

# Safety data sheet

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



ROTI®Mark SMALL-KOMBI , ready-to-use

article number: 1LCN  
Version: 1.0 en

date of compilation: 2021-09-30

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

### 1.1 Product identifier

Identification of the substance **ROTI®Mark SMALL-KOMBI , ready-to-use**  
Article number 1LCN  
Registration number (REACH) not relevant (mixture)

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

Relevant identified uses: Laboratory and analytical use  
Laboratory chemical  
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 Service City Hospital	Dudley Rd	B187QH Birmingham	844 892 0111	

## 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
3.3	Serious eye damage/eye irritation	2	Eye Irrit. 2	H319

### Supplemental hazard information

Code	Supplemental hazard information
EUH208	contains Iodoacetamide. May produce an allergic reaction

For full text of abbreviations: see SECTION 16

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## 2.2 Label elements

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

**Signal word**

**Warning**

**Pictograms**

GHS07



**Hazard statements**

H319

Causes serious eye irritation

**Precautionary statements**

**Precautionary statements - prevention**

P280

Wear protective gloves/eye protection

**Supplemental hazard information**

EUH208

Contains Iodoacetamide. May produce an allergic reaction.

**Labelling of packages where the contents do not exceed 125 ml**

Signal word: **Warning**

Symbol(s)



EUH208

Contains Iodoacetamide. May produce an allergic reaction.

## 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.

## 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
Glycerine	CAS No 56-81-5  EC No 200-289-5	15 – < 20			IOELV

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Name of substance	Identifier	Wt%	Classification acc. to GHS	Pictograms	Notes
Sodium dodecyl sulfate	CAS No 151-21-3 EC No 205-788-1	≤ 2	Acute Tox. 4 / H302 Skin Irrit. 2 / H315 Eye Dam. 1 / H318 Aquatic Chronic 3 / H412		
Iodoacetamide	CAS No 144-48-9 EC No 205-630-1	0,1 – 0,2	Acute Tox. 3 / H301 Skin Irrit. 2 / H315 Eye Irrit. 2 / H319 Skin Sens. 1 / H317 STOT SE 3 / H335		

## Notes

IOELV: Substance with a community indicative occupational exposure limit value

Name of substance	Identifier	Specific Conc. Limits	M-Factors	ATE	Exposure route
Sodium dodecyl sulfate	CAS No 151-21-3 EC No 205-788-1	-	-	977 mg/kg	oral
Iodoacetamide	CAS No 144-48-9 EC No 205-630-1	-	-	74 mg/kg	oral

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 all cases of doubt, or when symptoms persist, seek medical advice.

#### 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

Rinse mouth. Call a doctor if you feel unwell.

### 4.2 Most important symptoms and effects, both acute and delayed

Irritation, Allergic reactions

### 4.3 Indication of any immediate medical attention and special treatment needed

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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 (CO<sub>2</sub>)

#### 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

In case of fire may be liberated: Nitrogen oxides (NO<sub>x</sub>), Carbon monoxide (CO), Carbon dioxide (CO<sub>2</sub>)

### 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

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

No special measures are necessary.

#### 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

Keep in a cool place.

#### Incompatible substances or mixtures

Observe hints for combined storage.

#### Consideration of other advice:

#### Specific designs for storage rooms or vessels

Recommended storage temperature: -20 °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 <sup>3</sup> ]	STEL [ppm]	STEL [mg/m <sup>3</sup> ]	Ceiling-C [ppm]	Ceiling-C [mg/m <sup>3</sup> ]	Notation	Source
GB	glycerol	56-81-5	WEL		10					mist	EH40/2005

#### Notation

Ceiling-C Ceiling value is a limit value above which exposure should not occur

mist As mists

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	End-point	Threshold level	Protection goal, route of exposure	Used in	Exposure time
Glycerine	56-81-5	DNEL	56 mg/m <sup>3</sup>	human, inhalatory	worker (industry)	chronic - local effects
Sodium dodecyl sulfate	151-21-3	DNEL	285 mg/m <sup>3</sup>	human, inhalatory	worker (industry)	chronic - systemic effects
Sodium dodecyl sulfate	151-21-3	DNEL	4.060 mg/kg bw/day	human, dermal	worker (industry)	chronic - systemic effects

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Relevant PNECs of components of the mixture						
Name of substance	CAS No	End-point	Threshold level	Organism	Environmental compartment	Exposure time
Glycerine	56-81-5	PNEC	8,85 mg/l	aquatic organisms	water	intermittent release
Glycerine	56-81-5	PNEC	0,885 mg/l	aquatic organisms	freshwater	short-term (single instance)
Glycerine	56-81-5	PNEC	0,088 mg/l	aquatic organisms	marine water	short-term (single instance)
Glycerine	56-81-5	PNEC	1.000 mg/l	aquatic organisms	sewage treatment plant (STP)	short-term (single instance)
Glycerine	56-81-5	PNEC	3,3 mg/kg	aquatic organisms	freshwater sediment	short-term (single instance)
Glycerine	56-81-5	PNEC	0,33 mg/kg	aquatic organisms	marine sediment	short-term (single instance)
Glycerine	56-81-5	PNEC	0,141 mg/kg	terrestrial organisms	soil	short-term (single instance)
Sodium dodecyl sulfate	151-21-3	PNEC	0,176 mg/l	aquatic organisms	freshwater	short-term (single instance)
Sodium dodecyl sulfate	151-21-3	PNEC	0,018 mg/l	aquatic organisms	marine water	short-term (single instance)
Sodium dodecyl sulfate	151-21-3	PNEC	1,35 mg/l	aquatic organisms	sewage treatment plant (STP)	short-term (single instance)
Sodium dodecyl sulfate	151-21-3	PNEC	6,97 mg/kg	aquatic organisms	freshwater sediment	short-term (single instance)
Sodium dodecyl sulfate	151-21-3	PNEC	0,697 mg/kg	aquatic organisms	marine sediment	short-term (single instance)
Sodium dodecyl sulfate	151-21-3	PNEC	1,29 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



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### • 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.

### • type of material

NBR (Nitrile rubber)

### • material thickness

>0,11 mm

### • 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: A (against organic gases and vapours with a boiling point of > 65 °C , 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	blue
Odour	characteristic
Melting point/freezing point	not determined
Boiling point or initial boiling point and boiling range	100 °C at 1.013 hPa
Flammability	non-combustible
Lower and upper explosion limit	not determined
Flash point	not determined
Auto-ignition temperature	not determined
Decomposition temperature	not relevant
pH (value)	5 – 6 (20 °C)
Kinematic viscosity	not determined

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### Solubility(ies)

Water solubility miscible in any proportion

### Partition coefficient

Partition coefficient n-octanol/water (log value): this information is not available

Vapour pressure not determined

Density ~1 g/cm<sup>3</sup>

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:

Miscibility completely miscible with water

## SECTION 10: Stability and reactivity

### 10.1 Reactivity

This material is not reactive under normal ambient conditions.

### 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

No known hazardous reactions.

### 10.4 Conditions to avoid

There are no specific conditions known which have to be avoided.

### 10.5 Incompatible materials

There is no additional information.

### 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 estimate (ATE) of components of the mixture

Name of substance	CAS No	Exposure route	ATE
Sodium dodecyl sulfate	151-21-3	oral	977 mg/kg
Iodoacetamide	144-48-9	oral	74 mg/kg

#### Acute toxicity of components of the mixture

Name of substance	CAS No	Exposure route	Endpoint	Value	Species
Glycerine	56-81-5	dermal	LD50	>10.000 mg/kg	rabbit
Glycerine	56-81-5	oral	LD50	12.600 mg/kg	rat
Sodium dodecyl sulfate	151-21-3	oral	LD50	977 mg/kg	rat
Sodium dodecyl sulfate	151-21-3	dermal	LD50	>2.000 mg/kg	rat
Iodoacetamide	144-48-9	oral	LD50	74 mg/kg	mouse

#### Skin corrosion/irritation

Shall not be classified as corrosive/irritant to skin.

#### Serious eye damage/eye irritation

Causes serious eye irritation.

#### Respiratory or skin sensitisation

Contains Iodoacetamide. May produce an allergic reaction.

#### 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).

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## Aspiration hazard

Shall not be classified as presenting an aspiration hazard.

## Symptoms related to the physical, chemical and toxicological characteristics

### • If swallowed

Data are not available.

### • If in eyes

Causes serious eye irritation

### • If inhaled

Data are not available.

### • If on skin

May produce an allergic reaction, pruritis, localised redness

### • Other information

none

## 11.2 Endocrine disrupting properties

None of the ingredients are listed.

## 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
Glycerine	56-81-5	LC50	54.000 mg/l	rainbow trout (Oncorhynchus mykiss)	96 h
Sodium dodecyl sulfate	151-21-3	LC50	29 mg/l	fish	96 h
Sodium dodecyl sulfate	151-21-3	ErC50	>120 mg/l	algae	72 h

#### Aquatic toxicity (chronic) of components of the mixture

Name of substance	CAS No	Endpoint	Value	Species	Exposure time
Sodium dodecyl sulfate	151-21-3	EC50	135 mg/l	microorganisms	3 h

## Biodegradation

Data are not available.

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## 12.2 Process of degradability

Degradability of components of the mixture						
Name of substance	CAS No	Process	Degradation rate	Time	Method	Source
Glycerine	56-81-5	biotic/abiotic	63 %	14 d		
Sodium dodecyl sulfate	151-21-3	biotic/abiotic	90 %	28 d		
Sodium dodecyl sulfate	151-21-3	carbon dioxide generation	95 %	28 d		ECHA

## 12.3 Bioaccumulative potential

Data are not available.

Bioaccumulative potential of components of the mixture				
Name of substance	CAS No	BCF	Log KOW	BOD5/COD
Glycerine	56-81-5		-1,75 (pH value: 7,4, 25 °C)	
Sodium dodecyl sulfate	151-21-3		≤-2,03 (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

None of the ingredients are listed.

## 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.

### 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. Waste catalogue ordinance (Germany).

### 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.

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## SECTION 14: Transport information

- 14.1 UN number or ID number** not subject to transport regulations
- 14.2 UN proper shipping name** not assigned
- 14.3 Transport hazard class(es)** none
- 14.4 Packing group** not assigned
- 14.5 Environmental hazards** non-environmentally hazardous acc. to the dangerous goods regulations
- 14.6 Special precautions for user**  
There is no additional information.
- 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

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

Not subject to ADR, RID and ADN.

#### International Maritime Dangerous Goods Code (IMDG) - Additional information

Not subject to IMDG.

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

Not subject to ICAO-IATA.

## 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
ROTI®Mark SMALL-KOMBI	this product meets the criteria for classification in accordance with Regulation No 1272/2008/EC		R3	3
Iodoacetamide	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:

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## Legend

- (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.;

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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	2,055 %
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### Industrial Emissions Directive (IED)

VOC content	0,055 %
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### 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)

none of the ingredients are listed

### Water Framework Directive (WFD)

List of pollutants (WFD)				
Name of substance	Name acc. to inventory	CAS No	Listed in	Remarks
Sodium dodecyl sulfate	Metals and their compounds		A)	
Iodoacetamide	Organohalogen compounds and substances which may form such compounds in the aquatic environment		A)	

### Legend

A) Indicative list of the main 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

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### 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	AICS	not all ingredients are listed
CA	DSL	not all ingredients are listed
CN	IECSC	not all ingredients are listed
EU	ECSI	not all ingredients are listed
EU	REACH Reg.	not all ingredients are listed
JP	CSCL-ENCS	not all ingredients are listed
JP	ISHA-ENCS	not all ingredients are listed
KR	KECI	not all ingredients are listed
MX	INSQ	not all ingredients are listed
NZ	NZIoC	not all ingredients are listed
PH	PICCS	not all ingredients are listed
TR	CICR	not all ingredients are listed
TW	TCSI	not all ingredients are listed
US	TSCA	not all ingredients are listed

#### Legend

AICS	Australian Inventory of Chemical Substances
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
ISHA-ENCS	Inventory of Existing and New Chemical Substances (ISHA-ENCS)
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.



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## SECTION 16: Other information

### Abbreviations and acronyms

Abbr.	Descriptions of used abbreviations
Acute Tox.	Acute toxicity
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)
Aquatic Chronic	Hazardous to the aquatic environment - chronic hazard
ATE	Acute Toxicity Estimate
BCF	Bioconcentration factor
BOD	Biochemical Oxygen Demand
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)
EH40/2005	EH40/2005 Workplace exposure limits ( <a href="http://www.nationalarchives.gov.uk/doc/open-government-licence/">http://www.nationalarchives.gov.uk/doc/open-government-licence/</a> )
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of Notified Chemical Substances
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
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
IATA	International Air Transport Association
IATA/DGR	Dangerous Goods Regulations (DGR) for the air transport (IATA)
ICAO	International Civil Aviation Organization
IMDG	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
LC50	Lethal Concentration 50%: the LC50 corresponds to the concentration of a tested substance causing 50 % lethality during a specified time interval

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Abbr.	Descriptions of used abbreviations
LD50	Lethal Dose 50 %: the LD50 corresponds to the dose of a tested substance causing 50 % lethality during a specified time interval
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)
Skin Corr.	Corrosive to skin
Skin Irrit.	Irritant to skin
Skin Sens.	Skin sensitisation
STEL	Short-term exposure limit
STOT SE	Specific target organ toxicity - single exposure
SVHC	Substance of Very High Concern
TWA	Time-weighted average
VOC	Volatile Organic Compounds
vPvB	Very Persistent and very Bioaccumulative
WEL	Workplace exposure limit

## 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).

## 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 chapter 2 and 3)

Code	Text
H301	Toxic if swallowed.
H302	Harmful if swallowed.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.

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Code	Text
H412	Harmful to aquatic life with long lasting effects.

## Disclaimer

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