Safety data sheet

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

Iodine ≥ 99,8%, p.a., ACS resublimated

article number: **X864**
Version: **5.1 en**
Replaces version of: 2024-09-19
Version: (5)

date of compilation: 2015-11-17
Revision: 2024-10-09

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

1.1 Product identifier

Identification of the substance	**Iodine** ≥ 99,8%, p.a., ACS resublimated
Article number	X864
Registration number (REACH)	01-2119485285-30-xxxx
Index number in CLP Annex VI	053-001-00-3
EC number	231-442-4
CAS number	7553-56-2

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

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

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

1.4 Emergency telephone number

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

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
3.1O	Acute toxicity (oral)	4	Acute Tox. 4	H302
3.1D	Acute toxicity (dermal)	4	Acute Tox. 4	H312
3.1I	Acute toxicity (inhal.)	4	Acute Tox. 4	H332
3.2	Skin corrosion/irritation	2	Skin Irrit. 2	H315
3.3	Serious eye damage/eye irritation	2	Eye Irrit. 2	H319
3.8R	Specific target organ toxicity - single exposure (respir-atory tract irritation)	3	STOT SE 3	H335
3.9	Specific target organ toxicity - repeated exposure	1	STOT RE 1	H372
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

Delayed or immediate effects can be expected after short or long-term exposure. 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

GHS07, GHS08, GHS09

Hazard statements

H302+H312+H332	Harmful if swallowed, in contact with skin or if inhaled
H315	Causes skin irritation
H319	Causes serious eye irritation
H335	May cause respiratory irritation
H372	Causes damage to organs (thyroid gland) through prolonged or repeated exposure (if swallowed)
H400	Very toxic to aquatic life

Precautionary statements

Precautionary statements - prevention

P273	Avoid release to the environment

Precautionary statements - response

P302+P352	IF ON SKIN: Wash with plenty of water
P304+P340	IF INHALED: Remove person to fresh air and keep comfortable for breathing
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing

Labelling of packages where the contents do not exceed 125 ml
Signal word: **Danger**
Hazard pictogram(s):

H335	May cause respiratory irritation.
H372	Causes damage to organs (thyroid gland) through prolonged or repeated exposure (if swallowed).
P304+P340	IF INHALED: Remove person to fresh air and keep comfortable for breathing.

Labelling of packages where the contents do not exceed 10 ml

Signal word: Not required

Hazard pictogram(s):

Hazard statements: Not required

Precautionary statements: Not required

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 ≥ 0,1%.

SECTION 3: Composition/information on ingredients

3.1 Substances

Name of substance	Iodine
Molecular formula	I_2
Molar mass	253,8 $^{g}/_{mol}$
REACH Reg. No	01-2119485285-30-xxxx
CAS No	7553-56-2
EC No	231-442-4
Index No	053-001-00-3

Substance, Specific Conc. Limits, M-factors, ATE

Specific Conc. Limits	M-Factors	ATE	Exposure route
-	-	1.500 $^{mg}/_{kg}$ 1.100 $^{mg}/_{kg}$ >4,588 $^{mg}/_{l}$/4h	oral dermal inhalation: dust/mist

SECTION 4: First aid measures

4.1 Description of first aid measures

General notes

Take off contaminated clothing.

Following inhalation
If breathing is irregular or stopped, immediately seek medical assistance and start first aid actions.

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

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

Following ingestion
Rinse mouth with water (only if the person is conscious). Call a doctor.

4.2 Most important symptoms and effects, both acute and delayed
Breathing difficulties, Circulatory collapse, Diarrhoea, Vomiting, Irritation, Discoloration of the cornea, Cough, Dyspnoea, Corrosivity, Spasms

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
Non-combustible.

Hazardous combustion products
Hydrogen iodide (HI)

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.

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 under Section 8 of the safety data sheet) to prevent any contamination of skin, eyes and personal clothing. Do not breathe dust.

6.2 Environmental precautions
Keep away from drains, surface and ground water. Retain contaminated washing water and dispose of it. If substance has entered a water course or sewer, inform the responsible authority.

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. 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
Use extractor hood (laboratory). Provision of sufficient ventilation. Avoid dust formation.

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.

Incompatible substances or mixtures
Observe hints for combined storage. Incompatible materials: see section 10.

Consideration of other advice:

Ventilation requirements
Keep any substance that emits harmful vapours or gases in a place that allows these to be permanently extracted.

Specific designs for storage rooms or vessels
Recommended storage temperature: 15 – 25 °C

7.3 Specific end use(s)
No information available.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

National limit values

Occupational exposure limit values (Workplace Exposure Limits)

Country	Name of agent	CAS No	Identifier	TWA [mg/m³]	STEL [mg/m³]	Ceiling-C [mg/m³]	Notation	Source
IE	iodine	7553-56-2	OELV				iv	S.I. No. 619 of 2001

Notation

Ceiling-C	Ceiling value is a limit value above which exposure should not occur
iv	Inhalable fraction and vapour
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)

Human health values

Relevant DNELs and other threshold levels				
Endpoint	**Threshold level**	**Protection goal, route of exposure**	**Used in**	**Exposure time**
DNEL	0,07 mg/m³	human, inhalatory	worker (industry)	chronic - systemic effects
DNEL	0,01 mg/kg bw/day	human, dermal	worker (industry)	chronic - systemic effects

Environmental values

Relevant PNECs and other threshold levels				
End-point	**Threshold level**	**Organism**	**Environmental com-partment**	**Exposure time**
PNEC	18,13 µg/l	aquatic organisms	freshwater	short-term (single instance)
PNEC	60,01 µg/l	aquatic organisms	marine water	short-term (single instance)
PNEC	11 mg/l	aquatic organisms	sewage treatment plant (STP)	short-term (single instance)
PNEC	3,99 mg/kg	aquatic organisms	freshwater sediment	short-term (single instance)
PNEC	20,22 mg/kg	aquatic organisms	marine sediment	short-term (single instance)
PNEC	5,95 mg/kg	terrestrial organisms	soil	short-term (single instance)

8.2 Exposure controls

Individual protection measures (personal protective equipment)

Eye/face protection

Use safety goggle with side protection.

Skin protection

• hand protection

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

• type of material

NBR (Nitrile rubber)

• material thickness

>0,11 mm

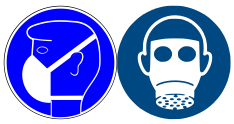
- **breakthrough times of the glove material**

>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: 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	-
Colour	dark violet
Odour	stinging
Melting point/freezing point	113 – 114 °C
Boiling point or initial boiling point and boiling range	184,4 °C at 1 atm (ECHA)
Flammability	non-combustible
Lower and upper explosion limit	not relevant (solid)
Flash point	not applicable
Auto-ignition temperature	not determined
Decomposition temperature	not relevant
pH (value)	not applicable
Kinematic viscosity	0,47 $^{mm^2}/_{s}$ not relevant
Dynamic viscosity	2,3 mPa s at 115 °C
Solubility(ies)	
Water solubility	<0,5 $^{g}/_{l}$ at 20 °C
Partition coefficient	
Partition coefficient n-octanol/water (log value):	2,49 (20 °C) (ECHA)
Vapour pressure	0,31 hPa at 25 °C

Density and/or relative density	
Density	4,93 $^{g}/_{cm^3}$ at 20 °C
Relative vapour density	8,8 (air = 1)
Particle characteristics	No data available.
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:	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
strong oxidiser,
Exothermic reaction with: Aldehydes, Metal powder, Phosphorus oxides (e.g. P2O5),
Danger of explosion: Acetylene, Alkali metals, Amines, Ammonium compounds, Azides, Reducing agents, Sodium, Potassium, Iodide

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

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

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

Acute toxicity

Exposure route	Endpoint	Value	Species	Method	Source
oral	LD50	14.000 $^{mg}/_{kg}$	not specified		TOXNET
inhalation: dust/mist	LC50	>4,588 $^{mg}/_{l}$/4h	rat		ECHA
dermal	LD50	>2.000 $^{mg}/_{kg}$	rabbit		ECHA

Skin corrosion/irritation
Causes skin irritation.

Serious eye damage/eye irritation
Causes serious eye irritation.

Respiratory or skin sensitisation
Shall not be classified as a respiratory or skin sensitiser.

Germ cell mutagenicity
Shall not be classified as germ cell mutagenic.

Carcinogenicity
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
Causes damage to organs (thyroid gland) through prolonged or repeated exposure (if swallowed).

Hazard category	Target organ	Exposure route
1	thyroid gland	if swallowed

Aspiration hazard
Shall not be classified as presenting an aspiration hazard.

Symptoms related to the physical, chemical and toxicological characteristics

- **If swallowed**
diarrhoea, vomiting
- **If in eyes**
discoloration of the cornea, Causes serious eye irritation
- **If inhaled**
Dyspnoea, Irritation to respiratory tract, cough
- **If on skin**
causes skin irritation
- **Other information**
Other adverse effects: Liver and kidney damage, Circulatory collapse, Spasms

11.2 Endocrine disrupting properties
Does not contain an endocrine disruptor (ED) at a concentration of ≥ 0,1%.

11.3 Information on other hazards
There is no additional information.

SECTION 12: Ecological information

12.1 Toxicity
Very toxic to aquatic life.

Aquatic toxicity (acute)				
Endpoint	**Value**	**Species**	**Source**	**Exposure time**
LC50	1,67 $^{mg}/_{l}$	fish	ECHA	96 h
ErC50	0,13 $^{mg}/_{l}$	algae	ECHA	72 h

Aquatic toxicity (chronic)				
Endpoint	**Value**	**Species**	**Source**	**Exposure time**
EC50	280 $^{mg}/_{l}$	microorganisms	ECHA	3 h

12.2 Persistence and degradability
Data are not available.

12.3 Bioaccumulative potential
Does not significantly accumulate in organisms.

n-octanol/water (log KOW)	2,49 (20 °C) (ECHA)

12.4 Mobility in soil

Henry's law constant	0,031 $^{Pa\ m^3}/_{mol}$ at 20 °C (ECHA)

12.5 Results of PBT and vPvB assessment
Data are not available.

12.6 Endocrine disrupting properties
Does not contain an endocrine disruptor (ED) at a concentration of ≥ 0,1%.

12.7 Other adverse effects
Data are not available.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

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

Sewage disposal-relevant information
Do not empty into drains. 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. Handle contaminated packages in the same way as the substance itself. Completely emptied packages can be recycled.

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

Properties of waste which render it hazardous
HP 4 irritant - skin irritation and eye damage

Properties of waste which render it hazardous
HP 5 specific target organ toxicity (STOT)/aspiration toxicity
HP 6 acute toxicity
HP 14 ecotoxic

13.3 Remarks

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

SECTION 14: Transport information

14.1 UN number or ID number

ADRRID	UN 3495
IMDG-Code	UN 3495
ICAO-TI	UN 3495

14.2 UN proper shipping name

ADRRID	IODINE
IMDG-Code	IODINE
ICAO-TI	Iodine

14.3 Transport hazard class(es)

ADRRID	8 (6.1)
IMDG-Code	8 (6.1)
ICAO-TI	8 (6.1)

14.4 Packing group

ADRRID	III
IMDG-Code	III
ICAO-TI	III

14.5 Environmental hazards

hazardous to the aquatic environment

14.6 Special precautions for user

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

14.7 Maritime transport in bulk according to IMO instruments

The cargo is not intended to be carried in bulk.

14.8 Information for each of the UN Model Regulations

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

Proper shipping name	IODINE
Particulars in the transport document	UN3495, IODINE, 8 (6.1), III, (E), environmentally hazardous
Classification code	CT2
Danger label(s)	8+6.1, "Fish and tree"

Environmental hazards	yes (hazardous to the aquatic environment)
Special provisions (SP)	279, 802(ADN)
Excepted quantities (EQ)	E1
Limited quantities (LQ)	5 kg
Transport category (TC)	3
Tunnel restriction code (TRC)	E
Hazard identification No	86

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

Classification code	CT2
Danger label(s)	8+6.1, "Fish and tree"

Environmental hazards	Yes Hazardous to water
Special provisions (SP)	279, 802(ADN)
Excepted quantities (EQ)	E1
Limited quantities (LQ)	5 kg
Transport category (TC)	3
Hazard identification No	86

International Maritime Dangerous Goods Code (IMDG) - Additional information

Proper shipping name	IODINE
Particulars in the shipper's declaration	UN3495, IODINE, 8 (6.1), III, MARINE POLLUTANT
Marine pollutant	yes (hazardous to the aquatic environment)
Danger label(s)	8+6.1, "Fish and tree"

Special provisions (SP)	279
Excepted quantities (EQ)	E1
Limited quantities (LQ)	5 kg
EmS	F-A, S-B
Stowage category	B

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

Proper shipping name	Iodine
Particulars in the shipper's declaration	UN3495, Iodine, 8 (6.1), III

Environmental hazards	yes (hazardous to the aquatic environment)
Danger label(s)	8+6.1

Special provisions (SP)	A113
Excepted quantities (EQ)	E1
Limited quantities (LQ)	5 kg

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
Iodine	substances in tattoo inks and permanent make-up		R75	75

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

Legend

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.
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
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 %
VOC content	0 $^{g}/_{l}$

Industrial Emissions Directive (IED)

VOC content	0 %
VOC content	0 $^{g}/_{l}$

Directive on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS)
not listed

Regulation concerning the establishment of a European Pollutant Release and Transfer Register (PRTR)
not listed

Water Framework Directive (WFD)
not listed

Regulation on the marketing and use of explosives precursors
not listed

Regulation on drug precursors
not listed

Regulation on substances that deplete the ozone layer (ODS)
not listed

Regulation concerning the export and import of hazardous chemicals (PIC)
not listed

Regulation on persistent organic pollutants (POP)
not listed

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

National inventories

Country	Inventory	Status
AU	AIIC	substance is listed
CA	DSL	substance is listed
CN	IECSC	substance is listed
EU	ECSI	substance is listed
EU	REACH Reg.	substance is listed
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
DSL	Domestic Substances List (DSL)
ECSI	EC Substance Inventory (EINECS, ELINCS, NLP)

Legend

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

According to REACH, Article 14 (1) a chemical safety assessment has been carried out for this substance or components of this mixture when the substance has been registered in quantities of 10 tonnes or more per year per registrant.

SECTION 16: Other information

Indication of changes (revised safety data sheet)

Section	Former entry (text/value)	Actual entry (text/value)	Safety-relevant
2.2		Labelling of packages where the contents do not exceed 125 ml: change in the listing (table)	yes
2.2		Hazard pictogram(s):	yes
2.2		Hazard pictogram(s):: change in the listing (table)	yes
2.2		Labelling of packages where the contents do not exceed 10 ml	yes
2.2		Signal word: Not required	yes
2.2		Hazard pictogram(s):	yes
2.2		Hazard pictogram(s):: change in the listing (table)	yes
2.2		Hazard statements: Not required	yes
2.2		Precautionary statements: Not required	yes

Abbreviations and acronyms

Abbr.	Descriptions of used abbreviations
ADR	Accord relatif au transport international des marchandises dangereuses par route (Agreement concerning the International Carriage of Dangerous Goods by Road)
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)
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)

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

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

Code	Text
H302	Harmful if swallowed.
H312	Harmful in contact with skin.
H315	Causes skin irritation.
H319	Causes serious eye irritation.
H332	Harmful if inhaled.
H335	May cause respiratory irritation.
H372	Causes damage to organs (thyroid gland) through prolonged or repeated exposure (if swallowed).
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.