

Safety Data Sheet

ProphyPaste blue, green, red, yellow

Issued on: December 1, 2013

Version No.:

2

Revised: November 27, 2014

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1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

| 1.1 PRODUCT IDENTIFIER | ITEM NUMBER |
|------------------------------------|-------------|
| ProphyPaste blue 96g/60ml | 731113 |
| ProphyPaste green 97g/60ml | 731114 |
| ProphyPaste red 84g/60ml | 731112 |
| ProphyPaste yellow 84g/60ml | 731111 |
| ProphyPaste blue single dose 2g | 690123 |
| ProphyPaste green single dose 2g | 690122 |
| ProphyPaste red single dose 2g | 690121 |
| ProphyPaste yellow single dose 2 g | 690120 |
| ProphyPaste mix single dose 2g | 690119 |

1.2 RELEVANTA IDENTIFIED USES OF THE SUBSTANCE OR MIXTURE, AND USES ADVISED AGAINST
Tooth polishing paste. Medical device. Invasive and ready to use.

1.3 DETAILS OF THE SUPPLIER OF THE SAFETY DATA SHEET

Supplier: Directa AB, Box 723, SE-194 27 Upplands Väsby, Sweden.

Phone: +46 (0)8-506 505 75

Website: www.directadental.se

E-mail: info@directadental.se

1.4 EMERGENCY TELEPHONE

Posion centre 112 (in acute emergencies) (EU, EES, GSM networks), + 46 (0)8-33 12 31 (office hours)

2. HAZARDS IDENTIFICATION

2.1 CLASSIFICATION OF THE SUBSTANCE OR THE MIXTURE

In accordance with CLP (Regulation (EC) No 1272/2008): –

In accordance with the Swedish regulation KIFS 2005:7: –

2.2 LABEL ELEMENTS

The labelling requirements of the above regulations do not apply as this is a ready to use invasive medical device.

Classification in accordance with the Swedish regulation KIFS 2005:7:

R PHRASES

-

S PHRASES

-

ADDITIONAL INFORMATION (LABEL)

This safety data sheet is available on request to professional users.

The labelling requirements of the above regulations do not apply as this product is a ready to use invasive medical device.

OTHER HAZARDS

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3. COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Composition in accordance with CLP (Regulation (EC) No 1272/2008).

| Chemical name | EC No | Reg. No | CAS No | Pct./Conc. | Pictogram | H code(s)* | Category |
|--------------------|-----------|------------------|------------|------------|-----------------|--------------------------------|---|
| Titanium dioxide** | 236-675-5 | 01-2119489379-17 | 13463-67-7 | 0.1-5% | — | — | — |
| Sodium fluoride | 231-667-8 | 01-2119539420-47 | 7681-49-4 | <0,3% | GHS06 Hazard | H301 H319 H315 EUH032 | Acute Tox. 3 Eye Irrit. 2 Skin Irrit. 2 |

* For full wording of R phrases and H codes refer to section 16.

**Substance with exposure limit.

Composition in accordance with the Swedish regulation KIFS 2005:7

| Chemical name | EC No | CAS No | Pct./Conc. | Symbol(s) | R phrase(s)* |
|--------------------|-----------|------------|------------|-----------|--------------|
| Titanium dioxide** | 236-675-5 | 13463-67-7 | 0.1-5% | — | — |
| Sodium fluoride | 231-667-8 | 7681-49-4 | <0,3% | T | R25-36/38-32 |

* For full wording of R phrases and H codes refer to section 16.

**Substance with exposure limit.

Percentage of pigment of respective product:

CCS Prophy Paste Blue

| Substance | CAS No | EC No | Percentage % |
|-------------------------------------|-----------|------------|--------------|
| Colour Acid Blue 9 (CI 42090, E133) | 3844-45-9 | 3398-8-223 | 0.01-0.09 |

CCS Prophy Paste Green

| Substance | CAS No | EC No | Percentage % |
|--|-----------|------------|--------------|
| Colour Acid Blue 9 (CI 42090, E133) | 3844-45-9 | 3398-8-223 | 0.01-0.09 |
| Colour Acid Yellow 23 (CI 19140, E133) | 1934-21-0 | 217-699-5 | 0.01-0.09 |

CCS Prophy Paste Red

| Substance | CAS No | EC No | Percentage % |
|-------------------------------------|------------|-----------|--------------|
| Colour Acid Red 51 (CI 45430, E133) | 16423-68-0 | 240-474-8 | 0.01-0.09 |

CCS Prophy Paste Yellow

| Substance | CAS No | EC No | Percentage % |
|--|-----------|-----------|--------------|
| Colour Acid Yellow 23 (CI 19140, E133) | 1934-21-0 | 217-699-5 | 0.01-0.09 |

4. FIRST AID MEASURES

4.1 DESCRIPTION OF FIRST AID MEASURES

GENERAL NOTES

Keep person warm and at rest. Never make an unconscious person drink or eat. At the slightest uncertainty or if irritation persists, contact a physician. Show this safety data sheet to the doctor in attendance.

INHALATION

Bring victim into fresh air and let rest. Contact a physician if irritation persists.

SKIN CONTACT

Remove contaminated clothes, shoes, jewelry and wash before reuse. Flush skin with water and soap for several minutes. Contact a physician if irritation persists.

EYE CONTACT

Rinse with soft tempered water for several minutes. Keep eyelids widely open. Remove contact lenses, if present. Immediately contact a physician.

INGESTION

Rinse mouth with water. Contact a physician in case of ingestion of large amounts and if irritation persists.

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4.2 MOST IMPORTANT SYMPTOMS AND EFFECTS, BOTH ACUTE AND DELAYED

May cause short term irritating of eyes. With long term contact: drying of skin.

4.3 INDICATION OF ANY IMMEDIATE MEDICAL ATTENTION AND SPECIAL TREATMENT NEEDED

Washbasin and eyewash possibilities.

5. FIREFIGHTING MEASURES

5.1 EXTINGUISHING MEDIA

Water, carbon dioxide, or foam.

5.2 SPECIAL HAZARDS ARISING FROM THE SUBSTANCE OR MIXTURE

Possible release of dangerous smoke gases in case of fire.

5.3 ADVICE FOR FIREFIGHTERS

Wear full protective equipment including breathing apparatus. Prevent fire and extinguishing water from reaching drains. Control poisonous smoke with water.

6. ACCIDENTAL RELEASE MEASURES

6.1 PERSONAL PRECAUTIONS, PROTECTIVE EQUIPMENT AND EMERGENCY PROCEDURES

Use protective equipment, refer to section 8. Avoid contact with skin and eyes. Provide for sufficient ventilation.

6.2 ENVIRONMENTAL PRECAUTIONS

Prevent discharge of larger amounts to drains or surrounding environment/water course.

6.3 METHODS AND MATERIAL FOR CONTAINMENT AND CLEANING UP

Clean up spill by mechanical means and place in an appropriate container. Smaller amounts can be wiped up using paper and a damp cloth. The spill must be disposed of in accordance with section 13. Clean contaminated surfaces and objects.

6.4 REFERENCE TO OTHER SECTIONS

See section 8 and 13 for information on protective equipment and waste disposal.

7. HANDLING AND STORAGE

7.1 PRECAUTIONS FOR SAFE HANDLING

Use protective equipment, refer to section 8. This product is intended for dental professional use only.

7.2 CONDITIONS FOR SAFE STORAGE, INCLUDING ANY INCOMPATIBILITIES

Store at cool and aired place (0-25°C). Keep the product in its package. Recommended storage period: 3 years.

7.3 SPECIFIC END USE(S)

See EWC code in section 13.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1 CONTROL PARAMETERS

NATIONAL OCCUPATIONAL EXPOSURE LIMITS (SWEDISH REGULATION AFS 2011:18)

Titanium dioxide:

NGV = (total) 5 mg/m³

DNEL

Data not available.

PNEC

Data not available.

8.2 EXPOSURE CONTROLS

RESPIRATORY PROTECTION

Not required in normal conditions. Use breathing protection in case of insufficient ventilation.

HAND PROTECTION

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Not required in normal conditions. Use protective gloves in case of long term or repeated contact. Check the breakthrough time of the gloves prior to use.

EYE/FACE PROTECTION

Use tight safety goggles in risk for eye splash.

PROTECTIVE CLOTHING

Not required in normal conditions.

HYGIENIC MEASURES

Do not eat, drink, smoke or take snuff at the work place. Remove all contaminated clothes. Wash hands and/or face before breaks and at the end of work. Use a protective hand lotion in case of skin irritation.

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 INFORMATION ON BASIC PHYSICAL AND CHEMICAL PROPERTIES

| | |
|---------------------|------------------------------|
| Appearance | High viscosity paste |
| Colour | Blue/green/yellow/red |
| Odour | Peppermint |
| pH | 5.0-6.0 |
| Solubility in water | Forms suspension with water. |

9.2 OTHER INFORMATION

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10. STABILITY AND REACTIVITY

10.1 REACTIVITY

Stable for 3 years under recommended handling and storage conditions.

10.2 CHEMICAL STABILITY

Stable for 3 years under recommended handling and storage conditions.

10.3 POSSIBILITY OF HAZARDOUS REACTIONS

Stable for 3 years under recommended handling and storage conditions.

10.4 CONDITIONS TO AVOID

Avoid temperatures of > 25°C and < 0°C.

10.5 INCOMPATIBLE MATERIALS

No known.

10.6 HAZARDOUS DECOMPOSITION MATERIALS

When heated the product irritating vapours may be formed.

11. TOXICOLOGICAL INFORMATION

11.1 INFORMATION ON TOXICOLOGICAL EFFECTS

| | ACUTE EFFECTS | CHRONIC EFFECTS |
|--------------|--|-----------------|
| SKIN CONTACT | With long term contact: drying of skin. | – |
| EYE CONTACT | May cause short term irritating. | – |
| INHALATION | – | – |
| INGESTION | Ingestion of large amounts may cause abdominal pain. | – |

ACUTE TOXICITY

Titanium dioxide:

LD₅₀ Oral rat: >100000 mg/kg body weight (no acute toxicity)

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Inhalation of large amounts of titanium dioxide dust can reduce lung capacity. It is not known whether this effect is caused by the titanium dioxide itself or if it is a "general" dust effect (A&H 1989:31).

Sodium fluoride:

LD50 Oral rat: 52 mg/kg body weight (poisonous if ingested)

The effect of long term exposure to soluble fluorides is the effect on the bones.

Calculations from the WHO, which are based on the intake of food, indicate that skeletal effects appear at an air condition of 0.8 to 2.0 mg F/m³ for an 8-hour workday. The effect at acute exposure to hydrogen fluoride, fluoric acid and aqueous acid fluoride solutions is irritation of the mucous membranes This was reported in an experimental study on the exposure to HF at 0.7-2.4 mg/m³. The toxicity of the fluoride is not affected by solubility, sparingly soluble fluorides are generally less toxic. Death has been reported after mouth intake of very low doses (approx. 18 mg F/kg) among adults, even lower for children (approx. 4 mg F/kg).

IRRITATION

May cause short term irritating of eyes after direct contact.

CORROSIVITY

No known corrosive effect.

SENSITISATION

No known sensitising effect.

REPEATED DOSE TOXICITY

No known toxicity with repeated dosage.

CARCINOGENICITY

No known carcinogenicity.

MUTAGENICITY

No known mutagenicity.

TOXICITY FOR REPRODUCTION

No known toxicity for reproduction.

INTERACTIVE EFFECTS

No known interactive effects.

ABSENCE OF SPECIFIC DATA

Data on the toxicity of this product is not available.

12. ECOLOGICAL INFORMATION

12.1 TOXICITY

Not classified as an environmental hazard.

ECOTOXICITY OF COMPONENTS

Titanium dioxide:

Toxicity

LC₅₀ Fish 96h: >1000 mg/l species: Fundulus heteroclitus (not hazardous)

EC₅₀ Daphnia 48h: >1000 mg/l species: D. magna (not hazardous)

Sodium fluoride:

Toxicity

LC50 Fish 96h: 51 mg/l species: Oncorhynchus mykiss (hazardous)

EC50 Daphnia 48h: 338 mg/l species: D. magna (not hazardous)

Accumulative

BCF: 2.3 (not expected to bio accumulate)

12.2 PERSISTENCE AND DEGRADABILITY

No data available.

12.3 BIOACCUMULATIVE POTENTIAL

No data available.

12.4 MOBILITY IN SOIL AND WATER

Forms suspension with water.

12.5 RESULTS OF PBT OCH vPvB ASSESSMENT

Data not available.

12.6 OTHER ADVERSE EFFECTS

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No other adverse effects expected.

ADDITIONAL INFORMATION

This product is not classified as hazardous to the environment. The prudence concept must be followed. Do not discharge into drains or water course.

13. DISPOSAL CONSIDERATIONS

13.1 WASTE FROM RESIDUES / UNUSED PRODUCTS

In accordance with the Swedish regulation SFS 2011:927 an unused product is classified as non-hazardous waste.

Suggested EWC codes:

18 WASTES FROM HUMAN OR ANIMAL HEALTH CARE AND/OR RELATED RESEARCH (except kitchen and restaurant wastes not arising from immediate health care)

18 01 07 chemicals other than those mentioned in 18 01 06

CONTAMINATED PACKAGING

Take thoroughly cleaned packaging to a local recycling plant.

14. TRANSPORT INFORMATION

Not classified as dangerous goods under international transportation regulations (ADR/RID/IMO/DGR).

14.1 ENVIRONMENTAL HAZARDS

–

14.2 SPECIFIC PRECAUTIONS

–

14.3 BULK TRANSPORTATION IN ACCORDANCE WITH ANNEX II OF MARPOL 73/78 AND THE IBC CODE

Not applicable as the product is not classified as dangerous goods.

15. REGULATORY INFORMATION

15.1 SAFETY, HEALTH AND ENVIRONMENTAL REGULATIONS / LEGISLATION SPECIFIC FOR THE SUBSTANCE OR MIXTURE

Safety data sheet and classification in accordance with CLP (regulation (EC) No 1272/2008 and regulation (EU) No 453/2010, Annex I) and Swedish regulation KIFS 2005:7.

Council Directive 93/42/EEC concerning medical devices.

15.2 CHEMICAL SAFETY ASSESSMENT

A chemical safety assessment (CSA) has been carried out for this product.

16. OTHER INFORMATION

Classification in accordance with CLP (Regulation (EC) No 1272/2008)

Pictogram:

–

Signal words:

–

Precautionary statements:

–

Hazard statements:

–

Content: sodium fluoride.

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Further information:

EUH210 – Safety data sheet available on request.

FULL TEXT OF R PHRASES UNDER SECTION 3

R32 – Contact with acids liberates very toxic acid

R36/38 – Irritating to eyes and skin

R25 – Toxic if swallowed

FULL TEXT OF H CODES UNDER SECTION 3

H301– Toxic if swallowed

H315 – Causes skin irritation

H319 – Causes serious eye irritation

EUH032 – *“Contact with acids liberates very toxic gas”*

KEY OR LEGEND OF ABBREVIATIONS AND ACRONYMS

–

REFERENCES TO LITERATURE AND DATA SOURCES

See chemical safety assessment (CSA) for sources.

REVISION AMENDMENTS

Version 1 (November 27, 2013): master document.

OTHER

The information contained in this safety data sheet is a complement to other information. The user must decide if the given information is adequate. The responsibility for product safety and the information contained in this safety data sheet rests with Directa AB.