

Mouthguard/EVA Materials

Material Composition: Ethylene Vinyl Acetate Copolymer

We certify that the referenced material is manufactured by
Keystone Industries-Myerstown 52 West King Street, Myerstown, PA 17067

Biocompatibility:

The material used complies with FDA regulation 21 CFR 177.1350 "Ethylene-Vinyl acetate copolymers" relevant to indirect food additives. They may be used as articles or components of articles intended for use in contact with non-alcoholic food subject to the extraction limitations on the finished food contact article as specified in 21 CFR 177.1350. The EVA also complies with FDA Regulation 21 CFR 175.105 "Adhesives" as it pertains to indirect food additives. Accordingly the material is appropriate and acceptable for use in medical devices intending to contact the oral cavity.

The EVA/Mouthguard materials are not tested according to ISO10993-1 as they have been manufactured for over 20 years with no adverse events occurring. The product has been determined substantially equivalent to other products existing in the market. There have been no changes to the product composition, manufacturing processes, formulation, intended use or primary packaging that would necessitate biocompatibility study completion. Customer complaints and lack of adverse event reports were utilized in determining the safety of this product. Keystone maintains a product technical file according to requirements of the Medical Device Directive MDD93/42/EEC and conducts periodic Risk Management/Risk Review activities according to the requirements of ISO14971.

Latex Statement

EVA products do not contain Latex.

DEHP/ Phthalate/BPA Statement

Di(2-ethylhexyl) phthalate (DEHP) is not intentionally used in the raw materials used by Keystone Industries-Myerstown in the manufacture of the EVA Vacuum forming materials. Our suppliers have indicated they do not intentionally add this ingredient into the raw material. The material "blanks" are used in dental laboratories/dental offices in the fabrication of Mouthguards, bleaching, bruxism appliances, nightguards, etc. Raw materials are not routinely tested for the presence of this material. Based on composition knowledge, these substances are not expected to be present. The EVA Material does not contain BPA.

Shelf Life:

EVA products do not expire as they are not expected to degrade over a certain period of time. Yellowing may occur if the material is not stored under adequate climate controlled storage conditions. MSDS information is available upon request.

Signed:  Date: 8/22/13
Tracey Schwear
Manager of Quality Assurance & Regulatory Affairs