

CERTIFICATE OF COMPLIANCE

DATE:	April 19, 2024
SUBJECT:	REGULATORY COMPLIANCE FOR VALUE PLASTICS PRODUCTS
PART AFFECTED:	ALL VALUE PLASTICS PRODUCTS WITH SUFFIX OF -40
MATERIAL TYPE:	UDEL P-1700 POLYSULFONE RESIN
SUPPLIER:	SOLVAY http://www.solvay.com/

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

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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				The resins comply with FAR 21 CFR 177.1655 and may be used in articles intended for repeated use in contact with foods. Additionally, they are approved by the NSF, by the Department of Agriculture for contact with meat and poultry, and by the 3-A Sanitary Standards of the Dairy Association.
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)				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				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				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
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				No animal fats, oils, milk products or other animal products are used as components of, or in the manufacture of, Udel® P-1700 CL.
15	California Prop 65	Y				This product can expose you to chemicals including 4,4'-isopropylidenediphenol (CAS-No.: 80-05-7) , which is/are known to the State of California to cause birth defects or other reproductive harm. For more information go to www.P65Warnings.ca.gov .

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				This product does not contain any hazardous air pollutants (HAP), as defined by the U.S. Clean Air Act Section 112.
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	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.
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				This material conforms to the substance limits and prohibition requirements of this regulation.
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	Y				The material supplier has declared that this material complies with Directives listed.
27	EU Commission Decision 2009/251/EC – Dimethylfumarate	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.
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) –	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.
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	Meets the criteria outlined in the EU MDR 2017/745 regulation (Paragraph 10.4.1) for CMR and endocrine disrupting substances. Substances as outlined in Section 10.4.1 a & b are not contained at concentrations above 0.1% (w/w). <ul style="list-style-type: none"> • No animal fats, oils, milk products or other animal products are used as components of, or in the manufacture of this product. • Phthalates are not intentionally added to or used during the manufacture of Udel® products. However, we do not conduct any analyses to determine if any impurities exist.
33	EU-Food Contact	Y				This product meets these standards
34	EU-Pharmacopeia (7th Edition)	Y				This product 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)	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.
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				See Comment	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)				See Comment	Our Supplier has not indicated if this material meets these standards
43	International Inventories				See Comment	<p>Chemical Substance Control Law: Japan. CSCL, Specified and Monitoring substances (class 1 and 2, designated substances) This product does not intentionally contain any of the substances on this list. Prohibited Substances Korea. Prohibited Chemicals This product does not intentionally contain any of the substances on this list. Toxic Substances Korea. Designation of Toxic Substances This product does not intentionally contain any of the substances on this list. Harmful Substances Prohibited from Manufacturing Korea. Harmful Substances Prohibited from manufacturing This product does not intentionally contain any of the substances on this list. CANADA INVENTORY (DSL): All grades and colors of Udel P-1700 are on the DSL except GN 535. U.S. INVENTORY (TSCA): Listed on inventory. EC INVENTORY (EINECS/ELINCS): In compliance. JAPAN INVENTORY (MITI): All grades and colors of Udel P-1700 are on the Japanese inventory except BK 1615 and GN 421 & 535. AUSTRALIA INVENTORY (AICS): All grades and colors of Udel P-1700 are on the Australian AICS except GN 421 & 535. KOREA INVENTORY (ECL): All grades and colors of Udel P-1700 are on the Korea ECL except GN 421 & 535. PHILIPPINE INVENTORY (PICCS): Not determined.</p>
44	ISO 10993-1	Y				Our supplier has stated they meet this material meets these standards.
45	ISO 10993-10	Y				Our supplier has stated they meet this material meets these standards.
46	ISO 10993-11	Y				Our supplier has stated they meet this material meets these standards.

47	ISO 10993-12	Y				Our supplier has stated they meet this material meets these standards.
48	ISO 10993-18, EXTRACTABLES TESTING	Y				Our supplier has stated they meet this material meets these standards.
49	ISO 10993-2	Y				Our supplier has stated they meet this material meets these standards.
50	ISO 10993-3	Y				Our supplier has stated they meet this material meets these standards.
51	ISO 10993-4	Y				Our supplier has stated they meet this material meets these standards.
52	ISO 10993-5	Y				Our supplier has stated they meet this material meets these standards.
53	ISO 10993-6	Y				Our supplier has stated they meet this material meets these standards.
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				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	Natural 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				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 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	y				Tested at 82°C (180°F) (Commercial Hot): 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	y				Maximum Temperature of Use: 149°C (300°F): See https://www.nsf.org/certified-products-systems for reference.
66	Other Substance/compounds				See Comment	These substances are not intentional added to the product: Rubber / Latex, Red Phosphorus, Silicone, PVC, PCBs, PAHs, GADSK, Bovine/Transmissible Spongiform Encephalopathy (BSE/TSE), Bisphenol A, Azo dyes, columbite-tantalite (coltan), cassiterite (tin), gold, wolframite (tungsten), Alkylphenol Ethoxylates / Nonylphenol Ethoxylates (APE/NPE), Phthalates, Cadmium, hexavalent chromium, lead and mercury
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 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				<p>Not intentionally added in the manufacturing of or formulation. Due to the absence of use of these substances, we do not test for them.</p>
75	REACH	y				<p>The supplier of this raw material confirms that no substances present on the SVHC list are present above a .1% concentration.</p>
76	RoHS / RoHS 2 / RoHS 3	y				<p>The material supplier has declared that this material complies with 2011/65/EC and (EU) 2015/863.</p>
77	SARA (311,312) Hazard Class	y				<p>To the best of our knowledge, this product does not contain chemicals at levels which require reporting under this statute.</p>
78	SARA 313 Regulated Chemicals	y				<p>To the best of our knowledge, this product does not contain chemicals at levels which require reporting under this statute.</p>
79	SARA Title III – Section 302 Extremely Hazardous Chemicals:	y				<p>To the best of our knowledge, this product does not contain chemicals at levels which require reporting under this statute.</p>

80	Transport Classification	y			Not Regulated
81	TSCA			See Comment	<p>under the Toxic Substance Control Act (TSCA), the U.S. Environmental Protection Agency (EPA), issued expedited action on five Persistent, Bioaccumulate, and Toxic (PBT) chemicals. The EPA implemented a rule to prohibit all manufacture (including import), processing, and distribution in commerce of these five PBT chemicals/substances:</p> <ul style="list-style-type: none"> • PIP (3:1) [phenol, isopropylated phosphate (3:1); CAS: 68937-41-7] • DecaBDE [Decabromodiphenylether; CAS: 1163-19-5] • 2,4,6 - TTBP [2,4,6 - tris (tert-butyl) phenol; CAS:732-26-3] • PCTP [Pentachlorothiophenol; CAS: 133-49-3] • HCBd [Hexachlorobutadiene; CAS: 87-68-3] <p>Based on information supplied by the raw material vendor, all chemical substances in this product comply with applicable rules or orders under TSCA and are listed active on the TSCA inventory. However, this product has not been tested to determine the presence of these substances.</p>
82	Unactivated Partial Thromboplastin Time Assay (ISO)	y			Our Supplier has indicated that this material meets these standards
83	US Pharmacopoeia Class VI			See Comment	<p>USP Class VI testing has been completed for the base resin UDEL P-1700 NT 11. The results of that testing indicate that the specific lots tested did not yield extractants which were toxic or irritating upon either acute systemic or acute intracutaneous administration. Similarly, no significant adverse reactions were evident upon intramuscular implantation of these materials. Therefore, Udel P-1700 NT 11 is in compliance with USP criteria for a Class VI plastic.</p>
84	USDA			See Comment	Our Supplier has not indicated if this material meets these standards

85	USP 381 (Elastomeric Closures for injection)	y				Our Supplier has indicated that this material meets these standards
86	USP 643 (Total Organic Carbon)	y				Our Supplier has indicated that this material meets these standards
87	USP 661	y				Our Supplier has indicated that this material meets these standards
88	USP 85 (Endotoxin)	y				Our Supplier has indicated that this material meets these standards
89	USP 88	y				Our Supplier has indicated that this material meets these standards
90	USP 851 (Static Sorption Study of Phenol)	y				Our Supplier has indicated that this material meets these standards
91	USP 87 (L929 MEM Elution)	y				Our Supplier has indicated that this material meets these standards
92	Volatile Organic Compounds (VOCs)	y				This product does not contain any chemicals listed under the U.S. Clean Air Act Section 111 SOCM I Intermediate or Final VOC's (40 CFR 60.489). This product does not contain any VOC exemptions listed under the U.S. Clean Air Act Section 450.
93	WEEE	y				The material supplier has declared that this material complies with Directive 2002/96/EC.

