



SAFETY DATA SHEET

Kvet 1.23% APF Topical Foam (no xylitol) Vanilla

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

1.1 Product identifier

Product name : Kvet 1.23% APF Topical Foam (no xylitol) Vanilla
Product code : 8001474
Product use : Dental Products

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

Not applicable.

1.3 Details of the supplier of the safety data sheet

Keystone Industries GmbH
Werner-von-Siemens Str. 14a
78224 Singen, Germany
+49 77 31 91 21 01

Keystone Vet
Division of Keystone Research & Pharmaceutical
480 S Democrat Road
Gibbstown, NJ 08027 USA
800.333.3131

1.4 Emergency telephone number

National advisory body/Poison Center

Telephone number : 1-352-323-3500

Supplier

Telephone number : +49 (0) 7731912101

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Product definition : Mixture

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

Aerosol 1, H222, H229

The product is classified as hazardous according to Regulation (EC) 1272/2008 as amended.

Ingredients of unknown ecotoxicity : Percentage of the mixture consisting of ingredient(s) of unknown hazards to the aquatic environment: 8%

See Section 16 for the full text of the R phrases or H statements declared above.

See Section 11 for more detailed information on health effects and symptoms.

2.2 Label elements

Hazard pictograms :



Signal word : Danger

Hazard statements : Extremely flammable aerosol.
Pressurized container: may burst if heated.

Precautionary statements

General : Not applicable.

SECTION 2: Hazards identification

- Prevention** : Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Do not spray on an open flame or other ignition source. Do not pierce or burn, even after use.
- Response** : Not applicable.
- Storage** : Protect from sunlight. Do not expose to temperatures exceeding 50 °C/122 °F.
- Disposal** : Not applicable.
- Supplemental label elements** : Not applicable.
- Annex XVII - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles** : Not applicable.
- Special packaging requirements**
 - Containers to be fitted with child-resistant fastenings** : Not applicable.
 - Tactile warning of danger** : Not applicable.

2.3 Other hazards

- Other hazards which do not result in classification** : None known.

SECTION 3: Composition/information on ingredients

Substance/mixture : Mixture

May contain one or more of the following components in quantities considered hazardous:

Product/ingredient name	Identifiers	%	Classification Regulation (EC) No. 1272/2008 [CLP]	Type
sodium fluoride	EC: 231-667-8 CAS: 7681-49-4 Index: 009-004-00-7	≤1.5	Acute Tox. 2, H300 Skin Irrit. 2, H315 Eye Irrit. 2, H319 EUH032	[1] [2]

There are no additional ingredients present which, within the current knowledge of the supplier, are classified and contribute to the classification of the substance and hence require reporting in this section.

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 or the environment, are PBTs or vPvBs or have been assigned a workplace exposure limit and hence require reporting in this section.

Type

- [1] Substance classified with a health or environmental hazard
- [2] Substance with a workplace exposure limit
- [3] Substance meets the criteria for PBT according to Regulation (EC) No. 1907/2006, Annex XIII
- [4] Substance meets the criteria for vPvB according to Regulation (EC) No. 1907/2006, Annex XIII
- [5] Substance of equivalent concern

Occupational exposure limits, if available, are listed in Section 8.

SECTION 4: First aid measures

4.1 Description of first aid measures

- Eye contact** : Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Continue to rinse for at least 10 minutes. Get medical attention if irritation occurs.
- Inhalation** : Remove victim to fresh air and keep at rest in a position comfortable for breathing. If not breathing, if breathing is irregular or if respiratory arrest occurs, provide artificial respiration or oxygen by trained personnel. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation. Get medical attention if adverse health effects persist or are severe. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband.
- Skin contact** : Flush contaminated skin with plenty of water. Remove contaminated clothing and shoes. Get medical attention if symptoms occur. Wash clothing before reuse. Clean shoes thoroughly before reuse.
- Ingestion** : Wash out mouth with water. Remove dentures if any. Remove victim to fresh air and keep at rest in a position comfortable for breathing. 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. Do not induce vomiting unless directed to do so by medical personnel. If vomiting occurs, the head should be kept low so that vomit does not enter the lungs. Get medical attention if adverse health effects persist or are severe. Never give anything by mouth to an unconscious person. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband.
- Protection of first-aiders** : No action shall be taken involving any personal risk or without suitable training. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation.

4.2 Most important symptoms and effects, both acute and delayed

Potential acute health effects

- Eye contact** : No known significant effects or critical hazards.
- Inhalation** : No known significant effects or critical hazards.
- Skin contact** : No known significant effects or critical hazards.
- Ingestion** : No known significant effects or critical hazards.

Over-exposure signs/symptoms

- Eye contact** : Adverse symptoms may include the following:
irritation
redness
- Inhalation** : Adverse symptoms may include the following:
respiratory tract irritation
coughing
- Skin contact** : No specific data.
- Ingestion** : No specific data.

4.3 Indication of any immediate medical attention and special treatment needed

- Notes to physician** : Treat symptomatically. Contact poison treatment specialist immediately if large quantities have been ingested or inhaled.
- Specific treatments** : No specific treatment.

SECTION 5: Firefighting measures

5.1 Extinguishing media

- Suitable extinguishing media** : Use an extinguishing agent suitable for the surrounding fire.
- Unsuitable extinguishing media** : None known.

5.2 Special hazards arising from the substance or mixture

SECTION 5: Firefighting measures

- Hazards from the substance or mixture** : Extremely flammable aerosol. In a fire or if heated, a pressure increase will occur and the container may burst, with the risk of a subsequent explosion. Gas may accumulate in low or confined areas or travel a considerable distance to a source of ignition and flash back, causing fire or explosion. Bursting aerosol containers may be propelled from a fire at high speed. Runoff to sewer may create fire or explosion hazard.
- Hazardous thermal decomposition products** : Decomposition products may include the following materials:
 carbon dioxide
 carbon monoxide
 halogenated compounds
 metal oxide/oxides
- 5.3 Advice for firefighters**
- Special protective actions for fire-fighters** : 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. Move containers from fire area if this can be done without risk. Use water spray to keep fire-exposed containers cool.
- 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. Clothing for fire-fighters (including helmets, protective boots and gloves) conforming to European standard EN 469 will provide a basic level of protection for chemical incidents.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

- For non-emergency personnel** : No action shall be taken involving any personal risk or without suitable training. Evacuate surrounding areas. Keep unnecessary and unprotected personnel from entering. In the case of aerosols being ruptured, care should be taken due to the rapid escape of the pressurized contents and propellant. If a large number of containers are ruptured, treat as a bulk material spillage according to the instructions in the clean-up section. Do not touch or walk through spilled material. Shut off all ignition sources. No flares, smoking or flames in hazard area. Avoid breathing vapor or mist. Provide adequate ventilation. Wear appropriate respirator when ventilation is inadequate. Put on appropriate personal protective equipment.
- For emergency responders** : If specialized clothing is required to deal with the spillage, take note of any information in Section 8 on suitable and unsuitable materials. See also the information in "For non-emergency personnel".

6.2 Environmental precautions

- : 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).

6.3 Methods and materials for containment and cleaning up

- Small spill** : Stop leak if without risk. Move containers from spill area. Use spark-proof tools and explosion-proof equipment. Dilute with water and mop up if water-soluble. Alternatively, or if water-insoluble, absorb with an inert dry material and place in an appropriate waste disposal container. Dispose of via a licensed waste disposal contractor.
- Large spill** : Stop leak if without risk. Move containers from spill area. Use spark-proof tools and explosion-proof equipment. Approach release from upwind. Prevent entry into sewers, water courses, basements or confined areas. Wash spillages into an effluent treatment plant or proceed as follows. Contain and collect spillage with non-combustible, absorbent material e.g. sand, earth, vermiculite or diatomaceous earth and place in container for disposal according to local regulations. Dispose of via a licensed waste disposal contractor. Contaminated absorbent material may pose the same hazard as the spilled product.

SECTION 6: Accidental release measures

6.4 Reference to other sections : See Section 1 for emergency contact information.
 See Section 8 for information on appropriate personal protective equipment.
 See Section 13 for additional waste treatment information.

SECTION 7: Handling and storage

The information in this section contains generic advice and guidance. The list of Identified Uses in Section 1 should be consulted for any available use-specific information provided in the Exposure Scenario(s).

7.1 Precautions for safe handling

Protective measures : Put on appropriate personal protective equipment (see Section 8). Pressurized container: protect from sunlight and do not expose to temperatures exceeding 50°C. Do not pierce or burn, even after use. Do not ingest. Avoid contact with eyes, skin and clothing. Avoid breathing gas. Avoid breathing vapor or mist. Use only with adequate ventilation. Wear appropriate respirator when ventilation is inadequate. Store and use away from heat, sparks, open flame or any other ignition source. Use explosion-proof electrical (ventilating, lighting and material handling) equipment. Use only non-sparking tools. Empty containers retain product residue and can be hazardous.

Advice on general occupational hygiene : Eating, drinking and smoking should be prohibited in areas where this material is handled, stored and processed. Workers should wash hands and face before eating, drinking and smoking. Remove contaminated clothing and protective equipment before entering eating areas. See also Section 8 for additional information on hygiene measures.

7.2 Conditions for safe storage, including any incompatibilities

Store in accordance with local regulations. Store away from direct sunlight in a dry, cool and well-ventilated area, away from incompatible materials (see Section 10) and food and drink. Eliminate all ignition sources. Use appropriate containment to avoid environmental contamination.

Seveso Directive - Reporting thresholds (in tonnes)

Danger criteria

Category	Notification and MAPP threshold	Safety report threshold
P3a: Flammable aerosols containing flammable gases or flammable liquids	150	500
C7b: Highly flammable (R11)	5000	50000

7.3 Specific end use(s)

Recommendations : Not available.

Industrial sector specific solutions : Not available.

SECTION 8: Exposure controls/personal protection

The information in this section contains generic advice and guidance. Information is provided based on typical anticipated uses of the product. Additional measures might be required for bulk handling or other uses that could significantly increase worker exposure or environmental releases.

8.1 Control parameters

Occupational exposure limits

Product/ingredient name	Exposure limit values
sodium fluoride	EU OEL (Europe, 12/2009). Notes: list of indicative occupational exposure limit values TWA: 2.5 mg/m ³ 8 hours.

SECTION 8: Exposure controls/personal protection

Recommended monitoring procedures : If this product contains ingredients with exposure limits, personal, workplace atmosphere or biological monitoring may be required to determine the effectiveness of the ventilation or other control measures and/or the necessity to use respiratory protective equipment. Reference should be made to monitoring standards, such as the following: European Standard EN 689 (Workplace atmospheres - Guidance for the assessment of exposure by inhalation to chemical agents for comparison with limit values and measurement strategy) European Standard EN 14042 (Workplace atmospheres - Guide for the application and use of procedures for the assessment of exposure to chemical and biological agents) European Standard EN 482 (Workplace atmospheres - General requirements for the performance of procedures for the measurement of chemical agents) Reference to national guidance documents for methods for the determination of hazardous substances will also be required.

DNELs/DMELs

No DNELs/DMELs available.

PNECs

No PNECs available.

8.2 Exposure controls

Appropriate engineering controls : Use only with adequate ventilation. If user operations generate dust, fumes, gas, vapor or mist, use process enclosures, local exhaust ventilation or other engineering controls to keep worker exposure to airborne contaminants below any recommended or statutory limits. The engineering controls also need to keep gas, vapor or dust concentrations below any lower explosive limits. Use explosion-proof ventilation equipment.

Individual protection measures

Hygiene measures : Wash hands, forearms and face thoroughly after handling chemical products, before eating, smoking and using the lavatory and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.

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: safety glasses with side-shields.

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 : Personal protective equipment for the body should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product. When there is a risk of ignition from static electricity, wear anti-static protective clothing. For the greatest protection from static discharges, clothing should include anti-static overalls, boots and gloves. Refer to European Standard EN 1149 for further information on material and design requirements and test methods.

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 : Based on the hazard and potential for exposure, select a respirator that meets the appropriate standard or certification. Respirators must be used according to a respiratory protection program to ensure proper fitting, training, and other important aspects of use.

SECTION 8: Exposure controls/personal protection

Environmental exposure controls : Emissions from ventilation or work process equipment should be checked to ensure they comply with the requirements of environmental protection legislation. In some cases, fume scrubbers, filters or engineering modifications to the process equipment will be necessary to reduce emissions to acceptable levels.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance

Physical state : Liquid. [Foam]
Color : White.
Odor : Not available.
pH : 5.5 to 6.5
Melting point/freezing point : Not available.
Initial boiling point and boiling range : >35°C
Flash point : Closed cup: <23°C
Vapor pressure : Not available.
Vapor density : Not available.
Relative density : Not available.
Auto-ignition temperature : Not available.
Decomposition temperature : Not available.
Viscosity : Not available.

9.2 Other information

Aerosol product

Type of aerosol : Foam
Heat of combustion : 3.621 kJ/g

No additional information.

SECTION 10: Stability and reactivity

10.1 Reactivity : No specific test data related to reactivity available for this product or its ingredients.
10.2 Chemical stability : The product is stable.
10.3 Possibility of hazardous reactions : Under normal conditions of storage and use, hazardous reactions will not occur.
10.4 Conditions to avoid : Avoid all possible sources of ignition (spark or flame).
10.5 Incompatible materials : No specific data.
10.6 Hazardous decomposition products : Under normal conditions of storage and use, hazardous decomposition products should not be produced.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute toxicity

Product/ingredient name	Result	Species	Dose	Exposure
sodium fluoride	LD50 Oral	Rat	31 mg/kg	-

Acute toxicity estimates

SECTION 11: Toxicological information

Route	ATE value
Oral	2520.3 mg/kg

Irritation/Corrosion

Product/ingredient name	Result	Species	Score	Exposure	Observation
sodium fluoride	Eyes - Moderate irritant	Rabbit	-	24 hours 20 milligrams	-

Information on the likely routes of exposure : Not available.

Potential acute health effects

Eye contact : No known significant effects or critical hazards.
Inhalation : No known significant effects or critical hazards.
Skin contact : No known significant effects or critical hazards.
Ingestion : No known significant effects or critical hazards.

Symptoms related to the physical, chemical and toxicological characteristics

Eye contact : Adverse symptoms may include the following:
 irritation
 redness
Inhalation : Adverse symptoms may include the following:
 respiratory tract irritation
 coughing
Skin contact : No specific data.
Ingestion : No specific data.

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

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 effects

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.

Other information : Not available.

SECTION 12: Ecological information

12.1 Toxicity

Product/ingredient name	Result	Species	Exposure
sodium fluoride	Acute EC50 181000 µg/l Marine water	Algae - Skeletonema costatum	96 hours
	Acute EC50 850000 µg/l Fresh water	Algae - Scenedesmus subspicatus - Exponential growth phase	72 hours
	Acute EC50 179.4 mg/l Fresh water	Crustaceans - Cypris subglobosa	48 hours
	Acute EC50 98000 µg/l Fresh water	Daphnia - Daphnia magna - Neonate	48 hours
	Acute LC50 51000 µg/l Fresh water Chronic NOEC 14000 µg/l Fresh water Chronic NOEC 3.1 mg/l Fresh water	Fish - Oncorhynchus mykiss Daphnia - Daphnia magna Fish - Acipenser baerii - Juvenile (Fledgling, Hatchling, Weanling)	96 hours 21 days 90 days

12.4 Mobility in soil

Soil/water partition coefficient (K_{oc}) : Not available.

Mobility : Not available.

12.5 Results of PBT and vPvB assessment

PBT : Not applicable.

vPvB : Not applicable.

12.6 Other adverse effects : No known significant effects or critical hazards.

SECTION 13: Disposal considerations

The information in this section contains generic advice and guidance. The list of Identified Uses in Section 1 should be consulted for any available use-specific information provided in the Exposure Scenario(s).

13.1 Waste treatment methods

Product

Methods of disposal : 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. Dispose of surplus and non-recyclable products via a licensed waste disposal contractor. Waste should not be disposed of untreated to the sewer unless fully compliant with the requirements of all authorities with jurisdiction.

Hazardous waste : The classification of the product may meet the criteria for a hazardous waste.





Packaging

Methods of disposal : The generation of waste should be avoided or minimized wherever possible. Waste packaging should be recycled. Incineration or landfill should only be considered when recycling is not feasible.

Special precautions : This material and its container must be disposed of in a safe way. Empty containers or liners may retain some product residues. Do not puncture or incinerate container.

SECTION 14: Transport information

SECTION 14: Transport information

	ADR/RID	ADN	IMDG	IATA
14.1 UN number	UN1950	UN1950	UN1950	UN1950
14.2 UN proper shipping name	AEROSOLS	AEROSOLS	AEROSOLS	AEROSOLS
14.3 Transport hazard class(es)	2 	2 	2.1 	2.1 
14.4 Packing group	-	-	-	-
14.5 Environmental hazards	No.	No.	No.	No.
Additional information	<u>Tunnel code</u> (D)	-	-	-

14.6 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.

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

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
[EU Regulation \(EC\) No. 1907/2006 \(REACH\)](#)

[Annex XIV - List of substances subject to authorization](#)

[Annex XIV](#)

None of the components are listed.

[Substances of very high concern](#)

None of the components are listed.

Annex XVII - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles : Not applicable.

[Other EU regulations](#)

Europe inventory : All components are listed or exempted.

Priority List Chemicals (793/93/EEC) : Not determined

Industrial emissions (integrated pollution prevention and control) - Air : Listed

Aerosol dispensers :

SECTION 15: Regulatory information



Extremely flammable

Seveso Directive

This product is controlled under the Seveso Directive.

Danger criteria

Category

P3a: Flammable aerosols containing flammable gases or flammable liquids
 C7b: Highly flammable (R11)

15.2 Chemical Safety Assessment

: This product contains substances for which Chemical Safety Assessments are still required.

SECTION 16: Other information

✔ Indicates information that has changed from previously issued version.

Abbreviations and acronyms

: ATE = Acute Toxicity Estimate
 CLP = Classification, Labelling and Packaging Regulation [Regulation (EC) No. 1272/2008]
 DMEL = Derived Minimal Effect Level
 DNEL = Derived No Effect Level
 EUH statement = CLP-specific Hazard statement
 PBT = Persistent, Bioaccumulative and Toxic
 PNEC = Predicted No Effect Concentration
 RRN = REACH Registration Number
 vPvB = Very Persistent and Very Bioaccumulative

Procedure used to derive the classification according to Regulation (EC) No. 1272/2008 [CLP/GHS]

Classification	Justification
Aerosol 1, H222, H229	On basis of test data

Full text of abbreviated H statements

: H222, H229 Extremely flammable aerosol. Pressurized container: may burst if heated.
 H300 Fatal if swallowed.
 H315 Causes skin irritation.
 H319 Causes serious eye irritation.

Full text of classifications [CLP/GHS]

: Acute Tox. 2, H300 ACUTE TOXICITY (oral) - Category 2
 Aerosol 1, H222, H229 AEROSOLS - Category 1
 EUH032 Contact with acids liberates very toxic gas.
 Eye Irrit. 2, H319 SERIOUS EYE DAMAGE/ EYE IRRITATION - Category 2
 Skin Irrit. 2, H315 SKIN CORROSION/IRRITATION - Category 2

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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.

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