

Product Safety and Compliance

Lip Bumper

RDS-18.3 REV 00

This document is provided as assurance to clinicians and patients that orthodontic products sold by American Orthodontics have been designed, manufactured, and labeled with safety and effectiveness in mind.

Compliance with Medical Device Standards

American Orthodontics medical devices are designed, manufactured, labeled, and sold in compliance with globally recognized medical device regulations and standards. These regulations and standards require American Orthodontics to maintain a Quality Management System that includes specific focus on clinician and patient safety. This includes biological safety of medical devices per ISO 10993. Evidence of compliance is documented in certifications granted by recognized notified bodies; current certifications can be reviewed at <https://www.americanortho.com/resources/regulatory-compliance/>.

Material Information

The devices within the scope of this technical document are comprised of stainless steel components brazed together with a silver braze alloy.

Chemicals / Compounds

Arsenic (As): Not known to contain.

Bisphenols (e.g. BPA): Not known to contain.

Cadmium (Cd): Not known to contain.

Chromium (Cr) / Nickel (Ni): Contains Nickel and/or Chromium. Patients with an identified allergy to these metals should consult with their doctor before using this product. Devices with Nickel and/or Chromium are labeled with the following safety symbol:



Cobalt (Co): Not known to contain.

Gluten: Not known to contain.

Lead (Pb): Not known to contain.

Latex: Not known to contain.

Mercury (Hg): Not known to contain.

Nuts: Not known to contain.

Perfluorooctanoic Acid (PFOA): Not known to contain.

Phthalates / Plasticizers: Not known to contain.

Polyvinyl Chloride (PVC): Not known to contain.

MRI Information

This device is labelled as unsafe for use in MR environments.

Additional Requirements

USA OSHA (SDS) and Canada Hazardous Products Act: The devices within the scope of this document are classified as “articles” under OSHA and Canadian regulations. Articles that do not release hazardous substances during normal use or handling are exempt from SDS requirements. The devices within the scope of this document do not release hazardous substances during normal use or handling and are exempt from SDS requirements.

EU Substance Requirement (GSPR 10.4.1): The devices within the scope of this document do not contain substances which are carcinogenic, mutagenic or toxic to reproduction (CMR), of category 1A or 1B nor substances having endocrine-disrupting properties for which there is scientific evidence of probable serious effects to human health.

EU Biological Origin Requirement (GSPR 13): The devices within the scope of this document do not contain substances of biological origin, including tissues or cells of human / animal origin or their derivatives.

Note: Lip Bumpers manufactured by American Orthodontics can withstand temperatures of 121°C for 30 minutes or 132°C for 4 minutes.

Definitions

Term	Definition
Contains	The chemical or compound is present in the device based on composition information from American Orthodontics' suppliers, analytical testing, or both.
Not known to contain	1. Analytical measurement for the presence of the chemical or compound is not currently available; 2. If measurement is possible, a. The material has not been identified or disclosed to American Orthodontics and b. The material has not been specifically quantified or detected; OR c. Based on information from raw material suppliers, possible presence as an impurity or by-product at or below regulatory thresholds

Disclaimer: Some of the information presented and conclusions drawn herein are from sources other than direct test data on the product itself. The information was obtained from sources that American Orthodontics believes are reliable and is believed to be valid and accurate. American Orthodontics, however, makes no warranty, express or implied, regarding its correctness of the information provided. The conditions or method of handling, storage, use and disposal of the product are beyond American Orthodontics' control and may be beyond American Orthodontics' knowledge. For this and other reasons, American Orthodontics does not assume responsibility and expressly disclaims liability for loss, damage, or expense arising out of or in any way connected with the handling, storage, use or disposal of the product. The information contained herein may not be applicable if the product is used as a component in another product or used in a way other than recommended by the Company. Reasonable safety precautions must always be observed.