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CERTIFICATE OF COMPLIANCE

DATE: March 28, 2024
SUBJECT: REGULATORY COMPLIANCE FOR VALUE PLASTICS PRODUCTS
PART AFFECTED: ALL VALUE PLASTICS PRODUCTS WITH (-CM077)
MATERIAL TYPE: MPBT FG30 (F) 30% Glass Reinforced PBT Resin
SUPPLIER: Modified Plastics Inc.

Dear Valued Customer,

Thank you for your interest in Nordson MEDICAL's Value Plastics line of products. As part of our continuous improvement initiatives, and to provide the most timely and effective responses possible, we have created this comprehensive list of the most up to date regulatory compliance information available at <https://www.nordsonmedical.com/Components-and-Technologies/Fluid-Management-Components/Support/Material-Information/> and <https://www.nordsonmedical.com/Resources/Regulatory-Compliance>. The information contained herein generally fulfills the bulk of our customers' regulatory requirements, however if there is additional information required that is not provided here, please submit your request to LOV_QA-RA@nordsonmedical.com.

Please be informed that Nordson MEDICAL relies on information provided by our suppliers and vendors, whose materials make up the sole content of our products as there are no processing agents or mold releases used in the manufacture of our products. Nordson MEDICAL does not test or analyze these materials for ANY specified regulatory requirements; the information provided by the resin manufacturers has simply been compiled in a readily retrievable format as a service to our customers. Ultimately customers and end-users must make their own determinations ensuring the use of these products is safe, lawful, and suitable for their intended applications. Because of possible changes in the law and/or in regulations, we encourage our customers to periodically verify the status of the regulatory compliance. These compliance letters are typically updated annually, upon receiving new regulatory information, or as deemed necessary.

Regards,

Brian Benton

Manufacturing and Quality Manager

Nordson Medical

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USE OF THIS REGULATORY INFORMATION						
<p>The information provided as requested is intended to be used for informational purposes only. Nordson MEDICAL relies on information provided by their suppliers or vendors. Nordson MEDICAL makes no representation or warranty as to the completeness or accuracy of the information contained herein. It is intended for use by persons having technical skill, at their own discretion and risk, who will make their own determination as to its suitability for their purposes prior to use. As with any material, evaluation of compounds under end-use conditions prior to specification is essential. Ultimately, customers must make their own determination that use of this product is safe, lawful, and technically suitable for their intended applications.</p>						
ITEM	REGULATORY REQUIREMENTS	COMPLIANT				COMMENTS
		Y	N	N/A	See Comment	
1	Allergens (Global Food)	Y				Not intentionally added in the manufacturing of or formulation. Due to the absence of use of these substances, we do not test for them.
2	ELV Directive 2000/53/EC (Heavy Metal)	Y				Not intentionally added in the manufacturing of or formulation. Due to the absence of use of these substances, we do not test for them.
3	21 CFR 177.2510, 177.2600, 177.1520, 21 CFR 178.3297, 21 CFR 176.170, 21 CFR 177.1500, 21 CFR 177.1580, 21 CFR 177.1520(a)(3)(a) and (c) 3.1a, 21 CFR 177.1550, 21 CFR 177.2470, 21 CFR 177.2480, 21 CFR 177.2600, 21 CFR 177.2600 (Food Contact)				See Comment	Our Supplier has not indicated if this material meets these standards
4	3-A Sanitary Standards				See Comment	Our Supplier has not indicated if this material meets these standards

5	AD-DSL (the AeroSpace & Defence Declarable)	Y				AS far as our knowledge this product is Not listed/Not regulated. Although, Nordson does not monitor this list closely, Nordson Medical is focused on Medical Compliance especially to the ISO 13485 Standards. The customer is responsible for verifying this information for themselves.
6	Animal Derived Materials	Y				Not intentionally added in the manufacturing of or formulation. Due to the absence of use of these substances, we do not test for them.
7	Aromatic Amines	Y				Not intentionally added in the manufacturing of or formulation. Due to the absence of use of these substances, we do not test for them.
8	ASTM D3222				See Comment	Our Supplier has not indicated if this material meets these standards
9	ASTM F963 Standard Consumer Safety for Toy Safety				See Comment	Our Supplier has not indicated if this material meets these standards
10	BioCides	Y				Not intentionally added in the manufacturing of or formulation. Due to the absence of use of these substances, we do not test for them.
11	Biocompatibility	Y				This material is in compliance with Pharmacopoeia and Biocompatibility-Tests in Europe, United States, and Japan. Components have been tested by the raw material manufacturer under USP Class VI and ISO 10993 standards LISTED BELOW.
12	Bioterrorism Act of 2002	Y				The facility manufacturing these products not required to register with the Bioterrorism Act of 2002 because it is not a food facility.
13	BISPHENOL A (BPA)	Y				Not intentionally added in the manufacturing of or formulation. Due to the absence of use of these substances, we do not test for them.

14	BSE/TSE	Y			As per the manufacturer, the above-mentioned product is made solely from synthetic Plastic polymers. These products are free from known Bovine Spongiform Encephalopathy (BSE) and Transmittable Spongiform Encephalopathy (TSE) causing agents.
15	California Prop 65	Y			Manufacturer confirms that the materials used in the formulation of this product are not reportable per California's list of chemicals known to cause cancer or reproductive toxicity.
16	Canadian WHMIS INGREDIENT DISCLOSURE LIST, Canadian Domestic Substance List (DSL), AND OTHER APPLICABLE REGULATIONS	Y			All ingredients of this product are listed on the DSL Domestic Substances List or are not required to be listed on the DSL Domestic Substances List.
17	Chemicals of High Concern to Children (CHCC) Maine, Vermont, Washington	Y			To the best of our knowledge, this product does not contain chemicals at levels which require reporting under this statute.
18	China RoHS	Y			To the best of our knowledge, this product does not contain chemicals at levels which require reporting under this statute.
19	Clean Air Act, 40 CFR	Y			To the best of our knowledge this product is not intentionally manufactured or formulated with Class I or II substances as defined under 40 CFR part 82 of the Clean Air Act of 1993, as amended (58 FR 8136).
20	Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) - Reportable Quantity (RQ):	Y			The components in this product are either not CERCLA regulated, regulated but present in negligible concentrations, or regulated with no assigned reportable quantity.
21	CONEG	Y			Our supplier has indicated that none of the substances indicated in the 1998 revision of the "The Model Toxics in Packaging Legislation" are used in the formulation of manufacture of this material. These substances may be present as impurities, but their

					levels are expected to be below 100 ppm.
22	Conflict Minerals	Y			Not intentionally added in the manufacturing of or formulation. Due to the absence of use of these substances, we do not test for them.
23	Consumer Product Safety Improvement Act of 2008 (CPSIA)	Y			To the best of our knowledge This product is not manufactured or formulated with lead, di-(2-ethylhexyl) phthalate (DEHP), dibutyl phthalate (DBP), or benzyl butyl phthalate (BBP). Our supplier has indicated that it does not contain these materials above the limits set in the Consumer Product Safety Improvement Act of 2008, Title 1, Sections 101 and 108.
24	Drug Master File	Y			To the best of our knowledge this Material is not Listed.
25	Endotoxins			See Comment	Please be aware that Value Plastics does not perform endotoxin or bioburden testing on our components. The vast majority of our components are catalog products, and may be used in many applications, therefore we do not test or analyze our materials for any specified regulatory requirements. Ultimately, we leave it to the end-user to make their own determination that our products are safe and suited for their intended applications. However, our processes are highly automated with minimal operator contact, and our production processes don't involve water, so we believe endotoxin levels on our parts to be low.
26	EU 200/53/EC & 2002/525/EC - END-OF-Life Vehicles Regulation			See Comment	Our Supplier has not indicated if this material meets these standards
27	EU Commission Decision 2009/251/EC – Dimethylfumarate			See Comment	Not intentionally added in the manufacturing of or formulation. Due to the absence of use of these substances, we do not test for them.

28	EU Directive 2002/16/EC				See Comment	Our Supplier has not indicated if this material meets these standards
29	EU Directive 2003/11/EC				See Comment	Our Supplier has not indicated if this material meets these standards
30	EU Directive 76/769 EEC and Regulation EC 1907/2006 - Hexabromo Cyclododecane (HBCDD) and Hexachlorobenze (HCB) –				See Comment	Not intentionally added in the manufacturing of or formulation. Due to the absence of use of these substances, we do not test for them.
31	EU Directive 90/128 and subsequent ammendments				See Comment	Our Supplier has not indicated if this material meets these standards
32	EU MDR				See Comment	Our Supplier has not indicated if this material meets these standards
33	EU-Food Contact				See Comment	Our Supplier has not indicated if this material meets these standards
34	EU-Pharmacopeia (7th Edition)				See Comment	Our Supplier has not indicated if this material meets these standards
35	European Directive (94/62/EC) (Article 11), (2004/12/EC), and its ammendments Packaging and Packaging Waste				See Comment	Our Supplier has not indicated if this material meets these standards
36	European Regulation (EC) No. 1895/2005 (BADGE, BFDGE, NOGE)				See Comment	Our Supplier has not indicated if this material meets these standards
37	Formaldehyde	Y				Not intentionally added in the manufacturing of or formulation. Due to the absence of use of these substances, we do not test for them.
38	Genetically Modified Organism Free	Y				Not intentionally added in the manufacturing of or formulation. Due to the absence of use of these substances, we do not test for them.
39	GHS	Y				This mixture is not classified according to US-GHS.
40	Gluten-Free	Y				Not intentionally added in the manufacturing of or formulation. Due to the absence of use of these substances, we do not test for them.
41	ILFI – Red List Chemicals The International Living Future Institute	Y				Not intentionally added in the manufacturing of or formulation. Due to the

					absence of use of these substances, we do not test for them.
42	In Vitro Hemocompatibility Assay (ISO)	Y			Not intentionally added in the manufacturing of or formulation. Due to the absence of use of these substances, we do not test for them.
43	International Inventories			See Comment	To the best of our knowledge, this product does not contain chemicals at levels which require reporting under this statute.
44	ISO 10993-1			See Comment	This material has not been tested against these standards to our knowledge
45	ISO 10993-10			See Comment	This material has not been tested against these standards to our knowledge
46	ISO 10993-11			See Comment	This material has not been tested against these standards to our knowledge
47	ISO 10993-12			See Comment	This material has not been tested against these standards to our knowledge
48	ISO 10993-18, EXTRACTABLES TESTING			See Comment	This material has not been tested against these standards to our knowledge
49	ISO 10993-2			See Comment	This material has not been tested against these standards to our knowledge
50	ISO 10993-3			See Comment	This material has not been tested against these standards to our knowledge
51	ISO 10993-4			See Comment	This material has not been tested against these standards to our knowledge
52	ISO 10993-5			See Comment	This material has not been tested against these standards to our knowledge
53	ISO 10993-6			See Comment	This material has not been tested against these standards to our knowledge
54	Kosher		N		Supplier does not certify this resin to be Kosher or in compliance with Kosher requirements
55	Lactose	Y			Not intentionally added in the manufacturing of or formulation. Due to the absence of use of these substances, we do not test for them.

56	Latex	Y				Not intentionally added in the manufacturing of or formulation. Due to the absence of use of these substances, we do not test for them.
57	MA Right to Know Extraordinarily Hazardous Substance List	Y				To the best of our knowledge, this product does not contain chemicals at levels which require reporting under this statute.
58	Melamine	Y				Not intentionally added in the manufacturing of or formulation. Due to the absence of use of these substances, we do not test for them.
59	Natrual Rubber	Y				Not intentionally added in the manufacturing of or formulation. Due to the absence of use of these substances, we do not test for them.
60	Nitrosamines	Y				Not intentionally added in the manufacturing of or formulation. Due to the absence of use of these substances, we do not test for them.
61	NJ Right to Know Regulated Chemicals	Y				To the best of our knowledge, this product does not contain chemicals at levels which require reporting under this statute.
62	Nanoparticles	Y				Not intentionally added in the manufacturing of or formulation. Due to the absence of use of these substances, we do not test for them.
63	NSF 61				See Comment	See https://www.nsf.org/certified-products-systems for reference.
64	NSF-14				See Comment	See https://www.nsf.org/certified-products-systems for reference.
65	NSF-51				See Comment	See https://www.nsf.org/certified-products-systems for reference.
66	Other Substance/compounds				See Comment	Substances that are not intentionally added: Heavy metals, lead
67	Ozone Depleting Substances	Y				Not intentionally added in the manufacturing of or formulation. Due to the

					absence of use of these substances, we do not test for them.
68	PA Right to Know Regulated Chemicals			See Comment	To the best of our knowledge, this product does not contain chemicals at levels which require reporting under this statute.
69	Persistent Organic Pollutants (POP)	Y			Not intentionally added in the manufacturing of or formulation. Due to the absence of use of these substances, we do not test for them.
70	PFAS (Per and Polyfluoroalkyl substances)	Y			Not intentionally added in the manufacturing of or formulation. Due to the absence of use of these substances, we do not test for them.
71	PFCA (Perfluoroalkyl carboxylic acid)	Y			Not intentionally added in the manufacturing of or formulation. Due to the absence of use of these substances, we do not test for them.
72	PFOA (Perflouroctanoic acid)	Y			Not intentionally added in the manufacturing of or formulation. Due to the absence of use of these substances, we do not test for them.
73	PFOS (Perflouroctane sulfonate)	Y			Not intentionally added in the manufacturing of or formulation. Due to the absence of use of these substances, we do not test for them.

74	Phthalates: Dibutyl phthalate Diethyl phthalate (DEHP) Di-isononyl phthalate Dimethyl phthalate DMP CAS# 131-11-3 Diethyl phthalate DEP CAS# 84-66-2 Diallyl phthalate DAP CAS# 131-17-9 Di-n-propyl phthalate DPP CAS# 131-16-8 Di-n-butyl phthalate DBP CAS# 84-74-2 Diisobutyl phthalate DIBP CAS# 84-69-5 Butyl cyclohexyl phthalate BCP CAS# 84-64-0 1,2-bis(2-methoxyethyl) ester DMEP CAS# 117-82-8 [bis(2-methoxyethyl) phthalate] Di-n-pentyl phthalate DNPP CAS# 131-18-0 1,2-Benzenedicarboxylic acid, dipentyl ester branched and linear CAS# 84779-61-3 Dicyclohexyl phthalate DCP CAS# 84-61-7 Butyl benzyl phthalate BBP CAS# 85-68-7 Di-n-hexyl phthalate DnHP CAS# 84-75-3	Y				Not intentionally added in the manufacturing of or formulation. Due to the absence of use of these substances, we do not test for them.
75	REACH	Y				Our supplier has indicated that this product does not contain any of the substances of very high concern above a limit of 0.1%.
76	RoHS / RoHS 2 / RoHS 3	Y				This material conforms to the substance limits and prohibition requirements of RoHS 2, directive 2011/65/EU, as amended by 2015/863/EU.
77	SARA (311,312) Hazard Class	Y				To the best of our knowledge, this product does not contain chemicals at levels which require reporting under this statute.
78	SARA 313 Regulated Chemicals	Y				To the best of our knowledge, this product does not contain chemicals at levels which require reporting under this statute.
79	SARA Title III – Section 302 Extremely Hazardous Chemicals:	Y				To the best of our knowledge, this product does not contain chemicals at levels which

					require reporting under this statute.
80	Transport Classification	Y			Not regulated as hazardous for shipment.
81	TSCA				Manufacturer confirms that the materials used in the formulation of this product are listed or considered exempt.
82	Unactivated Partial Thromboplastin Time Assay (ISO)			See Comment	This material has not been tested against these standards to our knowledge
83	US Pharmacopoeia Class VI	Y			The PBT resin is compliant and listed with USP Class IV.
84	USDA			See Comment	This material has not been tested against these standards to our knowledge
85	USP 381 (Elastomeric Closures for injection)			See Comment	This material has not been tested against these standards to our knowledge
86	USP 643 (Total Organic Carbon)			See Comment	This material has not been tested against these standards to our knowledge
87	USP 661			See Comment	This material has not been tested against these standards to our knowledge
88	USP 85 (Endotoxin)			See Comment	This material has not been tested against these standards to our knowledge
89	USP 88			See Comment	This material has not been tested against these standards to our knowledge
90	USP 851 (Static Sorption Study of Phenol)			See Comment	This material has not been tested against these standards to our knowledge
91	USP 87 (L929 MEM Elution)			See Comment	This material has not been tested against these standards to our knowledge
92	Volatile Organic Compounds (VOCs)	Y			Not intentionally added in the manufacturing of or formulation. Due to the absence of use of these substances, we do not test for them.
93	WEEE	Y			The WEEE-Directive regulates disposal and recycling of electrical and electronic waste. Compliance with the restrictions of this directive can only be confirmed by the producer of the final product. To our best knowledge this product is compliant.