Revision date: 2019-05-20

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

1.1. Product identifier

ANA Cal™

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

Use of the substance/mixture

medical use

Uses advised against

No information available.

1.3. Details of the supplier of the safety data sheet

Company name:	Nordiska Dental AB
Address:	Box 1082
City:	SE-262 21 Ängelholm
Telephone:	+46 4631 443360
e-mail:	info@nordiskadental.se

Telefax: +46 431 443399

1.4. Emergency

telephonenumber:

+46 431 443360

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Regulation (EC) No. 1272/2008

Hazard categories: Skin corrosion/irritation: Skin Irrit. 2 Serious eye damage/eye irritation: Eye Dam. 1 Specific target organ toxicity - single exposure: STOT SE 3 Hazard Statements: Causes skin irritation. Causes serious eye damage. May cause respiratory irritation.

2.2. Label elements

Regulation (EC) No. 1272/2008

Hazard components for labelling Calcium hydroxide

Signal word:

Pictograms:



Hazard statements

H315	Causes skin irritation.
H318	Causes serious eye damage.
H335	May cause respiratory irritation.

Danger

Precautionary statements

P261 Avoid breathing dust/fume/gas/mist/vapours/spray.

Page 1 of 8

Safety Data Sheet

ANA Cal™

Revision date: 2019-05-20

P280 P302+P352 Wear protective gloves/protective clothing/eye protection/face protection. IF ON SKIN: Wash with plenty of water.

Page 2 of 8

Safety Data Sheet

ANA Cal™

Revision date: 2019-05-20

Page 3 of 8

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 P403+P233	Immediately call a POISON CENTER/doctor. Store in a well-ventilated place. Keep container tightly closed.
P501	Dispose of waste according to applicable legislation.

2.3. Other hazards

No information available.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

Hazardous components

CAS No	Chemical name			Quantity
	EC No Index No REACH No			
	Classification according to Regu	Ilation (EC) No. 1272/2008	[CLP]	
1305-62-0	Calcium hydroxide			35 - <50 %
	215-137-3		01-2119475151-45	
	Skin Irrit. 2, Eye Dam. 1, STOT SE 3; H315 H318 H335			

Full text of H and EUH statements: see section 16.

SECTION 4: First aid measures

4.1. Description of first aid measures

General information

No special measures are necessary.

After inhalation

If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing.

After contact with skin

After contact with skin, wash immediately with plenty of water and soap. In case of skin irritation, consult a physician.

After contact with eyes

In case of contact with eyes flush immediately with plenty of flowing water for 10 to 15 minutes holding eyelids apart and consult an ophthalmologist.

After ingestion

If accidentally swallowed rinse the mouth with plenty of water (only if the person is conscious) and obtain immediate medical attention. Do NOT induce vomiting.

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

No known symptoms to date.

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

First Aid, decontamination, treatment of symptoms.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media

Water spray jet, Carbon dioxide (CO2), Foam, Dry extinguishing powder, alcohol resistant foam

Unsuitable extinguishing media

High power water jet

Revision date: 2019-05-20

5.2. Special hazards arising from the substance or mixture

No known hazardous decomposition products.

5.3. Advice for firefighters

Co-ordinate fire-fighting measures to the fire surroundings. In case of fire: Wear self-contained breathing apparatus.

Additional information

Collect contaminated fire extinguishing water separately. Do not allow entering drains or surface water. Dispose of waste according to applicable legislation.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

See protective measures under point 7 and 8. Personal protection equipment: see section 8

6.2. Environmental precautions

Do not allow to enter into surface water or drains. Do not allow to enter into soil/subsoil.

6.3. Methods and material for containment and cleaning up

Take up mechanically, placing in appropriate containers for disposal.

6.4. Reference to other sections

See protective measures under point 7 and 8. Disposal: see section 13

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Advice on safe handling

Avoid contact with eyes and skin. Wear personal protection equipment (refer to section 8). Keep container tightly closed.

Advice on protection against fire and explosion

Usual measures for fire prevention.

Further information on handling

No information available.

7.2. Conditions for safe storage, including any incompatibilities

Requirements for storage rooms and vessels

No special technical protective measures are necessary. Keep/Store only in original container.

Advice on storage compatibility

Keep away from food, drink and animal feedingstuffs.

Further information on storage conditions

Keep away from: Frost Heat Humidity

7.3. Specific enduse(s)

No information available.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Page 4 of 8

Revision date: 2019-05-20

Exposure limits (EH40)

CAS No	Substance	ppm	mg/m3	fibres/ml	Category	Origin
7727-43-7	Barium sulphate, inhalable dust	-	10		TWA (8 h)	WEL
		-	-		STEL (15 min)	WEL
1305-62-0	Calcium hydroxide	-	5		TWA (8 h)	WEL
		-	-		STEL (15 min)	WEL

DNEL/DMEL values

CAS No	Substance				
DNEL type		Exposure route	Effect	Value	
1305-62-0	Calcium hydroxide				
Worker DNEI	_, long-term	inhalation	local	1 mg/m3	
Worker DNEI	_, acute	inhalation	local	4 mg/m3	
Consumer DI	NEL, long-term	inhalation	local	1 mg/m3	
Consumer DI	NEL, acute	inhalation	local	4 mg/m3	
7727-43-7	Barium sulfate				
Worker DNEI	_, long-term	inhalation	systemic	10	
Worker DNEI	_, long-term	inhalation	local	10	
Consumer DI	NEL, long-term	inhalation	systemic	10	
Consumer DI	NEL, long-term	oral	systemic	13000	

PNEC values

CAS No	Substance	
Environment	al compartment	Value
1305-62-0	Calcium hydroxide	
Freshwater		0,49 mg/l
Marine water		0,32 mg/l
Soil 1080		1080 mg/kg
7727-43-7	Barium sulfate	
Freshwater		0,115 mg/l
Freshwater sediment 600,4 mg		600,4 mg/kg
Soil 207,7 r		207,7 mg/kg

8.2. Exposure controls

Appropriate engineering controls

No special measures are necessary.

Protective and hygiene measures

When using do not eat, drink, smoke, sniff. Wash hands before breaks and after work. Apply skin care products after work. Wash contaminated clothing prior to re-use. Avoid contact with skin, eyes and clothes.

Eye/face protection

Eye glasses

Hand protection

Tested protective gloves must be worn: DIN EN 374 Suitable material: NBR (Nitrile rubber) Page 5 of 8

Revision date: 2019-05-20

Butyl caoutchouc (butyl rubber)

Skin protection

Only wear fitting, comfortable and clean protective clothing.

Respiratory protection

Usually no personal respirative protection necessary.

Environmental exposure controls

No information available.

Partition coefficient: Viscosity / dynamic:

See section 7. No additional measures necessary.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state:	Paste
Colour:	white
Odour:	odourless

not determined pH-Value: Changes in the physical state not determined Melting point: Initial boiling point and boiling range: not determined Sublimation point: not determined Softening point: not determined Pour point: not determined Flash point: not applicable Flammability Non-flammable. Solid: Gas: not applicable **Explosive properties** not explosive according to EUA.14 Lower explosion limits: not applicable Upper explosion limits: not applicable Ignition temperature: not applicable Auto-ignition temperature Solid: No information available. Gas: not applicable Decomposition temperature: not applicable **Oxidizing properties** Not oxidizing. Vapour pressure: not applicable Density: not determined Bulk density: not determined Water solubility: partially soluble Solubility in other solvents

Page 6 of 8

Vapour density:

Test method

Revision date: 2019-05-20	Page 7 of 8
n	. «go r or o
0	
t	
a	
p	
p	
i	
c	
а	
b	
I	
e	
n	
0	
t	
а	
p	
p	
c	
a b	
e	
n	
0	
t	
а	
q	
q	
I	
i	
c	
a	
b	
I	
e	

not applicable

Revision date: 2019-05-20

Evaporation rate:

9.2. Other information

No information available.

SECTION 10: Stability and reactivity

10.1. Reactivity

This material is considered to be non-reactive under normal use conditions.

10.2. Chemical stability

The product is chemically stable under recommended conditions of storage, use and temperature.

10.3. Possibility of hazardous reactions

No information available.

10.4. Conditions to avoid

No information available.

10.5. Incompatible materials

Acid

10.6. Hazardous decomposition products

No information available.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity

Based on available data, the classification criteria are not met.

Irritation and corrosivity

Causes skin irritation.

Causes serious eye damage.

Sensitising effects

Based on available data, the classification criteria are not met.

Carcinogenic/mutagenic/toxic effects for reproduction

Based on available data, the classification criteria are not met.

STOT-single exposure

May cause respiratory irritation. ((Calcium hydroxide))

STOT-repeated exposure

Based on available data, the classification criteria are not met.

Aspiration hazard

Based on available data, the classification criteria are not met.

SECTION 12: Ecological information

12.1. Toxicity

No information available.

12.2. Persistence and degradability

No information available.

12.3. Bioaccumulative potential

No information available.

12.4. Mobility in soil

No information available.

12.5. Results of PBT and vPvB assessment

The substances in the mixture do not meet the PBT/vPvB criteria according to REACH, annex XIII.

Page 8 of 8

Revision date: 2019-05-20

12.6. Other adverse effects

No information available.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Advice on disposal

Dispose of waste according to applicable legislation.

Contaminated packaging

Dispose of waste according to applicable legislation.

SECTION 14: Transport information

Land transport (ADR/RID) 14.1. UN number: No dangerous good in sense of this transport regulation. No dangerous good in sense of this transport regulation. 14.2. UN proper shipping name: 14.3. Transport hazard class(es): No dangerous good in sense of this transport regulation. No dangerous good in sense of this transport regulation. 14.4. Packing group: Inland waterways transport (ADN) No dangerous good in sense of this transport regulation. 14.1. UN number: No dangerous good in sense of this transport regulation. 14.2. UN proper shipping name: 14.3. Transport hazard class(es): No dangerous good in sense of this transport regulation. No dangerous good in sense of this transport regulation. 14.4. Packing group: Marine transport (IMDG) No dangerous good in sense of this transport regulation. 14.1. UN number: 14.2. UN proper shipping name: No dangerous good in sense of this transport regulation. No dangerous good in sense of this transport regulation. 14.3. Transport hazard class(es): No dangerous good in sense of this transport regulation. 14.4. Packing group: Air transport (ICAO-TI/IATA-DGR) No dangerous good in sense of this transport regulation. 14.1. UN number: No dangerous good in sense of this transport regulation. 14.2. UN proper shipping name: No dangerous good in sense of this transport regulation. 14.3. Transport hazard class(es): 14.4. Packing group: No dangerous good in sense of this transport regulation. 14.5. Environmental hazards ENVIRONMENTALLY HAZARDOUS: no 14.6. Special precautions for user

No dangerous good in sense of this transport regulation.

14.7. Transport in bulk according to Annex II of Marpol and the IBC Code

No dangerous good in sense of this transport regulation.

SECTION 15:	Regulatory	information
--------------------	------------	-------------

$\underline{15.1.}\ \underline{Safety, health and environmental regulations/legislation specific for the substance or mixture}$

National regulatory information

1 - slightly water contaminating

Water contaminating class (D): <u>15.2.</u> Chemical safety assessment

Page 9 of 8

Revision date: 2019-05-20

For the following substances of this mixture a chemical safety assessment has been carried out: Calcium hydroxide

Page 10 of

Revision date: 2019-05-20

Barium sulfate

SECTION 16: Other information

Abbreviations and acronyms

ADR: Accord europeen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road) RID:Reglement international conernat le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail) IMDG: International Maritime Code for Dangerous Goods IATA: International Air Transport Association IATA-DGR: Dangerous Goods Refulations by the "International Air Transport Association" (IATA) ICAO: International Civil Aviation Organization ICAO-TI: Technical Instructions by the "International Civil Aviation Organization" (ICAO) CAS: Chemical Abstracts Service (division of the American Chemical Society) GHS: Globally Harmonized System of Classification and Labelling of Chemicals CLP: Regulation on Classification, Labelling and Packaging of Substances and Mixtures, LC50: Lethal concentration, 50 percent LD50: Lethal dose, 50 percent EC50: Effectice concentration, 50 percent **DNEL: Derived No Effect Level** PNEC: Predicted No Effect Concentration PBT: Persistent, Bioaccumulative and Toxic vPvB: very Persistent and very Bioaccumulative Relevant H and EUH statements (number and full text)

H315	Causes skin irritation.
H318	Causes serious eye damage.
H335	May cause respiratory irritation.

Further Information

The above information describes exclusively the safety requirements of the product and is based on our present-day knowledge. The information is intended to give you advice about the safe handling of the product named in this safety data sheet, for storage, processing, transport and disposal. The information cannot be transferred to other products. In the case of mixing the product with other products or in the case of processing, the information on this safety data sheet is not necessarily valid for the new made-up material.

(The data for the hazardous ingredients were taken respectively from the last version of the sub-contractor's safety data sheet.)

Page 11 of