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

Single-Element ICP - Standard Solution ROTI®Star 1 000 mg/l Sm

article number: 2458 date of compilation: 13.10.2016 Version: **2.0 en**

Revision: 07.03.2022

Replaces version of: 13.10.2016 Version: (1)

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

Product identifier 1.1

Identification of the substance **Single-Element** ICP - Standard Solution

ROTI®Star 1 000 mg/l Sm

Article number 2458

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)

Section	Hazard class	Cat- egory	Hazard class and category	Hazard statement
2.16	Substance or mixture corrosive to metals	1	Met. Corr. 1	H290
3.2	Skin corrosion/irritation	2	Skin Irrit. 2	H315
3.3	Serious eye damage/eye irritation	2	Eye Irrit. 2	H319

For full text of abbreviations: see SECTION 16

2.2 **Label elements**

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

Signal word Warning

Page 1 / 18 Malta (en)

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



Single-Element ICP - Standard Solution ROTI®Star 1 000 mg/l Sm

article number: 2458

Pictograms

GHS05



Hazard statements

H290 May be corrosive to metals H315 Causes skin irritation H319 Causes serious eye irritation

Precautionary statements

Precautionary statements - prevention

P280 Wear protective gloves/protective clothing/eye protection/face protection

Labelling of packages where the contents do not exceed 125 ml

Signal word: Warning

Symbol(s)



2.3 Other hazards

Results of PBT and vPvB assessment

This mixture does not contain any substances that are assessed to be a PBT or a vPvB.

SECTION 3: Composition/information on ingredients

3.1 **Substances**

not relevant (mixture)

3.2 **Mixtures**

Description of the mixture

Name of sub- stance	Identifier	Wt%	Classification acc. to GHS	Pictograms	Notes
Nitric acid% [C ≤ 70 %]	CAS No 7697-37-2 EC No 231-714-2 Index No 007-030-00-3	2	Ox. Liq. 3 / H272 Met. Corr. 1 / H290 Acute Tox. 3 / H331 Skin Corr. 1A / H314 Eye Dam. 1 / H318 EUH071		B(a) GHS-HC IOELV

Notes

The classification refers to an aqueous solution

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

Malta (en) Page 2 / 18

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



Single-Element ICP - Standard Solution ROTI®Star 1 000 mg/l Sm

article number: 2458

Name of sub- stance	Identifier	Specific Conc. Limits	M-Factors	ATE	Exposure route
Nitric acid% [C ≤ 70 %]	CAS No 7697-37-2 EC No 231-714-2 Index No 007-030-00-3	Ox. Liq. 3; H272: C ≥ 65 % Skin Corr. 1A; H314: C ≥ 20 % Skin Corr. 1B; H314: 5 % ≤ C < 20 %	-	2,65 ^{mg} / _l /4h	inhalation: va- pour

For full text of abbreviations: see SECTION 16

SECTION 4: First aid measures

4.1 Description of first aid measures



General notes

Take off contaminated clothing.

Following inhalation

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

Following skin contact

Rinse skin with water/shower. In 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. Call a doctor if you feel unwell.

4.2 Most important symptoms and effects, both acute and delayed

Irritation

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 (CO₂)

Unsuitable extinguishing media

water jet

Malta (en) Page 3 / 18

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

ROTH

Single-Element ICP - Standard Solution ROTI®Star 1 000 mg/l Sm

article number: 2458

5.2 Special hazards arising from the substance or mixture

Non-combustible.

Hazardous combustion products

In case of fire may be liberated: Nitrogen oxides (NOx)

5.3 Advice for firefighters

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

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures



For non-emergency personnel

Avoid contact with skin, eyes and clothes. Do not breathe vapour/spray.

6.2 Environmental precautions

Keep away from drains, surface and ground water. The product is an acid. Before discharge into sewage plants the product normally needs to be neutralised.

6.3 Methods and material for containment and cleaning up

Advice on how to contain a spill

Covering of drains.

Advice on how to clean up a spill

Absorb with liquid-binding material (sand, diatomaceous earth, acid- or universal binding agents).

Other information relating to spills and releases

Place in appropriate containers for disposal. Ventilate affected area.

6.4 Reference to other sections

Hazardous combustion products: see section 5. Personal protective equipment: see section 8. Incompatible materials: see section 10. Disposal considerations: see section 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

No special measures are necessary.

Advice on general occupational hygiene

Wash hands before breaks and after work. Keep away from food, drink and animal feedingstuffs.

7.2 Conditions for safe storage, including any incompatibilities

Keep 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

Malta (en) Page 4 / 18

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



Single-Element ICP - Standard Solution ROTI®Star 1 000 mg/l Sm

article number: 2458

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	nitric acid	7697-37- 2	IOELV			1	2,6				2006/15/ EC
MT	nitric acid	7697-37- 2	OELV			1	2,6				CAP. 424

Notation

Ceiling-C

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 15-minute period (unless otherwise specified)

TWA

Time-weighted average (long-term exposure limit): measured or calculated in relation to a reference period of 8 hours time-weighted average (unless otherwise specified)

8.2 **Exposure controls**

Individual protection measures (personal protective equipment)

Eye/face protection





Use safety goggle with side protection.

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

Page 5 / 18 Malta (en)

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

Single-Element ICP - Standard Solution ROTI®Star 1 000 mg/l Sm

article number: 2458

breakthrough times of the glove material

>480 minutes (permeation: level 6)

other protection measures

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

Respiratory protection





Respiratory protection necessary at: Aerosol or mist formation.

Environmental exposure controls

Keep away from drains, surface and ground water.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state liquid

Colour colourless

Odour characteristic

Melting point/freezing point ~0 °C at 1.013 mPa

Boiling point or initial boiling point and boiling

range

~100 °C at 1.013 mPa

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) <2

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 not determined

Density and/or relative density

Density $\sim 1 \, {\rm g/_{cm^3}}$ at 20 °C

Relative vapour density information on this property is not available

Malta (en) Page 6 / 18

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



Single-Element ICP - Standard Solution ROTI®Star 1 000 mg/l Sm

article number: 2458

Particle characteristics not relevant (liquid)

Other safety parameters

Oxidising properties none

9.2 Other information

Information with regard to physical hazard

classes:

Corrosive to metals category 1: corrosive to metals

Other safety characteristics:

Miscibility completely miscible with water

SECTION 10: Stability and reactivity

10.1 Reactivity

Substance or mixture corrosive to metals.

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: Ammonia (NH3), Bases, Metals, Reducing agents, Strong alkali, Organic solvents

10.4 Conditions to avoid

Keep away from heat.

10.5 Incompatible materials

different metals (due to the release of hydrogen in an acid/alkaline medium)

10.6 Hazardous decomposition products

Hazardous combustion products: see section 5.

SECTION 11: Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

Test data are not available for the complete mixture.

Classification procedure

The method for classification of the mixture is based on ingredients of the mixture (additivity formula).

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

Acute toxicity

Shall not be classified as acutely toxic.

Malta (en) Page 7 / 18

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



Single-Element ICP - Standard Solution ROTI®Star 1 000 mg/l Sm

article number: 2458

Acute toxicity estimate (ATE) of components of the mixture

Name of substance	CAS No	Exposure route	ATE
Nitric acid% [C ≤ 70 %]	7697-37-2	inhalation: vapour	2,65 ^{mg} / _l /4h

Acute toxicity of components of the mixture

Name of substance	CAS No	Exposure route	Endpoint	Value	Species
Nitric acid% [C ≤ 70 %]	7697-37-2	inhalation: va- pour	LC50	>2,65 ^{mg} / _l /4h	rat

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

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

Causes serious eye irritation

• If inhaled

Data are not available.

• If on skin

causes skin irritation

Other information

This information is based upon the present state of our knowledge.

Malta (en) Page 8 / 18

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



Single-Element ICP - Standard Solution ROTI®Star 1 000 mg/l Sm

article number: 2458

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.

12.4 Mobility in soil

Data are not available.

12.5 Results of PBT and vPvB assessment

Data are not available.

12.6 Endocrine disrupting properties

None of the ingredients are listed.

12.7 Other adverse effects

Data are not available.

SECTION 13: Disposal considerations

13.1 Waste treatment methods



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

Sewage disposal-relevant information

Do not empty into drains.

Waste treatment of containers/packagings

It is a dangerous waste; only packagings which are approved (e.g. acc. to ADR) may be used.

13.2 Relevant provisions relating to waste

The allocation of waste identity numbers/waste descriptions must be carried out according to the EEC, specific to the industry and process. Waste catalogue ordinance (Germany).

13.3 Remarks

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

Malta (en) Page 9 / 18

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

Single-Element ICP - Standard Solution ROTI®Star 1 000 mg/l Sm

article number: 2458

SECTION 14: Transport information

UN number or ID number

ADR UN 3264 IMDG-Code UN 3264 ICAO-TI UN 3264

14.2 UN proper shipping name

ADR CORROSIVE LIQUID, ACIDIC, INORGANIC, N.O.S.

IMDG-Code CORROSIVE LIQUID, ACIDIC, INORGANIC, N.O.S.

ICAO-TI Corrosive liquid, acidic, inorganic, n.o.s.

Nitric acid ...% [C ≤ 70 %] Technical name (hazardous ingredients)

14.3 Transport hazard class(es)

ADR 8 **IMDG-Code** 8 ICAO-TI 8

14.4 Packing group

ADR III **IMDG-Code** III ICAO-TI III

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

gerous goods regulations

14.6 Special precautions for user

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

Maritime transport in bulk according to IMO instruments 14.7

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

CORROSIVE LIQUID, ACIDIC, INORGANIC, N.O.S. Proper shipping name

Particulars in the transport document UN3264, CORROSIVE LIQUID, ACIDIC, INORGAN-IC, N.O.S., (contains: Nitric acid ...% [C \leq 70 %]), 8, III, (E)

Classification code C1 Danger label(s) 8



Special provisions (SP) 274 Excepted quantities (EQ) E1

Malta (en) Page 10 / 18

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



Single-Element ICP - Standard Solution ROTI®Star 1 000 mg/l Sm

article number: 2458

Limited quantities (LQ) 5 L

Transport category (TC) 3

Tunnel restriction code (TRC) E

Hazard identification No 80

International Maritime Dangerous Goods Code (IMDG) - Additional information

Proper shipping name CORROSIVE LIQUID, ACIDIC, INORGANIC, N.O.S.

Particulars in the shipper's declaration UN3264, CORROSIVE LIQUID, ACIDIC, INORGANIC, N.O.S., (contains: Nitric acid ...% $[C \le 70 \%]$), 8,

ΤÍ

Marine pollutant Danger label(s) 8



Special provisions (SP)

Excepted quantities (EQ)

Limited quantities (LQ)

EmS

F-A, S-B

Stowage category

A

Segregation group 1 - Acids

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

Proper shipping name Corrosive liquid, acidic, inorganic, n.o.s.

Particulars in the shipper's declaration UN3264, Corrosive liquid, acidic, inorganic, n.o.s.,

(contains: Nitric acid ...% [C \leq 70 %]), 8, III

Danger label(s) 8



Special provisions (SP)

Excepted quantities (EQ)

Limited quantities (LQ)

1 L

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

Malta (en) Page 11 / 18

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



75

R75

Single-Element ICP - Standard Solution ROTI®Star 1 000 mg/l Sm

article number: 2458

Dangerous substances with restrictions (REACH, Annex XVII) **CAS No** Name of substance Name acc. to inventory Restriction No Single-Element this product meets the criteria for R3 3 classification in accordance with Regulation No 1272/2008/EC

substances in tattoo inks and permanent make-up

Legend

R3

Nitric acid ...% [C ≤ 70 %]

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, 2. Articles not complying with paragraph 1 shall not be placed on the market.

 3. 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 packbefore the placing on the market, that the following require aging 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.';

Page 12 / 18 Malta (en)

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



Single-Element ICP - Standard Solution ROTI®Star 1 000 mg/l Sm

article number: 2458

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";

(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 13 / 18 Malta (en)

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



Single-Element ICP - Standard Solution ROTI®Star 1 000 mg/l Sm

article number: 2458

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 % 0 ⁹ / ₁

Industrial Emissions Directive (IED)

VOC content	0 %
VOC content (Water content was discounted)	0 ^g / _l

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

Explosives precursors which are subject to restrictions						
Name of substance	CAS No	Type of registration	Remarks	Limit value	Upper limit value for the pur- pose of licensing under Article 5(3)	
Nitric acid% [C ≤ 70 %]	7697-37-2	Annex I		3 % w/w	10 % w/w	

Legend

annex I

Substances which shall not be made available to members of the general public on their own, or in mixtures or substances including them, except if the concentration is equal to or lower than the limit values set out below

Malta (en) Page 14 / 18

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

Single-Element ICP - Standard Solution ROTI®Star 1 000 mg/l Sm

article number: 2458

Additional statements

If the product is passed on to third parties, in accordance with Article 7 "Notification of the supply chain" of Regulation EU 2019/1148, the information obligation is subject to the entire supply chain and all other provisions mentioned in Article 7 on restricted and regulated raw materials.

Regulation on drug precursors

none of the ingredients are listed

Regulation on substances that deplete the ozone layer (ODS)

none of the ingredients are listed

Regulation concerning the export and import of hazardous chemicals (PIC)

none of the ingredients are listed

Regulation on persistent organic pollutants (POP)

none of the ingredients are listed

Other information

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

National inventories

Country	Inventory	Status
AU	AICS	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	not all ingredients are listed
NZ	NZIoC	all ingredients are listed
PH	PICCS	not all ingredients are listed
TR	CICR	not all ingredients are listed
TW	TCSI	all ingredients are listed
US	TSCA	all ingredients are listed

Legend

AICS CICR CSCL-ENCS Australian Inventory of Chemical Substances

DSL ECSI IECSC

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

INSQ 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

TSCA Toxic Substance Control Act

Page 15 / 18 Malta (en)

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



Single-Element ICP - Standard Solution ROTI®Star 1 000 mg/l Sm

article number: 2458

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
2.1		Classification according to Regulation (EC) No 1272/2008 (CLP): change in the listing (table)	yes
2.1	Remarks: For full text of Hazard- and EU Hazard-state- ments: see SECTION 16.		yes
2.2		Pictograms: change in the listing (table)	yes
2.2		Precautionary statements - prevention: change in the listing (table)	yes
2.2	Precautionary statements - response		yes
2.2		Precautionary statements - response: 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: This mixture does not contain any substances that are assessed to be a PBT or a vPvB.	yes

Abbreviations and acronyms

Abbr.	Descriptions of used abbreviations	
2006/15/EC	Commission Directive establishing a second list of indicative occupational exposure limit values in implementation of Council Directive 98/24/EC and amending Directives 91/322/EEC and 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	
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	
DGR	Dangerous Goods Regulations (see IATA/DGR)	

Malta (en) Page 16 / 18

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



Single-Element ICP - Standard Solution ROTI®Star 1 000 mg/l Sm

article number: 2458

Abbr.	Descriptions of used abbreviations
EC No	The EC Inventory (EINECS, ELINCS and the NLP-list) is the source for the seven-digit EC number, an identifier of substances commercially available within the EU (European Union)
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of Notified Chemical Substances
EmS	Emergency Schedule
Eye Dam.	Seriously damaging to the eye
Eye Irrit.	Irritant to the eye
GHS	"Globally Harmonized System of Classification and Labelling of Chemicals" developed by the United Nations
IATA	International Air Transport Association
IATA/DGR	Dangerous Goods Regulations (DGR) for the air transport (IATA)
ICAO	International Civil Aviation Organization
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
IOELV	Indicative occupational exposure limit value
LC50	Lethal Concentration 50%: the LC50 corresponds to the concentration of a tested substance causing 50 % lethality during a specified time interval
Met. Corr.	Substance or mixture corrosive to metals
NLP	No-Longer Polymer
Ox. Liq.	Oxidising liquid
PBT	Persistent, Bioaccumulative and Toxic
ppm	Parts per million
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
RID	Règlement concernant le transport International ferroviaire des marchandises Dangereuses (Regulations concerning the International carriage of Dangerous goods by Rail)
Skin Corr.	Corrosive to skin
Skin Irrit.	Irritant to skin
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.

Malta (en) Page 17 / 18

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



Single-Element ICP - Standard Solution ROTI®Star 1 000 mg/l Sm

article number: 2458

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
H272	May intensify fire; oxidiser.
H290	May be corrosive to metals.
H314	Causes severe skin burns and eye damage.
H315	Causes skin irritation.
H318	Causes serious eye damage.
H319	Causes serious eye irritation.
H331	Toxic if inhaled.

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 18 / 18