SAFETY DATA SHEET

Sealapex Canal Sealant Base

Section 1. Identifi	cation	
GHS product identifier	: Sealapex Canal Sealant Base	
Other means of identification	: Not available.	
Product type	: Paste.	
Relevant identified uses of t	he substance or mixture and uses advised against	
Product use	: Dental product: Endodontic Obturation Systems and Fill Products	
Area of application	: Professional applications.	
Manufacturer	: SybronEndo Endodontics 1717 West Collins Avenue Orange, CA 92867-5422 Telephone no.: 1-800-KERR-123	
e-mail address of person responsible for this SDS	: edwin.varela@kavokerrgroup.com	
Emergency telephone number (with hours of operation)	: CHEMTREC® (24 hours) U.S. : 1-800-424-9300 International: +1-703-527-3887	

Section 2. Hazards identification

OSHA/HCS status	 This material is considered hazardous by the OSHA Hazard Communication Standard (29 CFR 1910.1200). Health effects are based on the uncured material. 	I
Classification of the substance or mixture	 SKIN IRRITATION - Category 2 SERIOUS EYE DAMAGE - Category 1 SPECIFIC TARGET ORGAN TOXICITY (SINGLE EXPOSURE) (Respiratory tract irritation) - Category 3 Percentage of the mixture consisting of ingredient(s) of unknown toxicity: 45.2% 	
GHS label elements Hazard pictograms		
Signal word	: Danger	
Hazard statements	 Causes serious eye damage. Causes skin irritation. May cause respiratory irritation. 	
Precautionary statements		
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Section 2. Hazards identification

Prevention	: Wear protective gloves. Wear eye or face protection. Use only outdoors or in a well- ventilated area. Avoid breathing dust. Wash hands thoroughly after handling.
Response	: IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing. Call a POISON CENTER or physician if you feel unwell. IF ON SKIN: Wash with plenty of soap and water. Take off contaminated clothing. Wash contaminated clothing before reuse. If skin irritation occurs: Get medical attention. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER or physician.
Storage	: Store locked up.
Disposal	 Dispose of contents and container in accordance with all local, regional, national and international regulations.
Supplemental label elements	: Do not taste or swallow. Wash thoroughly after handling.
Hazards not otherwise classified	: Causes digestive tract burns.

Section 3. Composition/information on ingredients

Substance/mixture	: Mixture
Other means of	: Not available.
identification	

CAS number/other identifiers

CAS number: Not applieProduct code: Not availation			
Ingredient name	Other names	%	CAS number
N-ethyl-o(or p)-toluenesulphonamide	N-ethyl-o(or p)- toluenesulphonamide	30-60	8047-99-2
Calcium oxide	calcium oxide	30-60	1305-78-8
zinc oxide	zinc oxide	1-5	1314-13-2
zinc distearate	zinc distearate	1-5	557-05-1

Any concentration shown as a range is to protect confidentiality or is due to batch variation.

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 and hence require reporting in this section.

Section 4. First aid measures

Description of necessary f	<u>rst aid measures</u>		
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.		
Inhalation	 No special measures required. If inhaled, remove to fresh air. Get medical attention if symptoms occur. 		
Skin contact	: No special measures required. In case of contact, immediately flush skin with plenty of water. 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.		
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Section 4. First aid measures

Most important symptoms/	effects, acute and delayed		
Potential acute health effe	ects		
Eye contact	: Causes serious eye damage.		
Inhalation	 May cause respiratory irritation. Exposure to decomposition products may cause a health hazard. Serious effects may be delayed following exposure. 		
Skin contact	: Causes skin irritation.		
Ingestion	: Corrosive to the digestive tract. Causes burns. May cause burns to mouth, throat and stomach.		
Over-exposure signs/sym	<u>ptoms</u>		
Eye contact	: Adverse symptoms may include the following: pain watering redness		
Inhalation	: Adverse symptoms may include the following: respiratory tract irritation coughing		
Skin contact	: Adverse symptoms may include the following: pain or irritation redness blistering may occur		
Ingestion	: Adverse symptoms may include the following: stomach pains		
Indication of immediate me	dical attention and special treatment needed, if necessary		
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. 		
Specific treatments	: No specific treatment.		
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 extinguishing media	: Use an extinguishing agent suitable for the surrounding fire.
Unsuitable extinguishing media	: Do not use water jet.
Specific hazards arising from the chemical	: No specific fire or explosion hazard.

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Section 5. Fire-fighting measures

Hazardous thermal decomposition products	: Decomposition products may include the following materials: carbon dioxide carbon monoxide nitrogen oxides sulfur oxides phosphorus oxides metal oxide/oxides
Special protective actions 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, protec	tive equipment and emergency procedures	
For non-emergency personnel	: Low release. For professional use only. Handling of product in very small amounts or in situations where release is highly unlikely	
For emergency responders	: Low release. See also the information in "For non-emergency personnel".	
Environmental precautions	: Low release. Avoid dispersal of spilled 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).	
Methods and materials for co	ntainment and cleaning up	
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 materia appropriate waste disposal container.	I and place in an

Section 7. Handling and storage

Precautions for safe handling

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Protective measures	pecial measures are required for small quantities under itions of product use. For professional use only. Put on ective equipment (see Section 8). Handle with care and	appropriate personal
Advice on general occupational hygiene	ng, drinking and smoking should be prohibited in areas willed, stored and processed. Workers should wash hand ing and smoking. Remove contaminated clothing and pring eating areas. See also Section 8 for additional info sures.	s and face before eating, protective equipment before
Conditions for safe storage, including any incompatibilities	e in accordance with local regulations. Store in original et sunlight in a dry, cool and well-ventilated area, away for Section 10) and food and drink. Store locked up. Keep ed until ready for use. Containers that have been opener aled and kept upright to prevent leakage. Do not store is appropriate containment to avoid environmental contar	om incompatible materials container tightly closed and d must be carefully n unlabeled containers.

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Section 8. Exposure controls/personal protection

Control parameters

Occupational exposure limits

Ingredient name	Exposure limits
Calcium oxide	ACGIH TLV (United States, 6/2013).
	TWA: 2 mg/m ³ 8 hours.
	OSHA PEL 1989 (United States, 3/1989).
	TWA: 5 mg/m ³ 8 hours.
	NIOSH REL (United States, 10/2013).
	TWA: 2 mg/m ³ 10 hours.
	OSHA PEL (United States, 2/2013).
	TWA: 5 mg/m ³ 8 hours.
zinc oxide	NIOSH REL (United States, 10/2013).
	CEIL: 15 mg/m ³ Form: Dust
	TWA: 5 mg/m ³ 10 hours. Form: Dust and
	fumes
	STEL: 10 mg/m ³ 15 minutes. Form: Fume
	OSHA PEL 1989 (United States, 3/1989).
	TWA: 5 mg/m ³ 8 hours. Form: Fume
	STEL: 10 mg/m ³ 15 minutes. Form: Fume
	TWA: 5 mg/m ³ 8 hours. Form: Respirable
	fraction
	TWA: 10 mg/m ³ 8 hours. Form: Total dust
	OSHA PEL (United States, 2/2013).
	TWA: 5 mg/m ³ 8 hours. Form: Fume
	TWA: 5 mg/m ³ 8 hours. Form: Respirable
	fraction
	TWA: 15 mg/m ³ 8 hours. Form: Total dust
	ACGIH TLV (United States, 6/2013).
	TWA: 2 mg/m ³ 8 hours. Form: Respirable
	fraction
	STEL: 10 mg/m ³ 15 minutes. Form:
	Respirable fraction
zinc distearate	OSHA PEL 1989 (United States, 3/1989).
	TWA: 5 mg/m ³ 8 hours. Form: Respirable
	fraction
	TWA: 10 mg/m ³ 8 hours. Form: Total dust
	NIOSH REL (United States, 10/2013).
	TWA: 5 mg/m ³ 10 hours. Form: Respirable
	fraction
	TWA: 10 mg/m ³ 10 hours. Form: Total
	OSHA PEL (United States, 2/2013).
	TWA: 5 mg/m ³ 8 hours. Form: Respirable
	fraction
	TWA: 15 mg/m ³ 8 hours. Form: Total dust
	ACGIH TLV (United States, 6/2013).
	TWA: 10 mg/m³ 8 hours. Form: Total
	particulate mass

Appropriate engineering controls	: No special measures are required for conditions of product use.	or small quantities un	der normal and intended	
Environmental exposure controls	: No special measures are required for conditions of product use.	or small quantities un	der normal and intended	
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Section 8. Exposure controls/personal protection

Individual protection measures

Hygiene measures	 No special measures are required for small quantities under normal and intended conditions of product use.
Eye/face 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	
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.
Body protection	 No special measures are required for small quantities under normal and intended conditions of product use.
Other skin protection	 Appropriate footwear and any additional skin protection measures should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.
Respiratory 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	: Solid. [Viscous. Paste.]	
Color	: Off-white.	
Odor	: Odorless.	
Odor threshold	: Not available.	
рН	: Not available.	
Melting point	: Not available.	
Boiling point	: Not available.	
Flash point	: Not available.	
Evaporation rate	: Not available.	
Flammability (solid, gas)	: Not available.	
Lower and upper explosive (flammable) limits	: Not available.	
Vapor pressure	: Not available.	
Vapor density	: Not available.	
Relative density	: 1.3 [Water = 1]	
Solubility	: Insoluble in the following materials: cold water and hot water.	
Solubility in water	: Not available.	
Partition coefficient: n- octanol/water	: Not available.	
Auto-ignition temperature	: Not available.	
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Section 9. Physical and chemical properties

Decomposition temperature	: Not available.
SADT	: Not available.
Viscosity	: Not available.
Section 10. Stabili	ty and reactivity
Reactivity	: No specific test data related to reactivity available for this product or its ingredients.
Chemical stability	: The product is stable.
Possibility of hazardous reactions	: Under normal conditions of storage and use, hazardous reactions will not occur.
	Under normal conditions of storage and use, hazardous polymerization 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.

Section 11. Toxicological information

Information on toxicological effects

Acute toxicity

Product/ingredient name	Result	Species	Dose	Exposure
N-ethyl-o(or p)- toluenesulphonamide	LD50 Oral	Rat	2250 mg/kg	-
zinc distearate	LC50 Inhalation Dusts and mists LD50 Oral	Rat Rat	>200 mg/l >10 g/kg	1 hours -
Conclusion/Summary	: Based on the criteria of the proto 10993-5.	ocol, this produ	uct is considered nor	n-cytotoxic per ISO

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	-

Sensitization

Not available.

Conclusion/Summary

Skin

: Kligman score: Grade I (weak sensitizer)

Mutagenicity

Not available.

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Section 11. Toxicological information

Conclusion/Summary

ry : No mutagenic effect.

Carcinogenicity

Not available.

Reproductive toxicity

Not available.

Teratogenicity

Not available.

Specific target organ toxicity (single exposure)

Name	Category	Route of exposure	Target organs
Calcium oxide	Category 3		Respiratory tract irritation
zinc distearate	Category 3		Respiratory tract irritation

Specific target organ toxicity (repeated exposure)

Not available.

Aspiration hazard

Not available.

Information on the likely : Routes of entry anticipated: Oral, Dermal, Inhalation.

routes of exposure

Potential acute health	effects
Eye contact	: Causes serious eye damage.
Inhalation	 May cause respiratory irritation. Exposure to decomposition products may cause a health hazard. Serious effects may be delayed following exposure.
Skin contact	: Causes skin irritation.
Ingestion	: Corrosive to the digestive tract. Causes burns. May cause burns to mouth, throat and stomach.

Symptoms related to the physical, chemical and toxicological characteristics

Eye contact	: Adverse symptoms may include the following: pain watering redness
Inhalation	: Adverse symptoms may include the following: respiratory tract irritation coughing
Skin contact	: Adverse symptoms may include the following: pain or irritation redness blistering may occur
Ingestion	: Adverse symptoms may include the following: stomach pains

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

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Section 11. Toxicological information

Short term exposure	
Potential immediate effects	: Not available.
Potential delayed effects	: Not available.
Long term exposure	
Potential immediate effects	: Not available.
Potential delayed effects	: Not available.
Potential chronic health effe	<u>cts</u>
Not available.	
General	: 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.

Numerical measures of toxicity

Acute toxicity estimates

Route	ATE value
Oral	2941.3 mg/kg

Section 12. Ecological information

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
zinc oxide	Acute EC50 0.042 mg/l Fresh water	Algae - Pseudokirchneriella subcapitata - Exponential growth phase	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 and degradability

Not available.

Bioaccumulative potential

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Section 12. Ecological information

Product/ingredient name	LogPow	BCF	Potential
Calcium oxide	-	2.34	low
zinc oxide	-	60960	high
zinc distearate	1.2	-	low

Mobility in soil

Soil/water partition : Not coefficient (Koc)

: 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 minimized 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

	DOT Classification	IMDG	ΙΑΤΑ
UN number	UN3077	UN3077	UN3077
UN proper shipping name	Environmentally hazardous substances, solid, n.o.s. (zinc oxide). Marine pollutant (zinc oxide)	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (zinc oxide). Marine pollutant (zinc oxide)	Environmentally hazardous substance, solid, n.o.s. (zinc oxide)
Transport hazard class(es)	9	9	9
Packing group	Ш	Ш	Ш
Environmental hazards	Yes.	Yes.	Yes.
Additional information	Non-bulk packages of this product are not regulated as hazardous materials unless transported by inland waterway. The marine pollutant mark is not required when transported on inland waterways in sizes of ≤5 L or ≤5 kg. Limited quantity Yes. <u>Special provisions</u> 8, 146, 335, A112, B54, B120,	The marine pollutant mark is not required when transported in sizes of ≤5 L or ≤5 kg. Energency schedules (EmS) F-A, S-F Special provisions 274, 335, 966, 967	The environmentally hazardous substance mark is not required when transported in sizes of ≤5 L or ≤5 kg. Passenger and Cargo Aircraft Quantity limitation: 400 kg Packaging instructions: 956 Cargo Aircraft Only Quantity limitation: 400 kg Packaging instructions: 956 Limited Quantities - Passenger Aircraft Quantity limitation: 30 kg Packaging instructions: Y956

Section 14. Transport information

Special provisions A97, A158, A179

Special precautions for user : Transport within user's premises: always transport in closed containers that are upright and secure. Ensure that persons transporting the product know what to do in the event of an accident or spillage.

Transport in bulk according : Not available. to Annex II of MARPOL 73/78 and the IBC Code

Section 15. Regulatory information

U.S. Federal regulations	:	TSCA 8(a) PA United States Clean Water A Clean Water A	inventory Act (CWA)	(TSC) 307: z	A 8b): Not de inc oxide; zin	termined. c distearate	products with s	ilica
Clean Air Act Section 112 (b) Hazardous Air Pollutants (HAPs)	:	Not listed						
Clean Air Act Section 602 Class I Substances	:	Not listed						
Clean Air Act Section 602 Class II Substances	:	Not listed						
DEA List I Chemicals (Precursor Chemicals)	:	Not listed						
DEA List II Chemicals (Essential Chemicals)	:	Not listed						
SARA 302/304 Composition/information No products were found.	<u>on i</u>	ngredients						
SARA 304 RQ SARA 311/312	:	Not applicable						
Classification Composition/information		Immediate (ac	ute) health	hazar	d			
Name		%	Fir ha	re zard	Sudden release of	Reactive	Immediate (acute)	Delayed (chronic)

		hazard	release of pressure		(acute) health hazard	(chronic) health hazard
N-ethyl-o(or p)-toluenesulphonamide	30-60	No.	No.	No.	Yes.	No.
Calcium oxide	30-60	No.	No.	No.	Yes.	No.
zinc oxide	1-5	No.	No.	No.	Yes.	No.
zinc distearate	1-5	Yes.	No.	No.	Yes.	No.

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Section 15. Regulatory information

	Product name	CAS number	%
Form R - Reporting requirements	zinc oxide	1314-13-2	1-5
	zinc distearate	557-05-1	1-5
Supplier notification	zinc oxide	1314-13-2	1-5
	zinc distearate	557-05-1	1-5

SARA 313 notifications must not be detached from the SDS and any copying and redistribution of the SDS shall include copying and redistribution of the notice attached to copies of the SDS subsequently redistributed.

State regulations

Massachusetts	 The following components are listed: CALCIUM OXIDE; ZINC OXIDE FUME; ZINC STEARATE; TITANIUM DIOXIDE
New York	: None of the components are listed.
New Jersey	 The following components are listed: CALCIUM OXIDE; LIME; ZINC OXIDE; ZINC STEARATE; OCTADECANOIC ACID, ZINC SALT; TITANIUM DIOXIDE; TITANIUM OXIDE (TiO2)
Pennsylvania	 The following components are listed: CALCIUM OXIDE (CAO); ZINC OXIDE (ZNO); OCTADECANOIC ACID, ZINC SALT; TITANIUM OXIDE (TIO2)
Colifornia Dron CE	

California Prop. 65

WARNING: This product contains a chemical known to the State of California to cause cancer.

Ingredient name	Cancer		• •	Maximum acceptable dosage level
Titanium dioxide	Yes.	No.	No.	No.

Section 16. Other information

Hazardous Material Information System (U.S.A.)



Caution: HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks Although HMIS® ratings are not required on SDSs under 29 CFR 1910. 1200, the preparer may choose to provide them. HMIS® ratings are to be used with a fully implemented HMIS® program. HMIS® is a registered mark of the National Paint & Coatings Association (NPCA). HMIS® materials may be purchased exclusively from J. J. Keller (800) 327-6868.

The customer is responsible for determining the PPE code for this material.

National Fire Protection Association (U.S.A.)



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Section 16. Other information

Copyright ©2001, National Fire Protection Association, Quincy, MA 02269. This warning system is intended to be interpreted and applied only by properly trained individuals to identify fire, health and reactivity hazards of chemicals. The user is referred to certain limited number of chemicals with recommended classifications in NFPA 49 and NFPA 325, which would be used as a guideline only. Whether the chemicals are classified by NFPA or not, anyone using the 704 systems to classify chemicals does so at their own risk.

<u>History</u>	
Date of issue/Date of revision	: 04/07/2015
Date of previous issue	: 04/07/2015
Version	: 1
Prepared by	: IHS
Key to abbreviations	: ATE = Acute Toxicity Estimate BCF = Bioconcentration Factor GHS = Globally Harmonized System of Classification and Labelling of Chemicals IATA = International Air Transport Association IBC = Internediate 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) UN = United Nations
References	: HCS (U.S.A.)- Hazard Communication Standard 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.