

SAFETY DATA SHEET



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

| | | | | | | | | | | | | |
|--|--|--|--|----------------------|------------------------------|---------------|--------|------------------|---|----------------------|-----|-----------------|
| Material Name | POLIDENT DENTURE CLEANSER TABLETS WHITENING | | | | | | | | | | | |
| Synonym(s) | POLIDENT OVERNIGHT SOAK TABLETS, TRIPLEMINT * JAPANESE SMOKERS POLIDENT * MFC 50077 * DENTURE CLEANING, FORMULATED PRODUCT | | | | | | | | | | | |
| Recommended Use | Medical Device | | | | | | | | | | | |
| Supplier Details | <p>GlaxoSmithKline UK 980 Great West Road Brentford, Middlesex TW8 9GS UK UK General Information (normal business hours): +44-20-8047-5000</p> <p>GlaxoSmithKline US 5 Moore Drive Research Triangle Park, NC 27709 USA US General Information (normal business hours): +1-888-825-5249</p> <p>Email Address: msds@gsk.com Website: www.gsk.com</p> <p>EMERGENCY PHONE NUMBERS -</p> <p>TRANSPORT EMERGENCIES (by country / geographic region):</p> <table border="0" style="width: 100%;"> <tr> <td style="width: 80%;">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: +1 612 221 3999, Ext 221 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. HAZARD IDENTIFICATION

Globally Harmonised System Classification & Labelling

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|----------------------------|--|
| Classification | Reproductive toxicity Category 2 Serious eye damage/eye irritation Category 2 Skin sensitization Category 1 |
| Hazard Symbol(s) | |
| Signal Word(s) | Warning |
| Hazard Statement(s) | Suspected of damaging fertility. Suspected of damaging the unborn child. Causes serious eye irritation. May cause an allergic skin reaction. |

Material POLIDENT DENTURE CLEANSER TABLETS WHITENING

Precautionary Statement(s) Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Use personal protective equipment as required. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists, get medical advice/attention. IF exposed or concerned: Get medical advice/attention. Dispose of contents/container in accordance with local regulation.

Other Hazards**Fire and Explosion**

Expected to be non-combustible.

Health

Not expected to be a significant health hazard unless product is crushed or broken. Exposure might occur via ingestion; eyes; skin.
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.

Environment

No information is available about the potential of this product to produce adverse environmental effects. This product contains an ingredient(s) that is harmful to aquatic organisms; and may cause long-term adverse effects in the aquatic environment.

* 3. COMPOSITION / INFORMATION ON INGREDIENTS

| Ingredients | CAS # | Percent | EC-No. | EU Classification |
|--|------------|---------|-----------|--|
| CITRIC ACID | 77-92-9 | <15 | 201-069-1 | Xi, R36 |
| PEPPERMINT OIL | 8006-90-4 | 1.1 | | Xi, N, R38, R43, R51, R53 |
| POTASSIUM PEROXYMONOSULFATE | 10058-23-8 | 10 | 233-187-4 | C, R34, R52 |
| SODIUM BENZOATE | 532-32-1 | <3 | 208-534-8 | Xi, R36/37/38 |
| SODIUM CARBONATE | 497-19-8 | <30 | 207-838-8 | Xi, R36 |
| SODIUM LAURYL SULFOACETATE | 1847-58-1 | 2 | 217-431-7 | Xn, R22 |
| SODIUM PERBORATE MONOHYDRATE | 10332-33-9 | 18 | 234-390-0 | Repr. Cat. 2, Repr. Cat. 3, T, Xi, Xn, O, R61, R62, R22, R23, R37, R41, R8 |
| SUBTILISIN | 9014-01-1 | 0.5 | 232-752-2 | Xi, Xn, R52, R42, R37/38, R41 |
| Other components below reportable levels | | 20.02 | | |

* 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

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|--|---|
| Medical Treatment | Because of the potential for acute or delayed eye damage, consider referral to an ophthalmologist. Treat according to locally accepted protocols. For additional guidance, refer to the local poison control information centre. |
| Medical Conditions Caused or Aggravated by Exposure | New or expectant mothers might be at greater risk from overexposure. Risk assessments must take this into consideration. Female employees anticipating pregnancy or with a confirmed pregnancy must be encouraged to notify an occupational health professional or their line manager. This will act as the trigger for individual re-assessment of the employee's work practices. |
| Health Surveillance Procedures | The need for pre-placement and periodic health surveillance must be determined by risk assessment. Following assessment, if the risk of exposure is considered significant then exposed individuals should receive health surveillance focused on detecting skin conditions. In the event of overexposure, individuals should receive post-exposure health surveillance focused on detecting skin conditions and adrenal suppression. |
| Antidotes | No specific antidotes are recommended. |

5. FIRE-FIGHTING MEASURES

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|--|---|
| Fire and Explosion Hazards | Not expected for the product, although the packaging is combustible. |
| Suitable Extinguishing Media | Water, dry powder or foam extinguishers are recommended. Carbon dioxide extinguishers may be ineffective. |
| Special Protective Equipment and Precautions for Firefighters | 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. |
| Specific Hazards arising from the Material | Toxic, corrosive or flammable thermal decomposition products are expected when the product is exposed to fire. |

6. ACCIDENTAL RELEASE MEASURES

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|-----------------------------------|--|
| 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**PRECAUTIONS FOR SAFE HANDLING**

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|------------------------------------|---|
| General Requirements | Avoid breaking or crushing tablets. |
| CONDITIONS FOR SAFE STORAGE | No storage requirements necessary for occupational hazards. Follow product information storage instructions to maintain efficacy. |

8. EXPOSURE CONTROLS / PERSONAL PROTECTION**OCCUPATIONAL EXPOSURE LIMITS**

| | |
|---|------------------------------------|
| INGREDIENT | CITRIC ACID ANHYDROUS |
| GSK Occupational Hazard Category | 1 |
| GSK Occupational Exposure Limit | 5000 mcg/m ³ (8 HR TWA) |
| INGREDIENT | SODIUM CARBONATE |
| GSK Occupational Hazard Category | 1 |
| GSK Occupational Exposure Limit | 5000 mcg/m ³ (8 HR TWA) |

| | | |
|---|-----------------------------|---|
| INGREDIENT | SUBTILISIN | |
| GSK Occupational Hazard Category | 5 | RESPIRATORY SENSITISER, SKIN SENSITISER |
| INGREDIENT | POTASSIUM PEROXYMONOSULFATE | |
| GSK Occupational Hazard Category | 3 | CORROSIVE |

PERSONAL PROTECTIVE EQUIPMENT

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|--------------------------------------|--|
| Eye Protection | Wear approved safety glasses with side shields if eye contact is possible. |
| Other Equipment or Procedures | Follow all local regulations if personal protective equipment (PPE) is used in the workplace. Wear appropriate clothing to avoid skin contact. Wash hands and arms thoroughly after handling. An eye wash station should be available. |

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance

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|----------------------|---------|
| Physical Form | Tablet. |
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10. STABILITY AND REACTIVITY

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

* 11. TOXICOLOGY INFORMATION

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|------------------------------|---|
| Target Organ Effects | No specific target organ effects have been identified. |
| Routes of Exposure | |
| Oral Toxicity | Not expected to be toxic following ingestion. |
| Inhalation Toxicity | No studies have been conducted. |
| Skin Effects | Minor irritation might occur following direct contact with damaged skin. |
| Eye Effects | Severe irritation might occur following direct contact with eyes. May cause intense reddening, swelling and pain with possible irreversible damage to vision. |
| Sensitisation | Allergic skin reactions might occur following dermal exposure. Symptoms of hypersensitivity may include skin rash, hives, itching, and/or difficulty breathing. |
| Genetic Toxicity | The ingredient sodium perborate monohydrate has caused genetic toxicity in laboratory studies. However, the relevance of these effects to humans from occupational exposure is not known. |
| Carcinogenicity | No components are listed as carcinogens by GSK, IARC, NTP or US OSHA. |
| Reproductive Effects | The ingredient sodium perborate monohydrate has caused adverse effects on the development of unborn offspring in animal studies. The ingredient sodium perborate monohydrate has caused adverse effects to fertility in animal studies. |
| Other Adverse Effects | None known for occupational exposure. |

12. ECOLOGICAL INFORMATION

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|----------------|--|
| Summary | No information is available about the potential of this product to produce adverse environmental effects. This material contains at least one ingredient that has been tested, and which may be harmful if released directly to the environment. Consult the MSDS of each ingredient for specific information about potential environmental effects. Appropriate precautions should be taken to limit release of this mixture to the environment. Local regulations and procedures should be consulted prior to environmental release. |
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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.

Basic Shipping Description: 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

Classification(s) Reproductive Category 3, Xn, Xi; R41, R43, R62, R63

Symbol(s) Harmful (Xn)



Risk Phrase(s) R41 - Risk of serious damage to eyes.
 R43 - May cause sensitisation by skin contact.
 R62 - Possible risk of impaired fertility.
 R63 - Possible risk of harm to the unborn child.

Safety Phrase(s) S24/25 - Avoid contact with skin and eyes.
 S26 - In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
 S36/37/39 - Wear suitable protective clothing, gloves and eye/face protection.
 S53 - Avoid exposure - obtain special instructions before use.

US OSHA Standard (29 CFR Part 1910.1200)

Classification This product is classified as hazardous according to the OSHA Hazard Communication Standard.

Target Organ Statement No specific target organ effects known.

Other Regulations

TSCA Status Exempt

16. OTHER INFORMATION

References GSK Hazard Determination

SDS Version Number 5

SDS Sections Updated

Sections
 COMPOSITION / INFORMATION ON INGREDIENTS
 FIRST-AID MEASURES

Subsections

Antidotes
 Health Surveillance Procedures
 Medical Conditions Caused or Aggravated by Exposure

GHS Classification
 HAZARDS IDENTIFICATION

Disposal
 Environment

SDS Sections Updated**Sections**

HAZARDS IDENTIFICATION

IDENTIFICATION OF SUBSTANCE / PREPARATION AND OF
COMPANY

REGULATORY INFORMATION

TOXICOLOGY INFORMATION

TRANSPORT INFORMATION

Subsections

Health

Prevention

Response

Eye Effects

Genetic Toxicity

Inhalation Toxicity

Reproductive Effects

Sensitisation

Skin Toxicity

Target Organ Effects

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.