

Habitrol Patch

Safety Data Sheet

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

Date of issue: 08/13/2014

Revision date: 03/12/2015

Version: 2.0

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product form : Mixture
Product name : Habitrol Patch

1.2. Relevant identified uses of the substance or mixture and uses advised against

Use of the substance/mixture : OTC Drug Product

1.3. Details of the supplier of the safety data sheet

Dr. Reddy's Laboratories Ltd.
8-2-337 Road No. 3, Banjara Hills
Hyderabad 500-034, - India
T +91-40-49002900 - F +91-40-49002999

1.4. Emergency telephone number

Emergency number : CHEMTREC (24 hrs., 7 days per week): United States: (800) 424-9300 CCN614136

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

GHS-US classification

Not classified

2.2. Label elements

GHS-US labelling

No labelling applicable

2.3. Other hazards

No additional information available

2.4. Unknown acute toxicity (GHS-US)

Not applicable

SECTION 3: Composition/information on ingredients

3.1. Substance

Not applicable

3.2. Mixture

Name	Product identifier	%	GHS-US classification
L-Nicotine	(CAS No) 54-11-5	< 1	Acute Tox. 3 (Oral), H301 Acute Tox. 1 (Dermal), H310 Aquatic Chronic 2, H411

Full text of H-phrases: see section 16

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general : Get medical advice/attention if you feel unwell.
First-aid measures after inhalation : If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing. Artificial respiration and/or oxygen if necessary.
First-aid measures after skin contact : When symptoms occur: rinse immediately with plenty of water.
First-aid measures after eye contact : In case of contact, immediately flush eyes with plenty of water.
First-aid measures after ingestion : Rinse mouth. Drink plenty of water. Do not induce vomiting. Call a physician immediately.

4.2. Most important symptoms and effects, both acute and delayed

Symptoms/injuries after inhalation : In high concentrations : Difficulty in breathing.
Chronic symptoms : Effects of excessive exposures may cause. Headache. Gastrointestinal complaints. Disorientation. Dizziness. Nausea. Sweating. Convulsions. Cardiac arrhythmias.

4.3. Indication of any immediate medical attention and special treatment needed

if swallowed. Give activated charcoal. Treat symptomatically. Keep under medical supervision for at least 48 hours.

Habitrol Patch

Safety Data Sheet

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media : Use extinguishing media appropriate for surrounding fire.
Unsuitable extinguishing media : Water.

5.2. Special hazards arising from the substance or mixture

Fire hazard : Not flammable.
Reactivity : No dangerous reactions known.

5.3. Advice for firefighters

Firefighting instructions : Do not allow run-off from fire fighting to enter drains or water courses.
Protection during firefighting : Do not enter fire area without proper protective equipment, including respiratory protection.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

Protective equipment : Wear suitable gloves.
Emergency procedures : Stop leak, if possible without risk.

6.1.2. For emergency responders

Protective equipment : Wear suitable gloves.
Emergency procedures : Ventilate area.

6.2. Environmental precautions

Avoid release to the environment.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up : Recover the product mechanically.

6.4. Reference to other sections

Section 13: disposal information. Section 7: safe handling. Section 8: personal protective equipment.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Avoid breathing mist, vapours.
Hygiene measures : Handle in accordance with good industrial hygiene and safety procedures.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Do not store near food, foodstuffs, drugs, or potable water supplies.
Incompatible products : Water. Moisture.
Incompatible materials : Heat sources. Sources of ignition.
Storage area : Store in dry, cool, well-ventilated area.

7.3. Specific end use(s)

No additional information available

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Habitrol Patch		
ACGIH	Not applicable	
OSHA	Not applicable	
L-Nicotine (54-11-5)		
ACGIH	ACGIH TWA (mg/m ³)	0.5 mg/m ³
ACGIH	Remark (ACGIH)	GI dam; CNS impair; card impair
OSHA	OSHA PEL (TWA) (mg/m ³)	0.5 mg/m ³

8.2. Exposure controls

Appropriate engineering controls : Either local exhaust or general room ventilation is usually required.
Personal protective equipment : Avoid all unnecessary exposure.

Habitrol Patch

Safety Data Sheet

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

Hand protection	: In case of repeated or prolonged contact wear gloves.
Eye protection	: Chemical goggles or safety glasses.
Respiratory protection	: None under normal use.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Liquid
Appearance	: Cloth impregnated with liquid.
Colour	: Colourless.
Odour	: No data available
Odour threshold	: No data available
pH	: No data available
Relative evaporation rate (butyl acetate=1)	: No data available
Melting point	: No data available
Freezing point	: No data available
Boiling point	: No data available
Flash point	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Flammability (solid, gas)	: No data available
Vapour pressure	: No data available
Relative vapour density at 20 °C	: No data available
Relative density	: No data available
Solubility	: No data available
Log Pow	: No data available
Log Kow	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosive properties	: Product is not explosive.
Oxidising properties	: No oxidizing properties.
Explosive limits	: No data available

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

No dangerous reactions known.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

Hazardous polymerization will not occur.

10.4. Conditions to avoid

Moisture. Heat.

10.5. Incompatible materials

Water.

10.6. Hazardous decomposition products

Thermal decomposition generates : Carbon oxides. metallic oxides.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity : Not classified

L-Nicotine (54-11-5)

LD50 oral rat	70 mg/kg
---------------	----------

Habitrol Patch

Safety Data Sheet

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

LD50 dermal rat	50 mg/kg
ATE US (oral)	70.000 mg/kg bodyweight
ATE US (dermal)	50.000 mg/kg bodyweight

Skin corrosion/irritation	: Not classified
Serious eye damage/irritation	: Not classified
Respiratory or skin sensitisation	: Not classified
Germ cell mutagenicity	: Not classified
Carcinogenicity	: Not classified
Reproductive toxicity	: Not classified
Specific target organ toxicity (single exposure)	: Not classified
Specific target organ toxicity (repeated exposure)	: Not classified
Aspiration hazard	: Not classified
Symptoms/injuries after inhalation	: In high concentrations : Difficulty in breathing.
Chronic symptoms	: Effects of excessive exposures may cause. Headache. Gastrointestinal complaints. Disorientation. Dizziness. Nausea. Sweating. Convulsions. Cardiac arrhythmias.
Skin and eye contact	: Skin and eyes contact

SECTION 12: Ecological information

12.1. Toxicity

No additional information available

12.2. Persistence and degradability

L-Nicotine (54-11-5)	
Persistence and degradability	Readily biodegradable.
Biodegradation	71 % 28 d

12.3. Bioaccumulative potential

L-Nicotine (54-11-5)	
Log Pow	-2.67

12.4. Mobility in soil

No additional information available

12.5. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Sewage disposal recommendations	: Do not dispose of waste into sewer.
Waste disposal recommendations	: Dispose in a safe manner in accordance with local/national regulations.

SECTION 14: Transport information

In accordance with DOT
Not considered a dangerous good for transport regulations

Additional information

Other information : No supplementary information available.

ADR

No additional information available

Transport by sea

No additional information available

Air transport

No additional information available

Habitrol Patch

Safety Data Sheet

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

SECTION 15: Regulatory information

15.1. US Federal regulations

L-Nicotine (54-11-5)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
Listed on United States SARA Section 313	
RQ (Reportable quantity, section 304 of EPA's List of Lists)	100 lb
SARA Section 302 Threshold Planning Quantity (TPQ)	100 lb

15.2. International regulations

CANADA

L-Nicotine (54-11-5)
Listed on the Canadian DSL (Domestic Substances List) inventory.

EU-Regulations

L-Nicotine (54-11-5)
Listed on the EEC inventory EINECS (European Inventory of Existing Commercial Chemical Substances)

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Not classified

Classification according to Directive 67/548/EEC [DSD] or 1999/45/EC [DPD]

Xn; R21

15.2.2. National regulations

No additional information available

15.3. US State regulations

L-Nicotine (54-11-5)				
U.S. - California - Proposition 65 - Carcinogens List	U.S. - California - Proposition 65 - Developmental Toxicity	U.S. - California - Proposition 65 - Reproductive Toxicity - Female	U.S. - California - Proposition 65 - Reproductive Toxicity - Male	No significance risk level (NSRL)
No	Yes	No	No	

L-Nicotine (54-11-5)

U.S. - Massachusetts - Right To Know List
U.S. - New Jersey - Right to Know Hazardous Substance List
U.S. - Pennsylvania - RTK (Right to Know) List

SECTION 16: Other information

Indication of changes	: Revised format.
Revision date	: 03/12/2015
Data sources	: ACGIH 2000. European Chemicals Agency (ECHA) Registered Substances list. Accessed at http://echa.europa.eu/ . Kristen Forsberg and S.Z. Mansdorf, "Quick Selection Guide to Chemical Protective Clothing", Fifth Edition. National Fire Protection Association; Fire Protection Guide to Hazardous Materials; 10th edition. TSCA Chemical Substance Inventory. Accessed at http://www.epa.gov/oppt/existingchemicals/pubs/tscainventory/howto.html .
Abbreviations and acronyms	: ACGIH (American Conference of Government Industrial Hygienists). ATE: Acute Toxicity Estimate. CAS (Chemical Abstracts Service) number. CLP: Classification, Labelling, Packaging. GHS: Globally Harmonized System (of Classification and Labeling of Chemicals). LD50: Lethal Dose for 50% of the test population. OSHA: Occupational Safety & Health Administration. TSCA: Toxic Substances Control Act.

Habitrol Patch

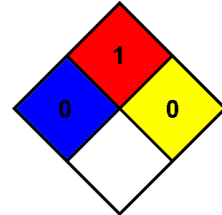
Safety Data Sheet

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

Full text of H-phrases:

Acute Tox. 1 (Dermal)	Acute toxicity (dermal), Category 1
Acute Tox. 3 (Oral)	Acute toxicity (oral), Category 3
Aquatic Chronic 2	Hazardous to the aquatic environment — Chronic Hazard, Category 2
H301	Toxic if swallowed
H310	Fatal in contact with skin
H411	Toxic to aquatic life with long lasting effects

NFPA health hazard : 0 - Exposure under fire conditions would offer no hazard beyond that of ordinary combustible materials.
NFPA fire hazard : 1 - Must be preheated before ignition can occur.
NFPA reactivity : 0 - Normally stable, even under fire exposure conditions, and not reactive with water.



SDS US (GHS HazCom 2012)

SDS Prepared by: The Redstone Group, LLC.
6397 Emerald Pkwy
Suite 200
Dublin, Ohio, USA 43016
614.923.7472
www.redstonegrp.com

Dr. Reddy's Laboratories provides the information contained herein in good faith but makes no representation as to its comprehensiveness or accuracy. This document is intended only as a brief summary and general guide to the appropriate precautionary handling of this material by a properly trained person using this product. Individuals receiving the information must exercise their independent judgment in determining its appropriateness for any particular purpose. DR. REDDY'S LABORATORIES MAKES NO REPRESENTATIONS OR WARRANTIES, EITHER EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION ANY WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE WITH RESPECT TO THE INFORMATION SET FORTH HEREIN OR THE PRODUCT TO WHICH THE INFORMATION REFERS. ACCORDINGLY, DR. REDDY'S LABORATORIES WILL NOT BE RESPONSIBLE FOR DAMAGES RESULTING FROM USE OF OR RELIANCE UPON THIS INFORMATION.