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

ROTI®Aqua-Phenol, ready-to-use, for RNA extraction

article number: A980 date of compilation: 2015-08-20 Version: **3.0 en** Revision: 2021-04-23

Replaces version of: 2016-06-22

Version: (2)

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

Product identifier 1.1

Identification of the substance ROTI®Aqua-Phenol, ready-to-use, for RNA ex-

traction

Article number A980

Registration number (REACH) not relevant (mixture)

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

Relevant identified uses: Laboratory chemical

Laboratory and analytical use

Uses advised against: Do not use for squirting or spraying. Do not use

for products which come into direct contact with the skin. Do not use for products which come into contact with foodstuffs. Do not use for private

purposes (household).

1.3 Details of the supplier of the safety data sheet

> Carl Roth GmbH + Co KG Schoemperlenstr, 3-5 D-76185 Karlsruhe Germany

Telephone:+49 (0) 721 - 56 06 0 Telefax: +49 (0) 721 - 56 06 149 e-mail: sicherheit@carlroth.de Website: www.carlroth.de

Competent person responsible for the safety data :Department Health, Safety and Environment

sheet:

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

1.4 **Emergency telephone number**

Name	Street	Postal code/city	Telephone	Website
National Poisons Information Service City Hospital	Dudley Rd	B187QH Birmingham	844 892 0111	

SECTION 2: Hazards identification

2 1 Classification of the substance or mixture

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

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Section	Hazard class	Cat- egory	Hazard class and category	Hazard statement
3.10	Acute toxicity (oral)	3	Acute Tox. 3	H301
3.1D	Acute toxicity (dermal)	4	Acute Tox. 4	H312
3.1I	Acute toxicity (inhal.)		Acute Tox. 4	H332
3.2	Skin corrosion/irritation	1B	Skin Corr. 1B	H314
3.3	Serious eye damage/eye irritation	1	Eye Dam. 1	H318
3.5	3.5 Germ cell mutagenicity		Muta. 2	H341
3.9	Specific target organ toxicity - repeated exposure		STOT RE 2	H373
4.1C	Hazardous to the aquatic environment - chronic hazard	2	Aquatic Chronic 2	H411

For full text of abbreviations: see SECTION 16

The most important adverse physicochemical, human health and environmental effects

Skin corrosion produces an irreversible damage to the skin; namely, visible necrosis through the epidermis and into the dermis. Delayed or immediate effects can be expected after short or long-term exposure. Spillage and fire water can cause pollution of watercourses.

2.2 Label elements

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

Signal word D	anger
---------------	-------

Pictograms

GHS05, GHS06, GHS08, GHS09



Hazard statements

H301 Toxic if swallowed

H312+H332 Harmful in contact with skin or if inhaled
H314 Causes severe skin burns and eye damage
H341 Suspected of causing genetic defects

H373 May cause damage to organs through prolonged or repeated exposure

H411 Toxic to aquatic life with long lasting effects

Precautionary statements

Precautionary statements - prevention

P201 Obtain special instructions before use

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

ing protection

Precautionary statements - response

P304+P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact

lenses, if present and easy to do. Continue rinsing

P310 Immediately call a POISON CENTER/doctor

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For professional users only

Hazardous ingredients for labelling: Phenol

Labelling of packages where the contents do not exceed 125 ml

Signal word: Danger

Symbol(s)







H301 Toxic if swallowed.

H314 Causes severe skin burns and eye damage.
 H341 Suspected of causing genetic defects.
 P201 Obtain special instructions before use.

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

P304+P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to

do. Continue rinsing.

P310 Immediately call a POISON CENTER/doctor.

contains: Phenol

2.3 Other hazards

This material is combustible, but will not ignite readily.

Results of PBT and vPvB assessment

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

SECTION 3: Composition/information on ingredients

3.1 Substances

not relevant (mixture)

3.2 Mixtures

Description of the mixture

Name of sub- stance	Identifier	Wt%	Classification acc. to GHS	Pictograms	Notes
Phenol	CAS No 108-95-2 EC No 203-632-7 Index No 604-001-00-2 REACH Reg. No 01-2119882293- 32-xxxx	< 50	Acute Tox. 3 / H301 Acute Tox. 3 / H311 Acute Tox. 3 / H331 Skin Corr. 1B / H314 Eye Dam. 1 / H318 Muta. 2 / H341 STOT RE 2 / H373 Aquatic Chronic 2 / H411		GHS-HC IOELV

Notes

GHS-HC: Harmonised classification (the classification of the substance corresponds to the entry in the list according to 1272/

2008/EC, Annex VI)

IOELV: Substance with a community indicative occupational exposure limit value

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Name of sub- stance	Identifier	Specific Conc. Limits	M-Factors	ATE	Exposure route
Phenol	CAS No 108-95-2 EC No 203-632-7 Index No 604-001-00-2	Skin Corr. 1B; H314: C ≥ 3 % Skin Irrit. 2; H315: 1 % ≤ C < 3 % Eye Dam. 1; H318: C ≥ 3 % Eye Irrit. 2; H319: 1 % ≤ C < 3 %	-	100 ^{mg} /kg 630 ^{mg} /kg 0,5 ^{mg} / _I /4h	oral dermal inhalation: dust/ mist

For full text of abbreviations: see SECTION 16

SECTION 4: First aid measures

4.1 Description of first aid measures



General notes

Take off immediately all contaminated clothing.

Following inhalation

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

Following skin contact

After contact with skin, wash immediately with plenty of water. Immediate medical treatment required because corrosive injuries that are not treated are hard to cure.

Following eye contact

In case of contact with eyes flush immediately with plenty of flowing water for 10 to 15 minutes holding eyelids apart and consult an ophthalmologist. Protect uninjured eye.

Following ingestion

Rinse mouth immediately and drink plenty of water. Call a physician immediately. If swallowed danger of perforation of the esophagus and the stomach (strong corrosive effects). 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

Corrosion, Vomiting, Risk of blindness, Gastric perforation, Risk of serious damage to eyes

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)

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Unsuitable extinguishing media

water jet

5.2 Special hazards arising from the substance or mixture

Ingredients of the mixture combustible. The product itself does not burn.

Hazardous combustion products

Carbon monoxide (CO), Carbon dioxide (CO₂)

5.3 Advice for firefighters

In case of fire and/or explosion do not breathe fumes. Do not allow firefighting water to enter drains or water courses. Fight fire with normal precautions from a reasonable distance. Wear self-contained breathing apparatus. Wear full chemical protective clothing.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures



For non-emergency personnel

Use personal protective equipment as required. 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.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Provision of sufficient ventilation. Handle and open container with care. Avoid exposure. Clear contaminated areas thoroughly.

Measures to prevent fire as well as aerosol and dust generation



Keep away from sources of ignition - No smoking.

Measures to protect the environment

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Avoid release to the environment.

Advice on general occupational hygiene

When using do not eat or drink. Thorough skin-cleansing after handling the product.

7.2 Conditions for safe storage, including any incompatibilities

Keep in a cool place.

Incompatible substances or mixtures

Observe hints for combined storage.

Consideration of other advice:

Store locked up.

Ventilation requirements

Keep any substance that emits harmful vapours or gases in a place that allows these to be permanently extracted.

Specific designs for storage rooms or vessels

Recommended storage temperature: 2 - 8 °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)

Cou ntr y	Name of agent	CAS No	Identi- fier	TW A [pp m]	TWA [mg/ m³]	STE L [pp m]	STEL [mg/ m³]	Ceil ing- C [pp m]	Ceil- ing-C [mg/ m³]	Nota- tion	Source
EU	phenol	108-95-2	IOELV	2	8	4	16				2009/ 161/EU
GB	phenol	108-95-2	WEL	2	7,8	4	16				EH40/ 2005

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)

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

hours time-weighted average (unless otherwise specified)

Relevant DNELs	Relevant DNELs of components of the mixture												
Name of sub- stance	CAS No	End- point	Threshol d level	Protection goal, route of exposure	Used in	Exposure time							
Phenol	108-95-2	DNEL	8 mg/m³	human, inhalat- ory	worker (industry)	chronic - systemic effects							
Phenol	108-95-2	DNEL	16 mg/m³	human, inhalat- ory	worker (industry)	acute - local ef- fects							
Phenol	108-95-2	DNEL	1,23 mg/kg bw/day	human, dermal	worker (industry)	chronic - systemic effects							

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Relevant PNECs of components of the mixture

Name of sub- stance	CAS No	End- point	Threshol d level	Organism	Environmental compartment	Exposure time
Phenol	108-95-2	PNEC	0,008 ^{mg} / _l	aquatic organ- isms	freshwater	short-term (single instance)
Phenol	108-95-2	PNEC	0,001 ^{mg} / _l	aquatic organ- isms	marine water	short-term (single instance)
Phenol	108-95-2	PNEC	2,1 ^{mg} / _l	aquatic organ- isms	sewage treatment plant (STP)	short-term (single instance)
Phenol	108-95-2	PNEC	0,091 ^{mg} / kg	aquatic organ- isms	freshwater sedi- ment	short-term (single instance)
Phenol	108-95-2	PNEC	0,009 ^{mg} / kg	aquatic organ- isms	marine sediment	short-term (single instance)
Phenol	108-95-2	PNEC	0,136 ^{mg} / kg	terrestrial organ- isms	soil	short-term (single instance)

8.2 Exposure controls

Individual protection measures (personal protective equipment)

Eye/face protection





Use safety goggle with side protection. Wear face protection.

Skin protection



hand protection

Wear suitable gloves. Chemical protection gloves are suitable, which are tested according to EN 374. Check leak-tightness/impermeability prior to use. 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

FKM (fluoro rubber), Butyl caoutchouc (butyl rubber)

material thickness

≥0,4 mm

• breakthrough times of the glove material

>480 minutes (permeation: level 6)

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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. Type: A-P2 (combined filters against particles and organic gases and vapours, colour code: Brown/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 liquid

Colour clear - colourless
Odour characteristic
Melting point/freezing point not determined
Boiling point or initial boiling point and boiling not determined

range

Flammability non-combustible Lower and upper explosion limit not determined

Flash point 81 °C

Auto-ignition temperature not determined

Decomposition temperature not relevant
pH (value) not determined

Kinematic viscosity not determined

Solubility(ies)

Water solubility miscible in any proportion

Partition coefficient

Partition coefficient n-octanol/water (log value): this information is not available

Vapour pressure not determined

Density $1,06 \, \mathrm{g}/\mathrm{cm}^3$

Relative vapour density information on this property is not available

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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

lasses: (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.

If heated

Vapours may form explosive mixtures with air.

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, Aldehydes, Strong alkali, Strong acid

10.4 Conditions to avoid

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

10.5 Incompatible materials

different plastics, Rubber articles, Light metals

10.6 Hazardous decomposition products

Hazardous combustion products: see section 5.

SECTION 11: Toxicological information

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

Test data are not available for the complete mixture.

Classification procedure

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

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

Acute toxicity

Toxic if swallowed. Harmful in contact with skin. Harmful if inhaled.

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Acute toxicity estimate (ATE) of components of the mixture

Name of substance	CAS No	Exposure route	ATE
Phenol	108-95-2	oral	100 ^{mg} / _{kg}
Phenol	108-95-2	dermal	630 ^{mg} / _{kg}
Phenol	108-95-2	inhalation: dust/mist	0,5 ^{mg} / _l /4h

Acute toxicity of components of the mixture

Name of substance	CAS No	Exposure route	Endpoint	Value	Species
Phenol	108-95-2	oral	LD50	317 ^{mg} / _{kg}	rat
Phenol	108-95-2	dermal	LD50	630 ^{mg} / _{kg}	rabbit

Skin corrosion/irritation

Causes severe skin burns and eye damage.

Serious eye damage/eye irritation

Causes serious eye damage.

Respiratory or skin sensitisation

Shall not be classified as a respiratory or skin sensitiser.

Germ cell mutagenicity

Suspected of causing genetic defects.

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

May cause damage to organs through prolonged or repeated exposure.

Aspiration hazard

Shall not be classified as presenting an aspiration hazard.

Symptoms related to the physical, chemical and toxicological characteristics

If swallowed

If swallowed danger of perforation of the esophagus and the stomach (strong corrosive effects)

• If in eyes

causes burns, Causes serious eye damage, risk of blindness

• If inhaled

Data are not available.

• If on skin

causes severe burns, causes poorly healing wounds

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Other information

Other adverse effects: Cardiovascular system, Liver and kidney damage

11.2 Endocrine disrupting properties

None of the ingredients are listed.

11.3 Information on other hazards

There is no additional information.

SECTION 12: Ecological information

12.1 Toxicity

Toxic to aquatic life with long lasting effects.

Aquatic toxicity (acute) of components of the mixture

Name of sub- stance	CAS No	Endpoint	Value	Species	Exposure time
Phenol	108-95-2	LC50	8,9 ^{mg} / _l	fish	96 h
Phenol	108-95-2	EC50	3,1 ^{mg} / _l	aquatic invertebrates	48 h

Aquatic toxicity (chronic) of components of the mixture

Name of sub- stance	CAS No	Endpoint	Value	Species	Exposure time
Phenol	108-95-2	LC50	21,93 ^{mg} / _l	fish	14 d
Phenol	108-95-2	EC50	10 ^{mg} / _l	aquatic invertebrates	16 d

Biodegradation

Data are not available.

12.2 Process of degradability

Degradability of components of the mixture

Name of substance	CAS No	Process	Degrada- tion rate	Time	Method	Source
Phenol	108-95-2	biotic/abiotic	85 %	14 d		
Phenol	108-95-2	carbon dioxide generation	45,5 %	3 d		ECHA
Phenol	108-95-2	oxygen deple- tion	96 %	20 d		ECHA

12.3 Bioaccumulative potential

Data are not available.

Bioaccumulative potential of components of the mixture

Name of substance	CAS No	BCF	Log KOW	BOD5/COD
Phenol	108-95-2 17,5 1,47 (30 °C)			

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12.4 Mobility in soil

Data are not available.

12.5 Results of PBT and vPvB assessment

Data are not available.

12.6 Endocrine disrupting properties

None of the ingredients are listed.

12.7 Other adverse effects

Data are not available.

SECTION 13: Disposal considerations

13.1 Waste treatment methods



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

Sewage disposal-relevant information

Do not empty into drains. Avoid release to the environment. Refer to special instructions/safety data sheets.

Waste treatment of containers/packagings

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

13.2 Relevant provisions relating to waste

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

13.3 Remarks

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

SECTION 14: Transport information

14.1 UN number or ID number

ADR/RID/ADN UN 2821
IMDG-Code UN 2821
ICAO-TI UN 2821

14.2 UN proper shipping name

ADR/RID/ADN PHENOL SOLUTION

IMDG-Code PHENOL SOLUTION

ICAO-TI Phenol solution

14.3 Transport hazard class(es)

ADR/RID/ADN 6.1 IMDG-Code 6.1

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ICAO-TI 6.1

14.4 Packing group

ADR/RID/ADN III
IMDG-Code III
ICAO-TI III

14.5 Environmental hazards hazardous to the aquatic environment

Environmentally hazardous substance (aquatic Phenol

environment):

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

Transport of dangerous goods by road, rail and inland waterway (ADR/RID/ADN) - Additional information

Proper shipping name PHENOL SOLUTION

Particulars in the transport document UN2821, PHENOL SOLUTION, 6.1, III, (E), environ-

mentally hazardous

Classification code T1

Danger label(s) 6.1, "Fish and tree"

Environmental hazards yes (hazardous to the aguatic environment)

Special provisions (SP) 802(ADN)

Excepted quantities (EQ) E1
Limited quantities (LQ) 5 L
Transport category (TC) 2
Tunnel restriction code (TRC) E
Hazard identification No 60
Emergency Action Code 2X

International Maritime Dangerous Goods Code (IMDG) - Additional information

Proper shipping name PHENOL SOLUTION

Particulars in the shipper's declaration UN2821, PHENOL SOLUTION, 6.1, III, MARINE

POLLUTANT

Marine pollutant yes (hazardous to the aquatic environment), (Phenol)

Danger label(s) 6.1, "Fish and tree"



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Special provisions (SP) 223 Excepted quantities (EQ) F1 5 L Limited quantities (LQ) **EmS** F-A, S-A Stowage category

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

Phenol solution Proper shipping name

Particulars in the shipper's declaration UN2821, Phenol solution, 6.1, III

Environmental hazards **YES** (hazardous to the aquatic environment)

Danger label(s) 6.1



Special provisions (SP) **A3** Excepted quantities (EQ) E1 Limited quantities (LQ) 2 L

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

none of the ingredients are listed

Dangerous substances with restrictions (REACH, Annex XVII)

Name of substance	Name acc. to inventory	CAS No	Restriction	No
ROTI®Aqua-Phenol	this product meets the criteria for classification in accordance with Reg- ulation No 1272/2008/EC		R3	3
ROTI®Aqua-Phenol	substances in tattoo inks and permanent make-up		R75	75

Legend

1. Shall not be used in:

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

tricks and jokes,

- games for one or more participants, or any article intended to be used as such, even with ornamental aspects, 2. Articles not complying with paragraph 1 shall not be placed on the market.

3. Shall not be placed on the market if they contain a colouring agent, unless required for fiscal reasons, or perfume,

- 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 require-

(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

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Legend

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

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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 weight:

(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

(f) in the case of a substance is the invalid in the legislation (EC) No 1223/2009 (17), the substance is present in the mixture in a concentration equal to or greater than 0,00005 % by weight;

(f) in the case of a substance for which a condition of one or more of the following kinds is specified in column g (Product type, Body parts) of the table in Annex IV to Regulation (EC) No 1223/2009, the substance is present in the mixture in a concentration equal to or greater than 0,00005 % by weight:

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

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

(n) in the case of a substance listed in Appendix 13 to this Annex, the substance is present in the mixture in a concentration equal to or greater than the concentration limit specified for that substance in that Appendix.

2. For the purposes of this entry use of a mixture "for tattooing purposes" means injection or introduction of the mixture into a person's skin, mucous membrane or eyeball, by any process or procedure (including procedures commonly referred to as permanent make-up, cosmetic tattooing, micro-blading and micro-pigmentation), with the aim of making a mark or design on his or her body.

3. If a substance not listed in Appendix 13 falls within more than one of points (a) to (g) of paragraph 1, the strictest concentration limit laid down in the points in question shall apply to that substance. If a substance listed in Appendix 13 also falls within one or more of points (a) to (g) of paragraph 1, the concentration limit laid down in point (h) of paragraph 1 shall apply to that substance.

as also falls within one of more of points (a) to (g) of paragraph 1, the concentration limit faid down in point (ii) of paragraph 1 shall apply to that substance.

4. By way of derogation, paragraph 1 shall not apply to the following substances until 4 January 2023:
(a) Pigment Blue 15:3 (CI 74160, EC No 205-685-1, CAS No 147-14-8);
(b) Pigment Green 7 (CI 74260, EC No 215-524-7, CAS No 1328-53-6).

5. If Part 3 of Annex VI to Regulation (EC) No 1272/2008 is amended after 4 January 2021 to classify or re-classify a substance such that the substance then becomes caught by point (a), (b), (c) or (d) of paragraph 1 of this entry, or such that it then falls within a different one of those points from the one within which it fell previously, and the date of application of that now or revised classification in fifty the date referred to in paragraph 1 or as the case may be paragraph. plication of that new or revised classification is after the date referred to in paragraph 1 or, as the case may be, paragraph 4 of this entry, that amendment shall, for the purposes of applying this entry to that substance, be treated as taking effect on the date of application of that new or revised classification.

6. If Annex II or Annex IV to Regulation (EC) No 1223/2009 is amended after 4 January 2021 to list or change the listing of a substance such that the substance then becomes caught by point (e), (f) or (g) of paragraph 1 of this entry, or such that it then falls within a different one of those points from the one within which it fell previously, and the

amendment takes effect after the date referred to in paragraph 1 or, as the case may be, paragraph 4 of this entry, that amendment shall, for the purposes of applying this entry to that substance, be treated as taking effect from the date falling 18 months after entry into force of the act by which that amendment was made.

7. Suppliers placing a mixture on the market for use for tattooing purposes shall ensure that, after 4 January 2022, the mixture is marked with the following information:

(a) the statement "Mixture for use in tattoos or permanent make-up";

(a) the statement "Mixture for use in tattoos or permanent make-up";
(b) a reference number to uniquely identify the batch;
(c) the list of ingredients in accordance with the nomenclature established in the glossary of common ingredient names pursuant to Article 33 of Regulation (EC) No 1223/2009, or in the absence of a common ingredient name, the IUPAC name. In the absence of a common ingredient name or IUPAC name, the CAS and EC number. Ingredients shall be listed in descending order by weight or volume of the ingredients at the time of formulation. "Ingredient" means any substance added during the process of formulation and present in the mixture for use for tattooing purposes. Impurities shall not be regarded as ingredients. If the name of a substance, used as ingredient within the meaning of this entry, is already required to be stated on the label in accordance with Regulation (EC) No 1272/2008, that ingredient does not need to be marked in accordance with this Regulation;
(d) the additional statement "pH regulator" for substances falling under point (d)(i) of paragraph 1;
(e) the statement "Contains nickel. Can cause allergic reactions." if the mixture contains nickel below the concentration limit specified in Appendix 13;

tion limit specified in Appendix 13

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

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

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

The information shall be written in the official language(s) of the Member State(s) where the mixture is placed on the market, unless the Member State(s) concerned provide(s) otherwise.

Where necessary because of the size of the package, the information listed in the first subparagraph, except for point (a), shall be included instead in the instructions for use.

Before using a mixture for tattooing purposes, the person using the mixture shall provide the person undergoing the procedure with the information marked on the package or included in the instructions for use pursuant to this paragraph. 8. Mixtures that do not contain the statement "Mixture for use in tattoos or permanent make-up" shall not be used for

tattooing purposes.

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

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

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

None of the ingredients are listed. (Or Concentration of the substance in a mixture: <0.1 % Mass concentration)

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			
E2	environmental hazards (hazardous to the aquatic environment, cat. 2)	200 500	57)			

Notation

57) Hazardous to the Aquatic Environment in category Chronic 2

Deco-Paint Directive

VOC content	41,73 %
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Industrial Emissions Directive (IED)

VOC content	41,73 %

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
Phenol	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		A)	

Legend

A) Indicative list of the main pollutants

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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

National inventories

Country	Inventory	Status	
AU	AICS	all ingredients are listed	
CA	DSL	all ingredients are listed	
CN	IECSC	all ingredients are listed	
EU	ECSI	all ingredients are listed	
EU	REACH Reg.	all ingredients are listed	
JP	CSCL-ENCS	all ingredients are listed	
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	

Legend

AICS Australian Inventory of Chemical Substances
CICR Chemical Inventory and Control Regulation
CSCL-ENCS List of Existing and New Chemical Substances (CSCL-ENCS)
DSL Domestic Substances List (DSL)
ECSI EC Substance Inventory (EINECS, ELINCS, NLP)
IECSC Inventory of Existing Chemical Substances Produced or Imported in China INSQ National Inventory of Chemical Substances
ISHA-ENCS Inventory of Existing and New Chemical Substances (ISHA-ENCS)
KECI Korea Existing Chemicals Inventory

KECI NZIoC

Korea Existing Chemicals Inventory
New Zealand Inventory of Chemicals
Philippine Inventory of Chemicals and Chemical Substances (PICCS)

REACH Reg. REACH registered substances

TCSI TSCA Taiwan Chemical Substance Inventory **Toxic Substance Control Act**

15.2 Chemical Safety Assessment

Chemical safety assessments for substances in this mixture were not carried out.

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SECTION 16: Other information

Indication of changes (revised safety data sheet)

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

Restructuring: section 9, section 14

Section	Former entry (text/value)	Actual entry (text/value)	Safety- relev- ant
2.1		Classification according to Regulation (EC) No 1272/2008 (CLP): change in the listing (table)	yes
2.1	Remarks: For full text of Hazard- and EU Hazard-state- ments: see SECTION 16.		yes
2.1		The most important adverse physicochemical, human health and environmental effects: Skin corrosion produces an irreversible damage to the skin; namely, visible necrosis through the epidermis and into the dermis. Delayed or immediate effects can be expected after short or long-term exposure. Spillage and fire water can cause pollution of watercourses.	yes
2.2		Pictograms: change in the listing (table)	yes
2.2		Hazard statements: change in the listing (table)	yes
2.2		Precautionary statements - prevention: change in the listing (table)	yes
2.2		Labelling of packages where the contents do not exceed 125 ml: change in the listing (table)	yes
2.2		Labelling of packages where the contents do not exceed 125 ml: change in the listing (table)	yes
2.3	Other hazards: There is no additional information.	Other hazards: This material is combustible, but will not ignite readily.	yes
2.3		Results of PBT and vPvB assessment: This mixture does not contain any substances that are assessed to be a PBT or a vPvB.	yes

Abbreviations and acronyms

Abbr.	Descriptions of used abbreviations
2009/161/EU	Commission Directive establishing a third list of indicative occupational exposure limit values in implementation of Council Directive 98/24/EC and amending Commission Directive 2000/39/EC
Acute Tox.	Acute toxicity
ADN	Accord européen relatif au transport international des marchandises dangereuses par voies de naviga- tion intérieures (European Agreement concerning the International Carriage of Dangerous Goods by In- land Waterways)
ADR	Accord européen relatif au transport international des marchandises dangereuses par route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

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Abbr.	Descriptions of used abbreviations
ADR/RID/ADN	European Agreements concerning the International Carriage of Dangerous Goods by Road/Rail/Inland Waterways (ADR/RID/ADN)
Aquatic Chronic	Hazardous to the aquatic environment - chronic hazard
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)
EH40/2005	EH40/2005 Workplace exposure limits (http://www.nationalarchives.gov.uk/doc/open-government-li- cence/)
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of Notified Chemical Substances
EmS	Emergency Schedule
Eye Dam.	Seriously damaging to the eye
Eye Irrit.	Irritant to the eye
GHS	"Globally Harmonized System of Classification and Labelling of Chemicals" developed by the United Nations
IATA	International Air Transport Association
IATA/DGR	Dangerous Goods Regulations (DGR) for the air transport (IATA)
ICAO	International Civil Aviation Organization
ICAO-TI	Technical instructions for the safe transport of dangerous goods by air
IMDG	International Maritime Dangerous Goods Code
IMDG-Code	International Maritime Dangerous Goods Code
index No	The Index number is the identification code given to the substance in Part 3 of Annex VI to Regulation (EC) No 1272/2008
IOELV	Indicative occupational exposure limit value
LC50	Lethal Concentration 50%: the LC50 corresponds to the concentration of a tested substance causing 50 % lethality during a specified time interval
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

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Abbr.	Descriptions of used abbreviations
Muta.	Germ cell mutagenicity
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)
Skin Corr.	Corrosive to skin
Skin Irrit.	Irritant to skin
STEL	Short-term exposure limit
STOT RE	Specific target organ toxicity - repeated exposure
SVHC	Substance of Very High Concern
TWA	Time-weighted average
VOC	Volatile Organic Compounds
vPvB	Very Persistent and very Bioaccumulative
WEL	Workplace exposure limit

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.

Transport of dangerous goods by road, rail and inland waterway (ADR/RID/ADN). 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 chapter 2 and 3)

Code	Text
H301	Toxic if swallowed.
H311	Toxic in contact with skin.
H312	Harmful in contact with skin.
H314	Causes severe skin burns and eye damage.
H318	Causes serious eye damage.
H331	Toxic if inhaled.
H332	Harmful if inhaled.
H341	Suspected of causing genetic defects.
H373	May cause damage to organs through prolonged or repeated exposure.

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Code	Text
H411	Toxic to aquatic life with long lasting effects.

Disclaimer

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

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