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 (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

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.Medicinal Product

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
Website: 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-METYYLI-2-PYRROLIDINYYLI)PYRI DIINI	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.

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.

Most important symptoms/effects, acute and delayed Direct contact with eyes may cause temporary irritation. The possible symptoms of overexposure include: increased heart rate; increased blood pressure; salivation; abdominal pain; depression. Headache. Dizziness. Nausea, vomiting.

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 Take off immediately all contaminated clothing. IF exposed or concerned: Get medical advice/attention. Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves. Discard any shoes or clothing items that cannot be decontaminated. 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 Water. Foam. Dry chemical powder. Carbon dioxide (CO2).

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 Move containers from fire area if you can do so without risk.

Specific methods Use standard firefighting procedures and consider the hazards of other involved materials.

General fire hazards No unusual fire or explosion hazards noted.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures Keep unnecessary personnel away. Wear appropriate protective equipment and clothing during clean-up. For personal protection, see section 8 of the SDS. Ensure adequate ventilation. Local authorities should be advised if significant spillages cannot be contained.

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.

Large Spills: Stop the flow of material, if this is without risk. Dike the spilled material, where this is possible. 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. 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. Do not get in eyes, on skin, or on clothing. Do not taste or swallow. When using, do not eat, drink or smoke. Provide adequate ventilation. Wash hands thoroughly after handling. Avoid release to the environment. Wash contaminated clothing before reuse.

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

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
		3	REPRODUCTIVE HAZARD

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.
Skin protection	
Hand protection	Not normally needed. For prolonged or repeated skin contact use suitable protective gloves.
Other	Not normally needed.
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.
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	Clear. Opaque.
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.
Possibility of hazardous reactions	Hazardous polymerization does not occur.

Conditions to avoid	Contact with incompatible materials.
Incompatible materials	Strong acids. Strong oxidizing agents.
Hazardous decomposition products	None known. Irritating and/or toxic fumes and gases may be emitted upon the product's decomposition.

11. Toxicological information

Information on likely routes of exposure

Inhalation	Under normal conditions of intended use, this material is not expected to be an inhalation hazard.
Skin contact	Health injuries are not known or expected under normal use. Irritation might occur following direct contact.
Eye contact	Health injuries are not known or expected under normal use. Direct contact with eyes may cause temporary irritation.
Ingestion	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; abdominal pain; depression. Headache. Dizziness. Nausea, vomiting.

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)		
Acute		
Dermal		
LD50	Rat	140 mg/kg
Oral		
LD50	Rat	188 mg/kg

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. Based on available data, the classification criteria are not met.

Skin sensitization Due to partial or complete lack of data the classification is not possible.

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
sister chromatid exchange
Result: Positive

Carcinogenicity Based on available data, the classification criteria are not met. Health injuries are not known or expected under normal use.

Carcinogenicity

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)			
Aquatic			
Acute			
Crustacea	EC50	Water flea (Daphnia pulex)	0.242 mg/l, 48 hours Static renewal test
Fish	EC50	Rainbow trout (Adult Oncorhyncus 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

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 m^3/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. 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). 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 = 833 LBS), 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)
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

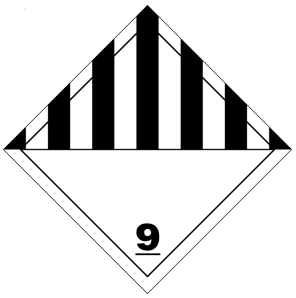
Marine pollutant Yes

EmS F-A, S-F

Special precautions for user 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

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		

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 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 09-22-2014

Revision date 05-22-2017

Version # 15

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.