

Cyclohexanon

Version number: 8.0
Replaces version of: 20.12.2022 (7)

Revision: 18.03.2024

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

1.1 Product identifier

Identification of the substance	Cyclohexanon
Registration number (REACH)	01-2119453616-35-xxxx
EC number	203-631-1
Index number in CLP Annex VI	606-010-00-7
CAS number	108-94-1

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

Relevant identified uses	Industrial use
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1.3 Details of the supplier of the safety data sheet

FRIEDRICH SCHARR KG
Liebknechtstraße 50
70565 Stuttgart
Germany

Telephone: +49 711 7868-0
Telefax: +49 711 7868-489
e-mail: info@scharr.de
Website: www.scharr.de

e-mail (competent person) produktsicherheit@scharr.de

1.4 Emergency telephone number

Poison centre			
Country	Name	Postal code/city	Telephone
Germany	Giftinformation Freiburg	79106 Freiburg im Breisgau	+49 (0)761 19240

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

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

Hazard class	Category	Hazard class and category	Hazard statement
flammable liquid	3	Flam. Liq. 3	H226
acute toxicity (oral)	4	Acute Tox. 4	H302
acute toxicity (dermal)	4	Acute Tox. 4	H312
acute toxicity (inhal.)	4	Acute Tox. 4	H332
skin corrosion/irritation	2	Skin Irrit. 2	H315
serious eye damage/eye irritation	1	Eye Dam. 1	H318
specific target organ toxicity - single exposure (respiratory tract irritation)	3	STOT SE 3	H335

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For full text of abbreviations: see SECTION 16.

The most important adverse physicochemical, human health and environmental effects

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)

- signal word danger

- pictograms

GHS02, GHS05, GHS07



- hazard statements

H226	Flammable liquid and vapour.
H302+H312+H332	Harmful if swallowed, in contact with skin or if inhaled.
H315	Causes skin irritation.
H318	Causes serious eye damage.
H335	May cause respiratory irritation.

- precautionary statements

P210	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P261	Avoid breathing dust/fume/gas/mist/vapours/spray.
P280	Wear protective gloves/protective clothing/eye protection/face protection/hearing protection/....
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P370+P378	In case of fire: Use sand, carbon dioxide or powder extinguisher to extinguish.
P403+P233	Store in a well-ventilated place. Keep container tightly closed.
P403+P235	Store in a well-ventilated place. Keep cool.
P501	Dispose of contents/container to industrial combustion plant.

2.3 Other hazards

Results of PBT and vPvB assessment

According to the results of its assessment, this substance is not a PBT or a vPvB.

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	cyclohexanone
Identifiers	
REACH Reg. No	01-2119453616-35-xxxx
EC No	203-631-1
CAS No	108-94-1
Index No	606-010-00-7

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Specific Conc. Limits	M-Factors	ATE	Exposure route
-	-	500 mg/kg 1.100 mg/kg >11 mg/l/4h	oral dermal inhalation: vapour

SECTION 4: First aid measures

4.1 Description of first aid measures

General notes

Do not leave affected person unattended. Remove victim out of the danger area. Take off immediately all contaminated clothing. In all cases of doubt, or when symptoms persist, seek medical advice. In case of unconsciousness place person in the recovery position. Never give anything by mouth. Self-protection of the first aider.

Following inhalation

If breathing is irregular or stopped, immediately seek medical assistance and start first aid actions. In case of respiratory tract irritation, consult a physician. Provide fresh air.

Following skin contact

Wash with plenty of soap and water.

Following eye contact

Remove contact lenses, if present and easy to do. Continue rinsing. Irrigate copiously with clean, fresh water for at least 10 minutes, holding the eyelids apart.

Following ingestion

Rinse mouth with water (only if the person is conscious). Do NOT induce vomiting. Call a physician immediately.

4.2 Most important symptoms and effects, both acute and delayed

Breathing difficulties. Headache. Vertigo.

4.3 Indication of any immediate medical attention and special treatment needed

Subsequent observance for pneumonia and pulmonary oedema. Supervise the blood circulation.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media

Water spray, BC-powder, Carbon dioxide (CO₂), Sand

Unsuitable extinguishing media

Water jet

5.2 Special hazards arising from the substance or mixture

In case of insufficient ventilation and/or in use, may form flammable/explosive vapour-air 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. Danger of bursting container.

Hazardous combustion products

Carbon monoxide (CO), Carbon dioxide (CO₂)

5.3 Advice for firefighters

In case of fire and/or explosion do not breathe fumes. Co-ordinate firefighting measures to the fire surroundings. Do not allow firefighting water to enter drains or water courses. Collect contaminated firefighting water separately. Fight fire with normal precautions from a reasonable distance.

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SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

Remove persons to safety. Ventilate affected area. Avoidance of ignition sources.

For emergency responders

Wear breathing apparatus if exposed to vapours/dust/spray/gases. Provision of sufficient ventilation.

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

Wipe up with absorbent material (e.g. cloth, fleece). Collect spillage: sawdust, kieselgur (diatomite), sand, universal binder

Appropriate containment techniques

Use of adsorbent materials.

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

Recommendations

- measures to prevent fire as well as aerosol and dust generation

Use local and general ventilation. Avoidance of ignition sources. Keep away from sources of ignition - No smoking. Take precautionary measures against static discharge. Use only in well-ventilated areas. Due to danger of explosion, prevent leakage of vapours into cellars, flues and ditches. Ground/bond container and receiving equipment. Use explosion-proof electrical/ventilating/lighting/equipment. Use only non-sparking tools.

- specific notes/details

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.

Advice on general occupational hygiene

Wash hands after use. Do not eat, drink and smoke in work areas. Remove contaminated clothing and protective equipment before entering eating areas. Never keep food or drink in the vicinity of chemicals. Never place chemicals in containers that are normally used for food or drink. Keep away from food, drink and animal feedingstuffs.

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7.2 Conditions for safe storage, including any incompatibilities

Managing of associated risks

- explosive atmospheres

Keep container tightly closed and in a well-ventilated place. Use local and general ventilation. Keep cool. Protect from sunlight.

- flammability hazards

Keep away from sources of ignition - No smoking. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Take precautionary measures against static discharge. Protect from sunlight.

- ventilation requirements

Keep any substance that emits harmful vapours or gases in a place that allows these to be permanently extracted. Use local and general ventilation. Ground/bond container and receiving equipment.

- Lagerklasse (storage class according to TRGS 510, 3 (flammable and desensitizing explosive liquids) Germany)

- packaging compatibilities

Only packagings which are approved (e.g. acc. to ADR) may be used.

7.3 Specific end use(s)

See section 16 for a general overview.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational exposure limit values (Workplace Exposure Limits)								
Country	Name of substance	CAS No	Identifier	TWA [ppm]	TWA [mg/m ³]	STEL [ppm]	STEL [mg/m ³]	Source
AT	cyclohexanone	108-94-1	MAK	5	20	20	80	GKV
CH	cyclohexanone	108-94-1	MAK	25	100	50	200	SUVA
DE	cyclohexanone	108-94-1	MAK					DFG
DE	cyclohexanone	108-94-1	AGW	20	80	20	80	TRGS 900
EU	cyclohexanone	108-94-1	IOELV	10	40,8	20	81,6	2000/39/EC

Notation

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)

Biological limit values						
Country	Name of agent	Parameter	Notation	Identifier	Value	Source
CH	cyclohexanone	1,2-cyclohexanediol		BAT	100 mg/l	SUVA
CH	cyclohexanone	cyclohexanol		BAT	12 mg/l	SUVA

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Human health values

Relevant DNELs and other threshold levels				
Endpoint	Threshold level	Protection goal, route of exposure	Used in	Exposure time
DNEL	10 mg/m ³	human, inhalatory	worker (industry)	chronic - systemic effects
DNEL	20 mg/m ³	human, inhalatory	worker (industry)	acute - systemic effects
DNEL	10 mg/m ³	human, inhalatory	worker (industry)	chronic - local effects
DNEL	20 mg/m ³	human, inhalatory	worker (industry)	acute - local effects
DNEL	4 mg/kg bw/day	human, dermal	worker (industry)	chronic - systemic effects
DNEL	4 mg/kg bw/day	human, dermal	worker (industry)	acute - systemic effects

Environmental values

Relevant PNECs and other threshold levels				
End-point	Threshold level	Organism	Environmental compartment	Exposure time
PNEC	0,329 mg/l	aquatic organisms	water	intermittent release
PNEC	0,356 mg/l	aquatic organisms	freshwater	short-term (single instance)
PNEC	0,036 mg/l	aquatic organisms	marine water	short-term (single instance)
PNEC	10 mg/l	aquatic organisms	sewage treatment plant (STP)	short-term (single instance)
PNEC	2,69 mg/kg	aquatic organisms	freshwater sediment	short-term (single instance)
PNEC	0,269 mg/kg	aquatic organisms	marine sediment	short-term (single instance)
PNEC	0,328 mg/kg	terrestrial organisms	soil	short-term (single instance)

8.2 Exposure controls

Appropriate engineering controls

General ventilation.

Individual protection measures (personal protective equipment)

Eye/face protection

Wear eye/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. In the case of wanting to use the gloves again, clean them before taking off and air them well. 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.

- type of material

PE: polyethylene, CR: chloroprene (chlorobutadiene) rubber, IIR: isobutene-isoprene (butyl) rubber

- material thickness

> 0,35 mm

- breakthrough times of the glove material

0,4 mm

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>120 minutes (permeation: level 4)

- other protection measures

Take recovery periods for skin regeneration. Preventive skin protection (barrier creams/ointments) is recommended. Wash hands thoroughly after handling.

Respiratory protection

[In case of inadequate ventilation] wear respiratory protection. Combination filtering device (EN 141). Type: A (against organic gases and vapours with a boiling point of > 65 °C, colour code: Brown).

Environmental exposure controls

Use appropriate container to avoid environmental contamination. 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	-31 °C
Boiling point or initial boiling point and boiling range	154,3 °C at 1.013 hPa
Evaporation rate	not determined
Flammability	flammable liquid in accordance with GHS criteria
Lower and upper explosion limit	1,1 vol% - 9,4 vol%
Flash point	44 °C at 1.013 hPa
Auto-ignition temperature	420 °C at 1.013 hPa
pH (value)	6,6 (in aqueous solution: 60 g/l, 20 °C)

Solubility(ies)

Water solubility	86 g/l at 20 °C
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Partition coefficient

Partition coefficient n-octanol/water (log value)	0,86 (25 °C)
Soil organic carbon/water (log KOC)	1,18

Vapour pressure	7 hPa at 30 °C
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Density and/or relative density

Density	946,5 kg/m ³ at 20 °C
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Particle characteristics	not relevant (liquid)
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9.2 Other information

Information with regard to physical hazard classes	there is no additional information
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Other safety characteristics

Temperature class (EU, acc. to ATEX)	T2 (maximum permissible surface temperature on the equipment: 300°C)
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SECTION 10: Stability and reactivity

10.1 Reactivity

Concerning incompatibility: see below "Conditions to avoid" and "Incompatible materials". It's a reactive substance. The mixture contains reactive substance(s). Risk of ignition.

If heated:

Risk of ignition

10.2 Chemical stability

See below "Conditions to avoid".

10.3 Possibility of hazardous reactions

In case of insufficient ventilation and/or in use, may form flammable/explosive vapour-air mixture.

10.4 Conditions to avoid

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

Hints to prevent fire or explosion

Use explosion-proof electrical/ventilating/lighting/equipment. Use only non-sparking tools. Take precautionary measures against static discharge.

10.5 Incompatible materials

Oxidisers

10.6 Hazardous decomposition products

Reasonably anticipated hazardous decomposition products produced as a result of use, storage, spill and heating are not known. 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

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

Acute toxicity

Harmful if swallowed. Harmful in contact with skin. Harmful if inhaled.

- acute toxicity estimate (ATE)

Oral 500 mg/kg
Dermal 1.100 mg/kg
Inhalation: vapour >11 mg/l/4h

Acute toxicity			
Exposure route	Endpoint	Value	Species
oral	LD50	2.650 mg/kg	rat
dermal	LD50	3.160 mg/kg	rabbit
inhalation: vapour	LC50	>6,2 mg/l/4h	rat

Skin corrosion/irritation

Causes skin irritation.

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

May cause respiratory irritation.

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.

11.2 Information on other hazards

There is no additional information.

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SECTION 12: Ecological information

12.1 Toxicity

Acc. to 1272/2008/EC: Shall not be classified as hazardous to the aquatic environment.
Verordnung über Anlagen zum Umgang mit wassergefährdenden Stoffen (Ordinance on facilities for handling substances hazardous to water) (AwSV): WGK 1, slightly hazardous to water (Germany)

Aquatic toxicity (acute)			
Endpoint	Value	Species	Exposure time
ErC50	32,9 mg/l	algae	72 h
EC50	>100 mg/l	aquatic invertebrates	48 h
LC50	732 mg/l	fish	96 h

Aquatic toxicity (chronic)			
Endpoint	Value	Species	Exposure time
EC50	>1.000 mg/l	microorganisms	30 min

12.2 Persistence and degradability

Biodegradation

The substance is readily biodegradable. The relevant substances of the mixture are readily biodegradable. Data are not available.

Process of degradability		
Process	Degradation rate	Time
oxygen depletion	90 – 100 %	28 d

12.3 Bioaccumulative potential

Data are not available.

n-octanol/water (log KOW)	0,86 (25 °C)
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12.4 Mobility in soil

Henry's law constant	1,21 Pa m ³ /mol at 25 °C
The Organic Carbon normalised adsorption coefficient	1,18 (ECHA)

12.5 Results of PBT and vPvB assessment

According to the results of its assessment, this substance is not a PBT or a vPvB.

12.6 Endocrine disrupting properties

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

12.7 Other adverse effects

Data are not available.

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SECTION 13: Disposal considerations

13.1 Waste treatment methods

Waste treatment-relevant information

Solvent reclamation/regeneration.

Sewage disposal-relevant information

Do not empty into drains. Avoid release to the environment. Refer to special instructions/safety data sheets.

Waste treatment of containers/packagings

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

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.

Remarks

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

SECTION 14: Transport information

14.1 UN number or ID number

ADR/RID/ADN	UN 1915
IMDG-Code	UN 1915
ICAO-TI	UN 1915

14.2 UN proper shipping name

ADR/RID/ADN	CYCLOHEXANONE
IMDG-Code	CYCLOHEXANONE
ICAO-TI	Cyclohexanone

14.3 Transport hazard class(es)

ADR/RID/ADN	3
IMDG-Code	3
ICAO-TI	3

14.4 Packing group

ADR/RID/ADN	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.

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Information for each of the UN Model Regulations

Transport of dangerous goods by road, rail and inland waterway (ADR/RID/ADN) - additional information

Classification code F1

Danger label(s) 3



Excepted quantities (EQ) E1

Limited quantities (LQ) 5 L

Transport category (TC) 3

Tunnel restriction code (TRC) D/E

Hazard identification No 30

International Maritime Dangerous Goods Code (IMDG) - additional information

Marine pollutant -

Danger label(s) 3



Special provisions (SP) -

Excepted quantities (EQ) E1

Limited quantities (LQ) 5 L

EmS F-E, S-D

Stowage category A

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

Danger label(s) 3



Excepted quantities (EQ) E1

Limited quantities (LQ) 10 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
cyclohexanone	this product meets the criteria for classification in accordance with Regulation No 1272/2008/EC		R3	3

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Dangerous substances with restrictions (REACH, Annex XVII)				
Name of substance	Name acc. to inventory	CAS No	Restriction	No
cyclohexanone	flammable / pyrophoric		R40	40
cyclohexanone	substances in tattoo inks and permanent make-up		R75	75

Legend

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,
2. Articles not complying with paragraph 1 shall not be placed on the market.
3. 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.
4. 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 packaging 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.;

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.
2. 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.

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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.

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Legend

8. Mixtures that do not contain the statement "Mixture for use in tattoos or permanent make-up" shall not be used for tattooing purposes.
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

not 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
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

Industrial Emissions Directive (IED)

VOC content	100 %
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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 persistent organic pollutants (POP)

not listed

National regulations (Germany)

Verordnung über Anlagen zum Umgang mit wassergefährdenden Stoffen (Ordinance on facilities for handling substances hazardous to water) (AwSV)

Wassergefährdungsklasse, WGK 1 slightly hazardous to water
(water hazard class)

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Technical instructions on air quality control (Germany)

Number	Group of substances	Class	Conc.	Mass flow	Mass concentration	Notation
5.2.5	organic substances		≥ 25 wt%	0,5 kg/h	50 mg/m ³	3)

Notation

3) a total mass flow of 0.50 kg/h or a total mass concentration of 50 mg/m³, each of which to be indicated as total carbon, shall not be exceeded (except organic particulate matter)

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

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)
ECSI	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
NCI	National Chemical 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

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

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SECTION 16: Other information

Indication of changes (revised safety data sheet)

Section	Former entry (text/value)	Actual entry (text/value)
2.3		Endocrine disrupting properties: Does not contain an endocrine disruptor (ED) at a concentration of $\geq 0,1\%$.
3.1		Index No: change in the listing (table)
8.2	Type of material: IIR: isobutene-isoprene (butyl) rubber	Type of material: PE: polyethylene, CR: chloroprene (chlorobutadiene) rubber, IIR: isobutene-isoprene (butyl) rubber
8.2	Material thickness: > 0,7 mm	Material thickness: > 0,35 mm
8.2	Breakthrough times of the glove material: 0,4 mm >480 minutes (permeation: level 6)	Breakthrough times of the glove material: 0,4 mm >120 minutes (permeation: level 4)
8.2	Respiratory protection: [In case of inadequate ventilation] wear respiratory protection. Type: AX (gas filters and combined filters against low-boiling point organic compounds, colour code: Brown).	Respiratory protection: [In case of inadequate ventilation] wear respiratory protection. Combination filtering device (EN 141). Type: A (against organic gases and vapours with a boiling point of > 65 °C, colour code: Brown).
11.1		- acute toxicity estimate (ATE): change in the listing (table)
12.5	Results of PBT and vPvB assessment: Data are not available.	Results of PBT and vPvB assessment: According to the results of its assessment, this substance is not a PBT or a vPvB.
12.6	Endocrine disrupting properties: Not listed.	Endocrine disrupting properties: Does not contain an endocrine disruptor (ED) at a concentration of $\geq 0,1\%$.

Abbreviations and acronyms

Abbr.	Descriptions of used abbreviations
2000/39/EC	Commission Directive establishing a first list of indicative occupational exposure limit values in implementation of Council Directive 98/24/EC
ADN	Accord européen relatif au transport international des marchandises dangereuses par voies de navigation intérieures (European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways)
ADR	Accord relatif au transport international des marchandises dangereuses par route (Agreement concerning the International Carriage of Dangerous Goods by Road)
ADR/RID/ADN	Agreements concerning the International Carriage of Dangerous Goods by Road/Rail/Inland Waterways (ADR/RID/ADN)
AGW	Workplace exposure limit
ATE	Acute Toxicity Estimate
CAS	Chemical Abstracts Service (service that maintains the most comprehensive list of chemical substances)
CLP	Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures
DFG	Deutsche Forschungsgemeinschaft MAK-und BAT-Werte-Liste, Senatskommission zur Prüfung gesundheitsschädlicher Arbeitsstoffe, Wiley-VCH, Weinheim

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Abbr.	Descriptions of used abbreviations
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)
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 Nations
GKV	Grenzwerteverordnung
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
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)
STEL	Short-term exposure limit
SUVA	Grenzwerte am Arbeitsplatz, Suva
SVHC	Substance of Very High Concern

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Abbr.	Descriptions of used abbreviations
TRGS	Technische Regeln für Gefahrstoffe (technical rules for hazardous substances, Germany)
TRGS 900	Arbeitsplatzgrenzwerte (TRGS 900)
TWA	Time-weighted average
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.

Transport of dangerous goods by road, rail and inland waterway (ADR/RID/ADN). 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.
H302	Harmful if swallowed.
H312	Harmful in contact with skin.
H315	Causes skin irritation.
H318	Causes serious eye damage.
H332	Harmful if inhaled.
H335	May cause respiratory irritation.

Disclaimer

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