

SAFETY DATA SHEET

according to Regulation (EC) No. 453/2010
Dental Use

SUNSTAR

GUM BUTLER  **GUIDOR** 

Date Issued : 04/18/2017
SDS No : 168-250.2
Date Revised : 05/18/2017
Revision No : 1

Butler® Monsterz Clear Fluoride Varnish (All Flavors)

SECTION 1 : Identification of the substance/preparation and of the company/undertaking

1.1. Product identifier

Product code : 1219P (3B/1005218, 3C/1005219, IY/71122, 7T/1006179)
Product name : Butler® Monsterz Clear Fluoride Varnish (All Flavors)
Product description : 5% Sodium Fluoride Varnish

1.2. Relevant identified uses of the substance or mixture and uses advised against

Relevant identified uses : Professional Dental Varnish

1.3. Details of the supplier of the safety data sheet

Manufacturer

Sunstar Americas Inc.
301 E Central Road
Schaumburg, IL 60195

Service Number : 847-794-4400
E-Mail : <http://www.gumbrand.com>

1.4. Emergency telephone number

Emergency number : 1-800-752-7869

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation(EC) No 1272/2008 [CLP]

Health : Acute Toxicity (Oral), Category 3
Acute Toxicity (Inhalation), Category 1
Acute Toxicity (Dermal), Category 4

Environmental : Flammable Liquids, Category 2

2.2. Label elements

Classification according to Regulation(EC) No 1272/2008 [CLP]

Hazard pictogram(s) :



Flame



Skull and
crossbones

Signal Word : DANGER

Hazard statement(s) : H225: Highly flammable liquid and vapour.
H312: Harmful in contact with skin.
H302: Harmful if swallowed.
H331: Toxic if inhaled.

Precautionary statement(s)

Prevention : P280: Wear protective gloves/protective clothing/eye protection/face protection.
P240: Ground and bond container and receiving equipment.

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P210: Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

P233: Keep container tightly closed.

P243: Take action to prevent static discharges.

P241: Use explosion-proof [electrical/ventilating/lighting] equipment.

P242: Use non-sparking tools.

P270: Do not eat, drink or smoke when using this product.

P264: Wash hands thoroughly after handling.

P260: Do not breathe dust/mist.

P271: Use only outdoors or in a well-ventilated area.

P284: [In case of inadequate ventilation] wear respiratory protection.

Response

: P370+P378: In case of fire: Use Water spray, alcohol-resistant foam, dry chemical or carbon dioxide to extinguish.

P301 + P310: IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician.

P330: Rinse mouth.

P304+P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing.

P310: Immediately call a POISON CENTER or doctor/physician.

P302+P352: IF ON SKIN: Wash with plenty of soap and water.

P312: Call a POISON CENTER or doctor/physician if you feel unwell.

P363: Wash contaminated clothing before reuse.

Storage

: P273: Avoid release to the environment.

P403+P235: Store in a well-ventilated place. Keep cool.

P403+P233: Store in a well-ventilated place. Keep container tightly closed.

P405: Store locked up.

Disposal

: P501: Dispose of in compliance with governmental regulation. (EC 1975L0442-21/11/2003)

2.3. Other hazards

Conclusion: The substance does not fulfill the PBT and vPvB criteria for screening assessment; there are no indications of P or B properties.

SECTION 3: Composition / information on ingredients

3.1. Substances

Not Applicable

3.2. Mixtures

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Chemical Name	CAS	EINECS No.	Wt.%	Classification according to Regulation(EC) No 1272/2008 [CLP]
Synthetic Resin	68990-02-3	273-574-5	< 60	Not classified
Ethyl Alcohol	64-17-5	200-578-6	< 30	Flam. Liq.,Cat. 2; Skin Irr.,Cat. 2; Eye Irr.,Cat. 2; Acute Tox. (O),Cat. 4; STOT SE,Cat. 1; H225; H319
Sodium Fluoride	007681-49-4	231-667-8	5	Skin Irr.,Cat. 2; Eye Irr.,Cat. 2A; Acute Tox. (O),Cat 3; H301; H315; H319
Methyl ester of hydrogenated rosin	8050-15-5	232-476-2	5	Aquatic Chronic,Cat 3; H412

For full text of H-statements: see SECTION 16.

SECTION 4: First aid measures

4.1. Description of first aid measures

- Following eyes** : Flush eyes with water for at least 15 minutes. Get medical attention if eye irritation develops or persists.
- Following skin** : Wash with soap and water. Get medical attention if irritation develops or persists.
- Following ingestion** : If swallowed in large quantities, rinse mouth out with water. Seek medical advice if you feel unwell.
- Following inhalation** : If inhaled, remove victim to fresh air. Seek immediate medical assistance.

4.2. Most important symptoms and effects, both acute and delayed

- Eyes** : May cause irritation.
- Skin** : May cause irritation.
- Ingestion** : May be harmful if swallowed in large quantities.
- Inhalation** : Toxic if inhaled

4.3. Indication of any immediate medical attention and special treatment needed

- Notes to physician** : NAP

SECTION 5: Fire fighting measures

5.1. Extinguishing media

- Extinguishing media** : Water spray, alcohol-resistant foam, dry chemical or carbon dioxide

5.2. Special hazards arising from the substance or mixture

- Hazardous combustion products** : Not determined

5.3. Advice for firefighters

- Fire fighting procedures** : General: Evacuate all personnel; use protective equipment for fire-fighting. Use self-contained breathing apparatus when the product is involved in fire.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

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General procedures : Refer to Section 8 for Personal Protective Equipment.

6.2. Environmental precautions

Water spill : Do not allow to enter sewers or drains that may lead to waterways.

6.3. Methods and material for containment and cleaning up

Small Spill : Wipe up small amounts with chemical resistant or damp rag which is washed with large amounts of water after each use. After cleaning, flush away traces with water.

Large Spill : Remove all sources of ignition. Ventilate area of leak or spill. Pick up spill for recovery or disposal and place into sealed containers.

6.4. Reference to other sections

Reference to other sections : NAP

SECTION 7: Handling and storage

7.1. Precautions for safe handling

General procedures : Avoid prolonged inhalation and contact with eyes and skin.

Handling : Keep away from heat, sparks, and flame. Avoid contact with skin and eyes. Avoid inhalation of vapor or mist.

Storage : See product labeling.

7.2. Conditions for safe storage, including any incompatibilities

Shelf life : See product labeling

7.3. Specific end use(s)

Specific end use(s) : Professional Dental Varnish

SECTION 8: Exposure controls / personal protection

8.1. Control parameters

Control parameters : Sodium Fluoride CAS: 7681-49-4

Control Parameters	Exposure Limits
OSHA PEL	TWA 2.5 mg/m ³ F TWA 2.5 mg/m ³ dust (vacated) TWA 2.5 mg/m ³
ACGIH TLV	TWA 2.5 mg/m ³ F
NIOSH REL	TWA 2.5 mg/m ³
NIOSH IDLH	250 mg/m ³ F TWA: 2.5 mg/m ³ F

Ethyl Alcohol CAS: 64-17-5

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Control Parameters	Exposure Limits
OSHA PEL General Industry	1000 ppm (1900 mg/m ³) TWA
OSHA PEL - Construction Industry	1000 ppm (900 mg/m ³) TWA
OSHA PEL Shipyard Employment	1000 ppm(1900 mg/m ³) TWA
NIOSH REL	1000 ppm(1900 mg/m ³) TWA
ACGIH TLV	1000 ppm(1880 mg/m ³) STEL
CAL/OSHA PEL	1000 ppm(1900 mg/m ³) TWA

8.2. Exposure controls

- Eye/face protection** : Wear eye protection.
- Skin protection** : Wear suitable protective clothing and gloves.
- Respiratory protection** : Use only in well-ventilated areas.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

- Physical state** : Viscous solution
- Colour** : White
- Odour** : Flavor dependent
- Flash point** : > 29°C
- Specific gravity** : 1.02

9.2. Other information

- Additional information** : No further relevant information available.

SECTION 10: Stability and reactivity

10.1. Reactivity

- Reactivity** : Stable

10.2. Chemical stability

- Chemical stability** : Stable when stored and handled under recommended conditions.

10.3. Possibility of hazardous reactions

- Hazardous polymerization** : None

10.4. Conditions to avoid

- Conditions to avoid** : Heat, flames and sparks. Extremes of temperature and direct sunlight.

10.5. Incompatible materials

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Incompatible materials : Not Determined

10.6. Hazardous decomposition products

Hazardous decomposition products : None known

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute

Dermal LD₅₀ : > 1000 mg/kg Rat/Rabbit

Notes : ~59% of the mixture consists of components of unknown toxicity (Dermal)

Oral LD₅₀ : > 270 mg/kg Rat/Guinea Pig/Mouse

Notes : ~43% of the mixture consists of components of unknown toxicity (Oral).

Inhalation LC₅₀ : > 0.03 mg/L/4H vapors Mouse

Notes : ~84% of the mixture consists of components of unknown toxicity (Inhalation).
This substance is a viscous gel, therefore, chance of inhalation is extremely low.

Germ cell mutagenicity : The components in this product are not reported to produce mutagenic effects in humans.

Carcinogenicity : None of the components of this material are listed by IARC, NTP, or CA Prop 65 as carcinogens.

Reproductive toxicity : The components in this product are not reported to cause reproductive effects in humans.

Other information : Device is biocompatible when used as directed by dental professionals per ISO 10993-1.

SECTION 12: Ecological information

12.1. Toxicity

Aquatic toxicity (acute) : Do not allow to enter sewers or drains that may lead to waterways.

12.2. Persistence and degradability

Persistence and degradability : Not classified

12.3. Bioaccumulative potential

Bioaccumulative potential : Not classified

12.4. Mobility in soil

Mobility in soil : Not Available

12.5. Results of PBT and vPvB assessment

Results of PBT and vPvB assessment : Conclusion: The substance does not fulfill the PBT and vPvB criteria for screening assessment; there are no indications of P or B properties.

12.6. Other adverse effects

Environmental data : No further relevant information available.

SECTION 13: Disposal considerations

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13.1. Waste treatment methods

Disposal method : Dispose of in compliance with governmental regulation.(EC 1975L0442-20/11/2003)

SECTION 14: Transport information

14.1. UN number

UN number : 1986

14.2. UN proper shipping name

UN proper shipping name : Alcohols, Flammable, Toxic, n.o.s. (Ethyl alcohol/Fluoride mixture)

14.3. Transport hazard class(es)

Hazard classification : 3(6.1)

14.4. Packing group

Packing group : II

14.5. Environmental hazards

Marine pollutant #1 : NAP

14.6. Special precautions for user

ADR - road : NAP

RID - rail : NAP

IMDG - sea : NAP

IATA - air : NAP

14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code

Transport in bulk : NAP

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

General information : Substances of very high concern (SVHC) according to REACH, Article 57: Contains no SVHC substances.

General comments : Please refer to Medical Devices Directive 93/42/EEC.

15.2. Chemical safety assessment

Chemical safety assessment : See Section 11

Additional information : None of the ingredients are listed as a carcinogen by IARC, NTP, or CA Prop 65.

SECTION 16: Other information

Relevant H-statements (number and full text) : Acute Tox. (O), Cat 3: Acute Toxicity (Oral), Category 3
 Acute Tox. (O), Cat. 4: Acute Toxicity (Oral), Category 4
 Aquatic Chronic, Cat 3: Chronic Hazards to the Aquatic Environment, Category 3
 Eye Irr., Cat. 2A: Eye Irritation, Category 2A
 Eye Irr., Cat. 2: Eye Irritation, Category 2

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Flam. Liq., Cat. 2: Flammable Liquids, Category 2
 STOT SE, Cat. 1: Target Organ Toxicity (Single exposure), Category 1
 Skin Irr., Cat. 2: Skin Irritation, Category 2
 H225: Highly flammable liquid and vapour.
 H301: Toxic if swallowed.
 H315: Causes skin irritation.
 H319: Causes serious eye irritation.
 H412: Harmful to aquatic life with long lasting effects.

Prepared by

: Anu Kattoju

Revision summary

: This SDS replaces the 04/18/2017 SDS. Revised: **Section 1:** MSDS
 No. **Section 3:** Wt.%. **Section 16:** Revision Summary.

General statements

: NAP = Not Applicable
 NE = Not Established
 TLV = Threshold Limit Value
 PEL = Permittable exposure limits
 MAK = Maximum Workplace Concentration
 STEL = Short-term exposure limit
 STEV = Short-term exposure value
 TWA = Time Weighted Average
 PPE = Personal Protective Equipment

Additional SDS information

: Revision #:1

Manufacturer disclaimer

: FOR DENTAL USE ONLY: Use as directed. The information and recommendations are taken from sources (raw material SDS(s) and manufacturer's knowledge) believed to be accurate; however, the manufacturer, makes no warranty with respect to the accuracy of the information or the suitability of the recommendation and assumes no liability to any user thereof. Each user should review these recommendations in the specific context of the intended use and determine whether they are appropriate.