



# SAFETY DATA SHEET

according to Regulation (EC) No.

Dental Use  
Date Issued : 04/2016  
SDS No : M20-17  
Date Revised :01/2017  
Revision No : 01

## Endo-Cal®

### SECTION 1: Identification of The Substance/Preparation and of The Company/Undertaking

#### 1.1 Product Identifier:

Product code: M20-17  
Trade Name (as labeled): Endo-Cal®  
Product Description: Calcium Hydroxide Paste

#### 1.2 Relevant Identified Uses of the Substance or Mixture and Uses Advised Against:

Relevant Identified Uses: For Professional Dental Use

#### 1.3 Details of the Supplier of the Safety Data Sheet:

Manufacturer/Supplier Name: MORVABON Trading & Manufacturing Co.  
Manufacturer/Supplier Address: No. 135, Seraj Bldg., Pardis Technology Park, 20<sup>th</sup> km  
Damavand Road, Tehran, IRAN  
Manufacturer/Supplier Telephone Number: +98(21)76251702  
Manufacturer/Supplier Zip code: 1657163871  
Email address: [Dent.pro@morvabon.com](mailto:Dent.pro@morvabon.com)

#### 1.5 Distributer Name:

Distributor Address: MORVABON Trending Co.  
No. 154, 7 Floor, Block C, Borjsaz Tower, Azadi Ave.,  
Tehran, IRAN  
Distributor Telephone Number: +98(21)66581438  
Distributor Zip code: 1313655666  
Email address: [info@morvabon.com](mailto:info@morvabon.com)

#### 1.4 Emergency Telephone Number:

Transportation Emergency Contact Number: +98(21)76251704

### SECTION 2: Hazards Identification

#### 2.1 Classification of the Substance or Mixture:

2.1.1	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Hazard Class	Hazard Category	Hazard Statement
		Skin irritation	2	H315
		Eye irritation	2	H319
2.1.2	Danger symbols	C		
2.1.3	R phrases	R34		

## 2.2 Label Elements:

Classification according to Directive 1999/45/EC

Hazard pictogram(s):



R& statement(s): R34: Causes burns

R&S statement(s): R26/27/28: Very toxic by inhalation, in contact with skin and if swallowed. R35: Causes severe burns.

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

Hazard pictogram(s):



Signal Word: DANGER

Restricted to use by dental professional only.

<b>Hazard statement(s)</b>	H318: Causes serious eye damage. H315: Skin irritation. 2. May cause skin irritation.
<b>Precautionary statement(s) Prevention</b>	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.
<b>Storage</b>	P273: Avoid release to the environment.
<b>Disposal</b>	P501: Dispose of in compliance with governmental regulation. (EC1975L0442-20/11/2003

## 2.3 Other Hazards:

<b>Immediate concerns</b>	Conclusion The substance does not fulfill the PBT and vPvB criteria for screening assessment; there are no indications of P or B properties.
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## SECTION 3: Composition / Information On Ingredients

### 3.1 Substances:

<b>Substances</b>	Not Applicable
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### 3.2 Mixture:

Components	C.A.S. #	EINECS #	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;	Xi; R 36/38	Not classified

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

## SECTION 4: First Aid Measure

### 4.1 Description of First Aid Measures:

<b>Eye</b>	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.
<b>Skin</b>	Immediately flush skin with plenty of water. Remove clothing. Get medical attention immediately. Wash clothing separately before reuse.
<b>Ingestion</b>	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.
<b>inhalation</b>	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:

<b>Eye</b>	Causes severe eye damage.
<b>Skin</b>	Irritating to skin.
<b>Ingestion</b>	Ingestion of this material can cause mouth, throat, esophageal, and gastrointestinal tract irritation.
<b>inhalation</b>	None expected for this product

### 4.3 Indication of Any Immediate Medical Attention and Special Treatment Needed:

<b>Notes to physician</b>	Corrosive
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## SECTION 5: Fire-Fighting Measures

### 5.1 Extinguishing Media:

<b>Extinguishing Media</b>	The material is non-combustible. If involved in fire water may be used to cool the surrounding areas.
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### 5.2 Special Hazards Arising from the Substance or Mixture:

<b>Hazardous combustion products</b>	None known.
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### 5.3 Advice for Fire-Fighters:

<b>Fire-fighting procedures</b>	General: Evacuate all personnel; use protective equipment for fire-fighting. Use
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### 5.4 Special protective equipment for fire-fighters

<b>Special protective equipment for fire-fighters</b>	Self-contained breathing apparatus
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## SECTION 6: ACCIDENTAL RELEASE MEASURES

### 6.1 Personal Precautions, Protective Equipment and Emergency Procedures:

<b>General procedures</b>	Refer to Section 8 for Personal Protective Equipment.
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### 6.2 Environmental Precautions:

<b>Water spill</b>	Do not allow to enter sewers or drains that may lead to waterways.
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### 6.3 Methods and Material for Containment and Cleaning up:

<b>Small Spill</b>	Clean up spills immediately, observing precautions in Protective Equipment section.
<b>Large Spill</b>	Collect in tightly closed containers

### 6.4 Reference to Other Sections:

<b>Reference to Other Sections</b>	Not Applicable
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## SECTION 7: Handling and Storage

### 7.1. Precautions for safe handling:

<b>Handling</b>	Use suitable protective equipment
<b>Storage</b>	See product labeling.

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

<b>Shelf Life</b>	See product labeling.
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### 7.3 Specific End Use (s):

<b>Specific End Use (s)</b>	Professional Dental Cavity Liner
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## SECTION 8: Exposure Controls / Personal Protection

### 8.1. Control parameters

Calcium Hydroxide CAS: 1305-62-0

Control Parameters	Exposure Limits
OSHA Maritime Industry	15 mg/m <sup>3</sup> TWA
OSHA General Industry	15 mg/m <sup>3</sup> TWA
NIOSH REL	5mg/m <sup>3</sup> TWA
ACGIH TLV	5mg/m <sup>3</sup> TWA
AIHA WHEEL	None

Calcium Hydroxide CAS: 1305-62-0

International Control Parameters

Canada

Alberta	= 5mg/m <sup>3</sup> TWA
British Columbia	= 5mg/m <sup>3</sup> TWA
Ontario	= 5mg/m <sup>3</sup> TWA
Quebec	= 5 mg/m <sup>3</sup> TWAEV

Calcium Hydroxide CAS: 1305-62-0

Australia: 5mg/m<sup>3</sup> TWA

Mexico + 5 mg/m<sup>3</sup> TWA

Barium Sulfate CAS: 7727-43-7

Control Parameters	Exposure Limits
ACGIH TLV	10 mg/m <sup>3</sup> TWA; The value is for particulate matter containing no asbestos and < 1% crystalline Silica
NIOSH REL	10 mg/m <sup>3</sup> TWA

### 8.2 Exposure Controls:

<b>Eye/ Face protection</b>	Wear safety glasses with side shields (or goggles) and a face shield.
<b>Skin protection</b>	Wear suitable protective clothing and gloves.
<b>Respiratory protection</b>	Good general ventilation should be sufficient to control airborne levels.

### 8.3 Environmental exposure controls

<b>Environmental exposure controls</b>	Avoid release into environment; calcium hydroxide may cause pH variation.
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## SECTION 9: Physical and Chemical Properties

### 9.1. Information on basic physical and chemical properties:

<b>Physical state</b>	High Viscosity Paste	<b>Oxidizing Properties</b>	Not Determined
<b>Appearance</b>	High Viscosity Paste	<b>Flash point</b>	Not applicable
<b>Color</b>	White to Off-White	<b>Viscosity</b>	Not applicable
<b>Odor</b>	Odorless	<b>Explosive Properties</b>	Not explosive
<b>pH</b>	12.0 to 13.0	<b>Solubility in Water</b>	Slight
<b>Specific gravity</b>	1.4 to 1.5	<b>Flammability (solid, gas)</b>	Not Flammable
<b>Density</b>	2.24 g/cm <sup>3</sup>	<b>Boiling point</b>	Decomposes

## 9.2 Other Information:

<b>Percent volatile</b>	Not Volatile
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## SECTION 10: Stability and Reactivity

### 10.1. Reactivity:

<b>Reactivity</b>	Stable
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### 10.2 Chemical Stability:

<b>Chemical Stability</b>	Stable when stored and handled under recommended conditions.
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### 10.3. Possibility of hazardous reactions:

<b>Hazardous polymerization</b>	None
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### 10.4 Conditions to Avoid:

<b>Conditions to Avoid</b>	Acidic conditions.
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### 10.5. Incompatible materials:

<b>Incompatible materials</b>	Strong acids, metals
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### 10.6. Hazardous decomposition products:

<b>Hazardous decomposition products</b>	None Known
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## SECTION 11: Toxicological Information

### 11.1 Information on Toxicological Effects:

<b>Dermal LD<sub>50</sub></b>	> 18000 mg/kg (Rabbit)
<b>Notes</b>	~55% of the mixture consists of components of unknown toxicity (dermal).
<b>Oral LD<sub>50</sub></b>	> 1200 mg/kg (mouse/rat/rabbit)
<b>Notes</b>	There are no components of unknown toxicity (Oral).
<b>Inhalation LC<sub>50</sub></b>	Not able to calculate ATE mix (inhalation) due to lack of data on the components.
<b>Other information</b>	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.
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### 12.2. Persistence and Degradability:

Persistence and degradability	Not classified
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### 12.3. Bio-accumulative potential:

Bio-accumulative potential	Not classified	Not Available
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### 12.4. Mobility in soil

Mobility in soil	Not Available
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### 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.
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### 12.6. Other adverse effects

Environmental data	Do not flush to sewer.
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## SECTION 13: Disposal Considerations

### 13.1. Waste treatment methods

Disposal methods	Dispose of in compliance with governmental regulation.(EC 1975L0442-20/11/2003)
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## SECTION 14: Transport Information

### 14.1. UN number:

UN number	3266
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### 14.2. UN proper shipping name:

UN proper shipping name	Corrosive liquid, basic inorganic, N.O.S. (Calcium hydroxide mixture)
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### 14.3. Transport hazard class(es):

Hazard classification	8
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**14.4. Packing group:**

<b>Packing group</b>	III
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**14.5. Environmental hazards:**

<b>Marine pollutant #1</b>	NAP
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**14.6. Special precautions for user:**

<b>ADR – road</b>	NAP
<b>RID – rail</b>	NAP
<b>IMDG – sea</b>	NAP
<b>IATA – air</b>	NAP

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

<b>Transport in bulk</b>	NAP
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<b>SECTION 15: Regulatory Information</b>
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**15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture:**

<b>General comments</b>	Please refer to Medical Devices Directive 93/42/EEC
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**15.2. Chemical safety assessment:**

<b>Chemical safety assessment</b>	See Section 11
<b>Additional information</b>	None of the ingredients are listed as a carcinogen by IARC, NTP, or CA Prop65.

<b>SECTION 16: Other Information</b>
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<b>Relevant R-phrases and/or H statements (number and full text)</b>	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.
<b>Prepared by</b>	Morvabon Trending & Manufacturing Co.
<b>Prepared Date</b>	5 May 2017
<b>Revision summary</b>	Converted MSDS to Reach SDS. Updated all sections.
<b>General statements</b>	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
<b>Manufacturer disclaimer</b>	<u>FOR DENTAL USE ONLY</u> : 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.