

SAFETY DATA SHEET

Sealapex Xpress Base and Catalyst

Section 1. Identification

Product name	: Sealapex Xpress Base and Catalyst
Other means of identification	: Not available.
Product type	: Paste.
<u>Relevant identified uses of the substance or mixture and uses advised against</u>	
Product use	: Dental product: Endodontic Obturation Systems and Fill Products
Manufacturer	: SybronEndo Endodontics Unit 10, 112-118 Talavera Road North Ryde, NSW 2113 Australia Telephone no.: 1 800 643 603 Email general queries: kerraust.orders@sybrondental.com Email technical queries: peter.green@sybrondental.com
Emergency telephone number (with hours of operation)	: 61 401 690 670 (24 hours)
e-mail address of person responsible for this SDS	: peter.green@sybrondental.com

Section 2. Hazards identification

HSNO Classification	: 8.2 - CORROSIVE TO DERMAL TISSUE - Category C 8.3 - CORROSIVE TO OCULAR TISSUE - Category A 6.9 - SPECIFIC TARGET ORGAN TOXICITY (SINGLE OR REPEATED EXPOSURE) - Category B 9.1 - AQUATIC ECOTOXICITY - Category B Percentage of the mixture consisting of ingredient(s) of unknown hazards to the aquatic environment: 57.5% Health effects are based on the uncured material.
----------------------------	--

This material is classified as hazardous according to criteria in the Hazardous Substances (Minimum Degrees of Hazard) Regulations 2001 and has been classified according to the Hazardous Substances (Classifications) Regulations 2001.

This material is not classified as a dangerous good according to criteria in New Zealand Standard 5433:2007 Transport of Dangerous Goods on Land.

GHS label elements

Signal word	: Danger
Hazard statements	: Causes severe skin burns and eye damage. May cause damage to organs. Toxic to aquatic life with long lasting effects.
Precautionary statements	
Prevention	: Wear protective gloves. Wear eye or face protection. Wear protective clothing. Avoid release to the environment. Do not breathe vapour. Do not eat, drink or smoke when using this product. Wash thoroughly after handling.
Response	: Collect spillage. Immediately call a POISON CENTER or doctor/physician. IF SWALLOWED: Rinse mouth. Do NOT induce vomiting. IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower. Wash contaminated clothing before reuse. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. IF INHALED: Remove to fresh air and keep at rest in a position comfortable for breathing.
Storage	: Store locked up.

Version : 1

Date of issue/Date of revision : 12/30/2014.

Section 2. Hazards identification

Disposal : Dispose of contents and container in accordance with all local, regional, national and international regulations.

Symbol :



Other hazards which do not result in classification : Causes digestive tract burns.

Section 3. Composition/information on ingredients

Substance/mixture : Mixture

Other means of identification : Not available.

CAS number/other identifiers

CAS number : Not applicable.

EC number : Mixture.

Product code : Not available.

Ingredient name	%	CAS number
dibismuth trioxide	>=25 - <35	1304-76-3
N-ethyl-o(or p)-toluenesulphonamide	>=15 - <20	8047-99-2
calcium oxide	>=10 - <20	1305-78-8
isobutyl salicylate	>=1 - <3	87-19-4
titanium dioxide	>=1 - <5	13463-67-7
Silane, dichlorodimethyl-, reaction products with silica	>=1 - <5	68611-44-9
zinc oxide	>=0.25 - <2.5	1314-13-2
Rosin, oligomers	>=1 - <5	65997-05-9

There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as hazardous to health or the environment and hence require reporting in this section.

Occupational exposure limits, if available, are listed in Section 8.

Section 4. First-aid measures

Description of necessary first aid measures

Inhalation : No special measures required. If inhaled, remove to fresh air. Get medical attention if symptoms occur.

Ingestion : Wash out mouth with water. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Stop if the exposed person feels sick as vomiting may be dangerous. Get medical attention if adverse health effects persist or are severe.

Skin contact : No special measures required. In case of contact, immediately flush skin with plenty of water. Get medical attention if symptoms occur.

Eye contact : No special measures are required. In case of contact with eyes, rinse immediately with plenty of water. Get medical attention if symptoms occur.

Most important symptoms/effects, acute and delayed

Potential acute health effects

Inhalation : May give off gas, vapor or dust that is very irritating or corrosive to the respiratory system. Exposure to decomposition products may cause a health hazard. Serious effects may be delayed following exposure.

Ingestion : May cause burns to mouth, throat and stomach. Corrosive to the digestive tract. Causes burns.

Skin contact : Causes severe burns.

Eye contact : Causes serious eye damage.

Over-exposure signs/symptoms

Version : 1

Date of issue/Date of revision : 12/30/2014.

Section 4. First-aid measures

- Inhalation** : No specific data.
- Ingestion** : Adverse symptoms may include the following:
stomach pains
- Skin** : Adverse symptoms may include the following:
pain or irritation
redness
blistering may occur
- Eyes** : Adverse symptoms may include the following:
pain
watering
redness

Indication of immediate medical attention and special treatment needed, if necessary

- Specific treatments** : Not available.
- Notes to physician** : In case of inhalation of decomposition products in a fire, symptoms may be delayed. The exposed person may need to be kept under medical surveillance for 48 hours.
- Protection of first-aiders** : In case of major fire and large quantities: No action shall be taken involving any personal risk or without suitable training. If it is suspected that fumes are still present, the rescuer should wear an appropriate mask or self-contained breathing apparatus. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation. Wash contaminated clothing thoroughly with water before removing it, or wear gloves.

See toxicological information (Section 11)

Section 5. Fire-fighting measures

Extinguishing media

- Suitable** : Use an extinguishing agent suitable for the surrounding fire.
- Not suitable** : None known.
- Specific hazards arising from the chemical** : In a fire or if heated, a pressure increase will occur and the container may burst. This material is toxic to aquatic life with long lasting effects. Fire water contaminated with this material must be contained and prevented from being discharged to any waterway, sewer or drain.
- Hazardous thermal decomposition products** : Decomposition products may include the following materials:
carbon dioxide
carbon monoxide
nitrogen oxides
sulfur oxides
phosphorus oxides
halogenated compounds
metal oxide/oxides
- Hazchem code** : Not available.
- Special precautions for fire-fighters** : In case of major fire and large quantities: Promptly isolate the scene by removing all persons from the vicinity of the incident if there is a fire. No action shall be taken involving any personal risk or without suitable training.
- Special protective equipment for fire-fighters** : Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode.

Section 6. Accidental release measures

- Personal precautions, protective equipment and emergency procedures** : Low release. For professional use only. Handling of product in very small amounts or in situations where release is highly unlikely
- Environmental precautions** : Low release. Avoid dispersal of spilt material and runoff and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air). Water polluting material. May be harmful to the environment if released in large quantities.

Methods and material for containment and cleaning up

Version : 1

Date of issue/Date of revision : 12/30/2014.

Section 6. Accidental release measures

- Small spill** : Small Quantity. For professional use only. Absorb with an inert material and place in an appropriate waste disposal container.
- Large spill** : Small Quantity. For professional use only. Absorb with an inert material and place in an appropriate waste disposal container.

Section 7. Handling and storage

- Precautions for safe handling** : No special measures are required for small quantities under normal and intended conditions of product use. For professional use only. Put on appropriate personal protective equipment (see Section 8). Handle with care and dispose of in a safe manner.
- Conditions for safe storage, including any incompatibilities** : Store in accordance with local regulations. Store in original container protected from direct sunlight in a dry, cool and well-ventilated area, away from incompatible materials (see Section 10) and food and drink. Keep container tightly closed and sealed until ready for use. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabelled containers. Use appropriate containment to avoid environmental contamination.

Section 8. Exposure controls/personal protection

Control parameters

Occupational exposure limits

Ingredient name	Exposure limits
calcium oxide	NZ OSH (New Zealand, 2/2013). WES-TWA: 2 mg/m ³ 8 hours.
titanium dioxide	NZ OSH (New Zealand, 2/2013). WES-TWA: 10 mg/m ³ 8 hours. Form: The value for inhalable dust containing no asbestos and less than 1% free silica.
zinc oxide	NZ OSH (New Zealand, 2/2013). WES-TWA: 5 mg/m ³ 8 hours. Form: Fume WES-STEL: 10 mg/m ³ 15 minutes. Form: Fume WES-TWA: 10 mg/m ³ 8 hours. Form: The value for inhalable dust containing no asbestos and less than 1% free silica.

- Recommended monitoring procedures** : If this product contains ingredients with exposure limits, personal, workplace atmosphere or biological monitoring may be required to determine the effectiveness of the ventilation or other control measures and/or the necessity to use respiratory protective equipment. Reference should be made to appropriate monitoring standards. Reference to national guidance documents for methods for the determination of hazardous substances will also be required.

- Appropriate engineering controls** : No special measures are required for small quantities under normal and intended conditions of product use.

- Environmental exposure controls** : No special measures are required for small quantities under normal and intended conditions of product use.

Individual protection measures

- Hygiene measures** : No special measures are required for small quantities under normal and intended conditions of product use.

- Respiratory protection** : No special measures are required for small quantities under normal and intended conditions of product use.

- Hand protection** : Chemical-resistant, impervious gloves complying with an approved standard should be worn at all times when handling chemical products if a risk assessment indicates this is necessary. Considering the parameters specified by the glove manufacturer, check during use that the gloves are still retaining their protective properties. It should be noted that the time to breakthrough for any glove material may be different for different glove manufacturers. In the case of mixtures, consisting of several substances, the protection time of the gloves cannot be accurately estimated.

Section 8. Exposure controls/personal protection

- Eye protection** : Safety eyewear complying with an approved standard should be used when a risk assessment indicates this is necessary to avoid exposure to liquid splashes, mists, gases or dusts. If contact is possible, the following protection should be worn, unless the assessment indicates a higher degree of protection: chemical splash goggles and/or face shield. If inhalation hazards exist, a full-face respirator may be required instead.
- Skin protection** : No special measures are required for small quantities under normal and intended conditions of product use.

Section 9. Physical and chemical properties

Appearance

- Physical state** : Liquid. [Paste.]
- Colour** : Off-white.
- Odour** : Odourless.
- Odour threshold** : Not available.
- pH** : Not available.
- Melting point** : Not available.
- Boiling point** : Not available.
- Flash point** : Not available.
- Burning rate** : Not applicable.
- Burning time** : Not applicable.
- Evaporation rate** : Not available.
- Flammability (solid, gas)** : Not available.
- Lower and upper explosive (flammable) limits** : Not available.
- Vapour pressure** : Not available.
- Vapour density** : Not available.
- Relative density** : 1.3 [Water = 1]
- Solubility** : Insoluble in the following materials: cold water and hot water.
- Partition coefficient: n-octanol/water** : Not available.
- Auto-ignition temperature** : Not available.
- Decomposition temperature** : Not available.
- SADT** : Not available.
- Viscosity** : Not available.
- Aerosol product**
- Type of aerosol** : Not applicable.
- Heat of combustion** : Not available.
- Ignition distance** : Not applicable.
- Enclosed space ignition - Time equivalent** : Not applicable.
- Enclosed space ignition - Deflagration density** : Not applicable.
- Flame height** : Not applicable.
- Flame duration** : Not applicable.

Section 10. Stability and reactivity

- Chemical stability** : The product is stable.
- Possibility of hazardous reactions** : Under normal conditions of storage and use, hazardous reactions will not occur.
- Conditions to avoid** : No specific data.
- Incompatible materials** : No specific data.
- Hazardous decomposition products** : Under normal conditions of storage and use, hazardous decomposition products should not be produced.
Under normal conditions of storage and use, hazardous polymerisation will not occur.

Section 11. Toxicological information

Information on the likely routes of exposure

- Inhalation** : May give off gas, vapor or dust that is very irritating or corrosive to the respiratory system. Exposure to decomposition products may cause a health hazard. Serious effects may be delayed following exposure.
- Ingestion** : May cause burns to mouth, throat and stomach. Corrosive to the digestive tract. Causes burns.
- Skin contact** : Causes severe burns.
- Eye contact** : Causes serious eye damage.

Symptoms related to the physical, chemical and toxicological characteristics

- Inhalation** : No specific data.
- Ingestion** : Adverse symptoms may include the following:
stomach pains
- Skin contact** : Adverse symptoms may include the following:
pain or irritation
redness
blistering may occur
- Eye contact** : Adverse symptoms may include the following:
pain
watering
redness

Delayed and immediate effects and also chronic effects from short and long term exposure

Acute toxicity

Product/ingredient name	Result	Species	Dose	Exposure
dibismuth trioxide	LD50 Oral	Rat	4 g/kg	-
N-ethyl-o(or p)-toluenesulphonamide	LD50 Oral	Rat	2250 mg/kg	-
isobutyl salicylate	LD50 Oral	Rat	1560 mg/kg	-
Silane, dichlorodimethyl-, reaction products with silica	LD50 Oral	Rat	>5000 mg/kg	-
Rosin, oligomers	LD50 Dermal	Rabbit	>2500 mg/kg	-

- Conclusion/Summary** : Based on the criteria of the protocol, this product is considered non-cytotoxic per ISO 10993-5.

Irritation/Corrosion

Product/ingredient name	Result	Species	Score	Exposure	Observation
N-ethyl-o(or p)-toluenesulphonamide	Eyes - Mild irritant	Rabbit	-	100 Micrograms	-
zinc oxide	Eyes - Mild irritant	Rabbit	-	24 hours 500 milligrams	-
	Skin - Mild irritant	Rabbit	-	24 hours 500 milligrams	-

Sensitisation

Not available.

Section 11. Toxicological information

Potential chronic health effects

General	: No known significant effects or critical hazards.
Inhalation	: No known significant effects or critical hazards.
Ingestion	: No known significant effects or critical hazards.
Skin contact	: No known significant effects or critical hazards.
Eye contact	: No known significant effects or critical hazards.
Carcinogenicity	: No known significant effects or critical hazards.
Mutagenicity	: No known significant effects or critical hazards.
Teratogenicity	: No known significant effects or critical hazards.
Developmental effects	: No known significant effects or critical hazards.
Fertility effects	: No known significant effects or critical hazards.

Chronic toxicity

Not available.

Carcinogenicity

Not available.

Mutagenicity

Not available.

Conclusion/Summary : No mutagenic effect.

Teratogenicity

Not available.

Reproductive toxicity

Not available.

Specific target organ toxicity

Name	Category	Route of exposure	Target organs
Silane, dichlorodimethyl-, reaction products with silica	Category B	Inhalation	Not determined

Aspiration hazard

Not available.

Numerical measures of toxicity

Acute toxicity estimates

Route	ATE value
Oral	5624.1 mg/kg
Dermal	223254.5 mg/kg

Section 12. Ecological information

Ecotoxicity : This material is toxic to aquatic life with long lasting effects.

Aquatic and terrestrial toxicity

Product/ingredient name	Result	Species	Exposure
calcium oxide	Chronic NOEC 100 mg/l Fresh water	Fish - Oreochromis niloticus - Juvenile (Fledgling, Hatchling, Weanling)	46 days
titanium dioxide	Acute EC50 5.83 mg/l Fresh water	Algae - Pseudokirchneriella subcapitata - Exponential growth phase	72 hours
	Acute LC50 3 mg/l Fresh water	Crustaceans - Ceriodaphnia dubia - Neonate	48 hours
	Acute LC50 5.5 ppm Fresh water	Daphnia - Daphnia magna -	48 hours

Version : 1

Date of issue/Date of revision : 12/30/2014.

Section 12. Ecological information

zinc oxide	Acute LC50 1000 mg/l Fresh water Acute LC50 >1000000 µg/l Marine water Chronic NOEC 0.984 mg/l Fresh water	Juvenile (Fledgling, Hatchling, Weanling) Fish - Pimephales promelas Fish - Fundulus heteroclitus	96 hours 96 hours
	Acute EC50 0.042 mg/l Fresh water	Algae - Pseudokirchneriella subcapitata - Exponential growth phase Algae - Pseudokirchneriella subcapitata - Exponential growth phase	72 hours 72 hours
	Acute LC50 98 µg/l Fresh water	Daphnia - Daphnia magna - Neonate	48 hours
	Acute LC50 1.1 ppm Fresh water Chronic NOEC 0.017 mg/l Fresh water	Fish - Oncorhynchus mykiss Algae - Pseudokirchneriella subcapitata - Exponential growth phase	96 hours 72 hours

Persistence/degradability

Not available.

Bioaccumulative potential

Product/ingredient name	LogP _{ow}	BCF	Potential
calcium oxide	-	2.34	low
titanium dioxide	-	352	low
zinc oxide	-	60960	high

Mobility in soil

Soil/water partition coefficient (K_{oc}) : Not available.

Other adverse effects : No known significant effects or critical hazards.

Section 13. Disposal considerations

Disposal methods : The generation of waste should be avoided or minimised wherever possible. Disposal of this product, solutions and any by-products should at all times comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements.

Section 14. Transport information

Regulatory information	UN number	Proper shipping name	Classes	PG*	Label	Additional information
New Zealand Class	Not regulated.	-	-	-		-
ADG Class	Not regulated.	-	-	-		-
UN Class	Not regulated.	-	-	-		-
ADR/RID Class	Not regulated.	-	-	-		-
IATA Class	Not regulated.	-	-	-		-
IMDG Class	Not regulated.	-	-	-		-

PG* : Packing group

Version : 1

Date of issue/Date of revision : 12/30/2014.

Section 15. Regulatory information

New Zealand Inventory of Chemicals (NZIoC)	: Not determined.
HSNO Approval Number	: Not available.
HSNO Group Standard	: Not available.
HSNO Classification	: 8.2 - CORROSIVE TO DERMAL TISSUE - Category C 8.3 - CORROSIVE TO OCULAR TISSUE - Category A 6.9 - SPECIFIC TARGET ORGAN TOXICITY (SINGLE OR REPEATED EXPOSURE) - Category B 9.1 - AQUATIC ECOTOXICITY - Category B
Australia inventory (AICS)	: Not determined.
Safety, health and environmental regulations specific for the product	: No known specific national and/or regional regulations applicable to this product (including its ingredients).

Section 16. Other information

History

Date of issue/Date of revision	: 12/30/2014.
Date of previous issue	: No previous validation.
Version	: 1
Prepared by	: IHS
Key to abbreviations	: ADN = European Provisions concerning the International Carriage of Dangerous Goods by Inland Waterway ADR = The European Agreement concerning the International Carriage of Dangerous Goods by Road ATE = Acute Toxicity Estimate BCF = Bioconcentration Factor GHS = Globally Harmonized System of Classification and Labelling of Chemicals IATA = International Air Transport Association IBC = Intermediate Bulk Container IMDG = International Maritime Dangerous Goods LogPow = logarithm of the octanol/water partition coefficient MARPOL 73/78 = International Convention for the Prevention of Pollution From Ships, 1973 as modified by the Protocol of 1978. ("Marpol" = marine pollution) RID = The Regulations concerning the International Carriage of Dangerous Goods by Rail UN = United Nations
References	: GHS - Globally Harmonized System of Classification and Labeling of Chemicals International transport regulations

✔ Indicates information that has changed from previously issued version.

Notice to reader

To the best of our knowledge, the information contained herein is accurate. However, neither the above-named supplier, nor any of its subsidiaries, assumes any liability whatsoever for the accuracy or completeness of the information contained herein.

Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.