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

Nitric acid ROTIPURAN® 68-70 %, p.a., ACS, ISO

article number: 1C8Y date of compilation: 25.06.2020 Version: **3.0 en** Revision: 31.01.2023

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Version: (2)



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

Product identifier 1.1

Identification of the substance Nitric acid ROTIPURAN® 68-70 %, p.a., ACS, ISO

Article number 1C8Y

Registration number (REACH) not relevant (mixture)

Index number in CLP Annex VI [007-030-00-3] EC number [231-714-2]

CAS number [7697-37-2]

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:

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

1.4 **Emergency telephone number**

SECTION 2: Hazards identification

Classification of the substance or mixture

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

| Section | Hazard class | Cat- egory | Hazard class and category | Hazard statement |
|---------|--|---------------|---------------------------|---------------------|
| 2.13 | Oxidising liquid | 3 | Ox. Liq. 3 | H272 |
| 2.16 | Substance or mixture corrosive to metals | 1 | Met. Corr. 1 | H290 |
| 3.1I | Acute toxicity (inhal.) | 3 | Acute Tox. 3 | H331 |
| 3.2 | Skin corrosion/irritation | 1A | Skin Corr. 1A | H314 |

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| Section | Hazard class | Cat- egory | Hazard class and category | Hazard statement |
|---------|-----------------------------------|---------------|---------------------------|---------------------|
| 3.3 | Serious eye damage/eye irritation | 1 | Eye Dam. 1 | H318 |

Supplemental hazard information

| Code | Supplemental hazard information |
|--------|------------------------------------|
| EUH071 | corrosive to the respiratory tract |

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.

2.2 Label elements

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

Signal word Danger

Pictograms

GHS03, GHS05, GHS06



Hazard statements

| H272 | May intensify fire; oxidiser |
|------|---------------------------------|
| H290 | May be corrosive to metals |
| H314 | Causes severe skin hurns and ex |

H314 Causes severe skin burns and eye damage

H331 Toxic if inhaled

Precautionary statements

Precautionary statements - prevention

P220 Keep/store away from combustible materials

P260 Do not breathe mist/vapours/spray

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

Precautionary statements - response

P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin

with water [or shower]

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

Supplemental hazard information

EUH071 Corrosive to the respiratory tract.

Hazardous ingredients for labelling: Nitric acid ...% [C ≤ 70 %]

Labelling of packages where the contents do not exceed 125 ml

Signal word: Danger

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Symbol(s)







H314 Causes severe skin burns and eye damage.

H331 Toxic if inhaled.

P260 Do not breathe mist/vapours/spray.

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

P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water or shower. P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to

do. Continue rinsing.

Immediately call a POISON CENTER/doctor. P310

EUH071 Corrosive to the respiratory tract. contains: Nitric acid ...% [C ≤ 70 %]

2.3 Other hazards

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 |
|----------------------------|---|-----------|--|------------|-------------------------|
| Nitric acid% [C ≤ 70 %] | CAS NO 7697-37-2 EC No 231-714-2 Index No 007-030-00-3 REACH Reg. No 01-2119487297- 23-xxxx | 65 – < 70 | Ox. Liq. 3 / H272 Met. Corr. 1 / H290 Acute Tox. 3 / H331 Skin Corr. 1A / H314 Eye Dam. 1 / H318 EUH071 | | B(a) GHS-HC IOELV |

The classification refers to an aqueous solution

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

| Name of sub- stance | Identifier | Specific Conc. Limits | M-Factors | ATE | Exposure route |
|----------------------------|---|--|-----------|---------------------------------------|-------------------------|
| Nitric acid% [C ≤ 70 %] | CAS No 7697-37-2 EC No 231-714-2 Index No 007-030-00-3 | Ox. Liq. 3; H272: C ≥ 65 % Skin Corr. 1A; H314: C ≥ 20 % Skin Corr. 1B; H314: 5 % ≤ C < 20 % | - | 2,65 ^{mg} / _l /4h | inhalation: va- pour |

For full text of abbreviations: see SECTION 16

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SECTION 4: First aid measures

4.1 Description of first aid measures



General notes

Take off immediately all contaminated clothing. Self-protection of the first aider.

Following inhalation

Call a physician immediately. If breathing is irregular or stopped, administer artificial respiration.

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).

4.2 Most important symptoms and effects, both acute and delayed

Corrosion, Gastric perforation, Risk of serious damage to eyes, Risk of blindness, Cough, Dyspnoea, Pulmonary oedema

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

Oxidising property. 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. Wear full chemical protective clothing.

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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. The product is an acid. Before discharge into sewage plants the product normally needs to be neutralised.

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

Provide adequate ventilation as well as local exhaustion at critical locations. Use extractor hood (laboratory). Handle and open container with care. Clear contaminated areas thoroughly.

Measures to prevent fire as well as aerosol and dust generation

Take any precaution to avoid mixing with combustibles.

Advice on general occupational hygiene

Wash hands before breaks and after work.

7.2 Conditions for safe storage, including any incompatibilities

Store in a well-ventilated place. Keep container tightly closed. Keep only in original container. May cause decomposition by long-term light influence.

Incompatible substances or mixtures

Observe hints for combined storage. Keep/store away from clothing/combustible materials. Take any precaution to avoid mixing with combustibles.

Protect against external exposure, such as

UV-radiation/sunlight, contact with air/oxygen

Consideration of other advice:

Store locked up.

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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: 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)

| 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 | nitric acid | 7697-37- 2 | IOELV | | | 1 | 2,6 | | | | 2006/15/ EC |
| MT | nitric acid | 7697-37- 2 | OELV | | | 1 | 2,6 | | | | CAP. 424 |

Notation

TWA

Ceiling-C Ceiling value is a limit value above which exposure should not occur

STFI 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 hours time-weighted average (unless otherwise specified)

8.2 **Exposure controls**

Individual protection measures (personal protective equipment)

Eve/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

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ROTH

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to substance mixtures, they may only be considered as a guide.

type of material

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

material thickness

0,7mm

• 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. Type: NO-P3 (against nitrous gases and particles, colour code: Blue/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 colourless - light yellow

Odour stinging

Melting point/freezing point not determined

Boiling point or initial boiling point and boiling 120 – 121 °C

range

Flammability non-combustible
Lower and upper explosion limit not determined
Flash point not determined
Auto-ignition temperature not determined
Decomposition temperature not relevant

Kinematic viscosity not determined

Solubility(ies)

pH (value)

Water solubility miscible in any proportion

Partition coefficient

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

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<1 (20 °C)

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

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Vapour pressure 9 – 9,5 hPa at 20 °C

Density and/or relative density

Density 1,39 – 1,41 ^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 oxidiser

9.2 Other information

Information with regard to physical hazard

classes:

Oxidising liquids

Spontaneous ignition Mean pressure rise time is less than or equal to

that of a 1:1 mixture, by mass, of 65 % aqueous

sodium chlorate solution and cellulose

Corrosive to metals category 1: corrosive to metals

Other safety characteristics:

Miscibility completely miscible with water

SECTION 10: Stability and reactivity

10.1 Reactivity

The mixture contains reactive substance(s). Oxidising property. 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: Acetone, Aldehydes, Alkali (lye), Alkali metals, Alcohols, Formic acid, Amines, Ammonia (NH3), Aniline, Combustible materials, Dichloromethane, Alkaline earth metal, Acetic anhydride, Hydrozarbons, Metal powder, Nitriles, Reducing agents, Strong alkali, Hydrogen peroxide,

=> Explosive properties

10.4 Conditions to avoid

UV-radiation/sunlight. Keep away from heat.

10.5 Incompatible materials

combustible materials, Cellulose, different metals

Release of flammable materials with

Metals, Light metals (due to the release of hydrogen in an acid/alkaline medium)

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

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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 inhaled.

Acute toxicity estimate (ATE) of components of the mixture

| Name of substance | CAS No | Exposure route | ATE |
|-------------------------|-----------|--------------------|---------------------------------------|
| Nitric acid% [C ≤ 70 %] | 7697-37-2 | inhalation: vapour | 2,65 ^{mg} / _l /4h |

Acute toxicity of components of the mixture

| Name of substance | CAS No | Exposure route | Endpoint | Value | Species |
|-------------------------|-----------|-------------------------|----------|--|---------|
| Nitric acid% [C ≤ 70 %] | 7697-37-2 | inhalation: va- pour | LC50 | >2,65 ^{mg} / _l /4h | rat |

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

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.

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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

corrosive to the respiratory tract, cough, Dyspnoea, pulmonary oedema

• If on skin

causes severe burns, causes poorly healing wounds

Other information

none

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

Shall not be classified as hazardous to the aquatic environment.

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

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.

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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.

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 2 oxidising

HP 4 irritant - skin irritation and eye damage

HP 6 acute toxicity

HP8 corrosive

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 | UN 2031 |
|-----------|---------|
| IMDG-Code | UN 2031 |
| ICAO-TI | UN 2031 |

14.2 UN proper shipping name

| ADR | NITRIC ACID |
|-----------|-------------|
| IMDG-Code | NITRIC ACID |
| ICAO-TI | Nitric acid |

14.3 Transport hazard class(es)

| ADR | 8 (5.1) |
|-----------|---------|
| IMDG-Code | 8 (5.1) |
| ICAO-TI | 8 (5.1) |

14.4 Packing group

| ADR | II |
|-----------|----|
| IMDG-Code | II |
| ICAO-TI | II |

14.5 Environmental hazardsnon-environmentally hazardous acc. to the dangerous 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.

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14.8 Information for each of the UN Model Regulations

Agreement concerning the International Carriage of Dangerous Goods by Road (ADR)Additional information

Proper shipping name NITRIC ACID

Particulars in the transport document UN2031, NITRIC ACID, 8 (5.1), II, (E)

Classification code CO1
Danger label(s) 8+5.1



Excepted quantities (EQ) E2
Limited quantities (LQ) 1 L
Transport category (TC) 2
Tunnel restriction code (TRC) E
Hazard identification No 85

International Maritime Dangerous Goods Code (IMDG) - Additional information

Proper shipping name NITRIC ACID

Particulars in the shipper's declaration UN2031, NITRIC ACID, 8 (5.1), II

Marine pollutant -

Danger label(s) 8+5.1





Excepted quantities (EQ) E2
Limited quantities (LQ) 1 L

EmS F-A, S-Q

Stowage category D

Segregation group 1 - Acids

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

Proper shipping name Nitric acid

Particulars in the shipper's declaration UN2031, Nitric acid, 8 (5.1), II

Danger label(s) 8+5.1





Special provisions (SP) A1
Excepted quantities (EQ) E0

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SECTION 15: Regulatory information

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

Restrictions according to REACH, Annex XVII

Dangerous substances with restrictions (REACH, Annex XVII)

| Name of substance | Name acc. to inventory | CAS No | Restriction | No |
|-------------------------|--|--------|-------------|----|
| Nitric acid | this product meets the criteria for classification in accordance with Reg- ulation No 1272/2008/EC | | R3 | 3 |
| Nitric acid% [C ≤ 70 %] | 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 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
- opaque containers not exceeding 1 litre by 1 December 2010.';

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Legend

R75

1. Shall not be placed on the market in mixtures for use for tattooing purposes, and mixtures containing any such substances shall not be used for tattooing purposes, after 4 January 2022 if the substance or substances in question is or are present in the following circumstances:

(a) in the case of a substance classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 as carcinogen category

1A, 1B or 2, or germ cell mutagen category 1A, 1B or 2, the substance is present in the mixture in a concentration equal to or greater than 0,00005 % by weight; (b) in the case of a substance classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 as reproductive toxicant category 1A, 1B or 2, the substance is present in the mixture in a concentration equal to or greater than 0,001 % by

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

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

(i) 0,1 % by weight, if the substance is used solely as a pH regulator

(ií) 0,01 % by weight, in all other cases;

(e) in the case of a substance listed in Annex II to Regulation (EC) No 1223/2009 (*1), the substance is present in the

mixture in a concentration equal to or greater than 0,00005 % by weight;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

tion limit specified in Appendix 13

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

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

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

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

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

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

tattooing purposes.

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Legend

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

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

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

None of the ingredients are listed.

Seveso Directive

2012/18/EU (Seveso III)

| No | Dangerous substance/hazard categories | Qualifying quantity (tonnes) for the application of lower and upper-tier requirements | | |
|----|---------------------------------------|---|-----|-----|
| H2 | acute toxic (cat. 2 + cat. 3, inhal.) | 50 | 200 | 41) |
| P8 | oxidising liquids and solids | 50 | 200 | 55) |

Notation

- Category 2, all exposure routes
- category 3, inhalation exposure route Oxidising liquids, category 1, 2 or 3, or oxidising solids, category 1, 2 or 3

Deco-Paint Directive

| VOC content | 0 % 0 ^g / _I |
|-------------|--------------------------------------|
|-------------|--------------------------------------|

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)

none of the ingredients are listed

Regulation on the marketing and use of explosives precursors

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| Explosives precursors which are subject to restrictions | | | | | | |
|---|-----------|-----|----------------------|--------------|----------------|--|
| Name of substance | CAS No | Wt% | Type of registration | Re- marks | Limit value | Upper limit value for the pur- pose of licens- ing un- der Art- icle 5(3) |
| Nitric acid% [C ≤ 70 %] | 7697-37-2 | 69 | Annex I | | 3 % w/w | 10 % w/w |

Legend

annex I

Substances which shall not be made available to members of the general public on their own, or in mixtures or substances including them, except if the concentration is equal to or lower than the limit values set out below

Additional statements

If the product is passed on to third parties, in accordance with Article 7 "Notification of the supply chain" of Regulation EU 2019/1148, the information obligation is subject to the entire supply chain and all other provisions mentioned in Article 7 on restricted and regulated raw materials.

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

| 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 |
| 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 |

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| Country | Inventory | Status |
|---------|-----------|--|
| TW | TCSI | all ingredients are listed |
| US | TSCA | all ingredients are listed as "ACTIVE" |

Legend

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

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

TCSI 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.

SECTION 16: Other information

Indication of changes (revised safety data sheet)

| Section | Former entry (text/value) | Actual entry (text/value) | Safety- relev- ant |
|---------|--|---|--------------------------|
| 15.1 | List of substances subject to authorisation (REACH, Annex XIV)/SVHC - candidate list: None of the ingredients are listed. (Or Concentration of the substance in a mixture: <0.1 % Mass concentration) | List of substances subject to authorisation (REACH, Annex XIV)/SVHC - candidate list: None of the ingredients are listed. | yes |
| 15.1 | | Explosives precursors which are subject to re- strictions: change in the listing (table) | yes |
| 15.1 | | Additional statements: If the product is passed on to third parties, in accordance with Article 7 "Notification of the supply chain" of Regulation EU 2019/1148, the information obligation is subject to the entire supply chain and all other provisions mentioned in Article 7 on restricted and regulated raw materials. | yes |
| 15.1 | | National inventories: change in the listing (table) | yes |

Abbreviations and acronyms

| Abbr. | Descriptions of used abbreviations |
|------------|--|
| 2006/15/EC | Commission Directive establishing a second list of indicative occupational exposure limit values in implementation of Council Directive 98/24/EC and amending Directives 91/322/EEC and 2000/39/EC |
| Acute Tox. | Acute toxicity |
| 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 |
| CAP. 424 | Occupational Health and Safety Authority Act (CAP. 424) |

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| Abbr. | Descriptions of used abbreviations |
|-------------|---|
| 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 |
| DGR | Dangerous Goods Regulations (see IATA/DGR) |
| EC No | The EC Inventory (EINECS, ELINCS and the NLP-list) is the source for the seven-digit EC number, an identifier of substances commercially available within the EU (European Union) |
| EINECS | European Inventory of Existing Commercial Chemical Substances |
| ELINCS | European List of Notified Chemical Substances |
| 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 |
| Met. Corr. | Substance or mixture corrosive to metals |
| NLP | No-Longer Polymer |
| Ox. Liq. | Oxidising liquid |
| PBT | Persistent, Bioaccumulative and Toxic |
| ppm | Parts per million |
| REACH | Registration, Evaluation, Authorisation and Restriction of Chemicals |
| 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 |

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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 |
|------|--|
| H272 | May intensify fire; oxidiser. |
| H290 | May be corrosive to metals. |
| H314 | Causes severe skin burns and eye damage. |
| H318 | Causes serious eye damage. |
| H331 | Toxic if inhaled. |

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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