

SAFETY DATA SHEET

Product name: Nobetec powder

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Revision:

Print date: 2022-12-12

Product No.:

SDS-ID: EU-EN/1.0

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1. Product identifier

Product name: Nobetec powder

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

Application: Temporary dental cement

1.3. Details of the supplier of the safety data sheet

Supplier: Directa AB
P.O. Box 723
SE-194 27 Upplands Väsby
Tel:+46 850650575
Fax:+46 85903060
info@directadental.com

1.4. Emergency telephone number

Emergency telephone: National Poison Control Centres are available in Member Countries.
or
+4608331231 (Only during office hours)

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SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

CLP: Skin Sens. 1;H317
Aquatic Acute 1;H400
Aquatic Chronic 1;H410

2.2. Label elements



Warning

Contains: Rosin

H317 May cause an allergic skin reaction.

H410 Very toxic to aquatic life with long lasting effects.

P261 Avoid breathing dust.

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 soap and water.

P333 + P313 If skin irritation or rash occurs: Get medical advice/attention.

P362 + P364 Take off contaminated clothing and wash it before reuse.

P391 Collect spillage.

P501 Dispose of contents/container in accordance with national regulations.

2.3. Other hazards

PBT/vPvB: This product does not contain any PBT or vPvB substances.

Other: Frequent inhalation of dust over a long period of time increases the risk of developing lung diseases.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.2. Mixtures

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CLP:

%:	CAS-No.:	EC No.:	REACH Reg. No:	Chemical name:	Hazard classification:	Notes:
30-70	1314-13-2	215-222-5	-	Zinc oxide	Aquatic Acute 1;H400 Aquatic Chronic 1;H410	
25-50	8050-09-7	232-475-7	-	Rosin	Skin Sens. 1;H317	
5-10	14807-96-6	238-877-9	-		-	#

Chemical name:	SCL	M (ac)	M (chr)	ATE(o) (mg/kg bw)	ATE(d) (mg/kg bw)	ATE(i) (dust/ mist, mg/L)	ATE(i) (gas, ppmV)	ATE(i) (vapou r, mg/L)
Zinc oxide	-	1	1	-	-	-	-	-
Rosin	-	-	-	-	-	-	-	-
		-	-	-	-	-	-	-

Notes: #: The substance has been assigned an exposure limit.

References: The full text for all hazard statements is displayed in section 16.

SECTION 4: FIRST AID MEASURES

4.1. Description of first aid measures

<u>Inhalation:</u>	Move into fresh air and keep at rest.
<u>Skin contact:</u>	Remove contaminated clothing. Wash skin thoroughly with soap and water.
<u>Eye contact:</u>	Immediately rinse with water for several minutes. Make sure to remove any contact lenses from the eyes before rinsing.
<u>Ingestion:</u>	Rinse mouth with water. Get medical attention if any discomfort continues.

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

<u>Symptoms/effects:</u>	May cause sensitisation by skin contact. May irritate the skin. May cause temporary eye irritation.
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4.3. Indication of any immediate medical attention and special treatment needed

<u>Medical attention/treatments:</u>	Treat symptomatically.
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SECTION 5: FIREFIGHTING MEASURES

5.1. Extinguishing media

Extinguishing media: This product is not flammable. Use fire-extinguishing media appropriate for surrounding materials.

5.2. Special hazards arising from the substance or mixture

Specific hazards: During fire, gases hazardous to health may be formed.

5.3. Advice for firefighters

Protective equipment for fire-fighters: Selection of respiratory protection for fire fighting: follow the general fire precautions indicated in the workplace.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions: Follow precautions for safe handling described in this safety data sheet. Avoid inhalation of dust and contact with skin and eyes.

6.2. Environmental precautions

Environmental precautions: Avoid discharge into water courses or onto the ground. Inform Authorities if large amounts are involved.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up: Sweep up and place into an appropriate container. Avoid spreading dust.

6.4. Reference to other sections

References: For personal protection, see section 8.
For waste disposal, see section 13.

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SECTION 7: HANDLING AND STORAGE

7.1. Precautions for safe handling

Safe handling advice: Avoid inhalation of dust and contact with skin and eyes. Observe good chemical hygiene practices. Avoid generating excess dust.

Technical measures: Keep the workplace clean. Use work methods which minimise dust production.

Technical precautions: Use mechanical ventilation in case of handling which causes formation of dust.

7.2. Conditions for safe storage, including any incompatibilities

Technical measures for safe storage: No special precautions.

Storage conditions: Store at moderate temperatures in dry, well ventilated area. Keep containers tightly closed.

7.3. Specific end use(s)

Specific use(s): The product is used as a temporary dental material in dental care. Prolonged skin contact with the product should be avoided due to risk of allergic eczema. If direct contact can not be avoided, personal protective equipment must be used, see section 8.

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SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

No occupational exposure limit assigned. Please note that there may be national occupational exposure limits.

8.2. Exposure controls

Engineering measures:

Provide adequate ventilation. Observe occupational exposure limits and minimise the risk of inhalation of dust.

Personal protection:

Personal protection equipment should be chosen according to the CEN standards and in discussion with the supplier of the personal protective equipment.

Respiratory equipment:

Under normal conditions of use respiration protection should not be required. In case of inadequate ventilation or risk of inhalation of dust, use suitable respiratory equipment with particle filter (type P3).

Hand protection:

Risk of contact: Wear protective gloves. Nitrile gloves are recommended. The most suitable glove must be chosen in collaboration with the supplier of gloves, who can inform about the breakthrough time of the glove material.

Eye protection:

Wear approved, tight fitting safety glasses where splashing is probable.

Skin protection:

Wear appropriate clothing to prevent repeated or prolonged skin contact.

Hygiene measures:

Wash hands after handling. Wash contaminated clothing before reuse.

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SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

<u>Physical state:</u>	Powder, dust.
<u>Colour:</u>	White / off-white.
<u>Odour:</u>	Odourless.
<u>Odour threshold:</u>	Not available.
<u>pH:</u>	Not available.
<u>Melting point / freezing point:</u>	Not available.
<u>Boiling point:</u>	Not available.
<u>Flash point:</u>	Not available.
<u>Evaporation rate:</u>	Not available.
<u>Explosion limits:</u>	Not available.
<u>Vapour pressure:</u>	Not available.
<u>Vapour density:</u>	Not available.
<u>Relative density:</u>	Not available.
<u>Solubility:</u>	Insoluble in water.
<u>Partition coefficient (n-octanol/water):</u>	Not available.
<u>Auto-ignition temperature (°C):</u>	Not available.
<u>Decomposition temperature (°C):</u>	Not available.
<u>Viscosity:</u>	Not available.
<u>Explosive properties:</u>	Non-explosive
<u>Oxidising properties:</u>	Non-oxidizing

9.2. Other information

<u>Other data:</u>	Not available.
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SECTION 10: STABILITY AND REACTIVITY

10.1. Reactivity

Reactivity: Not reactive.

10.2. Chemical stability

Stability: Stable under normal temperature conditions.

10.3. Possibility of hazardous reactions

Hazardous Reactions: None known.

10.4. Conditions to avoid

Conditions/materials to avoid: Avoid heat, flames and other sources of ignition.

10.5. Incompatible materials

Incompatible materials: Strong oxidising agents.

10.6. Hazardous decomposition products

Hazardous decomposition products: None under normal conditions.

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SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects

Acute Toxicity (Oral): Based on available data, the classification criteria are not met.
Acute Toxicity (Dermal): Based on available data, the classification criteria are not met.
Acute Toxicity (Inhalation): 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: Based on available data, the classification criteria are not met.
Respiratory or skin sensitisation: May cause an allergic skin reaction.
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.

Inhalation: Dust may irritate throat and respiratory system and cause coughing.
Skin contact: Prolonged contact may cause redness and irritation.
Eye contact: May cause temporary eye irritation.
Ingestion: May irritate and cause malaise.
Specific effects: May cause sensitisation by skin contact.

11.2. Information on other hazards

Endocrine disrupting properties: The product does not contain any substance identified as having endocrine disrupting properties.

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SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

Ecotoxicity: Very toxic to aquatic life with long lasting effects.

Zinc oxide:

LC50 (Oncorhynchus kisutch, 96 h): 0.8 mg/l

EC50 (Daphnia magna, 48 hours): 2.6 mg/l

IC50 (Pseudokirchneriella subcapitata, 72 hours): 0.1 mg/l

M-factor (acute): 1

M-factor (chronic): 1

12.2. Persistence and degradability

Degradability: The product consists mainly of inorganic compounds, which are not biodegradable.

12.3. Bioaccumulative potential

Bioaccumulative potential: Zinc is an essential substance. BCF decreases with increased exposure to zinc.

12.4. Mobility in soil

Mobility: Not considered mobile.

12.5. Results of PBT and vPvB assessment

PBT/vPvB: This product does not contain any PBT or vPvB substances.

12.6. Endocrine disrupting properties

Endocrine disrupting properties: The product does not contain any substance identified as having endocrine disrupting properties.

12.7. Other adverse effects

Other adverse effects: None known.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Dispose of waste and residues in accordance with local authority requirements.

Waste from residues: EWC-code: 18 01 06

Contaminated packaging: Dispose of contaminated packings as residue.

Empty packaging: Empty packaging is not considered hazardous.

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SECTION 14: TRANSPORT INFORMATION

The product is covered by international regulation on the transport of dangerous goods (IMDG, IATA, ADR/AND/RID).

14.1. UN number

UN-No: 3077

14.2. UN proper shipping name

Proper Shipping Name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Zinc oxide)

14.3. Transport hazard class(es)

Class: 9

14.4. Packing group

PG: III

14.5. Environmental hazards

Environmentally Hazardous substance: Yes.

14.6. Special precautions for user

Special precautions: -

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

Transport in bulk: Not relevant.

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SECTION 15: REGULATORY INFORMATION

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

Special provisions: As a general rule, persons under 18 years of age are not allowed to work with this product. Users must be carefully instructed in the proper work procedure, the dangerous properties of the product and the necessary safety instructions.

National regulation: Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC, with amendments.

Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 with amendments.

Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work, with amendments.

Commission Directive 2000/39/EC of 8 June 2000 establishing a first list of indicative occupational exposure limit values in implementation of Council Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work, with amendments.

Commission Directive 91/322/EEC of 29 May 1991 on establishing indicative limit values by implementing Council Directive 80/1107/EEC on the protection of workers from the risks related to exposure to chemical, physical and biological agents at work, with amendments.

Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work, with amendments.

Directive 2009/148/EC of the European Parliament and of the Council of 30 November 2009 on the protection of workers from the risks related to exposure to asbestos at work, with amendments.

Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives, with amendments.

2014/955/EC: Commission Decision of 18 December 2014 amending Decision 2000/532/EC as regards the list of wastes.

15.2. Chemical Safety Assessment

CSA status: No chemical safety assessment has been carried out.

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SECTION 16: OTHER INFORMATION

The user must be instructed in the proper work procedure and be familiar with the contents of these instructions.

For restrictions on use see section 15.

Abbreviations and acronyms used in the safety data sheet: CSA = Chemical Safety Assessment.
EC50 = Effective Concentration 50%.
LC50 = Lethal Concentration 50%.
PBT = Persistent, Bioaccumulative and Toxic.
vPvB = very Persistent and very Bioaccumulative.

Additional information: Classification according to Regulation (EC) No. 1272/2008: Calculation method.

Wording of H-statements:

H317 May cause an allergic skin reaction.
H400 Very toxic to aquatic life.
H410 Very toxic to aquatic life with long lasting effects.

The information on this data sheet represents our current data and is reliable provided that the product is used under the prescribed conditions and in accordance with the application specified on the packaging and/or in the technical guidance literature. Any other use of the product which involves using the product in combination with any other product or any other process is the responsibility of the user.