

SAFETY DATA SHEETS

This SDS packet was issued with item:

072801215

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

072804912 072804920 072805760

The safety data sheets (SDS) in this packet apply to one or more components included in the items listed below. Items listed below may require one or more SDS. Please refer to invoice for specific item number(s).

072801207

NEO DENTAL INTERNATIONAL INC.
Material Safety Sheet

IDENTITY

1.1 Product Trade Name : Vitapex
1.2 Product Use : Root Canal Filling Material

SECTION 1

1.3 Manufacturer / Importer : Neo Dental International Inc.
1.4 Address : 2505 South 320th Street, Suite #250
Federal Way, Wa 98003
1.5 Emergency Phone Number : 1-800-720-0096
1.6 Customer Service Number : 1-253-946-0814
1.7 Date Prepared : Jan. 10, 2003

SECTION 2 - Hazardous Ingredients

2.1 Hazardous Ingredient : Iodoform
2.2 PEL/TLV : 25mg/m3 (Iodine Fume)
2.3 DOT Hazard Classification : None
2.4 WHMIS Classification : None

SECTION 3 – Physical / Chemical Characteristics

3.1 Boiling Point : N/A
3.2 Vapor Point : N/A
3.3 Evaporation Point : N/A
3.4 Odor : None
3.5 Specific Gravity : None
3.6 Vapor Density : N/A
3.7 Melting Point : 100c
3.8 Solubility In Water : Low
3.9 Appearance : Yellow Paste

SECTION 4 – Fire and Explosion Hazard Data

4.1 Flash Point : None
4.2 Flammable Limits : N/A
4.3 Autoignition Temperature : N/A
4.4 Extinguishing Media : Water. Use any means suitable for
extinguishing surrounding fire.
4.5 Special Fire Fighting Procedures : Positive pressure, self contained breathing
apparatus.
4.6 Unusual Fire and Explosion Hazards : None

SECTION 5 – Reactivity Data

5.1 Stability : Stable
5.2 Conditions to Avoid (Stability) : Natural Light, excessive heat and humidity
5.3 Incompatibility : Strong oxidizing agents
5.4 Hazardous Decomposition or
Byproducts : Iodine
: Iodine fumes when heated to
decomposition
5.5 Hazardous Polymerization : Will not occur
5.6 Conditions to Avoid (Polymerization) : None

SECTION 6 – Health Hazard Data

6.1 Summary of Acute Hazards	: Minimal health hazard under normal conditions of use. : Not known to cause significant health problems.
6.2 Route of Exposure	: Inhalation, Eye contact, Skin absorption, Skin contact – N/A : Indigestion – Yes
6.3 Signs and Symptoms of Exposure	: None Known
6.4 Summary of Chronic Hazards	: Not Known to cause significant health problems.
6.4.1 Carcinogenicity	: NTP - N/A IARC Monographs – N/A OSHA regulated – No
6.4.2 Teratogenicity	: None Known
6.4.3 Mutagenicity	: None Known
6.4.4 Reproductive Toxicity	: None Known
6.5 Medical Conditions	: None Known
6.6 Emergency First Aid Procedures	: Not required

SECTION 7 – Precautions for Safe Handling & Use

7.1 Handling and Storage	: Keep in closed container stored in a cool, dry, ventilated area.
Precautions	: Avoid exposure to natural light and heat over 38 degrees.
7.2 Steps to be Taken if Material is released or spilled	: Wear gloves. Pick up spilled materials and place spilled materials in container for disposal.
7.3 Waste Disposal Method	: Follow all government regulations
7.4 Other Precautions	: Wash hands after use. Store away from food.

SECTION 8 – Control Measures

8.1 Respiratory Protection	: Not necessary under normal conditions
8.2 Ventilation	: No special ventilation required
8.3 Protective Gloves	: Impervious gloves recommended
8.4 Eye Protection	: Chemical safety gloves are recommended
8.5 Other Protective Clothing or Equipment	
	: Common uniform and equipment
8.6 Work / Hygienic Practices	: Use normal care when working with chemicals.

Safety Data Sheet

Page 1 of 5

1. Product & Company Identification

A. Product Name

Diapex

B. Purpose of Use & Restrictions on Use

Purpose of Use Temporary Filling material for infected root canals
Restrictions on Use For dental professionals only

C. Company Information

Company Name DiaDent Group International
Address 16 Osongsaengmyeong 4-ro, Osong-eup, Heungdeok-gu,
Cheongju-si, Chungcheongbuk-do, Republic of Korea
28161
Emergency Contact Number 82-43-266-2315

2. Hazard Identification

A. GHS Classification

Serious Eye Damage/Eye Irritation: Category 1
Serious skin corrosion/skin Irritation: Category 1

B. GHS Label elements including precautionary statements

Pictograms



Signal Words

DANGER

Hazard Statement(s)

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

Precautionary Statement(s)
Prevention

P260 Do not breathe dust/fume/gas/mist/vapors/spray
P264 Wash hands thoroughly after handling
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 a position comfortable for breathing.
P305+P351+P338 IF IN EYES: Rinse cautiously with water for
several minutes. Remove contact lenses if present and easy to

Storage
Disposal

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
P405 Store locked up
P501 Dispose of contents/container according to the related regulations.

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

Health	
Flammability	0
Reactivity	0
	0

3. Composition & Information on Ingredients

Chemical Identity	Common Name	CAS Number	% Volume
Iodoform	TRIIODOMETHANE	75-47-8	<40%
Calcium Hydroxide	HYDRATED LIME	1305-62-0	<30%
Oil Derivatives	-	-	<30%

4. First Aid Measures

A. Eyes	Get medical aid immediately if discomfort or irritation persists.
B. Skin	Consult a physician immediately if you feel discomfort.
C. Inhalation	Remove patient from exposure to fresh air immediately. Administer approved oxygen supply if breathing is difficult and get medical aid immediately.
D. Ingestion	Seek immediate medical help.
E. Notes to Physicians	Have a comprehensive understanding of the chemical and treat symptomatically and supportively.

5. Fire Fighting Measures

A. Appropriate Extinguishing Media

To extinguish a fire caused by or related to this chemical, use alcohol-resistant foam, Carbon Dioxide (CO₂), or water spray. Use dry sand or soil to smother the fire.

B. Specific hazard arising from the chemical

Toxic gases can be produced due to pyrolysis or combustion process.

C. Special protective equipment & Precautions for firefighters

Fire-fighters should wear appropriate protective equipment.

Stay a safe distance away from the fire while extinguishing.

If not dangerous, remove the container from the fire.

To dispose of fire water, pour it into a spacious dug lot and make sure it is not spilled or scattered outward.

6. Accidental Release Measures

A. Protective equipment & Emergency procedures

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

B. Environmental precautions

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

C. Purification / Removal Method

Dispose of the product as medical waste.

7. Handling & Storage

A. 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.

B. Conditions for Safe Storage

Store in a cool, dry place. Avoid exposure to direct light and heat.

8. Exposure control & Personal protection

A. Exposure Limits for Chemical Substances & Biological Exposure Limits

N/A

B. System Design (Proper Engineering Controls)

N/A

C. Personal protective equipment

Respiratory protection

N/A

Eye protection

Protective glasses

Hand protection

Latex gloves

Skin & body protection

Lab coats

9. Physical & Chemical Properties

A. Appearance

Physical state

Paste

Color

Yellow

B. Odor

Slight odor of Iodoform

C. Odor threshold value

N/A

D. pH

N/A

E. Melting point/Freezing point

N/A

F. Initial boiling point & Boiling range

N/A

G. Flash point

N/A

H. Evaporation rate

N/A

I. Flammability (solid, gas)

N/A

J. Maximum / minimum of the flammable or explosive limits

N/A

K. Vapor pressure

N/A

L. Solubility

N/A

M. Vapor density

N/A

N. Relative density

1.9-2.0 g/cm³

O. Partition coefficient: n-Octanol/water

N/A

P. Auto-ignition temperature

N/A

Q. Decomposition temperature

N/A

R. Viscosity

N/A

S. Molecular weight

N/A

10. Stability & Reactivity

A. Chemical stability & Possibility of hazardous reactions	Stable under suggested conditions of storage and use
B. Conditions to avoid	Direct light, excessive heat, and humidity
C. Incompatible materials	N/A
D. Hazardous decomposition or byproduct	Iodine

11. Toxicological Information

A. Possible routes of exposure	N/A
B. Information on harmful health effects (Symptoms related to the physical, chemical and toxicological characteristics)	
Acute toxicity	
Oral	N/A
Dermal	N/A
Inhalation	N/A
Skin corrosion/Irritation	May cause irritation on the skin
Serious Eyes damage/Irritation	May cause irritation on the eyes
Respiratory sensitization	N/A
Skin sensitization	May cause allergic reaction on the skin
Carcinogenicity	
Industrial Safety and Health Act	N/A
Notification of the Ministry of Employment and Labor	N/A
IARC	N/A
OSHA	N/A
ACGIH	N/A
NTP	N/A
EU CLP	N/A
Germ cell mutagenicity	N/A
Reproductive Toxicity	N/A
Specific Target Organ Toxicity (Single Exposure)	N/A
Specific Target Organ Toxicity (Repeated Exposure)	N/A
Aspiration Toxicity	N/A

12. Ecological information

A. Ecotoxicity	
Fish	N/A
Shellfish	N/A
Birds	N/A
B. Persistence & Degradability	
Persistence	N/A
Degradability	N/A
C. Bioaccumulative potential	
Accumulation	N/A
Biodegradability	N/A
D. Mobility in soil	N/A
E. Other adverse effects	N/A

13. Disposal Considerations

A. Product Disposal

If stated in the Wastes Control Act, dispose of the contents and container accordingly.

B. Precautions for Disposal

Dispose of the content according to the related regulations.

14. Transport Information

A. UN Number

Classification information on transportation of hazardous materials not available

B. Proper shipping name

N/A

C. Hazard class

N/A

D. Packing Group

N/A

E. Marine pollutant

N/A

F. Any special precautions which an user should be aware of or needs to comply with, in connection with transport or conveyance either within or outside their premises (Special precautions which a user needs to be aware of or needs to comply outside their premises with in connection with transport or conveyance either within or outside their premises)

Emergency procedures in case of fire

N/A

Emergency procedures in case of spill/leak

N/A

15. Regulatory Information

A. Regulations according to the Industrial Safety and Health Act

N/A

B. Regulations according to the Toxic Chemicals Control Act

N/A

C. Regulations according to the Safety Control of Dangerous Substances Act

N/A

D. Regulations according to the Wastes Control Act

N/A

E. Other regulations according to domestic and foreign laws

- Follow the regulations of the KFDA (Korea Food & Drug Administration).

- Follow the regulations of the Directive 93/42/EEC and 2007/42/EC.

16. Other Information

A. Source of Data

N/A

B. Date of Creation

07 / 21 / 2014

C. Revision Number and Revision Date

Revision Number

0

Date of Last Revision

07 / 21 / 2014

E. Other Information

The information and recommendations are taken from sources (raw material SDS(s) and manufacturer's knowledge) believed to be accurate and reliable. It is intended to describe the product according to various safety requirements; however, the manufacturer makes no warranty with respect to the accuracy and completeness of the information or the suitability of the recommendation and assumes no liability to any user thereof.

SAFETY DATA SHEET

Section1: Identification

Product Name : VITAPEX
Supplier's details : Neo Dental International, Inc.
1112 South 344th Street, Suite 311, Federal Way WA 98003
Tel: 1-253-946-0814 Fax: 1-253-946-0885
Manufacturer : Neo Dental Chemical Products Co., Ltd.
3-1-3, Hiroo Shibuya-ku, Tokyo 150-0012 Japan
Tel: 81-3-3400-3768 Fax: 81-3-3499-0613

Section2: Hazards Identification

GHS Classification

Physical hazards	Flammable liquid	: Not applicable
Health hazards	Acute toxicity (oral)	: Category 5
	Skin corrosion/irritation	: Category 2
	Serious eye damage/Eye irritation	: Category 1
	Skin sensitization	: Not classified
	Germ cell mutagenicity	: Not classified
	Reproductive toxicity	: Not classified
	Specific target organ toxicity single exposure	: Category 1 (respiratory system)
	Reproductive toxicity	: Category 3 (anesthetic properties)
	Specific target organ toxicity repeated exposure	: Category 2 (lung)
	Acute aquatic toxicity	: Category 2

Label elements

Pictograms (Hazard symbols)



Signal words : Danger
Hazard statements : - Causes skin irritation
- Causes serious eye damage
- May cause drowsiness or dizziness
- Toxic to aquatic life

Section3: Composition/Information on Ingredients

Substance/Mixture : Mixture
Chemical name : Not applicable
Generic name : Not applicable

Ingredients and composition

Ingredients	Iodoform	Calcium hydroxide	Others
Composition	40 - 50 %	30 - 40 %	20 - 30 %
Molecular Formula	CHI ₃	Ca(OH) ₂	—
CAS number	75-47-8	1305-62-0	—

Hazardous Ingredients : <Calcium hydroxide>Acute toxic substance
<Iodoform>Acute toxic substance and corrosive/irritant substance

Section4: First-Aid Measures

Eye contact : Immediately irrigate with water or saline solution and see an ophthalmologist.
Skin contact : After immediate wiping with alcohol-impregnated cotton, wash with running water and soap. Get medical attention, if necessary.
Inhalation : Immediately move the victim to fresh air, keep rest and warm, seek medical attention as soon as possible.
Ingestion : Immediately rinse the mouth and get medical attention.
Most important symptoms/effects : If hypersensitivity reaction appears, avoid contact with this product and consult a medical doctor.

Section5: Fire-Fighting Measures

Extinguishing media : Carbon dioxide, powder, foam, water spray
Specific hazards : Heat may lead to degradation of iodoform contained in this product and generation of corrosive and toxic gas.
Specific methods of fire-fighting : In case of fire in the surrounding area, immediately remove the containers to a safe place. If the containers cannot be removed, sprinkle the containers and the surrounding area with water to cool down.
Special protective actions for fire-fighters : Wear a gas mask for halogen and remove this product to a safe place if you can as combustion may lead to degradation and generation of iodine gas.

Section6: Accidental Release Measures

Personal precautions : Wear appropriate protective equipment such as rubber glove. Avoid direct contact. Ventilate Properly.
Environmental precautions : Do not discharge the product directly into rivers or sewage systems.
Methods and materials for containment and cleaning up : Collect with appropriate apparatus and wipe with alcohol-impregnated cotton.
Prevention of secondary hazards : Keep away from fire.

Section7: Handling and Storage

Handling

- Protective measures : Wear protective equipment such as rubber glove to avoid direct contact with the skin.
- Precautions : Ventilation must be performed as required.
- Precautions for safe handling : Keep away from fire.

Storage

- Appropriate storage place : - After using the product, be sure to cover the container and keep away from direct sunlight and high temperature at 37°C or higher.
- Keep away from fire and heat source.
- Safe packaging materials : - Synthetic resin (polypropylene)
- Keep only in original container.

Section8: Exposure Controls/Personal Protection

- Appropriate engineering controls : Appropriate ventilation must be performed.
- Control concentration : Not specified
- Allowable concentration : Not specified
- Individual protection measures
- Respiratory protection : Gas mask for halogen gas (depending on conditions)
- Hand protection : Polyurethane gloves
- Eye protection : Eye protection (depending on conditions)
- Skin/body protection : Protective clothing and protective boots (depending on conditions)

Section9: Physical and Chemical Properties

Physical state

- Shape : Paste
- Color : Yellow
- Odor : Iodoform odor
- pH : 12

Specific temperatures/temperature ranges at which changes in physical state occur

- Boiling point : No information
- Boiling temperature : No information
- Melting point : No information
- Decomposition temperature : <Iodoform>120°C
<Calcium Oxide>580°C
- flash point : No information
- Explosives : No information
- Density : About 2
- Solubility : Soluble in ethanol.

Section10: Stability and Reactivity

Stability	: Decomposes at 120°C and generates iodine gas.
Reactivity	: No information
Conditions to avoid	: Avoid high temperature (37°C or higher).
Hazardous decomposition products	: Iodine gas

Section11: Toxicological Information

Acute toxicity	: Oral Rat LD ₅₀ = 2,800 - 3,800 mg/kg <Iodoform>Oral Rat LD ₅₀ = 355mg/kg <Calcium Hydroxide>Oral Rat LD ₅₀ = 7,340mg/kg
Local effects	: <Iodoform>Symptoms may occur such as iododerma-like irruption, urticarial rash, papule, blister as hypersensitivity reaction and skin itching and burning sensation.
Sensitization	: <Iodoform>Yes
Chronic toxicity	: <Iodoform>Continuous use on a large scale may cause iodism.
Mutagenicity	: <Calcium hydroxide>Cyt-rat/ast : 1,200 mg/kg

Section12: Ecological Information

Toxicity	: <Calcium Hydroxide> TLm96 : 1000 - 10 ppm
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Section13: Disposal Considerations

Residues	: Dispose of in accordance with local regulations.
Chemical container/packaging	: Dispose of in accordance with local regulations. Before disposing of empty containers, discharge contents completely.

Section14: Transport Information

International regulations	: Not applicable
Domestic regulations	: Not applicable
Specific precautionary transport measures and conditions	: Avoid high temperature (37°C or higher).

Section15: Regulatory Information

Lows and regulations	: Pharmaceutical Affairs Law (Medical devices)
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Section 16: Other Information

References : - Individual ingredient MSDS
- Company data

- Please take care when handling this product because the evaluation of the danger and hazards may not be sufficient.
- In the event no information regarding this product is available, information about individual ingredients is described.
- This material safety data sheet is a necessary document that briefly summarizes the precautions for proper use of the company product under normal handling conditions.
- Properly handle this product under the responsibility of the user with reference to the material safety data sheet.
- The information contained herein is based on the latest information and findings of the manufacturer. These data and assessments are not guaranteed. In addition, the material safety data sheet may be revised in the event of amendments to the laws and regulations and new findings.