

SAFETY DATA SHEET

Issuing Date: 8 May 2019 Revision Date: 8 May 2019 ECR#26475

Safety Data Sheet (in compliance with Regulation (EC) 1907/2006, Regulation (EC) 1272/2008 and Regulation (EC) 453/2010)

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

1.1 Product Identifier:

Trade Name (as labeled): Kids Kare, 0.4% Stannous Fluoride Gel

Product Form: Mixture

1.2 Relevant Identified Uses of the Substance or Mixture and Uses Advised Against:

Recommended Use: Dental Preventive – Fluoride Treatment
Restrictions on Use: For use only under dental supervision

1.3 Details of the Supplier of the Safety Data Sheet:

Manufacturer/Supplier Name:Den-Mat Holdings, LLC.Manufacturer/Supplier Address:1017 West Central Ave

Lompoc, CA 93436

Manufacturer/Supplier Telephone Number: 805-346-3700

1.4 Emergency Telephone Number:

Emergency Contact Telephone Number: Den-Mat Holdings, LLC

805-346-3700

2. HAZARDS IDENTIFICATION

2.1 Classification of the Substance or Mixture:

The product as manufactured is a semi-solid composed of encapsulated chemical ingredients. No hazardous exposures are anticipated during normal product handling and use conditions.

GHS Classification:				
Не	ealth	Environmental	Physical	
Skin Irritant 3	(H315)	Not Hazardous	No Physical Hazards	
Eye Irritant 2B	(H319)			

EU Classification: Irritant (Xi), R36 (eye irritant), R38 (skin irritant)

2.2 Label Elements:

Hazard pictograms (GHS-US)



Signal Word: Danger

Hazard Phrases	Precautionary Phrases
H315 - Causes skin irritation	P102 ó Keep out of reach of children
H319 - Causes serious eye irritation	P103 ó Read label before use
	P233 ó Keep container tightly closed
	P301+P310 - IF SWALLOWED: Immediately call a
	POISON CENTER or doctor/physician
	P302+P352 - IF ON SKIN: Wash with plenty of soap and
	water
	P305+P351+P338 ó IF IN EYES: Rinse cautiously with
	water for several minutes. Remove contact lenses, if
	present and easy to do. Continue rinsing
	P332+P313 - If skin irritation occurs: Get medical
	advice/attention
	P337+P313 - If eye irritation persists: Get medical
	advice/attention
	P501 - Dispose of contents and container in accordance
	with local and national regulations.

Revision Date: 8 May 2019

2.3 Other Hazards: None known.

2.4 Unknown acute toxicity (GHS-US): No data available.

3. COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances: Not Applicable

3.2 Mixture:

Hazardous Components	C.A.S. #	Classification	WT %
Glycerin	56-81-5	Not classified	>98%*
Flavor	Mixture	Not classified	<5%*

The exact concentration is being withheld as a trade secret.

4. FIRST AID MEASURES

4.1 Description of First Aid Measures:			
Eye	Immediately flush victim's eyes with large quantities of water for several minutes, holding the eyelids apart. Get medical attention if irritation persists.		
Skin	Remove contaminated clothing. Wash skin thoroughly with soap and water. If irritation develops, get medical attention. Launder clothing before re-use.		
Inhalation	Not applicable.		
Ingestion	If more than the normal amount used for brushing is swallowed, drink 1-2 glasses of milk. Get immediate medical attention.		

4.2 Most Important Symptoms and Effects, Both Acute and Delayed:

Not expected to present a significant hazard under anticipated conditions of normal use. May cause eye and skin irritation. May be harmful if swallowed.

Revision Date: 8 May 2019

4.3 Indication of Any Immediate Medical Attention and Special Treatment Needed:

Immediate medical attention should not be required except in cases of high quantities of ingestion.

Note to Physicians (Treatment, Testing, and Monitoring): Treat symptomatically.

5. FIRE-FIGHTING MEASURES

5.1 Extinguishing Media:	Use Chemical Foam, CO2, Dry Chemical Powder, or Water Spray. NOTE: Water may be ineffective in extinguishing the fire.
--------------------------	--

5.2 Special Hazards Arising from the Substance or Mixture:

Not determined.

5.3 Advice for Fire-Fighters:		
Fire Fighting Procedures:	General: Evacuate all personnel; use protective equipment for fire-fighting.	
Precautions for Fire	Firefighters should wear full emergency equipment and approved positive pressure self-	
Fighters:	containing breathing apparatus.	

Recommended Protective Equipment for Fire Fighters:			
EYES/FACE	HANDS	RESPIRATORY	THERMAL
E y			

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal Precautions, Protective Equipment and Emergency Procedures:

Remove all ignition sources such as open flames, spark producing equipment, pilot lights, etc. Avoid contact with skin, eyes or clothing. Wear appropriate protective clothing as described in Section 8.

Recommended Personal Protective Equipment for Containment and Clean-up:			
EYES/FACE	HANDS	RESPIRATORY	SKIN

6.2 Environmental Precautions:

Prevent entry into sewers and waterways. Report releases as required by local, state, and national authorities. Avoid contact with skin, eyes or clothing. Wear appropriate protective clothing as described in Section 8.

Revision Date: 8 May 2019

6.3 Methods and Material for Containment and Cleaning up:

Clean up with absorbent material and remove residue with alcohol damp wipe. Rinse spill area with water. Use nonsparking tools and equipment.

.4 Reference to Other Sections:

Refer to Section 8 for Personal Protective Equipment and Section 13 for Disposal information.

7. HANDLING AND STORAGE

7.1 Precautions for Safe Handing:

Avoid contact with the eyes, skin and clothing. Wear protective clothing and equipment as described in Section 8. Wash horoughly after handling. Keep away from heat, sparks, flames, and other sources of ignition.

'.2 Conditions for Safe Storage, Including Any Incompatibilities:

Store in a cool, dry, well-ventilated area away from heat, direct sunlight and all sources of ignition. Store away from ncompatible materials. Keep container closed to prevent contamination.

.3 Specific End Use (s): No specific end use.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control Parameters: No additional information available.

8.2 Exposure Controls:

Appropriate Engineering Controls: None required under normal product handling conditions.

Individual Protection Measures (PPE)

Specific Eve/face Protection: Chemical safety goggles should be worn if needed to avoid eye contact.

Specific Skin Protection: Wear impervious gloves such as natural rubber or neoprene if needed to avoid skin contact. Consult glove supplier for thickness and breakthrough times.

Specific Respiratory Protection: None should be needed under normal use. If exposure limits are exceeded an approved respirator or supplied air respirator appropriate should be used. Respirator selection and use should be based on contaminant type, form and concentration. Follow applicable regulations and good Industrial Hygiene

Specific Thermal Hazards: None required.

Recommended Personal Protective Equipment				
EYES/FACE	HANDS	RESPIRATORY	SKIN	





9. PHYSICAL AND CHEMICAL PROPERTIES

Revision Date: 8 May 2019

9.1 Information on Basic Physical and Chemical Properties:

Appearance:	Gel	Explosive limits:	Not Available
Odor:	Characteristic of flavor	Vapor pressure (mmHg):	Not Available
Odor threshold:	Not Available	Vapor density:	Not Available
рН:	6.00-7.50	Relative density:	1.35 to 1.40g/cc @25°C/77°F
Melting/freezing point:	65°F (18.33°C)	Solubility(ies):	Soluble
Initial boiling point and boiling range:	552.97°F (289.43°C)	Partition coefficient: n-octanol/water:	Not Available
Flash point:	390°F (198.9°C)	Auto-ignition temperature:	739°F (392.78°C)
Evaporation rate:	Not Available	Decomposition temperature:	Not Available
Flammability (solid, gas):	Not Available	Viscosity:	5,000-20,000cp @ 25°C

9.2 Other Information: None available.

10. STABILITY AND REACTIVITY

- **0.1 Reactivity:** Stable at ambient temperature and under normal conditions of use.
- 10.2 Chemical Stability: Stable at standard temperature and pressure.
- **0.3 Possibility of Hazardous Reactions:** None known.
- 0.4 Conditions to Avoid: Keep away from heat, sparks, incompatible materials, flames and other sources of ignition.
- **0.5 Incompatible materials:** Keep away from open flames.
- **0.6 Hazardous Decomposition Products:** None known.

11. TOXICOLOGICAL INFORMATION

11.1 Information on Toxicological Effects:

Chronic Effects:	No chronic health effects reported.
Target Organs:	No target organs reported.
Carcinogenicity	Not classified.
NTP:	No
IARC:	No

12. ECOLOGICAL INFORMATION

Revision Date: 8 May 2019

2.1 Toxicity: No data available

2.2 Persistence and Degradability: No data available

2.3 Bio-accumulative Potential: No data available

2.4 Mobility in Soil: No data available

2.5 Results of PBT and vPvB Assessment: No data available

2.6 Other Adverse Effects: No data available

13. DISPOSAL CONSIDERATIONS

13.1 Waste Treatment Methods:

Regulations: Dispose in accordance with all national and local regulations.

Households: Product used in household may be disposed of in refuse or sewer.

Properties (Physical/Chemical) Affecting Disposal: None currently known.

Waste Treatment Recommendations: Dispose in accordance with national and local regulations.

US EPA: This material is not considered a hazardous waste under the United States Resource Conservation and Recovery Act when disposed.

14. TRANSPORT INFORMATION

14.1. UN number

UN number: N/A 14.2. UN proper shipping name

UN proper shipping name: Not Dangerous Goods

14.3. Transport hazard class(es) Hazard classification: N/A

14.4. Packing group

Packing group: N/A

14.5. Environmental hazards

Marine Pollutant #1: N/A

14.6. Special precautions for user

ADR ó road: Not Dangerous Goods
RID- rail: Not Dangerous Goods IMDG
ó sea: Not Dangerous Goods IATA ó air:

Not Dangerous Goods

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

Transport in bulk: Not Dangerous Goods

15. REGULATORY INFORMATION

15.1 Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture: <u>U.S.</u>

Federal Regulations

EPA Registration Number: Not Applicable

Kids Kare Toothpaste Berry Gel with Fluoride

TSCA 6 All intentionally added components of this product are listed on the US TSCA Inventory. SARA 313/302/304/311/312 chemicals: None.

U.S. States

California: This product has been evaluated and does not require warning labeling under California Proposition 6.

15.2 Chemical Safety Assessment: None required.

16. OTHER INFORMATION			
HMIS Hazard Rating:			
Health: 1	Flammability: 0	Reactivity: 0	

Revision Date: 8 May 2019

Supersedes: 16 Feb, 2016 Date updated: 8 May 2019

Change Control Document #: ECR#26475

Revision Summary: 8 May 2019: Converted SDS to Den-Mat format.

Data Sources: US NLM ChemID Plus and HSDB, Substance SDS for components, IUCLID Dataset EU Chemical

Bureau, ESIS, Country websites for occupational exposure limits.

Manufacturer disclaimer:

FOR DENTAL USE ONLY. The information and recommendations are taken from sources (raw material MSDS(s), SDS(s) and manufacturers 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