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

N,N'-Dicyclohexylcarbodiimide PEPTIPURE® ≥98 %

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Version: (2)

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

Product identifier 1.1

N,N'-Dicyclohexylcarbodiimide PEPTIPURE® Identification of the substance

>98 %

4193 Article number

01-2119943713-36-xxxx, Registration number (REACH)

The substance/product is registered with strictly controlled conditions as defined in Article 18(4) of Regulation (EC) No. 1907/2006 (REACH Regulation) and must therefore be handled as such.

Index number in CLP Annex VI 615-019-00-5

EC number 208-704-1 538-75-0 CAS number

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

Relevant identified uses: Isolated intermediate

Follow and fullfill the strictly controlled conditions for transported isolated intermediates according to Regulation (EC) No 1907/2006 [REACH],

article 18(4)

Uses advised against: 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 | |

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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- egory | Hazard class and category | Hazard statement |
|---------|-----------------------------------|---------------|---------------------------|---------------------|
| 3.10 | Acute toxicity (oral) | 4 | Acute Tox. 4 | H302 |
| 3.1D | Acute toxicity (dermal) | 3 | Acute Tox. 3 | H311 |
| 3.3 | Serious eye damage/eye irritation | 1 | Eye Dam. 1 | H318 |
| 3.45 | Skin sensitisation | 1 | Skin Sens. 1 | H317 |

For full text of abbreviations: see SECTION 16

2.2 Label elements

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

Signal word Danger

Pictograms

GHS05, GHS06



Hazard statements

H302 Harmful if swallowed H311 Toxic in contact with skin

H317 May cause an allergic skin reaction

H318 Causes serious eye damage

Precautionary statements

Precautionary statements - prevention

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

Precautionary statements - response

P301+P312 IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell

P302+P352 IF ON SKIN: Wash with plenty of soap and water

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact

lenses, if present and easy to do. Continue rinsing

Labelling of packages where the contents do not exceed 125 ml

Signal word: **Danger**

Symbol(s)



H311 Toxic in contact with skin.

H317 May cause an allergic skin reaction.

H318 Causes serious eye damage.

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Wear protective gloves/protective clothing/eye protection/face protection. IF ON SKIN: Wash with plenty of soap and water. P280

P302+P352

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

do. Continue rinsing.

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.

SECTION 3: Composition/information on ingredients

Substances

Name of substance N,N'-Dicyclohexylcarbodiimide

Molecular formula $C_{13}H_{22}N_2$ Molar mass 206,3 g/mol

REACH Reg. No 01-2119943713-36-xxxx

CAS No 538-75-0 EC No 208-704-1 Index No 615-019-00-5

Substance, Specific Conc. Limits, M-factors, ATE

| Specific Conc. Limits | M-Factors | ATE | Exposure route |
|-----------------------|-----------|--|----------------|
| - | - | 1.110 ^{mg} / _{kg} 300 ^{mg} / _{kg} | oral dermal |

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

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. In case of skin reactions, consult a physician.

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.

Following ingestion

Rinse mouth with water (only if the person is conscious). Call a doctor.

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4.2 Most important symptoms and effects, both acute and delayed

Vomiting, Risk of blindness, Risk of serious damage to eyes, Allergic reactions

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, 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 (CO₂)

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.

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.

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. Ventilate affected area.

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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 dust formation. Clear contaminated areas thoroughly.

Advice on general occupational hygiene

Thorough skin-cleansing after handling the product.

Conditions for safe storage, including any incompatibilities 7.2

Store in a dry place. Keep container tightly closed. Hygroscopic.

Incompatible substances or mixtures

Observe hints for combined storage.

Protect against external exposure, such as

high temperatures, humidity

Consideration of other advice:

Store locked up.

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)

| Cour | Name of agent | CAS No | Identifi- er | TWA [mg/ m³] | STEL [mg/ m³] | Ceil- ing-C [mg/ m³] | Nota- tion | Source |
|------|------------------------|--------|-----------------|--------------------|---------------------|-------------------------------|---------------|-----------|
| GB | isocyanates, compounds | | WEL | 0,02 | 0,07 | | NCO | EH40/2005 |

Notation

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

Measured total-NCO (isocyanate)

Short-term exposure limit: a limit value above which exposure should not occur and which is related to a 15-STEL

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) TWA

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Biological limit values

| Coun try | Name of agent | CAS No | Parameter | Nota tion | Identi- fier | Value | Material | Source |
|-------------|---|--------|-------------------------------|--------------|-----------------|----------------|----------|---------------|
| GB | Isocyanates (applies to HDI, IPDI, TDI and MDI) | | isocyanate-derived diamine | crea | BMGV | 1 µmol/ mol | urine | EH40/ 2005 |

Notation

crea Creatinine

Human health values

| Relevant DNELs and other threshold levels | | | | | |
|---|-------------------------|------------------------------------|-------------------|----------------------------|--|
| Endpoint | Threshold level | Protection goal, route of exposure | Used in | Exposure time | |
| DNEL | 0,212 mg/m ³ | human, inhalatory | worker (industry) | chronic - systemic effects | |
| DNEL | 0,034 mg/kg bw/day | human, dermal | worker (industry) | chronic - systemic effects | |

Environmental values

Relevant PNECs and other threshold levels Endpoint level Organism Environmental compartment partment

| End- point | Threshold level | Organism | Environmental com- partment | Exposure time |
|---------------|-------------------------------------|-----------------------|---------------------------------|------------------------------|
| PNEC | 0,17 ^{µg} / _l | aquatic organisms | freshwater | short-term (single instance) |
| PNEC | 0,1 ^{mg} / _l | aquatic organisms | sewage treatment plant (STP) | short-term (single instance) |
| PNEC | 0,144 ^{mg} / _{kg} | aquatic organisms | freshwater sediment | short-term (single instance) |
| PNEC | 0,014 ^{mg} / _{kg} | aquatic organisms | marine sediment | short-term (single instance) |
| PNEC | 0,007 ^{mg} / _{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



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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 quide.

type of material

NBR (Nitrile rubber)

material thickness

>0,11 mm

breakthrough times of the glove material

>480 minutes (permeation: level 6)

other protection measures

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

Respiratory protection





Respiratory protection necessary at: Dust formation. Particulate filter device (EN 143). P3 (filters at least 99,95 % 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 solid

Colour colourless - light yellow

Odour characteristic

Melting point/freezing point 32 – 36 °C

Boiling point or initial boiling point and boiling

range

148 – 152 °C at 15 hPa

Flammability this material is combustible, but will not ignite

readily

Lower and upper explosion limit not determined

Flash point 113 °C (c.c.)

Auto-ignition temperature not determined

Decomposition temperature not relevant

pH (value) not applicable

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Kinematic viscosity not relevant

Dynamic viscosity 5,81 mPa s at 55 °C

Solubility(ies)

Water solubility (practically insoluble)

Partition coefficient

Partition coefficient n-octanol/water (log value): 6,83 (25 °C) (TOXNET)

Vapour pressure 1,15 Pa at 20 °C

Density and/or relative density

Density $1,014 \, {}^{9}/_{cm^3}$ at 25 °C (ECHA)

Relative vapour density information on this property is not available

Bulk density $\sim 920 \text{ kg/m}^3$

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 (physical hazards): not relevant

Other safety characteristics: There is no additional information.

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

Moisture-sensitive. Hygroscopic solid.

10.3 Possibility of hazardous reactions

Violent reaction with: strong oxidiser

10.4 Conditions to avoid

Protect from moisture. Keep away from heat.

10.5 Incompatible materials

There is no additional information.

10.6 Hazardous decomposition products

Hazardous combustion products: see section 5.

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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

Harmful if swallowed. Toxic in contact with skin.

| Acute toxicity | | | | | |
|----------------|----------|-------------------------------------|---------|--------|--------|
| Exposure route | Endpoint | Value | Species | Method | Source |
| oral | LD50 | 1.110 ^{mg} / _{kg} | rat | | ECHA |

Skin corrosion/irritation

Shall not be classified as corrosive/irritant to skin.

Serious eye damage/eye irritation

Causes serious eye damage.

Respiratory or skin sensitisation

May cause an allergic skin reaction.

Germ cell mutagenicity

Shall not be classified as germ cell mutagenic.

Carcinogenicity

Shall not be classified as carcinogenic.

Reproductive toxicity

Shall not be classified as a reproductive toxicant.

Specific target organ toxicity - single exposure

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

Specific target organ toxicity - repeated exposure

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

Aspiration hazard

Shall not be classified as presenting an aspiration hazard.

Symptoms related to the physical, chemical and toxicological characteristics

If swallowed

vomiting, nausea

• If in eyes

Causes serious eye damage, risk of blindness

• If inhaled

Data are not available.

• If on skin

May produce an allergic reaction, pruritis, localised redness

Other information

none

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11.2 Endocrine disrupting properties

Not 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.

Biodegradation

Data are not available.

12.2 Process of degradability

Theoretical Oxygen Demand with nitrification: 2,966 ^{mg}/_{mg} Theoretical Oxygen Demand: 2,636 ^{mg}/_{mg}

Theoretical Carbon Dioxide: 2,773 mg/mg

12.3 Bioaccumulative potential

Does not significantly accumulate in organisms.

| n-octanol/water (log KOW) | 6,83 (25 °C) (TOXNET) |
|---------------------------|-----------------------|
| BCF | ≥0,2 - ≤0,7 (ECHA) |

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

Not 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.

Waste treatment of containers/packagings

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

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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

ADRRID UN 2811
IMDG-Code UN 2811
ICAO-TI UN 2811

14.2 UN proper shipping name

ADRRID TOXIC SOLID, ORGANIC, N.O.S. IMDG-Code TOXIC SOLID, ORGANIC, N.O.S.

ICAO-TI Toxic solid, organic, n.o.s.

Technical name N,N'-Dicyclohexylcarbodiimide

14.3 Transport hazard class(es)

ADRRID 6.1 IMDG-Code 6.1 ICAO-TI 6.1

14.4 Packing group

ADRRID III
IMDG-Code III
ICAO-TI III

14.5 Environmental hazards non-environmentally hazardous acc. to the dan-

gerous goods regulations

14.6 Special precautions for user

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

14.7 Maritime transport in bulk according to IMO instruments

The cargo is not intended to be carried in bulk.

14.8 Information for each of the UN Model Regulations

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

Proper shipping name TOXIC SOLID, ORGANIC, N.O.S.

Particulars in the transport document UN2811, TOXIC SOLID, ORGANIC, N.O.S., (N,N'-Di-

cyclohexylcarbodiimide), 6.1, III, (E)

Classification code T2
Danger label(s) 6.1

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Special provisions (SP) 274, 614, 802(ADN)

Excepted quantities (EQ) E1

Limited quantities (LQ) 5 kg

Transport category (TC) 2

Tunnel restriction code (TRC) E

Hazard identification No 60

Emergency Action Code 2X

Regulations concerning the International Carriage of Dangerous Goods by Rail (RID)Additional information

Classification code 6.1

Danger label(s) 6.1



Special provisions (SP) 274, 614, 802(ADN)

Excepted quantities (EQ) E1
Limited quantities (LQ) 5 kg
Transport category (TC) 2
Hazard identification No 60

International Maritime Dangerous Goods Code (IMDG) - Additional information

Proper shipping name TOXIC SOLID, ORGANIC, N.O.S.

Particulars in the shipper's declaration UN2811, TOXIC SOLID, ORGANIC, N.O.S., (N,N'-Di-

cyclohexylcarbodiimide), 6.1, III

Marine pollutant Danger label(s) 6.1



Special provisions (SP) 223, 274

Excepted quantities (EQ) E1
Limited quantities (LQ) 5 kg
EmS F-A, S-A

Stowage category A

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

Proper shipping name Toxic solid, organic, n.o.s.

Particulars in the shipper's declaration UN2811, Toxic solid, organic, n.o.s., (N,N'-Dicyclo-

hexylcarbodiimide), 6.1, III

Danger label(s) 6.1

Special provisions (SP) A3, A5

Excepted quantities (EQ) E1

Limited quantities (LQ) 10 kg

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 |
|-------------------------------|---|--------|-------------|----|
| N,N'-Dicyclohexylcarbodiimide | substances in tattoo inks and permanent make-up | | R75 | 75 |

Legend

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

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

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

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

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

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

(ii) "Rinse-off products";
(iii) "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;

(b) in the case of a substance listed in Annexalist 24, this case of a 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;

the mixture in a concentration, or in some other way, that does not accord with the condition specified in that column; (h) in the case of a substance listed in Appendix 13 to this Annex, the substance is present in the mixture in a concentration equal to or greater than the concentration limit specified for that substance in that Appendix.

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

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

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

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

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 to the list of ingredients in accordance with the nomenciature 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 of the process of the process of the process of the process of the label in accordance with Regulation (EC) No 1272/2008, that ingredients are not need to be marked in accordance with this Regulation.

ent 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 para-

graph. 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 °C and pressure of 101,3 kPa, or generate a vapour pressure of more than 300 kPa at temperature of 50 °C, with the exception of formaldehyde (CAS No 50-00-0, EC No 200-001-8).

10. This entry does not apply to the placing on the market of a mixture for use for tattooing purposes, or to the use of a mixture for tattooing purposes, when placed on the market exclusively as a medical device or an accessory to a medical device, within the meaning of Regulation (EU) 2017/745, or when used exclusively as a medical device or an accessory to a medical device, 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 application of lower and upper-tier requirements | Notes | | | |
| | not assigned | | | | | |

Deco-Paint Directive

| VOC content | 100 % 1.014 ^g / _I |
|-------------|--|
|-------------|--|

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Industrial Emissions Directive (IED)

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

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)

not listed

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 | AICS | 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 |
| JP | ISHA-ENCS | substance is listed |
| KR | KECI | substance is listed |
| MX | INSQ | substance is listed |
| NZ | NZIoC | substance is listed |
| PH | PICCS | substance is listed |
| TW | TCSI | substance is listed |

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| Country | Inventory | Status |
|---------|-----------|---------------------|
| US | TSCA | substance is listed |

Legend

AICS CSCL-ENCS

DSL ECSI IECSC

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

INSQ

ISHA-ENCS KECI

ISHA-ENCS
Inventory of Existing and New Chemical Substances (ISHA-ENCS)
KECI Korea Existing Chemicals Inventory
NZIOC New Zealand Inventory of Chemicals
PICCS Philippine Inventory of Chemicals and Chemical Substances (PICCS)
REACH Reg. REACH registered substances

TCSI Taiwan Chemical Substance Inventory

TSCA Toxic Substance Control Act

15.2 Chemical Safety Assessment

No Chemical Safety Assessment has been carried out for this substance.

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 |
| 2.2 | | Pictograms: change in the listing (table) | yes |
| 2.2 | | Hazard statements: change in the listing (table) | yes |
| 2.2 | | Precautionary statements - response: change in the listing (table) | yes |
| 2.2 | Precautionary statements - storage | | yes |
| 2.2 | | Precautionary statements - storage: 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 | yes |
| 2.3 | | Results of PBT and vPvB assessment: According to the results of its assessment, this substance is not a PBT or a vPvB. | yes |

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Abbreviations and acronyms

| Abbr. | Descriptions of used abbreviations |
|-----------|---|
| 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 relatif au transport international des marchandises dangereuses par route (Agreement concerning the International Carriage of Dangerous Goods by Road) |
| ATE | Acute Toxicity Estimate |
| BCF | Bioconcentration factor |
| 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 |
| EC No | The EC Inventory (EINECS, ELINCS and the NLP-list) is the source for the seven-digit EC number, an identi fier of substances commercially available within the EU (European Union) |
| 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 |
| 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 |
| 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) |
| STEL | Short-term exposure limit |
| SVHC | Substance of Very High Concern |
| | |

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| Abbr. | Descriptions of used abbreviations |
|-------|--|
| 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.

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 |
|------|--------------------------------------|
| H302 | Harmful if swallowed. |
| H311 | Toxic in contact with skin. |
| H317 | May cause an allergic skin reaction. |
| H318 | Causes serious eye damage. |

Disclaimer

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

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