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



#### Redox Standard ROTI®Calipure 220 mV (25 °C)

article number: 1C60 date of compilation: 15.06.2020 Version: **3.0 en** Revision: 07.07.2023

Replaces version of: 13.08.2021

Version: (2)

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

#### **Product identifier** 1.1

Identification of the substance **Redox Standard** ROTI®Calipure 220 mV (25 °C)

Article number 1C60

Registration number (REACH) not relevant (mixture)

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

Relevant identified uses: Laboratory and analytical use

Laboratory chemical

Uses advised against: Do not use for private purposes (household).

Food, drink and animal feedingstuffs.

#### 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:

sicherheit@carlroth.de

e-mail (competent person):

#### 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)

Sect	ion	Hazard class	Cat- egory	Hazard class and category	Hazard statement
4.1	IC	Hazardous to the aquatic environment - chronic hazard	3	Aquatic Chronic 3	H412

#### **Supplemental hazard information**

Code	Supplemental hazard information
EUH032	contact with acids liberates very toxic gas

For full text of abbreviations: see SECTION 16

## The most important adverse physicochemical, human health and environmental effects

Spillage and fire water can cause pollution of watercourses.

#### 2.2 **Label elements**

Page 1 / 17 Malta (en)

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



#### Redox Standard ROTI®Calipure 220 mV (25 °C)

article number: 1C60

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

Signal word Not required

Not required

**Pictograms** 

**Hazard statements** 

H412 Harmful to aquatic life with long lasting effects

#### **Precautionary statements**

#### **Precautionary statements - prevention**

P273 Avoid release to the environment

#### Supplemental hazard information

EUH032 Contact with acids liberates very toxic gas.

#### Labelling of packages where the contents do not exceed 125 ml

Signal word: Not required.

H412 Harmful to aquatic life with long lasting effects.
EUH032 Contact with acids liberates very toxic gas.

#### 2.3 Other hazards

## Results of PBT and vPvB assessment

Does not contain a PBT-/vPvB-substance in a concentration of  $\geq 0.1\%$ .

#### **Endocrine disrupting properties**

Does not contain an endocrine disruptor (EDC) in a concentration of  $\geq 0.1\%$ .

# **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
Tetrapotassium hex- acyanoferrate	CAS No 13943-58-3	2,5 – 10	Aquatic Chronic 3 / H412		
	EC No 237-722-2				
Potassium hexacyano- ferrate(III)	CAS No 13746-66-2 EC No 237-323-3	≤ 2,5	Eye Irrit. 2 / H319 Aquatic Chronic 2 / H411	<u>(!)</u>	

For full text of abbreviations: see SECTION 16

Malta (en) Page 2 / 17

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



#### Redox Standard ROTI®Calipure 220 mV (25 °C)

article number: 1C60

## **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 all cases of doubt, or when symptoms persist, seek medical advice.

#### Following eye contact

Rinse cautiously with water for several minutes. In all cases of doubt, or when symptoms persist, seek medical advice.

#### Following ingestion

Rinse mouth. Call a doctor if you feel unwell.

#### 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.

#### **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. 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.

Malta (en) Page 3 / 17

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



#### Redox Standard ROTI®Calipure 220 mV (25 °C)

article number: 1C60

## **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. 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.

#### 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.

#### Protect against external exposure, such as

UV-radiation/sunlight

#### 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.

Malta (en) Page 4 / 17

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



## Redox Standard ROTI®Calipure 220 mV (25 °C)

article number: 1C60

# **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.

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	
Tetrapotassium hexacyanoferrate	13943-58-3	DNEL	9 mg/kg bw/day	human, dermal	worker (industry)	chronic - systemic effects	
Potassium hexacy- anoferrate(III)	13746-66-2	DNEL	9 mg/kg bw/day	human, dermal	worker (industry)	chronic - systemic effects	

Relevant PNECs of components of the mixture							
Name of sub- stance	CAS No	End- point	Threshol d level	Organism	Environmental compartment	Exposure time	
Tetrapotassium hexacyanoferrate	13943-58-3	PNEC	100 <sup>mg</sup> / <sub>l</sub>	aquatic organ- isms	sewage treatment plant (STP)	short-term (single instance)	
Potassium hexacy- anoferrate(III)	13746-66-2	PNEC	1,7 <sup>µg</sup> / <sub>I</sub>	aquatic organ- isms	freshwater	short-term (single instance)	
Potassium hexacy- anoferrate(III)	13746-66-2	PNEC	0,17 <sup>µg</sup> / <sub>l</sub>	aquatic organ- isms	marine water	short-term (single instance)	
Potassium hexacy- anoferrate(III)	13746-66-2	PNEC	100 <sup>mg</sup> / <sub>l</sub>	aquatic organ- isms	sewage treatment plant (STP)	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**





Malta (en) Page 5 / 17

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



#### Redox Standard ROTI®Calipure 220 mV (25 °C)

article number: 1C60

#### hand protection

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

#### type of material

NBR (Nitrile rubber)

#### material thickness

>0,11 mm

#### breakthrough times of the glove material

>480 minutes (permeation: level 6)

#### other protection measures

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

#### **Respiratory protection**





Respiratory protection necessary at: Aerosol or mist formation. Usually no personal respirative protection necessary.

#### **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 light orange
Odour characteristic

Melting point/freezing point not determined

Boiling point or initial boiling point and boiling 100 °C

range

Kinematic viscosity

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) 6,5 – 7,5 (20 °C)

Malta (en) Page 6 / 17

not determined

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



#### Redox Standard ROTI®Calipure 220 mV (25 °C)

article number: 1C60

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 1,034 g/<sub>cm³</sub> at 20 °C

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 classes acc. to GHS classes: hazard classes acc. to GHS (physical hazards): not relevant

Other safety characteristics:

Miscibility completely miscible with water

# **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

Dangerous/dangerous reactions with: Strong acid

#### 10.4 Conditions to avoid

UV-radiation/sunlight.

#### 10.5 Incompatible materials

There is no additional information.

#### Release of toxic materials with

Acids.

#### 10.6 Hazardous decomposition products

Hazardous combustion products: see section 5.

Malta (en) Page 7 / 17

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



#### Redox Standard ROTI®Calipure 220 mV (25 °C)

article number: 1C60

# **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.

#### Acute toxicity of components of the mixture

Name of substance	CAS No	Exposure route	Endpoint	Value	Species
Tetrapotassium hexacyanoferrate	13943-58-3	oral	LD50	>5.110 <sup>mg</sup> / <sub>kg</sub>	rat
Tetrapotassium hexacyanoferrate	13943-58-3	dermal	LD50	>2.000 <sup>mg</sup> / <sub>kg</sub>	rat
Potassium hexacyanoferrate(III)	13746-66-2	oral	LD50	>5.110 <sup>mg</sup> / <sub>kg</sub>	rat
Potassium hexacyanoferrate(III)	13746-66-2	dermal	LD50	>2.000 <sup>mg</sup> / <sub>kg</sub>	rat

#### 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.

## **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.

Malta (en) Page 8 / 17

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



#### Redox Standard ROTI®Calipure 220 mV (25 °C)

article number: 1C60

#### • If in eyes

Data are not available.

#### • If inhaled

Data are not available.

#### • If on skin

Data are not available.

#### Other information

Health effects are not known.

#### 11.2 Endocrine disrupting properties

Does not contain an endocrine disruptor (EDC) in a concentration of  $\geq$  0,1%.

#### 11.3 Information on other hazards

There is no additional information.

# **SECTION 12: Ecological information**

#### 12.1 Toxicity

Harmful to aquatic life with long lasting effects.

### Aquatic toxicity (acute) of components of the mixture

Name of sub- stance	CAS No	Endpoint	Value	Species	Exposure time
Tetrapotassium hex- acyanoferrate	13943-58-3	LC50	>100 <sup>mg</sup> / <sub>l</sub>	fish	96 h
Tetrapotassium hex- acyanoferrate	13943-58-3	EC50	>100 <sup>mg</sup> / <sub>l</sub>	aquatic invertebrates	48 h
Tetrapotassium hex- acyanoferrate	13943-58-3	ErC50	3,1 <sup>mg</sup> / <sub>l</sub>	algae	72 h
Potassium hexacyano- ferrate(III)	13746-66-2	LC50	>100 <sup>mg</sup> / <sub>l</sub>	fish	96 h
Potassium hexacyano- ferrate(III)	13746-66-2	EC50	59 <sup>mg</sup> / <sub>l</sub>	aquatic invertebrates	48 h
Potassium hexacyano- ferrate(III)	13746-66-2	ErC50	1,7 <sup>mg</sup> / <sub>l</sub>	algae	72 h

#### Aquatic toxicity (chronic) of components of the mixture

Name of sub- stance	CAS No	Endpoint	Value	Species	Exposure time
Tetrapotassium hex- acyanoferrate	13943-58-3	EC50	>1.000 <sup>mg</sup> / <sub>I</sub>	microorganisms	3 h
Potassium hexacyano- ferrate(III)	13746-66-2	EC50	>1.000 <sup>mg</sup> / <sub>l</sub>	microorganisms	3 h

## 12.2 Persistence and degradability

Data are not available.

## 12.3 Bioaccumulative potential

Data are not available.

Malta (en) Page 9 / 17

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



#### Redox Standard ROTI®Calipure 220 mV (25 °C)

article number: 1C60

#### 12.4 Mobility in soil

Data are not available.

#### 12.5 Results of PBT and vPvB assessment

According to the results of its assessment, this substance is not a PBT or a vPvB. Does not contain a PBT-/vPvB-substance in a concentration of  $\geq 0.1\%$ .

#### 12.6 Endocrine disrupting properties

Does not contain an endocrine disruptor (EDC) in 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.

#### Waste treatment of containers/packagings

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 12 release of an acute toxic gas

HP 14 ecotoxic

#### 13.3 Remarks

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

# **SECTION 14: Transport information**

14.1 UN number or ID number 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.

Malta (en) Page 10 / 17

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



#### Redox Standard ROTI®Calipure 220 mV (25 °C)

article number: 1C60

#### 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

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.

# **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
Redox Standard	this product meets the criteria for classification in accordance with Reg- ulation No 1272/2008/EC		R3	3
Potassium hexacyanoferrate(III)	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, 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.
   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 require-
- 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 11 / 17 Malta (en)

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

#### Redox Standard ROTI®Calipure 220 mV (25 °C)

article number: 1C60

#### 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:

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

(g) in the case of a substance for which a condition is specified in column h (Maximum concentration in ready for use preparation) or column i (Other) of the table in Annex IV to Regulation (EC) No 1223/2009, the substance is present in the mixture in a concentration, or in some other way, that does not accord with the condition specified in that column; (h) in the case of a substance listed in Appendix 13 to this Annex, the substance is present in the mixture in a 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.

as also falls within one of more of points (a) to (g) of paragraph 1, the concentration limit faid down in point (ii) 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 now or revised classification in fifty the date referred to in paragraph 1 or as the case may be paragraph. 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 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 12 / 17 Malta (en)

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



#### Redox Standard ROTI®Calipure 220 mV (25 °C)

article number: 1C60

#### 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 %
VOC content (Water content was discounted)	0 g/l

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

VOC content	0 %
VOC content (Water content was discounted)	0 <sup>g</sup> / <sub>l</sub>

# Directive on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS)

none of the ingredients are listed

# Regulation concerning the establishment of a European Pollutant Release and Transfer Register (PRTR)

none of the ingredients are listed

#### **Water Framework Directive (WFD)**

# List of pollutants (WFD) Name of substance Name acc. to inventory CAS No Listed in Remarks Tetrapotassium hexacyanoferrate Metals and their compounds a) Potassium hexacyanoferrate(III) Metals and their compounds a)

#### Legend

A) Indicative list of the main pollutants

#### 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

Malta (en) Page 13 / 17

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



#### Redox Standard ROTI®Calipure 220 mV (25 °C)

article number: 1C60

#### 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	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
JP	ISHA-ENCS	not 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	all ingredients are listed
TR	CICR	not all ingredients are listed
TW	TCSI	all ingredients are listed
US	TSCA	all ingredients are listed (ACTIVE)

#### Legend

AIIC Australian Inventory of Industrial Chemicals

CICR CSCL-ENCS DSL ECSI

Chemical 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
Inventory of Existing and New Chemical Substances (ISHA ENCS) **IECSC** 

**INSQ** ISHA-ENCS Inventory of Existing and New Chemical Substances (ISHA-ENCS)

NET NOT SET TO S

Taiwan Chemical Substance Inventory

TCSI TSCA **Toxic Substance Control Act** 

#### 15.2 Chemical safety assessment

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

Page 14 / 17 Malta (en)

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



# Redox Standard ROTI®Calipure 220 mV (25 °C)

article number: 1C60

# **SECTION 16: Other information**

## **Indication of changes (revised safety data sheet)**

Section	Former entry (text/value)	Actual entry (text/value)	Safety- relev- ant
2.1	Classification according to Regulation (EC) No 1272/2008 (CLP): This mixture does not meet the criteria for clas- sification in accordance with Regulation No 1272/2008/EC.	Classification according to Regulation (EC) No 1272/2008 (CLP)	yes
2.1		Classification according to Regulation (EC) No 1272/2008 (CLP): change in the listing (table)	yes
2.1		Supplemental hazard information: change in the listing (table)	yes
2.1		The most important adverse physicochemical, human health and environmental effects: Spillage and fire water can cause pollution of watercourses.	yes
2.2		Hazard statements	yes
2.2		Hazard statements: change in the listing (table)	yes
2.2		Precautionary statements	yes
2.2		Precautionary statements - prevention	yes
2.2		Precautionary statements - prevention: change in the listing (table)	yes
2.2		Labelling of packages where the contents do not exceed 125 ml: Signal word: Not required.	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	Results of PBT and vPvB assessment: This mixture does not contain any substances that are assessed to be a PBT or a vPvB.	Results of PBT and vPvB assessment: Does not contain a PBT-/vPvB-substance in a concentration of ≥ 0,1%.	yes
2.3		Endocrine disrupting properties: Does not contain an endocrine disruptor (EDC) in a concentration of ≥ 0,1%.	yes
14.8	Transport of dangerous goods by road, rail and inland waterway (ADR/RID/ADN) - Additional information:  Not subject to ADR, RID and ADN.		yes
15.1	Restrictions according to REACH, Annex XVII: none of the ingredients are listed	Restrictions according to REACH, Annex XVII	yes
15.1		Dangerous substances with restrictions (REACH, Annex XVII): change in the listing (table)	yes

Malta (en) Page 15 / 17

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



# Redox Standard ROTI®Calipure 220 mV (25 °C)

article number: 1C60

Section	Former entry (text/value)	Actual entry (text/value)	Safety- relev- ant
15.1	List of substances subject to authorisation (REACH, Annex XIV)/SVHC - candidate list: None of the ingredients are listed. (Or Concentration of the substance in a mixture: <0.1 % Mass concentration)	List of substances subject to authorisation (REACH, Annex XIV)/SVHC - candidate list: None of the ingredients are listed.	yes
15.1	VOC content: 0 % , 0 <sup>g</sup> / <sub>l</sub>	VOC content: 0 %	yes
15.1		VOC content (Water content was discounted): 0 <sup>g</sup> / <sub>l</sub>	yes
15.1		List of pollutants (WFD): change in the listing (table)	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: change in the listing (table)	yes
15.2	Chemical Safety Assessment: Chemical safety assessments for substances in this mixture were not carried out.	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)
Aquatic Chronic	Hazardous to the aquatic environment - chronic hazard
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)
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of Notified Chemical Substances
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
Eye Dam.	Seriously damaging to the eye
Eye Irrit.	Irritant to the eye

Malta (en) Page 16 / 17

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



#### Redox Standard ROTI®Calipure 220 mV (25 °C)

article number: 1C60

Abbr.	Descriptions of used abbreviations
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
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).

#### **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
H319	Causes serious eye irritation.
H411	Toxic to aquatic life with long lasting effects.
H412	Harmful to aquatic life with long lasting effects.

#### 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 17 / 17