MATERIAL SAFETY DATA SHEET CALCEDENT

Version No.1 / Revision No. 1 / 05.03.2018

MATERIAL SAFETY DATA SHEET

1. INTRODUCTORY AND COMPANY DETAILS

Product Name: Calcedent for deep-penetration fluoridation

Other Names: Calcedent

Recommended Use: Kit for deep-penetration fluoridation

Company name: Nanoplant Höchst GmbH

Address: Neue Str. 67, pc 99846 Seebach, GERMANY

Telephone: +49 369 295 740 74

Fax: +49 369 295 740 67

2. HAZARDS IDENTIFICATION

Classification of the substance or mixture:

Classification according to Directive 1999/45/EC

The mixture has been assessed and/or tested for its physical, health and environmental hazards and the following classification applies.

Danger symbols: Xi

R phrases : R36/38

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

Health : Skin Corrosion, Category 1A

Label elements

This mixture contains magnesium hexafluorosilicate hydrate, copper chloride and calcium hydroxide. This materials is considered hazardous as defined by the OSHA Hazard Communication Standard.(29 CFR 1819.1200)

Classification according to Directive 1999/45/EC

Hazard pictogram(s)



📙 Xi – Irritant

R&S statement(s) R36/37/38: Irritating to eyes, respiratory system and skin.

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

Hazard pictogram(s)



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Signal Word WARNING

Hazard statement(s) H315: Causes skin irritation.

Precautionary statement(s)

Prevention P280: Wear protective gloves/protective clothing/eye protection/face protection.

Response P305: IF IN EYES:

P351: Rinse cautiously with water for several minutes.

P313: Get medical advice/attention.

P302+P352: IF ON SKIN: Wash with plenty of soap and water.

P332+P313: If skin irritation occurs: Get medical advice/attention.

Storage P273: Avoid release to the environment.

Disposal P501: Dispose of in compliance with governmental regulation.(EC 1975L0442-20/11/2003)

Other hazards

Immediate concerns: None

Chemical Name	CAS	EINECS No.	Wt. %	Classification according to Directive 67/548/EEC	Classification according to Regulation (EC) No.1272/2008 [CLP]
Calcium hydroxide	1305-62-0	215- 137-3	< 20 %	Xi; R36/38	H413; H314; H335; H290; H318
Magnesium hexafluorosilicate hydrate	18972-56- 0	241-022- 2	< 20 %	-	-
Copper chloride	7447-39-4	231-210- 2	< 0.1 %	Xn; R25;R36/37/38;R50 /53	_

3. COMPOSITION / INFORMATION ON INGREDIENTS

For full text of H-statements and R-phrases: see SECTION 16.

4 - FIRST AID MEASURES

Description of first aid measures

Following eyes Flush eye with water for 15 minutes. Get medical attention.



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Following skin or persists. Wash with soap and water. Get medical attention if irritation develops

Following ingestion No specific hazards are encountered under normal product use.

Following inhalation No specific treatment is necessary since this material is not likely to be

hazardous by inhalation. If exposed to excessive levels of dusts or fumes, remove to fresh air and get medical attention if cough or other symptoms develop.

Most important symptoms and effects, both acute and delayed

Eyes Causes eye irritation.

Skin Causes skin irritation.

Ingestion None expected for this product.

Inhalation None expected for this product.

Indication of any immediate medical attention and special treatment needed

Notes to physician Not Applicable

5 - FIRE-FIGHTING MEASURES

Extinguishing media Please see Fire Fighting Equipment under Section 5.3.

Special hazards arising from the substance or mixture

Hazardous combustion products: None known.

Explosion hazards Not Determined

Fire explosion Not Determined

Sensitive to static discharge Not Determined

Sensitivity to impact Not Determined

Advice for firefighters

Fire fighting procedures General: Evacuate all personnel; use protective equipment for fire-fighting. Use self-contained breathing apparatus when the product is involved in fire.

Fire fighting equipment Water spray only.

6 - ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

General procedures Refer to Section 8 for Personal Protective Equipment.

Environmental precautions

Water spill Do not allow to enter sewers or drains that may lead to waterways.

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Methods and material for containment and cleaning up

Small spill Wipe up small amounts with chemical resistant or damp rag which is washed with large amounts of water after each use. After cleaning, flush away traces with water.

Large spill After removal, flush contaminated area thoroughly with water.

Reference to other sections

Reference to other sections Not Applicable

7 - HANDLING AND STORAGE

Precautions for safe handling

Handling Use suitable protective equipment.

Storage See product labeling.

Conditions for safe storage, including any incompatibilities

Shelf life See product labeling

Specific end use(s)

Specific end use(s) Professional Dental Hemostatic Solution

8 - EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters: No information is available for the product.

Exposure controls

Eye/face protection Wear eye protection

Skin protection Wear suitable protective clothing and gloves.

Respiratory protection Good general ventilation should be sufficient to control airborne levels.

9 - PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties:

Physical state Liquids

Appearance Clear

Colour Colorless

Odour Without odor

Other informations:

Percent volatile Not Determined

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10 - STABILITY AND REACTIVITY

Reactivity: Stable

Chemical stability: Stable when stored and handled under recommended conditions.

Possibility of hazardous reactions: None

Conditions to avoid: Not Determined

Incompatible materials: Not Determined

Dangerous decomposition products: None known.

11 - TOXICOLOGICAL INFORMATION

Information on toxicological effects

Acute: Device is biocompatible when used as directed by dental professionals per ISO 13

12 - ECOLOGICAL INFORMATION

Aquatic toxicity (acute) 96-hour LC₅₀ Not Determined 48-hour EC₅₀ Not Determined 96-hour EC₅₀ Not Determined Persistence and degradability: Not Determined Bioaccumulative potential Not Determined Mobility in soil Not Determined Results of PBT and vPvB assessment Not Determined Other adverse effects Environmental data Not defined

13 - DISPOSAL CONSIDERATIONS

Waste treatment methods

Disposal method Dispose of in compliance with governmental regulation. (EC1975L0442-20/11/2003)

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14 TRANSPORT INFORMATION

Transport hazard class(es) Primary hazard class/division 8 Hazard classification 8 Packing group III Marine pollutant #1 Marine pollutant #1: N/A Special precautions for user ADR - road N/A RID - rail N/A IMDG - sea N/A IATA - air N/A Transport in bulk N/A

15 - REGULATORY INFORMATION

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

RoHS Please refer to Medical Devices Directive 93/42/EEC

Chemical Safety Assessment: See Section 11

16 - OTHER INFORMATION

Relevant R-phrases and/or H- statements (number and full text)

R22: Harmful if swallowed.

R36/37/38: Irritating to eyes, respiratory system and skin. H290: May be corrosive to metals.

H314: Causes severe skin burns and eye damage. H318: Causes serious eye damage.

H335: May cause respiratory irritation.

H413: May cause long lasting harmful effects to aquatic life.

Manufacturer disclaimer

FOR DENTAL USE ONLY: Use as directed.

The information and recommendations are taken from sources (raw material SDS(s) and manufacturer's knowledge) believed to be accurate; however, the manufacturer, makes no

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warranty with respect to the accuracy of the information or the suitability of the recommendation and assumes no liability to any user thereof. Each user should review these recommendations in the specific context of the intended use and determine whether they are appropriate.