

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Trade name or designation of the mixture	NICODERM CQ
Registration number	-
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
Issue date	22-September-2014
Version number	14
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1.2. Relevant identified uses of the substance or mixture and uses advised against

Identified uses 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.

Uses advised against No other uses are advised.

1.3. Details of the supplier of the safety data sheet

GlaxoSmithKline UK
980 Great West Road
Brentford, Middlesex TW8 9GS UK
UK General Information (normal business hours): +44-20-8047-5000
Email Address: msds@gsk.com
Website: www.gsk.com

1.4. Emergency telephone number

TRANSPORT EMERGENCIES::
UK In-country toll call: +(44)-870-8200418
International toll call: +1 703 527 3887
available 24 hrs/7 days; multi-language response

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

The mixture has been assessed and/or tested for its physical, health and environmental hazards and the following classification applies.

Classification according to Directive 67/548/EEC or 1999/45/EC as amended

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

Classification according to Regulation (EC) No 1272/2008 as amended

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

2.2. Label elements

Label according to Regulation (EC) No. 1272/2008 as amended

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

Supplemental label information None.

2.3. Other hazards

Assume that this product is capable of sustaining combustion.
Caution - Pharmaceutical agent. See section 11 for additional information on health hazards.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

General information

Chemical name	%	CAS-No. / EC No.	REACH Registration No.	INDEX No.	Notes
NICOTINE	10 - < 12	54-11-5 200-193-3	-	614-001-00-4	#
Classification:	DSD:	Repr. Cat. 3;R62-63, T+;R27, T;R25, Xi;R41, N;R50-51/53			
	CLP:	Acute Tox. 3;H301, Acute Tox. 1;H310, Eye Irrit. 2;H319, Repr. 2;H361, Aquatic Acute 1;H400, Aquatic Chronic 2;H411			

Other components below reportable levels 80 - < 90

CLP: Regulation No. 1272/2008.

DSD: Directive 67/548/EEC.

M: M-factor

vPvB: very persistent and very bioaccumulative substance.

PBT: persistent, bioaccumulative and toxic substance.

#: This substance has been assigned Community workplace exposure limit(s).

Composition comments The full text for all R- and H-phrases is displayed in section 16.

SECTION 4: First aid measures

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.

4.1. Description of 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 medical advice. If ingestion of a large amount does occur, call a poison control centre immediately.

4.2. Most important symptoms and effects, both 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.

4.3. Indication of any 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 centre.

SECTION 5: Firefighting measures

General fire hazards Assume that this product is capable of sustaining combustion.

5.1. Extinguishing media

Suitable extinguishing media	Foam. Dry chemical powder. Carbon dioxide (CO ₂). Water.
Unsuitable extinguishing media	None known.

5.2. Special hazards arising from the substance or mixture During fire, gases hazardous to health may be formed.

5.3. Advice for firefighters

Special protective equipment for firefighters	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
Special fire fighting procedures	Use water spray to cool unopened containers.

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

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

For non-emergency personnel	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.
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For emergency responders Keep unnecessary personnel away. Use personal protection recommended in Section 8 of the SDS.

6.2. 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.

6.3. Methods and material 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.

6.4. Reference to other sections For personal protection, see section 8. For waste disposal, see section 13.

SECTION 7: Handling and storage

7.1. 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.

7.2. Conditions for safe storage, including any incompatibilities Store in original tightly closed container. Store away from incompatible materials (see Section 10 of the SDS).

7.3. Specific end use(s) Medicinal Product

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Occupational exposure limits

GSK

Components	Type	Value	Note
NICOTINE (CAS 54-11-5)	15 MIN STEL	200 mcg/m ³	
	8 HR TWA	70 mcg/m ³	
	OHC	3	Reproductive hazard
		3	Skin

UK. EH40 Workplace Exposure Limits (WELs)

Components	Type	Value
NICOTINE (CAS 54-11-5)	STEL	1.5 mg/m ³
	TWA	0.5 mg/m ³

EU. Indicative Exposure Limit Values in Directives 91/322/EEC, 2000/39/EC, 2006/15/EC, 2009/161/EU

Components	Type	Value
NICOTINE (CAS 54-11-5)	TWA	0.5 mg/m ³

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

Recommended monitoring procedures Follow standard monitoring procedures.

Derived no-effect level (DNEL) Not available.

Predicted no effect concentrations (PNECs) Not available.

Exposure guidelines

UK EH40 WEL: Skin designation

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

8.2. Exposure controls

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

General information Personal protection equipment should be chosen according to the CEN standards and in discussion with the supplier of the personal protective equipment. Follow all local regulations if personal protective equipment (PPE) is used in the workplace.

Eye/face protection Not normally needed. If contact is likely, safety glasses with side shields are recommended. (eg. EN 166)

Skin protection

- Hand protection Not normally needed. For prolonged or repeated skin contact use suitable protective gloves. Select suitable chemical resistant protective gloves (EN 374) with a protective index 6 (>480min permeation time).

- Other Not normally needed. Wear suitable protective clothing as protection against splashing or contamination. (EN 14605 for splashes, EN ISO 13982 for dust)

Respiratory protection	No personal respiratory protective equipment normally required. When workers are facing concentrations above the exposure limit they must use appropriate certified respirators. Where breathable aerosols/dust are formed, use suitable combination filter for gases/vapours of organic, inorganic, acid inorganic, alkaline compounds and toxic particles (eg. EN 14387).
Thermal hazards	Wear appropriate thermal protective clothing, when necessary.
Hygiene measures	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.
Environmental exposure controls	
Hazard guidance and control recommendations	Contain spills and prevent releases and observe national regulations on emissions. Environmental manager must be informed of all major releases.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance

Physical state	Solid.
Form	Patch.
Colour	Not available.
Odour	Not available.
Odour 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.
Vapour pressure	Not available.
Vapour density	Not available.
Relative density	Not available.
Solubility(ies)	
Solubility (water)	Not available.
Solubility (other)	Not available.
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.
Explosive properties	Not available.
Oxidizing properties	Not available.

9.2. Other information Not relevant additional information available.

SECTION 10: Stability and reactivity

10.1. Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
10.2. Chemical stability	Material is stable under normal conditions.
10.3. Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
10.4. Conditions to avoid	Contact with incompatible materials.
10.5. Incompatible materials	Strong acids. Strong oxidising agents.
10.6. Hazardous decomposition products	Irritating and/or toxic fumes and gases may be emitted upon the products decomposition.

SECTION 11: Toxicological information

General information Occupational exposure to the substance or mixture may cause adverse effects.

Information on likely routes of exposure

Ingestion Harmful if swallowed. However, ingestion is not likely to be a primary route of occupational 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. May be harmful in contact with skin.

Eye contact Harmful in contact with eyes. Direct contact with eyes may cause temporary irritation.

Symptoms The following adverse effects have been noted with therapeutic use of this material: sweating; salivation; dry mouth; constipation; vomiting; abdominal pain; diarrhoea; headache; dizziness; visual disturbances; tremor; increased heart rate; nervousness; mental impairment; weakness.

NICOTINE nervous system

11.1. Information on toxicological effects

Acute toxicity Expected to be a low hazard for usual industrial or commercial handling by trained personnel. May be harmful in contact with skin.

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 sensitisation Not available.

Skin sensitisation This product is not expected to cause skin sensitisation.

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

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.
Mixture versus substance information	No information available.
Other information	Caution - Pharmaceutical agent.

SECTION 12: Ecological information

12.1. Toxicity 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.

12.2. Persistence and degradability Not available.

Biodegradability

Percent degradation (Aerobic biodegradation-ready)

NICOTINE 83.43 % , 28 days, OECD 301 CO2 evol

12.3. Bioaccumulative potential

Partition coefficient

n-octanol/water (log Kow)

NICOTINE 1.17

Bioconcentration factor (BCF)

NICOTINE 5

12.4. 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

12.5. Results of PBT and vPvB assessment Not available.

12.6. Other adverse effects Not available.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Residual waste	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.
EU waste code	The Waste code should be assigned in discussion between the user, the producer and the waste disposal company.
Disposal methods/information	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.
Special precautions	Dispose in accordance with all applicable regulations.

SECTION 14: Transport information

General

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.

ADR

14.1. UN number	UN3077
14.2. UN proper shipping name	Environmentally hazardous substances, solid, n.o.s. (NICOTINE, FORMULATED PRODUCT)
14.3. Transport hazard class(es)	
Class	9
Subsidiary risk	-
Label(s)	9
Hazard No. (ADR)	Not available.
Tunnel code	Not available.
14.4. Packing group	III
14.5. Environmental hazards	Yes
14.6. Special precautions for user	Not available.

IATA

14.1. UN number	UN3077
14.2. UN proper shipping name	Environmentally hazardous substance, solid, n.o.s. (NICOTINE, FORMULATED PRODUCT)
14.3. Transport hazard class(es)	9
Subsidiary class(es)	-
14.4. Packing group	III
Labels required	9
14.5. Environmental hazards	No.
ERG Code	9L
14.6. Special precautions for user	Not available.
Other information	
Cargo aircraft only	Allowed.
Additional Information:	
Passenger & cargo	Allowed.

IMDG

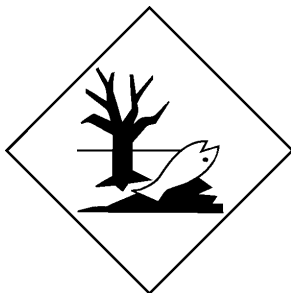
14.1. UN number	UN3077
14.2. UN proper shipping name	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (NICOTINE, FORMULATED PRODUCT)
14.3. Transport hazard class(es)	
Class	9
Subsidiary risk	-
14.4. Packing group	III
14.5. Environmental hazards	
Marine pollutant	No.
EmS	F-A, S-F
14.6. Special precautions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

14.7. Transport in bulk according to Annex II of MARPOL73/78 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.

ADR; IATA; IMDG





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.

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

EU regulations

Regulation (EC) No. 1005/2009 on substances that deplete the ozone layer, Annex I

Not listed.

Regulation (EC) No. 1005/2009 on substances that deplete the ozone layer, Annex II

Not listed.

Regulation (EC) No. 850/2004 On persistent organic pollutants, Annex I as amended

Not listed.

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 1 as amended

NICOTINE (CAS 54-11-5)

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 2 as amended

NICOTINE (CAS 54-11-5)

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 3 as amended

Not listed.

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex V as amended

Not listed.

Regulation (EC) No. 166/2006 Annex II Pollutant Release and Transfer Registry

Not listed.

Regulation (EC) No. 1907/2006, REACH Article 59(1) Candidate List as currently published by ECHA

Not listed.

Authorisations

Regulation (EC) No. 1907/2006, REACH Annex XIV Substances subject to authorization, as amended

Not listed.

Restrictions on use

Regulation (EC) No. 1907/2006, REACH Annex XVII Substances subject to restriction on marketing and use as amended

Not listed.

Directive 2004/37/EC: on the protection of workers from the risks related to exposure to carcinogens and mutagens at work

Not listed.

Directive 92/85/EEC: on the safety and health of pregnant workers and workers who have recently given birth or are breastfeeding

Not listed.

Other EU regulations

Directive 96/82/EC (Seveso II) on the control of major-accident hazards involving dangerous substances

Not listed.

Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work

NICOTINE (CAS 54-11-5)

Directive 94/33/EC on the protection of young people at work

NICOTINE (CAS 54-11-5)

Other regulations

The product is classified and labelled in accordance with EC directives or respective national laws. This Safety Data Sheet complies with the requirements of Regulation (EC) No 1907/2006. Pregnant women should not work with the product, if there is the least risk of exposure.

National regulations	Young people under 18 years old are not allowed to work with this product according to the EU Directive 94/33/EC on the protection of young people at work. Follow national regulation for work with chemical agents.
15.2. Chemical safety assessment	No Chemical Safety Assessment has been carried out.
SECTION 16: Other information	
List of abbreviations	Not available.
References	GSK Hazard Determination
Information on evaluation method leading to the classification of mixture	The classification for health and environmental hazards is derived by a combination of calculation methods and test data, if available.
Full text of any statements or R-phrases and H-statements under Sections 2 to 15	<p>R22 Harmful if swallowed.</p> <p>R25 Toxic if swallowed.</p> <p>R27 Very toxic in contact with skin.</p> <p>R41 Risk of serious damage to eyes.</p> <p>R50 Very toxic to aquatic organisms.</p> <p>R51/53 Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.</p> <p>R62 Possible risk of impaired fertility.</p> <p>R63 Possible risk of harm to the unborn child.</p> <p>H301 Toxic if swallowed.</p> <p>H310 Fatal in contact with skin.</p> <p>H319 Causes serious eye irritation.</p> <p>H361 Suspected of damaging fertility or the unborn child.</p> <p>H400 Very toxic to aquatic life.</p> <p>H411 Toxic to aquatic life with long lasting effects.</p>
Revision information	<p>Product and Company Identification: Product and Company Identification</p> <p>Composition / Information on Ingredients: Ingredients</p> <p>Physical & Chemical Properties:</p> <p>TOXICOLOGICAL INFORMATION:</p> <p>Transport Information: Material Transportation Information</p> <p>Regulatory Information: United States</p> <p>GHS: Classification</p>
Training information	Follow training instructions when handling this material.
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.