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CERTIFICATE OF COMPLIANCE

DATE: April 22, 2024
SUBJECT: REGULATORY COMPLIANCE FOR VALUE PLASTICS PRODUCTS
PART AFFECTED: ALL TUBING SOLD BY VALUE PLSTICS WITH AN *SILC* PART NUMBER
MATERIAL TYPE: ADVANTAPURE PLATINUM CURED SILICONE TUBING
SUPPLIER: NEW AGE INDUSTRIES

Dear Valued Customer,

Thank you for your interest in Nordson MEDICAL's 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

Value Plastics & LinkTech

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PROCESS: NEW AGE INDUSTRIES

USE OF THIS REGULATORY INFORMATION

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.

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)	y				21 CFR 177.2600, Rubber Articles Intended for Repeated Use Supplier has third party certificate of compliance on file
4	3-A Sanitary Standards	y				Supplier has third party certificate of compliance on file
5	AD-DSL (the AeroSpace & Defence Declarable)				See Comment	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		n			Our Supplier has not indicated if this material meets these standards
9	ASTM F963 Standard Consumer Safety for Toy Safety		n			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				Biocompatibility standards are listed below.
12	Bioterrorism Act of 2002	y				The facility manufacturing these products not required to register with the Bioterrorism
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				This material is not manufactured with any animal product and is considered to be free from BSE & TSE.
15	California Prop 65	y				No substance listed on California's Proposition 65 chemicals listing, known to the State of California to cause cancer or reproductive toxicity, is intentionally added in the manufacture of this product.
16	Canadian WHMIS INGREDIENT DISCLOSURE LIST, Canadian Domestic Substance List (DSL), AND OTHER APPLICABLE REGULATIONS				See Comment	To the best of our knowledge, this product does not contain chemicals at levels which require reporting under this statute.
17	Chemicals of High Concern to Children (CHCC) Maine, Vermont, Washington				See Comment	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 does not contain chemicals at levels which require reporting under this statute.

20	Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) - Reportable Quantity (RQ):	y				To the best of our knowledge, this product does not contain chemicals at levels which require reporting under this statute.
21	CONEG					To the best of our knowledge, this product does not contain chemicals at levels which require reporting under this statute.
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 does not contain chemicals at levels which require reporting under this statute.
24	Drug Master File	y				Not listed on the DMF
25	Endotoxins	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.
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	Our Supplier has not indicated if this material meets these standards
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	Our Supplier has not indicated if this material meets these standards
31	EU Directive 90/128 and subsequent amendments				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 amendments 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 product is not classified
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				Supplier has third party certificate of compliance on file
43	International Inventories				See Comment	Supplier has not indicated that this is listed on any international inventories.
44	ISO 10993-1				See Comment	Our Supplier has not indicated if this material meets these standards
45	ISO 10993-10				See Comment	Our Supplier has not indicated if this material meets these standards
46	ISO 10993-11				See Comment	Our Supplier has not indicated if this material meets these standards
47	ISO 10993-12				See Comment	Our Supplier has not indicated if this material meets these standards
48	ISO 10993-18, EXTRACTABLES TESTING	y				Supplier has third party certificate of compliance on file
49	ISO 10993-2				See Comment	Our Supplier has not indicated if this material meets these standards
50	ISO 10993-3				See Comment	Our Supplier has not indicated if this material meets these standards
51	ISO 10993-4				See Comment	Our Supplier has not indicated if this material meets these standards
52	ISO 10993-5				See Comment	Our Supplier has not indicated if this material meets these standards
53	ISO 10993-6				See Comment	Our Supplier has not indicated if this material meets these standards
54	Kosher		N			Our Supplier has not indicated if this material meets these standards
55	Lactose	y				Not used in manufacture of formulation of this material
56	Latex	y				Not used in manufacture of formulation of this material
57	MA Right to Know Extraordinarily Hazardous Substance List				See Comment	To the best of our knowledge, this product does not contain chemicals at levels which require reporting under this statute.

58	Melamine	y				Not used in manufacture of formulation of this material
59	Natrual Rubber	y				Not used in manufacture of formulation of this material
60	Nitrosamines	y				Not used in manufacture of formulation of this material
61	NJ 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.
62	Nanoparticles	y				Not used in manufacture of formulation of this material
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/ Tests				See Comment	Substances not used in manufacture of formulation of this material: Radioactive compounds, Polyaromatic hydrocarbons (PAHs), Organic phosphates, Phthalates, N-Nitroso Compounds, Aflatoxin-like compounds, Tin, Tantalum, Tungsten, and Gold, Bisphenol A (BPA), Aldehydes, Azoxy compounds, melamine, latex, natural rubber, Isocyanates, 2-Mercaptobenzothiazole (MBT) Supplier has third party certificate of compliance on file for: Static Sorption Study of Phenol (USP), Tests on Silicone Elastomer for Closures and Tubing (EP), Rabbit Pyrogen Test (ISO), Physiochemical Test for Plastics (USP), LAL Gel Clot Validation (USP), L929 MEM Elution (USP), Kligman Maximization (ISO), In Vitro Hemocompatibility Assay (ISO), Elastomeric Closures for Injection (USP), Ames Assay (ISO)
67	Ozone Depleting Substances	y				Not used in manufacture of formulation of this material
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 used in manufacture of formulation of this material
70	PFAS (Per and Polyfluoroalkyl substances)	y				Not used in manufacture of formulation of this material
71	PFCA (Perfluoroalkyl carboxylic acid)	y				Not used in manufacture of formulation of this material
72	PFOA (Perflouroctanoic acid)	y				Not used in manufacture of formulation of this material

73	PFOS (Perflouroctane sulfonate)	y				Not used in manufacture of formulation of this material
74	Phthalates: Dibutyl phthalate Diethyl phthalate (DEHP) Di-isononyl phthalateDimethyl 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 used in manufacture of formulation of this material
75	REACH	y				No restricted substances used in manufacture of formulation of this material
76	RoHS / RoHS 2 / RoHS 3	y				No restricted substances used in manufacture of formulation of this material
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				To the best of our knowledge, this product does not contain chemicals at levels which require reporting under this statute.
81	TSCA	y				To the best of our knowledge, this product does not contain chemicals at levels which require reporting under this statute.
82	Unactivated Partial Thromboplastin Time Assay (ISO)	y				Supplier has third party certificate of compliance on file
83	US Pharmacopoeia Class VI	y				Supplier has third party certificate of compliance on file
84	USDA				See Comment	Our Supplier has not indicated if this material meets these standards
85	USP 381 (Elastomeric Closures for injection)	y				Supplier has third party certificate of compliance on file
86	USP 643 (Total Organic Carbon)				See Comment	Our Supplier has not indicated if this material meets these standards
87	USP 661				See Comment	Our Supplier has not indicated if this material meets these standards
88	USP 85 (Endotoxin)				See Comment	Our Supplier has not indicated if this material meets these standards
89	USP 88				See Comment	Our Supplier has not indicated if this material meets these standards
90	USP 851 (Static Sorption Study of Phenol)	y				Supplier has third party certificate of compliance on file
91	USP 87 (L929 MEM Elution)	y				Supplier has third party certificate of compliance on file
92	Volatile Organic Compounds (VOCs)	y				Not used in manufacture of formulation of this material
93	WEEE	y				No restricted substances used in manufacture of formulation of this material