



# SAFETY DATA SHEET

## 1. Identification

<b>Product identifier</b>	<b>NICODERM CQ</b>
<b>Other means of identification</b>	
<b>Synonyms</b>	NICODERM CQ CLEAR PATCH 7MG, 14MG AND 21 MG (US) * NICODERM CQ PATCH 21 MG (US) * NIQUITIN CQ CLEAR PATCH 7 MG, 14 MG AND 21 MG (UK) * NIQUITIN CQ ORIGINAL PATCH 7 MG, 14 MG AND 21 MG (UK) * NICABATE CQ CLEAR PATCH 7 MG, 14 MG AND 21 MG (AUS) * NICABATE CQ OPAQUE PATCH 7 MG, 14 MG AND 21 MG (AUS) * NICABATE P CLASSIC PATCH 21MG (AUS) * NICABATE PRE-QUIT PATCH (AUS) * NICOTINE TRANSDERMAL SYSTEM * NICOTINE, FORMULATED PRODUCT
<b>Recommended use</b>	Consumer Healthcare 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.
<b>Recommended restrictions</b>	No other uses are advised.
<b>Manufacturer/Importer/Supplier/Distributor information</b>	

<b>COMPANY NAME</b>	GlaxoSmithKline US
<b>Address:</b>	5 Moore Drive Research Triangle Park, NC 27709 USA
<b>Telephone:</b>	+1-888-825-5249 (General Inquiries)
<b>Email:</b>	msds@gsk.com
<b>Website:</b>	www.gsk.com

## EMERGENCY CONTACTS

<b>Telephone:</b>	VERISK 3E GLOBAL INCIDENT RESPONSE +(1) 760 476 3971 (In country) +(1) 760 476 3962 or +(1) 866 519 4752 (International) 24/7; multi-language response
<b>Contract Number:</b>	334878

## 2. Hazard(s) identification

<b>Physical hazards</b>	Not classified.	
<b>Health hazards</b>	Not classified.	
<b>Environmental hazards</b>	Hazardous to the aquatic environment, long-term hazard	Category 3
<b>OSHA defined hazards</b>	Not classified.	
<b>Label elements</b>		
<b>Hazard symbol</b>	None.	
<b>Signal word</b>	None.	
<b>Hazard statement</b>	Harmful to aquatic life with long lasting effects.	
<b>Precautionary statement</b>		
<b>Prevention</b>	Wash thoroughly after handling. Avoid release to the environment.	
<b>Response</b>	Specific treatment (see on this label).	
<b>Storage</b>	Not available.	
<b>Disposal</b>	Dispose of contents/container in accordance with local/regional/national/international regulations.	

<b>Hazard(s) not otherwise classified (HNOC)</b>	None known.
<b>Supplemental information</b>	100% of the mixture consists of component(s) of unknown acute hazards to the aquatic environment. 100% of the mixture consists of component(s) of unknown long-term hazards to the aquatic environment.

### 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-METHYLPYRROLIDINE NICOTINE ALKALOID O-3825 RCRA P075 OHS16430 RTECS QS5250000 3-(N-METHYL-2-PYRROLIDINYL) PYRIDINE 3-(N-METYLI-2-PYRROLIDINYLI)PYRI DIINI	54-11-5	≤ 12
Other components below reportable levels			≥ 88

### 4. First-aid measures

<b>Inhalation</b>	Move to fresh air. Call a physician if symptoms develop or persist.
<b>Skin contact</b>	Wash off with soap and water. Get medical attention if irritation develops and persists.
<b>Eye contact</b>	Rinse with water. Get medical attention if irritation develops and persists.
<b>Ingestion</b>	Rinse mouth. Get medical attention if symptoms occur.
<b>Most important symptoms/effects, acute and delayed</b>	Not available.
<b>Indication of immediate medical attention and special treatment needed</b>	Treat symptomatically.
<b>General information</b>	Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

### 5. Fire-fighting measures

<b>Suitable extinguishing media</b>	Water fog. Foam. Dry chemical powder. Carbon dioxide (CO2).
<b>Unsuitable extinguishing media</b>	Do not use water jet as an extinguisher, as this will spread the fire.
<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>	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. 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**

This material is classified as a water pollutant under the Clean Water Act and should be prevented from contaminating soil or from entering sewage and drainage systems which lead to waterways. Stop the flow of material, if this is without risk. Following product recovery, flush area with water. 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**

Avoid prolonged exposure. Provide adequate ventilation. Wear appropriate personal protective equipment. Avoid release to the environment. Observe good industrial hygiene practices.

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

Store in tightly closed container. 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	Form
NICOTINE (CAS 54-11-5)	8 HR TWA	50 mcg/m3	
	OHC	3	REPRODUCTIVE HAZARD, SKIN

**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) Danger of cutaneous absorption

**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**

Good general ventilation should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level.

**Individual protection measures, such as personal protective equipment****Eye/face protection**

Wear safety glasses with side shields (or goggles).

**Skin protection****Hand protection**

Wear appropriate chemical resistant gloves.

<b>Other</b>	Wear suitable protective clothing.
<b>Respiratory protection</b>	In case of insufficient ventilation, wear suitable respiratory equipment.
<b>Thermal hazards</b>	Wear appropriate thermal protective clothing, when necessary.
<b>General hygiene considerations</b>	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.

## 9. Physical and chemical properties

### Appearance

<b>Physical state</b>	Solid.
<b>Form</b>	Patch Solid.
<b>Color</b>	Not available.
<b>Odor</b>	Not available.
<b>Odor threshold</b>	Not available.
<b>pH</b>	Not available.
<b>Melting point/freezing point</b>	Not available.
<b>Initial boiling point and boiling range</b>	Not available.
<b>Flash point</b>	Not available.
<b>Evaporation rate</b>	Not available.
<b>Flammability (solid, gas)</b>	Not available.
<b>Upper/lower flammability or explosive limits</b>	
<b>Flammability limit - lower (%)</b>	Not available.
<b>Flammability limit - upper (%)</b>	Not available.
<b>Explosive limit - lower (%)</b>	Not available.
<b>Explosive limit - upper (%)</b>	Not available.
<b>Vapor pressure</b>	Not available.
<b>Vapor density</b>	Not available.
<b>Relative density</b>	Not available.
<b>Solubility(ies)</b>	
<b>Solubility (water)</b>	Not available.
<b>Partition coefficient (n-octanol/water)</b>	Not available.
<b>Auto-ignition temperature</b>	Not available.
<b>Decomposition temperature</b>	Not available.
<b>Viscosity</b>	Not available.
<b>Other information</b>	
<b>Explosive properties</b>	Not explosive.
<b>Oxidizing properties</b>	Not oxidizing.

## 10. Stability and reactivity

<b>Reactivity</b>	The product is stable and non-reactive under normal conditions of use, storage and transport.
<b>Chemical stability</b>	Material is stable under normal conditions.
<b>Possibility of hazardous reactions</b>	Hazardous polymerization does not occur.
<b>Conditions to avoid</b>	Contact with incompatible materials.
<b>Incompatible materials</b>	Strong acids. Strong oxidizing agents.
<b>Hazardous decomposition products</b>	No hazardous decomposition products are known.

## 11. Toxicological information

### Information on likely routes of exposure

<b>Inhalation</b>	Not likely, due to the form of the product.
<b>Skin contact</b>	No adverse effects due to skin contact are expected.
<b>Eye contact</b>	Direct contact with eyes may cause temporary irritation.
<b>Ingestion</b>	Expected to be a low ingestion hazard.

**Symptoms related to the physical, chemical and toxicological characteristics** Direct contact with eyes may cause temporary irritation.

### Information on toxicological effects

#### Acute toxicity

Components	Species	Test Results
NICOTINE (CAS 54-11-5)		
<b>Acute</b>		
<b>Oral</b>		
LD50	-	3.34 mg/kg
	Rat	188 mg/kg

**Skin corrosion/irritation** Prolonged skin contact may cause temporary irritation.

#### Irritation Corrosion - Skin

NICOTINE

Acute dermal irritation  
Result: Positive  
Species: Rabbit

**Serious eye damage/eye irritation** Direct contact with eyes may cause temporary irritation.

#### Respiratory or skin sensitization

**Respiratory sensitization** Not a respiratory sensitizer.

**Skin sensitization** This product is not expected to cause skin sensitization.

#### Sensitization

NICOTINE

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

**Germ cell mutagenicity** No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.

#### Mutagenicity

NICOTINE

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

**Carcinogenicity** Not classifiable as to carcinogenicity to humans.

NICOTINE

Inhalation  
Result: Negative  
Species: Rat  
oral  
Result: Negative  
Species: Rat

#### IARC Monographs. Overall Evaluation of Carcinogenicity

Not listed.

**OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)**

Not listed.

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

Not listed.

**Reproductive toxicity** This product is not expected to cause reproductive or developmental effects.**Reproductivity**  
NICOTINEResult: Developmental effects including cleft palate at high doses  
Species: Mouse  
Result: Developmental toxicity at high doses  
Species: Rabbit  
Result: Negative  
Species: Rat  
Result: No evidence exists  
Species: Human**Specific target organ toxicity - single exposure** Not classified.**Specific target organ toxicity - repeated exposure** Not classified.**Aspiration hazard** Not an aspiration hazard.**12. Ecological information****Ecotoxicity** Harmful to aquatic life with long lasting effects.

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

**Persistence and degradability****Biodegradability****Percent degradation (Aerobic biodegradation-ready)**

NICOTINE 83.43 % , 28 days, OECD 301 CO2 evol

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

NICOTINE 1.17

**Bioconcentration factor (BCF)**

NICOTINE 5

**Mobility in soil** No data available.**Adsorption****Soil/sediment sorption - log Koc**

NICOTINE 2 Estimated

**Mobility in general****Volatility****Henry's law**NICOTINE 0 atm m<sup>3</sup>/mol Estimated**Other adverse effects** No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.**13. Disposal considerations****Disposal instructions** Collect and reclaim or dispose in sealed containers at licensed waste disposal site. 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

<b>Waste from residues / unused products</b>	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).
<b>Contaminated packaging</b>	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

<b>UN number</b>	UN3077
<b>UN proper shipping name</b>	Environmentally hazardous substances, solid, n.o.s. (NICOTINE RQ = 833 LBS), MARINE POLLUTANT
<b>Transport hazard class(es)</b>	
<b>Class</b>	9
<b>Subsidiary risk</b>	-
<b>Label(s)</b>	9
<b>Packing group</b>	III
<b>Environmental hazards</b>	
<b>Marine pollutant</b>	Yes
<b>Special provisions</b>	8, 146, 335, A112, B54, IB8, IP3, N20, T1, TP33
Read safety instructions, SDS and emergency procedures before handling.	

#### IATA

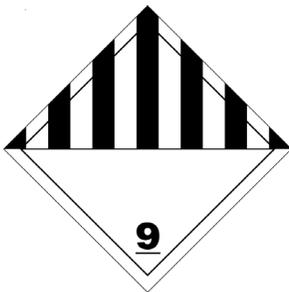
<b>UN number</b>	UN3077
<b>UN proper shipping name</b>	Environmentally hazardous substance, solid, n.o.s. (NICOTINE)
<b>Transport hazard class(es)</b>	9
<b>Subsidiary class(es)</b>	-
<b>Packaging group</b>	III
<b>Labels required</b>	Not available.
<b>Environmental hazards</b>	No.
<b>ERG Code</b>	9L

#### IMDG

<b>UN number</b>	UN3077
<b>UN proper shipping name</b>	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (NICOTINE), MARINE POLLUTANT
<b>Transport hazard class(es)</b>	
<b>Class</b>	9
<b>Subsidiary risk</b>	-
<b>Packing group</b>	III
<b>Environmental hazards</b>	
<b>Marine pollutant</b>	Yes
<b>EmS</b>	F-A, S-F
274,335,966,967	

**Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code** Not applicable.

#### DOT; IATA; IMDG



**Marine pollutant**

**General information** IMDG Regulated Marine Pollutant. DOT Regulated Marine Pollutant.

**15. Regulatory information**

**US federal regulations** This product is not known to be a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

**Toxic Substances Control Act (TSCA)****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**

Pyridine, 3-(1-methyl-2-pyrrolidinyl)-, (S)- (CAS 54-11-5) 100 LBS

**OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)**

Not listed.

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

**SARA 311/312 Hazardous chemical** No

**SARA 313 (TRI reporting)**

Chemical name	CAS number	% by wt.
NICOTINE	54-11-5	≤ 12

**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****California Proposition 65**

**WARNING:** This product can expose you to 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](http://www.P65Warnings.ca.gov).

**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)

**International Inventories**

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Industrial Chemicals (AICIS)	No

Country(s) or region	Inventory name	On inventory (yes/no)*
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
Taiwan	Taiwan Chemical Substance Inventory (TCSI)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

\*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

## 16. Other information, including date of preparation or last revision

<b>Issue date</b>	05-25-2018
<b>Revision date</b>	02-09-2022
<b>Version #</b>	18
<b>HMIS® ratings</b>	Health: 2* Flammability: 1 Physical hazard: 0
<b>NFPA ratings</b>	Health: 2 Flammability: 1 Instability: 0
<b>Disclaimer</b>	GlaxoSmithKline cannot anticipate all conditions under which this information and its product, or the products of other manufacturers in combination with its product, may be used. It is the user's responsibility to ensure safe conditions for handling, storage and disposal of the product, and to assume liability for loss, injury, damage or expense due to improper use. The information in the sheet was written based on the best knowledge and experience currently available.
<b>Revision information</b>	HazReg Data: International Inventories