



FENTANYL 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: Fentanyl Transdermal System

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 Technologies Inc.

110 Lake Street

St Albans, VT 05478

www.mylantech.com

+1 304-599-2595

Emergency Telephone Number

Emergency number : +1 877-446-3679

2. HAZARDS IDENTIFICATION

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

Classification of the Substance or Mixture

Classification (GHS-US)

Acute Tox. 4 (Oral) H302

Acute Tox. 3 (Dermal) H311

Skin Sens. 1 H317

Lact H362

Label Elements

GHS-US labeling

Hazard pictograms (GHS-US) :



Signal word (GHS-US) :

Danger

Hazard statements (GHS-US) :

H302 - Harmful if swallowed

H311 - Toxic in contact with skin

H317 - May cause an allergic skin reaction

H362 - May cause harm to breast-fed children

Precautionary statements (GHS-US) :

P201 - Obtain special instructions before use.

P260 - Do not breathe vapors.

P263 - Avoid contact during pregnancy/while nursing.

P264 - Wash hands, forearms, and exposed areas thoroughly after handling.

P270 - Do not eat, drink or smoke when using this product.

P272 - Contaminated work clothing should not be allowed out of the workplace.

P273 - Avoid release to the environment.

P280 - Wear protective clothing, protective gloves.

P301+P312 - IF SWALLOWED: Call a POISON CENTER or doctor/physician if you

feel unwell.
 P302+P352 - IF ON SKIN: Wash with plenty of soap and water.
 P308+P313 - If exposed or concerned: Get medical advice/attention.
 P312 - Call a POISON CENTER or doctor if you feel unwell.
 P321 - Specific treatment (see Section 4).
 P330 - If swallowed, rinse mouth.
 P333+P313 - If skin irritation or rash occurs: Get medical advice/attention.
 P361 - Remove/Take off immediately all contaminated clothing.
 P363 - Wash contaminated clothing before reuse.
 P391 - Collect spillage.
 P405 - Store locked up.
 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

Name	Product identifier	% (w/w)	Classification (GHS-US)
Fentanyl	(CAS No) 437-38-7	1 - 5	Acute Tox. 2 (Oral), H300 Acute Tox. 1 (Dermal), H310 Acute Tox. 2 (Inhalation:dust,mist), H330* Resp. Sens. 1, H334* Skin Sens. 1, H317 Lact, H362 Repr. 2, H361 Aquatic Chronic 4, H413
n-Heptane	(CAS No) 142-82-5	< 0.1	Flam. Liq. 2, H225 Skin Irrit. 2, H315 STOT SE 3, H336* Asp. Tox. 1, H304 Aquatic Acute 1, H400 Aquatic Chronic 1, H410

*Inhalation of the final product is not considered a potential route of exposure.

Full text of H-phrases: see section 16

4. FIRST AID MEASURES

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. Harmful if swallowed. Toxic in contact with skin. Causes skin irritation. Exposure may produce an allergic reaction.

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

Skin Contact: Absorbed through the skin. Toxic in contact with skin. May cause an allergic skin reaction.

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

Ingestion: Harmful if swallowed.

Chronic symptoms: Repeated or prolonged skin contact may cause dermatitis and defatting. Suspected of damaging fertility. Suspected of damaging the unborn child. Reproductive toxicity (Lact.). May produce an allergic 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, CO₂). Silicon oxides.

Other information: Refer to Section 9 for flammability properties.

6. ACCIDENTAL RELEASE MEASURES

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.

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. 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

Control Parameters

n-Heptane (142-82-5)		
USA ACGIH	ACGIH TWA (ppm)	400 ppm
USA ACGIH	ACGIH STEL (ppm)	500 ppm
USA OSHA	OSHA PEL (TWA) (mg/m ³)	2000 mg/m ³
USA OSHA	OSHA PEL (TWA) (ppm)	500 ppm
USA NIOSH	NIOSH REL (TWA) (mg/m ³)	350 mg/m ³
USA NIOSH	NIOSH REL (TWA) (ppm)	85 ppm
USA NIOSH	NIOSH REL (ceiling) (mg/m ³)	1800 mg/m ³
USA NIOSH	NIOSH REL (ceiling) (ppm)	440 ppm
USA IDLH	US IDLH (ppm)	750 ppm
Alberta	OEL STEL (mg/m ³)	2050 mg/m ³
Alberta	OEL STEL (ppm)	500 ppm
Alberta	OEL TWA (mg/m ³)	1640 mg/m ³
Alberta	OEL TWA (ppm)	400 ppm
British Columbia	OEL STEL (ppm)	500 ppm
British Columbia	OEL TWA (ppm)	400 ppm
Manitoba	OEL STEL (ppm)	500 ppm

Manitoba	OEL TWA (ppm)	400 ppm
New Brunswick	OEL STEL (mg/m ³)	2050 mg/m ³
New Brunswick	OEL STEL (ppm)	500 ppm
New Brunswick	OEL TWA (mg/m ³)	1640 mg/m ³
New Brunswick	OEL TWA (ppm)	400 ppm
New Foundland & Labrador	OEL STEL (ppm)	500 ppm
New Foundland & Labrador	OEL TWA (ppm)	400 ppm
Nova Scotia	OEL STEL (ppm)	500 ppm
Nova Scotia	OEL TWA (ppm)	400 ppm
Nunavut	OEL STEL (mg/m ³)	2049 mg/m ³
Nunavut	OEL STEL (ppm)	500 ppm
Nunavut	OEL TWA (mg/m ³)	1640 mg/m ³
Nunavut	OEL TWA (ppm)	400 ppm
Northwest Territories	OEL STEL (mg/m ³)	2049 mg/m ³
Northwest Territories	OEL STEL (ppm)	500 ppm
Northwest Territories	OEL TWA (mg/m ³)	1640 mg/m ³
Northwest Territories	OEL TWA (ppm)	400 ppm
Ontario	OEL STEL (ppm)	500 ppm
Ontario	OEL TWA (ppm)	400 ppm
Prince Edward Island	OEL STEL (ppm)	500 ppm
Prince Edward Island	OEL TWA (ppm)	400 ppm
Québec	VECD (mg/m ³)	2050 mg/m ³
Québec	VECD (ppm)	500 ppm
Québec	VEMP (mg/m ³)	1640 mg/m ³
Québec	VEMP (ppm)	400 ppm
Saskatchewan	OEL STEL (ppm)	500 ppm
Saskatchewan	OEL TWA (ppm)	400 ppm
Yukon	OEL STEL (mg/m ³)	2000 mg/m ³
Yukon	OEL STEL (ppm)	500 ppm
Yukon	OEL TWA (mg/m ³)	1600 mg/m ³
Yukon	OEL TWA (ppm)	400 ppm

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

Physical state	: Solid
Appearance	: Colorless Translucent Rectangular Patch
Odor	: Odorless
Odor threshold	: Not available
pH	: Not available
Relative evaporation rate (butyl acetate=1)	: Not available
Melting point	: Not available
Freezing point	: Not available
Boiling point	: Not available
Flash point	: Not available
Auto-ignition temperature	: Not available
Decomposition Temperature	: Not available

Flammability (solid, gas)	: Not available
Lower flammable limit	: Not available
Upper flammable limit	: Not available
Vapor pressure	: Not available
Relative vapor density at 20 °C	: Not available
Relative density	: Not available
Specific gravity density	: Not available
Solubility	: Not available
Log Pow	: Not available
Log Kow	: Not available
Viscosity, kinematic	: Not available
Viscosity, dynamic	: Not available
Explosion data - sensitivity to mechanical impact	: Not available
Explosion data - sensitivity to static discharge	: 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 Carbon oxides (CO, CO₂). Silicon oxides.

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects - Product

Acute toxicity: Harmful if swallowed. Toxic in contact with skin.
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: May cause harm to breast-fed children.
Specific target organ toxicity (single exposure): Not classified.
Aspiration hazard: Not classified

Information on Toxicological Effects - Ingredient(s)

LD50 and LC50 Data

n-Heptane (142-82-5)	
LD50 dermal rabbit	3000 mg/kg
LC50 inhalation rat (mg/l)	103 g/m ³ (Exposure time: 4 h)
ATE (dermal)	3000.000 mg/kg body weight
ATE (vapors)	103.000 mg/l/4h

12. ECOLOGICAL INFORMATION

Toxicity

n-Heptane (142-82-5)	
LC50 fish 1	375.0 mg/l (Exposure time: 96 h - Species: Cichlid fish)
EC50 Daphnia 1	> 10 mg/l (Exposure time: 24 h - Species: Daphnia magna)

Persistence and Degradability Not available

Bioaccumulative Potential

n-Heptane (142-82-5)	
Log Pow	4.66

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.

14. TRANSPORT INFORMATION

In Accordance With ICAO/IATA/DOT/TDG

UN Number Not regulated for transport

UN Proper Shipping Name Not regulated for transport

15. REGULATORY INFORMATION

US Federal Regulations

Fentanyl Transdermal System

SARA Section 311/312 Hazard Classes	Delayed (chronic) health hazard
	Immediate (acute) health hazard

n-Heptane (142-82-5)

Listed on the United States TSCA (Toxic Substances Control Act) inventory

EPA TSCA Regulatory Flag	T - T - indicates a substance that is the subject of a Section 4 test rule under TSCA.
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US State Regulations

n-Heptane (142-82-5)

U.S. - Massachusetts - Oil & Hazardous Material List - Groundwater Reportable Concentration - Reporting Category 1
U.S. - Massachusetts - Oil & Hazardous Material List - Groundwater Reportable Concentration - Reporting Category 2
U.S. - Massachusetts - Oil & Hazardous Material List - Reportable Quantity
U.S. - Massachusetts - Oil & Hazardous Material List - Soil Reportable Concentration - Reporting Category 1
U.S. - Massachusetts - Oil & Hazardous Material List - Soil Reportable Concentration - Reporting Category 2
U.S. - Massachusetts - Right To Know List
U.S. - New Jersey - Right to Know Hazardous Substance List
U.S. - New Jersey - Special Health Hazards Substances List
U.S. - Pennsylvania - RTK (Right to Know) List

Fentanyl (437-38-7)

U.S. - Pennsylvania - Schedule II Controlled Substances

Canadian Regulations

Fentanyl Transdermal System

WHMIS Classification	Class D Division 2 Subdivision A - Very toxic material causing other toxic effects
	Class D Division 2 Subdivision B - Toxic material causing other toxic effects
	Class D Division 1 Subdivision B - Toxic material causing immediate and serious toxic effects



n-Heptane (142-82-5)

Listed on the Canadian DSL (Domestic Substances List) inventory.

Listed on the Canadian Ingredient Disclosure List

WHMIS Classification	Class B Division 2 - Flammable Liquid
	Class D Division 2 Subdivision B - Toxic material causing other toxic effects

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

16. OTHER INFORMATION

- Indication of changes** : 02/11/2014
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. 1 (Dermal)	Acute toxicity (dermal) Category 1
Acute Tox. 2 (Inhalation:dust,mist)	Acute toxicity (inhalation:dust,mist) Category 2
Acute Tox. 2 (Oral)	Acute toxicity (oral) Category 2
Acute Tox. 3 (Dermal)	Acute toxicity (dermal) Category 3
Acute Tox. 4 (Oral)	Acute toxicity (oral) Category 4
Aquatic Acute 1	Hazardous to the aquatic environment - Acute Hazard Category 1
Aquatic Chronic 1	Hazardous to the aquatic environment - Chronic Hazard Category 1
Aquatic Chronic 4	Hazardous to the aquatic environment - Chronic Hazard Category 4
Asp. Tox. 1	Aspiration hazard Category 1
Flam. Liq. 2	Flammable liquids Category 2

Lact	Reproductive toxicity (Lact.)
Repr. 2	Reproductive toxicity Category 2
Resp. Sens. 1	Respiratory sensitisation Category 1
Skin Irrit. 2	Skin corrosion/irritation Category 2
Skin Sens. 1	Skin sensitization Category 1
STOT SE 3	Specific target organ toxicity (single exposure) Category 3
H225	Highly flammable liquid and vapor
H300	Fatal if swallowed
H302	Harmful if swallowed
H304	May be fatal if swallowed and enters airways
H310	Fatal in contact with skin
H311	Toxic in contact with skin
H315	Causes skin irritation
H317	May cause an allergic skin reaction
H330	Fatal if inhaled
H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled
H336	May cause drowsiness or dizziness
H361	Suspected of damaging fertility or the unborn child
H362	May cause harm to breast-fed children
H400	Very toxic to aquatic life
H410	Very toxic to aquatic life with long lasting effects
H413	May cause long lasting harmful effects to aquatic life

Party Responsible For The Preparation Of This Document:

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

This MSDS 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.

North America Mylan Pharmaceuticals