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



#### Buffer solution pH 10,00 ±0,01 (20 °C) ROTI®Calipure, ready-to-use, borate free

article number: 1LP6 date of compilation: 2021-10-25 Version: 2.0 en

Revision: 2023-12-19

Replaces version of: 2021-10-25

Version: (1)

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

#### **Product identifier** 1.1

Identification of the substance **Buffer solution pH 10,00 ±0,01 (20 °C)** 

ROTI®Calipure, ready-to-use, borate free

Article number 1LP6

Registration number (REACH) not relevant (mixture)

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

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:

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

#### 1.4 **Emergency telephone number**

Name	Street	Postal code/city	Telephone	Website
National Poisons Information Centre Beaumont Hospital	Beaumont Road	Dublin 9	+353 1 809 2166	https:// www.poisons.ie/

#### **SECTION 2: Hazards identification**

#### Classification of the substance or mixture 2.1

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

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

#### 2.2 **Label elements**

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

not required

Page 1 / 17 Ireland (en)

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



# Buffer solution pH 10,00 $\pm$ 0,01 (20 °C) ROTI®Calipure, ready-to-use, borate free

article number: 1LP6

#### 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 (ED) 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
Glycine	CAS No 56-40-6	< 2,5			
	EC No 200-272-2				
Sodium chloride	CAS No 7647-14-5	< 2,5			
	EC No 231-598-3				
Sodium hydroxide	CAS No 1310-73-2	< 2,5	Met. Corr. 1 / H290 Skin Corr. 1A / H314 Eye Dam. 1 / H318		GHS-HC
	EC No 215-185-5		Lyc bann. 1711310	<b>~</b>	
	Index No 011-002-00-6				
	REACH Reg. No 01-2119457892- 27-xxxx				

#### Notes

GHS-HC: Harmonised classification (the classification of the substance corresponds to the entry in the list according to 1272/2008/EC, Annex VI)

Name of sub- stance	Identifier	Specific Conc. Limits	M-Factors	ATE	Exposure route
Sodium hydrox- ide	CAS No 1310-73-2 EC No 215-185-5 Index No 011-002-00-6	Skin Corr. 1A; H314: C ≥ 5 % Skin Corr. 1B; H314: 2 % ≤ C < 5 % Skin Irrit. 2; H315: 0,5 % ≤ C < 2 % Eye Dam. 1; H318: C ≥ 2 % Eye Irrit. 2; H319: 0,5 % ≤ C < 2 %	-	-	

For full text of abbreviations: see SECTION 16

Ireland (en) Page 2 / 17

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



# Buffer solution pH 10,00 $\pm$ 0,01 (20 °C) ROTI®Calipure, ready-to-use, borate free

article number: 1LP6

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

#### 4.1 Description of first aid measures



#### **General notes**

Take off contaminated clothing.

#### Following inhalation

Provide fresh air.

#### Following skin contact

Rinse skin with water/shower.

#### Following eye contact

Rinse cautiously with water for several minutes. 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. Fight fire with normal precautions from a reasonable distance. Wear self-contained breathing apparatus.

Ireland (en) Page 3 / 17

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



# Buffer solution pH 10,00 $\pm$ 0,01 (20 °C) ROTI®Calipure, ready-to-use, borate free

article number: 1LP6

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

#### 6.1 Personal precautions, protective equipment and emergency procedures



#### For non-emergency personnel

No special measures are necessary.

#### 6.2 Environmental precautions

Keep away from drains, surface and ground water. 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.

#### Advice on how to clean up a spill

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

#### Other information relating to spills and releases

Place in appropriate containers for disposal.

#### 6.4 Reference to other sections

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

# **SECTION 7: Handling and storage**

#### 7.1 Precautions for safe handling

No special measures are necessary.

#### Advice on general occupational hygiene

Keep away from food, drink and animal feedingstuffs.

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

Keep container tightly closed.

#### **Incompatible substances or mixtures**

Observe hints for combined storage.

#### Consideration of other advice:

#### Specific designs for storage rooms or vessels

Recommended storage temperature: 15 - 25 °C

#### 7.3 Specific end use(s)

No information available.

Ireland (en) Page 4 / 17

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



#### Buffer solution pH 10,00 ±0,01 (20 °C) ROTI®Calipure, ready-to-use, borate free

article number: 1LP6

## **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
ΙE	sodium hydroxide	1310-73- 2	OELV			2					S.I. No. 619 of 2001

Notation

Ceiling-C STEL

Ceiling value is a limit value above which exposure should not occur Short-term exposure limit: a limit value above which exposure should not occur and which is related to a 15-minute period (unless otherwise specified)

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

**TWA** 

hours time-weighted average (unless otherwise specified)

#### **Relevant DNELs of components**

Name of sub- stance	CAS No	End- point	Threshol d level	Protection goal, route of exposure	Used in	Exposure time
Sodium chloride	7647-14-5	DNEL	2.069 mg/ m³	human, inhalat- ory	worker (industry)	chronic - systemic effects
Sodium chloride	7647-14-5	DNEL	2.069 mg/ m³	human, inhalat- ory	worker (industry)	acute - systemic effects
Sodium chloride	7647-14-5	DNEL	295,5 mg/ kg bw/day	human, dermal	worker (industry)	chronic - systemic effects
Sodium chloride	7647-14-5	DNEL	295,5 mg/ kg bw/day	human, dermal	worker (industry)	acute - systemic effects

#### **Relevant PNECs of components**

Name of sub- stance	CAS No	End- point	Threshol d level	Organism	Environmental compartment	Exposure time
Sodium chloride	7647-14-5	PNEC	5 <sup>mg</sup> / <sub>l</sub>	aquatic organ- isms	freshwater	short-term (single instance)
Sodium chloride	7647-14-5	PNEC	500 <sup>mg</sup> / <sub>l</sub>	aquatic organ- isms	sewage treatment plant (STP)	short-term (single instance)
Sodium chloride	7647-14-5	PNEC	4,86 <sup>mg</sup> / <sub>kg</sub>	terrestrial organ- isms	soil	short-term (single instance)

#### 8.2 **Exposure controls**

Individual protection measures (personal protective equipment)

**Eye/face protection** 



Ireland (en) Page 5 / 17

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



# Buffer solution pH 10,00 $\pm$ 0,01 (20 °C) ROTI®Calipure, ready-to-use, borate free

article number: 1LP6

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.

#### 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 colourless
Odour odourless

Melting point/freezing point not determined

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

range

Flammability non-combustible
Lower and upper explosion limit not determined
Flash point not determined
Auto-ignition temperature not determined
Decomposition temperature not relevant
pH (value) 10 (20 °C)

Ireland (en) Page 6 / 17

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



# Buffer solution pH 10,00 $\pm$ 0,01 (20 °C) ROTI®Calipure, ready-to-use, borate free

article number: 1LP6

Kinematic viscosity not determined

Solubility(ies)

Water solubility miscible in any proportion

Partition coefficient

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

Vapour pressure 23 hPa at 20 °C

Density and/or relative density

Density 1,003 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 hazard classes acc. to GHS

classes: (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

No known hazardous reactions.

#### 10.4 Conditions to avoid

There are no specific conditions known which have to be avoided.

#### 10.5 Incompatible materials

There is no additional information.

#### 10.6 Hazardous decomposition products

Hazardous combustion products: see section 5.

Ireland (en) Page 7 / 17

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



# Buffer solution pH 10,00 $\pm$ 0,01 (20 °C) ROTI®Calipure, ready-to-use, borate free

article number: 1LP6

# **SECTION 11: Toxicological information**

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

Test data are not available for the complete mixture.

#### Classification procedure

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

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

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

#### **Acute toxicity**

Shall not be classified as acutely toxic.

#### **Acute toxicity of components**

Name of substance	CAS No	Exposure route	Endpoint	Value	Species
Glycine	56-40-6	oral	LD50	7.930 <sup>mg</sup> / <sub>kg</sub>	rat
Sodium chloride	7647-14-5	oral	LD50	3.000 <sup>mg</sup> / <sub>kg</sub>	rat
Sodium chloride	7647-14-5	dermal	LD50	>10.000 <sup>mg</sup> / <sub>kg</sub>	rabbit

#### 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

Ireland (en) Page 8 / 17

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



# Buffer solution pH 10,00 $\pm$ 0,01 (20 °C) ROTI®Calipure, ready-to-use, borate free

article number: 1LP6

Data are not available.

#### • 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 (ED) 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

Shall not be classified as hazardous to the aquatic environment.

## Aquatic toxicity (acute) of components

Name of sub- stance	CAS No	Endpoint	Value	Species	Exposure time
Glycine	56-40-6	LC50	>1.000 <sup>mg</sup> / <sub>l</sub>	fish	96 h
Glycine	56-40-6	EC50	>220 <sup>mg</sup> / <sub>l</sub>	aquatic invertebrates	48 h
Sodium chloride	7647-14-5	LC50	5.840 <sup>mg</sup> / <sub>l</sub>	fish	96 h
Sodium hydroxide	1310-73-2	LC50	<180 <sup>mg</sup> / <sub>l</sub>	fish	96 h
Sodium hydroxide	1310-73-2	EC50	40,4 <sup>mg</sup> / <sub>l</sub>	aquatic invertebrates	48 h

#### Aquatic toxicity (chronic) of components

Name of sub- stance	CAS No	Endpoint	Value	Species	Exposure time
Sodium chloride	7647-14-5	EC50	2.430 <sup>mg</sup> / <sub>l</sub>	algae	120 h
Sodium hydroxide	1310-73-2	EC50	22 <sup>mg</sup> / <sub>l</sub>	microorganisms	15 min

#### 12.2 Persistence and degradability

Degra	dah	ility	οf	co	mn	nne	nts
Deula	uau	HILLY	UI	LU	ши	Ulic	:11L3

Name of substance	CAS No	Process	Degrada- tion rate	Time	Method	Source
Glycine	56-40-6	oxygen deple- tion	76 – 82 %	14 d		ECHA

Ireland (en) Page 9 / 17

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



# Buffer solution pH 10,00 $\pm$ 0,01 (20 °C) ROTI®Calipure, ready-to-use, borate free

article number: 1LP6

#### 12.3 Bioaccumulative potential

Data are not available.

#### **Bioaccumulative potential of components**

Name of substance	CAS No	BCF	Log KOW	BOD5/COD
Glycine	56-40-6		-3,21	

#### 12.4 Mobility in soil

Data are not available.

#### 12.5 Results of PBT and vPvB assessment

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 (ED) 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



Consult the appropriate local waste disposal expert about waste disposal.

#### 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.

#### 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

Ireland (en) Page 10 / 17

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



#### Buffer solution pH 10,00 ±0,01 (20 °C) ROTI®Calipure, ready-to-use, borate free

article number: 1LP6

#### 14.6 Special precautions for user

There is no additional information.

#### Maritime transport in bulk according to IMO instruments

The cargo is not intended to be carried in bulk.

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

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	(RFACH	Annex XVII)	١
Dangerous	<b>3ub3tantes</b>	VVICII	1 6301 100113	(1167611,	WILLICY VATT	,

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

#### Legend

1. Shall not be placed on the market in mixtures for use for tattooing purposes, and mixtures containing any such substances shall not be used for tattooing purposes, after 4 January 2022 if the substance or substances in question is or are present in the following circumstances:
(a) in the case of a substance classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 as carcinogen category

1A, 1B or 2, or germ cell mutagen category 1A, 1B or 2, the substance is present in the mixture in a concentration equal to or greater than 0,00005 % by weight; (b) in the case of a substance classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 as reproductive toxicant

category 1A, 1B or 2, the substance is present in the mixture in a concentration equal to or greater than 0,001 % by

(c) in the case of a substance classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 as skin sensitiser category 1, 1A or 1B, the substance is present in the mixture in a concentration equal to or greater than 0,001 % by weight;

(d) in the case of a substance classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 as skin corrosive category 1, 1A, 1B or 1C or skin irritant category 2, or as serious eye damage category 1 or eye irritant category 2, the substance is present in the mixture in a concentration equal to or greater than:

(i) 0,1 % by weight, if the substance is used solely as a pH regulator; (ii) 0,01 % by weight, in all other cases;

(ii) 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 products";

(iii) "Not to be used in eye products"

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

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).

Page 11 / 17 Ireland (en)

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



#### Buffer solution pH 10,00 ±0,01 (20 °C) ROTI®Calipure, ready-to-use, borate free

article number: 1LP6

#### Legend

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 sub-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, 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:

mixture is marked with the following information: (a) the statement "Mixture for use in tattoos or permanent make-up";

(b) a reference number to uniquely identify the batch;
(c) the list of ingredients in accordance with the nomenclature established in the glossary of common ingredient names pursuant to Article 33 of Regulation (EC) No 1223/2009, or in the absence of a common ingredient name, the IUPAC name. In the absence of a common ingredient name or IUPAC name, the CAS and EC number. Ingredients shall 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 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 concentra-

tión limit specified in Appendix 13;

(f) the statement "Contains chromium (VI). Can cause allergic reactions." if the mixture contains chromium (VI) below

the concentration limit specified in Appendix 13; (g) safety instructions for use insofar as they are not already required to be stated on the label by Regulation (EC) No 1272/2008.

The information shall be clearly visible, easily legible and marked in a way that is indelible.

The information shall be written in the official language(s) of the Member State(s) where the mixture is placed on the market, unless the Member State(s) concerned provide(s) otherwise.
Where necessary because of the size of the package, the information listed in the first subparagraph, except for point

(a), shall be included instead in the instructions for use.

Before using a mixture for tattooing purposes, the person using the mixture shall provide the person undergoing the procedure with the information marked on the package or included in the instructions for use pursuant to this para-

graph. 8. Mixtures that do not contain the statement "Mixture for use in tattoos or permanent make-up" shall not be used for

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

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

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

None of the ingredients are listed.

#### **Seveso Directive**

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

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

Page 12 / 17 Ireland (en)

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



# Buffer solution pH 10,00 $\pm$ 0,01 (20 °C) ROTI®Calipure, ready-to-use, borate free

article number: 1LP6

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 Sodium hydroxide Metals and their compounds a) Sodium chloride 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

#### 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**

Ireland (en) Page 13 / 17

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



#### Buffer solution pH 10,00 ±0,01 (20 °C) ROTI®Calipure, ready-to-use, borate free

article number: 1LP6

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	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 CICR CSCL-ENCS DSL ECSI IECSC Australian Inventory of Industrial Chemicals Chemical Inventory and Control Regulation List of Existing and New Chemical Substances (CSCL-ENCS)

Domestic Substances List (DSL)
EC Substance Inventory (EINECS, ELINCS, NLP)
Inventory of Existing Chemical Substances Produced or Imported in China National Inventory of Chemical Substances
Inventory of Existing and New Chemical Substances (ISHA-ENCS)

INSQ ISHA-ENCS

KECI Korea Existing Chemicals Inventory

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

Taiwan Chemical Substance Inventory

Toxic Substance Control Act

#### 15.2 Chemical safety assessment

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

#### SECTION 16: Other information

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

Section	Former entry (text/value)	Actual entry (text/value)	Safety- relev- ant
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 (ED) in a concentration of ≥ 0,1%.	yes

Ireland (en) Page 14 / 17

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



# Buffer solution pH 10,00 $\pm 0,01$ (20 °C) ROTI®Calipure, ready-to-use, borate free

article number: **1LP6** 

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	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
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 9/1	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)
ATE	Acute Toxicity Estimate
BCF	Bioconcentration factor
BOD	Biochemical Oxygen Demand
CAS	Chemical Abstracts Service (service that maintains the most comprehensive list of chemical substances)
Ceiling-C	Ceiling value
CLP	Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures
COD	Chemical oxygen demand
DGR	Dangerous Goods Regulations (see IATA/DGR)
DNEL	Derived No-Effect Level
EC50	Effective Concentration 50 %. The EC50 corresponds to the concentration of a tested substance causing 50 % changes in response (e.g. on growth) during a specified time interval
EC No	The EC Inventory (EINECS, ELINCS and the NLP-list) is the source for the seven-digit EC number, an identifier of substances commercially available within the EU (European Union)
ED	Endocrine disruptor
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of Notified Chemical Substances

Ireland (en) Page 15 / 17

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



# Buffer solution pH 10,00 $\pm$ 0,01 (20 °C) ROTI®Calipure, ready-to-use, borate free

article number: 1LP6

Abbr.	Descriptions of used abbreviations	
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	
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	
log KOW	n-Octanol/water	
Met. Corr. Substance or mixture corrosive to metals		
NLP	No-Longer Polymer	
PBT	Persistent, Bioaccumulative and Toxic	
PNEC	Predicted No-Effect Concentration	
ppm Parts per million		
REACH Registration, Evaluation, Authorisation and Restriction of Chemicals		
RID	Règlement concernant le transport International ferroviaire des marchandises Dangereuses (Regula- tions concerning the International carriage of Dangerous goods by Rail)	
S.I. No. 619 of 2001	Safety, Health and Welfare at Work (Chemical Agents) Regulations 2001	
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.

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

Ireland (en) Page 16 / 17

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



# Buffer solution pH 10,00 $\pm$ 0,01 (20 °C) ROTI®Calipure, ready-to-use, borate free

article number: 1LP6

#### **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
H290	May be corrosive to metals.
H314	Causes severe skin burns and eye damage.
H318	Causes serious eye damage.

#### **Disclaimer**

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

Ireland (en) Page 17 / 17