



# SAFETY DATA SHEET

## 1. Identification

<b>Product identifier</b>	<b>NICOTINELL PATCH</b>
<b>Other means of identification</b>	
<b>Synonyms</b>	STEP 1 PATCH 52.5 MG (21 MG / 24 HRS) * STEP 2 PATCH 35 MG (14 MG / 24 HRS) * STEP 3 PATCH 17.5 MG (7 MG / 24 HRS) * HABITROL PATCH 7MG, 14MG AND 21MG (NZ) * NICOTINE, FORMULATED PRODUCT
<b>Recommended use</b>	Medicinal Product.

This safety data sheet is written to provide health, safety and environmental information for people handling this formulated product in the workplace. It is not intended to provide information relevant to medicinal use of the product. In this instance patients should consult prescribing information/package insert/product label or consult their pharmacist or physician. For health and safety information for individual ingredients used during manufacturing, refer to the appropriate safety data sheet for each ingredient.

**Recommended restrictions** No other uses are advised.

### Manufacturer/Importer/Supplier/Distributor information

GlaxoSmithKline US  
5 Moore Drive  
Research Triangle Park, NC 27709 USA  
US General Information (normal business hours): +1-888-825-5249

Email Address: [msds@gsk.com](mailto:msds@gsk.com)  
Website: [www.gsk.com](http://www.gsk.com)

CHEMTREC EMERGENCY PHONE NUMBERS -  
TRANSPORT EMERGENCIES:  
Customer Number: CCN9484  
US / International toll call +1 703 527 3887  
available 24 hrs/7 days; multi-language response

## 2. Hazard(s) identification

### Classified hazards

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

### Label elements

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

### Hazard(s) not otherwise classified (HNOC)

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

## 3. Composition/information on ingredients

### Mixtures

Chemical name	Common name and synonyms	CAS number	%
NICOTINE	1-METHYL-2-(3-PYRIDYL) PYRROLIDONE NICOCIDE NICO-FUME L-3-(1-METHYL 1-2-PYRROLIDYL) PYRIDINE BLACK LEAF BETA-PYRIDYL-ALPHA-N-METHYLPYR ROLIDINE NICOTINE ALKALOID O-3825 RCRA P075 OHS16430 RTECS QS5250000 3-(N-METHYL-2-PYRROLIDINYL)PYRIDI NE 3-(N-METYLI-2-PYRROLIDINYLI)PYRI DIINI	54-11-5	17.5, 35 & 52.2 MG

Other components below reportable levels

>95%

\*Designates that a specific chemical identity and/or percentage of composition has been withheld as a trade secret.

#### 4. First-aid measures

<b>Inhalation</b>	Move to fresh air. If breathing is difficult, trained personnel should give oxygen. Call a physician if symptoms develop or persist. Under normal conditions of intended use, this material is not expected to be an inhalation hazard.
<b>Skin contact</b>	Immediately flush skin with plenty of water. Take off contaminated clothing and wash before reuse. Get medical attention if symptoms occur.
<b>Eye contact</b>	Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.
<b>Ingestion</b>	If swallowed, rinse mouth with water (only if the person is conscious). If ingestion of a large amount does occur, call a poison control center immediately. Do not induce vomiting without advice from poison control center.
<b>Most important symptoms/effects, acute and delayed</b>	Direct contact with eyes may cause temporary irritation. The possible symptoms of overexposure include: increased blood pressure; increased heart rate; salivation; depression. Headache. Dizziness. Nausea, vomiting. Abdominal pain.
<b>Indication of immediate medical attention and special treatment needed</b>	No specific antidotes are recommended. Treat according to locally accepted protocols. For additional guidance, refer to the current prescribing information or to the local poison control information center.
<b>General information</b>	In the case of accident or if you feel unwell, seek medical advice immediately (show the label where possible). Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves. Pre-placement and periodic health surveillance is not usually indicated. The final determination of the need for health surveillance should be determined by local risk assessment.

#### 5. Fire-fighting measures

<b>Suitable extinguishing media</b>	Water. Foam. Dry chemical powder. Carbon dioxide (CO2).
<b>Unsuitable extinguishing media</b>	None known.
<b>Specific hazards arising from the chemical</b>	During fire, gases hazardous to health may be formed.
<b>Special protective equipment and precautions for firefighters</b>	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
<b>Fire fighting equipment/instructions</b>	Move containers from fire area if you can do so without risk. Use water spray to cool unopened containers.
<b>Specific methods</b>	Use standard firefighting procedures and consider the hazards of other involved materials.
<b>General fire hazards</b>	No unusual fire or explosion hazards noted.

#### 6. Accidental release measures

<b>Personal precautions, protective equipment and emergency procedures</b>	Keep unnecessary personnel away. Keep people away from and upwind of spill/leak. Wear appropriate protective equipment and clothing during clean-up. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. Local authorities should be advised if significant spillages cannot be contained. For personal protection, see section 8 of the SDS.
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**Methods and materials for containment and cleaning up**

Prevent product from entering drains.

Large Spills: Stop the flow of material, if this is without risk. Sweep up or vacuum up spillage and collect in suitable container for disposal. Following product recovery, flush area with water. Small Dry Spills: With clean shovel place material into clean, dry container and cover loosely; move containers from spill area. Clean surface thoroughly to remove residual contamination.

Never return spills to original containers for re-use. For waste disposal, see section 13 of the SDS.

**Environmental precautions**

Avoid release to the environment. Inform appropriate managerial or supervisory personnel of all environmental releases. Contact local authorities in case of spillage to drain/aquatic environment. Prevent further leakage or spillage if safe to do so. Avoid discharge into drains, water courses or onto the ground.

**7. Handling and storage****Precautions for safe handling**

Do not handle, store or open near an open flame, sources of heat or sources of ignition. Protect material from direct sunlight. Avoid prolonged exposure. Avoid breathing dust/fume/gas/mist/vapors/spray. Avoid contact with eyes, skin, and clothing. Provide adequate ventilation. Avoid release to the environment.

**Conditions for safe storage, including any incompatibilities**

Keep away from heat, sparks and open flame. Store in a cool, dry place out of direct sunlight. Store in a closed container away from incompatible materials. Store away from incompatible materials (see Section 10 of the SDS).

**8. Exposure controls/personal protection****Occupational exposure limits**

The following constituents are the only constituents of the product which have a PEL, TLV or other recommended exposure limit. At this time, the other constituents have no known exposure limits.

**GSK**

Components	Type	Value	Note
NICOTINE (CAS 54-11-5)	15 MIN STEL	200 mcg/m3	
	8 HR TWA	70 mcg/m3	
	OHC	3	SKIN REPRODUCTIVE HAZARD
		3	

**US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)**

Components	Type	Value
NICOTINE (CAS 54-11-5)	PEL	0.5 mg/m3

**US. ACGIH Threshold Limit Values**

Components	Type	Value
NICOTINE (CAS 54-11-5)	TWA	0.5 mg/m3

**US. NIOSH: Pocket Guide to Chemical Hazards**

Components	Type	Value
NICOTINE (CAS 54-11-5)	TWA	0.5 mg/m3

**Biological limit values**

No biological exposure limits noted for the ingredient(s).

**Exposure guidelines****US - California OELs: Skin designation**

NICOTINE (CAS 54-11-5) Can be absorbed through the skin.

**US - Minnesota Haz Subs: Skin designation applies**

NICOTINE (CAS 54-11-5) Skin designation applies.

**US - Tennessee OELs: Skin designation**

NICOTINE (CAS 54-11-5) Can be absorbed through the skin.

**US ACGIH Threshold Limit Values: Skin designation**

NICOTINE (CAS 54-11-5) Can be absorbed through the skin.

**US NIOSH Pocket Guide to Chemical Hazards: Skin designation**

NICOTINE (CAS 54-11-5) Can be absorbed through the skin.

**US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)**

NICOTINE (CAS 54-11-5) Can be absorbed through the skin.

**Appropriate engineering controls**

General ventilation normally adequate. An Exposure Control Approach (ECA) is established for operations involving this material based upon the OEL/Occupational Hazard Category and the outcome of a site- or operation-specific risk assessment.

## Individual protection measures, such as personal protective equipment

<b>Eye/face protection</b>	Not normally needed. If contact is likely, safety glasses with side shields are recommended.
<b>Skin protection</b>	
<b>Hand protection</b>	Not normally needed. For prolonged or repeated skin contact use suitable protective gloves.
<b>Other</b>	Not normally needed. Wear suitable protective clothing as protection against splashing or contamination.
<b>Respiratory protection</b>	No personal respiratory protective equipment normally required. Use a NIOSH/MSHA approved respirator if there is a risk of exposure to dust/fume at levels exceeding the exposure limits. When workers are facing concentrations above the exposure limit they must use appropriate certified respirators.
<b>Thermal hazards</b>	Wear appropriate thermal protective clothing, when necessary.

## General hygiene considerations

Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants. For advice on suitable monitoring methods, seek guidance from a qualified environment, health and safety professional.

## 9. Physical and chemical properties

### Appearance

<b>Physical state</b>	Solid.
<b>Form</b>	Patch.
<b>Color</b>	Tan

**Odor** Not available.

**Odor threshold** Not available.

**pH** Not available.

**Melting point/freezing point** Not available.

**Initial boiling point and boiling range** Not available.

**Flash point** Not available.

**Evaporation rate** Not available.

**Flammability (solid, gas)** Not available.

### Upper/lower flammability or explosive limits

**Flammability limit - lower (%)** Not available.

**Flammability limit - upper (%)** Not available.

**Explosive limit - lower (%)** Not available.

**Explosive limit - upper (%)** Not available.

**Vapor pressure** Not available.

**Vapor density** Not available.

**Relative density** Not available.

### Solubility(ies)

**Solubility (water)** Not available.

**Partition coefficient (n-octanol/water)** Not available.

**Auto-ignition temperature** Not available.

**Decomposition temperature** Not available.

**Viscosity** Not available.

### Other information

**Explosive properties** Not explosive.

**Oxidizing properties** Not oxidizing.

## 10. Stability and reactivity

**Reactivity** The product is stable and non-reactive under normal conditions of use, storage and transport.

**Chemical stability** Material is stable under normal conditions.

<b>Possibility of hazardous reactions</b>	No dangerous reaction known under conditions of normal use.
<b>Conditions to avoid</b>	Heat, flames and sparks. Contact with incompatible materials.
<b>Incompatible materials</b>	Strong acids. Strong oxidizing agents.
<b>Hazardous decomposition products</b>	Irritating and/or toxic fumes and gases may be emitted upon the product's decomposition.

## 11. Toxicological information

### Information on likely routes of exposure

<b>Inhalation</b>	Under normal conditions of intended use, this material is not expected to be an inhalation hazard.
<b>Skin contact</b>	Health injuries are not known or expected under normal use. Irritation might occur following direct contact.
<b>Eye contact</b>	Health injuries are not known or expected under normal use. Direct contact with eyes may cause temporary irritation.
<b>Ingestion</b>	Health injuries are not known or expected under normal use. May be harmful if swallowed.

**Symptoms related to the physical, chemical and toxicological characteristics** Direct contact with eyes may cause temporary irritation. The possible symptoms of overexposure include: increased heart rate; increased blood pressure; salivation; depression. Headache. Dizziness. Nausea, vomiting. Abdominal pain.

### Information on toxicological effects

**Acute toxicity** Expected to be a low hazard for usual industrial or commercial handling by trained personnel. May be harmful if swallowed. Expected to be a low ingestion hazard.

Components	Species	Test Results
NICOTINE (CAS 54-11-5)		
<b>Acute</b>		
<b>Dermal</b>		
LD50	Rat	140 mg/kg
<b>Oral</b>		
LD50	Rat	188 mg/kg

\* Estimates for product may be based on additional component data not shown.

**Skin corrosion/irritation** Health injuries are not known or expected under normal use.

#### Irritation Corrosion - Skin NICOTINE

Acute dermal irritation  
Result: Positive  
Species: Rabbit

**Serious eye damage/eye irritation** Health injuries are not known or expected under normal use. Direct contact with eyes may cause temporary irritation.

### Respiratory or skin sensitization

**Respiratory sensitization** Health injuries are not known or expected under normal use.  
**Skin sensitization** Health injuries are not known or expected under normal use.

#### Sensitization NICOTINE

Local lymph node assay; OECD 429  
Result: Negative  
Species: Mouse

**Germ cell mutagenicity** Health injuries are not known or expected under normal use. Contains components that produced genotoxicity in laboratory tests. Not expected to be genotoxic under occupational exposure conditions.

#### Mutagenicity NICOTINE

Ames  
Result: Negative  
In vitro cytogenetics assay  
Result: Negative  
in vitro micronucleus assay  
Result: Positive  
Organ: gingivum  
Mouse micronucleus test  
Result: Negative

**Mutagenicity**  
NICOTINE

sister chromatid exchange  
Result: Positive

**Carcinogenicity**

Health injuries are not known or expected under normal use. Not expected to produce cancer in humans under occupational exposure conditions.

NICOTINE

Inhalation  
Result: Negative  
Species: Rat  
oral  
Result: Negative  
Species: Rat  
tumour promotor  
Species: Mouse

**IARC Monographs. Overall Evaluation of Carcinogenicity**

Not listed.

**OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)**

Not regulated.

**US. National Toxicology Program (NTP) Report on Carcinogens**

Not listed.

**Reproductive toxicity**

Health injuries are not known or expected under normal use. Components in this product have been shown to cause birth defects and reproductive disorders in laboratory animals. These effects are linked only to high doses of this substance; low doses did not produce this adverse effect.

**Reproductivity**

NICOTINE

Result: Developmental effects including cleft palate.  
Species: Mouse  
Result: Developmental toxicity.  
Species: Rabbit  
Result: Developmental toxicity.  
Species: Rat

**Specific target organ toxicity - single exposure**

Not assigned.

**Specific target organ toxicity - repeated exposure**

Not assigned.

**Aspiration hazard**

Not likely, due to the form of the product.

**Chronic effects**

Not available.

**Further information**

Caution - Pharmaceutical agent. Occupational exposure to the substance or mixture may cause adverse effects.

**12. Ecological information**

**Ecotoxicity**

Contains a substance which causes risk of hazardous effects to the environment.

Components	Species	Test Results	
NICOTINE (CAS 54-11-5)			
<b>Aquatic</b>			
<i>Acute</i>			
Crustacea	EC50	Water flea (Daphnia pulex)	0.242 mg/l, 48 hours Static renewal test
Fish	EC50	Rainbow trout (Adult Oncorhynchus mykiss)	4 mg/l, 96 hours

\* Estimates for product may be based on additional component data not shown.

**Persistence and degradability**

Not available.

**Biodegradability**

**Percent degradation (Aerobic biodegradation-ready)**

NICOTINE

83.43 % , 28 days, OECD 301 CO2 evol

**Bioaccumulative potential**

Not available.

**Partition coefficient n-octanol / water (log Kow)**

NICOTINE

1.17

**Bioconcentration factor (BCF)**

NICOTINE

5

**Mobility in soil**

Not available.

**Adsorption****Soil/sediment sorption - log Koc**

NICOTINE

2 Estimated

**Mobility in general** Not available.**Volatility****Henry's law**

NICOTINE

0 atm m<sup>3</sup>/mol Estimated**Other adverse effects** Not available.**13. Disposal considerations****Disposal instructions** Collect and reclaim or dispose in sealed containers at licensed waste disposal site. Do not discharge into drains, water courses or onto the ground. Do not allow this material to drain into sewers/water supplies. Do not contaminate ponds, waterways or ditches with chemical or used container. Dispose of contents/container in accordance with local/regional/national/international regulations.**Local disposal regulations** Dispose in accordance with all applicable regulations.**Hazardous waste code** The waste code should be assigned in discussion between the user, the producer and the waste disposal company.**US RCRA Hazardous Waste P List: Reference**

NICOTINE (CAS 54-11-5)

P075

**Waste from residues / unused products** Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions). Avoid discharge into water courses or onto the ground.**Contaminated packaging** Since emptied containers may retain product residue, follow label warnings even after container is emptied. Empty containers should be taken to an approved waste handling site for recycling or disposal.**14. Transport information****DOT**

**UN number** UN3077  
**UN proper shipping name** Environmentally hazardous substances, solid, n.o.s. (NICOTINE RQ = 286 LBS)  
**Transport hazard class(es)**  
**Class** 9  
**Subsidiary risk** -  
**Label(s)** 9  
**Packing group** III  
**Special precautions for user** Read safety instructions, SDS and emergency procedures before handling.  
**Special provisions** 8, 146, 335, A112, B54, IB8, IP3, N20, T1, TP33  
**Packaging exceptions** 155  
**Packaging non bulk** 213  
**Packaging bulk** 240

**IATA**

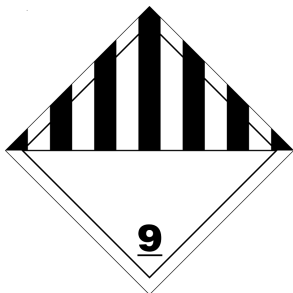
**UN number** UN3077  
**UN proper shipping name** Environmentally hazardous substance, solid, n.o.s. (NICOTINE)  
**Transport hazard class(es)** 9  
**Subsidiary class(es)** -  
**Packaging group** III  
**Labels required** Not available.  
**Environmental hazards** No.  
**ERG Code** 9L  
**Special precautions for user** Not available.  
**Other information**  
**Cargo aircraft only** Allowed with restrictions.  
**Passenger & cargo** Allowed with restrictions.

**IMDG**

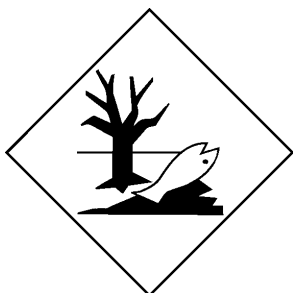
**UN number** UN3077  
**UN proper shipping name** ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (NICOTINE), MARINE POLLUTANT  
**Transport hazard class(es)**  
**Class** 9

**Subsidiary risk** -  
**Packing group** III  
**Environmental hazards**  
**Marine pollutant** Yes  
**EmS** F-A, S-F  
**Special precautions for user** Read safety instructions, SDS and emergency procedures before handling.  
**Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code** Not applicable.

DOT; IATA; IMDG



Marine pollutant



General information

Classifications are for the material when offered for transport as fully regulated. Depending on the specific transport details (Ship-From/Ship To locations, quantities being shipped, type of packaging and mode of transport) it may be possible to ship this material in a manner other than fully regulated. (One example is IATA Limited or Excepted Quantity. There are others.) Be sure to review all regulatory agency packaging instructions and special provisions, referenced in this section, to identify options applicable to the specifics of your shipment.

## 15. Regulatory information

**US federal regulations**

This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

**TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)**

Not regulated.

**CERCLA Hazardous Substance List (40 CFR 302.4)**

NICOTINE (CAS 54-11-5)

Listed.

**SARA 304 Emergency release notification**

NICOTINE (CAS 54-11-5)

100 LBS

**OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)**

Not regulated.

**Superfund Amendments and Reauthorization Act of 1986 (SARA)**

**Hazard categories**

Immediate Hazard - Yes  
 Delayed Hazard - Yes  
 Fire Hazard - No  
 Pressure Hazard - No  
 Reactivity Hazard - No



**SARA 302 Extremely hazardous substance**

Chemical name	CAS number	Reportable quantity (pounds)	Threshold planning quantity (pounds)	Threshold planning quantity, lower value (pounds)	Threshold planning quantity, upper value (pounds)
NICOTINE	54-11-5	100	100		
<b>SARA 311/312 Hazardous chemical</b>	No				
<b>SARA 313 (TRI reporting)</b>					
Chemical name	CAS number	% by wt.			
NICOTINE	54-11-5	17.5, 35 & 52.2 MG			

**Other federal regulations****Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List**

Not regulated.

**Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)**

Not regulated.

**Safe Drinking Water Act (SDWA)**

Not regulated.

**US state regulations**

WARNING: This product contains a chemical known to the State of California to cause birth defects or other reproductive harm.

**US - California Proposition 65 - CRT: Listed date/Developmental toxin**

NICOTINE (CAS 54-11-5)

Listed: April 1, 1990

**US. California. Candidate Chemicals List. Safer Consumer Products Regulations (Cal. Code Regs, tit. 22, 69502.3, subd. (a))**

NICOTINE (CAS 54-11-5)

**16. Other information, including date of preparation or last revision****Issue date** 07-28-2016**Revision date** 05-22-2017**Version #** 02**Further information** HMIS® is a registered trade and service mark of the ACA.**HMIS® ratings** Health: 2\*  
Flammability: 1  
Physical hazard: 0**NFPA ratings** Health: 2  
Flammability: 1  
Instability: 0**References** GSK Hazard Determination**Disclaimer** The information and recommendations in this safety data sheet are, to the best of our knowledge, accurate as of the date of issue. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose.**Revision information** This document has undergone significant changes and should be reviewed in its entirety.