SAFETY DATA SHEET



1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

Material NICODERM CQ

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

Company Name GlaxoSmithKline, Corporate Environment, Health & Safety

980 Great West Road

Brentford, Middlesex TW8 9GS UK

UK General Information: +44-20-8047-5000 Transport Emergency (EU) +44-1865-407333

Medical Emergency +1-612-221-3999, Ext 221
Information and Advice: US number, available 24 hours

Multi-language response

GlaxoSmithKline, Corporate Environment, Health & Safety

One Franklin Plaza, 200 N 16th Street

Philadelphia, PA 19102-1225 US

US General Information: +1-888-825-5249 Transport Emergency (non EU) +1-703-527-3887

US number, available 24 hours Multi-language response

2. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredients	CAS RN	Percentage
NICOTINE	54-11-5	< 12
TRADE SECRET INGREDIENTS	Unassigned	88.0

3. HAZARDS IDENTIFICATION

Fire and Explosion Expected to be non-combustible.

* **Health** Exposure might occur via ingestion; skin; eyes.

May produce allergic skin reactions. Possible effects of overexposure in the workplace include: symptoms of hypersensitivity (such as skin rash, hives,

itching, and difficulty breathing).

Health effects information is based on hazards of components.

EnvironmentNo information is available about the potential of this product to produce

adverse environmental effects.

4. FIRST-AID MEASURES

Ingestion Never attempt to induce vomiting. Do not attempt to give any solid or liquid

by mouth if the exposed subject is unconscious or semi-conscious. Wash out the mouth with water. If the exposed subject is fully conscious, give

plenty of water to drink. Obtain medical attention.

Inhalation Physical form suggests that risk of inhalation exposure is negligible.

Skin Contact Using appropriate personal protective equipment, remove contaminated

clothing and flush exposed area with large amounts of water. Obtain medical attention if skin reaction occurs, which may be immediate or

delayed.

Eye Contact Wash immediately with clean and gently flowing water. Continue for at least

15 minutes. Obtain medical attention.

NOTES TO HEALTH PROFESSIONALS

Medical Treatment Medical treatment in cases of overexposure should be treated as an

overdose of nicotine. Treat according to locally accepted protocols. For additional guidance, refer to the local poison control information centre.

Medical Conditions
Caused or Aggravated

Caused or Aggrava by Exposure

Antidotes No specific antidotes are recommended.

5. FIRE-FIGHTING MEASURES

Fire and Explosion Hazards Not expected for the product, although the packaging is combustible.

Extinguishing Media Water, dry powder or foam extinguishers are recommended. Carbon dioxide

extinguishers may be ineffective.

None for occupational exposure.

Special Firefighting Procedures

For single units (packages): No special requirements needed. For larger amounts (multiple packages/pallets) of product: Since toxic, corrosive or flammable vapours might be evolved from fires involving this product and associated packaging, self contained breathing apparatus and full protective equipment are recommended for firefighters. If possible, contain and collect firefighting water for later disposal.

Hazardous Combustion

Products when th

Toxic, corrosive or flammable thermal decomposition products are expected

when the product is exposed to fire.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions Wear protective clothing and equipment consistent with the degree of

hazard.

Environmental Precautions For large spills, take precautions to prevent entry into waterways, sewers, or

surface drainage systems.

Clean-up Methods Collect and place it in a suitable, properly labelled container for recovery or

disposal.

Decontamination Procedures

No specific decontamination or detoxification procedures have been

identified for this product.

7. HANDLING AND STORAGE

HANDLING

General Requirements No special control measures required for the normal handling of this

product. Normal room ventilation is expected to be adequate for routine

handling of this product.

STORAGE No storage requirements necessary for occupational hazards. Follow

product information storage instructions to maintain efficacy.

NICODERM CQ Material

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

NICOTINE INGREDIENT

GSK Occupational

Hazard Category

GSK Occupational 70 MCG/M3 (8 HR TWA) **Exposure Limit**

3

200 mcg/m3 (15 MIN STEL)

Other Equipment or **Procedures**

None required for normal handling. Wash hands and arms thoroughly after

SKIN. REPRODUCTIVE HAZARD

handling.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance

Physical Form Multi layered adhesive patches.

10. STABILITY AND REACTIVITY

This product is expected to be stable. **Stability Conditions to Avoid** None for normal handling of this product.

TOXICOLOGICAL INFORMATION 11.

Oral Toxicity Not expected to be toxic following ingestion.

Inhalation Toxicity No studies have been conducted.

Skin Effects Irritation is not expected following direct contact.

Eye Effects Irritation is not expected following direct contact with eyes.

* Sensitisation Allergic skin reactions might occur following repeated contact with this

material in susceptible individuals.

Genetic Toxicity Not expected to be genotoxic under occupational exposure conditions.

No components are listed as carcinogens by GSK, IARC, NTP or US OSHA. Carcinogenicity

This material can produce central nervous system stimulation. Other Adverse Effects

12. ECOLOGICAL INFORMATION

No information is available about the potential of this product to produce Summary

adverse environmental effects. Local regulations and procedures should be

consulted prior to environmental release.

13. DISPOSAL CONSIDERATIONS

Collect for recycling or recovery if possible. The disposal method for Disposal

Recommendations rejected products/returned goods must ensure that they cannot be re-sold or

re-used. The recommended method of disposal is incineration.

Observe all local and national regulations when disposing of this product. **Regulatory Requirements**

14. TRANSPORT INFORMATION

The SDS should accompany all shipments for reference in the event of spillage or accidental release. Only authorised persons trained and competent in accordance with appropriate national and international regulatory requirements may prepare dangerous goods for transport.

UN Classification and Labelling

Transport Information Transportation and shipping of this product is not restricted. It has no known, significant hazards requiring special packaging or labelling for air, maritime, US

or European ground transport purposes.

15. REGULATORY INFORMATION

Material NICODERM CQ

The information included below is an overview of the major regulatory requirements. It should not be considered to be an exhaustive summary. Local regulations should be consulted for additional requirements.

EU Classification and Labelling

Exempt from requirements of EU Dangerous Preparations directive - product regulated as a medicinal product, cosmetic product or medical device.

US OSHA Standard (29 CFR Part 1910.1200)

Classification Exempt when packaged for sale to consumers in a retail establishment.

Other US Regulations

TSCA Status Exempt

16. OTHER INFORMATION

References GSK Hazard Determination

Date Approved/Revised 30-Aug-2006 SDS Version Number 13

SDS Sections Updated

Sections Subsections

COMPOSITION / INFORMATION ON INGREDIENTS

HAZARDS IDENTIFICATION Health

IDENTIFICATION OF SUBSTANCE / PREPARATION AND OF

COMPANY

REGULATORY INFORMATION US Environmental (EPA) Requirements

TOXICOLOGY INFORMATION Sensitisation

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.