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

ROTH

Iodine ≥ 99,5% resublimated

article number: **7335**Version: **4.0 en**date of compilation: 17.11.2015
Revision: 03.03.2024

Replaces version of: 11.02.2021

Version: (3)

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

1.1 Product identifier

Identification of the substance Iodine ≥ 99,5% resublimated

Article number 7335

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
Department Health, Safety and Environment

sheeṫ:

e-mail (competent person): sicherheit@carlroth.de

1.4 Emergency telephone number

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
3.10	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

Malta (en) Page 1 / 20

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



Iodine ≥ 99,5% resublimated

article number: 7335

Section	Hazard class	Cat- egory	Hazard class and category	Hazard statement
3.3	Serious eye damage/eye irritation	2	Eye Irrit. 2	H319
3.8R	Specific target organ toxicity - single exposure (respirat- ory 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

Symbol(s)







H335 May cause respiratory irritation.

H372 Causes damage to organs (thyroid gland) through prolonged or repeated exposure (if swallowed).

Malta (en) Page 2 / 20

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



Iodine ≥ 99,5% resublimated

article number: 7335

P304+P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.

2.3 Other hazards

Results of PBT and vPvB assessment

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

Endocrine disrupting properties

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

SECTION 3: Composition/information on ingredients

3.1 Substances

Name of substance Iodine

Molecular formula I₂

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.

Malta (en) Page 3 / 20

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



Iodine ≥ 99,5% resublimated

article number: 7335

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.

Malta (en) Page 4 / 20

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



Iodine ≥ 99,5% resublimated

article number: 7335

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.

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)

This information is not available.

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/m ³	human, inhalatory	worker (industry)	chronic - systemic effects		
DNEL	0,01 mg/kg bw/ day	human, dermal	worker (industry)	chronic - systemic effects		

Malta (en) Page 5 / 20

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



Iodine ≥ 99,5% resublimated

article number: 7335

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.

Malta (en) Page 6 / 20

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



Iodine ≥ 99,5% resublimated

article number: 7335

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 184,4 °C at 1 atm (ECHA)

range

Flammability non-combustible
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 $0,47 \, \mathrm{mm^2}/_{\mathrm{s}}$ 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/_{cm³} at 20 °C

Relative vapour density 8,8 (air = 1)

Malta (en) Page 7 / 20

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



Iodine ≥ 99,5% resublimated

article number: 7335

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.

Malta (en) Page 8 / 20

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



Iodine ≥ 99,5% resublimated

article number: 7335

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 \geq 0,1%.

11.3 Information on other hazards

There is no additional information.

Malta (en) Page 9 / 20

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



Iodine ≥ 99,5% resublimated

article number: 7335

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

	1
Henry's law constant	0,031 ^{Pa m³} / _{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 $\geq 0.1\%$.

12.7 Other adverse effects

Data are not available.

SECTION 13: Disposal considerations

13.1 Waste treatment methods



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

Sewage disposal-relevant information

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

Malta (en) Page 10 / 20

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

Iodine ≥ 99,5% resublimated

article number: 7335

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

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	HIN	num	hor	or ID	num	her
14.1	UIV	num	Der	or iv	mum	Der

ADR	UN 3495
IMDG-Code	UN 3495
ICAO-TI	UN 3495

14.2 UN proper shipping name

ADR	IODINE
IMDG-Code	IODINE
ICAO-TI	Iodine

14.3 Transport hazard class(es)

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

14.4 Packing group

ADR	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

Malta (en) Page 11 / 20

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

ROTH

Iodine ≥ 99,5% resublimated

article number: 7335

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)

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

Malta (en) Page 12 / 20

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



Iodine ≥ 99,5% resublimated

article number: 7335

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

Name of substance	Name acc. to inventory	CAS No	Restriction	No
Iodine	substances in tattoo inks and permanent make-up		R75	75

Legend

- 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;
- (II) U,U I % 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 mixture and the products applied on mixture and the products applied on mixture and the products applied to the p
- (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

- 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
- plication 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 tattoning purposes shall ensure that after 4 January 2022, the
- 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

Page 13 / 20 Malta (en)

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



Iodine ≥ 99,5% resublimated

article number: 7335

Legend

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 ingredi-

ent 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 para-

graph.

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. ively 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/	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

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)

Page 14 / 20 Malta (en)

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

Iodine ≥ 99,5% resublimated

article number: 7335

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

Australian Inventory of Industrial Chemicals Chemical Inventory and Control Regulation AIIC CICR DSL ECSI IECSC

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

TSCA **Toxic Substance Control Act**

Malta (en) Page 15 / 20

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



Iodine ≥ 99,5% resublimated

article number: 7335

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- relev- ant
1.1	Index No: 053-001-00-3		yes
1.1		EC number: 231-442-4	yes
1.1	EC number: 231-442-4	CAS number: 7553-56-2	yes
2.1		Classification according to Regulation (EC) No 1272/2008 (CLP): change in the listing (table)	yes
2.1		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.	yes
2.2		Labelling of packages where the contents do not exceed 125 ml: change in the listing (table)	yes
2.2		Labelling of packages where the contents do not exceed 125 ml: change in the listing (table)	yes
2.3	Other hazards: There is no additional information.	Other hazards	yes
2.3		Results of PBT and vPvB assessment: According to the results of its assessment, this substance is not a PBT or a vPvB.	yes
2.3		Endocrine disrupting properties: Does not contain an endocrine disruptor (ED) at a concentration of ≥ 0,1%.	yes
3.1	Index No: 053-001-00-3		yes
11.1		Acute toxicity: change in the listing (table)	yes
12.1		Aquatic toxicity (chronic): change in the listing (table)	yes
14.1	UN number: 3495	UN number or ID number	yes
14.1		ADR: UN 3495	yes
14.1		IMDG-Code: UN 3495	yes
14.1		ICAO-TI: UN 3495	yes

Malta (en) Page 16 / 20

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



Iodine ≥ 99,5% resublimated

article number: **7335**

Section	Former entry (text/value)	Actual entry (text/value)	Safety- relev- ant
14.2	UN proper shipping name: IODINE	UN proper shipping name	yes
14.2	Hazardous ingredients: Iodine		yes
14.2		ADR: IODINE	yes
14.2		IMDG-Code: IODINE	yes
14.2		ICAO-TI: Iodine	yes
14.3	Transport hazard class(es): class 6.1 hazard - toxic substances class 8 hazard - corrosive substances	Transport hazard class(es)	yes
14.3	Class: 8 (corrosive substances)		yes
14.3		ADR: 8 (6.1)	yes
14.3		IMDG-Code: 8 (6.1)	yes
14.3		ICAO-TI: 8 (6.1)	yes
14.4	Packing group: III (substance presenting low danger)	Packing group	yes
14.4		ADR: III	yes
14.4		IMDG-Code: III	yes
14.4		ICAO-TI: III	yes
14.8	UN number: 3495		yes
14.8	Class: 8		yes
14.8	Packing group: III		yes
14.8	UN number: 3495		yes
14.8	Class: 8		yes
14.8	Subsidiary risk(s): 6.1		yes
14.8	Marine pollutant: yes (P) (hazardous to the aquatic environment)	Marine pollutant: yes (hazardous to the aquatic environment)	yes
14.8	Packing group: III		yes
14.8	UN number: 3495		yes

Malta (en) Page 17 / 20

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



Iodine ≥ 99,5% resublimated

article number: 7335

Section	Former entry (text/value)	Actual entry (text/value)	Safety- relev- ant
14.8	Class: 8		yes
14.8	Subsidiary risk(s): 6.1		yes
14.8	Packing group: III		yes
14.8		Danger label(s): change in the listing (table)	yes
14.8		Danger label(s): change in the listing (table)	yes
15.1	• Regulation 649/2012/EU concerning the export and import of hazardous chemicals (PIC): Not listed.		yes
15.1	Regulation 1005/2009/EC on substances that deplete the ozone layer (ODS): Not listed.		yes
15.1	Regulation 850/2004/EC on persistent organic pollutants (POP): Not listed.		yes
15.1	Restrictions according to REACH, Annex XVII: not listed	Restrictions according to REACH, Annex XVII	yes
15.1	• Restrictions according to REACH, Title VIII: None.		yes
15.1		Dangerous substances with restrictions (REACH, Annex XVII): change in the listing (table)	yes
15.1		List of substances subject to authorisation (REACH, Annex XIV)/SVHC - candidate list: Not listed.	yes
15.1		Deco-Paint Directive	yes
15.1		VOC content: 0 %	yes
15.1		VOC content: 0 ^g / _l	yes
15.1		Industrial Emissions Directive (IED)	yes
15.1		VOC content: 0 %	yes
15.1	Regulation 111/2005/EC laying down rules for the monitoring of trade between the Com- munity and third countries in drug precursors: not listed	VOC content: 0 ^g / _l	yes
15.1	National inventories: Substance is listed in the following national inventories:		yes
15.1		National inventories: change in the listing (table)	yes
15.1		Regulation on the marketing and use of explosives precursors: not listed	yes

Malta (en) Page 18 / 20

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



Iodine ≥ 99,5% resublimated

article number: 7335

Section	Former entry (text/value)	Actual entry (text/value)	Safety- relev- ant
15.1		Regulation on substances that deplete the ozone layer (ODS): not listed	yes
15.1		Regulation concerning the export and import of hazardous chemicals (PIC): not listed	yes
15.1		Regulation on persistent organic pollutants (POP): not listed	yes
15.1		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.	yes
15.1		National inventories	yes
15.1		National inventories: change in the listing (table)	yes
15.2	Chemical Safety Assessment: No Chemical Safety Assessment has been car- ried out for this substance.	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.	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)
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)
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

Malta (en) Page 19 / 20

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



Iodine ≥ 99,5% resublimated

article number: 7335

Abbr.	Descriptions of used abbreviations
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
SVHC	Substance of Very High Concern
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). 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.

Malta (en) Page 20 / 20