

# SAFETY DATA SHEET

Biofreeze UltraFlex Lidocaine Patch



HEALTH • HYGIENE • HOME

## 1. Product and company identification

**Product name** : Biofreeze UltraFlex Lidocaine Patch  
**Distributed by** : RB Health (US) LLC  
Morris Corporate Center IV  
399 Interpace Parkway (P.O. Box 225)  
Parsippany, New Jersey 07054-0225  
+1 973 404 2600

**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 #** : D8409683

**Formulation #** : 3303650

### 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.

**Hazard statements** : No known significant effects or critical hazards.

### Precautionary statements

**General** : Not applicable.

**Code #** : 3303650\_D8409683  
US

**SDS #** : D8409683

**Date of issue** : 22/08/2024

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## 2. Hazards identification

- 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	%	CAS number
lidocaine	≥1 - ≤5	137-58-6

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

- 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.

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## 4. First aid measures

### 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".

**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).

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## 6. Accidental release measures

### 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. Note: see Section 1 for emergency contact information and Section 13 for waste disposal.

## 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

Not applicable.

- 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

- 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.

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## 8. Exposure controls/personal protection

- 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, initial boiling point, and boiling range** : Not available.
- Flash point** : Closed cup: >93.3°C (>199.9°F)
- 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.
- Viscosity** : Not applicable.
- Particle characteristics**
- Median particle size** : Not available.

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## 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	-

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

#### Irritation/Corrosion

Not available.

#### 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.

#### 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

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)

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## 11. Toxicological information

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.
- 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

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## 11. Toxicological information

Product/ingredient name	Oral (mg/kg)	Dermal (mg/kg)	Inhalation (gases) (ppm)	Inhalation (vapors) (mg/l)	Inhalation (dusts and mists) (mg/l)
Biofreeze Lidocaine Patch_3303650_D8409683 US lidocaine	7925 317	N/A N/A	N/A N/A	N/A N/A	N/A N/A

## 12. Ecological information

### Toxicity

Not available.

### Persistence and degradability

Not available.

### Bioaccumulative potential

Product/ingredient name	LogP <sub>ow</sub>	BCF	Potential
lidocaine	2.44	-	low

### Mobility in soil

Soil/water partition coefficient (K<sub>oc</sub>) : 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 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

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## 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** :

**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.

**SARA 304 RQ** : Not applicable.

### SARA 311/312

**Classification** : Not applicable.

#### Composition/information on ingredients

Name	%	Classification
lidocaine	≥1 - ≤5	ACUTE TOXICITY (oral) - Category 4

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## 15. Regulatory information

### State regulations

- Massachusetts** : The following components are listed: Mineral Oil; BHT (Butylated Hydroxytoluene)  
**New York** : None of the components are listed.  
**New Jersey** : The following components are listed: BHT (Butylated Hydroxytoluene)  
**Pennsylvania** : The following components are listed: BHT (Butylated Hydroxytoluene)

### 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		1
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.

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



NFPA (30B) aerosol Flammability Not applicable

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