

Safety data sheet (1907/2006/EEC)

Product Name: AphtoFix® mouth ulcer cream

Version History			
Version	Date	Comments	Author
00	25/03/2013	Creation of New Document	BJ
01	30/01/2015	Update of CAS Nr. and INCI name of some ingredients	SS

1. Identification of the substance/preparation and of the company undertaking

Material Trade Name	AphtoFix®
Use of Substance/preparation	Mouth ulcer cream
Company Identification	bonyfAG Heiligkreuz 16 9490 Vaduz Principality of Liechtenstein/Europe Telephone: +423 232 78 15 Fax: +423 232 51 88
Emergency Number	+423 232 78 15 (Only During Office Hours)

2. Hazard Identification

Avoid contact with eyes. Avoid ingesting large amounts deliberately.

For statements and labelling refer to section 15. Regulatory Information

3. Composition/Information on Ingredients

Ingredient Name	CAS Number	EC-Number
Cellulose Gum	9004-32-4	n/a
PVM/ PM Orarez Ms	62386-95-2	n/a
Petrolatum	8009-03-8	232-373-2
Paraffinum Liquidum	8042-47-5	232-455-8
Citric Acid	77-92-9	201-069-1
Sodium Lauryl Sulfate	151-21-3	205-788-1
Lactose Monohydrate	5989-81-1	n/a
Sodium Bicarbonate	144-55-8	205-633-8
Sodium Chloride	7647-14-5	231-598-3
HDK V15	112945-52-5	n/a
HDK H15	68611-44-9	n/a
Potassium Monopersulfate	70693-62-8	274-778-7
Sodium Carbonate	497-19-8	207-838-8
Peppermint Flavour	n/a	n/a
Menthol EP	2216-51-5	218-690-9
PVP	9003-39-8	n/a
Menthyl Lactate (Frescolat 600190)	59259-38-0	n/a
Yellothin IP 100 (Soja Lecithin)	8002-43-5	n/a

4. First Aid Measures

General instructions	In the case of persistent problems, seek medical advice (Show label or SDS where possible).
Contact with skin	Obtain medical attention if skin reaction occurs or continues (show label or SDS where possible).
Contact with eyes	Wash with clean and gently flowing water. Seek medical advice if irritation occurs.

Ingestion	If conscious, rinse mouth with water. Drink plenty of water. Do not force vomiting. Seek medical advice immediately (show label or SDS where possible).
Inhalation	Risk of inhalation exposure is negligible. (The product is a cream)
Instructions for doctor	Because of the small potential for acute or delayed eye irritation, consider referral to an ophthalmologist.

5. Fire-Fighting Measures

Suitable extinguishing media	Water, foam, dry powder, sand. Water is recommended for fires involving packaging.
Unsuitable extinguishing media	Organic compounds.
Particular hazards caused by the substances or the product itself, its combustion products or resulting gases	Under the effect of heat the product may release oxygen and act as an oxidising agent if flammable substances are present. The vapour released may contain traces of sulphur dioxide.
Special protective equipment for fire-fighting	For single units (packages): No special requirements needed. For larger amounts of product (multiple packages/pallets): Toxic, corrosive or flammable vapours might develop from fires involving this product and associated packaging. Self-contained breathing apparatus and full protective equipment are recommended for fire-fighters.

Keep quench water away from drains, subsoil and water systems. Provide for the possibility of adequate retention of quench water. Dispose of contaminated extinguishing water in accordance with national, provincial and/or local community regulations.

6. Accidental Release Measures

Personal precautions	When dealing with the product in bulk amounts, wear gloves and safety goggles. Avoid contact with skin, eyes and clothing.
Environmental precautions	Keep away from drains, surface and ground-water and soil. Alert the competent authorities.
Methods for mopping	Industrial: Mop up mechanically. Avoid using water as the product activates (becomes adhesive) on contact with humidity. Place in clean, properly labelled, and dry plastic containers. Recycle or dispose of them according to regulations. Household: Product used in household may be disposed of in refuse or sewer.

7. Handling and Storage

Safety instructions for handling (for bulk quantities)	Avoid contact with eyes. Wear personal protection equipment if available. Change contaminated and impregnated clothes. Do not eat, drink or smoke (avoid sneezing) when working (to prevent contamination of the product). Always wash hands and face before/after taking a break or leaving work.
Storage	
Conditions for storage rooms and vessels	Store in a cool and dry place away from flammable substances. Keep away from sources of heat and humidity.
Advice for storage of materials	Avoid exposure to solar radiation, and heat sources. Keep away from flammable substances. In case of fire, provide for the possibility of adequate retention of quench water. Keep quench water away from drains, subsoil or water systems. Dispose of contaminated quench water as well as combustion products in accordance with the local Community regulations. Keep out of reach of children.

8. Exposure Controls/Personal Protection

Exposure Limits	None established
Occupational exposure controls (in the work place)	
General protection and hygiene measures	When handling chemicals the usual protection measures must be followed. Contact of the open product with eyes should be avoided. Do not eat, drink, smoke (avoid sneezing) at work. Keep away from food and beverages. Wash

	hands and face before/after taking a break or leaving work.
Respiratory protection	None required
Hand protection	None required, however use of gloves is recommended to prevent contaminating the product. Use chemical resistant gloves classified under Standard EN374: Protective gloves against chemicals and micro-organisms.
Eye protection	None required, however, if using safety glasses (with side shields) they should be consistent with EN 166 or equivalent.
Skin protection	Wear adequate protective clothing when working with open product. Avoid contamination of clothing by product. Change contaminated or impregnated clothes and rinse them immediately with water.
Environmental exposure controls	
Ventilation	General ventilation should be sufficient for most operations.

The above section only applies to the product when used in an industrial setting.

9. Physical And Chemical Properties

Form	Thick yellowish cream
Colour	Off-white / yellowish
Odour	Peppermint

Information about the protection of health, safety and environment

pH	~7
Melting point	No test data available.
Flash point	No test data available.
Flammability	No test data available.
Explosive Properties	No test data available.
Oxidising Properties	No test data available.
Vapour pressure	No test data available.
Relative density	No test data available.
Solubility	Partly soluble
Water Solubility	Partly soluble
Viscosity	~50

10. Stability and Reactivity

General Information	The product is stable. Small possibility of deterioration when exposed to heat, heat sources or humidity. Avoid contact with flammable substances. The product contains oxidising agents and inorganic effervescent oxygen compounds, which release oxygen.
Conditions to Avoid	Solar radiation, heat, heat sources and humidity.
Materials to Avoid	Avoid contact with flammable substances or with humidity (water)
Hazardous Decomposition Products	Water, oxygen, inorganic salts (Borax, Potassium Hydrogen Monopersulfate). Upon decomposition by heat (combustion), small amounts of sulphur dioxide may occur in the vapour.

11. Toxicological Information

According to our present state of knowledge no damaging effect is expected when product is used in accordance with the instructions for use and standard practices are respected.

Route of Exposure

Skin Contact	Not irritating to skin (Source: STERLAB 10993-5 and 10993-10 report)
Eye Contact	Irritation may occur following direct contact with eyes.
Inhalation	No studies have been conducted.
Ingestion	Expected to be non-toxic following ingestion.
Sensitisation	No sensitisation after 2 hours contact (Source: STERLAB 10993-5 and 10993-10)

	report)
Genetic Toxicity	No studies have been conducted. However not expected to be genotoxic under occupational exposure conditions.
Carcinogenicity	No studies have been conducted. However not expected to be carcinogenic under occupational exposure conditions.
Developmental Toxicity	No studies have been conducted. Instructions for use clearly state to seek advice from doctor if pregnant or breastfeeding.
Reproductive Toxicity	No studies have been conducted.

12. Ecological Information

No test data is available about the potential of this product to produce adverse environmental effects. The product contains at least one ingredient which may be harmful if released directly to the environment however it is present at a concentration below 0.3%. Appropriate precautions should be taken to limit release of the mixture to the environment. Local regulations and procedures should be consulted prior to environmental release.

Ecotoxicity	Contains at least one component classified as dangerous to aquatic organisms. However it is present at a very low concentration of ~0.3%.
Mobility	No test data available.
Persistence and degradability	No biodegradation tests available for this product. The product is partly soluble in water.
Bioaccumulative potential	No test data available.
Results of PTB assessment	No test data available.
Other adverse effects	No other adverse effects known.

This product is intended for dispersive use and should not be disposed of directly into the environment. Avoid runoff into sewers, water or groundwater.

13. Disposal Considerations

Material	Larger quantities of the product should be disposed of as inorganic laboratory chemicals in accordance with the local Community regulations. Contact a licensed professional waste disposal service to dispose of this material. Small quantities of the product may be disposed of as a household waste.
Un-cleaned packaging	Recommendation: Empty packaging in the best possible way, and dispose of it in accordance with the local community regulations.

14. Transport Information

Dangerous goods according to transport regulation	No
Identification of product	Cream for mouth ulcers/sores and gum irritations/sores.
Road and Rail	Not regulated for transport.
Ocean	Not regulated for transport.
Air	Not regulated for transport.
Inland waterways	Not regulated for transport.
Other applicable information	Transport and shipping of this product is not restricted. It has no known significant hazards requiring special packaging or labelling for air, maritime or ground transport purposes. Information for transport: Store cool and dry. Keep away from heat sources and humidity.

The SDS should accompany all shipments for reference in the event of spillage or accidental release.

15. Regulatory Information

Labelling in accordance with EC directives:

N/A

Classification and labelling according to EU Regulation (EC) 1272/2008 (CLP Regulation) and Globally Harmonized System (GHS):
N/A

16. Other Information

The data given here is based on current knowledge and experience. The purpose of this Safety Data Sheet is to describe the product in terms of its safety requirements. The data does not signify any warranty with regard to product's properties. Properties of the product are to be found in the respective product leaflet (Technical Data Sheet). This version supersedes all previous versions.