1. IDENTIFICATION

Product identifier: Nicotine Transdermal Patch 17.5mg, 35.0mg, 52.5mg
Synonyms: None

Global Contact: Perrigo Company
Address: 515 Eastern Avenue
          Allegan, MI 49010 USA
Telephone number: +1 269-673-8451
Emergency telephone: +1 888-464-2986

Australian Contact: Perrigo Australia
Address: 25-29 Delawney Street
          Balcatta, Western Australia 6021 Australia
Telephone number: +61 9441 7800
Emergency telephone: +1 760-476-3962 Code 333304
Poisons Information Centre: 13 11 26

New Zealand Contact: Orion Laboratories (NZ) Pty Ltd
Address: PO Box 781
          Whangaparaoa, New Zealand
Telephone number: +61 9441 7800
Emergency telephone: +1 760-476-3962 Code 333304
National Poisons Centre: 0800 764 766

Recommended use: Nicotine replacement therapy.
Restrictions on use: None known.
HSNO Number: Not applicable

2. HAZARD(S) IDENTIFICATION

Classification:

<table>
<thead>
<tr>
<th>Physical</th>
<th>Health</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not hazardous</td>
<td>Not hazardous</td>
</tr>
</tbody>
</table>

Label Elements

Not hazardous in accordance with the GHS, the WHS Regulations and HSNO Regulations.

3. COMPOSITION / INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS No.</th>
<th>Concentration</th>
<th>Substance Classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nicotine Polacrilex</td>
<td>Mixture</td>
<td>4-12%</td>
<td>Acute Toxicity Category 4 (H302, H312)</td>
</tr>
</tbody>
</table>
4. FIRST-AID MEASURES

**Inhalation:** Remove victim to fresh air. If irritation occurs or symptoms develop, get medical attention.

**Skin contact:** In the case of unintended skin contact, wash skin with soap and water. If irritation or other symptoms develop, get immediate medical attention. Remove contaminated clothing and wash it before reuse.

**Eye contact:** Immediately flush eyes with water while lifting the upper and lower lids. Get medical attention if irritation persists.

**Ingestion:** If swallowed, rinse mouth with water. Do not induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to a person who is unconscious or convulsing. Get medical attention if any adverse effects occur.

**Most important symptoms/effects, acute and delayed:** May cause eye irritation. Swallowing or widespread skin contact may cause nicotine overdose with symptoms of nervous system stimulation, nausea, vomiting, dizziness, diarrhea, weakness or rapid heartbeat.

**Indication of immediate medical attention and special treatment, if necessary:** Immediate medical attention is required for ingestion or skin contact above the recommended dosage.

5. FIRE-FIGHTING MEASURES

**Extinguishing media:** Use water spray, carbon dioxide, dry chemical or foam to extinguish a fire.

**Specific hazards arising from the chemical:** This product is not a fire hazard but may burn under fire conditions.

**Special protective equipment and precautions for fire-fighters:** Firefighters should wear positive pressure self-contained breathing apparatus and full protective clothing for all fires involving chemicals.

6. ACCIDENTAL RELEASE MEASURES

**Personal precautions, protective equipment, and emergency procedures:** Wear appropriate protective clothing and equipment as described in Section 8 to avoid skin contact.

**Environmental Precautions:** Prevent spill from entering sewers and water courses. Report releases as required by local and national authorities.

**Methods and materials for containment and cleaning up:** Collect using methods that avoid damage to patches (scoop up carefully) and place in appropriate container for disposal. Clean area thoroughly.

7. HANDLING AND STORAGE

**Precautions for safe handling:** Avoid contact with eyes, skin and clothing. Wash thoroughly with soap and water after handling.
Conditions for safe storage, including any incompatibilities: Store as indicated on product packaging in a secure location.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure guidelines:

<table>
<thead>
<tr>
<th>Component</th>
<th>Exposure Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nicotine Polacrilex (as nicotine)</td>
<td>70 ug/m³ TWA (Perrigo OEL) skin</td>
</tr>
<tr>
<td></td>
<td>0.5 mg/m³ TWA AU OEL skin</td>
</tr>
<tr>
<td>Coconut Oil (as vegetable oil mist)</td>
<td>10 mg/m³ TWA AU OEL</td>
</tr>
</tbody>
</table>

Appropriate engineering controls: No special requirements. Use with adequate general or local exhaust ventilation to keep exposures below minimize exposure levels.

Individual protection measures:

Respiratory protection: None needed under normal use conditions. If exposure limits are exceeded, an approved particulate respirator is recommended. Selection of respiratory protection depends on the contaminant type, form and concentration. Select in accordance with national regulations and good Industrial Hygiene practice.

Skin protection: Impervious gloves recommended for handling unpackaged patches.

Eye protection: Chemical safety goggles recommended for handling unpackaged patches.

Other: None known.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance (physical state, color, etc.): Round with yellowish ochre backing foil

Odour: Not applicable

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Odour threshold</td>
<td>Not applicable</td>
</tr>
<tr>
<td>pH</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Melting point/freezing point</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Boiling Point</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Flash point</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>Not flammable</td>
</tr>
<tr>
<td>VOC</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Flammable limits: LEL</td>
<td>Not applicable</td>
</tr>
<tr>
<td>UEL</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Vapor pressure</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Vapor density</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Relative density</td>
<td>Not available</td>
</tr>
<tr>
<td>Solubility(ies)</td>
<td>Partially soluble in water</td>
</tr>
<tr>
<td>Partition coefficient: n-octanol/water</td>
<td>Not available</td>
</tr>
<tr>
<td>Auto-ignition temperature</td>
<td>Not available</td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td>Not available</td>
</tr>
<tr>
<td>Viscosity</td>
<td>Not applicable</td>
</tr>
</tbody>
</table>

10. STABILITY AND REACTIVITY

Reactivity: Not reactive under normal conditions of use.

Chemical stability: Stable.

Possibility of hazardous reactions: None known.

Conditions to avoid: None known.

Incompatible materials: Avoid oxidizing agents.

Hazardous decomposition products: Thermal decomposition may yield carbon and nitrogen oxides.

11. TOXICOLOGICAL INFORMATION

Acute effects of exposure:

Inhalation: No adverse effects expected.

Ingestion: Swallowing may cause nicotine overdose with symptoms of nervous system stimulation, nausea, vomiting, dizziness, diarrhea, weakness or rapid heartbeat.
Skin contact: Contact may cause slight irritation. Overdose or widespread skin contact may cause effects similar to those described under ingestion.

Eye contact: Contact may cause slight irritation with redness and tearing.

Chronic Effects: No adverse effects are expected.

Skin Sensitization: Components are not known to be sensitizers.

Respiratory Sensitization: Components are not known to be sensitizers.

Germ Cell Mutagenicity: None of the components have been shown to cause germ cell mutagenicity.

Reproductive Toxicity: Nicotine may cause adverse effects on development and fertility based on animal studies.

Carcinogenicity: None of the components are listed as carcinogens or suspected carcinogens by IARC, US NTP, ACGIH or are classified as carcinogens under the GHS.

Acute Toxicity Values: Acute Oral Toxicity Estimate (ATE) calculated: >2500 mg/kg. Acute Dermal Toxicity Estimate (ATE) calculated: 8,333 mg/kg.

Nicotine Polacrilex (20% nicotine): Oral rat LD50 >300 mg/kg; Dermal rabbit LD50 >1000 mg/kg.

12. ECOLOGICAL INFORMATION

Ecotoxicity values: If desorbed from the resin nicotine is toxic to aquatic organisms. Nicotine: EL50 daphnia magna 0.242 mg/L/48 hr; ErC50 algae (desmodesmus subspicatus) 37 mg/L/72 hr.; LC50 Oncorhynchus mykiss 4 mg/L/96 hr.

Persistence and degradability: Nicotine is slowly degradable.

Bioaccumulative potential: Nicotine has a low potential to bioaccumulate. Nicotine log Pow 0.28 @ pH 7.4

Mobility in soil: Although desorption from the resin would occur slowly, the estimated Koc of nicotine (100) indicates high soil mobility.

Other adverse effects: None known.

13. DISPOSAL CONSIDERATIONS

Dispose in accordance with all local and national regulations. No specific disposal method is recommended.

14. TRANSPORT INFORMATION

<table>
<thead>
<tr>
<th>UN Number</th>
<th>Proper shipping name</th>
<th>Hazard Class</th>
<th>Packing Group</th>
<th>Environmental Hazard</th>
</tr>
</thead>
<tbody>
<tr>
<td>IMDG</td>
<td>Not Regulated</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>IATA</td>
<td>Not Regulated</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ADG</td>
<td>Not Regulated</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Transport in bulk (according to Annex II of MARPOL 73/78 and the IBC Code): Not applicable – product is transported only in packaged form.

Special precautions: None known.

Hazchem or Emergency Action Code: None

15. REGULATORY INFORMATION

Safety, health, and environmental regulations specific for the product in question.

Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP): Not scheduled.

Australia Inventory: This product is a drug and is exempt from AICS.

New Zealand Inventory: This product is a drug and is exempt from HSNO regulations.
16. OTHER INFORMATION

**SDS Revision History:** New AU/NZ SDS  
**Date of preparation/revision:** 08 September 2015  
**Date of previous revision:** New SDS

Full Text of GHS Classification and H Phrases from Section 3:
H302 Harmful if swallowed.  
H312 Harmful in contact with skin.  
H412 Harmful to aquatic life with long lasting effects.

List of Abbreviations or Acronyms:
ACGIH American Conference of Industrial Hygienists  
ADG Australian Dangerous Goods  
AICS Australian Inventory of Chemical Substances  
AU Australia  
EC Effective Concentration  
EU European Union  
GHS Globally Harmonized System of Classification and Labelling of Chemicals  
HSNO Hazardous Substances and New Organisms  
IARC International Agency of Research on Cancer  
IATA International Air Transport Association  
IMDG International Maritime Dangerous Goods  
LC Lethal Concentration  
LD Lethal Dosage  
LEL Lower Explosive Limit  
NZ New Zealand  
OEL Occupational Exposure Limits  
PEL Permissible Exposure Limit  
SDS Safety Data Sheet  
STEL Short Term Exposure Limit  
TWA Time-Weighted Average  
UEL Upper Explosive Limit  
US OSHA United States Occupational Safety and Health Administration  
US NTP United States National Toxicology Program  
VOC Volatile Organic Compounds  
WES Workplace Exposure Standards  
WHS Work Health and Safety

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