

Safety Data Sheet

acc. to HCS and GHS

Printing date 08/13/2014

Reviewed on 08/13/2014

1 Identification

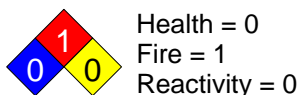
- **Product identifier**
- **Trade name:** Habitrol Patch
- **Details of the supplier of the Safety Data Sheet**
- **Manufacturer/Supplier:**
Novartis Consumer Health, Inc.
200 Kimball Drive
Parsippany, NJ 07054
USA
- **Information department:**
Novartis Consumer and Professional Affairs Call Center
(800) 452-0051 (24 hours / 7 days a week)
- **Emergency telephone number:**
ChemTel Inc.
(800)255-3924, +1 (813)248-0585



2 Hazard(s) identification

- **Classification of the substance or mixture**
The product is not classified as hazardous according to the Globally Harmonized System (GHS).

-
- **Label elements**
 - **GHS label elements** Not Regulated
 - **Hazard pictograms** Not Regulated
 - **Signal word** Not Regulated
 - **Hazard statements** Not Regulated
 - **Hazard description:**
 - **WHMIS-symbols:** Not hazardous under WHMIS.
 - **Classification system:**
 - **NFPA ratings (scale 0 - 4)**



Health = 0
Fire = 1
Reactivity = 0

- **HMIS-ratings (scale 0 - 4)**



Health = 0
Fire = 1
Reactivity = 0

- **Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

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3 Composition/information on ingredients

- **Chemical characterization: Mixtures**
- **Description:** Mixture of the substances listed below with nonhazardous additions.

- **Dangerous components:**

9004-34-6	Cellulose	<25%
7429-90-5	Aluminum metal	< 10%
	⚠ Water-react. 1, H260	
54-11-5	nicotine	< 1.0%
	⚠ Acute Tox. 3, H301; Acute Tox. 1, H310	

4 First-aid measures

- **Description of first aid measures**
- **General information:**
Symptoms of poisoning may even occur after several hours; therefore medical observation for at least 48 hours after the accident.
- **After inhalation:**
Unlikely route of exposure.
Supply fresh air; consult doctor in case of complaints.
- **After skin contact:**
Product is manufactured for topical use. If irritation occurs, discontinue use and wash affected area with soap and water.
- **After eye contact:**
Unlikely route of exposure.
Remove contact lenses if worn.
Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.
- **After swallowing:**
Rinse out mouth and then drink plenty of water.
Do not induce vomiting; immediately call for medical help.
- **Most important symptoms and effects, both acute and delayed**
Symptoms expected solely from excessive usage or overdose.
Adverse health effects are not reasonably expected from normal use of product.
Headache
Gastric or intestinal disorders
Dizziness
Nausea
Profuse sweating
Disorientation
- **Danger**
Danger of impaired breathing.
Danger of disturbed cardiac rhythm.
Danger of convulsion.
- **Indication of any immediate medical attention and special treatment needed**
If swallowed, gastric irrigation with added, activated carbon.
May produce a cholinergic effect.
If necessary oxygen respiration treatment.

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Monitor circulation, possible shock treatment.
Medical supervision for at least 48 hours.

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5 Fire-fighting measures

- **Extinguishing media**
- **Suitable extinguishing agents:** Use fire fighting measures that suit the environment.
- **For safety reasons unsuitable extinguishing agents:** None.
- **Special hazards arising from the substance or mixture** No further relevant information available.
- **Advice for firefighters**
- **Protective equipment:**
 - Wear self-contained respiratory protective device.
 - Wear fully protective suit.
- **Additional information** No further relevant information available.

6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures**
 - For large spills, wear protective clothing.
- **Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **Methods and material for containment and cleaning up:**
 - Pick up mechanically.
 - Dispose contaminated material as waste according to item 13.
 - Send for recovery or disposal in suitable receptacles.
- **Reference to other sections**
 - See Section 7 for information on safe handling.
 - See Section 8 for information on personal protection equipment.
 - See Section 13 for disposal information.

7 Handling and storage

- **Precautions for safe handling** No special precautions are necessary if used correctly.
- **Information about protection against explosions and fires:** No special measures required.
- **Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:**
 - Avoid storage near extreme heat, ignition sources or open flame.
 - Protect from humidity and water.
- **Information about storage in one common storage facility:** Store away from foodstuffs.
- **Further information about storage conditions:** Store in cool, dry conditions in well sealed receptacles.
- **Specific end use(s)** No further relevant information available.

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8 Exposure controls/personal protection

- **Additional information about design of technical systems:** No further data; see item 7.
- **Control parameters**

· Components with limit values that require monitoring at the workplace:

9004-34-6 Cellulose

PEL (USA)	Long-term value: 15* 5** mg/m ³ *total dust **respirable fraction
REL (USA)	Long-term value: 10* 5** mg/m ³ *total dust **respirable fraction
TLV (USA)	Long-term value: 10 mg/m ³
EL (Canada)	Long-term value: 10* 3** mg/m ³ *total dust, **respirable fraction
EV (Canada)	Long-term value: 10 mg/m ³ paper fibre, total dust
LMPE (Mexico)	Long-term value: 10 mg/m ³

7429-90-5 Aluminum metal

PEL (USA)	Long-term value: 15*; 15** mg/m ³ *Total dust; ** Respirable fraction
REL (USA)	Long-term value: 10* 5** mg/m ³ as Al*Total dust**Respirable/pyro powd./welding f.
TLV (USA)	Long-term value: 1* mg/m ³ as Al; *as respirable fraction
EL (Canada)	Long-term value: 1.0 mg/m ³ respirable, as Al
EV (Canada)	Long-term value: 5 mg/m ³ aluminium-containing (as aluminium)
LMPE (Mexico)	Long-term value: 1* mg/m ³ A4, *fracción respirable

54-11-5 nicotine

PEL (USA)	Long-term value: 0.5 mg/m ³ Skin
REL (USA)	Long-term value: 0.5 mg/m ³ Skin
TLV (USA)	Long-term value: 0.5 mg/m ³ Skin
EL (Canada)	Long-term value: 0.5 mg/m ³ Skin
EV (Canada)	Long-term value: 0.5 mg/m ³ Skin
LMPE (Mexico)	Long-term value: 0.5 mg/m ³ PIEL

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- **Additional information:** The lists that were valid during the creation were used as basis.
- **Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**
The usual precautionary measures for handling chemicals should be followed.
Keep away from foodstuffs, beverages and feed.
Avoid contact with the eyes and skin.
Clean skin thoroughly immediately after handling the product.
- **Breathing equipment:**
Not required under normal conditions of use.
For spills, respiratory protection may be advisable.
- **Protection of hands:**
Gloves not required under normal conditions of use.
Wear protective gloves to handle contents of damaged or leaking units.
The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation
- **Material of gloves**
The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.
- **Penetration time of glove material**
The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.
- **Eye protection:**
 Safety glasses
- **Body protection:**
Not required under normal conditions of use.
Protection may be required for spills.
- **Limitation and supervision of exposure into the environment**
No further relevant information available.

9 Physical and chemical properties

- **Information on basic physical and chemical properties**
- **General Information**
- **Appearance:**

Form:	Permeable container containing liquid and/or solid contents plus inert carrier materials.
Color:	According to product specification
- **Odor:** Characteristic
- **Odor threshold:** Not determined.
- **pH-value:** Not applicable.

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- **Change in condition**
 - Melting point/Melting range:** Undetermined.
 - Boiling point/Boiling range:** Undetermined.
- **Flash point:** Not applicable.
- **Flammability (solid, gaseous):** Product is not flammable.
- **Auto-ignition temperature:** Not determined.
- **Decomposition temperature:** Not determined.
- **Auto igniting:** Product is not self-igniting.
- **Danger of explosion:** Product does not present an explosion hazard.
- **Explosion limits:**
 - Lower:** Not determined.
 - Upper:** Not determined.
- **Vapor pressure:** Not applicable.
- **Density:** Not determined.
- **Relative density** Not determined.
- **Vapour density** Not applicable.
- **Evaporation rate** Not applicable.
- **Solubility in / Miscibility with**
 - Water:** Chemical is soluble; packaging is not soluble.
- **Partition coefficient (n-octanol/water):** Not determined.
- **Viscosity:**
 - Dynamic:** Not applicable.
 - Kinematic:** Not applicable.
- **Other information** No further relevant information available.

10 Stability and reactivity

- **Reactivity**
- **Chemical stability**
- **Thermal decomposition / conditions to be avoided:** No decomposition if used and stored according to specifications.
- **Possibility of hazardous reactions** Toxic fumes may be released if heated above the decomposition point.
- **Conditions to avoid** No further relevant information available.
- **Incompatible materials:** No further relevant information available.
- **Hazardous decomposition products:** Possible in traces.

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11 Toxicological information

- Information on toxicological effects
- Acute toxicity:

· LD/LC50 values that are relevant for classification:
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54-11-5 nicotine

Oral	LD50	50 mg/kg (rat)
Dermal	LD50	50 mg/kg (rat)

- Primary irritant effect:
- on the skin: No irritant effect.
- on the eye: No irritating effect.
- Sensitization: No sensitizing effects known.
- Additional toxicological information:
When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us.
- Carcinogenic categories

· NTP (National Toxicology Program)

None of the ingredients is listed.

· OSHA-Ca (Occupational Safety & Health Administration)

None of the ingredients is listed.

12 Ecological information

- Toxicity
- Aquatic toxicity: No further relevant information available.
- Persistence and degradability: No further relevant information available.
- Bioaccumulative potential: No further relevant information available.
- Mobility in soil: No further relevant information available.
- Additional ecological information:
- General notes:
Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.
- Results of PBT and vPvB assessment
- PBT: Not applicable.
- vPvB: Not applicable.
- Other adverse effects: No further relevant information available.

13 Disposal considerations

- Waste treatment methods
- Recommendation:
Smaller quantities can be disposed of with household waste.

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Can be burned with household garbage after consulting with the waste disposal facility operator and the pertinent authorities and adhering to the necessary technical regulations.

The user of this material has the responsibility to dispose of unused material, residues and containers in compliance with all relevant local, state and federal laws and regulations regarding treatment, storage and disposal for hazardous and nonhazardous wastes. Residual materials should be treated as hazardous.

- **Uncleaned packagings:**
- **Recommendation:** Disposal must be made according to official regulations.

14 Transport information

- **UN-Number**
- **DOT, ADR, ADN, IMDG, IATA** Not Regulated
- **UN proper shipping name**
- **DOT, ADR, ADN, IMDG, IATA** Not Regulated
- **Transport hazard class(es)**
- **DOT, ADR, ADN, IMDG, IATA**
- **Class** Not Regulated
- **Packing group**
- **DOT, ADR, IMDG, IATA** Not Regulated
- **Environmental hazards:**
- **Marine pollutant:** No
- **Special precautions for user** Not applicable.
- **Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code** Not applicable.
- **UN "Model Regulation":** -

15 Regulatory information

- **Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **SARA**

- **Section 355 (extremely hazardous substances):**

54-11-5	nicotine
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- **Section 313 (Specific toxic chemical listings):**

7429-90-5	Aluminum metal
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- **TSCA (Toxic Substances Control Act):**

All ingredients are listed.

- **Proposition 65 (California)**

- **Chemicals known to cause cancer:**

None of the ingredients are listed.

- **Chemicals known to cause reproductive toxicity for females:**

None of the ingredients are listed.

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- **Chemicals known to cause reproductive toxicity for males:**

None of the ingredients is listed.

- **Chemicals known to cause developmental toxicity:**

54-11-5 | nicotine

- **Carcinogenic categories**

- **EPA (Environmental Protection Agency)**

None of the ingredients is listed.

- **IARC (International Agency for Research on Cancer)**

None of the ingredients is listed.

- **TLV (Threshold Limit Value established by ACGIH)**

7429-90-5 | Aluminum metal

A4

- **NIOSH-Ca (National Institute for Occupational Safety and Health)**

None of the ingredients is listed.

- **State Right to Know Listings**

None of the ingredients is listed.

- **Canadian substance listings:**

- **Canadian Domestic Substances List (DSL)**

All ingredients are listed.

- **Canadian Ingredient Disclosure list (limit 0.1%)**

None of the ingredients is listed.

- **Canadian Ingredient Disclosure list (limit 1%)**

7429-90-5 | Aluminum metal

- **Other regulations, limitations and prohibitive regulations**

This product has been classified in accordance with hazard criteria of the Controlled Products Regulations and the SDS contains all the information required by the Controlled Products Regulations.

- **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

- **Date of preparation / last revision** 08/13/2014 / -

- **Abbreviations and acronyms:**

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

DOT: US Department of Transportation

IATA: International Air Transport Association

GHS: Globally Harmonized System of Classification and Labelling of Chemicals

ACGIH: American Conference of Governmental Industrial Hygienists

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

NFPA: National Fire Protection Association (USA)

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HMIS: Hazardous Materials Identification System (USA)

WHMIS: Workplace Hazardous Materials Information System (Canada)

DNEL: Derived No-Effect Level (REACH)

PNEC: Predicted No-Effect Concentration (REACH)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

Water-react. 1: Substances and Mixtures which, in contact with water, emit flammable gases, Hazard Category 1

Acute Tox. 3: Acute toxicity, Hazard Category 3

Acute Tox. 1: Acute toxicity, Hazard Category 1

Sources

SDS Prepared by:

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