

CERTIFICATE OF COMPLIANCE

DATE: April 12, 2024
SUBJECT: REGULATORY COMPLIANCE FOR VALUE PLASTICS PRODUCTS
PART: ALL VALUE PLASTICS PRODUCTS WITH SUFFIX OF -VP1
AFFECTED: Trilliant™ HC5420-0002 LL Natural
MATERIAL: Avient (PolyOne) Corporation

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

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				This material, when used as recommended is acceptable for food contact applications regulated under the provisions of the Food, Drug, and Cosmetic Act and subsequent amendments as outlined in Title 21 of the Code of Federal Regulations with limitations on use as referenced in Tables 1 and 2, Section 176.170(c).
4	3-A Sanitary Standards	Y				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				This material does not contain any ingredient materials that are animal derived.
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				SEE COMMENT	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				Bisphenol A derived chemicals are not intentionally added or used during the manufacture of this material.
14	BSE/TSE	Y				This material does not contain any ingredient materials that are animal derived.
15	California Prop 65	Y				None of the ingredients used in the manufacture of this material contain substances on the State of 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				SEE COMMENT	All components of this material are on the Canadian Domestic Substances List or are exempt.
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				SEE COMMENT	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				SEE COMMENT	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):				SEE COMMENT	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)				SEE COMMENT	Our Supplier has not indicated if this material meets these standards

24	Drug Master File	Y				To the best of our knowledge this Material is not Listed.
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	This product does not intentionally contain substances that are Carcinogenic, Mutagenic, or Reprotoxic, or Endocrine-disrupting Substances at concentrations above 0.1% weight-by-weight (w/w).
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 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)				SEE COMMENT	This material has not been tested against these standards to our knowledge
43	International Inventories				SEE COMMENT	Australia inventory (AICS): All components are listed or exempted. Taiwan inventory (CSNN): All components are listed or exempted. Malaysia Inventory (EHS Register): Not determined. EINECS: All components are listed or exempted. Japan inventory: All components are listed or exempted. China inventory (IECSC): All components are listed or exempted. Korea inventory: All components are listed or exempted. New Zealand Inventory of Chemicals (NZIoC): All components are listed or exempted.
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				Dry natural rubber, natural rubber latex, and latex derived ingredients are not intentionally added or used during the manufacture 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 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				Dry natural rubber, natural rubber latex, and latex derived ingredients are not intentionally added or used during the manufacture of this material.
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				SEE COMMENT	To the best of our knowledge, this product does not contain chemicals at levels which require reporting under this statute.
62	Nonaparticles	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					Halogenated or phosphorous
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 or used during the manufacture of this material
71	PFCA (Perfluoroalkyl carboxylic acid)	Y				Not intentionally added or used during the manufacture of this material
72	PFOA (Perflouroctanoic acid)	Y				Not intentionally added or used during the manufacture of this material
73	PFOS (Perflouroctane sulfonate)	Y				Not intentionally added or used during the manufacture of this material

74	<p>Phthalates: Dibutyl phthalate Dioctyl 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</p>	Y			<p>Not intentionally added or used during the manufacture of this material</p>
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75	REACH	Y				This material does not contain any of the Annex XIV candidate chemicals proposed to be Substances of Very High Concern above the 0.1% threshold as stated in REACH (Article 57, Regulation No. 1907/2006) determined either through (i) non-use of the substance, (ii) mass balance calculation, or (iii) specific testing.
76	RoHS / RoHS 2 / RoHS 3	Y				The material supplier has declared that this material complies with Directives 2011/65/EC and (EU) 2015/863.
77	SARA (311,312) Hazard Class				SEE COMMENT	AS far as our knowledge this product is Not listed/Not regulated.
78	SARA 313 Regulated Chemicals				SEE COMMENT	AS far as our knowledge this product is Not listed/Not regulated.
79	SARA Title III – Section 302 Extremely Hazardous Chemicals:				SEE COMMENT	AS far as our knowledge this product is Not listed/Not regulated.
80	Transport Classification	Y				Not regulated as hazardous for shipment.
81	TSCA	Y				This material is not intentionally formulated with any of the following compounds: <ul style="list-style-type: none"> • Decabromodiphenyl ether (DecaBDE) • Phenol, isopropylated phosphate (3:1) (PIP (3:1)) • 2,4,6-Tris(tert-butyl) phenol (2,4,6-TTBP) <ul style="list-style-type: none"> • Hexachlorobutadiene (HCBd) • Pentachlorothiophenol (PCTP)
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				This material meets the requirements for Plastic Class VI testing per USP <88>.
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	Y				This material meets the requirements for Plastic Class VI testing per USP <88>.
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				SEE COMMENT	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.

