

## 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**

GlaxoSmithKline UK  
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## EMERGENCY PHONE NUMBERS -

TRANSPORT EMERGENCIES (by country / geographic region):  
 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  
 available 24 hrs/7 days; multi-language response

MEDICAL EMERGENCIES: +1 612 221 3999, Ext 221  
 available 24 hrs/7 days; multi-language response

## \* 2. HAZARDS IDENTIFICATION

**Fire and Explosion Hazards**

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.  
 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).  
 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.

**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

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

<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>	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.
<b>Medical Conditions Caused or Aggravated by Exposure</b>	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.
<b>Health Surveillance Procedures</b>	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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<b>Antidotes</b>	No specific antidotes are recommended.
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<b>* 5. FIRE-FIGHTING MEASURES</b>
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<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.

<b>* 6. ACCIDENTAL RELEASE MEASURES</b>
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<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.

<b>* 7. HANDLING AND STORAGE</b>
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**HANDLING**

<b>General Requirements</b>	Avoid breaking or crushing tablets.
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**STORAGE**

No storage requirements necessary for occupational hazards. Follow product information storage instructions to maintain efficacy.
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<b>* 8. EXPOSURE CONTROLS / PERSONAL PROTECTION</b>
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**OCCUPATIONAL EXPOSURE LIMITS**

<b>INGREDIENT</b>	CITRIC ACID ANHYDROUS
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<b>GSK Occupational Hazard Category</b>	1
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<b>GSK Occupational Exposure Limit</b>	5000 mcg/m3 (8 HR TWA)
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<b>INGREDIENT</b>	SODIUM CARBONATE
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<b>GSK Occupational Hazard Category</b>	1
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<b>GSK Occupational Exposure Limit</b>	5000 mcg/m3 (8 HR TWA)
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<b>INGREDIENT</b>	SUBTILISIN
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<b>GSK Occupational Hazard Category</b>	5	RESPIRATORY SENSITISER, SKIN SENSITISER
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**PERSONAL PROTECTIVE EQUIPMENT**

<b>Eye Protection</b>	Wear approved safety glasses with side shields if eye contact is possible.
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<b>Other Equipment or Procedures</b>	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.
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<b>* 9. PHYSICAL AND CHEMICAL PROPERTIES</b>
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**Appearance**

<b>Physical Form</b>	Tablet.
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**\* 10. STABILITY AND REACTIVITY**

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<b>Stability</b>	This product is expected to be stable.
<b>Conditions to Avoid</b>	None for normal handling of this product.

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**\* 11. TOXICOLOGY INFORMATION**

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<b>Target Organ Effects</b>	No specific target organ effects have been identified.
<b>Routes of Exposure</b>	
<b>Oral Toxicity</b>	Not expected to be toxic following ingestion.
<b>Inhalation Toxicity</b>	No studies have been conducted.
<b>Skin Effects</b>	Minor irritation might occur following direct contact with damaged skin.
<b>Eye Effects</b>	Severe irritation might occur following direct contact with eyes. May cause intense reddening, swelling and pain with possible irreversible damage to vision.
<b>Sensitisation</b>	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.
<b>Genetic Toxicity</b>	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.
<b>Carcinogenicity</b>	No components are listed as carcinogens by GSK, IARC, NTP or US OSHA.
<b>Reproductive Effects</b>	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.
<b>Other Adverse Effects</b>	None known for occupational exposure.

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**\* 12. ECOLOGICAL INFORMATION**

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<b>Summary</b>	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**

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<b>Disposal Recommendations</b>	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.
<b>Regulatory Requirements</b>	Observe all local and national regulations when disposing of this product.

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**\* 14. TRANSPORT INFORMATION**

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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**

<b>Transport Information</b>	Not regulated in transport.
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**\* 15. REGULATORY INFORMATION**

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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, 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**

ACCIDENTAL RELEASE MEASURES

COMPOSITION / INFORMATION ON INGREDIENTS

DISPOSAL CONSIDERATIONS

ECOLOGICAL INFORMATION

**Subsections**

Clean-up Methods  
 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**

ECOLOGICAL INFORMATION

**Subsections**

Ecotoxicity  
EHAC Notation  
Fish  
GSK Environmental Hazard Category  
Hydrolysis  
Log Kow  
Microbial Growth Inhibition  
Microtox  
Mobility  
Other Adverse Effects  
Other Species - Aquatic  
Other Species - Terrestrial  
Partitioning  
PBT Assessment  
Persistence/Degradation  
Photolysis  
Solubility  
Summary  
Very bioaccumulative  
Very persistent  
Volatility  
Administrative  
Containment  
Dermal  
Environmental  
Exposure Controls  
Eye Protection  
Gloves  
Inhalation  
Occupational Hygiene Air Monitoring Methods  
Occupational Hygiene Surface Monitoring Methods  
Oral  
Other Equipment or Procedures  
Other Exposure Limits  
Other Information  
Other Protective Equipment  
Respirators  
Surface Exposure Target  
Ventilation  
Extinguishing Media  
Fire and Explosion Hazards  
Hazardous Combustion Products  
Special Firefighting Procedures  
Sustained Combustibility  
Antidotes  
Eye Contact  
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  
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PHYSICAL AND CHEMICAL PROPERTIES

**Subsections**

Ingestion

Inhalation

Medical Conditions Caused or Aggravated by Exposure

Medical Treatment

Skin Contact

General Requirements

Handling

Ignition Controls

Protective Systems

Specific uses

Storage

Adverse effects

Chemical Hazards

Conditions Aggravated by Exposure

Disposal

Environment

Eye Contact

Health

Ingestion

Inhalation

Overview

Prevention

Response

Skin Contact

Storage

Summary

Supplemental Information

Thermal Hazards

Classification

Disclaimer Safety Data Sheet

Disclaimer Safety Summary

Disclaimer Technical Sheet

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Nature of/Reason for Amendment

Other Information

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

**Subsections**

Dust Electrostatic Properties  
Dust Explosion  
Evaporation Rate  
Explosive Properties  
Flammability  
Flash Point  
Freezing Point  
Gas Group/T-Rating  
General  
Lower Explosive Limit  
Melting Point  
MIE - Liquid  
Octanol Water Distribution Coefficient  
Odour  
Oxidising Properties  
Oxygen Balance  
Packaging  
Particle Size  
pH of Aqueous Solutions  
Physical Form  
Refractive Index  
Relative Density  
Relative Self Ignition Temperature  
Solubility (Other)  
Surface Tension  
Train Fire  
Upper Explosive Limit  
Vapour Density  
Vapour Pressure  
Viscosity  
Volatile Components  
Water Solubility  
Wetted

REGULATORY INFORMATION  
STABILITY AND REACTIVITY

Chemical Stability  
Conditions to Avoid  
Hazardous Decomposition Products  
Incompatible Materials  
Possibility of Hazardous Reactions  
Reactivity

TOXICOLOGY INFORMATION

Aspiration toxicity  
Carcinogenicity  
Dermal  
Eye Effects  
Genetic Toxicity  
Inhalation Toxicity  
Oral Toxicity



**SDS Sections Updated****Sections**

TOXICOLOGY INFORMATION

TRANSPORT INFORMATION

**Subsections**

Other Adverse Effects  
Pharmacological Effects  
Reproductive Effects  
Respiratory sensitization  
Sensitisation  
Skin Toxicity  
Specific Target Organ Toxicity - Repeated Exposure  
Specific Target Organ Toxicity - Single Exposure  
Symptoms of Overexposure  
Target Organ Effects  
Toxicokinetics, metabolism and distribution  
Class/Division  
Emergency Action Code  
Emergency Response Guide Number  
EMS Number  
European Ground Transport  
Exceptions  
Hazard Identification Number  
Item  
Marginal  
Marine Pollutant  
MFAG 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.