

Safety data sheet

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



Hyperforin / Adhyperforin Dicyclohexylammonium salt, Mixture 4:1 ROTICHROM® HPLC

article number: **6495**
Version: **1.0 en**

date of compilation: 2021-09-07

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

1.1 Product identifier

Identification of the substance	Hyperforin / Adhyperforin Dicyclohexylammonium salt, Mixture 4:1 ROTICHROM® HPLC
Article number	6495
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 squirting or spraying. Do not use for products which come into direct contact with the skin. 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)

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Section	Hazard class	Cat-egory	Hazard class and category	Hazard statement
3.10	Acute toxicity (oral)	4	Acute Tox. 4	H302
3.2	Skin corrosion/irritation	1B	Skin Corr. 1B	H314
3.3	Serious eye damage/eye irritation	1	Eye Dam. 1	H318
4.1A	Hazardous to the aquatic environment - acute hazard	1	Aquatic Acute 1	H400

For full text of abbreviations: see SECTION 16

The most important adverse physicochemical, human health and environmental effects

Skin corrosion produces an irreversible damage to the skin; namely, visible necrosis through the epidermis and into the dermis. Spillage and fire water can cause pollution of watercourses.

2.2 Label elements

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

Signal word

Danger

Pictograms

GHS05, GHS07,
GHS09



Hazard statements

H302 Harmful if swallowed
H314 Causes severe skin burns and eye damage
H400 Very toxic to aquatic life

Precautionary statements

Precautionary statements - prevention

P260 Do not breathe dust/fume/gas/mist/vapours/spray
P280 Wear protective gloves/eye protection/face protection

Precautionary statements - response

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

Hazardous ingredients for labelling:

Hyperforin (dicyclohexylammonium) salt

Labelling of packages where the contents do not exceed 125 ml

Signal word: **Danger**

Symbol(s)



H314 Causes severe skin burns and eye damage.

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P260 Do not breathe dust/fume/gas/mist/vapours/spray.
P280 Wear protective gloves/eye protection/face protection.
P301+P330+P331 IF SWALLOWED: rinse mouth. Do NOT induce vomiting.
P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water or shower.
P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

contains: Hyperforin (dicyclohexylammonium) salt

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
Hyperforin (dicyclohexylammonium) salt	CAS No 238074-03-8	80	Acute Tox. 4 / H302 Skin Corr. 1B / H314 Aquatic Acute 1 / H400		

Name of substance	Identifier	Specific Conc. Limits	M-Factors	ATE	Exposure route
Hyperforin (dicyclohexylammonium) salt	CAS No 238074-03-8	-	-	500 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 immediately all contaminated clothing. Self-protection of the first aider.

Following inhalation

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

Following skin contact

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

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Following eye contact

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

Following ingestion

Rinse mouth immediately and drink plenty of water. Rinse mouth with water (only if the person is
conscious). Call a physician immediately. If swallowed danger of perforation of the esophagus and
the stomach (strong corrosive effects). Call a doctor.

4.2 Most important symptoms and effects, both acute and delayed

Corrosion, Vomiting, Risk of blindness, Gastric perforation, Risk of serious damage to eyes

4.3 Indication of any immediate medical attention and special treatment needed

none

SECTION 5: Firefighting measures

5.1 Extinguishing media



Suitable extinguishing media

co-ordinate firefighting measures to the fire surroundings
water, foam, dry extinguishing powder, ABC-powder

Unsuitable extinguishing media

water jet

5.2 Special hazards arising from the substance or mixture

None.

Hazardous combustion products

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

5.3 Advice for firefighters

In case of fire and/or explosion do not breathe fumes. Do not allow firefighting water to enter drains
or water courses. Fight fire with normal precautions from a reasonable distance. Wear self-contained
breathing apparatus. Wear full chemical protective clothing.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures



For non-emergency personnel

Wearing of suitable protective equipment (including personal protective equipment referred to un-
der Section 8 of the safety data sheet) to prevent any contamination of skin, eyes and personal cloth-
ing. Avoid contact with skin, eyes and clothes. Do not breathe dust.

6.2 Environmental precautions

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

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of it.

6.3 Methods and material for containment and cleaning up

Advice on how to contain a spill

Covering of drains. Take up mechanically.

Advice on how to clean up a spill

Take up mechanically. Control of dust.

Other information relating to spills and releases

Place in appropriate containers for disposal.

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

Handle and open container with care. Avoid dust formation. Clear contaminated areas thoroughly.

Measures to prevent fire as well as aerosol and dust generation

Removal of dust deposits.

Measures to protect the environment

Avoid release to the environment.

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 dry place. Keep in a cool place.

Incompatible substances or mixtures

Observe hints for combined storage.

Consideration of other advice:

Ventilation requirements

Use local and general ventilation.

Specific designs for storage rooms or vessels

Recommended storage temperature: -20 °C

7.3 Specific end use(s)

No information available.

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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 [mg/m ³]	STEL [mg/m ³]	Ceiling-C [mg/m ³]	Notation	Source
IE	dusts non-specific		OELV	10			i	S.I. No. 619 of 2001
IE	dusts non-specific		OELV	4			r	S.I. No. 619 of 2001

Notation

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

i Inhalable fraction

r Respirable fraction

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)

8.2 Exposure controls

Individual protection measures (personal protective equipment)

Eye/face protection



Use safety goggle with side protection. Wear face protection.

Skin protection



• hand protection

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

• type of material

NBR (Nitrile rubber)

• material thickness

>0,11 mm

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- **breakthrough times of the glove material**

>480 minutes (permeation: level 6)

- **other protection measures**

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

Respiratory protection



Respiratory protection necessary at: Dust formation. Particulate filter device (EN 143). P2 (filters at least 94 % of airborne particles, colour code: White).

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	solid
Form	powder, crystalline
Colour	colourless
Odour	odourless
Melting point/freezing point	not determined
Boiling point or initial boiling point and boiling range	100 °C (unknown)
Flammability	this material is combustible, but will not ignite readily
Lower and upper explosion limit	not determined
Flash point	not applicable
Auto-ignition temperature	not determined
Decomposition temperature	not relevant
pH (value)	not applicable
Kinematic viscosity	not relevant
<u>Solubility(ies)</u>	
Water solubility	not determined
<u>Partition coefficient</u>	
Partition coefficient n-octanol/water (log value):	this information is not available
Vapour pressure	not determined

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Density	not determined
Relative vapour density	information on this property is not available
Particle characteristics	No data available.
<u>Other safety parameters</u>	
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:	There is no additional information.

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

Violent reaction with: strong oxidiser

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.

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

Harmful if swallowed.

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Acute toxicity estimate (ATE) of components of the mixture			
Name of substance	CAS No	Exposure route	ATE
Hyperforin (dicyclohexylammonium) salt	238074-03-8	oral	500 mg/kg

Skin corrosion/irritation

Causes severe skin burns and eye damage.

Serious eye damage/eye irritation

Causes serious eye damage.

Respiratory or skin sensitisation

Shall not be classified as a respiratory or skin sensitiser.

Germ cell mutagenicity

Shall not be classified as germ cell mutagenic.

Carcinogenicity

Shall not be classified as carcinogenic.

Reproductive toxicity

Shall not be classified as a reproductive toxicant.

Specific target organ toxicity - single exposure

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

Specific target organ toxicity - repeated exposure

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

Aspiration hazard

Shall not be classified as presenting an aspiration hazard.

Symptoms related to the physical, chemical and toxicological characteristics

• If swallowed

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

• If in eyes

causes burns, Causes serious eye damage, risk of blindness

• If inhaled

Data are not available.

• If on skin

causes severe burns, causes poorly healing wounds

• 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.

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SECTION 12: Ecological information

12.1 Toxicity

Very toxic to aquatic life.

Biodegradation

Data are not available.

12.2 Process of degradability

Data are not available.

12.3 Bioaccumulative potential

Data are not available.

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. 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.

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

ADR/RID/ADN	UN 1759
IMDG-Code	UN 1759
ICAO-TI	UN 1759

14.2 UN proper shipping name

ADR/RID/ADN	CORROSIVE SOLID, N.O.S.
IMDG-Code	CORROSIVE SOLID, N.O.S.
ICAO-TI	Corrosive solid, n.o.s.
Technical name (hazardous ingredients)	Hyperforin (dicyclohexylammonium) salt

14.3 Transport hazard class(es)

ADR/RID/ADN	8
IMDG-Code	8
ICAO-TI	8

14.4 Packing group

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

14.5 Environmental hazards

	hazardous to the aquatic environment
Environmentally hazardous substance (aquatic environment):	Hyperforin (dicyclohexylammonium) salt

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

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

Proper shipping name	CORROSIVE SOLID, N.O.S.
Particulars in the transport document	UN1759, CORROSIVE SOLID, N.O.S., (contains: Hyperforin (dicyclohexylammonium) salt), 8, II, (E), environmentally hazardous
Classification code	C10
Danger label(s)	8, "Fish and tree"



Environmental hazards	yes (hazardous to the aquatic environment)
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Special provisions (SP)	274
Excepted quantities (EQ)	E2
Limited quantities (LQ)	1 kg
Transport category (TC)	2
Tunnel restriction code (TRC)	E
Hazard identification No	80

International Maritime Dangerous Goods Code (IMDG) - Additional information

Proper shipping name	CORROSIVE SOLID, N.O.S.
Particulars in the shipper's declaration	UN1759, CORROSIVE SOLID, N.O.S., (contains: Hyperforin (dicyclohexylammonium) salt), 8, II, MARINE POLLUTANT
Marine pollutant	yes (hazardous to the aquatic environment), (Hyperforin (dicyclohexylammonium) salt)
Danger label(s)	8, "Fish and tree"



Special provisions (SP)	274
Excepted quantities (EQ)	E2
Limited quantities (LQ)	1 kg
EmS	F-A, S-B
Stowage category	A

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

Proper shipping name	Corrosive solid, n.o.s.
Particulars in the shipper's declaration	UN1759, Corrosive solid, n.o.s., (contains: Hyperforin (dicyclohexylammonium) salt), 8, II
Environmental hazards	yes (hazardous to the aquatic environment)
Danger label(s)	8



Special provisions (SP)	A3
Excepted quantities (EQ)	E2
Limited quantities (LQ)	5 kg

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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
Hyperforin (dicyclohexylammonium) salt	substances in tattoo inks and permanent make-up		R75	75

Legend

- R75
- 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:
 - 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;
 - 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;
 - 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;
 - 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:
 - 0,1 % by weight, if the substance is used solely as a pH regulator;
 - 0,01 % by weight, in all other cases;
 - 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;
 - 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:
 - "Rinse-off products";
 - "Not to be used in products applied on mucous membranes";
 - "Not to be used in eye products";
 - 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;
 - 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.
 - 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.
 - 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.
 - By way of derogation, paragraph 1 shall not apply to the following substances until 4 January 2023:
 - Pigment Blue 15:3 (CI 74160, EC No 205-685-1, CAS No 147-14-8);
 - Pigment Green 7 (CI 74260, EC No 215-524-7, CAS No 1328-53-6).
 - 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.
 - 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.
 - 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:
 - the statement "Mixture for use in tattoos or permanent make-up";
 - a reference number to uniquely identify the batch;
 - 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

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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.

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. (Or Concentration of the substance in a mixture: <0.1 % Mass concentration)

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
E1	environmental hazards (hazardous to the aquatic environment, cat. 1)	100 200	56)

Notation

56) Hazardous to the Aquatic Environment in category Acute 1 or Chronic 1

Deco-Paint Directive

VOC content	0 %
-------------	-----

Industrial Emissions Directive (IED)

VOC content	0 %
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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)

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none of the ingredients are listed

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
TW	TCSI	not all ingredients are listed

Legend

TCSI Taiwan Chemical Substance Inventory

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
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)
ADR/RID/ADN	Agreements concerning the International Carriage of Dangerous Goods by Road/Rail/Inland Waterways (ADR/RID/ADN)
Aquatic Acute	Hazardous to the aquatic environment - acute hazard
ATE	Acute Toxicity Estimate
CAS	Chemical Abstracts Service (service that maintains the most comprehensive list of chemical substances)
Ceiling-C	Ceiling value
CLP	Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures
DGR	Dangerous Goods Regulations (see IATA/DGR)

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Abbr.	Descriptions of used abbreviations
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
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
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
NLP	No-Longer Polymer
PBT	Persistent, Bioaccumulative and Toxic
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
SVHC	Substance of Very High Concern
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).

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).

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

Code	Text
H302	Harmful if swallowed.
H314	Causes severe skin burns and eye damage.
H318	Causes serious eye damage.
H400	Very toxic to aquatic life.

Disclaimer

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