

1. Product and Company Identification

Material name **FABIOR FOAM 0.1%**
Version # 02
Revision date 10-04-2012
Product use Medicinal Product

This safety data sheet is written to provide health, safety and environmental information for people handling this formulated product in the workplace. It is not intended to provide information relevant to medicinal use of the product. In this instance patients should consult prescribing information/package insert/product label or consult their pharmacist or physician. For health and safety information for individual ingredients used during manufacturing, refer to the appropriate safety data sheet for each ingredient.

Synonym(s) TAZAROTENE FOAM 0.1% * FORMULATION CODE: SFW0260-03 * STIEFEL PRODUCT * TAZAROTENE, FORMULATED PRODUCT

Manufacturer

Stiefel Laboratories, Inc. (a GSK company)
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available 24 hrs/7 days; multi-language response

2. Hazards Identification**Emergency overview**

This product is extremely flammable.
Aerosol containers may violently rupture when exposed to the heat of fire.
Caution - Pharmaceutical agent.
Not expected to be a significant health hazard unless product is spilt.
Health effects information is based on hazards of components.
Contains ingredient(s) that: have produced adverse effects on foetal development in laboratory animals
Possible effects of overexposure in the workplace include: irritation; redness; itching; burning.
No information is available about the potential of this material to produce adverse environmental effects.

OSHA regulatory status

This product is exempt from the requirements of the OSHA Hazard Communication Standard.

Potential health effects**Eyes**

Eye irritation may occur.

Skin

Irritation might occur following direct contact. Adverse effects might occur following repeated skin contact. Assessment based upon effects of individual components.

Inhalation

Adverse effects might occur following inhalation. Assessment based upon effects of individual components.

Ingestion

Adverse effects might occur following ingestion. Assessment based upon effects of individual components.

Target organs May cause adverse effects on: liver; the developing foetus.
Signs and symptoms Possible effects of overexposure in the workplace include: irritation; redness; itching; burning.

3. Composition / Information on Ingredients

Components	CAS #	Percent
PHARMACEUTICAL GRADE PETROLATUM	8009-03-8	4.0 - 6.0
ISOBUTANE	75-28-5	4.0 - 5.0
DIISOPROPYL ADIPATE	6938-94-9	3.0 - 5.0
N-BUTANE	106-97-8	1.0 - 2.0
PROPANE	74-98-6	1.0 - 2.0
TAZAROTENE	118292-40-3	0.1
Other components below reportable levels		>80.0

4. First Aid Measures

First aid procedures

Eye contact Wash immediately with clean and gently flowing water. Continue for at least 15 minutes. Obtain medical attention.

Skin contact Using appropriate personal protective equipment, remove contaminated clothing and flush exposed area with large amounts of water. Obtain medical attention if skin reaction occurs, which may be immediate or delayed.

Inhalation Using appropriate personal protective equipment, move exposed subject to fresh air. If breathing is difficult or ceases, ensure and maintain ventilation. Give oxygen as appropriate. The exposed subject should be kept warm and at rest. Obtain medical attention in cases of known or possible over exposure, or with symptoms including chest pain, difficulty breathing, loss of consciousness or other adverse effects, which may be delayed.

Ingestion Never attempt to induce vomiting. Do not attempt to give any solid or liquid by mouth if the exposed subject is unconscious or semi-conscious. Wash out the mouth with water. If the exposed subject is fully conscious, give plenty of water to drink. Obtain medical attention.

Notes to physician Treat according to locally accepted protocols. For additional guidance, refer to the current prescribing information or to the local poison control information centre. No specific antidotes are recommended.

General advice Pre-placement and periodic health surveillance is not usually indicated. The final determination of the need for health surveillance should be determined by local risk assessment. New or expectant mothers might be at greater risk from overexposure. Risk assessments must take this into consideration. Female employees anticipating pregnancy or with a confirmed pregnancy must be encouraged to notify an occupational health professional or their line manager. This will act as the trigger for individual re-assessment of the employee's work practices.

5. Fire Fighting Measures

Extinguishing media

Suitable extinguishing media Water is recommended for fires involving packaging.

Protection of firefighters

Specific hazards arising from the chemical Toxic, corrosive or flammable thermal decomposition products are expected when the product is exposed to fire.

Protective equipment and precautions for firefighters Since toxic, corrosive or flammable vapours might be evolved from fires involving this material, self contained breathing apparatus and full protective equipment are recommended for firefighters.

Fire fighting equipment/instructions For single units (packages): No special requirements needed.
For larger amounts (multiple packages/pallets) of product: Since toxic, corrosive or flammable vapours might be evolved from fires involving the associated packaging, self contained breathing apparatus might be considered for fire fighters.
If possible, contain and collect firefighting water for later disposal.

Hazardous combustion products Toxic, corrosive or flammable thermal decomposition products are expected when the material is exposed to fire.

6. Accidental Release Measures

Personal precautions	Stop leak and eliminate all sources of ignition (no smoking, sparks or flames). Fence or cordon the affected area and do not allow individuals to touch or walk through the spilled material unless wearing appropriate protective clothing. Wear protective clothing and equipment consistent with the degree of hazard. Vapour-suppressing foam or water spray may be used to control vapours as appropriate.
Environmental precautions	Prevent entry into waterways, sewers, surface drainage systems and poorly ventilated areas.
Methods for containment	Spread an inert absorbent on the spill and place in a suitable, properly labelled container for recovery or disposal.
Methods for cleaning up	Equipment used for clean-up should be earthed (grounded) and non-sparking. No specific decontamination or detoxification procedures have been identified for this product. Water can be used for clean-up and decontamination operations.

7. Handling and Storage

Handling	Handle in open or well ventilated areas. Keep this material away from all forms of ignition such as open flames, mechanical sparks, frictional heat and hot surfaces.
Storage	Keep material in sealed containers in a cool, well-ventilated area away from sources of ignition.

8. Exposure Controls / Personal Protection

Occupational exposure limits

GSK Components	Type	Value	Form
TAZAROTENE (118292-40-3)	8 HR TWA	1 mcg/m3	
	OHC	5 5	SKIN REPRODUCTIVE HAZARD

US. ACGIH Threshold Limit Values

Components	Type	Value	Form
ISOBUTANE (75-28-5)	TWA	1000 ppm	
N-BUTANE (106-97-8)	TWA	1000 ppm	
PHARMACEUTICAL GRADE PETROLATUM (8009-03-8)	TWA	5 mg/m3	Inhalable fraction.
PROPANE (74-98-6)	TWA	1000 ppm	

US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)

Components	Type	Value	Form
PHARMACEUTICAL GRADE PETROLATUM (8009-03-8)	PEL	5 mg/m3	Mist.
PROPANE (74-98-6)	PEL	1800 mg/m3 1000 ppm	

Personal protective equipment

Eye / face protection	Wear approved safety glasses with side shields if eye contact is possible.
General hygiene considerations	An eye wash station should be available. Wash hands and arms thoroughly after handling. New or expectant mothers might be at greater risk from overexposure. Risk assessments must take this into consideration. Female employees anticipating pregnancy or with a confirmed pregnancy must be encouraged to notify an occupational health professional or their line manager. This will act as the trigger for individual re-assessment of the employee's work practices.

9. Physical & Chemical Properties

Appearance	Not available.
Physical state	Liquid.
Form	Aerosol container. Foam.
Color	White.
Odor	Not available.
Odor threshold	Not available.
pH	Not available

Vapor pressure	Not available
Vapor density	Not available
Boiling point	Not available.
Melting point/Freezing point	Not available.
Solubility (water)	Not available.
Specific gravity	Not available.
Relative density	Not available.
Flash point	Not available
Flammability limits in air, upper, % by volume	Not available.
Flammability limits in air, lower, % by volume	Not available.
Auto-ignition temperature	Not available.
Evaporation rate	Not available
Viscosity	Not available
Percent volatile	77 % estimated

10. Chemical Stability & Reactivity Information

Conditions to avoid	Pressurised container. Protect from sunlight and do not expose to temperatures exceeding 50 degrees C. Do not puncture or incinerate when empty. Do not overheat containers, they might violently rupture.
Incompatible materials	Not available.
Hazardous decomposition products	Toxic, corrosive or flammable thermal decomposition products are expected when the product is exposed to fire.

11. Toxicological Information

Toxicological data

Components	Species	Test Results
PHARMACEUTICAL GRADE PETROLATUM (8009-03-8)		
Acute		
<i>Oral</i>		
LD50	Rat	> 15 g/kg
TAZAROTENE (118292-40-3)		
Acute		
<i>Oral</i>		
LD50	Rat	> 2000 mg/kg
Chronic		
<i>Oral</i>		
LD	Monkey	1.6 mg/kg/day
Sensitization	No studies have been conducted. Sensitisation (allergic skin reaction) is not expected. Assessment based upon effects of individual components.	
Buehler test		
TAZAROTENE	Result: Negative Species: Guinea pig	
Acute effects	No studies have been conducted. Not expected to be toxic following ingestion. Assessment based upon effects of individual components.	
Carcinogenicity	No studies have been conducted. Not expected to produce cancer in humans under occupational exposure conditions. Some grades of petrolatum produced carcinogenic effects in a lifetime study in mice. These effects are suspected to be due to impurities that are not expected to be present in purified material used in this product.	

ACGIH Carcinogens

PHARMACEUTICAL GRADE PETROLATUM (CAS 8009-03-8)

A2 Suspected human carcinogen.

A4 Not classifiable as a human carcinogen.

US NTP Report on Carcinogens: Known carcinogen

PHARMACEUTICAL GRADE PETROLATUM (CAS 8009-03-8)

Known To Be Human Carcinogen.

Skin corrosion/irritation

Irritation might occur following direct contact.

Serious eye damage/eye irritation

Irritation might occur following direct contact with eyes.

Mutagenicity

Not expected to be genotoxic, based on effects of individual components.

Reproductive effects

The ingredient tazarotene has caused adverse effects on the development of unborn offspring in animal studies.

Symptoms and target organs

Accidental exposure or contact might produce: irritation; itching; burning; redness. Adverse effects might occur in the following organ(s) following overexposure: liver; the developing foetus. Assessment based upon information from animal studies.

Further information

This product contains active ingredient(s) with the following activity: a retinoid (vitamin A derivative).

12. Ecological Information

Ecotoxicological data

Components

Species

Test Results

TAZAROTENE (118292-40-3)

Aquatic

Acute

Algae

EC50

Algae

0.1 - 1 mg/l, 96 hours, QSAR Estimate

Crustacea

EC50

Daphnia

0.1 - 1 mg/l, 48 hours, QSAR Estimate

Fish

EC50

Fish

0.1 - 1 mg/l, 96 hours, QSAR Estimate

Ecotoxicity

No information is available about the potential of this material to produce adverse environmental effects. This material contains an active ingredient that may be very toxic to aquatic organisms. Consult the MSDS of the active ingredient for specific information about potential environmental effects. Appropriate precautions should be taken to limit release of this material to the environment. Local regulations and procedures should be consulted prior to environmental release.

Persistence and degradability

Not available.

Bioaccumulation / Accumulation

Bioaccumulative potential

Octanol/water partition coefficient log Kow

PROPANE

2.36

ISOBUTANE

2.76

N-BUTANE

2.89

TAZAROTENE

6 (Calculated).

13. Disposal Considerations

Disposal instructions

Observe all local and national regulations when disposing of this product. Collect for recycling or recovery if possible. The disposal method for rejected products/returned goods must ensure that they cannot be re-sold or re-used.

14. Transport Information

General

The SDS should accompany all shipments for reference in the event of spillage or accidental release. Only authorised persons trained and competent in accordance with appropriate national and international regulatory requirements may prepare dangerous goods for transport.

DOT

UN number

UN1950

UN proper shipping name

Aerosols, flammable (TAZAROTENE FOAM 0.1%)

Transport hazard class(es)

2.1

Packing group

Not applicable

IATA

UN number

UN1950

UN proper shipping name Aerosols, flammable (TAZAROTENE FOAM 0.1%)
Transport hazard class(es) 2.1
Packing group Not applicable.

IMDG

UN number UN1950
UN proper shipping name Aerosols, flammable (TAZAROTENE FOAM 0.1%)
Transport hazard class(es) 2.1
Packing group Not applicable.

DOT



IATA; IMDG



15. Regulatory Information

US federal regulations

Drug Enforcement Administration (DEA). List 2, Essential Chemicals (21 CFR 1310.02(b) and 1310.04(f)(2))

Not regulated.

DEA Essential Chemical Code Number

Not regulated.

Drug Enforcement Administration (DEA). List 1 & 2 Exempt Chemical Mixtures (21 CFR 1310.12(c))

Not regulated.

DEA Exempt Chemical Mixtures Code Number

Not regulated.

CERCLA (Superfund) reportable quantity

ISOBUTANE: 100

N-BUTANE: 100

PROPANE: 100

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories Immediate Hazard - No
Delayed Hazard - Yes
Fire Hazard - Yes
Pressure Hazard - No
Reactivity Hazard - No

Section 302 extremely hazardous substance No

Section 311 hazardous chemical No

Inventory status

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	No

Country(s) or region	Inventory name	On inventory (yes/no)*
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

State regulations

US - New Jersey RTK - Substances: Listed substance

ISOBUTANE (CAS 75-28-5)	Listed.
N-BUTANE (CAS 106-97-8)	Listed.
PROPANE (CAS 74-98-6)	Listed.

US - Pennsylvania RTK - Hazardous Substances: Listed substance

ISOBUTANE (CAS 75-28-5)	Listed.
N-BUTANE (CAS 106-97-8)	Listed.
PHARMACEUTICAL GRADE PETROLATUM (CAS 8009-03-8)	Listed.
PROPANE (CAS 74-98-6)	Listed.

16. Other Information

Recommended restrictions	No other uses are advised.
Further information	This material has not been assessed for HMIS or NFPA ratings. HMIS® is a registered trade and service mark of the NPCA.
HMIS® ratings	Health: Flammability: Physical hazard:
NFPA ratings	Health: Flammability: Instability:
Disclaimer	The information and recommendations in this safety data sheet are, to the best of our knowledge, accurate as of the date of issue. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose.
Issue date	03-03-2011
This data sheet contains changes from the previous version in section(s):	Product and Company Identification: Business Units Hazards Identification: EU Hazard Classifications Composition / Information on Ingredients: Ingredients Physical & Chemical Properties: Reports Toxicological Information: Transport Information: Regulatory Information: United States