



# Non-Chemical Product Technical Data Sheet

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

<b>Manufacturer:</b> RMO 2165 Earlywood Drive Franklin, IN 46131 USA SRN #: US-MF-00003482 T 1-800-525-6735 <a href="mailto:customerservice@rmortho.com">customerservice@rmortho.com</a> <a href="https://rmortho.com/">https://rmortho.com/</a>	<b>U.S. Federal Register:</b> FDA Registration: 1718476
<b>Australian Sponsor:</b> AB Orthodontics PTY LTD 13/15 Collins St Melbourne VIC 3000 Australia T +61 3 9650 2526	<b>EU Representative:</b> RMO Europe 300 rue Geiler de Kaysersberg 67411 Illkirch Cedex, France SRN #: FR_AR_000003900 T +33 3 88 40 67 40 <a href="https://www.rmoeurope.com/">https://www.rmoeurope.com/</a>

## SECTION 2: RMO Orthodontics Non-Chemical Products – Material Technical Information

Product Family	Material	Material Ingredient	Material Compliance Standard	Magnetic Resonance (MR) Safety
Metal Brackets	Silver Solder / Silver-Copper-Tin-Zinc Alloy / Silver Brazing / Brazing Alloy	Silver Copper Zinc Tin	ASTM B32 ISO 15841:2014 EN 1641:2009 ISO 7405:2018	MR Safe
	Stainless Steel (304, 316, 17-4)	Carbon Phosphorus Sulfur Iron Silicon Nickel Chromium Manganese Molybdenum Nitrogen Copper Niobium Tantalum	ASTM F138 ISO 15841:2014 EN 1641:2009 ISO 7405:2018 ASTM A313/A313M-18 ASTM A564	304 SS MR Safe 316 SS MR Conditional 17-4 SS MR Conditional
	NiTi / Nickel-Titanium / Nitinol / Nickel Titanium Alloy	Titanium Nickel Carbon Cobalt Copper Chromium Hydrogen Iron	ASTM F2063 ISO 15841:2014 EN 1641:2009 ISO 7405:2018	MR Safe



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Product Family	Material	Material Ingredient	Material Compliance Standard	Magnetic Resonance (MR) Safety
		Niobium Nitrogen plus oxygen		
Tubes	Silver Solder / Silver-Copper-Tin-Zinc Alloy / Silver Brazing / Brazing Alloy	Silver Copper Zinc Tin	ASTM B32 ISO 15841:2014 EN 1641:2009 ISO 7405:2018	MR Safe
	Stainless Steel (304,316, 17-4)	Carbon Phosphorus Sulfur Iron Silicon Nickel Chromium Manganese Molybdenum Nitrogen Copper Niobium Tantalum	ASTM F138 ISO 15841:2014 EN 1641:2009 ISO 7405:2018 ASTM A313/A313M-18 ASTM A564	304 SS MR Safe 316 SS MR Conditional 17-4 SS MR Conditional
Bands	Stainless Steel (304)	Carbon Phosphorus Sulfur Iron Silicon Nickel Chromium Manganese Nitrogen	ASTM F138 ISO 15841:2014 EN 1641:2009 ISO 7405:2018  ASTM A313/A313M-18	MR Safe
Wire and Appliances	Stainless Steel (Tru-Chrome - 302, 303, 304, 316)	Carbon Phosphorus Sulfur Iron Silicon Nickel Chromium Manganese Nitrogen	ASTM F138 ISO 15841:2014 EN 1641:2009 ISO 7405:2018 ASTM A313/A313M-18 ASTM A895	302 SS MR Safe 303 SS MR Safe 304 SS MR Safe 316 SS MR Conditional
	Elgiloy / Cobalt-Chromium-Nickel-Molybdenum Alloy	Nickel Cobalt Molybdenum Chromium Iron Manganese Carbon	ASTM F1058-16 ISO 15841:2014 EN 1641:2009 ISO 7405:2018	MR Safe



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Product Family	Material	Material Ingredient	Material Compliance Standard	Magnetic Resonance (MR) Safety
Wire and Appliances		Silicon Phosphorous Sulfur Beryllium		
	NiTi / Nickel-Titanium / Nitinol / Nickel Titanium Alloy	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
	Copper Nickel Titanium / CuNiTi	Nickel Titanium Copper Chromium Iron Manganese	ASTM F2063 ISO 15841:2014 EN 1641:2009 ISO 7405:2018	MR Safe
	Beta-Titanium / Ti-Beta / Titanium molybdenum / $\beta$ -Ti / Bendaloy / Beta III Alloy	Titanium Molybdenum Tin Zirconium Iron Oxygen Carbon Nitrogen Hydrogen Aluminum Cobalt	ASTM B265 ISO 15841:2014 EN 1641:2009 ISO 7405:2018	MR Safe
	Gold	Gold Silver Copper Nickel Zinc	ISO 27874:2008 ASTM F138 ISO 15841:2014 EN 1641:2009 ISO 7405:2018	MR Safe
	Silver Solder	Silver Copper Zinc Tin	ASTM B32 ISO 15841:2014 EN 1641:2009 ISO 7405:2018	MR Safe
	Polycarbonate (PC)	Bisphenol A polycarbonate polymers	ASTM D3935-21 ISO 11963:2012	N/A
	Urethane Dimethacrylate (UDMA)	N/A – Monomer	ISO 4049	N/A
	Polyethylene (PE)	N/A – Polymer	ASTM D4976-12AR20	N/A



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Product Family	Material	Material Ingredient	Material Compliance Standard	Magnetic Resonance (MR) Safety
			ASTM D638 ASTM D1693-21 ISO 17855-2:2016	
	Thermoplastic Polyurethane (TPU)	N/A – Elastomer / block copolymer	D5476-99 ISO 16365-1:2014	N/A
	Polytetrafluoroethylene (PTFE) / Teflon	N/A – Polymer	ASTM D4745 ASTM D3294	MR Safe
	Polystyrene	N/A – Polymer	FDA 21 CFR 177.1520	N/A
	Polypropylene	N/A – Polymer	21 CFR 177.1520(c)	N/A
Aesthetic Brackets	Polycrystalline Alumina Oxide	Aluminum oxide Iron oxide Sodium oxide Silicon dioxide	ISO 10993-5 ISO 10993-10 EN 1641:2009 ISO 7405:2018	N/A
	Monocrystalline Aluminum Oxide	Aluminum oxide Iron oxide Sodium oxide Silicon dioxide	ISO 10993-5 ISO 10993-10 EN 1641:2009 ISO 7405:2018	N/A
	NiTi / Nickel-Titanium / Nitinol / Nickel Titanium Alloy (SL Brackets Only)	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
	Polyurethane	Functional diisocyanates Functional diamines	ISO 10993-5 ISO 10993-10 EN 1641:2009 ISO 7405:2018	N/A
Elastics	Natural Rubber Latex	NRL Sulfur Zinc Oxide Polymetric Hindered Phenol Carbamate Derivative	ISO 10993-5 ISO 10993-10 EN 1641:2009 ISO 7405:2018	N/A
	Thermoplastic Elastomers (TPE) (Non-Latex eastics)	N/A	USP Class VI FDA 21 CFR 177.1210 ISO 10993-4 ISO 10993-5 ISO 10993-10 EN 1641:2009 ISO 7405:2018	N/A



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Product Family	Material	Material Ingredient	Material Compliance Standard	Magnetic Resonance (MR) Safety
	Polyurethane Elastomers (PU)	N/A – Polymer	ISO 16365-1:2014 ASTM D4274	MR Safe
	Styrene-Butadiene Rubber (SBR)	Butadiene Styrene	ASTM D4673-16	N/A
	Barium Sulfate / Barite	N/A	ASTM D715-86(2020) ISO 3262-2:2023	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 RMO Orthodontics 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 RMO Orthodontics 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.