

CERTIFICATE OF COMPLIANCE

DATE: January 3, 2024
SUBJECT: REGULATORY COMPLIANCE FOR VALUE PLASTICS PRODUCTS
PART AFFECTED: ALL VALUE PLASTICS PRODUCTS WITH SUFFIX OF -PK5
MATERIAL TYPE: Polyketone CS1826-CS8B382PK (M330F PRECO)
SUPPLIER: Hyosung

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				Comments below are mostly summaries of supplier compliance statements. Detailed supplier's statements available upon request. The manufacturer does not intentionally use allergens in the formulation of this product.
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)			N/A		To the Best of our Knowledge: This material has not been evaluated for compliance with the U.S. Federal Food, Drug and Cosmetics Act or the U.S. Food and Drug Administration regulations listed in Title 21 of the Code of Federal Regulations. Medical and pharmaceutical applications are not considered by these regulations.
4	3-A Sanitary Standards			N/A		This material has not be tested against these standards to our knowledge

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 of the listed molding compound grades. 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 of the listed molding compound grades. Due to the absence of use of these substances, we do not test for them.
8	ASTM D3222			N/A		Our Supplier has not indicated if this material meets these standards
9	ASTM F963 Standard Consumer Safety for Toy Safety			N/A		Our Supplier has not indicated if this material meets these standards
10	biocides	Y				Not intentionally added in the manufacturing of or formulation of the listed molding compound grades. 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			N/A		The facility manufacturing this product is not required to register with the Bioterrorism Act of 2002 because it is not a food facility.
13	BISPHENOL A (BPA)	Y				Not used in the manufacture or formulation of this product.
14	BSE/TSE	Y				Per the manufacturer, this 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				There are no California Proposition 65 reportable substances in this material.

16	Canadian WHMIS INGREDIENT DISCLOSURE LIST, Canadian Domestic Substance List (DSL), AND OTHER APPLICABLE REGULATIONS	Y				AS far as our knowledge this product is Not listed/Not regulated.
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				Based on a review of the final product composition, there are no listed substances known to be present above the reporting threshold.
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				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				No restricted substances are intentionally added or expected as process impurities above corresponding 0.1% threshold limits. (.01% for lead).
24	Drug Master File			N/A		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			N/A		Our Supplier has not indicated if this material meets these standards
27	EU Commission Décision 2009/251/EC – Diméthyle fumarate	y				To the best of our knowledge: This product does not use the biocide Dimethyl fumarate in its formulation or manufacture
28	EU Directive 2002/16/EC			N/A		Our Supplier has not indicated if this material meets these standards
29	EU Directive 2003/11/EC			N/A		Our Supplier has not indicated if this material meets these standards
30	EU Directive 76/769 EEC and Regulation EC 1907/2006 - Hexabromide Cyclooctane (HBCDD) and Hexachlorobenzene (HCB) –			N/A		Our Supplier has not indicated if this material meets these standards
31	EU Directive 90/128 and subsequent amendments			N/A		Our Supplier has not indicated if this material meets these standards
32	EU MDR			N/A		Our Supplier has not indicated if this material meets these standards
33	EU-Food Contact				See Comment	The composition of this material has not been assessed for use in contact with food according to the Commission Regulation (EU) 10/2011.
34	EU-Pharmacopeia (7th Edition)			N/A		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			N/A		Our Supplier has not indicated if this material meets these standards

36	European Regulation (EC) No. 1895/2005 (BADGE, BFDGE, NOGE)			N/A		Our Supplier has not indicated if this material meets these standards
37	Formaldehyde	Y				Not intentionally added in the manufacturing of or formulation of the listed molding compound grades. Due to the absence of use of these substances, we do not test for them.
38	Genetically Modified Organism Free					This product may utilize a component partially produced from plant material of unknown genetic origin in its formulation.
39	GHS	Y				This mixture is not classified according to US-GHS.
40	Gluten-Free				See Comment	This product may utilize a component partially produced from plant material of unknown genetic origin in its formulation.
41	ILFI – Red List Chemicals The International Living Future Institute	Y				Not intentionally added during the manufacture or formulation of this product.
42	In Vitro Hemocompatibility Assay (ISO)			N/A		This material has not be tested against these standards to our knowledge
43	International Inventories	Y				AS far as our knowledge this product is Not listed/Not regulated.
44	ISO 10993-1	Y				material complies with cytotoxicity, sensitization, and intracutaneous reactivity.
45	ISO 10993-10	Y				material complies with cytotoxicity, sensitization, and intracutaneous reactivity.
46	ISO 10993-11	Y				material complies with cytotoxicity, sensitization, and intracutaneous reactivity.
47	ISO 10993-12	Y				material complies with cytotoxicity, sensitization, and intracutaneous reactivity.
48	ISO 10993-18, EXTRACTABLES TESTING			N/A		This material has not be tested against these standards to our knowledge
49	ISO 10993-2	Y				material complies with cytotoxicity, sensitization, and intracutaneous reactivity.
50	ISO 10993-3	Y				material complies with cytotoxicity, sensitization, and intracutaneous reactivity.
51	ISO 10993-4	Y				material complies with cytotoxicity, sensitization, and intracutaneous reactivity.

52	ISO 10993-5	Y				material complies with cytotoxicity, sensitization, and intracutaneous reactivity.
53	ISO 10993-6			N/A		This material has not be 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 during the manufacture or formulation of this product.
56	Latex	Y				Not used in the manufacture or formulation of this product.
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 used in the manufacture or formulation of this product.
59	Natural Rubber	Y				Not used in the manufacture or formulation of this product.
60	Nitrosamines	Y				Not intentionally added during the manufacture or formulation of this product.
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				To the best of our knowledge, the above-mentioned products are not intentionally manufactured or formulated with this compound or substance.
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	<p>The following Material and compounds are Not intentionally used or added in the formulation or manufacture of this product, but due to the nature of these items we do not test for them: Aflatoxins, Alkylphenols/alkylphenols ethoxylate, Arsenic, Asbestos, Anodynes, Azoxy compounds, Benzotriazole, Beryllium, Beta hydroxy acids (BHA), Butylated hydroxytoluene 9BHT), Bisphenol A (BPS), Brominated compounds, Chlorofluorocarbons, Chlorinated naphthalene, Chlorinated paraffins, Creosote, Copper, Decabromodiphenyl ether (Deca-BDE), Dimethyl Fumarate (DMF), Dioxins, Halogenated Compounds, Hexabromocyclododecane, Iridium, Iron, Isocyanate, Jatropha, Lead, lindane, Melamine, Mercury, Mold Release, Molybdenum, Nickel, Nitrosamines, Nonylphenol-Nonylphenol ethoxylates, Octabromodiphenyl ethers, Organotin compounds, osmium, palladium, parabens, PCB, PCP, Pentabromodiphenyl ethers, Pentachlorophenol, Perchlorate, Platinum, Polycyclic Aromatic Hydrocarbons (PAH), Polybrominated biphenyls (PBB), Polybrominated Diphenyl Ethers (PBDEs), Polychlorinated biphenyls, Polychlorinated dibenzo-pdioxins/ Polychlorinated dibenzofurans, Polychlorinated Naphthalene (PCN), Polychlorinated Terphenyls (PCT), Polyvinyl Chloride, Polyurethane, Radioactive substances, Red Phosphorus, Rhodium, Rnase, Ruthenium, Silicone oils, TALC, Tin organic compounds, TNPP, toluene, triclosan, tri (2 4-di-tert-butylphenyl) phosphite, Vanadium, Vinyl Chloride, Vinylidene chloride, Xylene, Zinc</p>
67	Ozone Depleting Substances	Y				Supplier does not use Class I or Class II ODCs listed by the EPA or in the Resolution 2037/2000/EC in the manufacture or formulation of this product.

68	PA 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.
69	Persistent Organic Pollutants (POP)	Y				No substances used in the manufacture or formulation of product that are listed on EC 850/2004 Annex I as amended.
70	PFAS (Per and Polyfluoroalkyl substances)	Y				Not intentionally added during the manufacture or formulation of this product.
71	PFOA (Perfluoroalkyl carboxylic acid)	Y				Not intentionally added during the manufacture or formulation of this product.
72	PFOA (perfluorooctanoic acid)	Y				Not intentionally added during the manufacture or formulation of this product.
73	PFOS (Perfluorooctanoate sulfonate)	Y				Not intentionally added during the manufacture or formulation of this product.
74	Phthalates: Dibutyl phthalate Diocetyl 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 Di isobutyl 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 Di cyclohexyl phthalate DCP CAS# 84-61-7 Butyl benzyl phthalate BBP CAS# 85-68-7 Di-n-hexyl phthalate DnHP CAS# 84-75-3	Y				No Phthalates are intentionally added or expected as process impurities above corresponding 0.1% threshold limits.

75	REACH	Y				To the best of our knowledge, we do not expect this material to contain substances on the REACH / SVHC Candidate List at $\geq 0.1\%$ by weight. The presence of analytically detectable traces of these substances, which occur widely and have possibly been introduced into the product via raw materials, auxiliaries, and additives, cannot be excluded.
76	RoHS / RoHS 2 / RoHS 3	Y				The material supplier has declared that this material complies with 2011/65/EC and (EU) 2015/863.
77	SARA (311,312) Hazard Class	Y				AS far as our knowledge this product is Not listed/Not regulated.
78	SARA 313 Regulated Chemicals	Y				AS far as our knowledge this product is Not listed/Not regulated.
79	SARA Title III – Section 302 Extremely Hazardous Chemicals:	Y				AS far as our knowledge this product is Not listed/Not regulated.
80	Transport Classification	Y				Not listed/Not regulated.
81	TSCA	Y				Components are listed or considered exempt.
82	Unactivated Partial Thromboplastin Time Assay (ISO)			N/A		This material has not be tested against these standards to our knowledge
83	US Pharmacopoeia Class VI	Y				This material has been tested and has met the biocompatibility and physiochemical testing requirements according to USP Plastics Class VI.
84	USDA			N/A		This material has not be tested against these standards to our knowledge
85	USP 381 (Elastomeric Closures for injection)			N/A		This material has not be tested against these standards to our knowledge
86	USP 643 (Total Organic Carbon)			N/A		This material has not be tested against these standards to our knowledge
87	USP 661			N/A		This material has not be tested against these standards to our knowledge
88	USP 85 (Endotoxin)			N/A		This material has not be tested against these standards to our knowledge
89	USP 88			N/A		This material has not be tested against these standards to our knowledge
90	USP 851 (Static Sorption Study of Phenol)			N/A		This material has not be tested against these standards to our knowledge

91	USP 87 (L929 MEM Elution)			N/A		This material has not be tested against these standards to our knowledge
92	Volatile Organic Compounds (VOCs)	Y				Not used in the manufacture or formulation of this product.
93	WEEE			N/A		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.