



Safety Data Sheet

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Product Description

IOS Polymers SBS OE D Products

REF Numbers

Restrictions to use:

For use only by dental professionals.

Manufacturer : International Orthodontic Services
Address : 12811 Capricorn St. Stafford, TX 77477 USA
Phone No, : 1888-IOS-8882 (1888-461-8882)
Emergency Phone No, : +1 832 342 9487

DISCLAIMER: The information in this Safety Data Sheet (SDS) is believed to be correct as of the date issued. IOS MAKES NO WARRANTIES, EXPRESSED OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OR COURSE OF PERFORMANCE OR USAGE OF TRADE. User is responsible for determining whether the IOS product is fit for a particular purpose and suitable for user's method of use or application. Given the variety of factors that can affect the use and application of a IOS product, some of which are uniquely within the user's knowledge and control, it is essential that the user evaluate the IOS product to determine whether it is fit for a particular purpose and suitable for user's method of use or application.

Hazards Identification

HMIS Hazard Class

Health: 0 Flammability: 1 Physical Hazards: 0

Human Health Hazards

None

Environmental Hazards

None

Safety Hazards

Electrostatic charges may be generated during handling. Risk of self-ignition of bulk product above certain temperatures (Refer to Section 10). Specifically for milled grades and accumulated polymer dust: dust explosion could occur.

Special Notes

These components are synthetic rubber compounds, which are essentially non-toxic. Material is non-irritating. If polymer dusts are generated, they could scratch the eyes and cause minor irritation to the respiratory tract.

Composition

SUBSTANCES ARE NON-HAZARDOUS and NOT CLASSIFIED

First Aid Measures

Symptoms and Effects

None

Inhalation

If dust is inhaled, obtain medical attention.

Skin

Flush skin with water.

Eye

Flush eyes with water.

Ingestion

None

Advice to physicians

Treat symptoms.

Fire Fighting Measures

NFPA 704 Hazard Class

Health: 0 Flammability: 1 Instability: 0

Specific Hazards

Not flammable but will burn. Combustion products may include carbon monoxide and carbon dioxide.

Extinguishing Media

Foam, water spray or fog. Dry chemical powder, carbon dioxide, sand or earth may be used for small fires only.

Unsuitable Extinguishing Media

Water in a spray may disperse fire.

Protective Equipment

Full protective clothing and self-contained breathing apparatus

Accidental Release Measure

Personal Precautions

Avoid generating dust.

Environmental Precautions

None

Clean-up Methods - Small Spillage

Shovel up and place in a labeled, sealable container for subsequent disposal as required by local, state, federal, international or country specific regulations.

Clean-Up Methods - Large Spillage

Transfer to a labeled, sealable container for product recovery or disposal as required by local, state, federal, international or country specific regulations.

Protective Measures

Wear appropriate personal protective equipment (refer to Section 8) when responding to spills.

Spill Management

Shovel and sweep up or use industrial vacuum cleaner. Proper disposal should be evaluated based on the regulations of this material (refer to Section 13). Prevent entry into waterways, sewer, or confined areas.

Handling and Storage

Handling

Avoid generation of dust. Take precautionary measures against static discharges, earth/ground all equipment. Do not breathe dust. Use local exhaust over processing area.

When processing IOS Polymers products, maintain a fire watch if the material reaches 225 deg. C (437 deg. F) for IOSIR and IOS D (polymers and compounds), and 280 deg. C (536 deg. F) for IOS G (polymers and compounds). The temperatures listed are indicated only for safety reasons (risk of fire and product degradation) and are not recommended for processing.

Degradation of the polymer (polymer breakdown) will start at lower temperatures depending on the specific processing conditions. Therefore, operating below these temperatures does not guarantee the absence of product degradation.

For more information about processing precautions, consult the IOS Polymers product data documents or other technical literature available from your sales representative.

Static charge buildup can be a potential fire hazard when used in the presence of volatile, flammable vapors or in high airborne dust concentrations. All solid forms of IOS polymers can accumulate an electrostatic charge when rubbed, chafed or abraded and can charge unearthed components. Considering the risks of electrostatic discharges handling the products in potentially flammable atmospheres should be evaluated carefully. Suitable precautions should be taken at all times, in particular when emptying bags or other packaging. Earth/Ground equipment to dissipate charges that may develop. For more information, consult the IOS Polymers Static Electricity Safety Bulletin (Document Number K0073) available from your sales representative.

Storage

Keep container dry. Keep in a cool, well-ventilated place. All IOS polymers contain an antioxidant to aid in stabilizing the polymer over its recommended use and storage conditions. Exposure to direct sunlight or elevated temperatures over prolonged periods of time consumes the antioxidant at an increased rate and may lead to self heating and thermal degradation. Avoid storage under pressure or at elevated temperatures to minimize particulate clustering. Do not stack Flexible Intermediate Bulk Containers (FIBCs) or palletized bags.

Storage Temperatures

Ambient.

Product Transfer

Take precautionary measures against static discharge. Earth/Ground all equipment.

Other Information

IOS polymers may accumulate static charge during transport, handling and processing. Reducing the velocity of material transfer will reduce the likelihood that a charge will be created.

Exposure Controls/Personal Protection

Occupational Exposure

In the absence of occupational exposure standards for this product, it is recommended that the following be adopted:

Nuisance Dust TLV

TWA (8 h) 10 mg/m³

If dust is generated.

Engineering Control Measures

Use local exhaust ventilation.

Respiratory Protection

Where local exhaust ventilation is not practicable, and odors are detected use a negative pressure half face respirator equipped with a cartridge designed to protect against organic vapors and if dust is also present a particulate pre-filter should also be used. For high airborne dust concentrations use a cartridge designed to be used against nuisance dust.

Hand Protection

Cloth gloves if desired.

Eye Protection

Dust-tight mono goggles.

Body Protection

Standard issue work clothes which may include: apron, safety shoes or boots as necessary.

Physical and Chemical Properties

Physical State: Solid

Color: Translucent, White or Natural

Odor: Essentially odorless

Flash Point: None

Density: Typical between 880-950 kg/m³ at 20 Deg. C

Specific Gravity: <1

Bulk density (for solids): Typical 300-400 kg/m³ at 20 Deg. C

Solubility (In Water): Insoluble

N-octanol/water partition coefficient (log Pow): Not applicable

All other properties are not applicable.

Residual monomers

We do not routinely measure but analysis of representative products indicate isoprene, styrene, and 1,3-butadiene are not present at the detection limit of our instrumentation. Based on our manufacturing processes, we believe these results are typical for our polymers.

Reactivity and Stability

Stability

Stable under ambient conditions. Oxidizes exothermically above ambient temperature.

Conditions to Avoid

Avoid contact with strong oxidizing agents. Accumulation of product in areas exposed to elevated temperatures for extended periods in air may result in self-heating and auto ignition. Avoid elevated temperatures in storage for prolonged periods of time.

Hazardous Decomposition Products

Hazardous vapors from heated product are not expected to be generated under normal processing temperatures and conditions.

None under ambient conditions. Although highly dependent on temperature and environmental conditions, a variety of thermal decomposition products may be present if the product is over heated, is smoldering or catches fire. Typical decomposition products are ultimately oxides of carbon

Toxicological Information

Basis for Assessment

Toxicological data has not been determined for this product. Information is based on similar products.

Acute Toxicity Oral

Expected to be of low toxicity, LD50 > 2000 mg/kg

Acute Toxicity Dermal

Expected to be of low toxicity, LD50 > 2000 mg/kg

Acute Toxicity Inhalation

No data available, but not expected.

Skin Irritation

Not expected to be irritating.

Eye Irritation

Not expected to be irritating.

Skin Sensitization

Not expected to be a skin sensitizer.

Repeated Dose Toxicity

Repeated exposure does not cause toxic effects.

Mutagenicity

No data available, but not expected.

This product is not classified by the following: The International Agency for Research on Cancer (IARC), The National Toxicology Program (NTP) or The American Conference of Governmental Industrial Hygienists (ACGIH).

Other Information

IOS Polymers products are high molecular weight polymers which are non-toxic and biologically inactive. We do not intentionally add organic tin compounds or phthalates to our products.

These products are manufactured with synthetic raw materials that do not contain animal products or by-products. IOS Polymers do not contain natural rubber or natural rubber latex.

We do not use naturally occurring food allergens.

Ecological Information

Basis for assessment

No ecotoxicological data has been generated for this product. The information below is based on components and on similar products.

Mobility

Floats on water. Remains on surface of soil.

Persistence/Degradability

Not expected to be inherently biodegradable. Persists under anaerobic conditions.

Bioaccumulation

Not expected to bioaccumulate.

Acute Toxicity - Fish

Expected to be practically nontoxic, LC/EC/IC 50 > 1000 mg/L

Acute Toxicity - Invertebrates

Expected to be practically nontoxic, LC/EC/IC 50 > 1000 mg/L

Acute Toxicity - Algae

Expected to be practically nontoxic, LC/EC/IC 50 > 1000 mg/L

Acute Toxicity - Bacteria

Expected to be practically nontoxic, LC/EC/IC 50 > 1000 mg/L

Sewage Treatment

Expected to be practically nontoxic, LC/EC/IC 50 > 1000 mg/L

Disposal Considerations

Product Disposal

Recover or recycle if possible, otherwise; incinerate or use a licensed landfill.

Container Disposal

Remove all packaging for recovery or disposal.

Local Legislation

Consult local, state, federal, international or country specific regulations as appropriate.

FEDERAL LEGISLATION**Resource Conservation and Recovery Act - RCRA (40CFR 261)**

If this product becomes a waste and has not been chemically altered it is not considered a hazardous waste.

Emergency Planning and Community Right-to-Know Act (EPCRA)

Not regulated.

Comprehensive Environmental Response, Compensation and Liability Act (CERCLA/Superfund)

Not regulated.

Superfund Amendments and Reauthorization Act Title III:

Section 302 - Extremely Hazardous Substances

Section 304 - Hazardous Substances

Section 311 / 312 - Hazard Communication Standard

Section 313 - Toxic Chemical List

Not regulated.

Transport Information

US Department of Transportation (DOT) 49CFR 171-180

This product is not classified as hazardous.

International Air Transportation Association Classification (IATA)

This product is not classified.

International Maritime Organization (IMDG)

This product is not classified.

UN, IMO, ADR/RID, ICAO Code

This product is not dangerous.

Export Administration Regulations

Does not require a license: EAR 99

Regulatory Information

INTERNATIONAL LEGISLATION

GLOBAL CHEMICAL INVENTORY STATUS – All of the substances are acceptable for use under:

AUSTRALIA – Inventory of Chemical Substances (AICS)
 CANADA – (CEPA) Domestic Substances List (DSL)
 CHINA – Inventory of Existing Chemical Substances (IECSC)
 EU – European Inventory of Existing Chemical Substances (EINECS)
 JAPAN – Inventory of Existing and New Chemical Substances (IENCS)
 KOREA – Existing Chemicals Inventory (KECI)
 NEW ZEALAND – New Zealand Inventory of Chemicals (NZIOC)
 PHILIPPINES – Inventory of Chemicals and Chemical Substances (PICCS)
 USA – Toxic Substances Control Act (TSCA)

This document is compliant with the Globally Harmonized System (GHS) for the classification, labeling, and packaging (CLP) of substances and mixtures.

EU REACH Article 31 (Requirements for Safety Data Sheets) and Japan Ministry of Economy, Trade, and Industry (METI), Ministry of Health, Labor, and Welfare (MHLW) and Ministry of the Environment (MOE).

EU Directive 67/548/EEC, 1999/45/EC, 91/155/EEC, as amended by GHS (CLP) of substances and mixtures

Not classified.

OSHA Hazard Communication Standard 29FR 1910.1200

Not classified.

AUSTRALIAN MSDS LEGISLATION: National Code of Practice for the Preparation of Material Safety Data Sheets, 2nd Edition [NOHSC: 2011 (2003)] under s.38(i) of the *National Occupational Health and Safety Commission Act 1985* (Cwlth).

Not regulated.

CANADA Workplace Hazardous Materials Information System (WHMIS)

This product has been classified in accordance with the hazard criteria of the Controlled Products Regulations and the SDS contains all the information required. This is NOT a WHMIS controlled product.

EU Regulation (EC) 1907/2006 REACH

Polymers are exempted from registration and evaluation. Therefore, IOS products are exempted by regulation. Annex V exempts from registration additives used in our polymers as antioxidants, defoaming agents, stabilisers, etc., and exempts substances that are naturally occurring that have not been chemically modified, Article 2(7)(b). Use of our products in medical devices regulated by Council Directive 90/385/EEC of 20 June 1990 and 93/42/EEC of 14 June 1993 and Directive 98/79/EC, or used in cosmetic products by Directive 76/768/EEC or used as a food contact material under Regulation (EC) No 1935/2004 are also exempted.

EU Directive 2002/95/EC Restrictions of Hazardous Substances (RoHS) in electrical and electronic equipment
 Restricted substances: Lead, Mercury, Cadmium, Hexavalent Chromium, PBB and PBDE

Not regulated.

EU Directive 2002/96/EC Waste Electrical and Electronic Equipment (WEEE)

Not regulated.

EU Directive 91/689/EEC Hazardous Waste

Not regulated.

EU Directive 94/62/EC as amended by 2004/12/EC (Packaging and packaging waste)

Not regulated. The product meets the requirement for the total amount of cadmium, chromium, lead and mercury to be less than 100 parts per million.

EU Directive 2000/53/EC as amended in 2002 (End of life vehicle)

Not regulated.

EU Directive 2037/2000 Ozone Depleters (Class I or II) as defined in Montreal Protocol

Not regulated.

Article 19g(5) Federal Water Management Act (WHG) of 17 May 1999 (amended in July 2005)

Our products are classified into the Water Hazard Class WGK 1.

International Conventions**Chemical Weapons, Rotterdam PIC (Prior Informed Consent), Persistent Organic Pollutants (POP), Drug Precursors**

Not regulated.

UNITED STATES: FEDERAL REGULATIONS**Food and Drug Administration (FDA) 21 CFR 170-199**

Products on this SDS may conform with uses under food contact regulations as an article or a component of an article intended for food contact. Most IOS Polymers comply with worldwide regulations for food contact applications, including those of the Food and Drug Administration (FDA) and the European regulatory agencies. For specific clearances, consult your Sales Representative.

Toxic Substances Control Act (TSCA) Section 4, 5(a)(2), (e), (f), 6, 7 or 12(b)

Not regulated.

Clean Air Act Amendments Section 602 (Class I or II) Ozone Depleters

Not regulated.

Clean Air Act Section 111 Volatile Organic Compounds (VOC)

Not regulated

Clean Air Act Section 112 Hazardous Air Pollutants (HAP)

Not regulated.

Clean Water Act Section 307 Priority Pollutants

Not regulated.

UNITED STATES: STATE REGULATIONS**Right-to-Know Laws (Massachusetts, New Jersey, New York State, Pennsylvania)**

Not regulated.

Coalition of Northeastern Governors (CONEG)

Not regulated. The product meets the requirement for the total amount of cadmium, chromium, lead and mercury to be less than 100 parts per million.

Medical Devices, Healthcare and Cosmetic Applications and Trademark Usage

IOS Polymers' products should not be used in any devices or materials intended for implantation in the human body as defined by the U.S. Food and Drug Administration under 21 CFR 812.3(d) and 21 CFR 860.3(d). No customer of IOS Polymers LLC and/or any of its direct or indirect subsidiaries ("IOS Polymers"), or any other party, shall, without the express written consent of IOS Polymers for each specific, individual application, be permitted to manufacture,

use, sell, process, or otherwise supply, directly or indirectly, any IOS Polymers Product, or any compound containing or made from any IOS Polymers Product, in any of the following applications:

1. Cosmetics (exclusive of packaging or delivery applications);
2. Drugs and other Pharmaceuticals (exclusive of packaging or delivery applications); and
3. Medical devices; provided, that any medical device that satisfies any one of the following definitions shall not be deemed to fall within the foregoing medical device restriction: (a) any medical device falling within the definition of either a Class I or Class II medical device, as defined in any federal law or regulation of the United States or Canada, or (b) any medical device falling within the definition of a Class I or Class II(a) medical device, as defined by any applicable regulation of the European Union or any member state thereof.

No customer of IOS Polymers, or any other party, shall be permitted to use any of IOS Polymers' trade names, trademarks, logos or other similar identifying marks or characteristics for the manufacture, sale, or promotion of its cosmetics, drugs, pharmaceutical products/materials, or medical devices.

Please contact your IOS Polymers Sales Representative for more details before using our products in these specific applications.