## Safety data sheet

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

Nitrilotriacetic acid $\geq 99$ \%, p.a., ACS
article number: 4384
Version: 3.0 en
Replaces version of: 2022-07-29
Version: (2)

## 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)
EC number
CAS number
Alternative name(s)

Nitrilotriacetic acid $\geq 99$ \%, p.a., ACS
4384
01-2119471481-40-xxxx
205-355-7
139-13-9
Komplexon ${ }^{\circledR}$
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 products which come into contact with foodstuffs. 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) 721-56 060
Telefax: +49 (0) 721-56 06149
e-mail: sicherheit@carlroth.de
Website: www.carlroth.de

Competent person responsible for the safety data sheet:

Department Health, Safety and Environment
sicherheit@carlroth.de
1.4 Emergency telephone number

| Name | Street | Postal <br> code/city | Telephone | Website |
| :---: | :---: | :---: | :---: | :---: |
| National Poisons Information <br> Centre <br> Beaumont Hospital | Beaumont Road | Dublin 9 | +35318092166 | https:// <br> www.poisons.ie/ |

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## 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- <br> egory | Hazard class and <br> category | Hazard <br> statement |
| :---: | :---: | :---: | :---: | :---: |
| 3.3 | Serious eye damage/eye irritation | 2 | Eye Irrit. 2 | H319 |
| 3.6 | Carcinogenicity | 2 | Carc. 2 | H351 |

For full text of abbreviations: see SECTION 16

### 2.2 Label elements <br> Labelling according to Regulation (EC) No 1272/2008 (CLP)

Signal word Warning
Pictograms

GHS07, GHSO8


Hazard statements
H319
Causes serious eye irritation
H351
Suspected of causing cancer

Precautionary statements
Precautionary statements - prevention
P280 Wear protective gloves/eye protection

## Precautionary statements - response

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
P308+P313 IF exposed or concerned: Get medical advice/attention

For professional users only

Labelling of packages where the contents do not exceed 125 ml
Signal word: Warning
Symbol(s)


## H351 Suspected of causing cancer.

P280 Wear protective gloves/eye protection.
P308+P313 IF exposed or concerned: Get medical advice/attention.

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### 2.3 Other hazards

## Results of PBT and vPvB assessment

According to the results of its assessment, this substance is not a PBT or a vPvB.
Endocrine disrupting properties
Does not contain an endocrine disruptor (ED) at a concentration of $\geq 0,1 \%$.

## SECTION 3: Composition/information on ingredients

### 3.1 Substances

| Name of substance | Nitrilotriacetic acid |
| :--- | :--- |
| Molecular formula | $\mathrm{C}_{6} \mathrm{H}_{9} \mathrm{NO}_{6}$ |
| Molar mass | $191,1 \mathrm{~g} / \mathrm{mol}$ |
| REACH Reg. No | $01-2119471481-40-\mathrm{xxxx}$ |
| CAS No | $139-13-9$ |
| EC No | $205-355-7$ |

## SECTION 4: First aid measures

### 4.1 Description of first aid measures



## General notes

Take off contaminated clothing,

## Following inhalation

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

## Following skin contact

Rinse skin with water/shower.
Following eye contact
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

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

Irritation
4.3 Indication of any immediate medical attention and special treatment needed none

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## SECTION 5: Firefighting measures

### 5.1 Extinguishing media



## Suitable extinguishing media

co-ordinate firefighting measures to the fire surroundings!
water, foam, alcohol resistant foam, dry extinguishing powder, ABC-powder
Unsuitable extinguishing media
water jet
5.2 Special hazards arising from the substance or mixture

Combustible.

## Hazardous combustion products

In case of fire may be liberated: Nitrogen oxides (NOx), Carbon monoxide (CO), Carbon dioxide ( $\mathrm{CO}_{2}$ )

### 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

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

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

### 6.3 Methods and material for containment and cleaning up

Advice on how to contain a spill
Covering of drains. Take up mechanically.
Advice on how to clean up a spill
Take up mechanically. Control of dust.
Other information relating to spills and releases
Place in appropriate containers for disposal.

### 6.4 Reference to other sections

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

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## SECTION 7: Handling and storage

### 7.1 Precautions for safe handling

Provision of sufficient ventilation. Avoid exposure. Avoid dust formation.
Measures to prevent fire as well as aerosol and dust generation
Removal of dust deposits.
Advice on general occupational hygiene
Wash hands before breaks and after work. Keep away from food, drink and animal feedingstuffs.
7.2 Conditions for safe storage, including any incompatibilities

Store in a dry place.
Incompatible substances or mixtures
Observe hints for combined storage.
Consideration of other advice:

## Ventilation requirements

Use local and general ventilation.
Specific designs for storage rooms or vessels
Recommended storage temperature: $15-25^{\circ} \mathrm{C}$
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)

| Coun <br> try | Name of agent | CAS No | Identifi- <br> er | TWA <br> $\left[\mathrm{mg}^{3} /\right.$ <br> $\left.\mathrm{m}^{3}\right]$ | STEL <br> [mg/ <br> $\left.\mathrm{m}^{3}\right]$ | Ceil- <br> ing-C <br> [mg/ <br> $\left.\mathrm{m}^{3}\right]$ | Nota- <br> tion | Source |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| IE | dusts, non-specific |  | OELV | 10 |  |  | i | S.I. No. 619 <br> of 2001 |
| IE | dusts, non-specific |  | OELV | 4 |  |  | r | S.I. No. 619 <br> of 2001 |

## Notation

Ceiling-C Ceiling value is a limit value above which exposure should not occur
i Inhalable fraction
$r \quad$ Respirable fraction
STEL 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)

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Human health values
Relevant DNELs and other threshold levels

| Endpoint | Threshold <br> level | Protection goal, <br> route of exposure | Used in | Exposure time |
| :---: | :---: | :---: | :---: | :---: |
| DNEL | $29 \mathrm{mg} / \mathrm{m}^{3}$ | human, inhalatory | worker (industry) | chronic - local effects |
| DNEL | $29 \mathrm{mg} / \mathrm{m}^{3}$ | human, inhalatory | worker (industry) | acute - local effects |
| DNEL | $3,7 \mathrm{mg} / \mathrm{m}^{3}$ | human, inhalatory | worker (industry) | chronic - systemic effects |
| DNEL | $11,2 \mathrm{mg} / \mathrm{m}^{3}$ | human, inhalatory | worker (industry) | acute - systemic effects |
| DNEL | $169,6 \mathrm{mg} / \mathrm{kg}$ <br> bw/day | human, dermal | worker (industry) | chronic - systemic effects |

## Environmental values

## Relevant PNECs and other threshold levels

| End- <br> point | Threshold <br> level | Organism | Environmental com- <br> partment | Exposure time |
| :---: | :---: | :---: | :---: | :---: |
| PNEC | $0,93^{\mathrm{mg} / \mathrm{l}}$ | aquatic organisms | freshwater | short-term (single instance) |
| PNEC | $0,093^{\mathrm{mg} / \mathrm{l}}$ | aquatic organisms | marine water | short-term (single instance) |
| PNEC | $400 \mathrm{mg} / \mathrm{l}$ | aquatic organisms | sewage treatment plant <br> (STP) | short-term (single instance) |
| PNEC | $5,77 \mathrm{mg} / \mathrm{kg}$ | aquatic organisms | freshwater sediment | short-term (single instance) |
| PNEC | $0,577^{\mathrm{mg} / \mathrm{kg}}$ | aquatic organisms | marine sediment | short-term (single instance) |
| PNEC | $0,606 \mathrm{mg} / \mathrm{kg}$ | terrestrial organisms | soil | short-term (single instance) |

### 8.2 Exposure controls

Individual protection measures (personal protective equipment)
Eye/face protection


Use safety goggle with side protection.
Skin protection


## - hand protection

Wear suitable gloves. Chemical protection gloves are suitable, which are tested according to EN 374. 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 $22^{\circ} \mathrm{C}$ 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

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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
$>0,11 \mathrm{~mm}$
- breakthrough times of the glove material
>480 minutes (permeation: level 6)
- other protection measures

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


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

Environmental exposure controls
Keep away from drains, surface and ground water.

## SECTION 9: Physical and chemical properties

### 9.1 Information on basic physical and chemical properties

Physical state
Form
Colour
Odour
Melting point/freezing point
Boiling point or initial boiling point and boiling range

Flammability

Lower and upper explosion limit
Flash point
Auto-ignition temperature

Decomposition temperature
pH (value)
Kinematic viscosity
Dynamic viscosity
solid
powder
white
odourless
$242{ }^{\circ} \mathrm{C}$ (ECHA)
$160^{\circ} \mathrm{C}$ at 1.013 hPa (ECHA)
this material is combustible, but will not ignite readily
not determined
$100^{\circ} \mathrm{C}$ at 1.013 hPa (c.c.)
$>400^{\circ} \mathrm{C}$ at 1.013 Pa (relative self-ignition temperature for solids)
not relevant
1,7-2,7 (in aqueous solution: $10^{9} /{ }^{\prime}, 23^{\circ} \mathrm{C}$ )
$0,509 \mathrm{~mm}^{2} / \mathrm{s}$ at $20^{\circ} \mathrm{C}$ not relevant
$0,85 \mathrm{mPa}$ s at $20^{\circ} \mathrm{C}$

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Solubility(ies)
Water solubility $1,289 /$ at $22,5^{\circ} \mathrm{C}$ (ECHA)

Partition coefficient
Partition coefficient n-octanol/water (log value): $\quad-3,81\left(25^{\circ} \mathrm{C}\right)(\mathrm{ECHA})$
Soil organic carbon/water (log KOC)
1,42 (ECHA)

Vapour pressure
0 hPa at $20^{\circ} \mathrm{C}$
Density and/or relative density
Density
$1,67{ }^{9} / \mathrm{cm}^{3}$ (ECHA)
Relative vapour density
Bulk density
Information on this property is not available.
$\sim 350 \mathrm{~kg} / \mathrm{m}^{3}$

Particle characteristics
No data available.

Other safety parameters
Oxidising properties
none

### 9.2 Other information

Information with regard to physical hazard
hazard classes acc. to GHS classes:
(physical hazards): not relevant
Other safety characteristics:
Surface tension
$50,6 \mathrm{mN} / \mathrm{m}\left(20^{\circ} \mathrm{C}\right)(\mathrm{ECHA})$
Temperature class (EU, acc. to ATEX)

T3
Maximum permissible surface temperature on the equipment: $200^{\circ} \mathrm{C}$

## SECTION 10: Stability and reactivity

### 10.1 Reactivity

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

### 10.2 Chemical stability

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

### 10.3 Possibility of hazardous reactions

Violent reaction with: strong oxidiser, Metals, Strong alkali

### 10.4 Conditions to avoid

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

### 10.5 Incompatible materials

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aluminium, copper, zinc, Copper alloys, nickel

### 10.6 Hazardous decomposition products

Hazardous combustion products: see section 5.

## SECTION 11: Toxicological information

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

Classification according to GHS (1272/2008/EC, CLP)
Acute toxicity
Shall not be classified as acutely toxic.

| Acute toxicity |  |  |  |  |  |  |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| Exposure route | Endpoint | Value | Species | Method | Source |  |
| oral | LD50 | $>6.400 \mathrm{mg} / \mathrm{kg}$ | rat |  | ECHA |  |

Skin corrosion/irritation
Shall not be classified as corrosive/irritant to skin.
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

Suspected of causing cancer.

## 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.

- If in eyes

Causes serious eye irritation

- If inhaled

Data are not available.

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## - If on skin

Frequently or prolonged contact with skin may cause dermal irritation

- Other information

Other adverse effects: Liver and kidney damage, Due to its pH value (see section 9), irritation of the skin and eyes cannot be ruled out

### 11.2 Endocrine disrupting properties

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

### 11.3 Information on other hazards

There is no additional information.

## SECTION 12: Ecological information

### 12.1 Toxicity

Shall not be classified as hazardous to the aquatic environment.

## Aquatic toxicity (acute)

| Endpoint | Value | Species | Source | Exposure <br> time |
| :---: | :---: | :---: | :---: | :---: |
| LC50 | $114 \mathrm{mg} / \mathrm{l}$ | fish | ECHA | 96 h |
| EC50 | $1.000 \mathrm{mg} / \mathrm{l}$ | aquatic invertebrates | ECHA | 48 h |
| ErC50 | $>100 \mathrm{mg} / \mathrm{l}$ | algae | ECHA | 72 h |

## Aquatic toxicity (chronic)

| Endpoint | Value | Species | Source | Exposure <br> time |
| :---: | :---: | :---: | :---: | :---: |
| LC50 | $5,7 \mathrm{mg} / \mathrm{l}$ | aquatic invertebrates | ECHA | 21 d |

### 12.2 Persistence and degradability

Theoretical Oxygen Demand (without nitrification): $0,7533 \mathrm{mg} / \mathrm{mg}$
Theoretical Oxygen Demand (with nitrification): $1,088 \mathrm{mg} / \mathrm{mg}$
Theoretical Carbon Dioxide: $1,381 \mathrm{mg} / \mathrm{mg}$

## Biodegradation

The substance is readily biodegradable.

| Process of degradability |  |  |  | Degradation rate | Time |
| :---: | :---: | :---: | :---: | :---: | :---: |
| Process | $>90 \%$ | d |  |  |  |
| biotic/abiotic | $95 \%$ | 28 d |  |  |  |
| oxygen depletion | $89 \%$ | 14 d |  |  |  |
| carbon dioxide generation |  |  |  |  |  |

### 12.3 Bioaccumulative potential

Does not significantly accumulate in organisms.

| n-octanol/water (log KOW) | $-3,81\left(25^{\circ} \mathrm{C}\right)(E C H A)$ |
| :--- | :--- |

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### 12.4 Mobility in soil

| Henry's law constant | $0^{\mathrm{Pa} \mathrm{m}^{3} / \mathrm{mol}}$ at $25^{\circ} \mathrm{C}(\mathrm{ECHA})$ |
| :--- | :--- |
| The Organic Carbon normalised adsorption <br> coefficient | $1,42(\mathrm{ECHA})$ |

12.5 Results of PBT and vPvB assessment

Data are not available.

### 12.6 Endocrine disrupting properties

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

### 12.7 Other adverse effects

Data are not available.

## SECTION 13: Disposal considerations

### 13.1 Waste treatment methods



This material and its container must be disposed of as hazardous waste. Dispose of contents/container in accordance with local/regional/national/international regulations.
Sewage disposal-relevant information
Do not empty into drains.

## Waste treatment of containers/packagings

Handle contaminated packages in the same way as the substance itself. Completely emptied packages can be recycled.

### 13.2 Relevant provisions relating to waste

The allocation of waste identity numbers/waste descriptions must be carried out according to the EEC, specific to the industry and process.
Properties of waste which render it hazardous
HP 4 irritant - skin irritation and eye damage
HP 7 carcinogenic

### 13.3 Remarks

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

## SECTION 14: Transport information

### 14.1 UN number or ID number

14.2 UN proper shipping name
14.3 Transport hazard class(es)
14.4 Packing group
14.5 Environmental hazards
not subject to transport regulations
not assigned
none
not assigned
non-environmentally hazardous acc. to the dangerous goods regulations

### 14.6 Special precautions for user

There is no additional information.
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

International Maritime Dangerous Goods Code (IMDG) - Additional information
Not subject to IMDG.
International Civil Aviation Organization (ICAO-IATA/DGR) - Additional information
Not subject to ICAO-IATA.

## SECTION 15: Regulatory information

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 |  |
| Nitrilotriacetic acid | substances in tattoo inks and perman- <br> ent make-up |  | R75 | 75 |  |

## 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 $1 \mathrm{~A}, 1 \mathrm{~B}$ or 2 , or germ cell mutagen category $1 \mathrm{~A}, 1 \mathrm{~B}$ 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 $1,1 \mathrm{~A}$ or 1 B , 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 $1,1 \mathrm{~A}, 1 \mathrm{~B}$ or 1 C or skin irritant category 2 , or as serious eye damage category 1 or eye irritant category 2 , the substance is present in the mixture in a concentration equal to or greater than:
(i) $0,1 \%$ by weight, if the substance is used solely as a pH regulator;
(ii) 0,01 \% by weight, in all other cases;
(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";
$(\mathrm{g})$ in the case of a substance for which a condition is specified in column h (Maximum concentration in ready for use preparation) or column i (Other) of the table in Annex IV to Regulation (EC) No 1223/2009, the substance is present in the mixture in a concentration, or in some other way, that does not accord with the condition specified in that column; (h) in the case of a substance listed in Appendix 13 to this Annex, the substance is present in the mixture in a concentration equal to or greater than the concentration limit specified for that substance in that Appendix.
2. For the purposes of this entry use of a mixture "for tattooing purposes" means injection or introduction of the mixture into a person's skin, mucous membrane or eyeball, by any process or procedure (including procedures commonly referred to as permanent make-up, cosmetic tattooing, micro-blading and micro-pigmentation), with the aim of making a mark or design on his or her body.
3. If a substance not listed in Appendix 13 falls within more than one of points (a) to (g) of paragraph 1, the strictest concentration limit laid down in the points in question shall apply to that substance. If a substance listed in Appendix 13 also falls within one or more of points $(\mathrm{a})$ to $(\mathrm{g})$ of paragraph 1, the concentration limit laid down in point (h) of paragraph 1 shall apply to that substance.
4. By way of derogation, paragraph 1 shall not apply to the following substances until 4 January 2023:
(a) Pigment Blue 15:3 (CI 74160, EC No 205-685-1, CAS No 147-14-8);
(b) Pigment Green 7 (CI 74260, EC No 215-524-7, CAS No 1328-53-6),
5. If Part 3 of Annex VI to Regulation (EC) No 1272/2008 is amended after 4 January 2021 to classify or re-classify a sub-
article number: 4384

## Legend

stance such that the substance then becomes caught by point (a), (b), (c) or (d) of paragraph 1 of this entry, or such that it then falls within a different one of those points from the one within which it fell previously, and the date of application of that new or revised classification is after the date referred to in paragraph 1 or, as the case may be, paragraph 4 of this entry, that amendment shall, for the purposes of applying this entry to that substance, be treated as taking effect on the date of application of that new or revised classification.
6. If Annex II or Annex IV to Regulation (EC) No 1223/2009 is amended after 4 January 2021 to list or change the listing of a substance such that the substance then becomes caught by point (e), (f) or (g) of paragraph 1 of this entry, or such that it then falls within a different one of those points from the one within which it fell previously, and the amendment takes effect after the date referred to in paragraph 1 or, as the case may be, paragraph 4 of this entry, that amendment shall, for the purposes of applying this entry to that substance, be treated as taking effect from the date falling 18 months after entry into force of the act by which that amendment was made.
7. Suppliers placing a mixture on the market for use for tattooing purposes shall ensure that, after 4 January 2022, the mixture is marked with the following information:
(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;
(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.
9. This entry does not apply to substances that are gases at temperature of $20^{\circ} \mathrm{C}$ and pressure of $101,3 \mathrm{kPa}$, or generate a vapour pressure of more than 300 kPa at temperature of $50^{\circ} \mathrm{C}$, 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
Not listed.

## Seveso Directive

## 2012/18/EU (Seveso III)

| No | Dangerous substance/hazard categories | Qualifying quantity (tonnes) for the ap- <br> plication of lower and upper-tier re- <br> quirements | Notes |
| :---: | :---: | :---: | :---: |
|  | not assigned |  |  |

## Deco-Paint Directive

| VOC content | $100 \%$ |
| :--- | :--- |

## Industrial Emissions Directive (IED)

| VOC content | $0 \%$ |
| :--- | :--- |

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Directive on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS)
not listed
Regulation concerning the establishment of a European Pollutant Release and Transfer Register (PRTR)
not listed
Water Framework Directive (WFD)

| List of pollutants (WFD) |  |  |  |  |
| :---: | :---: | :---: | :---: | :---: |
| Name of substance | Name acc. to inventory | CAS No | Listed in | Remarks |
| Nitrilotriacetic acid | Substances and preparations, or <br> the breakdown products of such, <br> which have been proved to pos- <br> sess carcinogenic or mutagenic <br> properties or properties which <br> may affect steroidogenic, thyroid, <br> reproduction or other endocrine- <br> related functions in or via the <br> aquatic environment | a) |  |  |
|  |  |  |  |  |

## Legend

a) Indicative list of the main pollutants

## Regulation on the marketing and use of explosives precursors

not listed

## Regulation on drug precursors

not listed
Regulation on substances that deplete the ozone layer (ODS)
not listed
Regulation concerning the export and import of hazardous chemicals (PIC)
not listed
Regulation on persistent organic pollutants (POP)
not listed

## Other information

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

National inventories

| Country | Inventory | Status |
| :---: | :---: | :--- |
| AU | AIIC | substance is listed |
| CA | DSL | substance is listed |
| CN | IECSC | substance is listed |
| EU | ECSI | substance is listed |
| EU | REACH Reg. | substance is listed |
| JP | CSCL-ENCS | substance is listed |
| KR | KECI | substance is listed |
| $M X$ | INSQ | substance is listed |

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| Country | Inventory | Status |
| :---: | :---: | :---: |
| NZ | NZIoC | substance is listed |
| PH | PICCS | substance is listed |
| TW | TCSI | substance is listed |
| US | TSCA | substance is listed (ACTIVE) |
| VN | NCI | substance is listed |

Legend
AIIC Australian Inventory of Industrial Chemicals
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
KECI Korea Existing Chemicals Inventory
NCI National Chemical Inventory
NZIoC New Zealand Inventory of Chemicals
PICCS Philippine Inventory of Chemicals and Chemical Substances (PICCS)
REACH Reg. REACH registered substances
TCSI Taiwan Chemical Substance Inventory
TSCA Toxic Substance Control Act

### 15.2 Chemical safety assessment

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

## SECTION 16: Other information

Indication of changes (revised safety data sheet)

| Section | Former entry (text/value) | Actual entry (text/value) | Safety-relevant |
| :---: | :---: | :---: | :---: |
| 2.2 |  | Hazard statements: 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 |  | Endocrine disrupting properties: Does not contain an endocrine disruptor (ED) at a concentration of $\geq 0,1 \%$. | yes |
| 14.8 | Transport of dangerous goods by road, rail and inland waterway (ADR/RID/ADN) - Additional information: <br> Not subject to ADR, RID and ADN. |  | yes |
| 15.1 |  | National inventories: change in the listing (table) | yes |
| 15.2 | Chemical Safety Assessment: <br> No Chemical Safety Assessment has been carried out for this substance. | Chemical safety assessment: <br> 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 |

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## Abbreviations and acronyms

| Abbr. | Descriptions of used abbreviations |
| :---: | :---: |
| ADR | Accord relatif au transport international des marchandises dangereuses par route (Agreement concerning the International Carriage of Dangerous Goods by Road) |
| 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) |
| DNEL | Derived No-Effect Level |
| EC50 | Effective Concentration 50 \%. The EC50 corresponds to the concentration of a tested substance causing $50 \%$ changes in response (e.g. on growth) during a specified time interval |
| EC No | The EC Inventory (EINECS, ELINCS and the NLP-list) is the source for the seven-digit EC number, an identifier of substances commercially available within the EU (European Union) |
| ED | Endocrine disruptor |
| EINECS | European Inventory of Existing Commercial Chemical Substances |
| ELINCS | European List of Notified Chemical Substances |
| ErC50 | $\equiv \mathrm{EC} 50$ : in this method, that concentration of test substance which results in a $50 \%$ reduction in either growth (EbC50) or growth rate (ErC50) relative to the control |
| GHS | "Globally Harmonized System of Classification and Labelling of Chemicals" developed by the United Nations |
| IATA | International Air Transport Association |
| IATA/DGR | Dangerous Goods Regulations (DGR) for the air transport (IATA) |
| ICAO | International Civil Aviation Organization |
| IMDG | International Maritime Dangerous Goods Code |
| 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 |
| NLP | No-Longer Polymer |
| PBT | Persistent, Bioaccumulative and Toxic |
| PNEC | Predicted No-Effect Concentration |
| REACH | Registration, Evaluation, Authorisation and Restriction of Chemicals |
| RID | Règlement concernant le transport International ferroviaire des marchandises Dangereuses (Regulations concerning the International carriage of Dangerous goods by Rail) |
| S.I. No. 619 of 2001 | Safety, Health and Welfare at Work (Chemical Agents) Regulations 2001 |
| 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). Regulations concerning the International Carriage of Dangerous Goods by Rail (RID). International Maritime Dangerous Goods Code (IMDG). Dangerous Goods Regulations (DGR) for the air transport (IATA).

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

| Code | Text |
| :---: | :---: |
| H319 | Causes serious eye irritation. |
| H351 | Suspected of causing cancer. |

## Disclaimer

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

