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



## Single-Element IC - Standard Solution ROTI®Star 1 000 mg/l S<sub>2</sub>O<sub>3</sub><sup>2-</sup>

article number: 8207 date of compilation: 10.06.2016 Version: **2.0 en** 

Revision: 06.10.2022

Replaces version of: 10.06.2016

Version: (1)

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

#### **Product identifier** 1.1

Identification of the substance Single-Element IC - Standard Solution ROTI®Star

 $1.000 \text{ mg/l } S_2O_3^2$ 

Article number 8207

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 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 :Department Health, Safety and Environment

sheet:

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)

This mixture does not meet the criteria for classification in accordance with Regulation No 1272/2008/ FC.

#### 2.2 **Label elements**

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

not required

#### 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.

Page 1 / 15 Malta (en)

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



## Single-Element IC - Standard Solution ROTI®Star 1 000 mg/l S<sub>2</sub>O<sub>3</sub><sup>2-</sup>

article number: 8207

# **SECTION 3: Composition/information on ingredients**

#### 3.1 **Substances**

not relevant (mixture)

#### 3.2 **Mixtures**

## **Description of the mixture**

Name of sub- stance	Identifier	Wt%	Classification acc. to GHS	Pictograms	Notes
Isoamyl alcohol	CAS No 123-51-3 EC No 204-633-5 Index No 603-006-00-7	0,1	Flam. Liq. 3 / H226 Acute Tox. 4 / H332 Skin Irrit. 2 / H315 Eye Dam. 1 / H318 STOT SE 3 / H335 EUH066	<b>!</b>	C(a) GHS-HC IOELV

#### Notes

Mixture of isomers

GHS-HC: Harmonised classification (the classification of the substance corresponds to the entry in the list according to 1272/

2008/EC, Annex VI)

IOELV: Substance with a community indicative occupational exposure limit value

Name of sub- stance	Identifier	Specific Conc. Limits	M-Factors	ATE	Exposure route
Isoamyl alcohol	CAS No 123-51-3 EC No 204-633-5	-	-	11 <sup>mg</sup> / <sub>l</sub> /4h	inhalation: va- pour
	Index No 603-006-00-7				

For full text of abbreviations: see SECTION 16

## **SECTION 4: First aid measures**

#### 4.1 **Description of first aid measures**



## **General notes**

Take off contaminated clothing.

## Following inhalation

Provide fresh air.

## Following skin contact

Rinse skin with water/shower.

## Following eye contact

Rinse cautiously with water for several minutes.

## Following ingestion

Rinse mouth. Call a doctor if you feel unwell.

Malta (en) Page 2 / 15

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



## Single-Element IC - Standard Solution ROTI®Star 1 000 mg/l S<sub>2</sub>O<sub>3</sub><sup>2-</sup>

article number: 8207

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

Symptoms and effects are not known to date.

## 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 spray, alcohol resistant foam, dry extinguishing powder, BC-powder, carbon dioxide (CO<sub>2</sub>)

## Unsuitable extinguishing media

water jet

## 5.2 Special hazards arising from the substance or mixture

Non-combustible.

## 5.3 Advice for firefighters

In case of fire and/or explosion do not breathe fumes. Fight fire with normal precautions from a reasonable distance. Wear self-contained breathing apparatus.

## **SECTION 6: Accidental release measures**

## 6.1 Personal precautions, protective equipment and emergency procedures



## For non-emergency personnel

No special measures are necessary.

## **6.2** Environmental precautions

Keep away from drains, surface and ground water.

## 6.3 Methods and material for containment and cleaning up

## Advice on how to contain a spill

Covering of drains.

## Advice on how to clean up a spill

Wipe up with absorbent material (e.g. cloth, fleece).

## 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.

Malta (en) Page 3 / 15

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



## Single-Element IC - Standard Solution ROTI®Star 1 000 mg/l S<sub>2</sub>O<sub>3</sub><sup>2-</sup>

article number: 8207

# **SECTION 7: Handling and storage**

#### Precautions for safe handling 7.1

No special measures are necessary.

## Advice on general occupational hygiene

Keep away from food, drink and animal feedingstuffs.

#### 7.2 Conditions for safe storage, including any incompatibilities

Keep container tightly closed.

## **Incompatible substances or mixtures**

Observe hints for combined storage.

Consideration of other advice:

## 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)**

Cou ntr y	Name of agent	CAS No	Identi- fier	TW A [pp m]	TWA [mg/ m³]	STE L [pp m]	STEL [mg/ m³]	Ceil ing- C [pp m]	Ceil- ing-C [mg/ m³]	Nota- tion	Source
EU	isoamylalcohol	123-51-3	IOELV	5	18	10	37				2019/ 1831/EU
MT	isoamylalcohol	123-51-3	OELV	5	18	10	37				CAP. 424

#### Notation

Ceiling-C

STEL

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

Short-term exposure limit: a limit value above which exposure should not occur and which is related to a 15minute period (unless otherwise specified)
Time-weighted average (long-term exposure limit): measured or calculated in relation to a reference period of 8

TWA hours time-weighted average (unless otherwise specified)

. . . . . . . . . . . .

Relevant DNELs	Relevant DNELs of components of the mixture						
Name of sub- stance	CAS No	End- point	Threshol d level	Protection goal, route of exposure	Used in	Exposure time	
Isoamyl alcohol	123-51-3	DNEL	73,16 mg/ m³	human, inhalat- ory	worker (industry)	chronic - local ef- fects	
Isoamyl alcohol	123-51-3	DNEL	292 mg/m³	human, inhalat- ory	worker (industry)	acute - local ef- fects	

Malta (en) Page 4 / 15

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



## Single-Element IC - Standard Solution ROTI®Star 1 000 mg/l S<sub>2</sub>O<sub>3</sub><sup>2-</sup>

article number: 8207

Name of sub- stance	CAS No	End- point	Threshol d level	Organism	Environmental compartment	Exposure time
Isoamyl alcohol	123-51-3	PNEC	0,12 <sup>mg</sup> / <sub>l</sub>	aquatic organ- isms	freshwater	short-term (single instance)
Isoamyl alcohol	123-51-3	PNEC	0,012 <sup>mg</sup> / <sub>l</sub>	aquatic organ- isms	marine water	short-term (single instance)
Isoamyl alcohol	123-51-3	PNEC	37 <sup>mg</sup> / <sub>l</sub>	aquatic organ- isms	sewage treatment plant (STP)	short-term (single instance)
Isoamyl alcohol	123-51-3	PNEC	0,496 <sup>mg</sup> / kg	aquatic organ- isms	freshwater sedi- ment	short-term (single instance)
Isoamyl alcohol	123-51-3	PNEC	0,05 <sup>mg</sup> / <sub>kg</sub>	aquatic organ- isms	marine sediment	short-term (single instance)
Isoamyl alcohol	123-51-3	PNEC	0,029 <sup>mg</sup> / kg	terrestrial organ- isms	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

Hand protection is not required.

## **Respiratory protection**





Respiratory protection necessary at: Aerosol or mist formation.

## **Environmental exposure controls**

Keep away from drains, surface and ground water.

Malta (en) Page 5 / 15

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

## Single-Element IC - Standard Solution ROTI®Star 1 000 mg/l S<sub>2</sub>O<sub>3</sub><sup>2-</sup>

article number: 8207

## **SECTION 9: Physical and chemical properties**

## 9.1 Information on basic physical and chemical properties

Physical state liquid

Colour colourless
Odour odourless

Melting point/freezing point 0 °C

Boiling point or initial boiling point and boiling 100 °C at 1.013 hPa

range

Flammability non-combustible

Lower and upper explosion limit not determined Flash point not determined

Auto-ignition temperature not determined

Decomposition temperature not relevant

pH (value) not determined

Kinematic viscosity not determined

Solubility(ies)

Water solubility miscible in any proportion

Partition coefficient

Partition coefficient n-octanol/water (log value): not relevant (inorganic)

Vapour pressure 23 hPa at 20 °C

Density and/or relative density

Density  $\sim 1 \text{ g/}_{\text{cm}^3}$ 

Relative vapour density information on this property is not available

Particle characteristics not relevant (liquid)

Other safety parameters

Oxidising properties none

9.2 Other information

Information with regard to physical hazard hazard classes acc. to GHS

classes: (physical hazards): not relevant

Other safety characteristics:

Miscibility completely miscible with water

Malta (en) Page 6 / 15

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



## Single-Element IC - Standard Solution ROTI®Star 1 000 mg/l S<sub>2</sub>O<sub>3</sub><sup>2-</sup>

article number: 8207

## **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)

This mixture does not meet the criteria for classification in accordance with Regulation No 1272/2008/ EC.

## **Acute toxicity**

Shall not be classified as acutely toxic.

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

Name of substance	CAS No	Exposure route	ATE
Isoamyl alcohol	123-51-3	inhalation: vapour	11 <sup>mg</sup> / <sub>l</sub> /4h

#### Skin corrosion/irritation

Shall not be classified as corrosive/irritant to skin.

## Serious eye damage/eye irritation

Shall not be classified as seriously damaging to the eye or eye irritant.

## 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.

Malta (en) Page 7 / 15

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

# ROTH

## Single-Element IC - Standard Solution ROTI®Star 1 000 mg/l S<sub>2</sub>O<sub>3</sub><sup>2-</sup>

article number: 8207

## **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

Data are not available.

## • If in eyes

Data are not available.

#### If inhaled

essentially non-irritating

#### • If on skin

Data are not available.

## Other information

none

## 11.2 Endocrine disrupting properties

None of the ingredients are listed.

## 11.3 Information on other hazards

There is no additional information.

# **SECTION 12: Ecological information**

## 12.1 Toxicity

Shall not be classified as hazardous to the aquatic environment.

## **Biodegradation**

The methods for determining the biological degradability are not applicable to inorganic substances.

## 12.2 Process of degradability

Data are not available.

## 12.3 Bioaccumulative potential

Data are not available.

# Bioaccumulative potential of components of the mixture

Name of substance	CAS No	BCF	Log KOW	BOD5/COD
Isoamyl alcohol	123-51-3		1,35 (pH value: ~6,5)	

## 12.4 Mobility in soil

Data are not available.

Malta (en) Page 8 / 15

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

# ROTH

## Single-Element IC - Standard Solution ROTI®Star 1 000 mg/l S<sub>2</sub>O<sub>3</sub><sup>2-</sup>

article number: 8207

#### 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



Consult the appropriate local waste disposal expert about waste disposal.

## Sewage disposal-relevant information

Do not empty into drains.

#### 13.2 Relevant provisions relating to waste

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

#### 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.

# **SECTION 14: Transport information**

	14.1 UN number or ID number	not subject to transport regulations
--	-----------------------------	--------------------------------------

**14.2 UN proper shipping name** not assigned

**14.3 Transport hazard class(es)** none

**14.4 Packing group** not assigned

**14.5 Environmental hazards** non-environmentally hazardous acc. to the dan-

gerous goods regulations

## 14.6 Special precautions for user

There is no additional information.

## 14.7 Maritime transport in bulk according to IMO instruments

The cargo is not intended to be carried in bulk.

#### 14.8 Information for each of the UN Model Regulations

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

Not subject to ADR, RID and ADN.

International Maritime Dangerous Goods Code (IMDG) - Additional information

Not subject to IMDG.

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

Not subject to ICAO-IATA.

Malta (en) Page 9 / 15

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



## Single-Element IC - Standard Solution ROTI®Star 1 000 mg/l S<sub>2</sub>O<sub>3</sub><sup>2-</sup>

article number: 8207

## SECTION 15: Regulatory information

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
Isoamyl alcohol	this product meets the criteria for classification in accordance with Reg- ulation No 1272/2008/EC		R3	3
Isoamyl alcohol	flammable / pyrophoric		R40	40
Isoamyl alcohol	substances in tattoo inks and permanent make-up		R75	75

#### Legend

1. Shall not be used in:

- ornamental articles intended to produce light or colour effects by means of different phases, for example in ornamental lamps and ashtrays,

- tricks and jokes,

- games for one or more participants, or any article intended to be used as such, even with ornamental aspects,
- Articles not complying with paragraph 1 shall not be placed on the market.
   Shall not be placed on the market if they contain a colouring agent, unless required for fiscal reasons, or perfume, or both, if they
- can be used as fuel in decorative oil lamps for supply to the general public, and

present an aspiration hazard and are labelled with H304.

- 4. Decorative oil lamps for supply to the general public shall not be placed on the market unless they conform to the European Standard on Decorative oil lamps (EN 14059) adopted by the European Committee for Standardisation
- (CEN).
  5. Without prejudice to the implementation of other Union provisions relating to the classification, labelling and packaging of substances and mixtures, suppliers shall ensure, before the placing on the market, that the following requirements are met:
- ments are met:
  (a) lamp oils, labelled with H304, intended for supply to the general public are visibly, legibly and indelibly marked as follows: "Keep lamps filled with this liquid out of the reach of children"; and, by 1 December 2010, "Just a sip of lamp oil or even sucking the wick of lamps may lead to life-threatening lung damage";
  (b) grill lighter fluids, labelled with H304, intended for supply to the general public are legibly and indelibly marked by 1 December 2010 as follows: 'Just a sip of grill lighter fluid may lead to life threatening lung damage';
  (c) lamps oils and grill lighters, labelled with H304, intended for supply to the general public are packaged in black opaque containers not exceeding 1 litre by 1 December 2010."

  1 Shall not be used, as substance or as mixtures in aerosol dispensers where these aerosol dispensers are intended.

R40 1. Shall not be used, as substance or as mixtures in aerosol dispensers where these aerosol dispensers are intended for supply to the general public for entertainment and decorative purposes such as the following:
- metallic glitter intended mainly for decoration,
- artificial snow and frost,

- - 'whoopee' cushions,
  - silly string aerosols
  - imitation excrement,
  - horns for parties,
  - decorative flakes and foams,
  - artificial cobwebs
  - stink hombs
  - 2. Without prejudice to the application of other Community provisions on the classification, packaging and labelling of substances, suppliers shall ensure before the placing on the market that the packaging of aerosol dispensers referred to above is marked visibly, legibly and indelibly with: 'For professional users only'.

  - 3. By way of derogation, paragraphs 1 and 2 shall not apply to the aerosol dispensers referred to Article 8 (1a) of Council Directive 75/324/EEC (2).

    4. The aerosol dispensers referred to in paragraphs 1 and 2 shall not be placed on the market unless they conform to the requirements indicated.

Page 10 / 15 Malta (en)

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



## Single-Element IC - Standard Solution ROTI®Star 1 000 mg/l S<sub>2</sub>O<sub>3</sub><sup>2-</sup>

article number: 8207

#### 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

(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

(ií) 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:

(ii) "Rinse-off products";
(ii) "Not to be used in products applied on mucous membranes";
(iii) "Not to be used in eye products";

(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 concen-

(n) 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.

13 also falls within one or more of points (a) to (g) of paragraph 1, the concentration limit laid down in point (h) of paragraph 1 shall apply to that substance.

4. By way of derogation, paragraph 1 shall not apply to the following substances until 4 January 2023:
(a) Pigment Blue 15:3 (CI 74160, EC No 205-685-1, CAS No 147-14-8);
(b) Pigment Green 7 (CI 74260, EC No 215-524-7, CAS No 1328-53-6).

5. If Part 3 of Annex VI to Regulation (EC) No 1272/2008 is amended after 4 January 2021 to classify or re-classify a substance such that the substance then becomes caught by point (a), (b), (c) or (d) of paragraph 1 of this entry, or such that it then falls within a different one of those points from the one within which it fell previously, and the date of application of that new or revised classification is after the date referred to in paragraph 1 or, as the case may be, paragraph 4 of this entry, that amendment shall, for the purposes of applying this entry to that substance, be treated as taking effect on the date of application of that new or revised classification.

6. If Annex II or Annex IV to Regulation (EC) No 1223/2009 is amended after 4 January 2021 to list or change the listing of a substance such that the substance then becomes caught by point (e), (f) or (g) of paragraph 1 of this entry, or such that it then falls within a different one of those points from the one within which it fell previously, and the amendment takes effect after the date referred to in paragraph 1 or, as the case may be, paragraph 4 of this entry,

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";

(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;

tion 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.

Page 11 / 15 Malta (en)

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



## Single-Element IC - Standard Solution ROTI®Star 1 000 mg/l S<sub>2</sub>O<sub>3</sub><sup>2-</sup>

article number: **8207** 

#### Legend

9. This entry does not apply to substances that are gases at temperature of 20  $^{\circ}$ C and pressure of 101,3 kPa, or generate a vapour pressure of more than 300 kPa at temperature of 50  $^{\circ}$ C, with the exception of formaldehyde (CAS No 50-00-0, EC No 200-001-8).

10. This entry does not apply to the placing on the market of a mixture for use for tattooing purposes, or to the use of a mixture for tattooing purposes, when placed on the market exclusively as a medical device or an accessory to a medical device, within the meaning of Regulation (EU) 2017/745, or when used exclusively as a medical device or an accessory to a medical device, within the same meaning. Where the placing on the market or use may not be exclusively as a medical device or an accessory to a medical device, the requirements of Regulation (EU) 2017/745 and of this Regulation shall apply cumulatively.

## List of substances subject to authorisation (REACH, Annex XIV)/SVHC - candidate list

None of the ingredients are listed.

#### **Seveso Directive**

2012/	18/EU (Seveso III)		
No	Dangerous substance/hazard categories	Qualifying quantity (tonnes) for the application of lower and upper-tier requirements	Notes
	not assigned		

#### **Deco-Paint Directive**

VOC content	0,1 %
-------------	-------

#### **Industrial Emissions Directive (IED)**

VOC content	0,1 %
-------------	-------

# 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

#### 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.

Malta (en) Page 12 / 15

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



## Single-Element IC - Standard Solution ROTI®Star 1 000 mg/l S<sub>2</sub>O<sub>3</sub><sup>2-</sup>

article number: 8207

#### **National inventories**

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

Legend

AIIC CICR CSCL-ENCS DSL ECSI IECSC

Australian Inventory of Industrial Chemicals
Chemical Inventory and Control Regulation
List of Existing and New Chemical Substances (CSCL-ENCS)
Domestic Substances List (DSL)
EC Substance Inventory (EINECS, ELINCS, NLP)
Inventory of Existing Chemical Substances Produced or Imported in China
National Inventory of Chemical Substances
Korea Existing Chemicals Inventory

KECI Korea Existing Chemicals Inventory
NZIOC New Zealand Inventory of Chemicals
PICCS Philippine Inventory of Chemicals and Chemical Substances (PICCS)
REACH Reg. REACH registered substances

Taiwan Chemical Substance Inventory Toxic Substance Control Act

## 15.2 Chemical Safety Assessment

Chemical safety assessments for substances in this mixture were not carried out.

## **SECTION 16: Other information**

## Indication of changes (revised safety data sheet)

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

Restructuring: section 9, section 14

Section	Former entry (text/value)	Actual entry (text/value)	Safety- relev- ant
2.2	Signal word: not required		yes
2.3	Other hazards: There is no additional information.	Other hazards	yes
2.3		Results of PBT and vPvB assessment: This mixture does not contain any substances that are assessed to be a PBT or a vPvB.	yes

Malta (en) Page 13 / 15

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



# Single-Element IC - Standard Solution ROTI®Star 1 000 mg/l $S_2O_3^{2-}$

article number: 8207

## **Abbreviations and acronyms**

Abbr.	Descriptions of used abbreviations
2019/1831/EU	Commission Directive establishing a fifth list of indicative occupational exposure limit values pursuant to Council Directive 98/24/EC and amending Commission Directive 2000/39/EC
Acute Tox.	Acute toxicity
ADN	Accord européen relatif au transport international des marchandises dangereuses par voies de naviga- tion intérieures (European Agreement concerning the International Carriage of Dangerous Goods by In- land Waterways)
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
BCF	Bioconcentration factor
BOD	Biochemical Oxygen Demand
CAP. 424	Occupational Health and Safety Authority Act (CAP. 424)
CAS	Chemical Abstracts Service (service that maintains the most comprehensive list of chemical substances)
Ceiling-C	Ceiling value
CLP	Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures
COD	Chemical oxygen demand
DGR	Dangerous Goods Regulations (see IATA/DGR)
DNEL	Derived No-Effect Level
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
Eye Dam.	Seriously damaging to the eye
Eye Irrit.	Irritant to the eye
Flam. Liq.	Flammable liquid
GHS	"Globally Harmonized System of Classification and Labelling of Chemicals" developed by the United Nations
IATA	International Air Transport Association
IATA/DGR	Dangerous Goods Regulations (DGR) for the air transport (IATA)
ICAO	International Civil Aviation Organization
IMDG	International Maritime Dangerous Goods Code
index No	The Index number is the identification code given to the substance in Part 3 of Annex VI to Regulation (EC) No 1272/2008
IOELV	Indicative occupational exposure limit value
log KOW	n-Octanol/water
NLP	No-Longer Polymer
PBT	Persistent, Bioaccumulative and Toxic
PNEC	Predicted No-Effect Concentration

Malta (en) Page 14 / 15

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



## Single-Element IC - Standard Solution ROTI®Star 1 000 mg/l S<sub>2</sub>O<sub>3</sub><sup>2-</sup>

article number: 8207

Abbr.	Descriptions of used abbreviations
ppm	Parts per million
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
RID	Règlement concernant le transport International ferroviaire des marchandises Dangereuses (Regula- tions concerning the International carriage of Dangerous goods by Rail)
Skin Corr.	Corrosive to skin
Skin Irrit.	Irritant to skin
STEL	Short-term exposure limit
STOT SE	Specific target organ toxicity - single exposure
SVHC	Substance of Very High Concern
TWA	Time-weighted average
VOC	Volatile Organic Compounds
vPvB	Very Persistent and very Bioaccumulative

## 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).

## **Classification procedure**

Physical and chemical properties. The classification is based on tested mixture. Health hazards. Environmental hazards. The method for classification of the mixture is based on ingredients of the mixture (additivity formula).

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

Code	Text
H226	Flammable liquid and vapour.
H315	Causes skin irritation.
H318	Causes serious eye damage.
H332	Harmful if inhaled.
H335	May cause respiratory irritation.

## Disclaimer

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

Malta (en) Page 15 / 15