

## SAFETY DATA SHEET



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

|  |  |  |                      |                              |               |        |                  |   |                      |     |                 |
|--|--|--|----------------------|------------------------------|---------------|--------|------------------|---|----------------------|-----|-----------------|
| <b>Material</b>  | NICORETTE LOZENGE  |  |                      |                              |               |        |                  |   |                      |     |                 |
| <b>Synonym(s)</b>  | NIQUITIN CQ LOZENGE (UK) * COMMIT LOZENGE (US) * PROJECT ONE CENT * NICOTINE LOZENGE 2MG * NICOTINE LOZENGE 4MG * MFC50915 (2mg) * MFC50916 (4mg) * NICOTINE POLACRILEX, FORMULATED PRODUCT  |  |                      |                              |               |        |                  |   |                      |     |                 |
| <b>Recommended Use</b>   | Medicinal Product  |  |                      |                              |               |        |                  |   |                      |     |                 |
| <b>Company Name</b>  | <p>GlaxoSmithKline UK<br/>980 Great West Road<br/>Brentford, Middlesex TW8 9GS UK<br/>UK General Information (normal business hours): +44-20-8047-5000</p> <p>GlaxoSmithKline US<br/>5 Moore Drive<br/>Research Triangle Park, NC 27709 USA<br/>US General Information (normal business hours): +1-888-825-5249</p> <p>Email Address: <a href="mailto:msds@gsk.com">msds@gsk.com</a><br/>Website: <a href="http://www.gsk.com">www.gsk.com</a></p> <p>EMERGENCY PHONE NUMBERS -</p> <p>TRANSPORT EMERGENCIES (by country / geographic region):</p> <table border="0" style="width: 100%;"> <tr> <td>Africa / EU / Israel / Middle East (English / European languages):</td> <td style="text-align: right;">+44 (0) 1235 239 670</td> </tr> <tr> <td>Asia Pacific (except China):</td> <td style="text-align: right;">+65 3158 1074</td> </tr> <tr> <td>China:</td> <td style="text-align: right;">+86 10 5100 3039</td> </tr> <tr> <td>Middle East / Africa (Arabic-speaking countries):</td> <td style="text-align: right;">+44 (0) 1235 239 671</td> </tr> <tr> <td>US:</td> <td style="text-align: right;">+1 703 527 3887</td> </tr> </table> <p>available 24 hrs/7 days; multi-language response</p> <p>MEDICAL EMERGENCIES: <span style="float: right;">+1 612 221 3999, Ext 221</span><br/>available 24 hrs/7 days; multi-language response</p> | Africa / EU / Israel / Middle East (English / European languages): | +44 (0) 1235 239 670 | Asia Pacific (except China): | +65 3158 1074 | China: | +86 10 5100 3039 | Middle East / Africa (Arabic-speaking countries): | +44 (0) 1235 239 671 | US: | +1 703 527 3887 |
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### 2. HAZARDS IDENTIFICATION

|                                   |  |
|-----------------------------------|--|
| <b>Fire and Explosion Hazards</b> | Expected to be non-combustible.  |
| <b>Health</b>                     | Not expected to be a health hazard during normal handling. Health effects information is based on hazards of components. |
| <b>Environment</b>                | No information is available about the potential of this product to produce adverse environmental effects.                |

### 3. COMPOSITION / INFORMATION ON INGREDIENTS

| Ingredients                              | CAS #    | Percent   | EC-No.    |
|--|----------|-----------|-----------|
| NICOTINE POLACRILEX                      |          | 0.9 - 1.9 | 200-193-3 |
| SODIUM CARBONATE                         | 497-19-8 | 1 to 2.5  | 207-838-8 |
| Other components below reportable levels |          | > 90      |           |

Material NICORETTE LOZENGE

## 4. FIRST-AID MEASURES

|                     |   |
|---------------------|---|
| <b>Ingestion</b>    | 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. |
| <b>Inhalation</b>   | Physical form suggests that risk of inhalation exposure is negligible.  |
| <b>Skin contact</b> | 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.  |
| <b>Eye contact</b>  | Wash immediately with clean and gently flowing water. Continue for at least 15 minutes. Obtain medical attention.   |

## NOTES TO HEALTH PROFESSIONALS

|  |  |
|--|--|
| <b>Medical Treatment</b>                                   | 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. |
| <b>Medical Conditions Caused or Aggravated by Exposure</b> | None for occupational exposure.  |
| <b>Antidotes</b>   | No specific antidotes are recommended.   |

## 5. FIRE-FIGHTING MEASURES

|  |   |
|--|---|
| <b>Fire and Explosion Hazards</b>      | Not expected for the product, although the packaging is combustible.  |
| <b>Extinguishing Media</b>             | Water, dry powder or foam extinguishers are recommended. Carbon dioxide extinguishers may be ineffective.   |
| <b>Special Firefighting Procedures</b> | 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. |
| <b>Hazardous Combustion Products</b>   | Toxic, corrosive or flammable thermal decomposition products are expected when the product is exposed to fire.  |

## 6. ACCIDENTAL RELEASE MEASURES

|                                   |  |
|-----------------------------------|--|
| <b>Personal Precautions</b>       | Wear protective clothing and equipment consistent with the degree of hazard.                             |
| <b>Environmental Precautions</b>  | For large spills, take precautions to prevent entry into waterways, sewers, or surface drainage systems. |
| <b>Clean-up Methods</b>           | Collect and place it in a suitable, properly labelled container for recovery or disposal.                |
| <b>Decontamination Procedures</b> | 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.

## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

## OCCUPATIONAL EXPOSURE LIMITS

|   |  |                           |
|---|--|---------------------------|
| <b>INGREDIENT</b>                       | NICOTINE   |                           |
| <b>GSK Occupational Hazard Category</b> | 3  |                           |
| <b>GSK Occupational Exposure Limit</b>  | 70 MCG/M3 (8 HR TWA)<br>200 mcg/m3 (15 MIN STEL) | SKIN, REPRODUCTIVE HAZARD |

Material NICORETTE LOZENGE

INGREDIENT NICOTINE

GSK Occupational Hazard Category 3

GSK Occupational Exposure Limit 70 MCG/M3 (8 HR TWA) SKIN, REPRODUCTIVE HAZARD  
200 mcg/m3 (15 MIN STEL)

Other Equipment or Procedures None required for normal handling. Wash hands and arms thoroughly after handling.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

## Appearance

Physical Form Lozenge.

## 10. STABILITY AND REACTIVITY

Stability This product is expected to be stable.

Conditions to Avoid None for normal handling of this product.

## 11. TOXICOLOGY INFORMATION

## Routes of Exposure

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 Sensitisation (allergic skin reaction) is not expected.

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

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

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

## 12. ECOLOGICAL INFORMATION

Summary No information is available about the potential of this product to produce adverse environmental effects. Local regulations and procedures should be consulted prior to environmental release.

## 13. DISPOSAL CONSIDERATIONS

Disposal Recommendations Collect for recycling or recovery if possible. The disposal method for rejected products/returned goods must ensure that they cannot be re-sold or re-used. The recommended method of disposal is incineration.

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

## 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 Not regulated in transport.

## 15. REGULATORY INFORMATION

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

**SDS Version Number** 8

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.