Habitrol Patch

Safety Data Sheet

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SECTION 1: Identification

1.1. Identification

Product form : Mixture

Product name : Habitrol Patch

1.2. Recommended use and restrictions on use

Use of the substance/mixture : Pharmaceuticals

Restrictions on use : No additional information available

1.3. Supplier

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: Hazard(s) identification

2.1. Classification of the substance or mixture

GHS classification

Reproductive toxicity, Category 2	H361	Suspected of damaging fertility or the unborn child.

Full text of H statements : see section 16

2.2. GHS Label elements, including precautionary statements

GHS-US labelling

Hazard pictograms (GHS) :



Signal word (GHS) : Warning

Hazard statements (GHS) : H361 - Suspected of damaging fertility or the unborn child.

Precautionary statements (GHS) : P201 - Obtain special instructions before use.
P202 - Do not handle until all safety precautions have been read and understood.
P280 - Wear protective clothing, protective gloves.
P308+P313 - If exposed or concerned: Get medical advice/attention.
P405 - Store locked up.
P501 - Dispose of contents/container to Collection point.

2.3. Other hazards which do not result in classification

No additional information available

2.4. Unknown acute toxicity (GHS_US)

Not applicable

SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

Name	Product identifier	%	GHS classification
Microcrystalline cellulose	(CAS-No.) 9004-34-6	< 25	Comb. Dust
Aluminium	(CAS-No.) 7429-90-5	< 10	Flam. Sol. 1, H228 Water-react. 2, H261
L-Nicotine	(CAS-No.) 54-11-5	< 1	Acute Tox. 2 (Oral), H300 Acute Tox. 1 (Dermal), H310 Repr. 2, H361 Aquatic Chronic 2, H411

***Chemical name, CAS number and/or exact concentration have been withheld as a trade secret**

Full text of hazard classes and H-statements : 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. IF exposed or concerned: Get medical advice/attention.

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 (acute and delayed)

Symptoms/effects : Suspected of damaging fertility or the unborn child.

Symptoms/effects 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. Immediate medical attention and special treatment, if necessary

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

SECTION 5: Fire-fighting measures

5.1. Suitable (and unsuitable) extinguishing media

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

Unsuitable extinguishing media : Water.

5.2. Specific hazards arising from the chemical

Fire hazard : Not flammable.

Reactivity : No dangerous reactions known.

5.3. Special protective equipment and precautions for fire-fighters

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 without risks if possible.

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 : Mechanically recover the product.

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. Obtain special instructions before use. Do not handle until all safety precautions have been read and understood.

Hygiene measures : Handle in accordance with good industrial hygiene and safety procedures.

7.2. Conditions for safe storage, including any incompatibilities

Incompatible products : Water. Moisture.

Incompatible materials : Heat sources. Sources of ignition.
Storage area : Store in dry, cool, well-ventilated area. Keep out of reach of children.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Microcrystalline cellulose (9004-34-6)		
ACGIH	Local name	Cellulose
ACGIH	ACGIH TWA (mg/m³)	10 mg/m³
ACGIH	Remark (ACGIH)	TLV® Basis: URT irr
ACGIH	Regulatory reference	ACGIH 2019
OSHA	OSHA PEL (TWA) (mg/m³)	15 mg/m³ (Total dust) 5 mg/m³ (Respirable fraction)
OSHA	Regulatory reference (US-OSHA)	OSHA Annotated Table Z-1
NIOSH	NIOSH REL (TWA) (mg/m³)	10 mg/m³ (total dust) 5 mg/m³ (respirable dust)

Aluminium (7429-90-5)		
ACGIH	Local name	Aluminum metal and insoluble compounds
ACGIH	ACGIH TWA (mg/m³)	1 mg/m³ (R - Respirable particulate matter)
ACGIH	Remark (ACGIH)	TLV® Basis: Pneumoconiosis; LRT irr; neurotoxicity. Notations: A4 (Not classifiable as a Human Carcinogen)
ACGIH	Regulatory reference	ACGIH 2019
OSHA	OSHA PEL (TWA) (mg/m³)	15 mg/m³ (Total dust) 5 mg/m³ (Respirable fraction)
OSHA	Regulatory reference (US-OSHA)	OSHA Annotated Table Z-1
NIOSH	NIOSH REL (TWA) (mg/m³)	10 mg/m³
NIOSH	NIOSH REL (ceiling) (mg/m³)	5 mg/m³
NIOSH	Remark (NIOSH)	(total dust)

L-Nicotine (54-11-5)		
ACGIH	Local name	Nicotine
ACGIH	ACGIH TWA (mg/m³)	0.5 mg/m³
ACGIH	Remark (ACGIH)	GI dam; CNS impair; card impair
OSHA	OSHA PEL (TWA) (mg/m³)	0.5 mg/m³
NIOSH	NIOSH REL (TWA) (mg/m³)	0.5 mg/m³

8.2. Appropriate engineering controls

Appropriate engineering controls : Either local exhaust or general room ventilation is usually required.

8.3. Individual protection measures/Personal protective equipment

Personal protective equipment:

Avoid all unnecessary exposure.

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	:	No data available
Odour	:	characteristic
Odour threshold	:	No data available
pH	:	No data available
Melting point	:	No data available
Freezing point	:	No data available
Boiling point	:	No data available
Flash point	:	No data available
Relative evaporation rate (butylacetate=1)	:	No data available
Flammability (solid, gas)	:	Not flammable.
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
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity, kinematic	:	No data available
Viscosity, dynamic	:	No data available
Explosive limits	:	No data available
Explosive properties	:	Product is not explosive.
Oxidising properties	:	No oxidizing properties.

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 (CO, CO2). metallic oxides.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity (oral)	:	Not classified
Acute toxicity (dermal)	:	Not classified
Acute toxicity (inhalation)	:	Not classified

Microcrystalline cellulose (9004-34-6)	
LD50 oral rat	> 5 g/kg
LD50 dermal rabbit	> 2 g/kg

Microcrystalline cellulose (9004-34-6)	
LC50 inhalation rat (mg/l)	> 5800 mg/m³ (4hr)

Aluminium (7429-90-5)	
LD50 oral rat	> 15900 mg/kg
LC50 inhalation rat (mg/l)	> 2.3 mg/l/4h

L-Nicotine (54-11-5)	
LD50 oral rat	50 mg/kg mouse 3.3 mg/kg
LD50 dermal rat	50 mg/kg
ATE (oral)	50 mg/kg bodyweight
ATE (dermal)	50 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 : Suspected of damaging fertility or the unborn child.
STOT-single exposure : Not classified

STOT-repeated exposure : Not classified

Aspiration hazard : Not classified
Viscosity, kinematic : No data available

Likely routes of exposure : Skin and eye contact.
Symptoms/effects : Suspected of damaging fertility or the unborn child.
Symptoms/effects 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.

SECTION 12: Ecological information

12.1. Toxicity

Ecology - general : No ecotoxicological data about this product are known.

Aluminium (7429-90-5)	
LC50 fish 1	218.64 mg/l ASTM 2000; test material: aluminium chloride hexahydrate; Pimephales promelas
EC50 crustacea	1.4 mg/l OECD Guideline 202; test material: Aluminium hydroxide
LOEC (acute)	≈ 72.89 mg/l
NOEC (acute)	≈ 37.2 mg/l

12.2. Persistence and degradability

Habitrol Patch	
Persistence and degradability	Not established.

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

12.3. Bioaccumulative potential

Habitrol Patch	
Bioaccumulative potential	Not established.

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

12.4. Mobility in soil

Habitrol Patch	
Ecology - soil	No additional information available.

12.5. Other adverse effects

Other information : No additional information available.

SECTION 13: Disposal considerations

13.1. Disposal 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

Department of Transportation (DOT)

In accordance with DOT

Not regulated.

Transport by sea

Not regulated.

Air transport

Not regulated.

SECTION 15: Regulatory information

15.1. US Federal regulations

All components of this product are listed, or excluded from listing, on the United States Environmental Protection Agency Toxic Substances Control Act (TSCA) inventory

Chemical(s) subject to the reporting requirements of Section 313 or Title III of the Superfund Amendments and Reauthorization Act (SARA) of 1986 and 40 CFR Part 372.

Aluminium	CAS-No. 7429-90-5	< 10%
L-Nicotine	CAS-No. 54-11-5	< 1%

Microcrystalline cellulose (9004-34-6)	
EPA TSCA Regulatory Flag	XU - XU - indicates a substance exempt from reporting under the Chemical Data Reporting Rule, (40 CFR 711).

L-Nicotine (54-11-5)	
CERCLA RQ	100 lb
SARA Section 302 Threshold Planning Quantity (TPQ)	100 lb

15.2. International regulations

CANADA

Microcrystalline cellulose (9004-34-6)
Listed on the Canadian DSL (Domestic Substances List) inventory.

Aluminium (7429-90-5)
Listed on the Canadian DSL (Domestic Substances List) inventory.

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

EU-Regulations

Microcrystalline cellulose (9004-34-6)
Listed on the EEC inventory EINECS (European Inventory of Existing Commercial Chemical Substances)

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

National regulations

Microcrystalline cellulose (9004-34-6)
Listed on IECSC (Inventory of Existing Chemical Substances Produced or Imported in China) Listed on KECI (Korean Existing Chemicals Inventory) Listed on Taiwan National Chemical Inventory Listed on PICCS (Philippines Inventory of Chemicals and Chemical Substances) Listed on the AICS (Australian Inventory of Chemical Substances) Listed on NZIoC (New Zealand Inventory of Chemicals)

15.3. US State regulations

⚠ **WARNING:** This product can expose you to L-Nicotine, which is known to the State of California to cause birth defects or other reproductive harm. For more information go to www.P65Warnings.ca.gov.

Component	Carcinogenicity	Developmental toxicity	Reproductive toxicity male	Reproductive toxicity female	No significant risk level (NSRL)	Maximum allowable dose level (MADL)
L-Nicotine(54-11-5)		X				

Component	State or local regulations
Microcrystalline cellulose (9004-34-6)	U.S. - New Jersey - Right to Know Hazardous Substance List; U.S. - Pennsylvania - RTK (Right to Know) List
Aluminium(7429-90-5)	U.S. - Delaware - Pollutant Discharge Requirements - Reportable Quantities; U.S. - Idaho - Non-Carcinogenic Toxic Air Pollutants - Acceptable Ambient Concentrations; U.S. - New Jersey - Right to Know Hazardous Substance List; U.S. - Pennsylvania - RTK (Right to Know) List
L-Nicotine(54-11-5)	U.S. - Delaware - Pollutant Discharge Requirements - Reportable Quantities; U.S. - Idaho - Non-Carcinogenic Toxic Air Pollutants - Acceptable Ambient Concentrations; U.S. - Massachusetts - Right To Know List; U.S. - New Jersey - Right to Know Hazardous Substance List; U.S. - New York - Reporting of Releases Part 597 - List of Hazardous Substances; U.S. - Pennsylvania - RTK (Right to Know) List; U.S. - Washington - Permissible Exposure Limits - TWAs

SECTION 16: Other information

Revision date : 02/28/2020

Data sources : European Chemicals Agency (ECHA) Registered Substances list. Accessed at http://echa.europa.eu/. Krister Forsberg and S.Z. Mansdorf, "Quick Selection Guide to Chemical Protective Clothing", Fifth Edition. TSCA Chemical Substance Inventory. Accessed at http://www.epa.gov/oppt/existingchemicals/pubs/tscainventory/howto.html. European Chemicals Agency (ECHA) C&L Inventory database. Accessed at http://echa.europa.eu/web/guest/information-on-chemicals/cl-inventory-database. Manufacturer Information. National Fire Protection Association. Fire Protection Guide to Hazardous Materials; 10th edition. OSHA 29CFR 1910.1200 Hazard Communication Standard.

Other information : None.

Full text of H-statements:

H228	Flammable solid.
H261	In contact with water releases flammable gases.
H300	Fatal if swallowed.
H310	Fatal in contact with skin.
H361	Suspected of damaging fertility or the unborn child.
H411	Toxic to aquatic life with long lasting effects.

Abbreviations and acronyms:

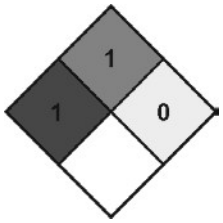
	ACGIH (American Conference of Government Industrial Hygienists)
	ATE: Acute Toxicity Estimate
	CAS (Chemical Abstracts Service) number
	CLP: Classification, Labelling, Packaging.
	EC50: Environmental Concentration associated with a response by 50% of the test population.

	GHS: Globally Harmonized System (of Classification and Labeling of Chemicals
	LD50: Lethal Dose for 50% of the test population
	OSHA: Occupational Safety & Health Administration
	STEL: Short Term Exposure Limits
	TSCA: Toxic Substances Control Act
	TWA: Time Weighted Average

NFPA health hazard : 1 - Materials that, under emergency conditions, can cause significant irritation.

NFPA fire hazard : 1 - Materials that must be preheated before ignition can occur.

NFPA reactivity : 0 - Normally stable, even under fire exposure conditions, and not reactive with water.



Indication of changes:
Handling and storage.

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