



SAFETY DATA SHEET

1. Identification

Product identifier

NICODERM CQ

Other means of identification

Synonyms

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 (AUSTRALIA) * NICABATE CQ OPAQUE PATCH 7 MG, 14 MG AND 21 MG (AUSTRALIA) * NICOTINE TRANSDERMAL SYSTEM * NICOTINE, FORMULATED PRODUCT

Recommended use

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

Manufacturer

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
Website: www.gsk.com
EMERGENCY PHONE NUMBERS -
TRANSPORT EMERGENCIES::
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-METHYLPYRRO LIDINE * NICOTINE ALKALOID * O-3825 * RCRA P075 * OHS16430 * RTECS QS5250000 * 3-(N-METHYL-2-PYRROLIDINYL)PYRIDINE * 3-(N-METYYLI-2-PYRROLIDINYLI)PYRIDII NI	54-11-5	10 - < 12
Other components below reportable levels			80 - < 90

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

4. First-aid measures

Inhalation	Move to fresh air. Call a physician if symptoms develop or persist. If breathing is difficult, trained personnel should give oxygen. Under normal conditions of intended use, this material is not expected to be an inhalation hazard.
Skin contact	Immediately flush skin with plenty of water. Take off contaminated clothing and wash before reuse. Get medical attention if symptoms occur.
Eye contact	Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.
Ingestion	If swallowed, rinse mouth with water (only if the person is conscious). Do not induce vomiting without advice from poison control center. If ingestion of a large amount does occur, call a poison control center immediately.
Most important symptoms/effects, acute and delayed	The following adverse effects have been noted with therapeutic use of this material: sweating; salivation; dry mouth; abdominal pain; constipation; vomiting; diarrhoea; headache; dizziness; visual disturbances; tremor; increased heart rate; nervousness; mental impairment; weakness.
Indication of immediate medical attention and special treatment needed	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.
General information	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

Suitable extinguishing media	Foam. Dry chemical powder. Carbon dioxide (CO ₂). Water.
Unsuitable extinguishing media	None known.
Specific hazards arising from the chemical	During fire, gases hazardous to health may be formed.
Special protective equipment and precautions for firefighters	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
Fire-fighting equipment/instructions	Use water spray to cool unopened containers.
Specific methods	Use standard firefighting procedures and consider the hazards of other involved materials.
General fire hazards	Assume that this product is capable of sustaining combustion.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures	Keep unnecessary personnel away. Keep people away from and upwind of spill/leak. Keep out of low areas. 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.
Methods and materials for containment and cleaning up	Stop the flow of material, if this is without risk. Collect spillage. Prevent entry into waterways, sewer, basements or confined areas. Following product recovery, flush area with water. For waste disposal, see section 13 of the SDS.
Environmental precautions	Avoid release to the environment. Contact local authorities in case of spillage to drain/aquatic environment. Prevent further leakage or spillage if safe to do so. Do not contaminate water. 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. Observe good industrial hygiene practices. Avoid release to the environment. Do not empty into drains.
Conditions for safe storage, including any incompatibilities	Store in original tightly closed container. Store away from incompatible materials (see Section 10 of the SDS).

8. Exposure controls/personal protection

Occupational exposure limits

GSK

Components

NICOTINE (CAS 54-11-5)

Type

15 MIN STEL

8 HR TWA

Value

200 mcg/m³

70 mcg/m³

Note

GSK Components	Type	Value	Note
	OHC	3	REPRODUCTIVE HAZARD
		3	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) 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 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. General ventilation normally adequate.

Individual protection measures, such as personal protective equipment

Eye/face protection Not normally needed. If contact is likely, safety glasses with side shields are recommended.

Hand protection Not normally needed. For prolonged or repeated skin contact use suitable protective gloves.

Skin protection

Other Not normally needed. Wear suitable protective clothing as protection against splashing or contamination.

Respiratory protection 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.

Thermal hazards 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

Physical state	Solid.
Form	Patch.
Color	Not available.

Components	Species	Test Results
NICOTINE (CAS 54-11-5)		
Acute		
<i>Dermal</i>		
LD50	Rat	140 mg/kg
<i>Oral</i>		
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.	
Serious eye damage/eye irritation	Harmful in contact with eyes. May be irritating to eyes.	
Respiratory or skin sensitization		
Respiratory sensitization	Not available.	
Skin sensitization	This product is not expected to cause skin sensitization.	
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
	Mouse micronucleus test	Result: Negative
	in vitro micronucleus assay	Result: Positive
	Organ: gingivum	sister chromatid exchange
		Result: Positive
Carcinogenicity	Health injuries are not known or expected under normal use.	
NICOTINE	Inhalation	Result: Negative
	Species: Rat	oral
		Result: Negative
	Species: Rat	tumour promotor
		Species: Mouse
OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)		
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	Nervous system.	
NICOTINE		nervous system
Specific target organ toxicity - repeated exposure	May cause damage to organs through prolonged or repeated exposure.	
NICOTINE		cardiovascular system
Aspiration hazard	Not likely, due to the form of the product.	
Further information	Caution - Pharmaceutical agent.	

12. Ecological information

Ecotoxicity The product contains a substance which may cause long-term adverse effects in the environment. Contains a substance which causes risk of hazardous effects to the environment.

Components	Species	Test Results	
NICOTINE (CAS 54-11-5)			
Aquatic			
<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.

Bioaccumulative potential

Partition coefficient n-octanol / water (log Kow)

NICOTINE 1.17

Bioconcentration factor (BCF)

NICOTINE 5

Mobility in soil

Adsorption

Soil/sediment sorption - log Koc

NICOTINE 2 Estimated

Mobility in general

Volatility

Henry's law

NICOTINE 0 atm m³/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 allow this material to drain into sewers/water supplies. Do not contaminate ponds, waterways or ditches with chemical or used container. Dispose in accordance with all applicable 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).

Contaminated packaging Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. Transport information

DOT

UN number UN3077

UN proper shipping name Environmentally hazardous substances, solid, n.o.s. (NICOTINE, FORMULATED PRODUCT), MARINE POLLUTANT

Transport hazard class(es)

Class 9

Subsidiary risk -

Label(s) 9

Packing group III

Environmental hazards

Marine pollutant Yes

Special precautions for user Not available.

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, FORMULATED PRODUCT)
Transport hazard class(es)	9
Subsidiary class(es)	-
Packaging group	III
Labels required	9
Environmental hazards	No.
ERG Code	9L
Special precautions for user	Not available.
Other information	

Cargo aircraft only Allowed.

Passenger & cargo Allowed.

IMDG

UN number	UN3077
UN proper shipping name	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (NICOTINE, FORMULATED PRODUCT)
Transport hazard class(es)	
Class	9
Subsidiary risk	-
Packing group	III
Environmental hazards	
Marine pollutant	No.
EmS	F-A, S-F
Special precautions for user	Not available.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code MARPOL Annex II applies to liquids used in a ship's operation that pose a threat to the marine environment. These materials may not be transported in bulk.

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 One or more components are not listed on 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

NICOTINE (CAS 54-11-5) 100 LBS

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

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	Threshold planning quantity	Threshold planning quantity, lower value	Threshold planning quantity, upper value
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NICOTINE	54-11-5	100	100 lbs		
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SARA 311/312 Hazardous chemical No

SARA 313 (TRI reporting)

Chemical name	CAS number	% by wt.
NICOTINE	54-11-5	10 - < 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

US. Massachusetts RTK - Substance List

NICOTINE (CAS 54-11-5)

US. New Jersey Worker and Community Right-to-Know Act

NICOTINE (CAS 54-11-5)

US. Pennsylvania Worker and Community Right-to-Know Law

NICOTINE (CAS 54-11-5)

US. Rhode Island RTK

NICOTINE (CAS 54-11-5)

US. California Proposition 65

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

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	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

Country(s) or region	Inventory name	On inventory (yes/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
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

Issue date	09-22-2014
Revision date	09-22-2014
Version #	14
Further information	HMIS® is a registered trade and service mark of the NPCA.
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	Product and Company Identification: Product and Company Identification Composition / Information on Ingredients: Ingredients Physical & Chemical Properties: Toxicological Information: Transport Information: Proper Shipping Name/Packing Group Regulatory Information: United States GHS: Classification