

Purdue Pharma L.P.

Material Safety Data Sheet

Butrans™ (buprenorphine) Transdermal System CIII 5, 10, and 20 mcg/hour pouch

Version: 17-July-10

1. CHEMICAL PRODUCT/COMPANY IDENTIFICATION

Material Identification: Butrans™ Transdermal System 5, 10, 20 mcg/hour in its final, heat-sealed multi-laminate pouch packaging ready for distribution to patients.

Chemical Name:

Active Ingredient: 6,14-ethenomorphinan-7-methanol, 17-(cyclopropylmethyl)- α -(1,1-dimethylethyl)-4, 5-epoxy-18, 19-dihydro-3-hydroxy-6-methoxy- α -methyl-, [5 α , 7 α , (S)].

Active Ingredient: Buprenorphine.

Synonyms:

Active Ingredient: 17-Cyclopropylmethyl-4,5 α -epoxy-7 α -(S)-1-hydroxy-1,2,2-trimethylpropyl-6-methoxy-6,14-endo-ethanomorphinan-3-ol.

Molecular Formula: N/A (Mixture).

Molecular

Weight:

N/A (Mixture).

Active Ingredient: C₂₉-H₄₁-N-O₄.

Molecular

Weight:

467.64

CAS Number: N/A (mixture).

Active Ingredient: 52485-79-7.

Product Use: Opioid analgesic.

Company Identification:

Responsible Party

Purdue Pharma L.P.
One Stamford Forum
201 Tresser Boulevard
Stamford, CT 06901-3431
Telephone: (888) 726-7535

EMERGENCY CONTACT

Chemtrec (800) 424-9300. For all international transportation emergencies, call Chemtrec collect at (703) 527-3887.

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2. HAZARDOUS COMPONENTS

Material	CAS Number	%	System Content (mg)
Each pouch package contains one Butrans TM Transdermal System.	52485-79-7	N/A	5 mcg/hour strength: 5 10 mcg/hour strength: 10 20 mcg/hour strength: 20

3. HAZARDS IDENTIFICATION

Emergency Overview

The ButransTM Transdermal System in its heat-sealed, multi-laminate pouch packaging ready for distribution to patients does not pose a workplace hazard.

ButransTM Transdermal System is a skin patch containing buprenorphine, a strong opioid analgesic, dissolved in the patch's adhesive layer. Each patch is packaged in a heat-sealed protective pouch made of multi-layer composite laminate.

Exposure to buprenorphine from ButransTM Transdermal System only occurs when the patch is removed from its protective pouch, the release liner is removed, and the adhesive surface of the patch is applied directly to the skin.

The pouch package that contains the ButransTM Transdermal System is not susceptible to spillage, breakage, leakage, or generation of dust or vapor.

Potential Health Effects

The ButransTM Transdermal System in its final, heat-sealed multi-laminate pouch packaging is ready for distribution to patients and does not pose a workplace hazard.

Carcinogenicity Information

ButransTM Transdermal System pouch, ButransTM Transdermal System itself, nor its active ingredient, buprenorphine, are listed by IARC, NTP, OSHA, or ACGIH as a carcinogen.

4. FIRST AID MEASURES

First Aid

INHALATION

Not a potential route of workplace exposure to the ButransTM Transdermal System pouch.

SKIN CONTACT

Skin contact with the ButransTM Transdermal System pouch causes no skin reactions.

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EYE CONTACT

Not a potential route of workplace exposure to the Butrans™ Transdermal System pouch.

INGESTION

Not a potential route of workplace exposure to the Butrans™ Transdermal System pouch.

Notes to Physicians

None.

5. FIRE FIGHTING MEASURES

Flammable Properties

The Butrans™ Transdermal System pouches are not considered flammable.

Minimum ignition energy: not applicable.

Minimum ignition temperature – dust cloud: not applicable.

Minimum ignition temperature – dust layer: not applicable.

Maximum explosion pressure (20 L sphere): not applicable.

Maximum rate of pressure rise: not applicable.

K_{st}: not applicable.

Extinguishing Media

Water spray, carbon dioxide, dry chemical powder, or foam as appropriate for the surrounding material.

Fire Fighting Instructions

Evacuate personnel to a safe area. Keep personnel removed and upwind of fire. Wear self-contained breathing apparatus. Wear full protective equipment.

NFPA

H=0;F=0;R=0

6. ACCIDENTAL RELEASE MEASURES

Safeguards (Personnel)

Not applicable.

Initial Containment

Not applicable.

Spill Clean-up

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Collect the spilled Butrans™ Transdermal System pouches for reuse or disposal as appropriate. Buprenorphine is a Schedule III controlled substance. All clean up 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

Handling (Personnel)

No special procedures.

Handling (Physical Aspects)

None applicable.

Storage

To maintain potency of Butrans™ Transdermal System, store pouches at 77°F (25°C); excursions permitted between 59°F to 86°F (15°C to 30°C).

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Engineering Controls

No special controls.

Personal Protective Equipment (PPE)

No special equipment. Wear normal workplace clothing.

Exposure Guidelines

Exposure Limits: Not applicable.

Exposure Guideline Comments: None.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical Data

Form: Solid. Sachet/pouch. Square or rectangular.
Color: White to off-white with print including Butrans™ Transdermal System CIII and strength (5, 10, or 20 mcg/hour) on one side.

10. STABILITY AND REACTIVITY

Chemical Stability

Not applicable.

Incompatibility with Other Materials

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Not applicable.

Conditions to Avoid

To maintain potency, avoid storage conditions outside the temperature range of 59°F to 86°F (15°C to 30°C).

Decomposition

Not applicable.

11. TOXICOLOGICAL INFORMATION

The Butrans™ Transdermal System is in its heat-sealed, multi-laminate pouch packaging ready for distribution to patients and does not pose a workplace hazard. Workplace handling of the Butrans™ Transdermal System pouches will not cause toxic effects.

12. Ecological Information

Ecotoxicological Information: No information available.

Chemical Fate Information: No information available.

13. Disposal Considerations

Disposal

Butrans™ Transdermal System contains buprenorphine, a Schedule III Controlled substance, in a multi-laminate pouch package. This material is not listed under the US RCRA. Disposal of the Butrans™ Transdermal System pouch package must be in accordance with federal, state/provincial, and local regulations.

14. Transportation Information

Shipping Information

Non-hazardous.

15. Regulatory/Statutory Information

US Federal: Butrans™ Transdermal System is subject to control under the US Federal Controlled Substances Act of 1970 as schedule III (C-III) drugs.

International: No information.

EC Labeling: No information.

16. Other Information

5 of 6; Butrans™ Transdermal System CIII 5, 10, 20 mcg/hour pouch MSDS

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The information contained in this Material Safety Data Sheet is believed to be accurate and represents the best information available at the time of preparation. However, no warranty, express or implied, with respect to such information, is made. The data in this Material Safety Data Sheet relate only to the specific material designated herein and does not relate to use in combination with any other material. The data in this Material Safety Data Sheet are subject to revision as additional knowledge and experience are gained.

This MSDS was prepared by the Nonclinical Drug Safety Evaluation of Purdue Pharma L.P.