

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

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	U.S. Federal Register: FDA Registration: 1420089
Australian Sponsor: Emergo Australia, 201 Sussex St. Darling Park, Tower II, Level 20 Sydney, NSW 2000 Australia T +61 2 9006 1662	EC Representative: Emergo Europe Westervoortsedijk 60 6827 AT Arnhem The Netherlands T +31 70 345 8570
Switzerland Representative: MedEnvoy Global BV Leidschendam-Voorburg, Zug Branch Office Gotthardstrasse 28, 6302 Zug, Switzerland T +41 41 462 01 42	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

SECTION 2: Reliance Non-Chemical Products – Material Technical Information

Product Family	Material	Material Ingredient	Material Compliance Standard	Magnetic Resonance (MR) Safety
TNT Archwires, Retainium, Extend Wires	Beta Titanium	Titanium Molybdenum Tin Zirconium	ASTM F138 ISO 15841:2014 EN 1641:2009 ISO 7405:2018	MR Safe
TNT Archwires	Nickel Titanium	Titanium Nickel Carbon Cobalt Copper Chromium Hydrogen Iron Niobium Nitrogen plus Oxygen	ASTM F2063 ISO 15841:2014 EN 1641:2009 ISO 7405:2018	MR Safe
TNT Archwires	Stainless Steel 304	Carbon Phosphorus Sulfur Iron Silicon Nickel Chromium Manganese Molybdenum Copper Cobalt	ASTM F138 ISO 15841:2014 EN 1641:2009 ISO 7405:2018 ASTM A580/A580M	MR Safe

Product Family	Material	Material Ingredient	Material Compliance Standard	Magnetic Resonance (MR) Safety
		Vanadium Titanium		
Ortho Flex Tech	Gold	Gold Silver Copper Nickel Zinc	ASTM F138 ISO 15841:2014 EN 1641:2009 ISO 7405:2018	MR Safe
	Nickel Free Gold	Gold Silver Copper Zinc	ASTM F138 ISO 15841:2014 EN 1641:2009 ISO 7405:2018	MR Safe
	Stainless Steel 316L	Iron Silicon Nickel Chromium Manganese Molybdenum Copper Cobalt Vanadium Titanium	ASTM F138 ISO 15841:2014 EN 1641:2009 ISO 7405:2018 ASTM A580/A580M	MR Conditional
Bond A Braid, Kobayashi Tie Hooks	Stainless Steel 304L	Iron Silicon Nickel Chromium Manganese Molybdenum Copper Cobalt Vanadium Aluminum Tantalum Titanium	ASTM F138 ISO 15841:2014 EN 1641:2009 ISO 7405:2018 ASTM A580/A580M	MR Safe
Renew Finishing System Points	Polyurethane (binding)	Functional diisocyanates Functional diamines	ISO 10993-5 ISO 10993-10 EN 1641:2009 ISO 7405:2018	N/A
	Aluminum Oxide (abrasive grit material)	Aluminum oxide Iron oxide Sodium oxide Silicon dioxide	ISO 10993-5 ISO 10993-10 EN 1641:2009 ISO 7405:2018	N/A
	Silicon Carbide (abrasive grit material)	Silicon carbide Quartz	ISO 10993-5 ISO 10993-10 EN 1641:2009 ISO 7405:2018	N/A
	Stainless Steel (shaft)	Chromium Carbon Manganese Silicon Phosphorous Sulphur	ISO 7405:2018 ASTM A580/A580M	N/A

Product Family	Material	Material Ingredient	Material Compliance Standard	Magnetic Resonance (MR) Safety
		Molybdenum		
Renew Finishing System Burs	Sintered Tungsten Carbide shank body	–	ISO 10993-5 ISO 10993-10 EN 1641:2009 ISO 7405:2018 BS EN ISO 1797:2017	N/A
	Diamond grit (diamond bur)	–	ISO 10993-5 ISO 10993-10 EN 1641:2009 ISO 7405:2018	N/A
Relastics	Natural rubber latex tubing (Latex Elastics)	NRL Sulfur Zinc Oxide Polymetric Hindered Phenol Carbamate Derivative	ISO 10993-5 ISO 10993-10 EN 1641:2009 ISO 7405:2018	N/A
	Thermoplastic Elastomer G2706-1000-00 (Non-Latex Elastics)	--	ISO 10993-5 ISO 10993-10 EN 1641:2009 ISO 7405:2018	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 : REACH (EU) 1907/2006

REACH Annex XVII (Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles)

The products as listed above contain no substance(s) listed on REACH Annex XVII (Restriction Conditions)

REACH Annex XIV (List of substances subject to authorisation)

The products as listed above contain no substance(s) listed on REACH Annex XIV (Authorisation List)

REACH Candidate List (SVHC)

The products as listed above contain no substance(s) listed on the REACH Candidate List.

SECTION 5 : California Proposition 65

Specific product codes for the product families as listed above contain nickel, a chemical 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 6 : Latex Statement

The latex Elastics contain natural rubber latex tubing. Latex is a known allergy and the product is labeled as containing latex per ISO 15223-1.

SECTION 7 : Magnetic Resonance (MR) Safety

The Reliance products that are metal have been assessed for Magnetic Resonance (MR) safety with results shown in the table above for the applicable products. The products are not labeled with the MRI Hazard per ASTM F2503-20 as the labeling for orthodontic devices will never be observed by radiologists in charge of MRI. The probability of orthodontic hardware-related incidents during MRI is low as all radiologists are familiar with necessary precautions and there have been no reportable events in the past 20+ years.

SECTION 8 : Nut and Gluten Ingredients

The non-chemical Reliance Orthodontic products 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 9 : Steel Restrictions from Russia

All Stainless Steel products as identified on this data sheet are compliant to COUNCIL REGULATION (EU) No 833/2014 of 31 July 2014 amended by Regulation (EU) No 2023/1214 effective September 30, 2023.