

SAFETY DATA SHEETS

This SDS packet was issued with item:

078909232

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

078451424 078451440 078451465 078451481 078818827 078823180 078824131 078909231 078909233 078909234

Safety Data Sheet

Section 1. Identification

Common/Trade name : **Apo-Fentanyl Matrix; Fentanyl Transdermal System; Fentanyl Patch; Fentanyl Transdermal System NOVAPLUS®**

Recommended use : Pharmaceutical industry. Dosage form
Therapeutic category: Pain management; analgesic (narcotic); opioid agonist

This Safety Data Sheet has been provided to inform workers of the safety, health and environmental information associated with this product. It is to be used by people handling the material within the workplace only. It is not meant for patients taking the medication. Patients should consult with their physician, pharmacist or the information provided on the label or on the insert.

Recommended restrictions : No other uses are advised.

Supplier	Canada Apotex Inc. 150 Signet Drive Toronto, Ontario M9L 1T9 416-749-9300	U.S. Apotex Corp. 2400 N. Commerce Parkway Suite 400 Weston, FLA 33326 Telephone: (954)384-8007 Toll Free: 1-800-706-5575
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Emergency phone : United States/Canada (Chemtrec) 1-800-424-9300 or
+1 703-527-3887 (24 hours)
For general information call:
1-(416)-749-9300 ext. 8483 (8 AM-4 PM)

Section 2. Hazards Identification

Classification of the substance or mixture : As per 29 CFR 1910.1200 (b)(6) and according to Article 1, item 5 a) of CLP Regulation (EC) 1272/2008, medicinal products (drugs) when it is in the solid, final form for direct administration to the patient or are packaged by the manufacturer for sale to consumers in a retail establishment are exempt from the requirements of classification, labels and SDS's.

GHS label elements : Exempt from requirements.

Hazards not otherwise classified : Exempt from requirements.

Section 3. Composition/Information on Ingredients

Name	CAS #	% (w/w)
Fentanyl	437-38-7	0.5 - 1
Isopropyl myristate	110-27-0	
Octyldodecanol	5333-42-6	
Polybutene	9003-29-6	
Polyisobutene	9003-27-4	

Specific chemical identity and/or percentage of composition has been withheld as a trade secret.

Chemical name : Not applicable

Synonyms : Not available.

Chemical family : Phenylpiperidine derivative

Molecular weight : Not applicable.

Chemical formula : Not applicable.

Section 4. First Aid Measures

Eye contact : Flush with copious quantities of water. If irritation persists, obtain medical advice.

Skin contact : Flush with copious amounts of water. Seek medical attention if irritation persist.

Inhalation : Remove from exposure. Persons developing serious hypersensitivity reactions must receive immediate medical attention. If not breathing give artificial respiration. If breathing is difficult give oxygen.

Ingestion : Never give anything by mouth if victim is losing consciousness, or is unconscious or convulsing. Rinse mouth thoroughly with water. If breathing is difficult, give oxygen. If breathing has stopped, trained personnel should begin artificial respiration, or if the heart has stopped, cardiopulmonary resuscitation (CPR) immediately. Seek medical attention.

Potential acute and delayed health effects : Refer to Sec. 11

Section 5. Fire Fighting Measures

Specific hazard arising from the chemical : During fire, gases hazardous to health may be formed.

Suitable extinguishing media and special protective equipment for firefighters : Extinguisher media: Use extinguishing media suitable for surrounding materials.
Special fire fighting procedures: As with all fires, evacuate personnel to safe area. Firefighters should use self-contained breathing equipment and protective clothing.

Section 6. Accidental Release Measures

Methods and materials for containment and cleaning up : Contain and clean up spillage and place into an appropriate labeled waste disposal container. Avoid generating dust or aerosols. Wash spill surface using appropriate cleaning solutions. Should clothing be contaminated, wash before reuse.

Protective equipment and personal precautions : Keep unnecessary personnel away. Wear appropriate personal protective equipment. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. For personal protection, refer to section 8 of the SDS.

Section 7. Handling and Storage

Precautions for safe handling : Avoid breathing dust.

Conditions for safe storage : Store in original unopened blister. Store up to 25°C (77°F); excursions permitted to 15 to 30°C (59 to 86°F). Fentanyl is a class II controlled substance. Comply with all DEA regulations regarding the handling and control of controlled substances.

Section 8. Exposure Controls/Personal Protection

Engineering Controls : The engineering control measures appropriate for a particular worksite depend on how this material is handled and on the extent of exposure. Ensure that control measures are designed to comply with occupational, environmental, fire and other applicable regulations. Control measures can include mechanical ventilation (local or general) and process enclosure. Administrative controls and personal protective equipment may also be required.

Personal Protection : Follow all appropriate safe work procedures and local regulations for disposal. Use only licensed disposal and waste hauling companies.

PERSONAL PROTECTIVE EQUIPMENT/RESPIRATORY PROTECTION GUIDELINES: Under normal work conditions, the use of respiratory protective equipment is not expected to be required. If the physical state of the finished product is altered by crushing, grinding or breakage or for spill cleaning, appropriate PPE may be required that includes NIOSH approved respirators.

EYE/FACE PROTECTION: Wear approved safety eyewear if eye contact is possible.

SKIN PROTECTION: Where there is a risk of contact when handling, wear suitable skin protection (e.g., gloves, lab coat/uniform) having resistance to the product.

HYGIENE MEASURES: In the event clothing becomes contaminated, remove promptly. Launder before use. When handling, do not eat, drink or smoke. Wash hands thoroughly after handling this material. Maintain good housekeeping.

Occupational exposure limits : Not established.

Section 9. Physical and Chemical Properties

Physical state and appearance : A rectangular patch sealed in its own protective blister.

pH : Not available.

Odor : Not available.

**Melting point/
Freezing point** : Not available.

Odor threshold : Not available.

Boiling point : Not available.

Conditions of instability : No additional remark.

Volatility : Not available.

Decomposition temperature : Not available.

Specific gravity : Not available.

Partition Coefficient: : Not available.

Evaporation rate : Not available.

Viscosity : Not available.

Vapor density : Not available.

Flash points : Not available.

Relative density : Not available.

Flammable limits : Not available.

Vapor pressure : Not available.

Autoignition temperature : Not applicable.

Flammability : Emits toxic fumes under fire conditions.

Solubility : Fentanyl: Practically insoluble in water. Freely soluble in alcohol and in methanol.

Section 10. Stability and Reactivity

Reactivity	: Not available.
Chemical Stability	: Stable under normal conditions of use.
Possibility of hazardous reactions	: Not available.
Hazardous decomp. products	: When heated to decomposition material emits toxic fumes.
Incompatible materials/ Conditions to avoid	: Not determined.

Section 11. Toxicological Information

Information on the likely routes of exposure : Skin contact. Eye contact. Ingestion.

Toxicity data : Fentanyl:
LDLo - R 0.036 mg/kg (oral-man)
TDLo: 0.143 mg/kg (administration on to the skin)
LD50: 18 mg/kg (oral-rat)
LD50: 368 mg/kg (oral-mouse)

Delayed and immediate effects and also chronic effects from short and long term exposure : Carcinogenicity: Not listed as carcinogen by IARC, NTP, ACGIH, or OSHA. In a two-year carcinogenicity study conducted in rats, fentanyl was not associated with an increased incidence of tumors at subcutaneous doses up to 33 mcg/kg/day in males or 100 mcg/kg/day in females (0.16 and 0.39 times the human daily exposure obtained via the 100 mcg/h patch based on AUC0-24h comparison).

Reproductive and Developmental Effects: Pregnancy Category: C. Adult rats of a Wistar substrain were used in studies to determine the possible teratological effects of fentanyl on dams and their offspring. Three successive generations received fentanyl subcutaneously during the first 21 days of pregnancy, in daily doses of 0.04, 0.08, 0.16 and 0.31 mg/rat. No congenital abnormalities were produced in the experimental groups, but there were dose-related decreases in dam survival, survival in utero and average litter size and weight. A slight delay in delivery time and an increased mortality of the newborn were also observed in rats receiving fentanyl. Reproduction studies in rats have shown that fentanyl can impair fertility at doses of 30 mcg/kg IV and 160 mcg/kg subQ (conversion would be equivalent to the range found in human dosing)

Mutagenicity data: Fentanyl tested negative in the Ames Assay, UDS assay and Mammalian Cell Transformation Assay. Fentanyl did not cause chromosomal aberrations in vitro in human lymphocytes or in Chinese hamster ovary cells in the presence or absence of an exogenous metabolic source.

Remark

Medical conditions aggravated by exposure: Hypersensitivity to material, opioid non-tolerance, liver or kidney dysfunction, hypothyroidism, seizure disorders, asthma or other respiratory disorders, heart arrhythmias, acute alcoholism or history of drug abuse or dependence, gallbladder disorders, inflammatory bowel disease, urinary disorders, low blood pressure, gastrointestinal obstruction, Addison's disease, myasthenia gravis, concurrent use of monoamine oxidase (MAO) inhibitors.

Persons sensitive to alfentanil or sufentanil may be sensitive to this material also.

Symptoms related to the physical, chemical and toxicological characteristics : Adverse effects of opioid analgesics may include dizziness, drowsiness, weakness, mood or mental changes (euphoria, agitation, confusion), nausea, vomiting, constipation, decreased or difficult urination, sweating, flushing, itching, and rash. Possible allergic reaction to material if inhaled, ingested, or in contact with skin. Overdose effects of opioid analgesics may include severe dizziness or drowsiness, cold and clammy skin, slow or troubled breathing, low blood pressure, slow or irregular heart rate, pinpoint pupils, seizures, hypothermia, decreased mental status, loss of consciousness, and death. This material may also cause muscle rigidity and respiratory depression that may persist for several hours following exposure.

Section 12. Ecological Information

Ecotoxicity : Environmental properties have not been thoroughly investigated. Releases to the environment should be avoided.

Persistence and degradability : Not available.

Bioaccumulative potential : Not available.

Mobility in soil : Not available.

Other adverse effects : Not available.

Section 13. Disposal Considerations

Waste Disposal : This is a controlled substance/product. Follow all appropriate safe work procedures and federal, provincial and local regulations for disposal. Use only licensed disposal and waste hauling companies.

Section 14. Transport information

Regulatory information	UN number	Proper shipping name	Class	Packing group	Label	Additional information (e.g., special precautions, environmental hazards, transport in bulk)
TDG- road Canada/U.S.			Not regulated.			
ICAO-Air			Not regulated.			
ADR			Not regulated.			
IMDG Class			Not regulated.			

Section 15. Regulatory Information

Canada Regulations : Covered by Food & Drug Act and therefore not regulated under WHMIS
Canadian Regulatory Information: OCS Controlled Substance: Schedule I.

Other Regulations : U.S. Regulatory Information: DEA Controlled Substance: Schedule II

Section 16. Other Information

References : RxList Monographs
RTECS Database
Apotex Product Monograph
U.S. Pharmacopeia
Meditext - Medical Management

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Notice to Reader

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 the accuracy or completeness of the information contained 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.

