

SAFETY DATA SHEET



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

Material	POLIDENT OVERNIGHT (US)												
Synonym(s)	PROJECT SHIITAKE * MFC 50768 * DENTURE CLEANER, FORMULATED PRODUCT												
Recommended Use	Medical Device												
Company Name	<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: 75%;">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. HAZARDS IDENTIFICATION

Fire and Explosion Hazards	Expected to be non-combustible.
Health	<p>Not expected to be a significant health hazard unless product is crushed or broken. Exposure might occur via ingestion; eyes; skin.</p> <p>Harmful if inhaled. May produce allergic skin reactions. Severe eye irritant. Possible effects of overexposure in the workplace include: symptoms of hypersensitivity (such as skin rash, hives, itching, and difficulty breathing).</p> <p>Contains ingredient(s) that: have produced adverse effects on foetal development in laboratory animals; have produced adverse effects on fertility in laboratory animals. Health effects information is based on hazards of components.</p>
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	14	201-069-1	Xi, R36

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PEPPERMINT OIL	8006-90-4	0.1 to 1		Xi, N, R38, R43, R51, R53
POTASSIUM PEROXYMONOSULFATE	10058-23-8	17	233-187-4	C, R34, R52
SODIUM BENZOATE	532-32-1	1 to 2.5	208-534-8	Xi, R36/37/38
SODIUM CARBONATE	497-19-8	8	207-838-8	Xi, R36
SODIUM LAURYL SULFOACETATE	1847-58-1	2.5 to 10	217-431-7	Xn, R22
SODIUM METASILICATE, ANHYDROUS	6834-92-0	2.5 to 10	229-912-9	C, Xi, R37, R34
SODIUM NITRITE	7632-00-0	0.1 to 1	231-555-9	T, O, N, R25, R50, R8
SODIUM PERBORATE	7632-04-4	18	231-556-4	Repr. Cat. 2, Repr. Cat. 3, T, Xi, Xn, O, R61, R22, R41, R52, R62, R23, R37, R8
SODIUM TRIPOLYPHOSPHATE	7758-29-4	2.5 to 10	231-838-7	Xi, R36/37/38, R52
SUBTILISIN	9014-01-1	0.5	232-752-2	Xi, Xn, R52, R42, R37/38, R41
Other components below reportable levels		20 to 40		

* 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	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.

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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.

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 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 Avoid breaking or crushing tablets.

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/m³ (8 HR TWA)

INGREDIENT SODIUM CARBONATE

GSK Occupational Hazard Category 1

GSK Occupational Exposure Limit 5000 mcg/m³ (8 HR TWA)

INGREDIENT SUBTILISIN

GSK Occupational Hazard Category 5 RESPIRATORY SENSITISER, SKIN SENSITISER

PERSONAL PROTECTIVE EQUIPMENT

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

Physical Form Tablet.

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* 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

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 repeated contact with this material in susceptible individuals. 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

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.

* 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.

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EU Classification and Labelling

Classification(s) Reproductive Category 3, T, Xn, Xi; R61, R41, R62, R22, R52, R43, R20

Symbol(s) Harmful (Xn)



Risk Phrase(s)
 R41 - Risk of serious damage to eyes.
 R62 - Possible risk of impaired fertility.
 R61 - May cause harm to the unborn child.
 R20 - Harmful by inhalation.
 R43 - May cause sensitisation by skin contact.
 R52 - Harmful to aquatic organisms.
 R22 - Harmful if swallowed.

Safety Phrase(s)
 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 US Regulations

TSCA Status Exempt

* 16. OTHER INFORMATION

References GSK Hazard Determination

SDS Version Number 4

SDS Sections Updated

Sections

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COMPOSITION / INFORMATION ON INGREDIENTS

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ECOLOGICAL INFORMATION

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- Decontamination Procedures
- Environmental Precautions
- Personal Precautions
- Spills
- Disposal Recommendations
- GSK Standards and Guidance
- Regulatory Requirements
- Waste management measures
- Activated Sludge Respiration
- Adsorption
- Algal
- Algal Degradation
- Bioaccumulation
- Biodegradation
- Crustacea
- Daphnid
- Desorption
- Distribution
- Earthworm

SDS Sections Updated**Sections**

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 Fish
 GSK Environmental Hazard Category
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 Log Kow
 Microbial Growth Inhibition
 Microtox
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 Health Surveillance Procedures

EXPOSURE CONTROLS / PERSONAL PROTECTION

FIRE FIGHTING MEASURES

FIRST-AID MEASURES

SDS Sections Updated**Sections**

FIRST-AID MEASURES

HANDLING AND STORAGE

HAZARDS IDENTIFICATION

IDENTIFICATION OF SUBSTANCE / PREPARATION AND OF
COMPANY
OTHER INFORMATION

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Classification
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Disclaimer Safety Summary
Disclaimer Technical Sheet
Information on Hazard Label
Nature of/Reason for Amendment
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References
Risk and Safety Phrases
SB Classification
Target Organ
Autoignition Temperature
Boiling Point
Clarity
Colour
Conductivity
Decomposition Temperature
Dissociation Constant

SDS Sections Updated**Sections**

PHYSICAL AND CHEMICAL PROPERTIES

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STABILITY AND REACTIVITY

TOXICOLOGY INFORMATION

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Dust Explosion
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Physical Form
Refractive Index
Relative Density
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Aspiration toxicity
Carcinogenicity
Dermal
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Genetic Toxicity
Inhalation Toxicity
Oral Toxicity

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TOXICOLOGY INFORMATION

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Subsections

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Reproductive Effects
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Specific Target Organ Toxicity - Single Exposure
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Target Organ Effects
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EMS Number
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Exceptions
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Item
Marginal
Marine Pollutant
MFRAG Number
NA Number
Packing Group
Packing Instructions
Proper Shipping Name
Reportable Quantity (RQ)
Special Instructions for Transport
Special Precautions for Transport
Subsidiary Risk
Summary
Technical Name
Transport Category
Transport Classification and Labelling
Transport Label(s)
Tremcard Number
UN Number

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.