SAFETY DATA SHEET

n!ce™

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

1.1 Product identifier

Product name : n!ce™

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

Product use : For manufacture of dental ceramic restorations

1.3 Details of the supplier of the safety data sheet

Institut Straumann AG
Peter Merian Weg 12
CH-4002 Basel
Switzerland
Tel: +41 61 965 11 11
Fax: +41 61 965 11 01

e-mail address of person responsible for this SDS : info@straumann.com

1.4 Emergency telephone number

National advisory body/Poison Centre

Telephone number : Tox Info Suisse :
145 (CH), +41 44 251 51 51 (from abroad), 24h

Supplier

Telephone number : Institut Straumann AG
CH, +41 61 965 11 11 (from abroad)

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Product definition : Mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP/GHS]

Not classified.
The product is not classified as hazardous according to Regulation (EC) 1272/2008 as amended.
See Section 11 for more detailed information on health effects and symptoms.

2.2 Label elements

Signal word : **No signal word.**

Hazard statements : No known significant effects or critical hazards.

Precautionary statements

- **Prevention** : Not applicable.
- **Response** : Not applicable.
- **Storage** : Not applicable.
- **Disposal** : Not applicable.

Supplemental label elements : Not applicable.

Annex XVII – Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles : Restricted to professional users.

2.3 Other hazards

Other hazards which do not result in classification : Handling and/or processing of this material may generate a dust which can cause mechanical irritation of the eyes, skin, nose and throat

SECTION 3: Composition/information on ingredients

3.1 Mixtures

There are no ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as hazardous to health or the environment, are PBTs, vPvBs or Substances of equivalent concern, or have been assigned a workplace exposure limit and hence require reporting in this section.

SECTION 4: First aid measures

4.1 Description of first aid measures

Eye contact : dust formation: Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Get medical attention if irritation occurs.

Inhalation : dust formation: Remove victim to fresh air and keep at rest in a position comfortable for breathing. Get medical attention if symptoms occur.

Skin contact : dust formation: Flush contaminated skin with plenty of water. Remove contaminated clothing and shoes. Get medical attention if symptoms occur.

Ingestion : dust formation: Wash out mouth with water. Remove victim to fresh air and keep at rest in a position comfortable for breathing. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Do not induce vomiting unless directed to do so by medical personnel. Get medical attention if symptoms occur.

Protection of first-aiders : No action shall be taken involving any personal risk or without suitable training.

4.2 Most important symptoms and effects, both acute and delayed

Potential acute health effects

Eye contact : No known significant effects or critical hazards.

Inhalation : No known significant effects or critical hazards.

Skin contact : No known significant effects or critical hazards.

Ingestion : No known significant effects or critical hazards.

Over-exposure signs/symptoms

Eye contact : No specific data.

Inhalation : No specific data.

Skin contact : No specific data.

Ingestion : No specific data.

4.3 Indication of any immediate medical attention and special treatment needed

Notes to physician : Treat symptomatically. Contact poison treatment specialist immediately if large quantities have been ingested or inhaled.

Specific treatments : No specific treatment.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media : Use dry chemical, CO_2, alcohol-resistant foam or water spray (fog). Use an extinguishing agent suitable for the surrounding fire.

Unsuitable extinguishing media : Do not use water jet.

5.2 Special hazards arising from the substance or mixture

Hazards from the substance or mixture : No specific fire or explosion hazard.

Hazardous thermal decomposition products : Decomposition products may include the following materials:
phosphorus oxides
metal oxide/oxides

5.3 Advice for firefighters

Special protective actions for fire-fighters : Promptly isolate the scene by removing all persons from the vicinity of the incident if there is a fire. No action shall be taken involving any personal risk or without suitable training.

Special protective equipment for fire-fighters : Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode. Clothing for fire-fighters (including helmets, protective boots and gloves) conforming to European standard EN 469 will provide a basic level of protection for chemical incidents.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel : No action shall be taken involving any personal risk or without suitable training.

For emergency responders : If specialised clothing is required to deal with the spillage, take note of any information in Section 8 on suitable and unsuitable materials.
See also the information in „For non-emergency personnel".

6.2 Environmental precautions

: Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air).

6.3 Methods and material for containment and cleaning up

Small pill : Vacuum or sweep up material and place in a designated, labelled waste container. Dispose of via a licensed waste disposal contractor.

Large pill : Vacuum or sweep up material and place in a designated, labelled waste container. Dispose of via a licensed waste disposal contractor.

6.4 Reference to other sections

: See Section 1 for emergency contact information.
See Section 8 for information on appropriate personal protective equipment.
See Section 13 for additional waste treatment information.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Protective measures : Put on appropriate personal protective equipment (see Section 8).
Only for dental and dental technical use.

Advice on general occupational hygiene : Eating, drinking and smoking should be prohibited in areas where this material is handled, stored and processed. Workers should wash hands and face before eating, drinking and smoking. Remove contaminated clothing and protective equipment before entering eating areas. See also Section 8 for additional information on hygiene measures.

7.2 Conditions for safe storage, including any incompatibilities

Store in accordance with local regulations. Store away from direct sunlight in a dry, cool and well-ventilated area, away from incompatible materials (see Section 10) and food and drink. Do not store in unlabelled containers.

7.3 Specific end use(s)

Section 7. Handling and storage: The information in this section contains generic advice and guidance.

SECTION 8: Exposure controls/personal protection

The information in this section contains generic advice and guidance. Information is provided based on typical anticipated uses of the product. Additional measures might be required for bulk handling or other uses that could significantly increase worker exposure or environmental releases.

8.1 Control parameters

Occupational exposure limits

No exposure limit value known.

Recommended monitoring procedures : If this product contains ingredients with exposure limits, personal, workplace atmosphere or biological monitoring may be required to determine the effectiveness of the ventilation or other control measures and/or the necessity to use respiratory protective equipment. Reference should be made to monitoring standards, such as the following: European Standard EN 689 (Workplace atmospheres - Guidance for the assessment of exposure by inhalation to chemical agents for comparison with limit values and measurement strategy) European Standard EN 14042 (Workplace atmospheres - Guide for the application and use of procedures for the assessment of exposure to chemical and biological agents) European Standard EN 482 (Workplace atmospheres - General requirements for the performance of procedures for the measurement of chemical agents) Reference to national guidance documents for methods for the determination of hazardous substances will also be required.

DNELs/DMELs

No DNELs/DMELs available.

PNECs

No PNECs available

8.2 Exposure controls

Appropriate engineering controls : Good general ventilation should be sufficient to control worker exposure to airborne contaminants.

Individual protection measures

Hygiene measures : Wash hands, forearms and face thoroughly after handling chemical products, before eating, smoking and using the lavatory and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Wash contaminated clothing before reusing.

Eye/face protection : When mechanical processing (grinding, sawing, drilling, milling), eye protection should generally be worn.

Skin protection

Hand protection : Chemical-resistant, impervious gloves complying with an approved standard should be worn at all times when handling chemical products if a risk assessment indicates this is necessary.

Body protection : lab coat.

Other skin protection : Wear suitable protective clothing, gloves and eye/face protection.

Respiratory protection : If dust is generated and ventilation is inadequate, use respirator that will protect against dust/mist.

Environmental exposure controls : Emissions from ventilation or work process equipment should be checked to ensure they comply with the requirements of environmental protection legislation. In some cases, fume scrubbers, filters or engineering modifications to the process equipment will be necessary to reduce emissions to acceptable levels.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance

Physical state : Solid.

Colour : Beige.

Odour : Odourless.

Odour threshold : Not available.

pH : Not applicable.

Melting point/freezing point : Not available.

Initial boiling point and boiling range : Not available.

Flash point : Non-flammable.

Evaporation rate : Not available.

Flammability (solid, gas) : Non-flammable.

Upper/lower flammability or explosive limits : Not available.

Vapour pressure : Not available.

Vapour density : Not available.

Relative density : 2.4 to 2.5

Solubility(ies) : Insoluble.
Partition coefficient: n-octanol/water : Not available.
Auto-ignition temperature : Not available.
Decomposition temperature : Not available.
Viscosity : Not available.
Explosive properties : Not available.
Oxidising properties : Not available.

9.2 Other information
No additional information.

SECTION 10: Stability and reactivity

10.1 Reactivity : No specific test data related to reactivity available for this product or its ingredients.
10.2 Chemical stability : The product is stable.
10.3 Possibility of hazardous reactions : Under normal conditions of storage and use, hazardous reactions will not occur.
10.4 Conditions to avoid : No specific data.
10.5 Incompatible materials : No specific data.
10.6 Hazardous decomposition products : Under normal conditions of storage and use, hazardous decomposition products should not be produced.

SECTION 11: Toxicological information

11.1 Information on toxicological effects
Acute toxicity :
Conclusion/Summary : Based on available data, the classification criteria are not met.
Acute toxicity estimates
Not available.
Irritation/Corrosion
Conclusion/Summary
Skin : Based on available data, the classification criteria are not met.
Eyes : Based on available data, the classification criteria are not met.
Sensitisation
Conclusion/Summary
Skin : Based on available data, the classification criteria are not met.
Respiratory : Based on available data, the classification criteria are not met.
Mutagenicity
Conclusion/Summary : Based on available data, the classification criteria are not met.
Carcinogenicity :
Conclusion/Summary : Based on available data, the classification criteria are not met.
Reproductive toxicity
Conclusion/Summary : Based on available data, the classification criteria are not met.
Teratogenicity
Conclusion/Summary : Based on available data, the classification criteria are not met.
Specific target organ toxicity (single exposure)
Not available.
Specific target organ toxicity (repeated exposure)
Not available.
Aspiration hazard
Not available.

Information on likely routes of exposure : Not available.
Potential acute health effects
Eye contact : No known significant effects or critical hazards.
Inhalation : No known significant effects or critical hazards.
Skin contact : No known significant effects or critical hazards.

Ingestion : No known significant effects or critical hazards.

Symptoms related to the physical, chemical and toxicological characteristics

Eye contact : No specific data.
Inhalation : No specific data.
Skin contact : No specific data.
Ingestion : No specific data.

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Short term exposure

Potential immediate effects : Not available.
Potential delayed effects : Not available.

Long term exposure

Potential immediate effects : Not available.
Potential delayed effects : Not available.

Potential chronic health effects

Product/ingredient name	Results	Species	Dose	Exposure	Remarks
Not available.					

Conclusion/Summary : Not available.
General : No known significant effects or critical hazards.
Carcinogenicity : No known significant effects or critical hazards.
Mutagenicity : No known significant effects or critical hazards.
Teratogenicity : No known significant effects or critical hazards.
Developmental effects : No known significant effects or critical hazards.
Fertility effects : No known significant effects or critical hazards.

Other information : Not available.

SECTION 12: Ecological information

12.1 Toxicity
Conclusion/Summary : Based on available data, the classification criteria are not met.

12.2 Persistence and degradability
Conclusion/Summary : Not available.

12.3 Bioaccumulative potential
Not available.

12.4 Mobility in soil
Soil/water partition coefficient (K_{OC}) : Not available.
Mobility : Not available.

12.5 Results of PBT and vPvB assessment
PBT : Not applicable.
vPvB : Not applicable.

12.6 Other adverse effects : No known significant effects or critical hazards.

SECTION 13: Disposal considerations

The information in this section contains generic advice and guidance.

13.1 Waste treatment methods

Product

Methods of disposal : The generation of waste should be avoided or minimised wherever possible. Disposal of this product, solutions and any by-products should at all times comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements. Dispose of surplus and non-recyclable products via a licensed waste disposal contractor. Waste should not be disposed of untreated to the sewer unless fully compliant with the requirements of all authorities with jurisdiction.

Hazardous waste : Within the present knowledge of the supplier, this product is not regarded as hazardous waste, as defined by EU Directive 2008/98/EC.

Packaging

Methods of disposal : The generation of waste should be avoided or minimised wherever possible. Waste packaging should be recycled. Incineration or landfill should only be considered when recycling is not feasible.

Special precautions : This material and its container must be disposed of in a safe way. Avoid dispersal of spilt material and runoff and contact with soil, waterways, drains and sewers.

SECTION 14: Transport information

	ADR/RID	ADN	IMDG	IATA
14.1 UN number	Not regulated.	Not regulated.	Not regulated.	Not regulated.
14.2 UN proper shipping name	-	-	-	-
14.3 Transport hazard class(es)	-	-	-	-
Label				
14.4 Packaging group	-	-	-	-
14.5 Environmental hazards	No.	No.	Marine Pollutant: No.	No.
Additional information	-	-	-	-

14.6 Special precautions for user : Transport within user's premises: always transport in closed containers that are upright and secure. Ensure that persons transporting the product know what to do in the event of an accident or spillage.

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code : Not available

SECTION 15: Regulatory information

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

EU Regulation (EC) No. 1907/2006 (REACH)

Annex XIV - List of substances subject to authorisation

Annex XIV

None of the components are listed.

Substances of very high concern

None of the components are listed.

Annex VXII – Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles : Restricted to professional users.

Other EU regulations

Europe inventory : All components are listed or exempted.

Ozone depleting substances (1005/2009/EU)

Not listed.

Prior Informed Consent (PIC) (649/2012/EU)

Not listed.

Seveso Directive

This product is not controlled under the Seveso Directive.

National regulations

VOC content : Exempt.

Hazard class for water : Not determined.

International regulations

Chemical Weapon Convention List Schedules I, II & III Chemicals

Not listed.

Montreal Protocol (Annexes A, B, C, E)

Not listed.

Stockholm Convention on Persistent Organic Pollutants

Not listed.

Rotterdam Convention on Prior Inform Consent (PIC)

Not listed.

UNECE Aarhus Protocol on POPs and Heavy Metals

Not listed.

International lists

National inventory

Australia : Not determined.

Canada : Not determined.

China : Not determined.

Japan : **Japan inventory (ENCS)**: Not determined.
Japan inventory (ISHL): Not determined.

Malaysia : Not determined.

New Zealand : Not determined.

Philippines : Not determined.

Republic of Korea : Not determined.

Taiwan : Not determined.

Turkey : Not determined.

United States : Not determined.

15.2 Chemical safety assessment : This product contains substances for which Chemical Safety Assessments are still required.

SECTION 16: Other information

Indicates information that has changed from previously issued version.

Abbreviations and acronyms : ATE = Acute Toxicity Estimate
CLP = Classification, Labelling and Packaging Regulation [Regulation (EC) No. 1272/2008]
DMEL = Derived Minimal Effect Level
DNEL = Derived No Effect Level
EUH statement = CLP-specific Hazard statement
PBT = Persistent, Bioaccumulative and Toxic
PNEC = Predicted No Effect Concentration
RRN = REACH Registration Number
vPvB = Very Persistent and Very Bioaccumulative

Procedure used to derive the classification according to Regulation (EC) No. 1272/2008 [CLP/GHS]

Classification	Justification
Not classified.	

Full text of abbreviated H statements : Not applicable.

Full text of classifications [CLP/GHS] : Not applicable.

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Date or previous issue		No previous validation
Version	:	1

Notice to reader

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