

**SECTION 8: Exposure controls / personal protection****8.1. Control parameters**

Control parameters: Calcium Hydroxide CAS: 1305-62-0

Control parameters	Exposure Limits
OSHA Maritime Industry	15 mg/m3 TWA
OSHA General Industry	15 mg/m3 TWA
NIOSH REL	5 mg/m3 TWA
ACGIH TLV	5 mg/m3 TWA
AIHA WHEEL	None

Calcium Hydroxide CAS: 1305-62-0

International Control Parameters

Canada

Alberta	= 5 mg/m3 TWA
British Columbia	= 5 mg/m3 TWA
Ontario	= 5 mg/m3 TWA
Quebec	= 5 mg/m3 TWAEV

Calcium Hydroxide CAS: 1305-62-0

Australia: 5mg/m3 TWA

Mexico + 5 mg/m3 TWA

Barium Sulfate CAS: 7727-43-7

Control parameters	Exposure Limits
ACGIH TLV	10 mg/m3 TWA; The value is for particulate matter containing no asbestos and < 1% crystalline Silica
NIOSH REL	10 mg/m3 TWA

**8.2. Exposure controls**

Eye/face protection: Wear safety glasses with side shields (or goggles) and a face shield.

Skin protection: Wear suitable protective clothing and gloves.

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

**SECTION 9: Physical and chemical properties****9.1. Information on basic physical and chemical properties**

Physical state: High viscosity paste

Color: White to off-white

Odor: Odorless or no characteristic odor

pH: 12.0 to 13.0

Specific gravity: 1.4 to 1.5

**9.2. Other information**

Percent volatile: Not volatile

**SECTION 10: Stability and reactivity****10.1. Reactivity**

Reactivity: Stable

**10.2. Chemical stability**

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

**10.3. Possibility of hazardous reactions**

Hazardous polymerization: None

**10.4. Conditions to avoid**

Conditions to avoid: Acidic conditions.

**10.5. Incompatible materials**

Incompatible materials: Strong acids, metals

**10.6. Hazardous decomposition products**

Hazardous decomposition products: None known.

**SECTION 11: Toxicological information****11.1. Information on toxicological effects**

Acute

Dermal LD50: &gt; 18000 mg/kg (Rabbit)

Notes: ~55% of the mixture consists of components of unknown toxicity (dermal).

Oral LD50: &gt; 1200 mg/kg (mouse/rat/rabbit)

Notes: There are no components of unknown toxicity (Oral).

Inhalation LC50: Not able to calculate ATE mix (inhalation) due to lack of data on the components.

Other information: Device is biocompatible when used as directed by dental professionals per ISO 10993-1.

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

Aquatic toxicity (acute): Do not allow to enter sewers or drains that may lead to waterways.

**12.2. Persistence and degradability**

Persistence and degradability: Not classified

**12.3. Bio-accumulative potential**

Bio-accumulative potential: Not classified

**12.4. Mobility in soil**

Mobility in soil: Not Available

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

Results of PBT and vPvB assessment: Conclusion The substance does not fulfill the PBT and vPvB criteria for screening assessment; there are no indications of P or B properties.

**12.6. Other adverse effects**

Environmental data: Do not flush to sewer.

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

Disposal method: Dispose of in compliance with governmental regulation.

(EC 1975L0442-20/11/2003)

**SECTION 14: Transport information****14.1. UN number**

UN number: 3266

**14.2. UN proper shipping name**

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: NAP

**14.6. Special precautions for user**

ADR - road: NAP

RID - rail: NAP

IMDG - sea: NAP

IATA - air: NAP

**14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code**

Transport in bulk: NAP

**SECTION 15: Regulatory information****15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture**

General comments: Please refer to Medical Devices Directive 93/42/EEC.

**15.2. Chemical safety assessment**

Chemical safety assessment: See Section 11

Additional information: None of the ingredients are listed as a carcinogen by IARC, NTP, or CA Prop 65.

**SECTION 16: Other information**

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

R34: Causes burns.

EYE DMG., Cat. 1: Eye Damage, Category 1

STOT SE, Cat. 3: Target Organ Toxicity (Single exposure), Category 3

Skin Irr., Cat. 2: Skin Irritation, Category 2

H315: Causes skin irritation.

H318: Causes serious eye damage.

H335: May cause respiratory irritation.

Prepared by: Peter G. Jordan

Revision summary: This SDS replaces the 09/29/2015 SDS. Revised: Section 1: MSDS No.

Section 2: EMERGENCY OVERVIEW - IMMEDIATE CONCERNS 2.3. Other hazards. Section 3: Wt. %.

Section 5: EXTINGUISHING MEDIA, FIRE-FIGHTING EQUIPMENT. Section 8: . Section 9: PHYSICAL

STATE, SPECIFIC GRAVITY. Section 11: ACUTE (DERMAL LD50 (rabbit), DERMAL LD50 (rabbit),

DERMAL LD50 (rabbit), ORAL LD50 (rat), INHALATION LC50 (rat), ORAL LD50 (rat), ORAL LD50

(rat), ORAL LD50 (rat) ACUTE, GENERAL COMMENTS. Section 12: CHEMICAL FATE INFORMATION,

DISTRIBUTION, ECOTOXICOLOGICAL INFORMATION, BIOACCUMULATION/ACCUMULATION,

AQUATIC TOXICITY (ACUTE) (48- HOUR EC50, 96-HOUR EC50), SECTION 12: Ecological

information. Section 14: VESSEL (IMO/IMDG) - MARINE POLLUTANT #1 ROAD AND RAIL (UK only)

(CDG) - SPECIAL PROVISIONS SECTION 14: Transport information, ADR - road, IMDG - sea, IATA -

air. Section 15: COMMENTS, GENERAL COMMENTS, RoHS. Section 16: GENERAL STATEMENTS.

General statements: NAP = Not Applicable

NE = Not Established

TLV = Threshold Limit Value

PEL = Permissible exposure limits

MAK = Maximum Workplace Concentration

STEL = Short-term exposure limit

STEV = Short-term exposure value

TWA = Time Weighted Average

PPE = Personal Protective Equipment

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 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.

**CLINICIAN'S CHOICE**  
DENTAL PRODUCTS INC.

167 Central Avenue, London, ON, Canada, N6A 1M6

For U.S. Distribution: Brookfield, CT, USA, 06804

1-800-265-3444 • (519) 641-3066 • www.clinicianschoice.com

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**TrueCal**<sup>TM</sup>  
35% Calcium Hydroxide Paste

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## INSTRUCTIONS FOR USE

### Description:

EndoEssentials TRUECAL is an aqueous, 12.5 pH, syringeable, radiopaque, calcium hydroxide paste. Use it as an endodontic treatment dressing. Superior delivery control of TRUECAL is obtained with an EndoFlex Tip attached.

### Indications:

TRUECAL is used for apexification procedures and as an intermediate inter-appointment canal treatment dressing. Calcium hydroxide has been recognized as an antibacterial agent due to its high pH as well as the ability to potentially stimulate healing of bone.

### Procedure:

Following instrumentation, remove luer lock cap from TRUECAL syringe and attach an EndoFlex Tip. Deliver TRUECAL short of the apex while slowly withdrawing tip.

### Precautions:

1. Material is basic. Use carefully and rinse with lots of water if material is inadvertently discharged in an undesired area.
2. Tips are disposable.
3. Deliver with an EndoFlex Tip, staying at least 2mm shy of the apex, always keeping the delivery tip loose in the canal. Don't deliver with plastic tips which can occlude tight in the canal.
4. Prefilled syringes are multi-dosage. Clean and disinfect between applications as appropriate.
5. We highly recommend using syringe covers to provide a protective barrier against cross-contamination.

**WARRANTY:** Clinician's Choice Dental Products warrants this product will be free from defects in material and manufacture. Clinician's Choice Dental Products makes no other warranties including any implied warranty of merchantability or fitness for a particular purpose. User is responsible for determining the suitability of the product for the user's application. If this product is defective within the warranty period, your exclusive remedy and Clinician's Choice Dental Products' sole obligation shall be repair or replacement of the product.

**LIMIT OF LIABILITY:** Except where prohibited by law, Clinician's Choice Dental Products will not be liable for any loss or damage arising from this product – whether direct, indirect, special, incidental or consequential, regardless of the theory asserted, including warranty, contract, negligence or strict liability.



## SAFETY DATA SHEET

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

#### 1.1. Product identifier

Product name: TrueCal 35% Calcium Hydroxide Paste  
Product description: Calcium Hydroxide Paste

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

Relevant identified uses: Professional Dental Cavity Liner

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

Manufacturer EC Responsible Person  
Clinician's Choice Dental Products, Inc  
167 Central Avenue, London, ON, Canada, N6A 1M6  
For US Distribution: Brookfield, CT, USA, 06804  
info@clinicianschoice.com

#### 1.4. Emergency telephone number

1-800-265-3444  
(519) 641-3066

### SECTION 2: Hazards identification

#### 2.1. 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: C

R phrases: R34

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

Acute Toxicity (Oral), Category 4

Skin Irritation, Category 2

Eye Damage, Category 1

### 2.2. Label elements

Classification according to Directive 1999/45/EC

Hazard pictogram(s):



Corrosive

R& statement(s): R34: Causes burns.

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

Hazard pictogram(s):



Corrosive



Exclamation mark

Signal Word: DANGER

Hazard statement(s): H318: Causes serious eye damage.

H315: Causes skin irritation.

PRECAUTIONARY STATEMENT(S)

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

Response: P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes.

Remove contact lenses, if present and easy to do. Continue rinsing.

P313: Get medical advice/attention.

P303+P361+P353: IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].

P315: Get immediate medical advice/attention.

P363: Wash contaminated clothing before reuse.

P301: IF SWALLOWED:

P330: Rinse mouth.

P310: Immediately call a POISON CENTER or doctor/physician.

P331: Do NOT induce vomiting.

Storage: P273: Avoid release to the environment.

Disposal: P501: Dispose of in compliance with governmental regulation.

(EC1975L0442-20/11/2003)

### 2.3. Other hazards

Conclusion The substance does not fulfill the PBT and vPvB criteria for screening assessment; there are no indications of P or B properties.

### SECTION 3: Composition / information on ingredients

#### 3.1. Substances

Not Applicable

#### 3.2. Mixtures

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	≤ 35	C; R34	Skin Irr., Cat. 2; EYE DMG., Cat. 1; STOT SE, Cat. 3; H315; H318; H335
Barium Sulfate	7727-43-7	231-784-4	≤ 20	Xi; R 36/38	Not classified

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

### SECTION 4: First aid measures

#### 4.1. Description of first aid measures

Following eyes: Immediately flush with plenty of water. After initial flushing, remove any contact lenses and continue flushing for at least 15 minutes. Have eyes examined and tested by medical personnel.

Following skin: Immediately flush skin with plenty of water. Remove clothing.

Get medical attention immediately. Wash clothing separately before reuse.

Following ingestion: If swallowed, rinse mouth with water, Do NOT Induce Vomiting. Give victim a glass of water or milk. Call a physician or poison control center if you feel unwell.

Following inhalation: No specific treatment is necessary since this material is not likely to be hazardous by inhalation.

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

Eyes: Causes severe eye damage.

Skin: Irritating to skin.

Ingestion: Ingestion of this material can cause mouth, throat, esophageal, and gastrointestinal tract irritation.

Inhalation: None expected for this product.

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

Notes to physician: Corrosive

### SECTION 5: Fire-fighting measures

#### 5.1. Extinguishing media

Extinguishing media: The material is non-combustible. If involved in fire water may be used to cool the surrounding areas.

#### 5.2. Special hazards arising from the substance or mixture

Hazardous combustion products: None known.

#### 5.3. 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.

### SECTION 6: Accidental release measures

#### 6.1. Personal precautions, protective equipment and emergency procedures

General procedures: Refer to Section 8 for Personal Protective Equipment.

#### 6.2. Environmental precautions

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

#### 6.3. Methods and material for containment and cleaning up

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

Large Spill: Collect in tightly closed containers.

#### 6.4. Reference to other sections

Reference to other sections: Not Applicable

### SECTION 7: Handling and storage

#### 7.1. Precautions for safe handling

Handling: Use suitable protective equipment.

Storage: See product labeling.

#### 7.2. Conditions for safe storage, including any incompatibilities

Shelf life: See product labeling

#### 7.3. Specific end use(s)

Specific end use(s): Professional Dental Cavity Liner