

1. Identification of the substance/mixture and of the company/undertaking**1.1. Product identifier**

Product name : Calcium Hydroxide, 2g with 20 tips

Product code : 9003663

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

Temporary filling material for infected root canals

1.3. Details of the supplier of the safety data sheet**Manufacturer:**

Henry Schein Inc.

135 Duryea Road

Melville, NY 11747 / USA

Authorized EU Representative:

Henry Schein Services GmbH

Monzastrasse 2a

63225 Langen / Germany

Contact :

cbdeurope@henryschein.com

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Tel: +49 6103 757 5000

Responsible for the Safety Data Sheet: Regulatory Affairs Europe - cbdeurope@henryschein.com

1.4. Emergency telephone number: +49 (0)6132 84463 - GBK GmbH (24h 7d/w - 365d/a)**2. Hazards identification****2.1. Classification of the substance or mixture****Classification according to Regulation (EC) No 1272/2008**

Serious Eye Damage / Eye Irritation, Category 1 (Eye Dam. 1, H318)

Serious Skin Corrosion / Skin Irritation, Category 1 (Skin Sens. 1, H314)

2.2. Label elements**Labelling according to Regulation (EC) No 1272/2008**

* GHS label elements including precautionary statements

- Hazard Pictograms



GHS05

- Signal word

: Danger

- Hazard statement(s)

: H314 Causes severe skin burns and eye damage

H318 Causes serious eye damage

- Precautionary Statement(s)

: P260 Do not breathe dust/fume/gas/mist/vapours/spray

Prevention

P264 Wash...thoroughly after handling

P271 Use only outdoors or in a well-ventilated area
 P280 Wear protective gloves/protective clothing/eye protection/ face protection

- Response : P301+P330+P331 IF SWALLOWED: Rinse mouth. Do NOT induce Vomiting.
 P303+P361+P353 IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower.
 P304+P340 IF INHALED: Remove victim to fresh air and keep at rest in apposition comfortable for breathing.
 P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do. Continue rinsing.
 P310 Immediately call a POISON CENTER or doctor/physician.
 P321 Provide specific treatment according to the situation.
 P363 Wash contaminated clothing before reuse.

- Disposal : P501 Dispose of contents/container according to the related regulations

2.3. Other hazards (according to the NFPA Rating System)

- Health : 0
- Flammability : 0
- Reactivity : 0

3. Composition/information on ingredients

3.1. Substances

Not Applicable

3.2. Mixtures

Chemical Name	CAS No.	EC 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	<30	C;R34	H318, H317, H412, H335, H314, H370, H290, H302, H312
Barium sulfate	7727-43-7	231-784-4	<35	Xi; R36/38	H302, H332, H371, H319, H373, H335, H315

4. First aids measures

4.1. Description of first aid measures

- Eyes : Get medical aid immediately if discomfort or irritation persists
- Skin : Consult physician immediately if you feel discomfort.
- Inhalation : Remove patient from exposure to fresh air immediately. Administer approved oxygen supply if breathing is difficult and get medical aid immediately.
- Ingestion : Seek immediate medical help.

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

- Eyes : Causes eye burns.
- Skin : Causes skin burns.
- Inhalation : None expected for this product
- Ingestion : Ingestion of this material can cause mouth, throat, esophageal, and gastrointestinal tract irritation.

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

- Notes to physician : Corrosive

5. Fire fighting measures

5.1. Extinguishing media

- Extinguishing media : Please see Fire Fighting Equipment under Section 5.3.

5.2. 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

5.3. Advice for firefighters

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

6. Accidental release measures**6.1. Personal precautions, protective equipment and emergency procedures**

Give special attention to chemical materials and conditions that must be avoided.

6.2. Environmental precautions

Prevent the inflow of this product to waterways, drains, basements, and confined spaces.

6.3. Methods and material for containment and cleaning up

Clean up spills immediately, observing precautions in Protective Equipment section.

6.4. Reference to other sections

Not Applicable

7. Handling and storage**7.1. Precautions for safe handling**

Follow all prevention measures on the SDS/labels.

Handle and store with care.

Give special attention to chemical materials and conditions that must be avoided.

Wear personal protective equipment while handling the product.

7.2. Conditions for safe storage, including any incompatibilities

Keep out of reach of children. Keep container closed. Store in cool place.

7.3. Specific end use(s)

Use only professional dentist

8. Exposure controls and personal protection**8.1. Control parameters**

Not determined

8.2. Exposure controls

- Eye protection : Wear safety glasses.
- 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**9.1. Information on basic physical and chemical properties**

- Appearance	: Paste	- Vapor pressure	: N/A
- Odor	: Odorless:	- Vapor density	: N/A
- Color	: off-white	- Relative density	: N/A
- pH	: 12.0 to 13.0	- Solubility(ies)	: Soluble

- Melting/freezing point	: N/A	- Partition coefficient :	: N/A
- Initial boiling point and boiling range	: N/A	n-octanol/water	
- Flash point	: N/A	- Auto-ignition temperature	: N/A
- Evaporation rate	: N/A	- Decomposition temperature	
- Flammability(solid, gas)	: N/A	- Viscosity	: N/A
- Upper/lower flammability or explosive limits	: N/A	- Explosive properties	: N/A
		- Oxidising properties	: N/A

9.2. Other information

None

10. Stability and reactivity

10.1. Reactivity

Stable

10.2. Chemical stability

Stable when stored and handled under recommended conditions.

10.3. Possibility of hazardous reactions

None

10.4. Conditions to avoid

Acidic conditions, extreme heat, direct light

10.5 Incompatible materials

Strong acids, metals

10.6. Hazardous decomposition products

None known

11. Toxicological information

11.1. Information on toxicological effects

Acute toxicity Device is biocompatible when used as directed by dental professionals per ISO 10993-1.

12. Ecological information

12.1. Toxicity

- Toxicity : Not determined
- Aquatic toxicity(acute) : Not determined

12.2. Persistence and degradability

Not determined

12.3. Bioaccumulative potential

Not determined

12.4. Mobility in soil

Not determined

12.5. Results of PBT and vPvB assessment

Not determined

12.6. Other adverse effects

None known

13. Disposal considerations**13.1. Waste treatment methods**

Dispose of in compliance with governmental regulation.(Council Directive 75/442/EEC(1975))

14. Transport information**4.1. UN Number**

UN Number : 3266

14.2. UN proper shipping name

Corrosive liquid, basic inorganic, N.O.S.(Calcium hydroxide mixture)

14.3. Transport hazard class(es)

Hazard classification : 8

14.4. Packing Group

Packing group : III

14.5. Environmental hazards

Marine pollutant #1 : N/A

14.6. Special precautions for user

- ADR - road : N/A

- RID - rail : N/A

- IMDG - sea : N/A

- IATA - air : N/A

14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Transport in bulk : N/A

15. Regulatory information

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

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

15.2. Chemical safety assessment

Chemical safety assessment : See Section 11

16. Other information

The information contained in the Safety data sheet is correct to the best of our knowledge at the date of issue. It is intended as a guide for the safe use, handling, disposal, storage and transportation and is not intended as warranty or as a specification. The information relates only to the product specified and may not be suitable for combinations with other materials or in processes other than those specifically described herein.

HISTORY

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 - * Revision number : 1
 - * Date of last revision : 22-7-2016
- **Prepared by** : Regulatory Affairs Europe