

Safety Data Sheet

Section 1. Identification

Common/Trade name : **Nicotine Transdermal System**
7 mg/day, 14 mg/day and 21 mg/day

Recommended use : Pharmaceutical industry. Dosage form
Therapeutic category: Treatment of smoking withdrawal syndrome.

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.

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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) |
|-------------------|----------------|---------|
| Nicotine | 54-11-5 | 7-13 |
| Silicone Adhesive | Not available. | 60-100 |

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

Chemical name : Not applicable

Synonyms : Not available.

Chemical family : Pyridine salt

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** : Remove contaminated clothing immediately and rinse skin generously with running water. Do not use soap or alcohol. Contact a doctor immediately.
- 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 contact with eyes.
- Conditions for safe storage** : Store between 20°-25°C (68°-77°F) away from heat.

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 handlings, do not eat, drink or smoke. Wash hands thoroughly after handling this material. Maintain good housekeeping.

Occupational exposure limits : Nicotine: ACGIH: TWA 0.5 mg/m³ (skin)

Section 9. Physical and Chemical Properties

Physical state and appearance : A square unit with rounded corners, comprised of a white release liner, a layer of adhesive, clear to light yellow in color and a clear backing imprinted overall in white with "Nicotine 7 mg/day", "Nicotine 14 mg/day" or "Nicotine 21 mg/day".

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 : Not available.

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 : Avoid exposure heat.

Section 11. Toxicological Information

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

Toxicity data : Nicotine:
LD50: 50 mg/kg (oral-rat)
LD50: 3 mg/kg (oral-mouse)
LD50: 140 mg/kg (dermal-rat)

Delayed and immediate effects and also chronic effects from short and long term exposure : Target organs: Central nervous system and cardiovascular system.

Carcinogenicity: Not listed as carcinogen by IARC, NTP, ACGIH, or OSHA.

Reproductive and Developmental Effects: Nicotine replacement therapy (and smoking) is not recommended during pregnancy. In pregnant women, miscarriage during nicotine replacement therapy has been reported, with nicotine as the possible cause. Birth defects have been demonstrated in offspring of mice given toxic doses of nicotine.

Mutagenicity data: DNA inhibition, mutagenicity, and chromosome aberrations have been demonstrated experimentally.

Remark

Medical conditions aggravated by exposure: Hypersensitivity to the material, heart problems, diabetes mellitus (insulin dependent), and hypertension.

Symptoms related to the physical, chemical and toxicological characteristics : Adverse effects may include nausea, dizziness, dry mouth, diarrhea, nervousness or restlessness, headache, vivid dreams or other sleep disturbances and irritability, severe skin irritation or discoloration, irregular heartbeats or palpitations, severe chest pain or tightening.
Overdose effects: pallor (extreme paleness), cold sweat, nausea, abnormal salivation, vomiting, abdominal pain or severe headache, disturbed hearing or vision, dizziness, mental confusion, or weakness.

Section 12. Ecological Information

Ecotoxicity : Not available.

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 : Follow all appropriate safe work procedures 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.
Not on the DSL list.

Other Regulations : Not available.

Section 16. Other Information

References : RTECS Database
Product Insert - Aveva

U.S. Pharmacopeia

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Notice to Reader

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