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

Phenolphthalein (C.I. 764) ROTI® Calipure Melting point standard

article number: 2919 date of compilation: 26.04.2019 Version: 3.0 en

Revision: 02.03.2024

Replaces version of: 17.10.2022

Version: (2)

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

Product identifier 1.1

Identification of the substance Phenolphthalein (C.I. 764) ROTI®Calipure Melt-

ing point standard

2919 Article number

It is not required to list the identified uses be-Registration number (REACH)

cause the substance is not subject to registration

according to REACH (< 1 t/a).

Index number in CLP Annex VI 604-076-00-1

EC number 201-004-7

CAS number 77-09-8

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

Relevant identified uses: Laboratory chemical

Laboratory and analytical use

Uses advised against: Do not use for products which come into contact

with foodstuffs. Do not use for private purposes (household). Food, drink and animal feeding-

stuffs.

Details of the supplier of the safety data sheet 1.3

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:

2.1

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

Emergency telephone number 1.4

SECTION 2: Hazards identification

Classification of the substance or mixture

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

Section	Hazard class	Cat- egory	Hazard class and category	Hazard statement
3.5	Germ cell mutagenicity	2	Muta. 2	H341
3.6	Carcinogenicity	1B	Carc. 1B	H350
3.7	Reproductive toxicity	2	Repr. 2	H361f

Page 1 / 16 Malta (en)

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



Phenolphthalein (C.I. 764) ROTI® Calipure Melting point standard

article number: 2919

For full text of abbreviations: see SECTION 16

2.2 Label elements

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

Signal word Danger

Pictograms

GHS08



Hazard statements

H341 Suspected of causing genetic defects

H350 May cause cancer

H361f Suspected of damaging fertility

Precautionary statements

Precautionary statements - prevention

P202 Do not handle until all safety precautions have been read and understood

P280 Wear protective gloves

Precautionary statements - response

P308+P313 IF exposed or concerned: Get medical advice/attention

For professional users only

Labelling of packages where the contents do not exceed 125 ml

Signal word: Danger

Symbol(s)



H341 Suspected of causing genetic defects.

H350 May cause cancer.

H361f Suspected of damaging fertility.

P202 Do not handle until all safety precautions have been read and understood.

P280 Wear protective gloves.

P308+P313 IF exposed or concerned: Get medical advice/attention.

2.3 Other hazards

Results of PBT and vPvB assessment

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

Endocrine disrupting properties

The substance has an endocrine disrupting potential.

Malta (en) Page 2 / 16

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



Phenolphthalein (C.I. 764) ROTI® Calipure Melting point standard

article number: 2919

SECTION 3: Composition/information on ingredients

3.1 Substances

Name of substance Phenolphthalein

Molecular formula $C_{20}H_{14}O_4$ Molar mass $318,3\,^g/_{mol}$

CAS No 77-09-8 EC No 201-004-7

Index No 604-076-00-1

Substance of Very High Concern (SVHC)

Name of substance	CAS No	EC No	Listed in	Remarks
Phenolphthalein	77-09-8	201-004-7	Candidate list	Carc. A57a

Legend

Candidate Substances meeting the criteria referred to in Article 57 and for eventual inclusion in Annex XIV

Carc. A57a Carcinogenic (article 57a)

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

Specific Conc. Limits	M-Factors	ATE	Exposure route
Carc. 1B; H350: C ≥ 1 %	-	-	

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.

Following eye contact

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

Following ingestion

In case of accident or unwellness, seek medical advice immediately (show directions for use or safety data sheet if possible).

4.2 Most important symptoms and effects, both acute and delayed

Symptoms and effects are not known to date.

Malta (en) Page 3 / 16

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



Phenolphthalein (C.I. 764) ROTI®Calipure Melting point standard

article number: 2919

4.3 Indication of any immediate medical attention and special treatment needed

none

SECTION 5: Firefighting measures

5.1 Extinguishing media



Suitable extinguishing media

co-ordinate firefighting measures to the fire surroundings! water, foam, dry extinguishing powder, ABC-powder

Unsuitable extinguishing media

water jet

5.2 Special hazards arising from the substance or mixture

Combustible.

Hazardous combustion products

In case of fire may be liberated: Carbon monoxide (CO), Carbon dioxide (CO₂)

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

Do not breathe dust. Avoid contact with skin, eyes and clothes. Use personal protective equipment as required.

6.2 Environmental precautions

Keep away from drains, surface and ground water. Retain contaminated washing water and dispose of it.

6.3 Methods and material for containment and cleaning up

Advice on how to contain a spill

Covering of drains. Take up mechanically.

Advice on how to clean up a spill

Take up mechanically. Control of dust.

Other information relating to spills and releases

Place in appropriate containers for disposal.

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 4 / 16

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



Phenolphthalein (C.I. 764) ROTI® Calipure Melting point standard

article number: 2919

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Avoid exposure. Avoid dust formation.

Measures to prevent fire as well as aerosol and dust generation

Removal of dust deposits.

Advice on general occupational hygiene

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

7.2 Conditions for safe storage, including any incompatibilities

Store in a dry place. Keep container tightly closed.

Incompatible substances or mixtures

Observe hints for combined storage.

Consideration of other advice:

Ventilation requirements

Use local and general ventilation.

Specific designs for storage rooms or vessels

Recommended storage temperature: 15 - 25 °C

7.3 Specific end use(s)

No information available.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

National limit values

Occupational exposure limit values (Workplace Exposure Limits)

This information is not available.

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 / 16

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



Phenolphthalein (C.I. 764) ROTI® Calipure Melting point standard

article number: 2919

hand protection

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

type of material

NBR (Nitrile rubber)

material thickness

>0,11 mm

breakthrough times of the glove material

>480 minutes (permeation: level 6)

other protection measures

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

Respiratory protection





Respiratory protection necessary at: Dust formation. Particulate filter device (EN 143). P2 (filters at least 94 % of airborne particles, colour code: White).

Environmental exposure controls

Keep away from drains, surface and ground water.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state solid

Form powder, crystalline

Colour white
Odour odourless

Melting point/freezing point 263,7 °C (ECHA)

Boiling point or initial boiling point and boiling >450 °C at 1.013 hPa (ECHA)

range

Flammability this material is combustible, but will not ignite

readily

Lower and upper explosion limit not determined

Flash point not applicable

Auto-ignition temperature 397 °C (ECHA)

Decomposition temperature not relevant

Malta (en) Page 6 / 16

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



Phenolphthalein (C.I. 764) ROTI® Calipure Melting point standard

article number: 2919

pH (value) not applicable

Kinematic viscosity not relevant

Solubility(ies)

Water solubility (practically insoluble)

Partition coefficient

Partition coefficient n-octanol/water (log value): 0,9 (pH value: 6,6, 25 °C) (ECHA)

Vapour pressure not determined

Density and/or relative density

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

Relative vapour density Information on this property is not available.

Bulk density $350 - 450 \text{ kg/m}^3$

Particle characteristics No data available.

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:

Surface tension $71.8 \,^{\text{mN}}/_{\text{m}} (20 \,^{\circ}\text{C}) (ECHA)$

SECTION 10: Stability and reactivity

10.1 Reactivity

The product in the delivered form is not dust explosion capable; the enrichment of fine dust however leads to the danger of dust explosion.

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.

Malta (en) Page 7 / 16

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



Phenolphthalein (C.I. 764) ROTI® Calipure Melting point standard

article number: 2919

10.6 Hazardous decomposition products

Hazardous combustion products: see section 5.

SECTION 11: Toxicological information

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

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

Acute toxicity

Shall not be classified as acutely toxic.

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

Suspected of causing genetic defects.

Carcinogenicity

May cause cancer.

Reproductive toxicity

Suspected of damaging fertility.

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 eves

Data are not available.

If inhaled

Data are not available.

• If on skin

Data are not available.

• Other information

none

11.2 Endocrine disrupting properties

This substance is known as an "endocrine disruptor".

Malta (en) Page 8 / 16

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



Phenolphthalein (C.I. 764) ROTI® Calipure Melting point standard

article number: 2919

Endocrine disrupting chemicals (EDC)

Name of substance	CAS No	Combined cat- egory	Human health category	Wildlife cat- egory
Phenolphthalein	77-09-8	CAT1	CAT1	CAT3b

Legend

CAT1 Category 1 - evidence of endocrine disruption in at least one species using intact animals CAT3b Category 3b - no evidence of endocrine disruption or no data available

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.

Aquatic toxicity (acute)

Endpoint	Value	Species	Source	Exposure time
EC50	>100 ^{mg} / _l	aquatic invertebrates	ECHA	24 h
ErC50	>3,33 ^{mg} / _l	algae	ECHA	72 h

12.2 Persistence and degradability

Theoretical Oxygen Demand: 2,161 ^{mg}/_{mg} Theoretical Carbon Dioxide: 2,765 ^{mg}/_{mg}

Biodegradation

Not readily biodegradable.

Process of degradability

Process	Degradation rate	Time
biotic/abiotic	76 %	28 d
oxygen depletion	76 %	28 d

12.3 Bioaccumulative potential

Does not significantly accumulate in organisms.

n-octanol/water (log KOW)	0,9 (pH value: 6,6, 25 °C) (ECHA)
---------------------------	-----------------------------------

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

This substance is known as an "endocrine disruptor".

Malta (en) Page 9 / 16

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



Phenolphthalein (C.I. 764) ROTI®Calipure Melting point standard

article number: 2919

Endocrine disrupting chemicals (EDC)

Name of substance	CAS No	Combined cat- egory	Human health category	Wildlife cat- egory
Phenolphthalein	77-09-8	CAT1	CAT1	CAT3b

Legend

CAT1 Category 1 - evidence of endocrine disruption in at least one species using intact animals CAT3b Category 3b - no evidence of endocrine disruption or no data available

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

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 7 carcinogenic

HP 10 toxic for reproduction

HP 11 mutagenic

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 / 16

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



Phenolphthalein (C.I. 764) ROTI® Calipure Melting point standard

article number: 2919

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
Phenolphthalein	carcinogenic		R28-30	28
Phenolphthalein	substances in tattoo inks and permanent make-up		R75	75

R28-30 1. Shall not be placed on the market, or used,

as substances

- as constituents of other substances, or,

- in mixtures

for supply to the general public when the individual concentration in the substance or mixture is equal to or greater than:

- either the relevant specific concentration limit specified in Part 3 of Annex VI to Regulation (EC) No 1272/2008, or,

- the relevant generic concentration limit specified in Part 3 of Annex I of Regulation (EC) No 1272/2008. Without prejudice to the implementation of other Community provisions relating to the classification, packaging and

labelling of substances and mixtures, suppliers shall ensure before the placing on the market that the packaging of such substances and mixtures is marked visibly, legibly and indelibly as follows: 'Restricted to professional users'.

2. By way of derogation, paragraph 1 shall not apply to:
(a) medicinal or veterinary products as defined by Directive 2001/82/EC and Directive 2001/83/EC;
(b) cosmetic products as defined by Directive 76/768/EEC;

(c) the following fuels and oil products:
- motor fuels which are covered by Directive 98/70/EC

- mineral oil products intended for use as fuel in mobile or fixed combustion plants,

- fuels sold in closed systems (e.g. liquid gas bottles); (d) artists' paints covered by Regulation (EC) No 1272/2008; (e) the substances listed in Appendix 11, column 1, for the applications or uses listed in Appendix 11, column 2. Where a date is specified in column 2 of Appendix 11, the derogation shall apply until the said date; (f) devices covered by Regulation (EU) 2017/745.

Page 11 / 16 Malta (en)

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



Phenolphthalein (C.I. 764) ROTI® Calipure Melting point standard

article number: 2919

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.

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 / 16 Malta (en)

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



Phenolphthalein (C.I. 764) ROTI® Calipure Melting point standard

article number: 2919

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

Substance of Very Hig	h Conce	rn (SVHC)				
Name acc. to invent- ory	CAS No	Listed in	Remarks	Latest application date	Sunset date	Date of in- clusion
phenolphthalein	77-09-8	Candidate list	Carc. A57a			19.12.2011

Legend

Candidate list Substances meeting the criteria referred to in Article 57 and for eventual inclusion in Annex XIV

Carc. A57a Carcinogenic (article 57a)

Seveso Directive

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

Deco-Paint Directive

VOC content	0 %
VOC content	0 ^g / _l

Industrial Emissions Directive (IED)

VOC content	0 %
VOC content	0 ^g / _l

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

not listed

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

not listed

Water Framework Directive (WFD)

Page 13 / 16 Malta (en)

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



Phenolphthalein (C.I. 764) ROTI® Calipure Melting point standard

article number: 2919

List of pollutants (WFD) Name of substance **CAS No** Listed in **Remarks** Name acc. to inventory Phenolphthalein Substances and preparations, or the breakdown products of such, which have been proved to possess carcinogenic or mutagenic properties or properties which may affect steroidogenic, thyroid, reproduction or other endocrinerelated functions in or via the aquatic environment

Legend

a)

Indicative list of the main pollutants

Regulation on the marketing and use of explosives precursors

not listed

Regulation on drug precursors

not listed

Regulation on substances that deplete the ozone layer (ODS)

not listed

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

not listed

Regulation on persistent organic pollutants (POP)

not listed

Other information

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

National inventories

Country	Inventory	Status
AU	AIIC	substance is listed
CA	DSL	substance is listed
CN	IECSC	substance is listed
EU	ECSI	substance is listed
EU	REACH Reg.	substance is listed
JP	CSCL-ENCS	substance is listed
KR	KECI	substance is listed
MX	INSQ	substance is listed
NZ	NZIoC	substance is listed
PH	PICCS	substance is listed
TW	TCSI	substance is listed
US	TSCA	substance is listed (ACTIVE)
VN	NCI	substance is listed

Malta (en) Page 14 / 16

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



Phenolphthalein (C.I. 764) ROTI® Calipure Melting point standard

article number: 2919

Legend

Australian Inventory of Industrial Chemicals 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

AIIC CSCL-ENCS DSL ECSI IECSC INSQ KECI NATIONAL Inventory of Chemical Substances

KECI Korea Existing Chemicals Inventory

NCI National Chemical Inventory

NZIOC New Zealand Inventory of Chemicals

PICCS Philippine Inventory of Chemicals and Chemical Substances (PICCS)

REACH Reg. REACH registered substances

This probability between Inventory

TCSI TSCA Taiwan Chemical Substance Inventory

Toxic Substance Control Act

15.2 Chemical safety assessment

No Chemical Safety Assessment has been carried out for this substance.

SECTION 16: Other information

Indication of changes (revised safety data sheet)

Section	Former entry (text/value)	Actual entry (text/value)	Safety- relev- ant
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		Substance of Very High Concern (SVHC): change in the listing (table)	yes
15.1	VOC content: 0 % , 0 ^g / _l	VOC content: 0 %	yes
15.1		VOC content: 0 ^g / _l	yes
15.1		National inventories: change in the listing (table)	yes

Abbreviations and acronyms

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

Malta (en) Page 15 / 16

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



Phenolphthalein (C.I. 764) ROTI® Calipure Melting point standard

article number: 2919

Abbr.	Descriptions of used abbreviations
ErC50	= EC50: in this method, that concentration of test substance which results in a 50 % reduction in either growth (EbC50) or growth rate (ErC50) relative to the control
GHS	"Globally Harmonized System of Classification and Labelling of Chemicals" developed by the United Nations
IATA	International Air Transport Association
IATA/DGR	Dangerous Goods Regulations (DGR) for the air transport (IATA)
ICAO	International Civil Aviation Organization
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
NLP	No-Longer Polymer
PBT	Persistent, Bioaccumulative and Toxic
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
SVHC	Substance of Very High Concern
VOC	Volatile Organic Compounds
vPvB	Very Persistent and very Bioaccumulative

Key literature references and sources for data

Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures. Regulation (EC) No. 1907/2006 (REACH), amended by 2020/878/EU.

Agreement concerning the International Carriage of Dangerous Goods by Road (ADR). International Maritime Dangerous Goods Code (IMDG). Dangerous Goods Regulations (DGR) for the air transport (IATA).

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

Code	Text
H341	Suspected of causing genetic defects.
H350	May cause cancer.
H361f	Suspected of damaging fertility.

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 16 / 16