



1. Identification

Product Name Calibra® Bio	SDS Code Number 507699 - Powder
Substance Identity Calibra® Bio (Bioceramic Luting Cement Powder)	Date of Last Revision 08/1/18
Manufactured for: DENTSPLY LLC	Address: DENTSPLY LLC 38 West Clarke Avenue Milford DE 19963-1805 http://www.dentsplysirona.com
Grades or Minor Variant Identities Not Applicable	Company Telephone Number (Product Inquiries) (302) 422-4511 (8:00 AM – 4:30 PM Eastern Time)
Product Use (for Canada) Bioceramic Dental Luting Cement	Emergency Telephone Number CHEMTREC: 1-800-424-9300 (24 hours) (Outside U.S. +1-703-527-3887) CCN6510

2. Hazard(s) Identification

NOT APPLICABLE

3. Composition/Information on Ingredients

Hazardous Components	C.A.S. Number	Exposure Limits	%
Strontium Fluoride	7783-48-4	2.5 mg/m ³	< than 5

4. First Aid Measures

First aid measures by route of exposure:

Inhalation: Remove to fresh air. Get medical attention if any discomfort continues.

Skin contact: Wash skin thoroughly with soap and water. If irritation occur: Seek medical advice.

Eye contact: Flush with water or physiological salt water, holding eye lids open, remember to remove contact lenses, if any. If irritation persists: Seek medical advice.

Ingestion: Rinse mouth and drink plenty of water. **Do not induce vomiting.** Keep at rest. Get medical attention if any discomfort continues.

Most important symptoms and effects (acute or delayed): Inhalation of dust may irritate throat and respiratory system and cause coughing. May cause slight irritation of skin and eyes. May cause hypersensitivity symptoms in some patients.

Immediate medical attention and special treatment needed, if necessary: Show this safety data sheet to a physician or emergency ward. Treat symptomatically.

5. Fire Fighting Measures

Flame Propagation or Burning Rate (for Solids): Not Applicable	Properties Contributing to Fire Intensity Not Applicable	Flammability Classification: Not Applicable	Other: Not Applicable
Extinguishing Media: Dry-powder, water mist (never water jet), alcohol resistant foam or carbon dioxide (CO2).		Extinguishing Media to Avoid: Water with full jet.	
Protection and Procedures for Firefighters: Firefighters should wear self-contained respiratory protective devices.			
Unusual Fire and Explosion Hazards: In case of surrounding fire the product may form hazardous decomposition products such as hydrofluoric acid. Product does not present an explosion hazard.			

6. Accidental Release Measures

Personal precautions, protective equipment and emergency procedures: Use personal protective equipment - see section 8.

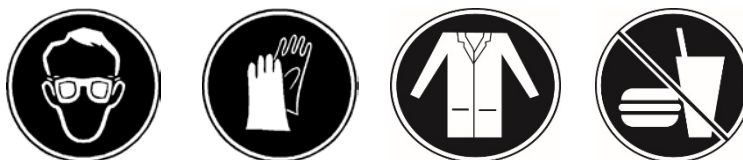
Avoid generation and spreading of dust. Do not empty into drains. Inform appropriate authorities in accordance with local regulations.

Methods and materials for containment and cleaning up: Sweep up and place in a suitable container. Flush area of spill with plenty of water. Further handling of spillage – see section 13.

7. Handling and Storage

Handling Practices and Warnings: Product is intended for dental use only. Handling of this product should be by trained dental healthcare professionals only. Observe normal care for working with chemicals. Use only as described in "Instruction for use". Provide adequate ventilation. Avoid contact with skin and eyes. Wash with water and soap after work. Do not eat, drink or smoke during use.
Storage Practices and Warnings: Store only in the original package. Keep package tightly sealed. Store in a dry area. Protect from exposure to direct light. Store away from food and beverages. Conditions for safe storage (including incompatible materials): Store dry at temperatures between +4°C and +25°C (39°F – 77°F). Keep away from substances mentioned in section 10.

8. Exposure Control / Personal Protection



Control parameters, including occupational exposure guidelines:

Occupational exposure limits: ACGIH TLV Cal/OSHA PEL NIOSH REL Alberta OHS Code 2009 (8h)

Strontium fluoride (as F) 2.5 mg/m³ 2.5 mg/m³ 2.5 mg/m³ 2.5 mg/m³ (listed under Fluorides)

American Conference of Governmental Industrial Hygienists = ACGIH Threshold Limit Value = TLV

National Institute for Occupational Safety and Health = NIOSH Recommended Exposure Limit = REL

Other exposure limit used or recommended: None known.

Appropriate engineering controls: Facilities storing or utilizing this material should be equipped with an eyewash facility and a safety shower. Provide adequate ventilation in working areas to keep airborne concentrations low.

Individual protection measures (e.g. personal protective equipment): PPE must follow OSHA regulations found in 29 CFR 1910.132 and should be chosen in collaboration with the supplier of such equipment. The recommended PPE and the specified standards are only suggestions, as a risk assessment of the relevant current work/operation may lead to other control measures.

Eye/face protection: Wear tight fitting safety goggles (as described by OSHA's eye and face protection regulations in 29 CFR 1910.133 or EN166).

Skin/hand protection: By prolonged contact: Wear protective gloves of for instance nitrile rubber. Breakthrough time of the ingredients is not available. Discard gloves at any suspicion of contamination.

Respiratory protection: Respiratory equipment is normally not required. In case of dust formation: Use a NIOSH/MSHA or EN149 approved respirator with a particle filter type P2. The filter has a limited lifetime and must be changed. Read the instruction. Follow the OSHA respirator regulations found in 29 CFR 1910.134 or European Standard EN 149.

9. Physical and Chemical Characteristics

Appearance: Capsules containing powder.		Odor: No characteristic odor.
Normal Physical State: Plastic capsule		Melting Point: Not Determined
Specific Gravity: Not Determined	Solubility in Water: Not soluble, reacts with water	pH: Not Determined
Vapor Pressure (mm Hg): Not Determined	Vapor Density (AIR=1): Not Determined	Evaporation Rate (Butyl Acetate =1): Not Determined
Flashpoint Method: Not Determined	Flammable (Explosive) Limits in Air LEL: Not Applicable UEL: Not Applicable	Autoignition Temperature: Not Determined
Other: Not Applicable		

10. Stability and Reactivity Data

Reactivity: Capsule content reacts with water.

Chemical stability: Stable under normal conditions and recommended use.

Possibility of hazardous reactions: None known.

Conditions to avoid: Water and moisture.

Incompatible materials: Strong oxidizers, strong acids and strong bases.

Hazardous decomposition products: When heated to high temperatures (decomposition), the product emits very toxic fumes such as Strontium oxides and corrosive hydrogen fluoride.

11. Toxicological Information

Toxicity Data, Epidemiology Studies, Carcinogenicity, Neurological Effects, Genetic Effects, Reproductive Effects, or Structure Activity Data:

Information on toxicological (health) effects: Likely routes of exposure: Inhalation, skin and ingestion.

Symptoms: Symptoms may occur if dust is released from the capsule by accident.

Emergency Overview Material is irritating to eyes, respiratory system and skin.

Delayed and immediate effects and chronic effects from short-term and long-term exposure: High concentration of inorganic fluorides may cause skeletal fluorosis with symptoms such as periodical pain and stiffness in the joints, headache, abdominal pain and muscle weakness. Later osteoporosis and bone damages may occur. Loss of weight. Anorexia and anemia are common findings in fluorine poisoning. Skin sensitization to polyacrylic acid may occur in very rare cases. Symptoms are redness, itching and eczema.

Routes of Exposure	Signs and Symptoms	Single, Repeated, or Lifetime Exposure	Severity (Mild, Moderate, Severe)	Acute and Chronic Health Effect(s)	Target Organ(s)
Eye	May cause slight irritation with redness and stinging.	Single	Mild	Irritation and possible corneal damage	Not Applicable
Skin	May cause slight irritation with redness.	Single	Mild	Irritation or possible allergic response. Severe allergic response may result in breathing difficulties.	Not Applicable
Inhalation	Inhalation may cause irritation of the respiratory system.	Single	Slight	Irritation	Not Applicable
Ingestion	May cause irritation of the gastrointestinal tract, nausea, vomiting, salivation, fever and headache.	Single	Slight	Irritation	Not Applicable
Mucosa	Material can cause irritation.	Single	Slight	Irritation of the mucosa	Not Applicable

Medical Conditions Aggravated by Exposure: Open sores and wounds of the skin.
Carcinogenicity NTP?: Not listed IARC monographs?: Not listed OSHA regulated?: No All components of this product are in compliance with the inventory listing Requirements of the U. S. Toxic Substances Control Act (TSCA) Chemical Substance Inventory.
Potential Environmental Effects Do not allow to enter sewers/ surface or ground water.
NFPA Hazard Classification Ratings (Scale 0-4), Health = 1, Fire = 1, Reactivity = 0

Acute Toxicity: Strontium fluoride: LD50 = 10.600 mg/kg (oral, rat). Source: RTECS. The chemical, physical and toxicology properties of strontium fluoride have not been thoroughly investigated and recorded.

Mutagenic toxicity: No available data/insufficient data.

Reproductive toxicity: No available data/insufficient data.

Carcinogenic toxicity: No available data/insufficient data. Substances are not mentioned on NTP's Report on Carcinogens (RoC), latest ed. Substances are not found to be potential carcinogens in IARC Monographs, or by OSHA.

Specific Target Organ Toxicity – single exposure / repeated exposure: No known effects.

12. Ecological Information

Ecotoxicity: No available or applicable data.

Persistence and degradability: Methods for determination of degradability are not valid for inorganic compounds.

Bioaccumulative potential: No available or applicable data.

Mobility in soil: Low mobility in soil is expected.

Other adverse effects: None known.

13. Disposal Considerations

Safe handling for disposal and methods of disposal, including any contaminated packaging: This material and its container must be disposed of as non-hazardous waste. Inform appropriate authorities in accordance with local regulations in case of leakage into sewers etc. and dispose of contents/container in accordance with applicable national regulations. Dispose/incinerate of contents/container and waste product in accordance with applicable local/regional/national/ international regulations in a permitted waste incineration facility/ industrial waste facility or at licensed waste disposal sites.

Properties (Physical/Chemical) Affecting Disposal: Dispose of material as solid waste in a closed container.

Disposal considerations: Dispose of contents/container in accordance with applicable local/regional/national/international regulations. See Section 8 for guidance on PPE. Incinerate and dispose of waste product in a permitted waste incineration facility/industrial waste facility. Chemical waste generators must determine whether a discarded chemical is classified as a hazardous waste. US EPA guidelines for the classification determination are listed in 40 CFR Parts 261.3. Additionally, waste generators must consult state and local hazardous waste regulations to ensure complete and accurate classification.

RCRA P-Series: None listed.

RCRA U-Series: None listed.

14. Transport Information

Regulated for Shipping: No. Not Regulated	DOT Shipping Name: Not Regulated	Packing Group: Not Applicable
Do Changes in Quantities, packaging, or shipment method change product classification? No	DOT Hazard Class: Not Applicable	UN Number: Not Applicable
Canadian Transportation of Dangerous Goods (TDG): None.		

15. Regulatory Information

This product has been classified in accordance with the hazard criteria of the Globally Harmonized System of Classification and Labeling of Chemicals and the SDS contains all of the information required by the Canadian Controlled Products Regulations.
U.S. Federal Regulations: <u>CERCLA 103 Reportable Quantity</u> : This product is not subject to CERCLA reporting requirements. Many states have more stringent release reporting requirements. Report spills required under federal, state and local regulations.
US Federal Regulations: <u>NATIONAL INVENTORY STATUS - U.S. Inventory (TSCA)</u> : CAS No. 7783-48-4 is listed on TSCA inventory. TSCA section 12b: None of the chemicals in the product are listed.
<u>Section 313 Toxic Chemicals</u> : This product contains the following chemicals subject to Annual Release Reporting Requirements Under SARA Title III, Section 313 (40 CFR 372): None of the chemicals are listed.
<u>Section 302 Extremely Hazardous Substances (TPQ)</u> : None of the chemicals are listed.
<u>EPA Toxic Substances Control Act (TSCA) Status</u> : All of the components of this product are listed on the TSCA inventory.
<u>Clean Air Act</u> : This product does not contain any hazardous air pollutants, no class 1 Ozone depletors and no class 2 Ozone depletors.
<u>Clean Water Act</u> : None of the chemicals in this product are listed as Hazardous Substances, as Priority Pollutants or as Toxic Pollutants under the CWA.
<u>U.S. State Regulations California Proposition 65</u> : This product does not contain any chemicals, which are on the California Proposition 65 list.
<u>International Regulations: Canadian Environmental Protection Act</u> : This product is a medical device and not subject to chemical notification requirements.
<u>European Community Labeling</u> : Not a dangerous preparation.
<u>European Inventory of New and Existing Chemicals Substances (EINECS)</u> : This product is a medical device and not subject to chemical notification requirements.
Other: Not Applicable

STATE REGULATIONS:

CAS No. 7783-48-4 can be found on the following state right to know lists: California, (listed as Fluorides) and (listed as Fluorides, inorganic) New Jersey, (listed as Fluorides) Pennsylvania, (listed as Fluorides) Minnesota, (listed as Fluorides, inorganic) and (listed as Fluorides)

16. Other Information

To the best of our knowledge this product does not contain gluten, wheat grains, flaxseed, natural rubber, or natural latex. All components are synthetically produced; none are derived from animal products. This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific products features and shall not establish a legally valid contractual relationship.

The attached safety data sheet covers the dangers and measures to be taken when large quantities of material are released, for example due to accidents during transport or storage by the dealer. For quantities of material typically used in clinical practice, information necessary for safe use and storage of the product is given in the DFU.

Abbreviations:

ACGIH = American Conference of Governmental Industrial Hygienists

AIHA = American Industrial Hygiene Association Workplace Environmental Exposure Level (WEEL)

EC50 = Effect Concentration 50%

FW = Fresh Water

IATA = International Air Transport Association

IMDG = International Maritime Dangerous Goods

LC50 = Lethal Concentration 50%

LD50 = Lethal Dose 50%

NIOSH = National Institute for Occupational Safety and Health

NTP = National Toxicology Program

OSHA = Occupational Safety and Health Administration

STEL = Short-term exposure limits

TWA = Time Weighted Average

WHMIS = Workplace Hazardous Materials Information System

Literature:

IARC = International Agency for Research on Cancer

RTECS = Register of Toxic Effects of Chemical Substances

Other information:

No special training is required. However, the user should be well instructed in the execution of his/her task, be familiar with this Safety Data Sheet and have normal training in the use of personal protective equipment. The above information, which is accurate to the best of our knowledge and belief, describes the safety aspects of our product but does not warrant any product properties.



1. Identification

Product Name Calibra® Bio	SDS Code Number 507699 - Liquid
Substance Identity Calibra® Bio (Bioceramic Luting Cement Liquid)	Date of Last Revision 08/1/18
Manufactured for: DENTSPLY LLC	Address: DENTSPLY LLC 38 West Clarke Avenue Milford DE 19963-1805 http://www.dentsplysirona.com
Grades or Minor Variant Identities Not Applicable	Company Telephone Number (Product Inquiries) (302) 422-4511 (8:00 AM – 4:30 PM Eastern Time)
Product Use (for Canada) Bioceramic Dental Luting Cement	Emergency Telephone Number CHEMTREC: 1-800-424-9300 (24 hours) (Outside U.S. +1-703-527-3887) CCN6510

2. Hazard(s) Identification



WARNING

Hazard statement(s)

- H315: Causes skin irritation.**
- H319: Causes serious eye irritation.**
- H335: May cause respiratory irritation.**

Precautionary statement(s)

- P280: Wear protective gloves/eye protection.**

Other hazards not otherwise classified:

Do not use in patients who have an allergy to polyacrylic acid. In very rare cases, the product may cause hypersensitivity symptoms in some patients. Discontinue use of the product if such symptoms occur and consult a doctor.

Ingredients with unknown acute toxicity: Not relevant.

3. Composition/Information on Ingredients

Hazardous Components	C.A.S. Number	Exposure Limits	%
Polyacrylic Acid	9003-01-4	Not Determined	< than 10
Tartaric Acid	87-69-4	Not Determined	< than 5
Trisodium nitrilotriacetate	5064-31-3	Not Determined	< than 1

Mixtures: The product consist of a powder base and a liquid base enclosed in a capsule (content 0.5 gm).

4. First Aid Measures

First aid measures by route of exposure:

Inhalation: Remove to fresh air. Get medical attention if any discomfort continues.

Skin contact: Wash skin thoroughly with soap and water. If irritation occur: Seek medical advice.

Eye contact: Flush with water or physiological salt water, holding eye lids open, remember to remove contact lenses, if any. If irritation persists: Seek medical advice.

Ingestion: Rinse mouth and drink plenty of water. **Do not induce vomiting.** Keep at rest. Get medical attention if any discomfort continues.

Most important symptoms and effects (acute or delayed): Inhalation of dust may irritate throat and respiratory system and cause coughing. May cause slight irritation of skin and eyes. May cause hypersensitivity symptoms in some patients.

Immediate medical attention and special treatment needed, if necessary: Show this safety data sheet to a physician or emergency ward. Treat symptomatically.

5. Fire Fighting Measures

Flame Propagation or Burning Rate (for Solids): Not Applicable	Properties Contributing to Fire Intensity Not Applicable	Flammability Classification: Not Applicable	Other: Not Applicable
Extinguishing Media: Dry-powder, water mist (never water jet), alcohol resistant foam or carbon dioxide (CO2).		Extinguishing Media to Avoid: Water with full jet.	
Protection and Procedures for Firefighters: Firefighters should wear self-contained respiratory protective devices.			

6. Accidental Release Measures

Personal precautions, protective equipment, and emergency procedures: Use personal protective equipment - see section 8.

Do not empty into drains. Inform appropriate authorities in accordance with local regulations.

Methods and materials for containment and cleaning up: Sweep up and place in a suitable container. Flush area of spill with plenty of water. Further handling of spillage - see section 13.

7. Handling and Storage

Handling Practices and Warnings: Product is intended for dental use only. Handling of this product should be by trained dental healthcare professionals only. Observe normal care for working with chemicals. Use only as described in "Instruction for use". Provide adequate ventilation. Avoid contact with skin and eyes. Wash with water and soap after work. Do not eat, drink or smoke during use.

Storage Practices and Warnings: Store only in the original package. Keep package tightly sealed. Store in a dry area. Protect from exposure to direct light. Store away from food and beverages. Conditions for safe storage (including incompatible materials): Store dry at temperatures between +4 and +25°C. (39°F- 77°F). Keep away from substances mentioned in section 10.

8. Exposure Control / Personal Protection



Occupational Exposure Limits: Not Applicable

OSHA Permissible Exposure Limits (PEL): No substance listed with an exposure limit.

Other exposure limit used or recommended: None known.

Appropriate engineering controls: Facilities storing or utilizing this material should be equipped with an eyewash facility and a safety shower. Provide adequate ventilation in working areas to keep airborne concentrations low.

Individual protection measures, such as personal protective equipment (PPE): PPE must follow OSHA regulations found in 29 CFR 1910.132 and should be chosen in collaboration with the supplier of such equipment. The recommended PPE and the specified standards are only suggestions, as a risk assessment of the relevant current work/operation may lead to other control measures.

Eye/face protection: Wear tight fitting safety goggles (as described by OSHA's eye and face protection regulations in 29 CFR 1910.133 or EN166) when risk of splashes.

Skin/hand protection: By prolonged contact: Wear protective gloves of for instance nitrile rubber. Breakthrough time of the ingredients is not available. Discard gloves at any suspicion of contamination.

Respiratory protection: Respiratory equipment is normally not required.

9. Physical and Chemical Characteristics

Appearance: Capsules containing liquid.		Odor: No characteristic odor.
Normal Physical State: Plastic capsule		Melting Point: Not Determined
Specific Gravity: Not Determined	Solubility in Water: Not soluble	pH: Not Determined
Vapor Pressure (mm Hg): Not Determined	Vapor Density (AIR=1): Not Determined	Evaporation Rate (Butyl Acetate =1): Not Determined
Flashpoint Method: Not Determined	Flammable (Explosive) Limits in Air LEL: Not Applicable UEL: Not Applicable	Autoignition Temperature: Not Determined
Other: Not Applicable		

10. Stability and Reactivity Data

Reactivity: None known.

Chemical stability: Stable under normal conditions and recommended use.

Possibility of hazardous reactions: None known.

Conditions to avoid: Strong heat.

Incompatible materials: Strong oxidizers, strong acids and strong bases.

Hazardous decomposition products: When heated to high temperatures (decomposition), the product emits very toxic fumes such as oxides of carbon.

11. Toxicological Information

Toxicity Data, Epidemiology Studies, Carcinogenicity, Neurological Effects, Genetic Effects, Reproductive Effects, or Structure Activity Data:

Information on toxicological (health) effects: Likely routes of exposure: Inhalation, skin and ingestion.

Symptoms: Symptoms may occur if dust is released from the capsule by accident.

Emergency Overview Material is irritating to eyes, respiratory system and skin.

Delayed and immediate effects and chronic effects from short-term and long-term exposure: High concentration of inorganic fluorides may cause skeletal fluorosis with symptoms such as periodical pain and stiffness in the joints, headache, abdominal pain and muscle weakness. Later osteoporosis and bone damages may occur. Loss of weight. Anorexia and anemia are common findings in fluorine poisoning. Skin sensitization to polyacrylic acid may occur in very rare cases. Symptoms are redness, itching and eczema.

Routes of Exposure	Signs and Symptoms	Single, Repeated, or Lifetime Exposure	Severity (Mild, Moderate, Severe)	Acute and Chronic Health Effect(s)	Target Organ(s)
Eye	May cause slight irritation with redness and stinging.	Single	Mild	Irritation and possible corneal damage	Not Applicable
Skin	May cause slight irritation with redness.	Single	Mild	Irritation or possible allergic response. Severe allergic response may result in breathing difficulties.	Not Applicable
Inhalation	Inhalation may cause	Single	Slight	Irritation	Not Applicable

	irritation of the respiratory system.				
Ingestion	May cause irritation of the gastrointestinal tract, nausea, vomiting, salivation, fever and headache.	Single	Slight	Irritation	Not Applicable
Mucosa	Material can cause irritation.	Single	Slight	Irritation of the mucosa	Not Applicable
Medical Conditions Aggravated by Exposure: Open sores and wounds of the skin.					
Carcinogenicity NTP?: Not listed IARC monographs?: Not listed OSHA regulated?: No All components of this product are in compliance with the inventory listing Requirements of the U. S. Toxic Substances Control Act (TSCA) Chemical Substance Inventory.					
Potential Environmental Effects Do not allow to enter sewers/ surface or ground water.					
NFPA Hazard Classification Ratings (Scale 0-4), Health = 1, Fire = 1, Reactivity = 0					

Acute Toxicity:

Hazard class	Data	Test	Data source
Acute toxicity:			
Inhalation	LC50 (rat) > 5 mg/l (NTA)	OECD 401	IUCLID
Dermal	LD50 (rat) > 2000 mg/kg (Tartaric acid)	OECD 402	RTECS
Oral	LD50 (rabbit) > 2000 mg/kg (NTA)	OECD 402	ECHA diss.
	LD50 (rat) = 2500 mg/kg (Polyacrylic acid)	No data	Supplier
	LD50 (rat) > 2000 mg/kg (Tartaric acid)	OECD 423	RTECS
	LD50 (rat) > 1440 mg/kg (NTA)	OECD 403	ECHA diss.
Corrosion/irritation:	Irritant to skin and eyes (Polyacrylic acid)	No data.	Supplier
	In vitro eye irritant (Tartaric acid)	OECD 437	ECHA diss.
	No skin irritation, rabbit (Tartaric acid)	OECD 404	RTECS
	No skin irritation, rabbit (NTA)	OECD 404	Supplier
	Eye irritation, rabbit (NTA)	OECD 405	Supplier
Sensitization:	Not a skin sensitizer (Tartaric acid)	OECD 429	RTECS
	Not a skin sensitizer, guinea pig (NTA)	OECD 406	Supplier

The chemical, physical and toxicology properties of strontium fluoride have not been thoroughly investigated and recorded.

Mutagenic toxicity: No available data/insufficient data.

Reproductive toxicity: No available data/insufficient data.

Carcinogenic toxicity: NTA is suspected of causing cancer (IARC monograph vol. 73: group 2B). NTA is mentioned on NTP's Report on Carcinogens (RoC), latest ed. Nitrotriacetic acid and its salts are reasonably anticipated to be a human carcinogen based on sufficient evidence of carcinogenicity from studies in experimental animals.

Specific Target Organ Toxicity: Polyacrylic acid may cause respiratory irritation.

12. Ecological Information

Toxicity Data, Environmental Fate, Physical/Chemical Data, or other Data Supporting Environmental Hazard Statements: Water Hazard class I (Self-assessment): slightly hazardous for water. Do not allow undiluted product or large quantities of it to reach ground water, water streams or sewage system.

Ecotoxicity:

Aquatic	Data	Test (Media)	Data source
Fish	LC50 (Brachydanio rerio, 96h) > 100 mg/l (Polyacrylic acid)	No data (FW)	Supplier
	LC50 (Pimephales promelas, 96h) = 127 mg/l (NTA)	No data (FW)	Supplier
Crustaceans	EC50 (Daphnia magna, 48h) > 100 mg/l (Polyacrylic acid)	No data (FW)	Supplier
	EC50 (Daphnia magna, 48h) = 93.3 mg/l (Tartaric acid)	OECD 202 (FW)	Supplier
	EC50 (Daphnia magna, 48h): 560-1000 mg/l (NTA)	No data (FW)	Supplier
Algae	EC50 (Scenedesmus subspicatus, 72h) > 180 mg/l (Polyacrylic acid)	No data (FW)	Supplier
	EC50 (Algae, 72h) = 51.4 mg/l (Tartaric acid)	OECD 201 (FW)	Supplier
	EC50 (Scenedesmus subspicatus, 72h) > 100 mg/l (NTA)	No data (FW)	Supplier

Persistence and degradability: Polyacrylic acid is not considered readily biodegradable.

Tartaric acid was degraded 85% in 28 days at an OECD 306 test and is considered rapidly degradable.

NTA was degraded >90% in 28 days at an OECD 301B test and is considered rapidly degradable.

The cured product is not expected to be biodegradable.

Bioaccumulative potential: Polyacrylic acid: Log K_{ow} = 0.44 (no significant bioaccumulative effect).

Tartaric acid: Log K_{ow} = 0.24 (no significant bioaccumulative effect).

Mobility in soil: Low mobility in soil is expected.

Other adverse effects: None known.

13. Disposal Considerations

Disposal considerations: Dispose of contents/container in accordance with applicable local/regional/national/international regulations. See Section 8 for guidance on PPE. Incinerate and dispose of waste product in a permitted waste incineration facility/industrial waste facility. Chemical waste generators must determine whether a discarded chemical is classified as a hazardous waste. US EPA guidelines for the classification determination are listed in 40 CFR Parts 261.3. Additionally, waste generators must consult state and local hazardous waste regulations to ensure complete and accurate classification.

RCRA P-Series: None listed.


RCRA U-Series: None listed.

14. Transport Information

Not dangerous goods according to US DOT.

UN-no.: Not Applicable **UN proper shipping name:** Not Applicable **Hazard Class:** Not Applicable **Packing Group:** Not Applicable **IMDG:** Not Applicable. **Canadian Transportation of Dangerous Goods (TDG):** None.

15.Regulatory Information

This product has been classified in accordance with the hazard criteria of the Globally Harmonized System of Classification and Labeling of Chemicals and the SDS contains all of the information required by the Canadian Controlled Products Regulations.
U.S. Federal Regulations: <u>CERCLA 103 Reportable Quantity:</u> This product is not subject to CERCLA reporting requirements. Many states have more stringent release reporting requirements. Report spills required under federal, state and local regulations
<u>EPA Toxic Substances Control Act (TSCA) Status:</u> All of the components of this product are listed on the TSCA inventory.
<u>U.S. State Regulations California Proposition 65:</u>  WARNING: This product can expose you to Nitrilotriacetic acid, trisodium salt monohydrate (NTA), which is known to the State of California to cause cancer. For more information go to www.P65Warnings.CA.gov .
<u>International Regulations: Canadian Environmental Protection Act:</u> This product is a medical device and not subject to chemical notification requirements.
<u>European Community Labeling:</u> Not a dangerous preparation.
<u>European Inventory of New and Existing Chemicals Substances (EINECS):</u> This product is a medical device and not subject to chemical notification requirements.
Other: Not Applicable

US Federal Regulations

NATIONAL INVENTORY STATUS - U.S. Inventory (TSCA):

CAS No. 87-69-4 is listed on TSCA inventory.

CAS No. 5064-31-3 is listed on TSCA inventory.

CAS No. 9003-01-4 is listed on TSCA inventory (polymer).

TSCA section 12b: None of the chemicals in the product are listed.

SARA Title III (Superfund Amendments and Reauthorization Act)

SARA Title III Sect. 302 Extremely Hazardous Substances (40 CFR 355): None of the chemicals are listed.

SARA Title III Sect. 311/312 Extremely Hazardous Categories (40 CFR 370.21): Immediate Hazard: None of the chemicals are listed.

Clean Air Act: This product does not contain any hazardous air pollutants, no class 1 Ozone depletors and no class 2 Ozone depletors.

Clean Water Act: None of the chemicals in this product are listed as Hazardous Substances, as Priority Pollutants or as Toxic Pollutants under the CWA.

16.Other Information

To the best of our knowledge this product does not contain gluten, wheat grains, flaxseed, natural rubber, or natural latex. All components are synthetically produced; none are derived from animal products. This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific products features and shall not establish a legally valid contractual relationship.

The attached safety data sheet covers the dangers and measures to be taken when large quantities of material are released, for example due to accidents during transport or storage by the dealer. For quantities of material typically used in clinical practice, information necessary for safe use and storage of the product is given in the DFU.

Abbreviations:

ACGIH = American Conference of Governmental Industrial Hygienists

AIHA = American Industrial Hygiene Association Workplace Environmental Exposure Level (WEEL)

EC50 = Effect Concentration 50%

FW = Fresh Water

IATA = International Air Transport Association

IMDG = International Maritime Dangerous Goods

LC50 = Lethal Concentration 50%

LD50 = Lethal Dose 50%

NIOSH = National Institute for Occupational Safety and Health

NTP = National Toxicology Program

OSHA = Occupational Safety and Health Administration

STEL = Short-term exposure limits

TWA = Time Weighted Average

WHMIS = Workplace Hazardous Materials Information System

Literature:

IARC = International Agency for Research on Cancer

RTECS = Register of Toxic Effects of Chemical Substances

Other information:

No special training is required. However, the user should be well instructed in the execution of his/her task, be familiar with this Safety Data Sheet and have normal training in the use of personal protective equipment. The above information, which is accurate to the best of our knowledge and belief, describes the safety aspects of our product but does not warrant any product properties.