



## LIDOCAINE TRANSDERMAL SYSTEM SAFETY DATA SHEET

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

### 1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY

#### Product Identifier

**Product name:** Lidocaine Transdermal System

**Synonyms:** Lidocaine Patch 5%

#### Intended Use of the Product

**Use of the substance/mixture:** Pharmaceutical. Transdermal. Use only as directed. Refer to product insert for usage instructions and product information.

#### Name, Address, and Telephone of the Responsible Party

##### Supplier:

Mylan N.V.  
Building 4, Trident Place  
Mosquito Way  
Hatfield,  
Hertfordshire  
AL10 9UL, United Kingdom  
+44 (0)1707 853000

[www.mylan.com](http://www.mylan.com)

##### Contact e-mail:

[SDScontact@Mylan.com](mailto:SDScontact@Mylan.com)

##### Emergency Telephone Number

##### Emergency number

: For Hazardous Materials Incident  
Spill, Leak, Fire, Exposure, or Accident  
Call CHEMTREC (24 Hours)  
Worldwide +1 703-741-5970

For reporting adverse health events, call:  
+1 877-446-3679

### 2. HAZARDS IDENTIFICATION

*Pharmaceutical Agent – Handling of this product in its final form presents minimal occupational exposure risk.*

**Patients/Consumers:** Please refer to the product information insert or product label for appropriate consumer-specific information about this product when used according to the physician's directions.

#### Classification of the Substance or Mixture

##### Classification (GHS-US)

Skin Sens. 1 H317

#### Label Elements

##### GHS-US labeling

##### Hazard pictograms (GHS-US)



##### Signal word (GHS-US)

: Warning

##### Hazard statements (GHS-US)

: H317 - May cause an allergic skin reaction

##### Precautionary statements (GHS-US)

: P261 - Avoid breathing dust/fume/gas/mist/vapors/spray.  
P272 - Contaminated work clothing should not be allowed out of the workplace.  
P280 - Wear protective gloves/protective clothing/eye protection/face protection.  
P302+P352 - IF ON SKIN: Wash with plenty of soap and water.  
P321 - Specific treatment (see section 4).

P333+P313 - If skin irritation or rash occurs: Get medical advice/attention.  
P362+P364 - Take off contaminated clothing and wash it before reuse.  
P501 - Dispose of contents/container according to local, regional, national, territorial, provincial, and international regulations.

#### **Other Hazards**

Not available

#### **Unknown acute toxicity (GHS-US)**

Not available

### **3. COMPOSITION/INFORMATION ON INGREDIENTS**

#### **Mixture**

<b>Name</b>	<b>Product identifier</b>	<b>% (w/w)</b>	<b>Classification (GHS-US)</b>
Acetamide, 2-(diethylamino)-N-(2,6-dimethylphenyl)-	(CAS No) 137-58-6	5	Acute Tox. 4 (Oral), H302 Skin Sens. 1, H317

Full text of H-phrases: see section 16

### **4. FIRST AID MEASURES**

*This is a pharmaceutical product in its final form. The risk of harmful exposure in the workplace is limited, however, the following guidance may be used as needed.*

#### **Description of First Aid Measures**

**General:** Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice.

**Inhalation:** The risk of inhalation exposure is negligible when product is in its final packaged form. If exposed and become symptomatic, move to fresh air and get medical attention if symptoms persist.

**Skin Contact:** Basic hygiene and appropriate precautions should prevent skin contact. If skin contact occurs, wash affected area with soap and water for at least 15 minutes. Should skin irritation, allergic reaction, or rash occur, remove contaminated clothing (if required) and seek medical advice.

**Eye Contact:** The risk of eye exposure is negligible when product is in its final packaged form. If eye contact occurs, flush immediately with water for at least 15 minutes. If easy to do, remove contact lenses. Get medical attention.

**Ingestion:** Ingestion is not an anticipated route of exposure. If accidental ingestion occurs, flush mouth out with water and get medical attention.

#### **Most Important Symptoms and Effects Both Acute and Delayed**

**General:** Please refer to the package insert for more detailed information.

**Inhalation:** Inhalation is not considered a potential route of exposure.

**Skin Contact:** Absorbed through the skin. Exposure may produce an allergic reaction.

**Eye Contact:** Not expected to be a primary route of exposure.

**Ingestion:** May be harmful if swallowed.

**Chronic symptoms:** Repeated or prolonged skin contact may cause dermatitis. May cause an allergic skin reaction.

#### **Indication of Any Immediate Medical Attention and Special Treatment Needed**

If exposed or concerned, get medical advice and attention.

### **5. FIREFIGHTING MEASURES**

#### **Extinguishing Media**

**Suitable extinguishing media:** Not flammable. Use extinguishing media appropriate for surrounding fire.

**Unsuitable extinguishing media:** None known.

#### **Special Hazards Arising From the Substance or Mixture**

**Fire hazard:** Not considered flammable but will burn at high temperatures.

**Explosion hazard:** Product is not explosive.

**Reactivity:** Hazardous reactions will not occur under normal conditions.

#### **Advice for Firefighters**

**Precautionary measures fire:** Exercise caution when fighting any chemical fire.

**Firefighting instructions:** Use water spray or fog for cooling exposed containers.

**Protection during firefighting:** Do not enter fire area without proper protective equipment, including respiratory protection.

**Hazardous Combustion Products:** Carbon oxides (CO, CO<sub>2</sub>). Silicon oxides.

**Other information:** Refer to Section 9 for flammability properties.

### **6. ACCIDENTAL RELEASE MEASURES**

*This is a pharmaceutical product in its final form. The risk of harmful exposure in the workplace is limited, however, the following guidance may be used as needed.*

#### **Personal Precautions, Protective Equipment and Emergency Procedures**

**General measures:** Do not get in eyes, on skin, or on clothing.

#### **For Non-Emergency Personnel**

**Protective equipment:** Use appropriate personal protection equipment (PPE).

**Emergency procedures:** Evacuate unnecessary personnel.

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### **For Emergency Personnel**

**Protective equipment:** Equip cleanup crew with proper protection.

### **Environmental Precautions**

Prevent entry to sewers and public waters.

### **Methods and Material for Containment and Cleaning Up**

**Methods for cleaning up:** For small quantities associated with normal therapeutic use, collect spillage and transfer to a closed waste container for disposal. For large or bulk quantities, after absorption with inert material, collect spillage by sweeping up spilled material and place in a labeled, sealed container for proper disposal.

### **Reference to Other Sections**

See heading 8, Exposure Controls and Personal Protection.

## **7. HANDLING AND STORAGE**

### **Precautions for Safe Handling**

**Patients/Consumers:** Patients should adhere to the instructions provided within the product information insert or product label for appropriate consumer-specific information about this product when used according to the physician's directions.

**Hygiene measures:** This SDS is for a pharmaceutical agent - Handling of this product in its final form presents minimal occupational exposure risk. In an occupational setting, handle in accordance with good industrial hygiene and safety procedures. Avoid contact with eyes, skin and clothing. Avoid breathing vapor or mist. Use appropriate personal protective equipment when handling and observe good personal hygiene measures after handling.

### **Conditions for Safe Storage, Including Any Incompatibilities**

**Storage conditions:** Store in a dry, cool and well-ventilated place. Protect from heat and direct sunlight.

### **Specific End Use(s)**

Pharmaceutical. Refer to product insert for usage instructions and product information.

## **8. EXPOSURE CONTROLS/PERSONAL PROTECTION**

*This is a pharmaceutical product in its final form. The risk of harmful exposure in the workplace is limited, however, the following guidance may be used as needed.*

### **Control Parameters**

No Occupational Exposure Limits (OELs) have been established for this product or its chemical components.

### **Exposure Controls**

**Appropriate engineering controls:** Not generally required. Site-specific risk assessments should be conducted to determine the appropriate exposure control measures. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits.

**Personal protective equipment:** Protective clothing. Gloves.

**Hand protection:** Wear protective gloves made from PVC, neoprene, nitrile, vinyl, or PVC/NBR.

**Eye protection:** In laboratory, medical or industrial settings, or operations in which airborne particulates will be generated, safety glasses with side shields are recommended.

**Skin and body protection:** In laboratory, medical or industrial settings, impervious disposable gloves and protective clothing are recommended if skin contact with drug product is possible.

**Respiratory protection:** When manufacturing or handling product in large quantities and dusts or particulates may be generated, maintain airborne concentrations below recommended limits. Workplace risk assessments should be completed before specifying and implementing respirator usage. NIOSH/MSHA approved respirators for protection should be used if respirators are found to be necessary.

## **9. PHYSICAL AND CHEMICAL PROPERTIES**

### **Information on Basic Physical and Chemical Properties**

<b>Physical state</b>	: Solid
<b>Appearance</b>	: A rectangular patch consisting of a pigmented backing film randomly printed with "Lidocaine Patch 5%" in brown ink, an adhesive matrix layer and a clear removable release liner. Each individual patch is packaged in a sealed pouch, imprinted with lot number and manufacture date.
<b>Odor</b>	: Not available
<b>Odor threshold</b>	: Not available
<b>pH</b>	: Not available
<b>Relative evaporation rate (butyl acetate=1)</b>	: Not available
<b>Melting point</b>	: Not available
<b>Freezing point</b>	: Not available
<b>Boiling point</b>	: Not available
<b>Flash point</b>	: Not available
<b>Auto-ignition temperature</b>	: Not available

<b>Decomposition Temperature</b>	: Not available
<b>Flammability (solid, gas)</b>	: Not available
<b>Lower flammable limit</b>	: Not available
<b>Upper flammable limit</b>	: Not available
<b>Vapor pressure</b>	: Not available
<b>Relative vapor density at 20 °C</b>	: Not available
<b>Relative density</b>	: Not available
<b>Specific gravity density</b>	: Not available
<b>Solubility</b>	: Not available
<b>Log Pow</b>	: Not available
<b>Log Kow</b>	: Not available
<b>Viscosity, kinematic</b>	: Not available
<b>Viscosity, dynamic</b>	: Not available
<b>Explosion data - sensitivity to mechanical impact</b>	: Not available
<b>Explosion data - sensitivity to static discharge</b>	: Not available

## 10. STABILITY AND REACTIVITY

### Reactivity

Hazardous reactions will not occur under normal conditions.

### Chemical Stability

Stable under normal conditions.

### Possibility of Hazardous Reactions

Hazardous polymerization will not occur.

### Conditions to Avoid

Direct sunlight. Extremely high or low temperatures.

### Incompatible Materials

Strong oxidizers. Strong bases. Strong acids.

### Hazardous Decomposition Products

Decomposition will not occur under normal conditions.

## 11. TOXICOLOGICAL INFORMATION

### Information on Toxicological Effects - Product

**Acute toxicity:** Not classified

**LD50 and LC50 Data:** Not available

**Respiratory or skin sensitization:** May cause an allergic skin reaction.

**Germ cell mutagenicity:** Not classified

**Teratogenicity:** Not available

**Carcinogenicity:** Not classified

**Specific target organ toxicity (repeated exposure):** Not classified

**Reproductive toxicity:** Not classified

**Specific target organ toxicity (single exposure):** Not classified

**Aspiration hazard:** Not classified

### Information on Toxicological Effects - Ingredient(s)

**LD50 and LC50 Data:** Not available

## 12. ECOLOGICAL INFORMATION

### Toxicity

Not available

### Persistence and Degradability

Not available

### Bioaccumulative Potential

Not available

## 13. DISPOSAL CONSIDERATIONS

**Waste disposal recommendations:** Dispose of waste material in accordance with all local, regional, national, provincial, territorial and international regulations. Do not dispose of waste into sewer.

<b>14.</b>	<b>TRANSPORT INFORMATION</b>
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*Transportation requirements can vary based on numerous factors such as regional regulations and shipment volume. It is the responsibility of the transporting organization to ensure compliance with all applicable laws and regulations regarding the transportation of this product.*

**In Accordance With ICAO/IATA/DOT/TDG**

**UN Number:** Not regulated for transport

**UN Proper Shipping Name:** Not regulated for transport

<b>15.</b>	<b>REGULATORY INFORMATION</b>
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**US Federal Regulations**

<b>Lidocaine Transdermal System</b>	
<b>SARA Section 311/312 Hazard Classes</b>	Delayed (chronic) health hazard

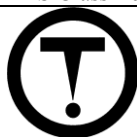
<b>Acetamide, 2-(diethylamino)-N-(2,6-dimethylphenyl)- (137-58-6)</b>	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	

**US State Regulations**

Not applicable

**Canadian Regulations**

<b>Lidocaine Transdermal System</b>	
<b>WHMIS Classification</b>	Class D Division 2 Subdivision B - Toxic material causing other toxic effects



<b>Acetamide, 2-(diethylamino)-N-(2,6-dimethylphenyl)- (137-58-6)</b>	
Listed on the Canadian DSL (Domestic Substances List) inventory.	

This product has been classified in accordance with the hazard criteria of the Controlled Products Regulations (CPR) and the SDS contains all of the information required by CPR.

<b>16.</b>	<b>OTHER INFORMATION</b>
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**Indication of changes** : 15 September 2016

**Data sources** : This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 29 CFR 1910.1200.

**Other information** : This document has been prepared in accordance with standards for workplace safety. The precautionary statements and warnings included might not apply in all cases. Your needs may vary depending on the potential for exposure in your workplace.

**GHS Full Text Phrases:**

Acute Tox. 4 (Oral)	Acute toxicity (oral) Category 4
Skin Sens. 1	Skin sensitization Category 1
H302	Harmful if swallowed
H317	May cause an allergic skin reaction

**Party Responsible For The Preparation Of This Document:**

Mylan Global Environmental, Health, and Safety Department  
Phone Number: 304-599-2595

*This SDS has been prepared for occupational exposure and intended to address some end-user concerns; however, patients/consumers are also strongly encouraged to review the product information insert or product label for consumer-specific information about this product. Patients/Consumers: Refer to the package insert or product label for appropriate consumer-specific information about this product when used according to manufacturer's directions. 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 completeness of the information 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.*

Mylan NA GHS SDS