

SAFETY DATA SHEET

Biofreeze Dual Active Relief Ultraflex Patch

*Lidocaine 4%**Menthol 1%*

HEALTH ▸ HYGIENE ▸ HOME

1. Product and company identification

Product name : Biofreeze Dual Active Relief Ultraflex Patch
Lidocaine 4%
Menthol 1%

Distributed by : RB Health (US) LLC
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Emergency telephone number (Medical) : 1-800-338-6167

Emergency telephone number (Transport) : 1-800-424-9300 (U.S. & Canada) CHEMTREC
Outside U.S. and Canada (North America), call Chemtrec:703-527-3887

Website: : <http://www.rbnainfo.com>

Product use : Medicated Patch

This SDS is designed for workplace employees, emergency personnel and for other conditions and situations where there is greater potential for large-scale or prolonged exposure, in accordance with the requirements of USDOL Occupational Safety and Health Administration.

This SDS is not applicable for consumer use of our products. For consumer use, all precautionary and first aid language is provided on the product label in accordance with the applicable government regulations, and shown in Section 15 of this SDS.

SDS # : D8412529

Formulation # : 3323447

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

Identified uses

OTC
Medicated Patch

2. Hazards identification

Classification of the substance or mixture : Not classified.

GHS label elements

Hazard pictograms : Not applicable.

Signal word : No signal word.

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2. Hazards identification

Hazard statements : No known significant effects or critical hazards.

Precautionary statements

General : Not applicable.

Prevention : Not applicable.

Response : Not applicable.

Storage : Not applicable.

Disposal : Not applicable.

Supplemental label elements : None known.

Hazards not otherwise classified : None known.

No known significant effects or critical hazards.

3. Composition/information on ingredients

Substance/mixture : Mixture

Ingredient name	%	Identifiers
lidocaine	≥2.9 - ≤5	CAS: 137-58-6
L-Menthol	≤1.8	CAS: 2216-51-5

There are no ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified and hence require reporting in this section.

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

4. First aid measures

Description of necessary 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. Get medical attention if irritation occurs.

Inhalation : Remove victim to fresh air and keep at rest in a position comfortable for breathing. Get medical attention if symptoms occur. In case of inhalation of decomposition products in a fire, symptoms may be delayed. The exposed person may need to be kept under medical surveillance for 48 hours.

Skin contact : Flush contaminated skin with plenty of water. Remove contaminated clothing and shoes. Get medical attention if symptoms occur.

Ingestion : Wash out mouth with water. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Do not induce vomiting unless directed to do so by medical personnel. Get medical attention if symptoms occur.

Most important symptoms/effects, acute and delayed

Potential acute health effects

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4. First aid measures

- 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** : No specific data.
Inhalation : No specific data.
Skin contact : No specific data.
Ingestion : No specific data.

Indication of immediate medical attention and special treatment needed, if necessary

- Notes to physician** : In case of inhalation of decomposition products in a fire, symptoms may be delayed. The exposed person may need to be kept under medical surveillance for 48 hours.
Specific treatments : No specific treatment.
Protection of first-aiders : No action shall be taken involving any personal risk or without suitable training.

See toxicological information (Section 11)

5. Fire-fighting measures

Extinguishing media

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

Specific hazards arising from the chemical : No specific fire or explosion hazard.

- Hazardous thermal decomposition products** : Decomposition products may include the following materials:
carbon dioxide
carbon monoxide
nitrogen oxides

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.

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.

6. Accidental release measures

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. Do not touch or walk through spilled material. 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".

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6. Accidental release measures

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).

Methods and materials for containment and cleaning up

Small spill : Move containers from spill area. Vacuum or sweep up material and place in a designated, labeled waste container. Dispose of via a licensed waste disposal contractor.

Large spill : Move containers from spill area. Prevent entry into sewers, water courses, basements or confined areas. Vacuum or sweep up material and place in a designated, labeled waste container. Dispose of via a licensed waste disposal contractor.

7. Handling and storage

Precautions for safe handling

Protective measures : Put on appropriate personal protective equipment (see Section 8).

Conditions for safe storage, including any incompatibilities : Store in accordance with local regulations. Store in original container protected from direct sunlight in a dry, cool and well-ventilated area, away from incompatible materials (see Section 10) and food and drink. Keep container tightly closed and sealed until ready for use. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabeled containers. Use appropriate containment to avoid environmental contamination. See Section 10 for incompatible materials before handling or use.

8. Exposure controls/personal protection

Control

Occupational exposure limits

None.

Biological exposure indices

No exposure indices known.

Appropriate engineering controls : Good general ventilation should be sufficient to control worker exposure to airborne contaminants.

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.

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

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8. Exposure controls/personal 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.
- 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.
- 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 9. Physical and chemical properties and safety characteristics

The conditions of measurement of all properties are at standard temperature and pressure unless otherwise indicated.

Appearance

- Physical state** : Solid. [patch]
- Color** : Not available.
- Odor** : Not available.
- Odor threshold** : Not available.
- pH** : Not available.
- Melting point/freezing point** : Not available.
- Boiling point or initial boiling point and boiling range** : Not available.
- Flash point** : Not applicable.
- Evaporation rate** : Not available.
- Flammability** : Not available.
- Lower and upper explosion limit/flammability limit** : Not applicable.
- Vapor pressure** : Not available.
- Relative vapor density** : Not applicable.
- Relative density** : Not available.
- Solubility(ies)** :

Media	Result
cold water	Not soluble
hot water	Not soluble

- Solubility in water** : Not available.
- Partition coefficient: n-octanol/water** : Not applicable.
- Auto-ignition temperature** : Not applicable.
- Decomposition temperature** : Not available.

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Section 9. Physical and chemical properties and safety characteristics

Viscosity : Dynamic (room temperature): Not available.
Kinematic (room temperature): Not available.
Kinematic (40°C (104°F)): Not available.

Particle characteristics

Median particle size : Not available.

10. Stability and reactivity

Reactivity : No specific test data related to reactivity available for this product or its ingredients.

Chemical stability : The product is stable.

Possibility of hazardous reactions : Under normal conditions of storage and use, hazardous reactions will not occur.

Conditions to avoid : No specific data.

Incompatible materials : No specific data.

Hazardous decomposition products : Under normal conditions of storage and use, hazardous decomposition products should not be produced.

11. Toxicological information

Information on toxicological effects

Acute toxicity

Product/ingredient name	Result	Species	Dose	Exposure
lidocaine	LD50 Oral	Rat	317 mg/kg	-
L-Menthol	LD50 Dermal	Rabbit	>5000 mg/kg	-
	LD50 Oral	Rat	3300 mg/kg	-

Conclusion/Summary : Based on test data, the classification criteria are not met.

Irritation/Corrosion

Product/ingredient name	Result	Species	Score	Exposure	Observation
L-Menthol	Eyes - Mild irritant	Mammal - species unspecified	-	0.7 %	-

Conclusion/Summary

Skin : Based on available data, the classification criteria are not met.

Eyes : Based on available data, the classification criteria are not met.

Respiratory : Based on available data, the classification criteria are not met.

Respiratory or skin sensitization

Not available.

Conclusion/Summary

Skin : Based on available data, the classification criteria are not met.

Respiratory : Based on available data, the classification criteria are not met.

Mutagenicity

Not available.

Conclusion/Summary : Based on available data, the classification criteria are not met.

Carcinogenicity

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11. Toxicological information

Not available.

Conclusion/Summary : Based on available data, the classification criteria are not met.

Reproductive toxicity

Not available.

Conclusion/Summary : Based on available data, the classification criteria are not met.

Teratogenicity

Not available.

Conclusion/Summary : Based on available data, the classification criteria are not met.

Specific target organ toxicity (single exposure)

Not available.

Specific target organ toxicity (repeated exposure)

Not available.

Aspiration hazard

Not available.

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 : No specific data.

Inhalation : No specific data.

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.

Conclusion/Summary : Based on available data, the classification criteria are not met.

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11. Toxicological information

- General** : No known significant effects or critical hazards.
Carcinogenicity : No known significant effects or critical hazards.
Mutagenicity : No known significant effects or critical hazards.
Reproductive toxicity : No known significant effects or critical hazards.

Numerical measures of toxicity

Acute toxicity estimates

Product/ingredient name	Oral (mg/kg)	Dermal (mg/kg)	Inhalation (gases) (ppm)	Inhalation (vapors) (mg/l)	Inhalation (dusts and mists) (mg/l)
Biofreeze Dual Active Relief Ultraflex Patch _3323447_D8412529 US	3602.3	N/A	N/A	N/A	N/A
lidocaine	317	N/A	N/A	N/A	N/A
L-Menthol	3300	N/A	N/A	N/A	N/A

12. Ecological information

Toxicity

Product/ingredient name	Result	Species	Exposure
L-Menthol	Acute LC50 18900 µg/l Fresh water	Fish - <i>Pimephales promelas</i>	96 hours

Persistence and degradability

Not available.

Bioaccumulative potential

Product/ingredient name	LogP _{ow}	BCF	Potential
lidocaine	2.44	-	Low
L-Menthol	3.15	7.76	Low

Mobility in soil

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

- Other adverse effects** : No known significant effects or critical hazards.

13. Disposal considerations

- Disposal methods** : 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. Waste packaging should be recycled. Incineration or landfill should only be considered when recycling is not feasible. This material and its container must be disposed of in a

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13. Disposal considerations

safe way. Empty containers or liners may retain some product residues. Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers.

14. Transport information

	DOT Classification	TDG Classification	IMDG	IATA
UN number	Not regulated.	Not regulated.	Not regulated.	Not regulated.
UN proper shipping name	-	-	-	-
Transport hazard class(es)	-	-	-	-
Packing group	-	-	-	-
Environmental hazards	No.	No.	No.	No.

Additional information

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.

Transport in bulk according to IMO instruments : Not available.

15. Regulatory information

U.S. Federal regulations : [TSCA 12\(b\) - Chemical export notification](#)

Not applicable.

Clean Air Act Section 112 (b) Hazardous Air Pollutants (HAPs) : Not listed

Clean Air Act Section 602 Class I Substances : Not listed

Clean Air Act Section 602 Class II Substances : Not listed

DEA List I Chemicals (Precursor Chemicals) : Not listed

DEA List II Chemicals (Essential Chemicals) : Not listed

[SARA 302/304](#)

[Composition/information on ingredients](#)

No products were found.

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SARA 304 RQ : Not applicable.

SARA 311/312

Classification : Not applicable.

Composition/information on ingredients

Name	%	Classification
lidocaine	≥2.9 - ≤5	ACUTE TOXICITY (oral) - Category 4
L-Menthol	≤1.8	SKIN IRRITATION - Category 2 EYE IRRITATION - Category 2B

State regulations

Massachusetts : The following components are listed: Mineral Oil

New York : None of the components are listed.

New Jersey : None of the components are listed.

Pennsylvania : None of the components are listed.

Label elements

Additional information / Recommendations

Additional information : For external use only Avoid contact with eyes.

Recommendations : No known significant effects or critical hazards.

Recommendations : No known significant effects or critical hazards.

16. Other information

Hazardous Material Information System (U.S.A.)

Health	/	0
Flammability		0
Physical hazards		0

Caution: HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. Although HMIS® ratings and the associated label are not required on SDSs or products leaving a facility under 29 CFR 1910.1200, the preparer may choose to provide them. HMIS® ratings are to be used with a fully implemented HMIS® program. HMIS® is a registered trademark and service mark of the American Coatings Association, Inc.

The customer is responsible for determining the PPE code for this material. For more information on HMIS® Personal Protective Equipment (PPE) codes, consult the HMIS® Implementation Manual.

National Fire Protection Association (U.S.A.)



NFPA (30B) aerosol Flammability Not applicable

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16. Other information

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Copyright ©2001, National Fire Protection Association, Quincy, MA 02269. This warning system is intended to be interpreted and applied only by properly trained individuals to identify fire, health and reactivity hazards of chemicals. The user is referred to certain limited number of chemicals with recommended classifications in NFPA 49 and NFPA 325, which would be used as a guideline only. Whether the chemicals are classified by NFPA or not, anyone using the 704 systems to classify chemicals does so at their own risk.

Key to abbreviations : ATE = Acute Toxicity Estimate
BCF = Bioconcentration Factor
GHS = Globally Harmonized System of Classification and Labelling of Chemicals
IATA = International Air Transport Association
IBC = Intermediate Bulk Container
IMDG = International Maritime Dangerous Goods
LogPow = logarithm of the octanol/water partition coefficient
MARPOL = International Convention for the Prevention of Pollution From Ships, 1973 as modified by the Protocol of 1978. ("Marpol" = marine pollution)
UN = United Nations

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▣ Indicates information that has changed from previously issued version.

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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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