

## SAFETY DATA SHEET

Safety data sheet according to (EC) No. 1907/2006.

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

### 1.1. Product identifier:

SIMPLEE ProphyPaste Blue 250 (artikelnummer 156825)  
SIMPLEE ProphyPaste Green 170 (artikelnummer 156826)  
SIMPLEE ProphyPaste Red 120 (artikelnummer 156827)  
SIMPLEE ProphyPaste Yellow 40 (artikelnummer 156828)

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

Paste for polishing teeth. Medical device.

### 1.3. Details of the supplier of the safety data sheet:

Directa AB  
Box 723 Tel. +46 850650575  
SE-194 27 Upplands Väsby

Responsible person for the safety data sheet (e-mail): [info@directadental.com](mailto:info@directadental.com)

### 1.4. Emergency telephone number:

NHS (England or Wales): Dial 111 or 0845 4647 NHS 24 (Scotland): Dial 111  
National Poisons Information Centre (Ireland): +353 (1) 809 2166 (8.00 a.m. to 10.00 p.m. 7 days a week).  
Healthcare Professionals: +353 (1) 809 2566 (24-hour service)

## SECTION 2: Hazards identification

### 2.1. Classification of the substance or mixture:

Irritant paste.

CLP (1272/2008): Eye Irrit. 2;H319

### 2.2. Label elements:



WARNING

H319: Causes serious eye irritation.

P280: Wear eye protection.

P337+P313: If eye irritation persists: Get medical advice/attention.

### 2.3. Other hazards:

PBT/vPvB: No ingredients are PBT/vPvB, according to the criteria in REACH Annex XIII.

Endocrine disrupting properties: The substances are not identified as having endocrine disrupting properties in accordance with the criteria set out in Regulation 2023/707.

## SECTION 3: Composition/information on ingredients

### 3.2. Mixtures:

% w/w	Substance name	CAS No.	EC No.	Index No.	REACH reg. No.	Classification	Note
<5	Titanium dioxide	13463-67-7	236-675-5	022-006-00-2	-	Carc. 2;H351i	1,2
1-<2	2-Phenoxy ethanol	122-99-6	204-589-7	603-098-00-9	-	Acute Tox. 4;H302 Eye Dam. 1;H318 STOT SE 3;H335	3
<1	Sodium fluoride	7681-49-4	231-667-8	009-004-00-7	-	Acute Tox. 3;H301 Skin Irrit. 2;H315 Eye Irrit. 2;H319 EUH032	4,5

1) The substance has an occupational exposure limit.

2) The classification as carcinogenic by inhalation only applies to mixtures in powder form with a content of 1% or more of titanium dioxide, which takes the form of or is part of particles, with an aerodynamic diameter of  $\leq 10 \mu\text{m}$ .

3) ATE (oral) = 1394 mg/kg

4) The substance has an EU occupational exposure limit.

5) ATE (oral) = 52 mg/kg

Wording of hazard statements - see section 16.

---

## SECTION 4: First-aid measures

---

**4.1. Description of first aid measures:**

Inhalation: Remove to fresh air. Keep at rest. In case of discomfort: Seek medical advice.

Skin contact: Remove all contaminated clothing. Wash skin with plenty of water and soap. If irritation persists: Seek medical advice.

Eye contact: Immediately flush with water or physiological salt water for at least 15 minutes, holding eye lids open, remember to remove contact lenses, if any. If irritation persists: seek medical advice.

Ingestion: Rinse mouth and drink plenty of water. In case of discomfort: Seek medical advice.

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

Eye irritation with redness and pain.

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

Show this safety data sheet to a physician or emergency ward.

---

## SECTION 5: Firefighting measures

---

**5.1. Extinguishing media:**

Not combustible. Use suitable extinguishing media for fighting surrounding fire.

**5.2. Special hazards arising from the substance or mixture:**

Not relevant.

**5.3. Advice for firefighters:**

When extinguishing surrounding fires use breathing apparatus with an independent source of air.

---

## SECTION 6: Accidental release measures

---

**6.1. Personal precautions, protective equipment and emergency procedures:**

Use personal protective equipment - see section 8.

**6.2. Environmental precautions:**

Do not empty into drains – see section 12. Inform appropriate authorities in accordance with local regulations.

**6.3. Methods and material for containment and cleaning up:**

Pick up and place in a suitable container. Clean with water. Further handling of spillage – see section 13.

**6.4. Reference to other sections:**

See above.

---

## SECTION 7: Handling and storage

---

**7.1. Precautions for safe handling:**

Avoid contact with eyes. After use wash with soap and plenty of water. Required access to water and eye wash fountain.

**7.2. Conditions for safe storage, including any incompatibilities:**

Store in tightly closed original packaging at room temperature in a well-ventilated place.

Store securely and out of reach of unauthorized personnel and separated from food, feed, drugs etc.

**7.3. Specific end use(s):**

See section 1.

---

## SECTION 8: Exposure controls/personal protection

---

**8.1. Control parameters:**

Occupational exposure limits, UK (EH40/ed.2020):

Substance	8-hour TWA	15-min STEL	Comments
Titanium dioxide, total inhalable	10 mg/m <sup>3</sup>	-	-
Titanium dioxide, respirable	4 mg/m <sup>3</sup>	-	-
Fluoride – inorganic as F	2,5 mg/m <sup>3</sup>	-	-

Occupational exposure limit values, Ireland (2021):

Substance	8-hour TWA	15-min STEL	Notes
Titanium dioxide, total inhalable dust	10 mg/m <sup>3</sup>	-	-
Titanium dioxide, respirable dust	4 mg/m <sup>3</sup>	-	-
Fluoride – inorganic as F	2,5 mg/m <sup>3</sup>	-	IOELV

IOELV: Indicative Occupational Exposure Limit Values set under the EU Chemical Agents Directive 98/24/EC. (for Ireland ~ note E in EU)

DNEL/PNEC: No CSR.

---

## SECTION 8: Exposure controls/personal protection (continued)

---

**8.2. Exposure controls:**

Appropriate engineering controls: Ensure adequate ventilation.

Personal protective equipment:

Respiratory protection: Not relevant during intended use.

Skin protection: In case of prolonged use: Wear protective gloves of nitrile rubber (EN374). Data about the breakthrough time of the ingredients are not available. Replacing the glove after use is therefore recommended.

Eye protection: Wear tightly fitting safety goggles (EN ISO 16321-1) when there is risk of splashes.

Environmental exposure controls: None particular.

---

## SECTION 9: Physical and chemical properties

---

**9.1. Information on basic physical and chemical properties:**

Physical state:	Paste
Colour:	Available in 4 colours: blue, green, red and yellow
Odour:	Mint
Melting point/freezing point (°C):	Not determined
Boiling point or initial boiling point and boiling range (°C):	Not determined
Flammability (solid, gas):	Not determined
Lower and upper explosion limit (vol-%):	Not determined
Flash point (°C):	Not determined
Auto-ignition temperature (°C):	Not determined
Decomposition temperature (°C):	Not determined
pH:	5.0-6.0
Kinematic viscosity:	Not determined
Solubility:	Can be suspended in water
Partition coefficient n-octanol/water (log value):	Not relevant – mixture (see section 12)
Vapour pressure:	Not determined
Density and/or relative density:	Not determined
Relative vapour density:	Not determined
Particle characteristics:	Not determined
<b>9.2. Other information:</b>	Not determined

---

## SECTION 10: Stability and reactivity

---

**10.1. Reactivity:**

No available information.

**10.2. Chemical stability:**

Stable under normal conditions (3 years) - see section 7.

**10.3. Possibility of hazardous reactions:**

None known

**10.4. Conditions to avoid:**

Avoid excessive heating and frost.

**10.5. Incompatible materials:**

Strong oxidizers, acids and bases.

**10.6. Hazardous decomposition products:**

None known.

---

## SECTION 11: Toxicological information

---

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

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

Skin corrosion/irritation: Based on available data, the classification criteria are not met.

Serious eye damage/irritation: Eye Irrit. 2;H319 Causes serious eye irritation.

Respiratory or skin sensitization: Based on available data, the classification criteria are not met.

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

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

Reproductive toxicity: 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.

**SECTION 11: Toxicological information (continued)**

Hazard class	Data	Test	Data source
Acute toxicity:			
Inhalation	LC <sub>50</sub> (rat) > 1000 mg/m <sup>3</sup> /6h (2-Phenoxy ethanol) LC <sub>50</sub> (rat) > 4,4 mg/l/4h (dust) (Titanium dioxide)	No data OECD 403	ECHA ECHA
Dermal	LD <sub>50</sub> (rabbit) > 2214 mg/kg (2-Phenoxy ethanol) LD <sub>50</sub> > 2000 mg/kg (Sodium fluoride) LD <sub>50</sub> (rat) > 2000 mg/kg (Titanium dioxide)	No data No data No data	ECHA ECHA ECHA
Oral	LD <sub>50</sub> (rat) = 1439 mg/kg (2-Phenoxy ethanol) LD <sub>50</sub> (rat) = 52 mg/kg (Sodium fluoride) LD <sub>50</sub> (rat) > 2000 mg/kg (Titanium dioxide)	No data No data OECD 420	ECHA ECHA ECHA
Corrosion/ irritation:	No skin irritation, rabbit (2-Phenoxy ethanol) Eye irritation, rabbit (2-Phenoxy ethanol) Eye irritation, rabbit (Sodium fluoride) No skin irritation, rabbit (Sodium fluoride) No skin and eye irritation, rabbit (Titanium dioxide)	OECD 404 OECD 405 Read-across Read-across No data	ECHA ECHA ECHA ECHA ECHA
Sensitization:	No skin sensitisation, guinea pig (2-Phenoxy ethanol) No skin sensitisation, guinea pig (Sodium fluoride) No skin sensitisation (Titanium dioxide)	In-vivo No data No data	ECHA ECHA ECHA
CMR:	No mutagenic or reproductive effects (Sodium fluoride)	Several	ECHA

Information on likely routes of exposure: Ingestion.

Symptoms:

Inhalation: Not relevant during intended use.

Skin: May cause slight irritation.

Eyes: Cause eye irritation with redness and pain.

Ingestion: Ingestion of large amounts of sodium fluoride may lead to irritation of the gastrointestinal tract with thirst, abdominal pain, nausea and diarrhoea.

Chronic effects: IARC has classified titanium dioxide as Group 2B (by inhalation). There is no significant exposure to titanium dioxide from pasty products containing titanium dioxide (IARC, Vol. 93, p. 272).

Large doses of sodium fluoride can cause shortness of breath, paralysis and convulsions.

Fluorides may cause kidney damage, stiffness with limited movement in the joints, discoloration of the tooth enamel and brittle bones

**11.2. Information on other hazards:** None known.

**SECTION 12: Ecological information****12.1. Toxicity:**

Aquatic	Data	Test (Media)	Data source
Fish	LC <sub>50</sub> (Brachyodanio rerio, 96h) = 154 mg/l (2-Phenoxy ethanol) NOEC (Pimephales promelas) = 24 mg/l (2-Phenoxy ethanol) LC <sub>50</sub> (Oncorhynchus mykiss, 96h) = 51 mg/l (Sodium fluoride) LC <sub>50</sub> (Fish, 96h) > 1000 mg/l (Titanium dioxide)	Semi-Static (FW) OECD 210 (FW) No data (FW) No data	ECHA ECHA ECHA ECHA
Crustaceans	EC <sub>50</sub> (Daphnia magna, 48h) > 100 mg/l (2-Phenoxy ethanol) NOEC (Daphnia magna, 21d) = 9,43 mg/l (2-Phenoxy ethanol) EC <sub>50</sub> (Daphnia magna, 48h) = 10,5 mg/l (Sodium fluoride) EC <sub>50</sub> (Daphnia magna, 48h) > 1000 mg/l (Titanium dioxide)	OECD 202 (FW) OECD 211 (FW) No data (FW) No data (FW)	ECHA ECHA ECHA ECHA
Algae	EC <sub>50</sub> (Desmodesmus subspicatus, 72h) > 100 mg/l (2-Phenoxy ethanol) NOEC (Desmodesmus subspicatus, 72h) = 46 mg/l (2-Phenoxy ethanol) EC <sub>50</sub> (Scenedesmus sp. 96h) = 43 mg/l (Sodium fluoride)	OECD 201 (FW) OECD 201 (FW) No data (FW)	ECHA ECHA ECHA

**12.2. Persistence and degradability:**

Sodium fluoride and titanium dioxide are inorganic substances, methods for the determination of the biological degradation is not applicable to inorganic substances.

2-Phenoxy ethanol was degraded > 90% at an OECD 301A test and is considered rapidly degradable.

**12.3. Bioaccumulative potential:**

2-Phenoxy ethanol: Log K<sub>ow</sub> = 1.16 (OECD 107) The bioconcentration factor (BCF) for 2-phenoxy ethanol is estimated at 0.35 in fish (OECD 305), the substance is therefore not considered to be bioaccumulative.

**12.4. Mobility in soil:**

No available or applicable data.

**12.5. Results of PBT and vPvB assessment:**

No ingredients are PBT/vPvB, according to the criteria in REACH Annex XIII.

---

**SECTION 12: Ecological information (continued)**

---

**12.6. Endocrine disrupting properties:**

None known.

**12.7. Other adverse effects:**

None known.

---

**SECTION 13: Disposal considerations**

---

**13.1. Waste treatment methods:**

Disposal should be according to local, state or national legislation. Dispose of through authority facilities or pass to chemical disposal company.

**EWC-Code:**

18 01 07

---

**SECTION 14: Transport information**

---

Not dangerous goods (ADR/RID/IMDG/IATA).

**14.1. UN number or ID number:** None.**14.2. UN proper shipping name:** None.**14.3. Transport hazard class(es):** None.**14.4. Packing group:** None.**14.5. Environmental hazards:** No.**14.6. Special precautions for user:** None.**14.7. Maritime transport in bulk according to IMO instruments:** Not relevant.

---

**SECTION 15: Regulatory information**

---

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

None.

**15.2. Chemical safety assessment:**

No CSR.

---

**SECTION 16: Other information**

---

**Hazard statements mentioned in section 3:**

H301: Toxic if swallowed.

H302: Harmful if swallowed.

H315: Causes skin irritation.

H318: Causes serious eye damage.

H319: Causes serious eye irritation.

H335: May cause respiratory irritation.

H351: Suspected of causing cancer by inhalation.

EUH032: Contact with acids liberates very toxic gas.

**Abbreviations:**

CMR = Carcinogenicity, mutagenicity and reproductive toxicity.

CSR = Chemical Safety Report

DNEL = Derived No-Effect Level

EC<sub>50</sub> = Effect Concentration 50 %

FW = Fresh Water

LC<sub>50</sub> = Lethal Concentration 50 %LD<sub>50</sub> = Lethal Dose 50 %

PBT = Persistent, Bioaccumulative, Toxic

PNEC = Predicted No-Effect Concentration

vPvB = very Persistent, very Bioaccumulative

**Literature:**

ECHA = European Chemical Agency Registration dossier.

**Training advice:**

No special training is required. However, the user should be well instructed in the execution of the task, be familiar with this Safety Data Sheet and have normal training in the use of personal protective equipment.

**Changes since the previous edition:**

Not relevant – 1. edition

Prepared by: Altos a/s – Tonsbakken 16-18 – DK-2740 Skovlunde - Phone +45 - 38 34 77 98 / PH - Quality control: PW