

SECTION 1: Identification of the Supplier of the Product Technical Data Sheet

<p>Manufacturer: Reliance Orthodontic Products, Inc. 1540 W. Thorndale Ave Itasca, IL 60143 USA T 630-773-4009, during normal business hours regulatory@relianceorthodontics.com www.RelianceOrthodontics.com</p>	<p>U.S. Federal Register: FDA Registration: 1420089</p>
<p>Australian Sponsor: Emergo Australia, 201 Sussex St. Darling Park, Tower II, Level 20 Sydney, NSW 2000 Australia T +61 2 9006 1662</p>	<p>EC Representative: Emergo Europe Westervoortsedijk 60 6827 AT Arnhem The Netherlands T +31 70 345 8570</p>
<p>Switzerland Representative: MedEnvoy Global BV Leidschendam-Voorburg, Zug Branch Office Gotthardstrasse 28, 6302 Zug, Switzerland T +41 41 462 01 42</p>	<p>U.K. Person Responsible: Emergo Consulting (UK) Limited c/o Cr360 - UL International Compass House, Vision Park Histon Cambridge CB24 9BZ England, United Kingdom T +44(0) 1223 772 671</p>

SECTION 2: Reliance Accessories Products – Material Technical Information

Product Family	Material	Material Compliance Standard
1 st and Final Pumice	SDS available	REACH (EU) 1907/2006
Aligner Removers (ReliaPry)	EP300R Polypropylene Light Blue masterbatch colorant Light Green masterbatch colorant White masterbatch colorant	USP Class VI FDA 21 CFR 73 Subpart D
Access Cheek Retractor	T302 Stainless Steel: <i>Carbon</i> <i>Manganese</i> <i>Phosphorus</i> <i>Silicon</i> <i>Sulfur</i> <i>Chromium</i> <i>Nickel</i> <i>Nitrogen</i> <i>Molybdenum</i> <i>Copper</i> Thermoplastic A430 plastic	ASTM-A313 ASTM-5688
Brush Handle	Polypropylene Black Nylon	N/A
CC Chain and Molds	14 karat nickel-free yellow gold: <i>Gold</i> <i>Silver</i> <i>Zinc</i> <i>Copper</i> Thermoplastic Elastomer G2755-1000-00	ASTM F138 ISO 15841:2014 EN 1641:2009 ISO 7405:2018

Product Family	Material	Material Compliance Standard
	Polypropylene	
Disposable Benda Brushes	612 Nylon Filament	N/A
Etchmaster	SDS available Stainless Steel handpiece	N/A
Mark II CR Syringe	500P Acetal Polymer R-5100 Polyphenylsulfone NT 15	ISO 10993
Micro Brush	Polypropylene Nylon	N/A
Mixing Pad	Base white paper Low density polyethylene coating	N/A
Mixing Well	Polypropylene PP700	21 CFR 177.1520(c)
Perfect A Smile Pontic Paste	SDS Available	REACH (EU) 1907/2006
ReliaBites	Poly(dimethylsiloxane) Dimethyl hydroxy-terminated Dimethicone Colorant	EN 14372:2004 FDA 21 CFR 177.2600 EN 14582:2016
ReliaBox	Dark Grey 7540C ABS and Polycarbonate TPE Rubber Gasket	N/A
ReliaMold Mini Molds	CL2250 Translucent Thermoplastic Elastomer	USP Class VI FDA 21 CFR 177.1210 ISO 10993 Part 4 ISO 10993 Part 5
Restore Polishing Paste	SDS available	REACH (EU) 1907/2006
Ring Well	Polypropylene	N/A
Safety Glasses	Polycarbonate lens Ultra-dura lense coating Nylon temple Texin frame	ANSI 787+ CSA Z94.3 Military Vo
Scoops	Polystyrene	FDA 177.1520
Spatula	500P Acetal Polymer NC010	N/A
Sponge Pellets	White Polyethylene	N/A
Syringe Assist	MG9641B High Density Polyethylene	N/A
Tips	Polypropylene Stainless Steel 304	FDA 21 CFR 177.1520
Tweezers	Stainless Steel	N/A
Self Mixing Tips	Polyethylene Polypropylene	N/A
UV Disclosing Light	Aluminum Alkaline button cell coin battery	N/A

SECTION 3 : RoHS (EU) 2011/65/EU, (EU) 2017/2012, (EU) 2015/863

The EU's Restriction of Hazardous Substances (RoHS) Directives are related to electrical and electronic equipment and not specifically to plastic and metal raw materials. This product complies with the RoHS Directive 2017/2012, 2011/65/EU and 2015/863 regarding the limits of mercury, cadmium, lead, chromium VI, polybrominated biphenyls (PBB), and polybrominated diphenyl ethers (PBDE).

SECTION 4 : California Proposition 65

Specific product codes for the product families as listed above contain nickel or carbon black, chemicals known to the State of California to cause cancer. Product labeling identifies the precautions associated with the material proposition 65 warning. Immediately remove the orthodontic appliance and instruct the patient to seek medical care in an allergic reaction.

SECTION 5 : Nut and Gluten Ingredients

The Reliance Orthodontic accessories are not formulated with any nut or gluten containing ingredients. The manufacturing site of the products does not manufacture or process nut or gluten containing products.

SECTION 6 : Phthalates

Based upon the information provided to Reliance Orthodontic Products, the above listed products do not contain phthalates such as DEHP, BBP, DBP and DIBP that are listed in the Candidate List of Substances of Very High Concern of the REACH regulation EU 1907/2006.