

Safety Data Sheet:

Retainer Brite and Insta-Fresh

Date Revised: **08/11/2017**

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1. PRODUCT IDENTIFICATION

Trade Name (as labeled):	Retainer Brite, Insta-Fresh
Chemical Name/Classification:	Antibacterial Dental Appliance Cleaner Tablets
Product Identifier (Part/Item Number):	RB-XXX, IF-XXX
U.N. Number:	N/A, non-regulated mixture
U.N. Dangerous Goods Classification:	N/A. Inorganic, Oxidizing Solid NOS
Recommended Use:	Cleaning removable dental/orthodontic appliances
Restrictions on Use:	Do not put tablets or cleaning solution in mouth.
Manufacturer Name:	Dentsply International Raintree Essix
Manufacturer Address:	7290 26th Court Each, Sarasota, FL 34243
Manufacturer Telephone Number:	1-800-883-8733 (Product Information)
24/7 Emergency Contact Telephone Number:	1-800-424-9300 (CHEMTREC)
Manufacturer Email address:	sales@essix.com

2. HAZARD(S) IDENTIFICATION



Hazard/Danger Classification: **WARNING**

Keep out of reach of children.

Do not take internally.

This is a low hazard product. However, chewing or swallowing the tablets or gargling with the solution may cause serious health effects. Do not take internally or ingest. Do not breathe dust created by tablets. Keep out of eyes and avoid extended contact with skin to minimize chance of irritation. The material is primarily inorganic and thus is not readily biodegradable. It offers no known environmental hazards under normal use conditions.

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Health	Environmental	Physical
H302: Harmful if swallowed. H332: Harmful if inhaled.	None known.	H319: Causes serious eye irritation. H315: Causes skin irritation.

Associated Hazards:

Hazard Statements	Precautionary Statements
Harmful if swallowed	Keep out of reach of children. Read label before use, and follow all usage instructions. Do not ingest tablets or gargle with solution made from tablets. Product is for external use only. Contact local poison control center and seek medical attention if product is ingested. If medical advice is needed, have product container/label at hand.
Harmful if inhaled	Do not breathe dust created by tablets. Product is for external use only.
Causes serious eye irritation	Do not get in eyes. Product is for external use only.
Causes skin irritation	Avoid prolonged exposure with skin. Wash hands thoroughly after handling tablets.

EU Classification: N/A

3. COMPOSITION AND INFORMATION ON INGREDIENTS

Composition Comment: When added to water, the product produces carbon dioxide bubbles for agitation, and a mild detergent and peroxide solution for cleaning dental appliances.

Components	C.A.S. # (EC#)	IUPAC Name	Substance Classification	WT %
Potassium Monopersulfate (Oxone)	70693-62-8 (274-778-7)	Potassium peroxymonosulfate	Oxidant, Corrosive	10-30
Citric Acid	77-92-9 (201-069-1)	Citric acid	N/A	Trade secret
Sodium Sulfate	7757-82-6 (231-820-9)	Sodium sulphate	Sensitizer	3-7
Sodium Carbonate (Soda Ash)	497-19-8 (207-838-8)	sodium carbonate	N/A	Trade secret
Sodium Bicarbonate	144-55-8 (205-633-8)	Sodium hydrogen carbonate	N/A	Trade secret
Sodium Percarbonate	15630-89-4 (239-707-6)	Disodium carbonate	Oxidizer, Corrosive	5-10

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Components	C.A.S. # (EC#)	IUPAC Name	Substance Classification	WT %
Peppermint Oil	8006-90-4	N/A	Irritant, Sensitizer	Trade secret
Sodium Lauryl Sulfoacetate	1847-58-1 (217-431-7)	Dodecyl sodium sulfoacetate	Corrosive	< 2

4. FIRST-AID MEASURES

Routes of Exposure	First Aid Instructions
Eye	Immediately flush eyes with plenty of water for at least 15 minutes, lifting lower and upper eyelids occasionally. Get medical attention immediately. This is considered a highly unlikely event.
Skin	If rash or irritation develops get medical attention. This is considered a highly unlikely event.
Inhalation	Remove victim to fresh air and provide oxygen if breathing is difficult. Get medical attention. If the victim has difficulty breathing or tightness of the chest, is dizzy, vomiting or unresponsive, give 100% oxygen with rescue breathing or CPR as required, and transport to the nearest medical facility. This is considered a highly unlikely event.
Ingestion	Do NOT induce vomiting. Give large amounts of water. Never give anything by mouth to an unconscious person. Call poison control center and seek medical attention.
Most important symptoms of exposure	Refer to acute and chronic exposure symptoms in section 16 below.
Other	STATEMENT OF PRACTICAL TREATMENT: Always have plenty of water available for first aid. Get medical attention if any symptoms develop or persist.
Note to Physicians (Treatment, Testing, and Monitoring): N/A	

5. FIRE-FIGHTING MEASURES

Suitable Extinguishing Media:	Use equipment and procedures appropriate to the main source of the fire. Use copious amounts of water to extinguish fires.
Fire Fighting Procedures:	Not applicable, product is not flammable. Non-hazardous decomposition may start around 120°C. The product contains oxidizing compounds as listed above, but in a form which reduces any oxidation hazard arising from their presence.

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Specific Hazards Arising from the Chemical:	Dry product will react with water and effervesce. Wet product in tight containers may rupture. No significant hazard is expected.
Precautions for Fire Fighters:	As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.
Recommended Protective Equipment for Fire Fighters: N/A	

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, PPE and Emergency Procedures: Physical form requires no specific personal protective equipment when cleaning up spills. Wear a dust mask if particulate count exceeds limits, and wear gloves as appropriate to the situation.



Environmental Precautions: Material is primarily inorganic, and thus not readily biodegradable. It is not considered to be an environmental hazard. Refer to Section 13 for Waste Disposal.

Methods and Materials for Containment and Clean-up: No special procedure, collect material for disposal.

7. HANDLING AND STORAGE

Precautions for Safe Handling: Handle in accordance with good hygiene and safety procedures. Avoid breathing dust if present. Wash hands thoroughly after handling.

Conditions for Safe Storage: Avoid conditions of heat and humidity.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Occupational Exposure Limits: for Particulates Not Otherwise Regulated (PNOR), 15 mg/m^3 TWA (total dust) and 5 mg/m^3 TWA (respirable fraction)

Biological Exposure Limits: N/A

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Appropriate Engineering Controls: A system of local and/or general exhaust is recommended to keep employee exposures below the Airborne Exposure Limits when working with this product in an industrial processing setting and when product is in powdered form.

Individual Protection Measures (PPE) Specific Eye/face Protection: When working with this product in industrial processing, goggles or safety glasses with side shields are recommended for airborne dust exposures in excess of the applicable limits.

Specific Eye Protection: When mechanically working with this product during industrial processing, if exposure to dust or powder is likely, goggles or safety glasses with side shields are recommended to reduce excessive exposure to airborne dust.

Specific Skin Protection: Wear rubber gloves during industrial processing as extended contact may irritate skin.

Specific Respiratory Protection: If the respirable particulate exposure limit is exceeded, wear a NIOSH approved dust mask.

Specific Thermal Hazards: N/A

Recommended Personal Protective Equipment:

EYES/FACE	SKIN	RESPIRATORY
		

Environmental Exposure Controls: N/A

General Hygiene Considerations and Work Practices: Handle in accordance with good hygiene and safety procedures. Avoid breathing dust if present. Wash hands thoroughly after handling.

Protective Measures During Repair and Maintenance of Contaminated Equipment: N/A

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance:	Light blue tablet, circle; compressed powder	Solubility:	Soluble in water
Odor:	Peppermint	Melting/freezing point:	N/A
Auto-ignition temperature:	N/A	Flash point:	N/A
pH:	6-9	Flammability:	Non-flammable

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Oxidizing properties:	Contains oxidizing compounds, in a form which reduces any hazard arising from their presence	Bulk density:	0.9 g/cc
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10. STABILITY AND REACTIVITY

Reactivity: N/A

Chemical Stability: The material is stable if kept dry and under normal use conditions. When added to water, the product produces carbon dioxide bubbles for agitation, and a mild detergent and peroxide solution for cleaning.

Possibility of Hazardous Reactions: N/A. Polymerization cannot occur.

Conditions to Avoid: Heat can melt the material, but the small amount of oxygen which may be released from some of the ingredients is believed to offer little or no hazard. Flames and pyrolysis can break down some of the ingredients, but no hazard is anticipated.

Incompatible materials: Water causes production of gaseous carbon dioxide and a solution of slowly reactive hydrogen peroxide.

Hazardous Decomposition Products: Carbon dioxide (CO₂), Hydrogen peroxide (H₂O₂)

11. TOXICOLOGICAL INFORMATION

Signs and Symptoms of Overexposure: This product has not been tested. Toxicological testing has not been conducted for this product overall. Available toxicological data for individual ingredients are summarized below.

See specific acute and chronic exposure information in section 16 below.

Emergency Overview: N/A

Likely Routes of Exposure

Inhalation: May cause irritation of respiratory tract.

Eye contact: Contact with eyes may cause irritation.

Skin contact: Prolonged contact with skin may cause redness and irritation.

Ingestion: Harmful if ingested.

LD50 & LD50 Data (as applicable)

Chemical Name	Oral LD50	Dermal LD50	Inhalation LC50
Oxone (CAS 70693-62-8)	= 1,204 mg/kg (rat)	> 11,000 mg/kg (rabbit)	> 14 mg/L, 1 hour (rat)
Citric acid (CAS 77-92-9)	= 3,000 mg/kg (rat)	not reported	not reported
Sodium carbonate (CAS 497-19-8)	= 4,090 mg/kg (rat)	not reported	= 2,300 mg/m ³ , 2 hour (rat)
Sodium percarbonate (CAS 15630-89-4)	= 1,034 mg/kg (rat)	not reported	not reported
Sodium sulfate (CAS 7757-82-6)	> 10,000 mg/kg (rat)	not reported	not reported
Sodium lauryl sulfoacetate (CAS 1847-58-1)	= 700 mg/kg (rat)	not reported	not reported

Medical Conditions Aggravated by Exposure: This product contains persulfates, a known allergen and sensitizer. For people who are allergic to persulfates, an allergic reaction may not occur after the first use or even until many years after use. Also, some symptoms may not appear for several minutes or even hours after actual use.

Toxicity: There are no toxicological data for this material. Adverse health effects are neither known nor expected under normal use. Product can be highly toxic if ingested. Follow all usage directions.

Carcinogenicity: This product does not contain any carcinogens or potential carcinogens as listed by OSHA, IARC or NTP.

Reproductive toxicity: This product does not contain any known or suspected reproductive hazards.

12. ECOLOGICAL INFORMATION**For Use By Affiliates of Dentsply Sirona Orthodontics**

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Ecotoxicity: Material is primarily inorganic and thus not readily biodegradable. It offers no known environmental hazard under normal consumer use.

Persistence and Degradability: Not readily biodegradable.

Bio-accumulative Potential: Not known

13. DISPOSAL CONSIDERATIONS

Regulations:

Unused material should be handled as non-hazardous waste and sent to an approved waste facility. However, processing, use, or contamination of this product may change the waste management options. Dispose of material in accordance with federal, state and local requirements, as applicable. (State and local disposal regulations may differ from federal disposal regulations.)

This product contains one or more substances that are listed with the State of California (CA) as a hazardous waste:

Chemical	CA Hazardous Waste Status
Sodium carbonate (CAS 497-19-8)	Corrosive
Sodium percarbonate (CAS 15630-89-4)	Ignitable

Properties (Physical/Chemical) Affecting Disposal: N/A

Waste Treatment Recommendations: N/A

14. TRANSPORT INFORMATION

UN Identification Number: N/A, non-regulated material. This product is not subject to regulation as a hazardous material for shipping.

UN Proper Shipping Name: Antibacterial Denture Cleanser Tablets, Non-regulated material, Inorganic, Oxidizing Solid – NOS (not otherwise specified)

Transport hazard class(es): N/A

Packing Group: N/A

Special precautions for user: N/A

15. REGULATORY INFORMATION

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NFPA Rating: Health- 0 Flammability- 0 Physical Hazard- 0
 NFPA numeric hazard values: 0 =Minimal, 1 =Slight, 2 =Moderate, 3 =Serious, 4 =Severe

HMIS Rating: Health- 1 Flammability- 0 Physical Hazard- 0 PPE: E

U.S. Federal Regulations

This product does not contain any known hazardous materials in reportable levels as defined by OSHA Hazard Communication Standard, 29 CFR 1910.1200 or as defined under SARA § 311 and § 312.

Comprehensive Environmental Response and Liability Act of 1980 (CERCLA): This material, as supplied, does not contain any substances regulated as hazardous substances under this act.

Toxic Substances Control Act (TSCA): All of the product components are listed on the US TSCA Inventory or are exempt.

Clean Water Act (CWA): This product does not contain any substances regulated as pollutants.

Clean Air Act (CAA): N/A

Superfund Amendments and Reauthorization Act (SARA) Title III Information: N/A

SARA Section 311/312 (40 CFR 370) Hazard Categories: N/A

This product contains the following toxic chemical(s) subject to reporting requirements of SARA Section 313 (40 CFR 372): None

State Regulations

California Proposition 65: This product does not contain any ingredients known to the State of California to cause cancer, birth defects or other reproductive harm.

International Regulations

This material or all of its components are listed on the Inventory of Existing Chemical Substances under: the Canadian Domestic Substances List (DSL), or considered as having been notified under the European Inventory of Existing Chemical Substances (EINECS). Other inventory lists: Japan (ENCS), Korea, Australia, China (Draft), Philippines (PICCS).

Canadian Environmental Protection Act: N/A

Canadian Workplace Hazardous Materials Information System (WHMIS): This SDS has been prepared according to the hazard criteria of the control Products Regulations (CPR) and contains all of the information required.

European Inventory of Existing Chemicals (EINECS): The components used to make this product are EU listed.

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REACH: N/A

16. OTHER INFORMATION

This is a low hazard product. However, chewing or swallowing the tablets or gargling with the solution may cause serious health effects.

Do not take internally.

Do not breathe dust.

Keep out of eyes and avoid extended contact with skin to minimize chance of irritation.

POTENTIAL HEALTH EFFECTS (ACUTE AND CHRONIC)

ACUTE EXPOSURE

INHALATION:

Dust may irritate nasal passages and respiratory tract

SKIN CONTACT:

May irritate skin on extended contact

INGESTION:

Do not ingest tablets or place them in mouth. Do not ingest or gargle with solutions containing denture cleanser. Read and follow all usage directions.

Symptoms from ingestion may include:

- Damage to the esophagus
- Abdominal pain
- Burns
- Breathing problems
- Seizures
- Bleaching of tissue
- Blood in the urine
- Internal bleeding
- Vomiting

EYE CONTACT:

Can cause moderate to severe irritation.

CHRONIC EXPOSURE

This product contains persulfates, a known allergen. Allergic reactions can occur with both proper and improper use of these cleaners. Reactions may become more frequent and severe with repeated use of the product.

Symptoms of an allergic reaction may include:

- Irritation
- Tissue damage

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- Rash
- Hives
- Gum tenderness
- Breathing problems
- Low blood pressure

AGGRAVATION OF PRE-EXISTING CONDITIONS:

Allergic reaction to persulfates.

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Full text of Classification abbreviations used in Section 2 and 3: N/A

Date of SDS Preparation/Revision: 11AUG2017, rev. 2

Data Sources: Dentsply International Raintree Essix technical and design history file information, along with individual raw material safety data sheets and applicable hazard communication regulations.

End of Safety Data Sheet