# SAFETY DATA SHEET

**Issue Date** 17-Jul-2010 **Revision Date** 01-Sep-2016 **Version** 2

## 1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION

**Product Name** Butrans® (buprenorphine) Transdermal System CIII 5, 7.5, 10, 15, 20 mcg/hour

**Synonyms** BTDS

**Other Information** **This is a controlled substance under Schedule III of the Controlled Substances Act.**

**Recommended Use** Opioid analgesic

**Uses advised against** Do not use without a prescription.

**Distributor Address** Purdue Pharma L.P.
One Stamford Forum
201 Tresser Boulevard
Stamford, Connecticut 06901-3431
(888) 726-7535

**24 Hour Emergency Phone Number** Chemtrec (800) 424-9300
For all international transportation emergencies, call Chemtrec collect at (703) 527-3887.

## 2. HAZARDS IDENTIFICATION

Drugs when in solid final form (e.g. capsules, tablets or pills) are considered exempt under the criteria of the Federal OSHA Hazard Communication Standard, 29 CFR 1910.1200. However, in an industrial setting where a component's occupational exposure limits may be surpassed, they can be considered hazardous.

**Emergency Overview**

**Appearance** Dermal patch **Physical state** Solid **Odor** No information available.

**Hazards Not Otherwise Classified (HNOC)**
Not Applicable.

**Other Information**
No information available.

## 3. COMPOSITION/INFORMATION ON INGREDIENTS

**Chemical Family** Opioid analgesic.

| Chemical Name | CAS No | Weight % |
|---|---|---|
| Buprenorphine | 52485-79-7 | 1-5 |
| Levulinic acid | 123-76-2 | 1-5 |
| Povidone (crospovidone) | 9003-39-8 | 1-5 |
| Polyacrylate | 9003-04-7 | 80-90 |

## 4. FIRST AID MEASURES

**First aid measures**

**Eye contact** In case of eye contact, immediately flush eyes with fresh water for at least 15 minutes while holding the eyelids open. Remove contact lenses if worn. Get medical attention if irritation persists.

**Skin contact** In case of contact, remove contaminated clothing. Immediately flush skin with copious amounts of water for at least 15 minutes. Obtain medical attention if skin reaction occurs.

**Inhalation** In case of inhalation, remove to fresh air. If not breathing, provide artificial respiration. If breathing is difficult, administer oxygen. Seek medical attention immediately.

**Ingestion** In case of accidental ingestion, wash out mouth with copious amounts of water. Seek medical attention immediately. Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person.

**Self-protection of the first aider** Do not use mouth-to-mouth method if victim ingested or inhaled the substance; give artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device.

**Most important symptoms and effects, both acute and delayed**

**Symptoms** May cause drowsiness, dizziness, or respiratory depression.

**Indication of any immediate medical attention and special treatment needed**

**Note to physicians** This material is an opioid or derivative. Reduced sensation of pain, CNS effects, and opioid-related effects may occur, including respiratory depression. Naloxone has been known to counter the effects of opioids.

## 5. FIRE-FIGHTING MEASURES

**Suitable Extinguishing Media**
Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

**Unsuitable Extinguishing Media** No information available.

**Specific hazards arising from the chemical**
No information available.

**Explosion Data**
**Sensitivity to Mechanical Impact** No information available.
**Sensitivity to Static Discharge** No information available.

**Protective equipment and precautions for firefighters**
As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent), and full protective gear.

## 6. ACCIDENTAL RELEASE MEASURES

**Personal precautions, protective equipment and emergency procedures**

**Personal precautions** Use personal protective equipment as required.

**Other Information** Do not smoke, eat or drink in areas where this material is handled or stored.

**Environmental precautions**

**Environmental precautions** Prevent product from entering drains. Do not flush into surface water or sanitary sewer system. See section 12 for additional Ecological Information.

**Methods and material for containment and cleaning up**

**Methods for containment** Prevent further leakage or spillage if safe to do so.

**Methods for cleaning up** Collect the spilled Butrans® Transdermal System pouches for reuse or disposal as appropriate. Buprenorphine is a Schedule III controlled substance. All cleanup operations should be witnessed by more than one individual. The amount of material collected should be assessed and documented. Notify appropriate company regulatory personnel. Dispose of all solid waste in accordance with federal, state, and local regulations.

## 7. HANDLING AND STORAGE

**Precautions for safe handling**

**Advice on safe handling** Avoid contact with skin and eyes. Use personal protective equipment as required.

**Conditions for safe storage, including any incompatibilities**

**Storage conditions** Buprenorphine is a Schedule III controlled substance and requires DEA-compliant storage. Keep container tightly closed. Protect from light.

**Incompatible materials** None known based on available information.

## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

**Exposure Guidelines**

| Chemical Name | Performance-Based Exposure Band (PBEB) | Company OEG (ug/m$^3$) |
|---|---|---|
| Buprenorphine | 4 (1-10 ug/m$^3$) | 1.2 |

**Engineering Controls** None under normal use conditions

**Individual Protection Measures (Personal Protective Equipment)**

**Eye/face protection** No special protective measures are necessary.

**Skin and body protection** No special protective measures are necessary.

**Respiratory protection** No protective equipment is needed under normal use conditions. If exposure limits are exceeded or irritation is experienced, ventilation and evacuation may be required.

**General Hygiene Considerations** Handle in accordance with good industrial hygiene and safety practice.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

**Physical and Chemical Properties**

| | |
|---|---|
| **Physical state** | Solid |
| **Appearance** | Dermal patch |
| **Odor** | No information available. |
| **Color** | Beige |
| **Odor threshold** | No information available. |

| Property | Values | Remark |
|---|---|---|
| **pH** | No information available. | |
| **Melting point / melting range** | No information available. | |
| **Boiling point / boiling range** | No information available. | |
| **Flash point** | No information available. | |
| **Evaporation rate** | No information available. | |
| **Flammability (solid, gas)** | No information available. | |
| **Flammability limits in air** | | |
| **Upper flammability limits** | | |
| **Lower flammability limits** | | |
| **Vapor pressure** | No information available. | |
| **Vapor density** | No information available. | |
| **Specific gravity** | No information available. | |
| **Water solubility** | No information available. | |
| **Solubility in other solvents** | No information available. | |
| **Partition coefficient (n-octanol/water)** | No information available. | |
| **Autoignition temperature** | No information available. | |
| **Decomposition temperature** | No information available. | |
| **Kinematic viscosity** | No information available. | |
| **Dynamic viscosity** | No information available. | |
| **Explosive properties** | No information available. | |
| **Oxidizing properties** | No information available. | |

**Other Information**

| | |
|---|---|
| **Softening point** | No information available. |
| **Molecular weight** | No information available. |
| **VOC content; (%)** | No information available. |
| **Density** | No information available. |
| **Bulk density** | No information available. |

## 10. STABILITY AND REACTIVITY

**Chemical stability** Stable under recommended storage conditions.

**Possibility of hazardous reactions** No information available.
**Hazardous polymerization** Hazardous polymerization does not occur.
**Conditions to avoid** Temperatures above 30 °C / 85 °F.
**Incompatible materials** None known based on available information.
**Hazardous decomposition products** None known based on available information.

## 11. TOXICOLOGICAL INFORMATION

**Information on likely routes of exposure**

**Product Information** No data available.

**Inhalation** No data available.

**Eye contact** No data available.

**Skin contact** No data available.

**Ingestion** No data available.

| Chemical Name | Oral LD50 | Dermal LD50 | Inhalation LC50 |
|---|---|---|---|
| Buprenorphine | >1000 mg/kg ( Rat ) | - | - |
| Levulinic acid | 1850 mg/kg ( Rat ) | 5 g/kg ( Rabbit ) | - |
| Povidone (crospovidone) | 100 g/kg ( Rat ) | - | - |
| Polyacrylate | 40 g/kg ( Rat ) | - | - |

**Information on toxicological effects**

**Symptoms** May cause drowsiness, dizziness, or respiratory depression.

**Sensitization** No information available.

**Delayed and immediate effects as well as chronic effects from short and long-term exposure**

**Germ cell mutagenicity** Buprenorphine results were negative in tests using Chinese hamster bone marrow and spermatogonia cells, and in a mouse lymphoma L5178Y assay. Results were equivocal in the Ames bacterial reverse mutation test (negative in studies conducted in two laboratories, but positive in frame shift mutation assay at high plate concentrations (5 mg/plate) in a third study).

**Carcinogenicity** Buprenorphine administered in rat diet at doses of 0.6, 5.5, and 56 mg/kg/day for 27 months resulted in statistically significant dose-related increases in testicular interstitial (Leydig's) cell tumors, according to the trend test adjusted for survival. Pair-wise comparison of the high dose against control, however, failed to show statistical significance. In an 86 week mouse study, buprenorphine was administered in the diet at doses of 8, 50, and 100 mg/kg/day and was not carcinogenic. Not listed by IARC, NTP, or US OSHA.

| Chemical Name | ACGIH | IARC | NTP | OSHA |
|---|---|---|---|---|
| Povidone (crospovidone) 9003-39-8 | | Group 3 | | |

**Legend**

***IARC (International Agency for Research on Cancer)***
*Group 3 - Not classifiable as a human carcinogen*

**Reproductive toxicity** Buprenorphine reproductive studies in rats demonstrated no evidence of impaired fertility at daily oral doses up to 80 mg/kg, or up to 5 mg/kg I.M. or S.C. Buprenorphine was not teratogenic in rats or rabbits after I.M. or S.C. doses up to 5 mg/kg/day, IV doses up to 0.8 mg/kg/day, or oral doses in rats (up to 160 mg/kg/day), and rabbits (up to 25 mg/kg/day). Significant increases in skeletal abnormalities (e.g. extra thoracic vertebra or ribs) were noted in rats after S.C. administration of 1 mg/kg/day and up, and in rabbits after I.M. administration of 5 mg/kg/day. However, these increases were not statistically significant. Increases in skeletal abnormalities after oral administration were not observed in rats, and increases in rabbits (1-25 mg/kg/day), were not statistically significant. An apparent lack of milk production during general reproduction studies with buprenorphine in rats caused decreased viability and lactation indices. Following administration of high doses of sublingual buprenorphine to pregnant women bupernorphine was found in breast milk.

**Developmental Toxicity** No information available.

**Teratogenicity** No information available.

**STOT-single exposure** No information available.

**STOT-repeated exposure** No information available.

**Chronic Toxicity** No information available.

**Subchronic toxicity** No information available.

**Aspiration hazard** Not Applicable.

**The following values are calculated based on chapter 3.1 of the GHS document.**

**Oral LD50** 663 mg/kg

**Dermal LD50** 196 mg/kg

## 12. ECOLOGICAL INFORMATION

**Ecotoxicity**

| Chemical Name | Algae/aquatic plants | Fish | Toxicity to microorganisms | Crustacea |
|---|---|---|---|---|
| Buprenorphine | NOEC 3.6 mg/L Growth Rate | NOEC 0.13 mg/L (FHM) for 28 days | | NOEC 0.26 mg/L (Daphnia) for 21 days |

Persistence and degradability No information available.

Bioaccumulation Material does not bioaccumulate.

| Chemical Name | Partition coefficient |
|---|---|
| Buprenorphine | 3.4 |

**Other adverse effects** No information available.

## 13. DISPOSAL CONSIDERATIONS

**Waste treatment methods**

**Disposal of wastes** Disposal should be in accordance with applicable regional, national, and local laws, and regulations.

**Contaminated Packaging** Do not reuse container.

## 14. TRANSPORT INFORMATION

**DOT** Not regulated.

**IATA** Not regulated.

## 15. REGULATORY INFORMATION

### International Inventories

| | |
|---|---|
| TSCA | Not determined. |
| DSL | Not determined. |

### Legend:

**TSCA** - United States Toxic Substances Control Act Section 8 (b) Inventory
**DSL/NDSL** - Canadian Domestic Substances List/Non-Domestic Substances List

### US Federal Regulations

**SARA 313**
Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372.

**SARA 311/312 Hazard Categories**

| | |
|---|---|
| **Acute Health Hazard** | No |
| **Chronic Health Hazard** | No |
| **Fire Hazard** | No |
| **Sudden Release of Pressure Hazard** | No |
| **Reactive Hazard** | No |

**CWA (Clean Water Act)**
This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42).

**CERCLA**
This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material.

### US State Regulations

**California Proposition 65**
This product does not contain any Proposition 65 chemicals.

**US State Right-to-Know Regulations**
**US EPA Label Information**
**EPA Pesticide Registration Number** Not Applicable.

## 16. OTHER INFORMATION

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| **NFPA** | **Health Hazards** 0 | **Flammability** 0 | **Instability** 0 | **Physical and Chemical Properties** - |
| **HMIS** | **Health Hazards** 0 | **Flammability** 0 | **Physical Hazards** 0 | **Personal protection** - |

## General Information

In an industrial setting, refer to NFPA 654, Standard for the Prevention of Fire and Dust Explosions from the Manufacturing, Processing, and Handling of Combustible Particulate Solids, for Safe Handling.

**Prepared By**

This SDS was prepared by the Environmental, Health, and Safety & Toxicology Departments of Purdue Pharma L.P.

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**Revision Note** Changes in Section 8 and Section 11.

## Disclaimer

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**End of Safety Data Sheet**