

# Safety data sheet

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



## Listeria Chromo Selective Supplement lyophilised

article number: **2947**  
Version: **1.0 en**

date of compilation: 20.08.2021

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

#### 1.1 Product identifier

|                                 |   |
|---------------------------------|---|
| Identification of the substance | <b>Listeria Chromo Selective Supplement</b> lyophilised |
| Article number                  | 2947  |
| Registration number (REACH)     | not relevant (mixture)                                  |

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

|                           |   |
|---------------------------|---|
| Relevant identified uses: | Laboratory chemical<br>Laboratory and analytical use  |
| 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 sheet: :Department Health, Safety and Environment

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

#### 1.4 Emergency telephone number

### SECTION 2: Hazards identification

#### 2.1 Classification of the substance or mixture

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

| Section | Hazard class  | Category | Hazard class and category | Hazard statement |
|---------|---|----------|---------------------------|------------------|
| 3.10    | Acute toxicity (oral)                                 | 2        | Acute Tox. 2              | H300             |
| 3.4R    | Respiratory sensitisation                             | 1        | Resp. Sens. 1             | H334             |
| 3.4S    | Skin sensitisation                                    | 1        | Skin Sens. 1              | H317             |
| 3.5     | Germ cell mutagenicity                                | 2        | Muta. 2                   | H341             |
| 3.7     | Reproductive toxicity                                 | 1B       | Repr. 1B                  | H360D            |
| 4.1C    | Hazardous to the aquatic environment - chronic hazard | 2        | Aquatic Chronic 2         | H411             |

For full text of abbreviations: see SECTION 16

#### The most important adverse physicochemical, human health and environmental effects

Spillage and fire water can cause pollution of watercourses.

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### 2.2 Label elements

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

##### Signal word

**Danger**

##### Pictograms

GHS06, GHS08,  
GHS09



##### Hazard statements

|       |   |
|-------|---|
| H300  | Fatal if swallowed  |
| H317  | May cause an allergic skin reaction                                       |
| H334  | May cause allergy or asthma symptoms or breathing difficulties if inhaled |
| H341  | Suspected of causing genetic defects                                      |
| H360D | May damage the unborn child   |
| H411  | Toxic to aquatic life with long lasting effects                           |

##### Precautionary statements

###### **Precautionary statements - prevention**

|      |  |
|------|--|
| P202 | Do not handle until all safety precautions have been read and understood |
| P261 | Avoid breathing dust   |
| P270 | Do not eat, drink or smoke when using this product                       |
| P273 | Avoid release to the environment   |

###### **Precautionary statements - response**

|           |   |
|-----------|---|
| P301+P310 | IF SWALLOWED: Immediately call a POISON CENTER/doctor |
|-----------|---|

For professional users only

###### **Hazardous ingredients for labelling:**

Cycloheximide, Ceftazidime , Nalidixic acid sodium salt, Polymyxin B sulphate

##### **Labelling of packages where the contents do not exceed 125 ml**

Signal word: **Danger**

Symbol(s)



|           |   |
|-----------|---|
| H300      | Fatal if swallowed.   |
| H317      | May cause an allergic skin reaction.  |
| H334      | May cause allergy or asthma symptoms or breathing difficulties if inhaled.    |
| H341      | Suspected of causing genetic defects.   |
| H360D     | May damage the unborn child.  |
| P202      | Do not handle until all safety precautions have been read and understood.     |
| P261      | Avoid breathing dust.   |
| P270      | Do not eat, drink or smoke when using this product.                           |
| P301+P310 | IF SWALLOWED: Immediately call a POISON CENTER/doctor.                        |
| contains: | Cycloheximide, Ceftazidime , Nalidixic acid sodium salt, Polymyxin B sulphate |

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### 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 substance          | Identifier  | Wt%       | Classification acc. to GHS  | Pictograms | Notes  |
|----------------------------|---|-----------|---|------------|--------|
| Cycloheximide              | CAS No<br>66-81-9<br><br>EC No<br>200-636-0<br><br>Index No<br>613-140-00-8 | 50 – < 75 | Acute Tox. 2 / H300<br>Muta. 2 / H341<br>Repr. 1B / H360D<br>Aquatic Chronic 2 / H411 |            | GHS-HC |
| Nalidixic acid sodium salt | CAS No<br>3374-05-8<br><br>EC No<br>222-159-7                               | 10 – < 25 | Acute Tox. 4 / H302<br>Resp. Sens. 1 / H334<br>Skin Sens. 1 / H317                    |            |        |
| Ceftazidime                | CAS No<br>72558-82-8<br><br>EC No<br>276-715-9                              | 10 – < 25 | Resp. Sens. 1 / H334<br>Skin Sens. 1 / H317   |            |        |
| Polymyxin B sulphate       | CAS No<br>1405-20-5<br><br>EC No<br>215-774-7                               | 3 – < 10  | Acute Tox. 4 / H302   |            |        |

#### Notes

GHS-HC: Harmonised classification (the classification of the substance corresponds to the entry in the list according to 1272/2008/EC, Annex VI)

| Name of substance          | Identifier  | Specific Conc. Limits | M-Factors | ATE         | Exposure route |
|----------------------------|---|-----------------------|-----------|-------------|----------------|
| Cycloheximide              | CAS No<br>66-81-9<br><br>EC No<br>200-636-0<br><br>Index No<br>613-140-00-8 | -                     | -         | 5 mg/kg     | oral           |
| Nalidixic acid sodium salt | CAS No<br>3374-05-8<br><br>EC No<br>222-159-7                               | -                     | -         | 1.700 mg/kg | oral           |

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| Name of substance    | Identifier                                    | Specific Conc. Limits | M-Factors | ATE       | Exposure route |
|----------------------|---|-----------------------|-----------|-----------|----------------|
| Polymyxin B sulphate | CAS No<br>1405-20-5<br><br>EC No<br>215-774-7 | -                     | -         | 790 mg/kg | oral           |

For full text of abbreviations: see SECTION 16

## SECTION 4: First aid measures

### 4.1 Description of first aid measures



#### General notes

Take off contaminated clothing.

#### Following inhalation

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

#### Following skin contact

After contact with skin, wash immediately with plenty of water. In case of skin reactions, consult a physician.

#### Following eye contact

Rinse cautiously with water for several minutes. In all cases of doubt, or when symptoms persist, seek medical advice.

#### Following ingestion

Rinse mouth immediately and drink plenty of water. Call a physician immediately.

### 4.2 Most important symptoms and effects, both acute and delayed

Allergic reactions, Irritant effects, Nausea, Vomiting, Breathing difficulties

### 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, alcohol resistant foam, dry extinguishing powder, ABC-powder

#### Unsuitable extinguishing media

water jet

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### 5.2 Special hazards arising from the substance or mixture

Combustible.

#### Hazardous combustion products

In case of fire may be liberated: Nitrogen oxides (NO<sub>x</sub>), Carbon monoxide (CO), Carbon dioxide (CO<sub>2</sub>)

### 5.3 Advice for firefighters

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

## SECTION 6: Accidental release measures

### 6.1 Personal precautions, protective equipment and emergency procedures



#### For non-emergency personnel

Do not breathe dust. Wearing of suitable protective equipment (including personal protective equipment referred to under Section 8 of the safety data sheet) to prevent any contamination of skin, eyes and personal clothing. Provide adequate ventilation.

### 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.

## SECTION 7: Handling and storage

### 7.1 Precautions for safe handling

Provision of sufficient ventilation. Avoid exposure. Avoid dust formation. Clear contaminated areas thoroughly.

#### Measures to prevent fire as well as aerosol and dust generation

Removal of dust deposits.

#### Measures to protect the environment

Avoid release to the environment.

#### Advice on general occupational hygiene

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

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### 7.2 Conditions for safe storage, including any incompatibilities

Keep container tightly closed. Keep in a cool place.

#### Incompatible substances or mixtures

Observe hints for combined storage.

#### Consideration of other advice:

Store locked up.

#### Ventilation requirements

Use local and general ventilation.

#### Specific designs for storage rooms or vessels

Recommended storage temperature: 2 – 8 °C

### 7.3 Specific end use(s)

No information available.

## SECTION 8: Exposure controls/personal protection

### 8.1 Control parameters

#### National limit values

#### Occupational exposure limit values (Workplace Exposure Limits)

Data are not available.

### 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 °C and permanent contact. Increased temperatures due to heated substances, body heat etc. and a reduction of the effective layer thickness by stretching can lead to a considerable reduction of the breakthrough time. If in doubt, contact manufacturer. At an approx. 1.5 times larger / smaller layer thickness, the respective breakthrough time is doubled / halved. The data apply only to the pure substance. When transferred to substance mixtures, they may only be considered as a guide.

#### • type of material

NBR (Nitrile rubber)

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- **material thickness**

>0,11 mm

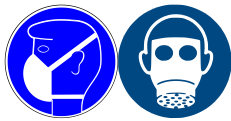
- **breakthrough times of the glove material**

>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   |
| Form   | powder  |
| Colour   | whitish - yellow  |
| Odour  | odourless   |
| Melting point/freezing point                             | not determined  |
| Boiling point or initial boiling point and boiling range | not determined  |
| Flammability   | this material is combustible, but will not ignite readily |
| Lower and upper explosion limit                          | not determined  |
| Flash point  | not applicable  |
| Auto-ignition temperature                                | not determined  |
| Decomposition temperature                                | not relevant  |
| pH (value)   | 4 - 7 (in aqueous solution: 20 g/l, 20 °C)                |
| Kinematic viscosity                                      | not relevant  |
| <u>Solubility(ies)</u>                                   |   |
| Water solubility   | miscible in any proportion                                |
| <u>Partition coefficient</u>                             |   |
| Partition coefficient n-octanol/water (log value):       | this information is not available                         |

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|   |   |
|---|---|
| Vapour pressure                                     | not determined  |
| Density   | not determined  |
| Relative vapour density                             | information on this property is not available               |
| Particle characteristics                            | No data available.  |
| <u>Other safety parameters</u>                      |   |
| Oxidising properties                                | none  |
| <b>9.2 Other information</b>                        |   |
| Information with regard to physical hazard classes: | hazard classes acc. to GHS (physical hazards): not relevant |
| Other safety characteristics:                       |   |
| Miscibility   | completely miscible with water                              |

## 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

No known hazardous reactions.

### 10.4 Conditions to avoid

Keep away from heat.

### 10.5 Incompatible materials

There is no additional information.

### 10.6 Hazardous decomposition products

Hazardous combustion products: see section 5.

## SECTION 11: Toxicological information

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

Test data are not available for the complete mixture.

#### Classification procedure

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

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

#### Acute toxicity

Fatal if swallowed.



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| Acute toxicity estimate (ATE) of components of the mixture |           |                |             |
|--|-----------|----------------|-------------|
| Name of substance  | CAS No    | Exposure route | ATE         |
| Cycloheximide  | 66-81-9   | oral           | 5 mg/kg     |
| Nalidixic acid sodium salt                                 | 3374-05-8 | oral           | 1.700 mg/kg |
| Polymyxin B sulphate                                       | 1405-20-5 | oral           | 790 mg/kg   |

| Acute toxicity of components of the mixture |           |                |          |           |         |
|---|-----------|----------------|----------|-----------|---------|
| Name of substance                           | CAS No    | Exposure route | Endpoint | Value     | Species |
| Cycloheximide                               | 66-81-9   | oral           | LD50     | 133 mg/kg | mouse   |
| Polymyxin B sulphate                        | 1405-20-5 | oral           | LD50     | 790 mg/kg | mouse   |

### Skin corrosion/irritation

Shall not be classified as corrosive/irritant to skin.

### Serious eye damage/eye irritation

Shall not be classified as seriously damaging to the eye or eye irritant.

### Respiratory or skin sensitisation

May cause allergy or asthma symptoms or breathing difficulties if inhaled. May cause an allergic skin reaction.

### Germ cell mutagenicity

Suspected of causing genetic defects.

### Carcinogenicity

Shall not be classified as carcinogenic.

### Reproductive toxicity

May damage the unborn child.

### 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

Data are not available.

#### • If inhaled

May produce an allergic reaction, cough, breathing difficulties

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- **If on skin**

May produce an allergic reaction, pruritis, localised redness

- **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

Toxic to aquatic life with long lasting effects.

#### Biodegradation

Data are not available.

### 12.2 Process of degradability

Data are not available.

### 12.3 Bioaccumulative potential

Data are not available.

#### Bioaccumulative potential of components of the mixture

| Name of substance | CAS No  | BCF | Log KOW | BOD5/COD |
|-------------------|---------|-----|---------|----------|
| Cycloheximide     | 66-81-9 |     | 0,55    |          |

### 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. Avoid release to the environment. Refer to special instructions/safety data sheets.

### Waste treatment of containers/packageings

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

### 13.2 Relevant provisions relating to waste

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

### 13.3 Remarks

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

## SECTION 14: Transport information

### 14.1 UN number or ID number

|             |         |
|-------------|---------|
| ADR/RID/ADN | UN 2811 |
| IMDG-Code   | UN 2811 |
| ICAO-TI     | UN 2811 |

### 14.2 UN proper shipping name

|  |                              |
|--|------------------------------|
| ADR/RID/ADN                            | TOXIC SOLID, ORGANIC, N.O.S. |
| IMDG-Code                              | TOXIC SOLID, ORGANIC, N.O.S. |
| ICAO-TI                                | Toxic solid, organic, n.o.s. |
| Technical name (hazardous ingredients) | Cycloheximide                |

### 14.3 Transport hazard class(es)

|             |     |
|-------------|-----|
| ADR/RID/ADN | 6.1 |
| IMDG-Code   | 6.1 |
| ICAO-TI     | 6.1 |

### 14.4 Packing group

|             |    |
|-------------|----|
| ADR/RID/ADN | II |
| IMDG-Code   | II |
| ICAO-TI     | II |

### 14.5 Environmental hazards

|  |                                      |
|--|--------------------------------------|
|  | hazardous to the aquatic environment |
| Environmentally hazardous substance (aquatic environment): | Cycloheximide                        |

### 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

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### 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., (contains: Cycloheximide), 6.1, II, (D/E), environmentally hazardous |
| Classification code   | T2   |
| Danger label(s)   | 6.1, "Fish and tree"   |
|  |  |
| Environmental hazards   | yes (hazardous to the aquatic environment)   |
| Special provisions (SP)   | 274, 614, 802(ADN)   |
| Excepted quantities (EQ)  | E4   |
| Limited quantities (LQ)   | 500 g  |
| Transport category (TC)   | 2  |
| Tunnel restriction code (TRC)   | D/E  |
| 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., (contains: Cycloheximide), 6.1, II, MARINE POLLUTANT |
| Marine pollutant  | yes (hazardous to the aquatic environment), (Cycloheximide)                                |
| Danger label(s)   | 6.1, "Fish and tree"   |
|  |  |
| Special provisions (SP)   | 274  |
| Excepted quantities (EQ)  | E4   |
| Limited quantities (LQ)   | 500 g  |
| EmS   | F-A, S-A   |
| Stowage category  | B  |

### 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., (contains: Cycloheximide), 6.1, II |
| Environmental hazards   | yes (hazardous to the aquatic environment)                               |
| Danger label(s)   | 6.1  |
|  |  |
| Special provisions (SP)   | A3, A5   |

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|                          |      |
|--------------------------|------|
| Excepted quantities (EQ) | E4   |
| Limited quantities (LQ)  | 1 kg |

### 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 |
| Nalidixic acid sodium salt                                 | substances in tattoo inks and permanent make-up |        | R75         | 75 |
| Cycloheximide  | toxic for reproduction                          |        | R28-30      | 30 |
| Ceftazidime  | substances in tattoo inks and permanent make-up |        | R75         | 75 |

##### Legend

R28-30 1. Shall not be placed on the market, or used,

- as substances,
- as constituents of other substances, or,
- in mixtures,

for supply to the general public when the individual concentration in the substance or mixture is equal to or greater than:

- either the relevant specific concentration limit specified in Part 3 of Annex VI to Regulation (EC) No 1272/2008, or,
- the relevant concentration specified in Directive 1999/45/EC where no specific concentration limit is set out in Part 3 of Annex VI to Regulation (EC) No 1272/2008.

Without prejudice to the implementation of other Community provisions relating to the classification, packaging and labelling of substances and mixtures, suppliers shall ensure before the placing on the market that the packaging of such substances and mixtures is marked visibly, legibly and indelibly as follows:

'Restricted to professional users'.

2. By way of derogation, paragraph 1 shall not apply to:

- (a) medicinal or veterinary products as defined by Directive 2001/82/EC and Directive 2001/83/EC;
- (b) cosmetic products as defined by Directive 76/768/EEC;
- (c) the following fuels and oil products:
  - motor fuels which are covered by Directive 98/70/EC,
  - mineral oil products intended for use as fuel in mobile or fixed combustion plants,
  - fuels sold in closed systems (e.g. liquid gas bottles);
- (d) artists' paints covered by Directive 1999/45/EC;
- (e) the substances listed in Appendix 11, column 1, for the applications or uses listed in Appendix 11, column 2. Where a date is specified in column 2 of Appendix 11, the derogation shall apply until the said date;
- (f) devices covered by Regulation (EU) 2017/745.

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- R75
1. Shall not be placed on the market in mixtures for use for tattooing purposes, and mixtures containing any such substances shall not be used for tattooing purposes, after 4 January 2022 if the substance or substances in question is or are present in the following circumstances:
    - (a) in the case of a substance classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 as carcinogen category 1A, 1B or 2, or germ cell mutagen category 1A, 1B or 2, the substance is present in the mixture in a concentration equal to or greater than 0,00005 % by weight;
    - (b) in the case of a substance classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 as reproductive toxicant category 1A, 1B or 2, the substance is present in the mixture in a concentration equal to or greater than 0,001 % by weight;
    - (c) in the case of a substance classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 as skin sensitiser category 1, 1A or 1B, the substance is present in the mixture in a concentration equal to or greater than 0,001 % by weight;
    - (d) in the case of a substance classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 as skin corrosive category 1, 1A, 1B or 1C or skin irritant category 2, or as serious eye damage category 1 or eye irritant category 2, the substance is present in the mixture in a concentration equal to or greater than:
      - (i) 0,1 % by weight, if the substance is used solely as a pH regulator;
      - (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";
    - (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 (a) to (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 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, 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.

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### Legend

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

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

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

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

### Seveso Directive

| 2012/18/EU (Seveso III) |                                       |   |       |
|-------------------------|---------------------------------------|---|-------|
| No                      | Dangerous substance/hazard categories | Qualifying quantity (tonnes) for the application of lower and upper-tier requirements | Notes |
| H2                      | acute toxic (cat. 2 + cat. 3, inhal.) | 50                      200   | 41)   |

#### Notation

- 41) - Category 2, all exposure routes  
- category 3, inhalation exposure route

### Deco-Paint Directive

|             |     |
|-------------|-----|
| VOC content | 0 % |
|-------------|-----|

### Industrial Emissions Directive (IED)

|             |     |
|-------------|-----|
| VOC content | 0 % |
|-------------|-----|

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

none of the ingredients are listed

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

none of the ingredients are listed

### Water Framework Directive (WFD)

| List of pollutants (WFD)   |   |        |           |         |
|----------------------------|---|--------|-----------|---------|
| Name of substance          | Name acc. to inventory  | CAS No | Listed in | Remarks |
| Nalidixic acid sodium salt | Metals and their compounds  |        | A)        |         |
| Cycloheximide              | Substances and preparations, or the breakdown products of such, which have been proved to possess carcinogenic or mutagenic properties or properties which may affect steroidogenic, thyroid, reproduction or other endocrine-related functions in or via the aquatic environment |        | A)        |         |

#### Legend

- A) Indicative list of the main pollutants

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### Regulation on the marketing and use of explosives precursors

none of the ingredients are listed

### Regulation on drug precursors

none of the ingredients are listed

### Regulation on substances that deplete the ozone layer (ODS)

none of the ingredients are listed

### Regulation concerning the export and import of hazardous chemicals (PIC)

none of the ingredients are listed

### Regulation on persistent organic pollutants (POP)

none of the ingredients are listed

### 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      | not all ingredients are listed |
| CA      | DSL       | not all ingredients are listed |
| CN      | IECSC     | all ingredients are listed     |
| EU      | ECSI      | all ingredients are listed     |
| JP      | CSCL-ENCS | not all ingredients are listed |
| JP      | ISHA-ENCS | not all ingredients are listed |
| KR      | KECI      | not all ingredients are listed |
| MX      | INSQ      | not all ingredients are listed |
| NZ      | NZIoC     | all ingredients are listed     |
| PH      | PICCS     | not all ingredients are listed |
| TW      | TCSI      | all ingredients are listed     |

#### Legend

|           |   |
|-----------|---|
| AICS      | Australian Inventory of Chemical Substances                             |
| CSCL-ENCS | List of Existing and New Chemical Substances (CSCL-ENCS)                |
| DSL       | Domestic Substances List (DSL)  |
| ECSI      | EC Substance Inventory (EINECS, ELINCS, NLP)                            |
| IECSC     | Inventory of Existing Chemical Substances Produced or Imported in China |
| INSQ      | National Inventory of Chemical Substances                               |
| ISHA-ENCS | Inventory of Existing and New Chemical Substances (ISHA-ENCS)           |
| KECI      | Korea Existing Chemicals Inventory                                      |
| NZIoC     | New Zealand Inventory of Chemicals                                      |
| PICCS     | Philippine Inventory of Chemicals and Chemical Substances (PICCS)       |
| TCSI      | Taiwan Chemical Substance Inventory                                     |

## 15.2 Chemical Safety Assessment

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



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### SECTION 16: Other information

#### Abbreviations and acronyms

| Abbr.           | Descriptions of used abbreviations  |
|-----------------|---|
| Acute Tox.      | Acute toxicity  |
| ADN             | Accord européen relatif au transport international des marchandises dangereuses par voies de navigation intérieures (European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways) |
| ADR             | Accord relatif au transport international des marchandises dangereuses par route (Agreement concerning the International Carriage of Dangerous Goods by Road)   |
| ADR/RID/ADN     | Agreements concerning the International Carriage of Dangerous Goods by Road/Rail/Inland Waterways (ADR/RID/ADN)   |
| Aquatic Chronic | Hazardous to the aquatic environment - chronic hazard   |
| ATE             | Acute Toxicity Estimate   |
| BCF             | Bioconcentration factor   |
| BOD             | Biochemical Oxygen Demand   |
| CAS             | Chemical Abstracts Service (service that maintains the most comprehensive list of chemical substances)  |
| CLP             | Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures  |
| COD             | Chemical oxygen demand  |
| DGR             | Dangerous Goods Regulations (see IATA/DGR)  |
| 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  |
| 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  |
| log KOW         | n-Octanol/water   |
| Muta.           | Germ cell mutagenicity  |
| NLP             | No-Longer Polymer   |
| PBT             | Persistent, Bioaccumulative and Toxic   |

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| Abbr.       | Descriptions of used abbreviations  |
|-------------|---|
| REACH       | Registration, Evaluation, Authorisation and Restriction of Chemicals  |
| Repr.       | Reproductive toxicity   |
| Resp. Sens. | Respiratory sensitisation   |
| RID         | Règlement concernant le transport International ferroviaire des marchandises Dangereuses (Regulations concerning the International carriage of Dangerous goods by Rail) |
| Skin Sens.  | Skin sensitisation  |
| SVHC        | Substance of Very High Concern  |
| VOC         | Volatile Organic Compounds  |
| vPvB        | Very Persistent and very Bioaccumulative  |

### Key literature references and sources for data

Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures.  
Regulation (EC) No. 1907/2006 (REACH), amended by 2020/878/EU.

Transport of dangerous goods by road, rail and inland waterway (ADR/RID/ADN). International Maritime Dangerous Goods Code (IMDG). Dangerous Goods Regulations (DGR) for the air transport (IATA).

### Classification procedure

Physical and chemical properties. The classification is based on tested mixture.

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

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

| Code  | Text   |
|-------|--|
| H300  | Fatal if swallowed.  |
| H302  | Harmful if swallowed.  |
| H317  | May cause an allergic skin reaction.                                       |
| H334  | May cause allergy or asthma symptoms or breathing difficulties if inhaled. |
| H341  | Suspected of causing genetic defects.                                      |
| H360D | May damage the unborn child.   |
| H411  | Toxic to aquatic life with long lasting effects.                           |

### Disclaimer

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