

Safety data sheet

according to Regulation (EC) No. 1907/2006 (REACH)



Karl-Fischer-ROTI®Hydroquant waterstandard , 30-40 ppm H₂O

article number: 207L
Version: 1.0 en

date of compilation: 2023-02-28

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

1.1 Product identifier

Identification of the substance **Karl-Fischer-ROTI®Hydroquant waterstandard , 30-40 ppm H₂O**
Article number 207L
Registration number (REACH) not relevant (mixture)

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

Relevant identified uses: Laboratory chemical
Laboratory and analytical use
Uses advised against: Do not use for products which come into contact with foodstuffs. Do not use for private purposes (household).

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 sheet: :Department Health, Safety and Environment

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	01 809 2166	https://www.poisons.ie/

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

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

Section	Hazard class	Cat-egory	Hazard class and category	Hazard statement
3.2	Skin corrosion/irritation	2	Skin Irrit. 2	H315
3.3	Serious eye damage/eye irritation	2	Eye Irrit. 2	H319
3.6	Carcinogenicity	2	Carc. 2	H351
3.8D	Specific target organ toxicity - single exposure (narcotic effects, drowsiness)	3	STOT SE 3	H336

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For full text of abbreviations: see SECTION 16

2.2 Label elements

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

Signal word

Warning

Pictograms

GHS07, GHS08



Hazard statements

H315	Causes skin irritation
H319	Causes serious eye irritation
H336	May cause drowsiness or dizziness
H351	Suspected of causing cancer

Precautionary statements

Precautionary statements - prevention

P280 Wear protective gloves/protective clothing/eye protection/face protection

For professional users only

Hazardous ingredients for labelling: Dichloromethane

Labelling of packages where the contents do not exceed 125 ml

Signal word: **Warning**

Symbol(s)



H351	Suspected of causing cancer.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
contains:	Dichloromethane

2.3 Other hazards

Results of PBT and vPvB assessment

This mixture does not contain any substances that are assessed to be a PBT or a vPvB.

Endocrine disrupting properties

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

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SECTION 3: Composition/information on ingredients

3.1 Substances

not relevant (mixture)

3.2 Mixtures

Description of the mixture

Name of substance	Identifier	Wt%	Classification acc. to GHS	Pictograms	Notes
Dichloromethane	CAS No 75-09-2 EC No 200-838-9 Index No 602-004-00-3	99 - < 100	Skin Irrit. 2 / H315 Eye Irrit. 2 / H319 Carc. 2 / H351 STOT SE 3 / H336		GHS-HC IARC: 2A IOELV

Notes

GHS-HC: Harmonised classification (the classification of the substance corresponds to the entry in the list according to 1272/2008/EC, Annex VI)

IARC: IARC group 2A: probably carcinogenic to humans (International Agency for Research on Cancer)

2A:

IOELV: Substance with a community indicative occupational exposure limit value

For full text of abbreviations: see SECTION 16

SECTION 4: First aid measures

4.1 Description of first aid measures



General notes

Take off contaminated clothing.

Following inhalation

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

Following skin contact

Rinse skin with water/shower. In case of skin irritation, consult a physician.

Following eye contact

Irrigate copiously with clean, fresh water for at least 10 minutes, holding the eyelids apart. In case of eye irritation consult an ophthalmologist.

Following ingestion

In case of accident or unwellness, seek medical advice immediately (show directions for use or safety data sheet if possible).

4.2 Most important symptoms and effects, both acute and delayed

Irritation, Nausea, Vomiting, Cough, Vertigo, Dyspnoea, Drowsiness, Dizziness, Narcosis

4.3 Indication of any immediate medical attention and special treatment needed

none

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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

Ingredients of the mixture combustible. The product itself does not burn.

Hazardous combustion products

Carbon monoxide (CO), Carbon dioxide (CO₂), Hydrogen chloride (HCl), Hydrogen halides (HX)

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.

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.

6.2 Environmental precautions

Keep away from drains, surface and ground water.

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.

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SECTION 7: Handling and storage

7.1 Precautions for safe handling

Avoid exposure. Provide adequate ventilation as well as local exhaustion at critical locations. When not in use, keep containers tightly closed.

Advice on general occupational hygiene

Wash hands before breaks and after work. Keep away from food, drink and animal feedingstuffs.

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.

Protect against external exposure, such as

direct light irradiation, UV-radiation/sunlight

Consideration of other advice:

Specific designs for storage rooms or vessels

Recommended storage temperature: 15 – 25 °C

7.3 Specific end use(s)

No information available.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

National limit values

Occupational exposure limit values (Workplace Exposure Limits)

Country	Name of agent	CAS No	Identifier	TWA [ppm]	TWA [mg/m ³]	STEL [ppm]	STEL [mg/m ³]	Ceiling-C [ppm]	Ceiling-C [mg/m ³]	Notation	Source
EU	methylene chloride (dichloromethane)	75-09-2	IOELV	100	353	200	706			H	2017/164/EU
IE	dichloromethane	75-09-2	OELV	100	353	200	706			H	S.I. No. 619 of 2001

Notation

Ceiling-C	Ceiling value is a limit value above which exposure should not occur
H	Absorbed through the skin
STEL	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)

Relevant DNELs of components of the mixture

Name of substance	CAS No	Endpoint	Threshold level	Protection goal, route of exposure	Used in	Exposure time
Dichloromethane	75-09-2	DNEL	706 mg/m ³	human, inhalatory	worker (industry)	acute - systemic effects

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Relevant DNELs of components of the mixture						
Name of substance	CAS No	End-point	Threshold level	Protection goal, route of exposure	Used in	Exposure time
Dichloromethane	75-09-2	DNEL	176 mg/m ³	human, inhalatory	worker (industry)	chronic - systemic effects
Dichloromethane	75-09-2	DNEL	12 mg/kg bw/day	human, dermal	worker (industry)	chronic - systemic effects

Relevant PNECs of components of the mixture						
Name of substance	CAS No	End-point	Threshold level	Organism	Environmental compartment	Exposure time
Dichloromethane	75-09-2	PNEC	0,31 mg/l	aquatic organisms	freshwater	short-term (single instance)
Dichloromethane	75-09-2	PNEC	0,031 mg/l	aquatic organisms	marine water	short-term (single instance)
Dichloromethane	75-09-2	PNEC	26 mg/l	aquatic organisms	sewage treatment plant (STP)	short-term (single instance)
Dichloromethane	75-09-2	PNEC	2,57 mg/kg	aquatic organisms	freshwater sediment	short-term (single instance)
Dichloromethane	75-09-2	PNEC	0,26 mg/kg	aquatic organisms	marine sediment	short-term (single instance)
Dichloromethane	75-09-2	PNEC	0,33 mg/kg	terrestrial organisms	soil	short-term (single instance)

8.2 Exposure controls

Individual protection measures (personal protective equipment)

Eye/face protection



Use safety goggle with side protection.

Skin protection



• hand protection

Wear suitable gloves. Chemical protection gloves are suitable, which are tested according to EN 374. 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.

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- **type of material**

FKM: fluoro-elastomer

- **material thickness**

0,7mm

- **breakthrough times of the glove material**

>120 minutes (permeation: level 4)

- **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: AX (gas filters and combined filters against low-boiling point organic compounds, colour code: Brown).

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	characteristic
Melting point/freezing point	-95 °C
Boiling point or initial boiling point and boiling range	40 °C
Flammability	non-combustible
Lower and upper explosion limit	13 vol% (LEL) - 22 vol% (UEL)
Flash point	not determined
Auto-ignition temperature	605 °C
Decomposition temperature	not relevant
pH (value)	6 – 8 (20 °C)
Kinematic viscosity	0,3233 mm ² /s at 20 °C
Dynamic viscosity	0,43 mPa s at 20 °C
<u>Solubility(ies)</u>	
Water solubility	20 g/l at 20 °C
<u>Partition coefficient</u>	
Partition coefficient n-octanol/water (log value):	this information is not available

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Vapour pressure	453 hPa at 20 °C
<u>Density and/or relative density</u>	
Density	1,33 g/cm ³ at 20 °C
Relative vapour density	information on this property is not available

Particle characteristics not relevant (liquid)

Other safety parameters

Oxidising properties none

9.2 Other information

Information with regard to physical hazard classes: hazard classes acc. to GHS (physical hazards): not relevant

Other safety characteristics:

Temperature class (EU, acc. to ATEX) T1
Maximum permissible surface temperature on the equipment: 450°C

SECTION 10: Stability and reactivity

10.1 Reactivity

This material is not reactive under normal ambient conditions.

10.2 Chemical stability

May cause decomposition by long-term light influence.

10.3 Possibility of hazardous reactions

Danger of explosion: Alkali metals, Nitric acid, Aluminium, Amines, Nitrogen oxides (NO_x),
Exothermic reaction with: Alkaline earth metal, Metal powder, Strong alkali

10.4 Conditions to avoid

Direct light irradiation. UV-radiation/sunlight.

10.5 Incompatible materials

Steel, aluminium, different plastics, Rubber articles

10.6 Hazardous decomposition products

Hazardous combustion products: see section 5.

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SECTION 11: Toxicological information

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

Test data are not available for the complete mixture.

Classification procedure

The method for classification of the mixture is based on ingredients of the mixture (additivity formula).

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

Acute toxicity

Shall not be classified as acutely toxic.

Acute toxicity of components of the mixture					
Name of substance	CAS No	Exposure route	Endpoint	Value	Species
Dichloromethane	75-09-2	oral	LD50	>2.000 mg/kg	rat
Dichloromethane	75-09-2	dermal	LD50	>2.000 mg/kg	rat

Skin corrosion/irritation

Causes skin irritation.

Serious eye damage/eye irritation

Causes serious eye irritation.

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

Suspected of causing cancer.

Reproductive toxicity

Shall not be classified as a reproductive toxicant.

Specific target organ toxicity - single exposure

May cause drowsiness or dizziness.

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

vomiting, nausea

• If in eyes

Causes serious eye irritation, corneal opacity

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• If inhaled

vertigo, dizziness, fatigue, narcosis

• If on skin

causes skin irritation

• Other information

Other adverse effects: Liver and kidney damage, Circulatory collapse, Headache, Dyspnoea, Blood pressure drop

11.2 Endocrine disrupting properties

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

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) of components of the mixture					
Name of substance	CAS No	Endpoint	Value	Species	Exposure time
Dichloromethane	75-09-2	LC50	193 mg/l	fish	96 h

Aquatic toxicity (chronic) of components of the mixture					
Name of substance	CAS No	Endpoint	Value	Species	Exposure time
Dichloromethane	75-09-2	LC50	471 mg/l	fish	8 d
Dichloromethane	75-09-2	EC50	2,590 mg/l	microorganisms	40 min

12.2 Persistence and degradability

Biodegradation

The relevant substances of the mixture are readily biodegradable.

Degradability of components of the mixture						
Name of substance	CAS No	Process	Degradation rate	Time	Method	Source
Dichloromethane	75-09-2	biotic/abiotic	5 - 26 %	28 d		
Dichloromethane	75-09-2	oxygen depletion	68 %	28 d		ECHA

12.3 Bioaccumulative potential

Data are not available.

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Bioaccumulative potential of components of the mixture

Name of substance	CAS No	BCF	Log KOW	BOD5/COD
Dichloromethane	75-09-2	39	1,25 (pH value: 7, 20 °C)	

12.4 Mobility in soil

Data are not available.

12.5 Results of PBT and vPvB assessment

Data are not available.

12.6 Endocrine disrupting properties

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

12.7 Other adverse effects

Data are not available.

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.

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

HP 4 irritant - skin irritation and eye damage

HP 7 carcinogenic

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.

SECTION 14: Transport information

14.1 UN number or ID number

ADRRID UN 1593

IMDG-Code UN 1593

ICAO-TI UN 1593

14.2 UN proper shipping name

ADRRID DICHLOROMETHANE



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IMDG-Code	DICHLOROMETHANE
ICAO-TI	Dichloromethane
14.3 Transport hazard class(es)	
ADRRID	6.1
IMDG-Code	6.1
ICAO-TI	6.1
14.4 Packing group	
ADRRID	III
IMDG-Code	III
ICAO-TI	III
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	DICHLOROMETHANE
Particulars in the transport document	UN1593, DICHLOROMETHANE, 6.1, III, (E)
Classification code	T1
Danger label(s)	6.1
	
Special provisions (SP)	516, 802(ADN)
Excepted quantities (EQ)	E1
Limited quantities (LQ)	5 L
Transport category (TC)	2
Tunnel restriction code (TRC)	E
Hazard identification No	60
Regulations concerning the International Carriage of Dangerous Goods by Rail (RID)Additional information	
Classification code	T1
Danger label(s)	6.1
	

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Special provisions (SP) 516, 802(ADN)

Excepted quantities (EQ) E1

Limited quantities (LQ) 5 L

Transport category (TC) 2

Hazard identification No 60

International Maritime Dangerous Goods Code (IMDG) - Additional information

Proper shipping name DICHLOROMETHANE

Particulars in the shipper's declaration UN1593, DICHLOROMETHANE, 6.1, III

Marine pollutant -

Danger label(s) 6.1



Special provisions (SP) -

Excepted quantities (EQ) E1

Limited quantities (LQ) 5 L

EmS F-A, S-A

Stowage category A

Segregation group 10 - Liquid halogenated hydrocarbons

International Civil Aviation Organization (ICAO-IATA/DGR) - Additional information

Proper shipping name Dichloromethane

Particulars in the shipper's declaration UN1593, Dichloromethane, 6.1, III

Danger label(s) 6.1



Excepted quantities (EQ) E1

Limited quantities (LQ) 2 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
Karl-Fischer-ROTI®Hydroquant water-standard	this product meets the criteria for classification in accordance with Regulation No 1272/2008/EC		R3	3
Dichloromethane	dichloromethane	75-09-2	R59	59

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Dangerous substances with restrictions (REACH, Annex XVII)				
Name of substance	Name acc. to inventory	CAS No	Restriction	No
Dichloromethane	substances in tattoo inks and permanent make-up		R75	75

Legend

- R3
- 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).
 - Without prejudice to the implementation of other Union provisions relating to the classification, labelling and packaging of substances and mixtures, suppliers shall ensure, before the placing on the market, that the following requirements are met:
 - 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";
 - 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';
 - 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.;
- R59
- Paint strippers containing dichloromethane in a concentration equal to or greater than 0,1 % by weight shall not be:
 - placed on the market for the first time for supply to the general public or to professionals after 6 December 2010;
 - placed on the market for supply to the general public or to professionals after 6 December 2011;
 - used by professionals after 6 June 2012.
 For the purposes of this entry:
 - 'professional' means any natural or legal person, including workers and self-employed workers undertaking paint stripping in the course of their professional activity outside an industrial installation;
 - 'industrial installation' means a facility used for paint stripping activities.
 - By way of derogation from paragraph 1, Member States may allow on their territories and for certain activities the use, by specifically trained professionals, of paint strippers containing dichloromethane and may allow the placing on the market of such paint strippers for supply to those professionals. Member States making use of this derogation shall define appropriate provisions for the protection of the health and safety of those professionals using paint strippers containing dichloromethane and shall inform the Commission thereof. Those provisions shall include a requirement that a professional shall hold a certificate that is accepted by the Member State in which that professional operates, or provide other documentary evidence to that effect, or be otherwise approved by that Member State, so as to demonstrate proper training and competence to safely use paint strippers containing dichloromethane. The Commission shall prepare a list of the Member States which have made use of the derogation in this paragraph and make it publicly available over the Internet.
 - A professional benefiting from the derogation referred to in paragraph 2 shall operate only in Member States which have made use of that derogation. The training referred to in paragraph 2 shall cover as a minimum:
 - awareness, evaluation and management of risks to health, including information on existing substitutes or processes, which under their conditions of use are less hazardous to the health and safety of workers;
 - use of adequate ventilation;
 - use of appropriate personal protective equipment that complies with Directive 89/686/EEC. Employers and self-employed workers shall preferably replace dichloromethane with a chemical agent or process which, under its conditions of use, presents no risk, or a lower risk, to the health and safety of workers. Professional shall apply all relevant safety measures in practice, including the use of personal protective equipment.
 - Without prejudice to other Community legislation on workers protection, paint strippers containing dichloromethane in concentrations equal to or greater than 0,1 % by weight may be used in industrial installations only if the following minimum conditions are met:
 - effective ventilation in all processing areas, in particular for the wet processing and the drying of stripped articles: local exhaust ventilation at strip tanks supplemented by forced ventilation in those areas, so as to minimise exposure and to ensure compliance, where technically feasible, with relevant occupational exposure limits;
 - measures to minimise evaporation from strip tanks comprising: lids for covering strip tanks except during loading and unloading; suitable loading and unloading arrangements for strip tanks; and wash tanks with water or brine to remove excess solvent after unloading;
 - measures for the safe handling of dichloromethane in strip tanks comprising: pumps and pipework for transferring paint stripper to and from strip tanks; and suitable arrangements for safe cleaning of tanks and removal of sludge;
 - personal protective equipment that complies with Directive 89/686/EEC comprising: suitable protective gloves, safety goggles and protective clothing; and appropriate respiratory protective equipment where compliance with relevant occupational exposure limits cannot be otherwise achieved;
 - adequate information, instruction and training for operators in the use of such equipment.
 - Without prejudice to other Community provisions concerning the classification, labelling and packaging of substances and mixtures, by 6 December 2011 paint strippers containing dichloromethane in a concentration equal to or greater than 0,1 % by weight shall be visibly, legibly and indelibly marked as follows:
'Restricted to industrial use and to professionals approved in certain EU Member States - verify where use is allowed.'

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Legend

- R75
1. Shall not be placed on the market in mixtures for use for tattooing purposes, and mixtures containing any such substances shall not be used for tattooing purposes, after 4 January 2022 if the substance or substances in question is or are present in the following circumstances:
 - (a) in the case of a substance classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 as carcinogen category 1A, 1B or 2, or germ cell mutagen category 1A, 1B or 2, the substance is present in the mixture in a concentration equal to or greater than 0,00005 % by weight;
 - (b) in the case of a substance classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 as reproductive toxicant category 1A, 1B or 2, the substance is present in the mixture in a concentration equal to or greater than 0,001 % by weight;
 - (c) in the case of a substance classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 as skin sensitiser category 1, 1A or 1B, the substance is present in the mixture in a concentration equal to or greater than 0,001 % by weight;
 - (d) in the case of a substance classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 as skin corrosive category 1, 1A, 1B or 1C or skin irritant category 2, or as serious eye damage category 1 or eye irritant category 2, the substance is present in the mixture in a concentration equal to or greater than:
 - (i) 0,1 % by weight, if the substance is used solely as a pH regulator;
 - (ii) 0,01 % by weight, in all other cases;
 - (e) in the case of a substance listed in Annex II to Regulation (EC) No 1223/2009 (*1), the substance is present in the mixture in a concentration equal to or greater than 0,00005 % by weight;
 - (f) in the case of a substance for which a condition of one or more of the following kinds is specified in column g (Product type, Body parts) of the table in Annex IV to Regulation (EC) No 1223/2009, the substance is present in the mixture in a concentration equal to or greater than 0,00005 % by weight:
 - (i) "Rinse-off products";
 - (ii) "Not to be used in products applied on mucous membranes";
 - (iii) "Not to be used in eye products";
 - (g) in the case of a substance for which a condition is specified in column h (Maximum concentration in ready for use preparation) or column i (Other) of the table in Annex IV to Regulation (EC) No 1223/2009, the substance is present in the mixture in a concentration, or in some other way, that does not accord with the condition specified in that column;
 - (h) in the case of a substance listed in Appendix 13 to this Annex, the substance is present in the mixture in a concentration equal to or greater than the concentration limit specified for that substance in that Appendix.
 2. For the purposes of this entry use of a mixture "for tattooing purposes" means injection or introduction of the mixture into a person's skin, mucous membrane or eyeball, by any process or procedure (including procedures commonly referred to as permanent make-up, cosmetic tattooing, micro-blading and micro-pigmentation), with the aim of making a mark or design on his or her body.
 3. If a substance not listed in Appendix 13 falls within more than one of points (a) to (g) of paragraph 1, the strictest concentration limit laid down in the points in question shall apply to that substance. If a substance listed in Appendix 13 also falls within one or more of points (a) to (g) of paragraph 1, the concentration limit laid down in point (h) of paragraph 1 shall apply to that substance.
 4. By way of derogation, paragraph 1 shall not apply to the following substances until 4 January 2023:
 - (a) Pigment Blue 15:3 (CI 74160, EC No 205-685-1, CAS No 147-14-8);
 - (b) Pigment Green 7 (CI 74260, EC No 215-524-7, CAS No 1328-53-6).
 5. If Part 3 of Annex VI to Regulation (EC) No 1272/2008 is amended after 4 January 2021 to classify or re-classify a substance such that the substance then becomes caught by point (a), (b), (c) or (d) of paragraph 1 of this entry, or such that it then falls within a different one of those points from the one within which it fell previously, and the date of application of that new or revised classification is after the date referred to in paragraph 1 or, as the case may be, paragraph 4 of this entry, that amendment shall, for the purposes of applying this entry to that substance, be treated as taking effect on the date of application of that new or revised classification.
 6. If Annex II or Annex IV to Regulation (EC) No 1223/2009 is amended after 4 January 2021 to list or change the listing of a substance such that the substance then becomes caught by point (e), (f) or (g) of paragraph 1 of this entry, or such that it then falls within a different one of those points from the one within which it fell previously, and the amendment takes effect after the date referred to in paragraph 1 or, as the case may be, paragraph 4 of this entry, that amendment shall, for the purposes of applying this entry to that substance, be treated as taking effect from the date falling 18 months after entry into force of the act by which that amendment was made.
 7. Suppliers placing a mixture on the market for use for tattooing purposes shall ensure that, after 4 January 2022, the mixture is marked with the following information:
 - (a) the statement "Mixture for use in tattoos or permanent make-up";
 - (b) a reference number to uniquely identify the batch;
 - (c) the list of ingredients in accordance with the nomenclature established in the glossary of common ingredient names pursuant to Article 33 of Regulation (EC) No 1223/2009, or in the absence of a common ingredient name, the IUPAC name. In the absence of a common ingredient name or IUPAC name, the CAS and EC number. Ingredients shall be listed in descending order by weight or volume of the ingredients at the time of formulation. "Ingredient" means any substance added during the process of formulation and present in the mixture for use for tattooing purposes. Impurities shall not be regarded as ingredients. If the name of a substance, used as ingredient within the meaning of this entry, is already required to be stated on the label in accordance with Regulation (EC) No 1272/2008, that ingredient does not need to be marked in accordance with this Regulation;
 - (d) the additional statement "pH regulator" for substances falling under point (d)(i) of paragraph 1;
 - (e) the statement "Contains nickel. Can cause allergic reactions." if the mixture contains nickel below the concentration limit specified in Appendix 13;
 - (f) the statement "Contains chromium (VI). Can cause allergic reactions." if the mixture contains chromium (VI) below the concentration limit specified in Appendix 13;
 - (g) safety instructions for use insofar as they are not already required to be stated on the label by Regulation (EC) No 1272/2008.The information shall be clearly visible, easily legible and marked in a way that is indelible. The information shall be written in the official language(s) of the Member State(s) where the mixture is placed on the market, unless the Member State(s) concerned provide(s) otherwise. Where necessary because of the size of the package, the information listed in the first subparagraph, except for point (a), shall be included instead in the instructions for use. Before using a mixture for tattooing purposes, the person using the mixture shall provide the person undergoing the procedure with the information marked on the package or included in the instructions for use pursuant to this paragraph.
 8. Mixtures that do not contain the statement "Mixture for use in tattoos or permanent make-up" shall not be used for tattooing purposes.

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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, 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

None of the ingredients are listed.

Seveso Directive

2012/18/EU (Seveso III)			
No	Dangerous substance/hazard categories	Qualifying quantity (tonnes) for the application of lower and upper-tier requirements	Notes
	not assigned		

Deco-Paint Directive

VOC content	100 % 1.330 g/l
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Industrial Emissions Directive (IED)

VOC content	100 %
VOC content	1.330 g/l

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

none of the ingredients are listed

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

Pollutant release and transfer registers (PRTR)			
Name of substance	CAS No	Remarks	Threshold for releases to air (kg/year)
Dichloromethane	75-09-2		1 000

Water Framework Directive (WFD)

List of pollutants (WFD)				
Name of substance	Name acc. to inventory	CAS No	Listed in	Remarks
Dichloromethane	dichloromethane	75-09-2	b)	
Dichloromethane	dichloromethane	75-09-2	c)	
Dichloromethane	Organohalogen compounds and substances which may form such compounds in the aquatic environment		a)	

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List of pollutants (WFD)				
Name of substance	Name acc. to inventory	CAS No	Listed in	Remarks
Dichloromethane	Substances and preparations, or the breakdown products of such, which have been proved to possess carcinogenic or mutagenic properties or properties which may affect steroidogenic, thyroid, reproduction or other endocrine-related functions in or via the aquatic environment		a)	

Legend

- A) Indicative list of the main pollutants
- B) List of priority substances in the field of water policy
- C) Environmental Quality Standards for Priority Substances and certain other pollutants

Regulation on the marketing and use of explosives precursors

none of the ingredients are listed

Regulation on drug precursors

none of the ingredients are listed

Regulation on substances that deplete the ozone layer (ODS)

none of the ingredients are listed

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

none of the ingredients are listed

Regulation on persistent organic pollutants (POP)

none of the ingredients are 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	all ingredients are listed
CA	DSL	all ingredients are listed
CN	IECSC	all ingredients are listed
EU	ECSI	all ingredients are listed
EU	REACH Reg.	all ingredients are listed
JP	CSCL-ENCS	all ingredients are listed
KR	KECI	all ingredients are listed
MX	INSQ	all ingredients are listed
NZ	NZIoC	all ingredients are listed
PH	PICCS	all ingredients are listed
TR	CICR	all ingredients are listed
TW	TCSI	all ingredients are listed

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Country	Inventory	Status
US	TSCA	all ingredients are listed as "ACTIVE"

Legend

AIIC	Australian Inventory of Industrial Chemicals
CICR	Chemical Inventory and Control Regulation
CSCL-ENCS	List of Existing and New Chemical Substances (CSCL-ENCS)
DSL	Domestic Substances List (DSL)
EC SI	EC Substance Inventory (EINECS, ELINCS, NLP)
IECSC	Inventory of Existing Chemical Substances Produced or Imported in China
INSQ	National Inventory of Chemical Substances
KECI	Korea Existing Chemicals Inventory
NZIoC	New Zealand Inventory of Chemicals
PICCS	Philippine Inventory of Chemicals and Chemical Substances (PICCS)
REACH Reg.	REACH registered substances
TCSI	Taiwan Chemical Substance Inventory
TSCA	Toxic Substance Control Act

15.2 Chemical Safety Assessment

Chemical safety assessments for substances in this mixture were not carried out.

SECTION 16: Other information

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 concerning the International Carriage of Dangerous Goods by Road)
BCF	Bioconcentration factor
BOD	Biochemical Oxygen Demand
Carc.	Carcinogenicity
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
COD	Chemical oxygen demand
DGR	Dangerous Goods Regulations (see IATA/DGR)
DNEL	Derived No-Effect Level
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 identifier of substances commercially available within the EU (European Union)
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of Notified Chemical Substances
EmS	Emergency Schedule
Eye Dam.	Seriously damaging to the eye
Eye Irrit.	Irritant to the eye
GHS	"Globally Harmonized System of Classification and Labelling of Chemicals" developed by the United Nations

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Abbr.	Descriptions of used abbreviations
IARC	International Agency for Research on Cancer
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
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)
log KOW	n-Octanol/water
NLP	No-Longer Polymer
PBT	Persistent, Bioaccumulative and Toxic
PNEC	Predicted No-Effect Concentration
ppm	Parts per million
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
RID	Règlement concernant le transport International ferroviaire des marchandises Dangereuses (Regulations 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
Skin Corr.	Corrosive to skin
Skin Irrit.	Irritant to skin
STEL	Short-term exposure limit
STOT SE	Specific target organ toxicity - single exposure
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.

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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).

Classification procedure

Physical and chemical properties. The classification is based on tested mixture. Health hazards. Environmental hazards. The method for classification of the mixture is based on ingredients of the mixture (additivity formula).

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

Code	Text
H315	Causes skin irritation.
H319	Causes serious eye irritation.
H336	May cause drowsiness or dizziness.
H351	Suspected of causing cancer.

Disclaimer

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