers for disposal. Ventilate affected area.

6.4 Reference to other sections

Hazardous combustion products: see section 5. Personal protective equipment: see section 8. Incompatible materials: see section 10. Disposal considerations: see section 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Provision of sufficient ventilation. Use extractor hood (laboratory). Handle and open container with care. Clear contaminated areas thoroughly.

Measures to prevent fire as well as aerosol and dust generation



Keep away from sources of ignition - No smoking.

Take precautionary measures against static discharge.

Advice on general occupational hygiene

Wash hands before breaks and after work. Keep away from food, drink and animal feedingstuffs. When using do not smoke.

7.2 Conditions for safe storage, including any incompatibilities

Store in a well-ventilated place. Keep container tightly closed.

Incompatible substances or mixtures

Observe hints for combined storage.

Consideration of other advice:

Ground/bond container and receiving equipment.

Ventilation requirements

Use local and general ventilation.

Specific designs for storage rooms or vessels

Recommended storage temperature: 15 - 25 °C

7.3 Specific end use(s)

No information available.

according to Regulation (EC) No. 1907/2006 (REACH), amended by 2020/878/EU



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SECTION 8: Exposure controls/personal protection

8.1 **Control parameters**

National limit values

Occupational exposure limit values (Workplace Exposure Limits)

Cou ntr y	Name of agent	CAS No	Identi- fier	TW A [pp m]	TWA [mg/ m³]	STE L [pp m]	STEL [mg/ m³]	Ceil ing- C [pp m]	Ceil- ing-C [mg/ m³]	Nota- tion	Source
EU	acetic acid	64-19-7	IOELV	10	25	20	50				2017/ 164/EU
IE	acetic acid	64-19-7	OELV	10	25	20	50				S.I. No. 619 of 2001

Notation

Ceiling-C STEL

Ceiling value is a limit value above which exposure should not occur Short-term exposure limit: a limit value above which exposure should not occur and which is related to a 15-minute period (unless otherwise specified)

TWA Time-weighted average (long-term exposure limit): measured or calculated in relation to a reference period of 8 hours time-weighted average (unless otherwise specified)

8.2 **Exposure controls**

Individual protection measures (personal protective equipment)

Eye/face protection



Use safety goggle with side protection. Wear face protection.

Skin protection



hand protection

Wear suitable gloves. Chemical protection gloves are suitable, which are tested according to EN 374. Check leak-tightness/impermeability prior to use. For special purposes, it is recommended to check the resistance to chemicals of the protective gloves mentioned above together with the supplier of these gloves. The times are approximate values from measurements at 22 ° C and permanent contact. Increased temperatures due to heated substances, body heat etc. and a reduction of the effective layer thickness by stretching can lead to a considerable reduction of the breakthrough time. If in doubt, contact manufacturer. At an approx. 1.5 times larger / smaller layer thickness, the respective breakthrough time is doubled / halved. The data apply only to the pure substance. When transferred to substance mixtures, they may only be considered as a guide.

type of material

Butyl caoutchouc (butyl rubber)

material thickness

0.7mm

according to Regulation (EC) No. 1907/2006 (REACH), amended by 2020/878/EU

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• breakthrough times of the glove material

>480 minutes (permeation: level 6)

• other protection measures

Take recovery periods for skin regeneration. Preventive skin protection (barrier creams/ointments) is recommended.

Respiratory protection



Respiratory protection necessary at: Aerosol or mist formation. Type: E (against acidic gases like sulphur dioxide or hydrogen chloride, colour code: Yellow).

Environmental exposure controls

Keep away from drains, surface and ground water.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state	liquid
Colour	colourless
Odour	pungent
Odour threshold	0,2 – 100,1 ppm
Melting point/freezing point	16,64 °C (ECHA)
Boiling point or initial boiling point and boiling range	117,9 °C at 101,3 kPa (ECHA)
Flammability	flammable liquid in accordance with GHS criteria
Lower and upper explosion limit	4 vol% (LEL) - 19,9 vol% (UEL)
Flash point	39 °C at 101,3 kPa (ECHA)
Auto-ignition temperature	463 °C (ECHA)
Decomposition temperature	not relevant
pH (value)	2,4 (ECHA)
Kinematic viscosity	1,015 ^{mm²} / _s at 25 °C
Dynamic viscosity	1,056 mPa s at 25 °C
Solubility(ies)	
Water solubility	602,9 ^g / _l at 25 °C (ECHA)
Partition coefficient	
Partition coefficient n-octanol/water (log value):	-0,17 (pH value: 7, 25 °C) (ECHA)
Soil organic carbon/water (log KOC)	0,062 (ECHA)

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	Vapour pressure	20,79 hPa at 25 °C
	Density and/or relative density	
	Density	1,05 ^g / _{cm³} at 20 °C
	Relative vapour density	2,07 at 20 °C (air = 1)
	Particle characteristics	not relevant (liquid)
	Other safety parameters	
	Oxidising properties	none
9.2	Other information	
	Information with regard to physical hazard classes:	There is no additional information.
	Other safety characteristics:	
	Maximum explosion pressure	6,3 bar
	Temperature class (EU, acc. to ATEX)	T1 Maximum permissible surface temperature on the equipment: 450°C

SECTION 10: Stability and reactivity

10.1 Reactivity

It's a reactive substance. Risk of ignition.

If heated

Risk of ignition. Vapours may form explosive mixtures with air.

10.2 Chemical stability

The material is stable under normal ambient and anticipated storage and handling conditions of temperature and pressure.

10.3 Possibility of hazardous reactions

Danger of explosion: Peroxides, Perchlorates, Hydrogen peroxide, Chromium(VI) oxide, Permanganates, for example potassium permanganate, strong oxidiser, **Violent reaction with:** Strong alkali, Aldehydes, Alkali hydroxide (caustic alkali), Alcohols, Nitric acid

10.4 Conditions to avoid

Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

10.5 Incompatible materials

different plastics, Rubber articles, iron, copper, bronze, brass, zinc

Release of flammable materials with

Metals (due to the release of hydrogen in an acid/alkaline medium)

10.6 Hazardous decomposition products

Hazardous combustion products: see section 5.

according to Regulation (EC) No. 1907/2006 (REACH), amended by 2020/878/EU



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SECTION 11: Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

Classification according to GHS (1272/2008/EC, CLP)

Acute toxicity

Shall not be classified as acutely toxic.

Acute toxicity

Exposure route	Endpoint	Value	Species	Method	Source
oral	LD50	3.310 ^{mg} / _{kg}	rat		TOXNET

Skin corrosion/irritation

Causes severe skin burns and eye damage.

Serious eye damage/eye irritation

Causes serious eye damage.

Respiratory or skin sensitisation

Shall not be classified as a respiratory or skin sensitiser.

Germ cell mutagenicity

Shall not be classified as germ cell mutagenic.

Carcinogenicity

Shall not be classified as carcinogenic.

Reproductive toxicity

Shall not be classified as a reproductive toxicant.

Specific target organ toxicity - single exposure

Shall not be classified as a specific target organ toxicant (single exposure).

Specific target organ toxicity - repeated exposure

Shall not be classified as a specific target organ toxicant (repeated exposure).

Aspiration hazard

Shall not be classified as presenting an aspiration hazard.

Symptoms related to the physical, chemical and toxicological characteristics

If swallowed

If swallowed danger of perforation of the esophagus and the stomach (strong corrosive effects)

• If in eyes

causes burns, Causes serious eye damage, risk of blindness

• If inhaled

irritant effects, cough, pain, choking, and breathing difficulties

• If on skin

causes severe burns, causes poorly healing wounds

• Other information

none

according to Regulation (EC) No. 1907/2006 (REACH), amended by 2020/878/EU



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11.2 Endocrine disrupting properties

Does not contain an endocrine disruptor (ED) at a concentration of $\ge 0,1\%$.

11.3 Information on other hazards

There is no additional information.

SECTION 12: Ecological information

12.1 Toxicity

Shall not be classified as hazardous to the aquatic environment.

Aquatic toxicity (acute)				
Endpoint	Value	Species	Source	Exposure time
LC50	>300,8 ^{mg} / _l	fish	ECHA	96 h
EC50	>300,8 ^{mg} / _l	aquatic invertebrates	ECHA	48 h
ErC50	>300,8 ^{mg} / _l	algae	ECHA	72 h

12.2 Persistence and degradability

Theoretical Oxygen Demand: 1,066 ^{mg}/_{mg} Theoretical Carbon Dioxide: 1,466 ^{mg}/_{mg}

Biodegradation

The substance is readily biodegradable.

Process of degradability			
Process	Degradation rate	Time	
biotic/abiotic	99 %	30 d	

12.3 Bioaccumulative potential

Does not significantly accumulate in organisms.

n-octanol/water (log KOW)	-0,17 (pH value: 7, 25 °C) (ECHA)
BCF	3,16 (ECHA)

12.4 Mobility in soil

Henry's law constant	0,21 ^{Pa m³} / _{mol} at 25 °C (ECHA)
The Organic Carbon normalised adsorption coefficient	0,062 (ECHA)

12.5 Results of PBT and vPvB assessment

Data are not available.

12.6 Endocrine disrupting properties

Does not contain an endocrine disruptor (ED) at a concentration of $\ge 0,1\%$.

12.7 Other adverse effects

Data are not available.

according to Regulation (EC) No. 1907/2006 (REACH), amended by 2020/878/EU



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SECTION 13: Disposal considerations

13.1 Waste treatment methods



This material and its container must be disposed of as hazardous waste. Dispose of contents/container in accordance with local/regional/national/international regulations.

Sewage disposal-relevant information

Do not empty into drains.

Waste treatment of containers/packagings

It is a dangerous waste; only packagings which are approved (e.g. acc. to ADR) may be used. Handle contaminated packages in the same way as the substance itself. Completely emptied packages can be recycled.

13.2 Relevant provisions relating to waste

The allocation of waste identity numbers/waste descriptions must be carried out according to the EEC, specific to the industry and process.

Properties of waste which render it hazardous

- **HP3** flammable
- HP 4 irritant skin irritation and eye damage
- HP 8 corrosive

13.3 Remarks

Waste shall be separated into the categories that can be handled separately by the local or national waste management facilities. Please consider the relevant national or regional provisions. Non-contaminated packages may be recycled.

SECTION 14: Transport information

14.1 UN number or ID number

	ADRRID	UN 2789
	IMDG-Code	UN 2789
	ICAO-TI	UN 2789
14.2	UN proper shipping name	
	ADRRID	ACETIC ACID, GLACIAL
	IMDG-Code	ACETIC ACID, GLACIAL
	ICAO-TI	Acetic acid, glacial
14.3	Transport hazard class(es)	
14.3	Transport hazard class(es) ADRRID	8 (3)
14.3	•	8 (3) 8 (3)
14.3	ADRRID	
14.3	ADRRID IMDG-Code	8 (3)
	ADRRID IMDG-Code ICAO-TI	8 (3)

according to Regulation (EC) No. 1907/2006 (REACH), amended by 2020/878/EU



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ICAU-II	

II

14.5 Environmental hazards

non-environmentally hazardous acc. to the dangerous goods regulations

14.6 Special precautions for user

Provisions for dangerous goods (ADR) should be complied within the premises.

14.7 Maritime transport in bulk according to IMO instruments

The cargo is not intended to be carried in bulk.

14.8 Information for each of the UN Model Regulations

Agreement concerning the International Carriage of Dangerous Goods by Road (ADR)Additional information

Proper shipping name	ACETIC ACID, GLACIAL
Particulars in the transport document	UN2789, ACETIC ACID, GLACIAL, 8 (3), II, (D/E)
Classification code	CF1
Danger label(s)	8+3
Excepted quantities (EQ)	E2
Limited quantities (LQ)	1 L
Transport category (TC)	2
Tunnel restriction code (TRC)	D/E
Hazard identification No	83

Regulations concerning the International Carriage of Dangerous Goods by Rail (RID)Additional information

Classification code	CF1
Danger label(s)	8+3
Excepted quantities (EQ)	E2
Limited quantities (LQ)	1 L
Transport category (TC)	2
Hazard identification No	83
International Maritime Dangerous Goods Code	e (IMDG) - Additional information
Proper shipping name	ACETIC ACID, GLACIAL
Particulars in the shipper's declaration	UN2789, ACETIC ACID, GLACIAL, 8 (3), II, 39°C c.c.
Marine pollutant	-
Danger label(s)	8+3

according to Regulation (EC) No. 1907/2006 (REACH), amended by 2020/878/EU



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Excepted quantities (EQ)	E2
Limited quantities (LQ)	1 L
EmS	F-E, S-C
Stowage category	A
Segregation group	1 - Acids
International Civil Aviation Organization (ICAO-	IATA/DGR) - Additional information
Proper shipping name	Acetic acid, glacial
Particulars in the shipper's declaration	UN2789, Acetic acid, glacial, 8 (3), II
Danger label(s)	8+3
Excepted quantities (EQ)	E2
Limited quantities (LQ)	0,5 L

SECTION 15: Regulatory information

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

Relevant provisions of the European Union (EU)

Restrictions according to REACH, Annex XVII

Dangerous substances with restrictions (REACH, Annex XVII)				
Name of substance	Name acc. to inventory	CAS No	Restriction	No
Acetic acid	this product meets the criteria for classification in accordance with Reg- ulation No 1272/2008/EC		R3	3
Acetic acid	flammable / pyrophoric		R40	40
Acetic acid	substances in tattoo inks and perman- ent make-up		R75	75

Leaend R3

1. Shall not be used in:

- ornamental articles intended to produce light or colour effects by means of different phases, for example in ornamental lamps and ashtrays,

- tricks and jokes,

games for one or more participants, or any article intended to be used as such, even with ornamental aspects,
Articles not complying with paragraph 1 shall not be placed on the market.
Shall not be placed on the market if they contain a colouring agent, unless required for fiscal reasons, or perfume, or both, if they

 can be used as fuel in decorative oil lamps for supply to the general public, and
 present an aspiration hazard and are labelled with H304.
 Decorative oil lamps for supply to the general public shall not be placed on the market unless they conform to the European Standard on Decorative oil lamps (EN 14059) adopted by the European Committee for Standardisation (CEN). 5. Without prejudice to the implementation of other Union provisions relating to the classification, labelling and pack-

aging of substances and mixtures, suppliers shall ensure, before the placing on the market, that the following requirements are met:

(a) lamp oils, labelled with H304, intended for supply to the general public are visibly, legibly and indelibly marked as follows: "Keep lamps filled with this liquid out of the reach of children"; and, by 1 December 2010, "Just a sip of lamp oil – or even sucking the wick of lamps – may lead to life-threatening lung damage";
(b) grill lighter fluids, labelled with H304, intended for supply to the general public are legibly and indelibly marked by 1 December 2010 as follows: 'Just a sip of grill lighter fluid may lead to life threatening lung damage';
(c) lamps oils and grill lighters, labelled with H304, intended for supply to the general public are packaged in black opaque containers not exceeding 1 litre by 1 December 2010.';

according to Regulation (EC) No. 1907/2006 (REACH), amended by 2020/878/EU



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Legend R40

- 1. Shall not be used, as substance or as mixtures in aerosol dispensers where these aerosol dispensers are intended for supply to the general public for entertainment and decorative purposes such as the following: metallic glitter intended mainly for decoration,
- artificial snow and frost,

- 'whoopee' cushions,
 silly string aerosols,
 imitation excrement,
 horns for parties,
 decorative flakes and foams,
- artificial cobwebs,
- stink bombs.

Without prejudice to the application of other Community provisions on the classification, packaging and labelling of substances, suppliers shall ensure before the placing on the market that the packaging of aerosol dispensers referred to above is marked visibly, legibly and indelibly with: 'For professional users only'.

- 3. By way of derogation, paragraphs 1 and 2 shall not apply to the aerosol dispensers referred to Article 8 (1a) of Council Directive 75/324/EEC (2).

4. The aerosol dispensers referred to in paragraphs 1 and 2 shall not be placed on the market unless they conform to the requirements indicated.

according to Regulation (EC) No. 1907/2006 (REACH), amended by 2020/878/EU



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graph. 8. Mixtures that do not contain the statement "Mixture for use in tattoos or permanent make-up" shall not be used for tattooing purposes. according to Regulation (EC) No. 1907/2006 (REACH), amended by 2020/878/EU



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Legend

9. This entry does not apply to substances that are gases at temperature of 20 °C and pressure of 101,3 kPa, or generate a vapour pressure of more than 300 kPa at temperature of 50 °C, with the exception of formaldehyde (CAS No 50-00-0, EC No 200-001-8).

10. This entry does not apply to the placing on the market of a mixture for use for tattooing purposes, or to the use of a mixture for tattooing purposes, when placed on the market exclusively as a medical device or an accessory to a medical device, within the meaning of Regulation (EU) 2017/745, or when used exclusively as a medical device or an accessory to a medical device, within the same meaning. Where the placing on the market or use may not be exclusively as a medical device or an accessory to a medical device or an accessory to a medical device, the requirements of Regulation (EU) 2017/745 and of this Regulation shall apply cumulatively.

List of substances subject to authorisation (REACH, Annex XIV)/SVHC - candidate list

Not listed.

Seveso Directive

2012/18/EU (Seveso III)					
Νο	Dangerous substance/hazard categories	Qualifying quantity (tonnes) for the ap- plication of lower and upper-tier re- quirements		Notes	
P5c	flammable liquids (cat. 2, 3)	5.000	50.000	51)	

Notation

51) Flammable liquids, categories 2 or 3 not covered by P5a and P5b

Deco-Paint Directive

VOC content	100 %
VOC content	1.040 ^g / _l

Industrial Emissions Directive (IED)

VOC content	100 %
VOC content	1.040 ^g / _l

Directive on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS)

not listed

Regulation concerning the establishment of a European Pollutant Release and Transfer Register (PRTR)

not listed

Water Framework Directive (WFD)

not listed

Regulation on the marketing and use of explosives precursors

not listed

Regulation on drug precursors

not listed

Regulation on substances that deplete the ozone layer (ODS)

not listed

Regulation concerning the export and import of hazardous chemicals (PIC)

not listed

according to Regulation (EC) No. 1907/2006 (REACH), amended by 2020/878/EU



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Regulation on persistent organic pollutants (POP)

not listed

Other information

Directive 94/33/EC on the protection of young people at work. Observe employment restrictions under the Maternity Protection Directive (92/85/EEC) for expectant or nursing mothers.

National inventories

Country	Inventory	Status
AU	AIIC	substance is listed
CA	DSL	substance is listed
CN	IECSC	substance is listed
EU	ECSI	substance is listed
EU	REACH Reg.	substance is listed
JP	CSCL-ENCS	substance is listed
KR	KECI	substance is listed
MX	INSQ	substance is listed
NZ	NZIoC	substance is listed
PH	PICCS	substance is listed
TR	CICR	substance is listed
TW	TCSI	substance is listed
US	TSCA	substance is listed (ACTIVE)
VN	NCI	substance is listed

Legend

Australian Inventory of Industrial Chemicals
Chemical Inventory and Control Regulation
List of Existing and New Chemical Substances (CSCL-ENCS)
Domestic Substances List (DSL)
EC Substance Inventory (EÌNEĆS, ELINCS, NLP)
Inventory of Existing Chemical Substances Produced or Imported in China
National Inventory of Chemical Substances
Korea Existing Chemicals Inventory
National Chemical Inventory
New Zealand Inventory of Chemicals
Philippine Inventory of Chemicals and Chemical Substances (PICCS)
REACH registered substances
Taiwan Chemical Substance Inventory
Toxic Substance Control Act

15.2 Chemical safety assessment

No Chemical Safety Assessment has been carried out for this substance.

according to Regulation (EC) No. 1907/2006 (REACH), amended by 2020/878/EU



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SECTION 16: Other information

Indication of changes (revised safety data sheet)

Section	Former entry (text/value)	Actual entry (text/value)	Safety- relev- ant
2.3	Results of PBT and vPvB assessment: According to the results of its assessment, this substance is not a PBT or a vPvB.		yes
2.3	Endocrine disrupting properties: Does not contain an endocrine disruptor (EDC) in a concentration of ≥ 0,1%.	Endocrine disrupting properties: Does not contain an endocrine disruptor (ED) at a concentration of ≥ 0,1%.	yes
15.1		National inventories: change in the listing (table)	yes

Abbreviations and acronyms

Abbr.	Descriptions of used abbreviations
2017/164/EU	Commission Directive establishing a fourth list of indicative occupational exposure limit values pursuant to Council Directive 98/24/EC, and amending Commission Directives 91/322/EEC, 2000/39/EC and 2009/ 161/EU
ADR	Accord relatif au transport international des marchandises dangereuses par route (Agreement concern- ing the International Carriage of Dangerous Goods by Road)
ATE	Acute Toxicity Estimate
BCF	Bioconcentration factor
CAS	Chemical Abstracts Service (service that maintains the most comprehensive list of chemical substances)
Ceiling-C	Ceiling value
CLP	Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures
DGR	Dangerous Goods Regulations (see IATA/DGR)
EC50	Effective Concentration 50 %. The EC50 corresponds to the concentration of a tested substance causing 50 % changes in response (e.g. on growth) during a specified time interval
EC No	The EC Inventory (EINECS, ELINCS and the NLP-list) is the source for the seven-digit EC number, an identi- fier of substances commercially available within the EU (European Union)
ED	Endocrine disruptor
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of Notified Chemical Substances
EmS	Emergency Schedule
ErC50	= EC50: in this method, that concentration of test substance which results in a 50 % reduction in either growth (EbC50) or growth rate (ErC50) relative to the control
GHS	"Globally Harmonized System of Classification and Labelling of Chemicals" developed by the United Na- tions
IATA	International Air Transport Association
IATA/DGR	Dangerous Goods Regulations (DGR) for the air transport (IATA)
ICAO	International Civil Aviation Organization
ICAO-TI	Technical instructions for the safe transport of dangerous goods by air
IMDG	International Maritime Dangerous Goods Code

according to Regulation (EC) No. 1907/2006 (REACH), amended by 2020/878/EU

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Abbr.	Descriptions of used abbreviations
IMDG-Code	International Maritime Dangerous Goods Code
index No	The Index number is the identification code given to the substance in Part 3 of Annex VI to Regulation (EC) No 1272/2008
IOELV	Indicative occupational exposure limit value
LC50	Lethal Concentration 50%: the LC50 corresponds to the concentration of a tested substance causing 50 % lethality during a specified time interval
LD50	Lethal Dose 50 %: the LD50 corresponds to the dose of a tested substance causing 50 % lethality during a specified time interval
LEL	Lower explosion limit (LEL)
NLP	No-Longer Polymer
PBT	Persistent, Bioaccumulative and Toxic
ppm	Parts per million
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
RID	Règlement concernant le transport International ferroviaire des marchandises Dangereuses (Regula- tions concerning the International carriage of Dangerous goods by Rail)
S.I. No. 619 of 2001	Safety, Health and Welfare at Work (Chemical Agents) Regulations 2001
STEL	Short-term exposure limit
SVHC	Substance of Very High Concern
TWA	Time-weighted average
UEL	Upper explosion limit (UEL)
VOC	Volatile Organic Compounds
vPvB	Very Persistent and very Bioaccumulative

Key literature references and sources for data

Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures. Regulation (EC) No. 1907/2006 (REACH), amended by 2020/878/EU.

Agreement concerning the International Carriage of Dangerous Goods by Road (ADR). Regulations concerning the International Carriage of Dangerous Goods by Rail (RID). International Maritime Dangerous Goods Code (IMDG). Dangerous Goods Regulations (DGR) for the air transport (IATA).

List of relevant phrases (code and full text as stated in section 2 and 3)

Code	Text
H226	Flammable liquid and vapour.
H314	Causes severe skin burns and eye damage.
H318	Causes serious eye damage.

Disclaimer

This information is based upon the present state of our knowledge. This SDS has been compiled and is solely intended for this product.