

## SAFETY DATA SHEET



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

<b>Material Name</b>	POLIDENT FOR PARTIALS										
<b>Synonym(s)</b>	MFC 51039 GEU * SODIUM PERCARBONATE, MIXTURE										
<b>Recommended Use</b>	Medical Device										
<b>Supplier Details</b>	<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> <tr> <td>Africa / EU / Israel / Middle East (English / European languages):</td><td>+44 (0) 1235 239 670</td></tr> <tr> <td>Asia Pacific (except China):</td><td>+65 3158 1074</td></tr> <tr> <td>China:</td><td>+86 10 5100 3039</td></tr> <tr> <td>Middle East / Africa (Arabic-speaking countries):</td><td>+44 (0) 1235 239 671</td></tr> <tr> <td>US:</td><td>+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 &amp; Labelling

<b>Classification</b>	Acute oral toxicity Category 4 Serious eye damage/eye irritation Category 2
<b>Hazard Symbol(s)</b>	
<b>Signal Word(s)</b>	Warning
<b>Hazard Statement(s)</b>	Harmful if swallowed. Causes serious eye irritation.
<b>Precautionary Statement(s)</b>	Wash hands thoroughly after handling. 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 SWALLOWED: Immediately call a POISON CENTER or doctor/physician. If skin irritation or rash occurs: Get medical advice/attention. Keep out of reach of children. Dispose of contents/container in accordance with local regulation.

**Material** POLIDENT FOR PARTIALS**Other Hazards****Fire and Explosion**

Expected to be non-combustible.

**Health**

Exposure might occur via inhalation; ingestion; skin; eyes.

Allergic skin reactions might occur following repeated contact with this material in susceptible individuals. Marked irritation might occur following repeated skin contact.

Health effects information is based on hazards of components.

**Environment**

No information is available about the potential of this material to produce adverse environmental effects.

**\* 3. COMPOSITION / INFORMATION ON INGREDIENTS**

<b>Ingredients</b>	<b>CAS #</b>	<b>Percent</b>	<b>EC-No.</b>	<b>EU Classification</b>
CITRIC ACID ANHYDROUS	77-92-9	20	201-069-1	Xi, R36
POTASSIUM CAROATE	70693-62-8	12	274-778-7	C, Xn, R22, R34, R52
SODIUM BENZOATE	532-32-1	2.5	208-534-8	Xi, R36/37/38
SODIUM CARBONATE	497-19-8	9.6	207-838-8	Xi, R36
SODIUM LAURYL SULFOACETATE	1847-58-1	1.5	217-431-7	Xn, R22
SODIUM NITRITE	7632-00-0	0.2	231-555-9	T, O, N, R25, R50, R8
SODIUM PERCARBONATE	15630-89-4	8	239-707-6	Xi, Xn, O, R22, R41, R8
Other components below reportable levels		46.2		

**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**

None for occupational 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.

**Suitable Extinguishing Media**

Water, dry powder or foam extinguishers are recommended. Carbon dioxide extinguishers may be ineffective.

**Material** POLIDENT FOR PARTIALS

<b>Special Protective Equipment and Precautions for Firefighters</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>Specific Hazards arising from the Material</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>	Fence or cordon the affected area and do not allow individuals to touch or walk through the spilled material unless wearing appropriate protective clothing. Avoid dust generation.
<b>Environmental Precautions</b>	Prevent entry into waterways, sewers, surface drainage systems and poorly ventilated areas. If spill is outdoors, cover with plastic sheet to minimise spreading or contact with rain.
<b>Clean-up Methods</b>	Collect and place it in a suitable, properly labelled container for recovery or disposal. After all solid or absorbent material has been collected, the area should be vacuumed with HEPA filter-equipped apparatus.
<b>Decontamination Procedures</b>	No specific decontamination or detoxification procedures have been identified for this material. Consider use of water, detergent solutions, or other soluble solvents (if specified in Section 9 of this SDS), for clean-up and decontamination operations.

## 7. HANDLING AND STORAGE

**PRECAUTIONS FOR SAFE HANDLING**

<b>General Requirements</b>	Avoid breaking or crushing tablets.
<b>CONDITIONS FOR SAFE STORAGE</b>	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>	CITRIC ACID ANHYDROUS
<b>GSK Occupational Hazard Category</b>	1
<b>GSK Occupational Exposure Limit</b>	5000 mcg/m3 (8 HR TWA)
<b>INGREDIENT</b>	SODIUM BENZOATE
<b>GSK Occupational Hazard Category</b>	1
<b>GSK Occupational Exposure Limit</b>	5000 MCG/M3 (8 HR TWA)
<b>INGREDIENT</b>	SODIUM CARBONATE
<b>GSK Occupational Hazard Category</b>	1
<b>GSK Occupational Exposure Limit</b>	5000 mcg/m3 (8 HR TWA)
<b>INGREDIENT</b>	SODIUM LAURYL SULFOACETATE
<b>GSK Occupational Hazard Category</b>	2

**PERSONAL PROTECTIVE EQUIPMENT**

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

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**Appearance****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.

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**11. TOXICOLOGY INFORMATION**

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**Target Organ Effects**

No specific target organ effects have been identified.

**Routes of Exposure****Oral Toxicity**

Ingestion may lead to irritation of the throat and difficulty breathing.

**Inhalation Toxicity**

No studies have been conducted.

**Skin Effects**

Marked irritation might occur following repeated skin contact.

**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.

**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.

**Reproductive Effects**

Not expected to produce adverse effects on fertility or development under occupational exposure conditions.

**Other Adverse Effects**

None known for occupational exposure.

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**12. ECOLOGICAL INFORMATION**

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**Summary**

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

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**13. DISPOSAL CONSIDERATIONS**

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**Disposal Recommendations**

For waste disposal purposes this material can be regarded as non-hazardous, however, all current local and national requirements must be observed when disposing of this material.

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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.

**Basic Shipping Description:**

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.

**Material** POLIDENT FOR PARTIALS**EU Classification and Labelling****Classification(s)** Xn; R22, R36**Symbol(s)** Harmful (Xn)**Risk Phrase(s)** R22 - Harmful if swallowed.

R36 - Irritating to eyes.

**Safety Phrase(s)** S26 - In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

S36/37 - Wear suitable protective clothing and gloves.

S39 - Wear eye/face protection.

S60 - This material and/or its container must be disposed of as hazardous waste.

**US OSHA Standard (29 CFR Part 1910.1200)****Classification** This material 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

**Ingredient Risk Phrase(s)**

R22 - Harmful if swallowed.  
 R25 - Toxic if swallowed.  
 R34 - Causes burns.  
 R36 - Irritating to eyes.  
 R36/37/38 - Irritating to eyes, respiratory system and skin.  
 R41 - Risk of serious damage to eyes.  
 R50 - Very toxic to aquatic organisms.  
 R52 - Harmful to aquatic organisms.  
 R8 - Contact with combustible material may cause fire.

**SDS Version Number** 1**SDS Sections Updated****Sections**

COMPOSITION / INFORMATION ON INGREDIENTS

GHS Classification

IDENTIFICATION OF SUBSTANCE / PREPARATION AND OF COMPANY

REGULATORY INFORMATION

**Subsections**

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.