

according to Regulation (EC) No 1907/2006

Revision date: 24.09.2020

smartrepair® rosa

Product code: 922

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

1.1. Product identifier

smartrepair® rosa

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

Use of the substance/mixture

Ligth curing repair material for use in dentistry.

1.3. Details of the supplier of the safety data sheet

Manufacturer

| | | |
|-------------------------|---|---------------------------|
| Company name: | DETAX GmbH & Co. KG | |
| Street: | Carl-Zeiss-Strasse | |
| Place: | D-76275 Ettlingen | |
| Telephone: | +49 7243/510-0 | Telefax: +49 7243/510-100 |
| e-mail: | post@detax.de | |
| Internet: | www.detax.de | |
| Responsible Department: | Emergency number: +49 7243/510-0 This number is only obtainable during office hours (Monday - Thursday 8.00 a.m. - 5.00 p.m., Friday 8.00 a.m. - 4.00 p.m.) | |

Importer / Distributer

| | | |
|---------------|--|------------------------------|
| Company name: | Ivoclar Vivadent Ltd | |
| Place: | PO Box 303011, North Harbour, Auckland, 0751 | |
| Telephone: | +64 9 914 9999 | Telefax: Fax: +64 9 914 9990 |
| e-mail: | info@ivoclarvivadent.com | |

1.4 Emergency telephone number:

0800 764 766
Poisons Hotline (24 hours / 7 days) NZ: National Poison Centre (New Zealand)

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Regulation (EC) No. 1272/2008

Hazard categories:

Skin corrosion/irritation: Skin Irrit. 2
Serious eye damage/eye irritation: Eye Irrit. 2
Respiratory or skin sensitisation: Skin Sens. 1
Reproductive toxicity: Repr. 2
Hazardous to the aquatic environment: Aquatic Chronic 2

Hazard Statements:

Causes skin irritation.
Causes serious eye irritation.
May cause an allergic skin reaction.
Suspected of damaging fertility or the unborn child.
Toxic to aquatic life with long lasting effects.

2.2. Label elements

Regulation (EC) No. 1272/2008

Hazard components for labelling

7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate
tetrahydrofurfuryl methacrylate THFMA purified grade
diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide

Signal word: Warning

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Pictograms:

Hazard statements

| | |
|------|--|
| H315 | Causes skin irritation. |
| H317 | May cause an allergic skin reaction. |
| H319 | Causes serious eye irritation. |
| H361 | Suspected of damaging fertility or the unborn child. |
| H411 | Toxic to aquatic life with long lasting effects. |

Precautionary statements

| | |
|-----------|---|
| P261 | Avoid breathing dust/fume/gas/mist/vapours/spray. |
| P273 | Avoid release to the environment. |
| P280 | Wear protective gloves/protective clothing/eye protection/face protection/hearing protection. |
| P302+P352 | IF ON SKIN: Wash with plenty of water. |
| P362+P364 | Take off contaminated clothing and wash it before reuse. |
| P391 | Collect spillage. |
| P501 | Dispose of contents/ container in accordance with local and national regulations. |

Additional advice on labelling

According to Regulation (EC) 1272/2008, art.1 No. 5 (d) this product as a medical product must not be labelled!

2.3. Other hazards

No information available.

SECTION 3: Composition/information on ingredients

3.2. Mixtures
Chemical characterization

Mixture of acrylic/ methacrylic resins with auxilliary matters.

Hazardous components

| CAS No | Chemical name | | | Quantity |
|------------|--|--------------|------------------|-------------|
| | EC No | Index No | REACH No | |
| | GHS Classification | | | |
| 72869-86-4 | 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxo-5,12-diazahexadecane-1,16-diyl bismethacrylate | | | 75 - < 80 % |
| | 276-957-5 | | 01-2120751202-68 | |
| | Skin Sens. 1B, Aquatic Chronic 2; H317 H411 | | | |
| 2455-24-5 | tetrahydrofurfuryl methacrylate THFMA purified grade | | | 15 - < 20 % |
| | | | | |
| | Repr. 2, Skin Irrit. 2, Eye Irrit. 2, Skin Sens. 1, STOT SE 3; H361 H315 H319 H317 H335 | | | |
| 75980-60-8 | diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide | | | < 1 % |
| | 278-355-8 | 015-203-00-X | | |
| | Repr. 2, Skin Sens. 1B, Aquatic Chronic 2; H361f H317 H411 | | | |
| 21245-02-3 | 2-Ethylhexyl 4-(dimethylamino)benzoate | | | < 1 % |
| | 244-289-3 | | 01-2120766649-35 | |
| | Repr. 1B; H360 | | | |

Full text of H and EUH statements: see section 16.

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SECTION 4: First aid measures

4.1. Description of first aid measures

After inhalation

Provide fresh air. When in doubt or if symptoms are observed, get medical advice.

After contact with skin

After contact with skin, wash immediately with plenty of water and soap. Take off immediately all contaminated clothing and wash it before reuse. Medical treatment necessary.

After contact with eyes

After contact with the eyes, rinse with water with the eyelids open for a sufficient length of time, then consult an ophthalmologist immediately.

After ingestion

Rinse mouth immediately and drink plenty of water. Induce vomiting when the affected person is not unconscious. Medical treatment necessary. Seek immediately medical advice. Do not induce vomiting. In case of spontaneous vomiting take care of an unhindered flow out of the vomit (danger of suffocation).

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

No information available.

4.3. Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media

Co-ordinate fire-fighting measures to the fire surroundings.

5.2. Special hazards arising from the substance or mixture

Non-flammable.

5.3. Advice for firefighters

Wear a self-contained breathing apparatus and chemical protective clothing. Full protection suit.

Additional information

Suppress gases/vapours/mists with water spray jet. Collect contaminated fire extinguishing water separately. Do not allow entering drains or surface water.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Provide adequate ventilation. Do not breathe gas/fumes/vapour/spray. Avoid contact with skin, eyes and clothes. Use personal protection equipment.

6.2. Environmental precautions

Do not allow to enter into surface water or drains.

6.3. Methods and material for containment and cleaning up

Absorb with liquid-binding material (e.g. sand, diatomaceous earth, acid- or universal binding agents). Treat the recovered material as prescribed in the section on waste disposal.

6.4. Reference to other sections

Safe handling: see section 7

Personal protection equipment: see section 8

Disposal: see section 13

SECTION 7: Handling and storage

7.1. Precautions for safe handling

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Advice on safe handling

If handled uncovered, arrangements with local exhaust ventilation have to be used. Do not breathe gas/fumes/vapour/spray.

Advice on protection against fire and explosion

No special fire protection measures are necessary.

7.2. Conditions for safe storage, including any incompatibilities**Requirements for storage rooms and vessels**

Keep container tightly closed. Keep locked up. Store in a place accessible by authorized persons only. Provide adequate ventilation as well as local exhaust at critical locations.

Hints on joint storage

Keep away from spontaneous flammable or combustible substances.

Further information on storage conditions

Keep only in the original container in a cool, dry and well-ventilated place, away from foodstuffs. Keep away from all kind of light. An inert gas blanket should not be applied, because the stability of the product depends on the presence of oxygen (air).

7.3. Specific end use(s)

Dental repair material.

For use by trained specialist staff.

SECTION 8: Exposure controls/personal protection**8.1. Control parameters****8.2. Exposure controls****Appropriate engineering controls**

If handled uncovered, arrangements with local exhaust ventilation have to be used. Do not breathe gas/fumes/vapour/spray.

Protective and hygiene measures

Remove contaminated, saturated clothing immediately. Draw up and observe skin protection programme.

Wash hands and face before breaks and after work and take a shower if necessary. When using do not eat, drink, smoke, sniff.

Eye/face protection

Suitable eye protection: goggles.

Hand protection

When handling with chemical substances, protective gloves must be worn with the CE-label including the four control digits. The quality of the protective gloves resistant to chemicals must be chosen as a function of the specific working place concentration and quantity of hazardous substances. 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.

Suitable are gloves of the following material: Butyl caoutchouc (butyl rubber)

Skin protection

Wear suitable protective clothing.

Respiratory protection

In case of inadequate ventilation wear respiratory protection.

SECTION 9: Physical and chemical properties**9.1. Information on basic physical and chemical properties**

| | |
|-----------------|-----------------------|
| Physical state: | Paste , low-viscosity |
| Colour: | pink |
| Odour: | characteristic |

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Test method

| | |
|--|---------------------------------|
| pH-Value: | not determined |
| Changes in the physical state | |
| Melting point: | not determined |
| Initial boiling point and boiling range: | not determined |
| Flash point: | >100 °C DIN 51755 |
| Flammability | |
| Solid: | not applicable |
| Gas: | not applicable |
| Explosive properties | |
| The product is not: Explosive. | |
| Lower explosion limits: | not determined |
| Upper explosion limits: | not determined |
| Auto-ignition temperature | |
| Solid: | not applicable |
| Gas: | not applicable |
| Decomposition temperature: | not determined |
| Oxidizing properties | |
| Not oxidizing. | |
| Vapour pressure: (at 20 °C) | <1 hPa |
| Density (at 20 °C): | 1,1 g/cm ³ DIN 51757 |
| Water solubility: | insoluble |
| Solubility in other solvents | |
| not determined | |
| Partition coefficient: | not determined |
| Viscosity / dynamic: (at 23 °C) | 6500 mPa·s Rheostress |
| Vapour density: | not determined |
| Evaporation rate: | not determined |
| 9.2. Other information | |
| Solid content: | not determined |

SECTION 10: Stability and reactivity

10.1. Reactivity

No hazardous reaction when handled and stored according to provisions.

10.2. Chemical stability

The product is stable under storage at normal ambient temperatures.

10.3. Possibility of hazardous reactions

No known hazardous reactions.

10.4. Conditions to avoid

Ultra-violet light and daylight initiate polymerisation of the product. Therefore keep only in tightly closed containers away from any sources of light. Keep at temperature not exceeding 25°C/ 77°F.

10.5. Incompatible materials

Reacts with : oxidising agents, radicals forming substances or heavy metal ions.

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10.6. Hazardous decomposition products

In case of fire, acrid acrylic fumes may occur.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity

Based on available data, the classification criteria are not met.

For the product itself no toxicological data are available. In products with a comparable composition, a LD50 (orally, species rat) of > 5000 mg/kg has been found.

| CAS No | Chemical name | | | | |
|------------|--|-------------------|---------|----------|--------|
| | Exposure route | Dose | Species | Source | Method |
| 72869-86-4 | 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate | | | | |
| | oral | LD50 >5000 mg/kg | Rat | OECD 401 | |
| | dermal | LD50 >2000 mg/kg | Rat | OECD 402 | |
| 75980-60-8 | diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide | | | | |
| | oral | LD50 >5000 mg/kg | Rat | | |
| | dermal | LD50 >2000 mg/kg | Rat | | |
| 21245-02-3 | 2-Ethylhexyl 4-(dimethylamino)benzoate | | | | |
| | oral | LD50 14,900 mg/kg | Rat | | |

Irritation and corrosivity

Causes skin irritation.

Causes serious eye irritation.

Sensitising effects

May cause an allergic skin reaction. (7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate; tetrahydrofurfuryl methacrylate THFMA purified grade; diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide)

Carcinogenic/mutagenic/toxic effects for reproduction

Suspected of damaging fertility or the unborn child. (tetrahydrofurfuryl methacrylate THFMA purified grade; diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide)

Germ cell mutagenicity: Based on available data, the classification criteria are not met.

Carcinogenicity: Based on available data, the classification criteria are not met.

STOT-single exposure

Based on available data, the classification criteria are not met.

STOT-repeated exposure

Based on available data, the classification criteria are not met.

Aspiration hazard

Based on available data, the classification criteria are not met.

Additional information on tests

This mixture is classified as hazardous according to regulation (EC) No. 1272/2008 [CLP]. Special hazards arising from the substance or mixture!

SECTION 12: Ecological information

12.1. Toxicity

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The product is not: Ecotoxic.

| CAS No | Chemical name | | | | | |
|------------|--|---------------|-----------|---------|---------------------------------|----------|
| | Aquatic toxicity | Dose | [h] [d] | Species | Source | Method |
| 72869-86-4 | 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxo-5,12-diazahexadecane-1,16-diyl bismethacrylate | | | | | |
| | Acute crustacea toxicity | EC50 mg/l | >1,2 | 48 h | Daphnia magna (Big water flea) | OECD 202 |
| 2455-24-5 | tetrahydrofurfuryl methacrylate THFMA purified grade | | | | | |
| | Acute fish toxicity | LC50 mg/l | 34,7 | 96 h | | GESTIS |
| 75980-60-8 | diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide | | | | | |
| | Acute algae toxicity | ErC50 mg/l | >2,01 | 72 h | Scenedesmus subspicatus | |
| | Acute crustacea toxicity | EC50 mg/l | 3,53 | 48 h | Daphnia magna (Big water flea) | |
| | Acute bacteria toxicity | (>1000 mg/l) | | 3 h | Activated sludge | |
| 21245-02-3 | 2-Ethylhexyl 4-(dimethylamino)benzoate | | | | | |
| | Acute fish toxicity | LC50 mg/l | 0,235 | 96 h | QSAR | |
| | Acute algae toxicity | ErC50 mg/l | <0,015 | 72 h | Pseudokirchneriella subcapitata | |
| | Acute crustacea toxicity | EC50 mg/l | >0,031 | 48 h | Daphnia magna (Big water flea) | |
| | Acute bacteria toxicity | (1000 mg/l) | | 3 h | Activated sludge | |

12.2. Persistence and degradability

The product has not been tested.

| CAS No | Chemical name | | | |
|------------|--|-------|----|--------|
| | Method | Value | d | Source |
| | Evaluation | | | |
| 75980-60-8 | diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide | | | |
| | | 0-10% | 28 | |
| | Not readily biodegradable (according to OECD criteria) | | | |

12.3. Bioaccumulative potential

The product has not been tested.

Partition coefficient n-octanol/water

| CAS No | Chemical name | Log Pow |
|------------|---|---------|
| 75980-60-8 | diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide | 3,1 |

BCF

| CAS No | Chemical name | BCF | Species | Source |
|------------|---|-------|-------------------------------|--------|
| 75980-60-8 | diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide | 47-55 | Cyprinus carpio (Common Carp) | |

12.4. Mobility in soil

The product has not been tested.

12.5. Results of PBT and vPvB assessment

Not identified as PBT/ vPvB substances

12.6. Other adverse effects

No information available.

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Further information

Avoid release to the environment.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Disposal recommendations

Do not allow to enter into surface water or drains. Dispose of waste according to applicable legislation.

Contaminated packaging

@1301.B130039 Handle contaminated packages in the same way as the substance itself.

SECTION 14: Transport information

Land transport (ADR/RID)

| | |
|--|---|
| 14.1. UN number: | UN 3082 |
| 14.2. UN proper shipping name: | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. Contains: 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diylbis methacrylate |
| 14.3. Transport hazard class(es): | 9 |
| 14.4. Packing group: | III |
| Hazard label: | 9 |
| Classification code: | M6 |
| Special Provisions: | 274 335 375 601 |
| Limited quantity: | 5 L/ 30 kg |
| Excepted quantity: | E1 |
| Transport category: | 3 |
| Hazard No: | 90 |
| Tunnel restriction code: | - |

Other applicable information (land transport)

Contains: 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diylbismethacrylate

Marine transport (IMDG)

| | |
|--|---|
| 14.1. UN number: | UN 3082 |
| 14.2. UN proper shipping name: | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. Contains: 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diylbis methacrylate |
| 14.3. Transport hazard class(es): | 9 |
| 14.4. Packing group: | III |
| Hazard label: | 9 |
| Marine pollutant: | YES |
| Special Provisions: | 274, 335, 969 |
| Limited quantity: | 5 L/ 30 kg |
| Excepted quantity: | E1 |
| EmS: | F-A, S-F |

Other applicable information (marine transport)

Contains: 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diylbismethacrylate
Flash point: > 100°C

Air transport (ICAO-TI/IATA-DGR)

| | |
|-------------------------|---------|
| 14.1. UN number: | UN 3082 |
|-------------------------|---------|

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| | | |
|--|---|--|
| 14.2. UN proper shipping name: | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. Contains: 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diylbis methacrylate | |
| 14.3. Transport hazard class(es): | 9 | |
| 14.4. Packing group: | III | |
| Hazard label: | 9 | |
| Special Provisions: | A97 A158 A197 | |
| Limited quantity Passenger: | 30 kg G | |
| Passenger LQ: | Y964 | |
| Excepted quantity: | E1 | |
| IATA-packing instructions - Passenger: | 964 | |
| IATA-max. quantity - Passenger: | 450 L | |
| IATA-packing instructions - Cargo: | 964 | |
| IATA-max. quantity - Cargo: | 450 L | |

Other applicable information (air transport)

Contains: 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diylbismethacrylate

14.5. Environmental hazards

ENVIRONMENTALLY HAZARDOUS: yes

14.6. Special precautions for user

No dangerous good in sense of this transport regulation.

14.7. Transport in bulk according to Annex II of Marpol and the IBC Code

No dangerous good in sense of this transport regulation.

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

Classified as Hazardous according to the criteria of the National Occupational Health and Safety Commission (NOHSC) approved criteria for the classifying hazardous substances [NOHSC: 1008] 3rd edition.

Standard for the Uniform Scheduling of Medicines and Poisons.

Carcinogen classification under WHS Regulation 2011, Schedule 10.

Notification status in accordance with section 3 and current national legislation.

HSNO Approval: HSR003747

EPA NZ Classes of hazardous properties:

Classification 6.8B Suspected human reproductive or developmental toxicants

Classification 8.1A Corrosive to metals

SECTION 16: Other information

Abbreviations and acronyms

ADR: Accord européen sur le transport des marchandises dangereuses par Route
(European Agreement concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonized System of Classification and Labelling of Chemicals

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service

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LC50: Lethal concentration, 50%
 LD50: Lethal dose, 50%
 CLP: Classification, labelling and Packaging
 REACH: Registration, Evaluation and Authorization of Chemicals
 GHS: Globally Harmonised System of Classification, Labelling and Packaging of Chemicals
 UN: United Nations
 DNEL: Derived No Effect Level
 DMEL: Derived Minimal Effect Level
 PNEC: Predicted No Effect Concentration
 ATE: Acute toxicity estimate
 LL50: Lethal loading, 50%
 EL50: Effect loading, 50%
 EC50: Effective Concentration 50%
 ErC50: Effective Concentration 50%, growth rate
 NOEC: No Observed Effect Concentration
 BCF: Bio-concentration factor
 PBT: persistent, bioaccumulative, toxic
 vPvB: very persistent, very bioaccumulative
 RID: Regulations concerning the international carriage of dangerous goods by rail
 ADN: European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
 (Accord européen relatif au transport international des marchandises dangereuses par voies de navigation
 intérieures)
 EmS: Emergency Schedules
 MFAG: Medical First Aid Guide
 ICAO: International Civil Aviation Organization
 MARPOL: International Convention for the Prevention of Marine Pollution from Ships
 IBC: Intermediate Bulk Container
 SVHC: Substance of Very High Concern
 @1602.B016012

Classification for mixtures and used evaluation method according to Regulation (EC) No. 1272/2008 [CLP]

| Classification | Classification procedure |
|-------------------------|--------------------------|
| Skin Irrit. 2; H315 | Calculation method |
| Eye Irrit. 2; H319 | Calculation method |
| Skin Sens. 1; H317 | Calculation method |
| Repr. 2; H361 | Calculation method |
| Aquatic Chronic 2; H411 | Calculation method |

Relevant H and EUH statements (number and full text)

H315 Causes skin irritation.
 H317 May cause an allergic skin reaction.
 H319 Causes serious eye irritation.
 H335 May cause respiratory irritation.
 H360 May damage fertility or the unborn child.
 H361 Suspected of damaging fertility or the unborn child.
 H361f Suspected of damaging fertility.
 H411 Toxic to aquatic life with long lasting effects.

Further Information

The information is based on the present level of our knowledge. It does not, however, give assurance of product properties and establishes no contract legal rights. The receiver of our product is singularly responsible for adhering to existing laws and regulations.

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Identified uses

| No | Short title | LCS | SU | PC | PROC | ERC | AC | TF | Specification |
|----|-------------|-----|----|----|------|-----|----|----|---------------|
| 1 | Gewerblich | - | - | - | - | - | - | - | 2 |

LCS: Life cycle stages

SU: Sectors of use

PC: Product categories

PROC: Process categories

ERC: Environmental release categories

AC: Article categories

TF: Technical functions

(The data for the hazardous ingredients were taken respectively from the last version of the sub-contractor's safety data sheet.)