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



date of compilation: 05.02.2016

Revision: 10.04.2024

ROTI®Nucleic Acid-free, ready-to-use

article number: **HP69** Version: **5.0 en** Replaces version of: 04.05.2022 Version: (4)

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

1.1 Product identifier

Identification of the substance

Article number

Registration number (REACH)

Unique formula identifier (UFI)

ROTI®Nucleic Acid-free , ready-to-use

HP69

not relevant (mixture)

ENG1-00JN-A00Y-1C2P

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

Relevant identified uses:

Uses advised against:

Laboratory chemical Laboratory and analytical use

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

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

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

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

For full text of abbreviations: see SECTION 16

2.2 Label elements

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

Signal word Warning

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

ROTI®Nucleic Acid-free, ready-to-use

article number: HP69



GHS05



Hazard statements

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

Precautionary statements

Precautionary statements - prevention

P280 Wear protective gloves/eye protection

Precautionary statements - response

P302+P352IF ON SKIN: Wash with plenty of waterP305+P351+P338IF IN EYES: Rinse cautiously with water for several minutes. Remove contact
lenses, if present and easy to do. Continue rinsing

Labelling of packages where the contents do not exceed 125 ml

Signal word: Warning

Symbol(s)



2.3 Other hazards

Results of PBT and vPvB assessment

Does not contain a PBT-/vPvB-substance at a concentration of \ge 0,1%.

Endocrine disrupting properties

Does not contain an endocrine disruptor (ED) at a concentration of $\ge 0,1\%$.

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
Sodium hydroxide	CAS No 1310-73-2 EC No 215-185-5 Index No 011-002-00-6	< 1	Met. Corr. 1 / H290 Skin Corr. 1A / H314 Eye Dam. 1 / H318	A CONTRACT OF CONTRACT.	GHS-HC



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



ROTI®Nucleic Acid-free, ready-to-use

article number: HP69

Name of sub- stance	Identifier	Wt%	Classification acc. to GHS	Pictograms	Notes
Potassium hydroxide	CAS No 1310-58-3 EC No 215-181-3 Index No 019-002-00-8	< 1	Met. Corr. 1 / H290 Acute Tox. 4 / H302 Skin Corr. 1A / H314 Eye Dam. 1 / H318		GHS-HC

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 %	-	-	
Potassium hy- droxide	CAS No 1310-58-3 EC No 215-181-3 Index No 019-002-00-8	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 %	-	333 ^{mg} / _{kg}	oral

Remarks

For full text of abbreviations: see SECTION 16

SECTION 4: First aid measures

4.1 **Description of first aid measures**



General notes

Take off contaminated clothing.

Following inhalation

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

Following skin contact

Rinse skin with water/shower. In case of skin irritation, consult a physician.

Following eye contact

Irrigate copiously with clean, fresh water for at least 10 minutes, holding the eyelids apart. In case of eye irritation consult an ophthalmologist.

Following ingestion

Rinse mouth. Call a doctor if you feel unwell.

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



ROTI®Nucleic Acid-free, ready-to-use

article number: HP69

- **4.2 Most important symptoms and effects, both acute and delayed** Irritation
- **4.3 Indication of any immediate medical attention and special treatment needed** none

SECTION 5: Firefighting measures

5.1 Extinguishing media



Suitable extinguishing media

co-ordinate firefighting measures to the fire surroundings! water spray, alcohol resistant foam, dry extinguishing powder, BC-powder, carbon dioxide (CO₂)

Unsuitable extinguishing media

water jet

5.2 Special hazards arising from the substance or mixture

Non-combustible.

5.3 Advice for firefighters

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

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures



For non-emergency personnel

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.

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.

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



ROTI®Nucleic Acid-free, ready-to-use

article number: HP69

SECTION 7: Handling and storage

7.1 Precautions for safe handling

No special measures are necessary.

Advice on general occupational hygiene

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

7.2 Conditions for safe storage, including any incompatibilities

Keep container tightly closed.

Incompatible substances or mixtures

Observe hints for combined storage.

Consideration of other advice:

Specific designs for storage rooms or vessels Recommended storage temperature: 15 – 25 °C

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.

Relevant DNELs of components								
Name of sub- stance	CAS No	End- point	Threshol d level	Protection goal, route of exposure	Used in	Exposure time		
Potassium hydrox- ide	1310-58-3	DNEL	1 mg/m³	human, inhalat- ory	worker (industry)	chronic - local ef- fects		

8.2 Exposure controls

Individual protection measures (personal protective equipment)

Eye/face protection



Use safety goggle with side protection.

Skin protection



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



ROTI®Nucleic Acid-free, ready-to-use

article number: HP69

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 consider-able 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



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	faintly perceptible
Melting point/freezing point	not determined
Boiling point or initial boiling point and boiling range	100 °C
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)	11 – 12 (20 °C)
Kinematic viscosity	not determined

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



ROTI®Nucleic Acid-free, ready-to-use

article number: HP69

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 ^g / _{cm³} at 20 °C
Relative vapour density	Information on this property is not available.
Particle characteristics	not relevant (liquid)
Other safety parameters	
Oxidising properties	none
Other information	
Information with regard to physical hazard classes:	
Corrosive to metals	category 1: corrosive to metals
Other safety characteristics:	
Miscibility	completely miscible with water

SECTION 10: Stability and reactivity

10.1 Reactivity

9.2

Substance or mixture corrosive to metals.

10.2 Chemical stability

The material is stable under normal ambient and anticipated storage and handling conditions of temperature and pressure.

10.3 Possibility of hazardous reactions

Violent reaction with: Strong acid

10.4 Conditions to avoid

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

10.5 Incompatible materials

different metals, aluminium

10.6 Hazardous decomposition products

Hazardous combustion products: see section 5.

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



ROTI®Nucleic Acid-free, ready-to-use

article number: HP69

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 estimate (ATE) of components					
Name of substance	CAS No	Exposure route	ΑΤΕ		
Potassium hydroxide	1310-58-3	oral	333 ^{mg} / _{kg}		

Acute toxicity of components

Name of substance	CAS No	Exposure route	Endpoint	Value	Species
Potassium hydroxide	1310-58-3	oral	LD50	333 ^{mg} / _{kg}	rat

Skin corrosion/irritation

Causes skin irritation.

Serious eye damage/eye irritation

Causes serious eye irritation.

Respiratory or skin sensitisation

Shall not be classified as a respiratory or skin sensitiser.

Germ cell mutagenicity

Shall not be classified as germ cell mutagenic.

Carcinogenicity

Shall not be classified as carcinogenic.

Reproductive toxicity

Shall not be classified as a reproductive toxicant.

Specific target organ toxicity - single exposure

Shall not be classified as a specific target organ toxicant (single exposure).

Specific target organ toxicity - repeated exposure

Shall not be classified as a specific target organ toxicant (repeated exposure).

Aspiration hazard

Shall not be classified as presenting an aspiration hazard.

Symptoms related to the physical, chemical and toxicological characteristics

If swallowed

Data are not available.

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

ROTI®Nucleic Acid-free, ready-to-use

article number: HP69

• If in eyes

Causes serious eye irritation

If inhaled

Data are not available.

• If on skin

causes skin irritation

• Other information

none

11.2 Endocrine disrupting properties

Does not contain an endocrine disruptor (ED) at a concentration of $\ge 0,1\%$.

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		
Sodium hydroxide	1310-73-2	LC50	<180 ^{mg} / _l	fish	96 h		
Sodium hydroxide	1310-73-2	EC50	40,4 ^{mg} / _l	aquatic invertebrates	48 h		

Aquatic toxicity (chronic) of components

Name of sub- stance	CAS No	Endpoint	Value	Species	Exposure time
Sodium hydroxide	1310-73-2	EC50	22 ^{mg} / _l	microorganisms	15 min

12.2 Persistence and degradability

Data are not available.

12.3 Bioaccumulative potential

Data are not available.

12.4 Mobility in soil

Data are not available.

12.5 Results of PBT and vPvB assessment

Does not contain a PBT-/vPvB-substance at a concentration of $\ge 0,1\%$.

12.6 Endocrine disrupting properties

Does not contain an endocrine disruptor (ED) at a concentration of $\ge 0,1\%$.

12.7 Other adverse effects

Data are not available.



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



ROTI®Nucleic Acid-free, ready-to-use

article number: HP69

SECTION 13: Disposal considerations

13.1 Waste treatment methods



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

Sewage disposal-relevant information

Do not empty into drains.

Waste treatment of containers/packagings

It is a dangerous waste; only packagings which are approved (e.g. acc. to ADR) may be used. 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 4 irritant - skin irritation and eye damage

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	.1 UN number or ID number		
	ADR	UN 1824	
	IMDG-Code	UN 1824	
	ICAO-TI	UN 1824	
14.2	UN proper shipping name		
	ADR	SODIUM HYDROXIDE SOLUTION	
	IMDG-Code	SODIUM HYDROXIDE SOLUTION	
	ICAO-TI	Sodium hydroxide solution	
14.3	Transport hazard class(es)		
	ADR	8	
	IMDG-Code	8	
	ICAO-TI	8	
14.4	Packing group		
	ADR	III	
	IMDG-Code	III	
	ICAO-TI	III	

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



ROTI®Nucleic Acid-free, ready-to-use

article number: **HP69**

- **14.5** Environmental hazardsnon-environmentally hazardous acc. to the dan-
gerous goods regulations
- 14.6 Special precautions for user

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

14.7 Maritime transport in bulk according to IMO instruments The cargo is not intended to be carried in bulk.

14.8 Information for each of the UN Model Regulations

Agreement concerning the International (information	Carriage of Dangerous Goods by Road (ADR)Additional
Proper shipping name	SODIUM HYDROXIDE SOLUTION
Particulars in the transport document	UN1824, SODIUM HYDROXIDE SOLUTION, 8, III, (E)
Classification code	C5
Danger label(s)	8
Excepted quantities (EQ)	E1
Limited quantities (LQ)	5 L
Transport category (TC)	3
Tunnel restriction code (TRC)	E
Hazard identification No	80
International Maritime Dangerous Goods	Code (IMDG) - Additional information
Proper shipping name	SODIUM HYDROXIDE SOLUTION
Particulars in the shipper's declaration	UN1824, SODIUM HYDROXIDE SOLUTION, 8, III
Marine pollutant	-
Danger label(s)	8
Special provisions (SP)	223
Excepted quantities (EQ)	E1
Limited quantities (LQ)	5 L
EmS	F-A, S-B
Stowage category	A
Segregation group	18 - Alkalis

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



ROTI®Nucleic Acid-free, ready-to-use

article number: HP69

International Civil Aviation Organization (ICAO-IATA/DGR) - Additional information			
Proper shipping name	Sodium hydroxide solution		
Particulars in the shipper's declaration	UN1824, Sodium hydroxide solution, 8, III		
Danger label(s)	8		
Special provisions (SP)	A3		
Excepted quantities (EQ)	E1		
Limited quantities (LQ)	1 L		

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture Relevant provisions of the European Union (EU)

Restrictions according to REACH, Annex XVII

Dangerous substances with restrictions (REACH, Annex XVII)				
Name of substance	Name acc. to inventory	CAS No	Restriction	No
ROTI®Nucleic Acid-free	this product meets the criteria for classification in accordance with Reg- ulation No 1272/2008/EC		R3	3
Potassium hydroxide	substances in tattoo inks and perman- ent make-up		R75	75
Sodium hydroxide	substances in tattoo inks and perman- ent make-up		R75	75

Legend

R3

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

tricks and iokes

- 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

 a can be used as fuel in decorative oil lamps for supply to the general public, and
 present an aspiration hazard and are labelled with H304.
 4. Decorative oil lamps for supply to the general public shall not be placed on the market unless they conform to the European Standard on Decorative oil lamps (EN 14059) adopted by the European Committee for Standardisation (CEN)

5. Without prejudice to the implementation of other Union provisions relating to the classification, labelling and packaging of substances and mixtures, suppliers shall ensure, before the placing on the market, that the following requirements are met

(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 on a container not exceeding 1 litre by 1 December 2010 ':

opaque containers not exceeding 1 litre by 1 December 2010.';

^{1.} Shall not be used in:

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





article number: HP69



1. Shall not be placed on the market in mixtures for use for tattooing purposes, and mixtures containing any such sub-stances 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

weight;

(c) in the case of a substance classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 as skin sensitiser cat-egory 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 cat-egory 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

(f) in the case of a substance in 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 concentration. (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 strictest in Appendix 13 also falls within one or more of points (a) to (g) of paragraph 1, the substance listed in Appendix 13 also falls within one or more of points (a) to (g) of paragraph 1, the 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.

A. 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 the paragraph 1 or substance then paragraph 1 or substance to paragraph 1 or substance then paragraph 1 or substance to paragraph 1 or su plication of that new or revised classification is after the date referred to in paragraph 1 or, as the case may be, para-graph 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 affect after the date referred to in paragraph 1 or as the case may be paragraph 4 of this entry.

amendment takes effect after the date referred to in paragraph 1 or, as the case may be, paragraph 4 of this entry, that amendment shall, for the purposes of applying this entry to that substance, be treated as taking effect from the date falling 18 months after entry into force of the act by which that amendment was made. 7. Suppliers placing a mixture on the market for use for tattooing purposes shall ensure that, after 4 January 2022, the mixture is marked with the following information: (a) the statement "Mixture for use in tattoos or permanent make-up"; (b) a reference number to uniquely identify the barch:

(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.

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



ROTI®Nucleic Acid-free, ready-to-use

article number: HP69

Legend

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 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 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)			
Νο	Dangerous substance/hazard categories	Qualifying quantity (tonnes) for the ap- plication of lower and upper-tier re- quirements	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 ^g / _l

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

none of the ingredients are listed

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

none of the ingredients are listed

Water Framework Directive (WFD)

List of pollutants (WFD)				
Name of substance	Name acc. to inventory	CAS No	Listed in	Remarks
Potassium hydroxide	Metals and their compounds		a)	
Sodium hydroxide	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

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



ROTI®Nucleic Acid-free, ready-to-use

article number: HP69

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	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)
VN	NCI	all ingredients are listed

Legend

AIICAustralian Inventory of Industrial ChemicalsCICRChemical Inventory and Control RegulationCSCL-ENCSList of Existing and New Chemical Substances (CSCL-ENCS)DSLDomestic Substances List (DSL)ECSIEC Substance Inventory (EINECS, ELINCS, NLP)IECSCInventory of Existing Chemical SubstancesISHA-ENCSInventory of Chemical SubstancesISHA-ENCSInventory of Existing and New Chemical Substances (ISHA-ENCS)KECIKorea Existing Chemicals InventoryNCINational Chemical InventoryNZIoCNew Zealand Inventory of Chemicals and Chemical Substances (PICCS)REACH Reg.REACH registered substancesTCSITaiwan Chemical SubstancesTSCAToxic 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.

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



ROTI®Nucleic Acid-free, ready-to-use

article number: HP69

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 at a concentration of \geq 0,1%.	yes
2.3		Endocrine disrupting properties: Does not contain an endocrine disruptor (ED) at a concentration of ≥ 0,1%.	yes
15.1	VOC content: 0 % 0 ^g / _l	VOC content: 0 %	yes
15.1		VOC content (Water content was discounted): 0 ^g / _l	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
Acute Tox.	Acute toxicity
ADR	Accord relatif au transport international des marchandises dangereuses par route (Agreement concern- ing the International Carriage of Dangerous Goods by Road)
ATE	Acute Toxicity Estimate
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 identi- fier 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
EmS	Emergency Schedule
Eye Dam.	Seriously damaging to the eye
Eye Irrit.	Irritant to the eye

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

® BOTH

ROTI®Nucleic Acid-free, ready-to-use

article number: HP69

Abbr.	Descriptions of used abbreviations
GHS	"Globally Harmonized System of Classification and Labelling of Chemicals" developed by the United Na- tions
IATA	International Air Transport Association
IATA/DGR	Dangerous Goods Regulations (DGR) for the air transport (IATA)
ICAO	International Civil Aviation Organization
ICAO-TI	Technical instructions for the safe transport of dangerous goods by air
IMDG	International Maritime Dangerous Goods Code
IMDG-Code	International Maritime Dangerous Goods Code
index No	The Index number is the identification code given to the substance in Part 3 of Annex VI to Regulation (EC) No 1272/2008
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
Met. Corr.	Substance or mixture corrosive to metals
NLP	No-Longer Polymer
PBT	Persistent, Bioaccumulative and Toxic
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
Skin Corr.	Corrosive to skin
Skin Irrit.	Irritant to skin
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
H290	May be corrosive to metals.
H302	Harmful if swallowed.
H314	Causes severe skin burns and eye damage.
H315	Causes skin irritation.

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



ROTI®Nucleic Acid-free, ready-to-use

article number: **HP69**

Code	Text
H318	Causes serious eye damage.
H319	Causes serious eye irritation.

Disclaimer

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