

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE OF THE COMPANY/UNDERTAKING

1.1 PRODUCT IDENTIFIER:

Product Name: Avalon Biomed NeoSEALER® EZFlo

Trade Name & Synonyms: NeoSEALER® EZFlo

1.2 RELEVANT IDENTIFIED USES OF SUBSTANCE OR MIXTURE/RECOMMENDED USE:

Dental materials for professional use only.

1.3 DETAILS OF THE MANUFACTURER OF THE SAFETY DATA SHEET:

Manufactured by: NuSmile Ltd.

Address: 3315 W. 12th Street Houston, TX 77008 USA

Website: www.avalonbiomed.com

Telephone Number: 713-861-0033; Int'l 1-800-346-5133

E-mail: info@avalonbiomed.com

1.3.1 DETAILS OF THE MANUFACTURER AUTHORIZED REPRESENTATIVE:

European Authorized Representative: MDSS GmbH

Address: Schiffgraben 41 30175 Hannover Germany

Website: www.mdss.com

Telephone Number: +49 511 6268630

E-mail: info@mdssar.com

United Kingdom Authorized Representative: MDSS-UK RP Ltd.

Address: Parkway House, Palatine Rd, Northenden, Wythenshawe Manchester M33 4db United Kingdom

Website: www.mdss.com

Telephone Number: +44 7898 375 115

E-mail: info@mdssar.com

Switzerland Authorized Representative: MDSS CH GmbH

Address: Laurenzenvorstadt 61 5000 Aarau Switzerland

Website: www.mdss.com

Telephone Number: +49 511 6262 8630

E-mail: info@mdssar.com

1.4 EMERGENCY CONTACT:

United States:

1-800-222-1222 (poison center); Availability: 24 hours

911 (general emergency services); Availability: 24 hours

Canada:

1-844-764-7669 (poison centres); Availability: 24 hours

911 (general emergency services); Availability: 24 hours

European Union:

112 (general emergency services); Availability: 24 hours

UK

999 (general emergency services); Availability: 24 hours

Switzerland:

145 (Toxicological Information Centre Tox Info Suisse); Availability: 24 hours

117 (general emergency services); Availability: 24 hours

*Contact applicable jurisdiction Poison Center in case of an emergency.

2. HAZARD IDENTIFICATION

2.1 CLASSIFICATION (OSHA/WHMIS/GHS/EU CLP/GB CLP):

Skin Irrit. Category 2 (H315); Eye Irrit. Category 2 (H319); STOT SE Category 3 (H335)

2.2 GHS/CLP LABEL ELEMENTS:

SYMBOL:



GHS07

SIGNAL WORD: Warning

HAZARD STATEMENTS:

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

PRECAUTIONARY STATEMENTS:

PREVENTION:

- P264 Wash hands, forearms, and face thoroughly after handling.
- P280 Wear eye protection.
- P260: Do not breathe dust/fume/gas/mist/vapours/spray.
- P262: Do not get in eyes, on skin, or on clothing.

RESPONSE:

- P342+P316: If experiencing respiratory symptoms: Get emergency medical help immediately.
- P332+P317: If skin irritation occurs: Get medical help.
- P337+P317: If eye irritation persists: Get medical help.
- P305+P354+P338: IF IN EYES: Immediately rinse with water for several minutes. Remove contact lenses if present and easy to do. Continue rinsing.

2.3 OTHER HAZARDS: Emergency Overview, it is unlikely that exposure to small amounts for short periods, may have any irritant or toxic effect.

ROUTES OF EXPOSURE	SIGNS AND SYMPTOMS	SINGLE, REPEATED, OR LIFETIME EXPOSURE	SEVERITY (MILD, MODERATE, SEVERE)	ACUTE AND CHRONIC HEALTH EFFECT(S) OF HAZARDOUS COMPONENT	TARGET ORGAN(S)
Eye	It can cause eye immediate or delayed irritation of cornea.	Single	Mild	May cause permanent eye damage if left untreated.	Eyes
Skin	Exposure may cause drying of the skin with mild irritation. Discomfort or pain cannot be relied upon to alert a person to hazardous skin exposure.	Single	Mild	Acute irritation to skin and mucous membranes. Can aggravate other skin conditions.	Skin
Inhalation	Exposure may cause irritation to the moist mucous membranes of the nose, throat, and upper respiratory system.	Single	Mild	Acute irritation to throat and respiratory system resulting in coughing. Frequent inhalation of large quantities of dry paste over a long period of time increases the risk of lung diseases.	Upper Respiratory System
Ingestion	Internal discomfort or ill effects are possible if large quantities are swallowed.	Single	Mild	Acute irritation to stomach causes vomiting.	Digestive System
Other	-	-	-	-	-

2.3.1 MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE: Pre-existing upper respiratory and lung diseases may be aggravated by inhalation.

2.3.2 CARCINOGENICITY (IARC, NTP): None known.

2.3.3 POTENTIAL ENVIRONMENTAL EFFECTS: Powder with moisture hardens into a solid mass that is not biodegradable.

3. COMPOSITION OF INGREDIENTS

HAZARDOUS COMPONENTS	CAS. NUMBER	EC NUMBER	CLASSIFICATION	%
Ta2O5-Tantalum pentoxide	1314-61-0	215-238-2	Skin Irrit. 2 (H315); Eye Irrit. 2 (H319); STOT SE 3 (H335).	<50
3CaO·SiO2-Tricalcium Silicate	12168-85-3	235-336-9	Skin Irrit. 2 (H315)	<25
CaAl2O4 -Calcium Aluminate	65997-16-2	266-045-5	Eye Irrit. 2 (H319)	<25
2CaO·SiO2-Dicalcium Silicate	10034-77-2	233-107-8	Not classified	<10
CaAl4O7-Calcium Dialuminate	12004-88-5	234-463-7	Not classified	<15
Al2Si2O5(OH)4·2H2O-Aluminosilicate	1332-58-7	310-194-1	Eye Irrit. 2 (H319) Skin Irrit. 2 (H315)	<10

4. FIRST AID MEASURES

Routes of Exposure	First Aid Instructions	Immediate Medical Attention	Effects	
			Acute	Delayed
Eye	Immediately flush eyes thoroughly with water. Continue flushing eye for at least 15 minutes, including under lids, to remove all particles. Call physician immediately.	Get medical attention immediately, even if no symptoms develop.	Irritation	Eye Damage
Skin	Immediately flush skin with plenty of cool soapy water. Remove contaminated clothing and wash contact areas thoroughly. Seek medical attention in all cases of prolonged exposure.	Get medical attention.	Irritation	Skin Condition
Inhalation	Move to fresh air. Seek medical help if coughing and other symptoms do not subside.	Get medical attention.	Irritation	Lung Disease
Ingestion	Do not induce vomiting. Vomiting should only be induced by medical personnel. If vomiting occurs/continues, seek medical attention. Never give anything by mouth to an unconscious or convulsing person.	Get medical attention.	Vomiting	-
Other	Seek medical advice after large-scale (>25 g) exposure.	-	-	-

Note to physicians (treatment, testing, and monitoring): Treat symptomatically.

5. FIRE AND EXPLOSION DATA

5.1 EXTINGUISHING MEDIA: Water spray, alcohol resistant foam, carbon dioxide, or dry chemical.

5.1.1 EXTINGUISHING MEDIA TO AVOID: None

5.2 SPECIAL HAZARDS ARISING FROM THE SUBSTANCE MIXTURE: Irritating fumes may be released by thermal decomposition which may be hazardous to health. Fire may produce thick black smoke. Fumes of silicon dioxide or carbon monoxide and carbon dioxide may evolve from material in a fire.

5.2.1 FLASHPOINT & METHOD: > 200 °C (open cup)

5.2.2 FLAMMABLE (EXPLOSIVE) LIMITS IN AIR LEL/UEL: N/A

5.2.3 AUTOIGNITION TEMPERATURE: 260°C

5.2.4 FLAME PROPAGATION OR BURNING RATE (FOR SOLIDS): N/A

5.2.5 PROPERTIES CONTRIBUTING TO FIRE INTENSITY: None

5.2.6 FLAMMABILITY CLASSIFICATION: 1

5.2.7 OTHER: Slight fire hazard. In case of combustion, it may generate minor amounts of CO & CO₂.

5.3 ADVICE FOR FIREFIGHTERS: Water jets should not be used directly on igniting products because they may disperse the material and intensify the fire. Self-contained breathing apparatus and protective clothing are required. Cool intact fire-exposed containers with water spray and remove them.

6. ACCIDENTAL RELEASE MEASURES

6.1 PERSONAL PRECAUTIONS, PROTECTIVE EQUIPMENT AND EMERGENCY PROCEDURES: Wear appropriate personal protective equipment to prevent contamination of skin, eyes and personal clothing. Avoid contact with eyes, extended skin exposure, actions that cause dried up product to become airborne, inhalation of dried product dust. Use a scoop or moist paper towel(s) to clean up spilled product.

6.2 ENVIRONMENTAL PRECAUTIONS: Prevent further spillage. Keep the product away from drains, surface and ground water.

6.3 METHODS AND MATERIAL FOR CONTAINMENT AND CLEANING UP: Wipe up spills with moist rags or vacuum immediately to prevent dust of material from being dispersed, and discard in trash. Avoid skin contact and inhalation. Dispose of container and unused contents in accordance with federal, state, and local requirements. Discard in trash. Prevent any material from entering drains or waterways.

6.4 REFERENCE TO OTHER SECTIONS: Evacuation Procedures: N/E; Special Instructions: N/E; Reporting Requirements: N/E

7. HANDLING AND STORAGE

7.1 PRECAUTIONS FOR SAFE HANDLING: Paste is caustic. Keep out of eyes, lungs, or contact with mucosal tissues. After incidental contact, wash and rinse with water. Wear suitable gloves and protective glasses during use. Keep well sealed and free of contamination by pyrogens. Protect from humidity. Do not contaminate with a contaminated instrument. Trained personnel use this product exclusively for dental purposes.

7.2 CONDITIONS FOR SAFE STORAGE, INCLUDING ANY INCOMPATIBILITIES: Store at temperatures at room temperature, do not refrigerate. Keep container tightly closed; material is hydrophilic. Inadequate storage conditions will shorten the shelf life.

7.3 SPECIFIC END USE(S): Dental materials for professional use only.

8. EXPOSURE CONTROL/PERSONAL PROTECTION

8.1 CONTROL PARAMETERS: No occupational exposure limits established for this mixture.

8.1.1 APPROPRIATE ENGINEERING CONTROLS: Use in a well-ventilated area.

8.2 EXPOSURE CONTROLS:

ROUTES OF ENTRY:	PERSONAL PROTECTIVE EQUIPMENT (PPE)
Eye/Face	Face mask & safety glasses
Hands/Skin	Wear latex or nitrile gloves and avoid skin contact.
Inhalation	Face mask

8.2.1 GENERAL HYGIENE CONSIDERATIONS AND WORK PRACTICES: Wear gloves as per universal precautions in dentistry. Wash your hands after use. No eating, drinking, or smoking while handling this product. Remove and wash clothing with spills of material on clothing.

8.2.2 PROTECTIVE MEASURES DURING REPAIR AND MAINTENANCE OF CONTAMINATED EQUIPMENT: Use water to remove dust. Use vinegar to dissolve hardened material.

9. PHYSICAL AND CHEMICAL CHARACTERISTICS

9.1 INFORMATION ON BASIC PHYSICAL AND CHEMICAL PROPERTIES:

Appearance: Paste	Boiling Point: N/A	Melting Point: N/A	Freezing Point: ~12°C (55°F)
Specific Gravity or Density (H ₂ O=1): ~2.5	Solubility in Water: Reacts & sets with water	pH: ~10-12 mixed with water	Odor: None
Vapor Pressure (mm Hg @ 20°C): ~0	Vapor Density (AIR= 1): N/A	Evaporation Rate (Butyl Acetate = 1): N/A	Normal Physical State: ☐ Liquid ☐ Gas x Solid

9.2 OTHER INFORMATION: None

10. STABILITY AND REACTIVITY DATA

10.1 REACTIVITY: Contact with water will result in hydration of the product leading to hardening.

10.2 CHEMICAL STABILITY: Stable under recommended storage conditions. Keep dry.

10.3 POSSIBILITY OF HAZARDOUS REACTIONS: May cause irritation.

10.4 CONDITIONS TO AVOID: Avoid unintentional contact with water to prevent premature setting.

10.5 INCOMPATIBLE MATERIALS: Keep dry to avoid reaction with moisture otherwise the product hardens into stable hydrates.

10.6 HAZARDOUS DECOMPOSITION PRODUCTS: Decomposition will not spontaneously occur. Contact with water will result in hydration of the product and lead to hardening.

11. TOXICOLOGICAL INFORMATION

11.1 INFORMATION ON HAZARD CLASSES:

NUMERICAL TOXICITY VALUES:

HAZARDOUS COMPONENTS	CAS. NUMBER	ORAL	DERMAL	INHALATION
Ta2O5-Tantalum pentoxide	1314-61-0	LD50: > 5.000 mg/kg. (Rat)	LD50: > 2.000 mg/kg (Rat) LD50: > 5.05 mg/l (Rat)	N/A
3CaO·SiO2-Tricalcium Silicate	12168-85-3	N/A	N/A	N/A
CaAl2O4 -Calcium Aluminate	65997-16-2	N/A	N/A	N/A
2CaO·SiO2-Dicalcium Silicate	10034-77-2	N/A	N/A	N/A
CaAl4O7-Calcium Dialuminate	12004-88-5	N/A	N/A	N/A
Al2Si2O5(OH)4·2H2O-Aluminosilicate	1332-58-7	N/A	N/A	N/A

11.2 INFORMATION ON OTHER HAZARDS:

11.2.1 ACUTE TOXICITY: Product is not classified as a toxic substance.

11.2.2 SKIN CORROSION / IRRITATION : May cause skin irritation.

11.2.3 SERIOUS EYE DAMAGE / IRRITATION: May cause serious eye irritation.

11.2.4 RESPIRATORY OR SKIN SENSITIZATION: May cause irritation.

11.2.5 GERM CELL MUTAGENICITY: No mutagenic effect.

11.2.6 CARCINOGENICITY (NTP, IARC, OSHA): No carcinogenic effect.

11.2.7 REPRODUCTIVE TOXICITY: Not available

11.2.8 SPECIFIC TARGET ORGAN TOXICITY (STOT) – SINGLE EXPOSURE: Product is not classified as a toxic substance.

11.2.9 SPECIFIC TARGET ORGAN TOXICITY (STOT) – REPEATED EXPOSURE: Product is not classified as a toxic substance.

11.2.10 ASPIRATION HAZARD: Not available.

11.2.11 INTERACTIVE EFFECTS: Not available.

12. ECOLOGICAL INFORMATION

12.1 TOXICITY: No specific ecotoxicological data is available for this mixture.

12.2 PERSISTENCE AND DEGRADABILITY: The product reacts with moisture to form a solid mass that is not biodegradable.

12.3 BIOACCUMULATIVE POTENTIAL: The product is not expected to bioaccumulate due to its inorganic composition and low mobility.

12.4 MOBILITY IN SOIL: The product has low mobility in soil. Upon contact with water, it hardens into a solid material, limiting dispersion in the environment.

12.5 RESULTS OF PBT AND VPVB ASSESSMENT: This mixture does not contain substances classified as PBT or vPvB.

12.6 ENDOCRINE DISRUPTING PROPERTIES: No data available.

12.7 OTHER ADVERSE EFFECTS: No known significant effects or critical hazards. Avoid release into the environment and prevent entry into drains, waterways, and soil.

13. DISPOSAL CONSIDERATIONS

13.1 WASTE TREATMENT METHODS:

13.1.1 REGULATIONS: Dispose of container and unused contents in accordance with federal/state/local/regional/national/international requirements. Do not pour into drains or waterways. Wash the contaminated surface with water.

13.1.2 PROPERTIES (PHYSICAL/CHEMICAL) AFFECTING DISPOSAL: Do not spread dust. When mixed with water, a solid, non-biodegradable mass will form.

14. TRANSPORT INFORMATION

14.1 UN NUMBER OR ID NUMBER: Not applicable, the product is not classified as Dangerous Goods.

14.2 UN PROPER SHIPPING NAME: Not applicable, the product is not classified as Dangerous Goods.

14.3 TRANSPORT HAZARD CLASS(ES): Not classified as a transport hazard in accordance with the UN Model Regulations.

14.4 PACKING GROUP: Not applicable, the product is not classified as Dangerous Goods.

14.5 ENVIRONMENTAL HAZARDS: Not applicable, the product is not classified as Dangerous Goods.

14.6 SPECIAL PRECAUTIONS FOR USER: Not applicable.

14.7 MARITIME TRANSPORT IN BULK ACCORDING TO IMO INSTRUMENTS: Not applicable.

15. REGULATORY INFORMATION

15.1 SAFETY, HEALTH AND ENVIRONMENTAL REGULATIONS/LEGISLATION SPECIFIC FOR THE SUBSTANCE OR MIXTURE: The regulations listed below are the key regulatory frameworks that impact the product. There are no specific/additional regulations that apply.

15.1.1 UNITES STATES OF AMERICA (USA):

This product is subject to the provisions of the following USA regulations:

- TSCA (Toxic Substances Control Act) inventory status
- OSHA Hazard Communication Standard (29 CFR 1910.1200)
- CERCLA / SARA (Sections 302, 311/312, 313)

15.1.2 CANADA (CA):

This product is subject to the provisions of the following CA regulations:

- DSL/NDL (Domestic Substances List / Non-Domestic Substances List)
- WHMIS classification (Workplace Hazardous Materials Information System)
- Canadian Environmental Protection Act (CEPA)

15.1.3 EUROPE (EU):

This product is subject to the provisions of the following EU regulations:

- Regulation (EC) No. 1272/2008 (CLP) on classification, labelling, and packaging of substances and mixtures
 - Regulation (EC) No. 1907/2006 (REACH) concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals
- Inclusive of various European Member State national regulations.

15.1.4 UNITED KINGDOM (UK):

This product is subject to the provisions of the following UK regulations:

- UK REACH (as amended)
- GB CLP (retained EU Regulation (EC) No 1272/2008 as amended)

15.2 CHEMICAL SAFETY ASSESSMENT: This device is classified as an irritant: Skin irritation (Category 2) Eye irritation (Category 2A/2) Respiratory Irritation (Category 3).

16. OTHER INFORMATION

This product must be used in accordance with the manufacturer's instructions. Users should be properly trained and are responsible for complying with all applicable laws and safe handling practices. The suitability of the product for its intended use must be determined by the user. The information provided is believed to be accurate but is not exhaustive and is intended as guidance only. It is based on current knowledge and does not constitute a guarantee of product properties. The manufacturer shall not be held liable for any damage resulting from handling, misuse, or improper use of this product.

N/A= not applicable. N/D= not determined. N/E= not established.