Nordson MEDICAL
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nordsonmedical.com

CERTIFICATE OF COMPLIANCE

DATE:	April 11th, 2023
SUBJECT:	**REGULATORY COMPLIANCE FOR VALUE PRODUCTS**
PART AFFECTED:	ALL VALUE PRODUCTS WITH SUFFIX OF -8012, -81
MATERIAL TYPE:	LUSTRAN 348 ABS (SNOW WHITE AND LACE WHITE)
SUPPLIER:	INEOS http://www.ineos.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 in order 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. 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.

Please contact us with any further questions you may have.

Sincerely,

Brian Benton
Manufacturing & Quality Manager

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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
		YES	NO	N/A	TBD	Comments below are mostly summaries of supplier compliance statements. Detailed supplier's statements available upon request.
1	Arsenic, Beryllium, Cadmium, Chromium(VI), Lead, Mercury, Selenium and their compounds	Y				Not used in the manufacture or formulation of this product.
2	Asbestos	Y				Not used in the manufacture or formulation of this product.
3	Azodyes (Directive 2002/61/EC)	Y				Not used in the manufacture or formulation of this product.
4	Benzotriazole	Y				Not used in the manufacture or formulation of this product.
5	Biocompatibility / ISO 10993	Y				Lustran ABS 348 resin is designated as "medical-grade" and has met the requirements of the FDA-Modified ISO 10993, Part I "Biological Evaluation of Medical Devices" tests with human tissue contact time of 30 days or less.
6	BHA	Y				Not used in the manufacture or formulation of this product.
7	BPA	Y				Not used in the manufacture or formulation of this product.
8	BPS	Y				Not used in the manufacture or formulation of this product.
9	BSE / TSE	Y				Please also be advised that these resins do contain materials that may be derived from vegetable oils as well as tallow sources. Our supplier has confirmed that they are using robust and rigorous processing conditions which comply with the relevant European directive EMA 410/01 rev 3. Due to heat treatment conditions of tallow during the production process of fatty acid derivatives, all possible BSE/TSE sources are inactivated.
10	California's Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65)	See Comments				From the list of California Proposition 65 chemicals (as of May 25, 2018) the supplier has confirmed the following are present in this resin: - Residual Styrene, CAS 100-42-5: ≤ 0.1% - Residual Acrylonitrile, CAS 107-13-1: ≤ 0.01%
11	Chlorinated naphthalenes	Y				Not used in the manufacture or formulation of this product.
12	Chlorinated paraffins and SCCP	Y				Not used in the manufacture or formulation of this product.
13	Conflict Minerals	Y				The following substances have not been intentionally added during the suppliers manufacturing process: Tin, Tantalum, Tungsten, or Gold sourced from the Democratic Republic of Congo.

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14	DEHP	Y				Not used in the manufacture or formulation of this product.
15	Dimethylfumarate	Y				Not used in the manufacture or formulation of this product.
16	Drug Master File	Y				13048
17	EU MDR	Y				Concerning regulation (EU) 2017/745 regarding materials used in medical devices; in reference to Annex I, Chapter II, Part 10.4 (substances), **the supplier confirms this resin does not contain the following substances at concentrations above 0.1 weight %** based on the formulation, manufacturing process and information from the raw material suppliers: - CMR Category 1A or 1B in accordance with Part 3 of Annex VI of Regulation (EC) No 1272/2008. - Endocrine-disrupting substances for which there is scientific evidence of probable serious effects to human health and which are identified either in accordance with the procedure set out in Article 59 of Regulation (EC) No 1907/2006 or, once a delegated act has been adopted by the Commission pursuant to the first subparagraph of Article 5(3) of Regulation (EU) No 528/2012. - Phthalates In addition, the following substances are not used as intentional additives or ingredients in the manufacture of this resin as referenced in part 10.6: - Nanoparticles (according to Commission recommendation 2011/696/EU and OECD, ISO, SCENIHR (2007b))
18	Europe Chapter 3.2.2 Pharmacopoeia	Y				Not used in the manufacture or formulation of this product.
19	FDA 21 CFR 181.32	Y				Not used in the manufacture or formulation of this product.
20	Flame Retardants (Non-halogenated or halogenated)	Y				Not used in the manufacture or formulation of this product.
21	Formaldehyde	Y				Not used in the manufacture or formulation of this product.
22	Hexabromo-cyclododecane (HBCD, CAS Nos. 25637-99-4, 3194-55-6)	Y				Not used in the manufacture or formulation of this product.
23	Human origin materials	Y				Not used in the manufacture or formulation of this product.
24	Japan Pharmacopoeia	Y				Not used in the manufacture or formulation of this product.
25	Jatropha	Y				Not used in the manufacture or formulation of this product.
26	Latex	Y				No Natural rubber and natural rubber latex and derivatives thereof are used in the manufacture or formulation of this product.
27	Lindane (CAS No. 58-89-9)	Y				Not used in the manufacture or formulation of this product.

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28	Melamine (CAS No. 108-78-1)	Y				Not used in the manufacture or formulation of this product.
29	Nanomaterials	Y				Not used in the manufacture or formulation of this product.
30	Nitrosamines	Y				Not used in the manufacture or formulation of this product.
31	Organotin compounds	Y				Not used in the manufacture or formulation of this product.
32	Perfluorinated chemicals (PFCs)	Y				Per- and polyfluoroalkyl substances (PFAS), including, but not exclusive to: PFOA, Perfluorooctanoic acid (CAS #335-67-1) PFOS, Perfluorooctane sulfonate (CAS #1763-23-1) are not used in the manufacture or formulation of this product.
33	PFAS PFOA PFOS	Y				Not used in the manufacture or formulation of this product.
34	Phthalates	Y				Not used in the manufacture or formulation of this product.
35	Polybrominated biphenyls (PBBs)	Y				Not used in the manufacture or formulation of this product.
36	REACH	Y				As of January 17th, 2023 there are no substances on the SVHC list that are present in this product.
37	RoHS / RoHS 2 / RoHS 3	Y				The material supplier has declared that this material complies with 2002/95/EC, 2003/11/EC and 2011/65/EU (also known as RoHS) and lastly amended by Commission Delegated Directive 2015/863/EU of 31 March 2015 .
38	TSCA	Y				This material is not intentionally formulated with any of the following compounds: • Decabromodiphenyl ether (DecaBDE) • Phenol, isopropylated phosphate (3:1) (PIP (3:1)) • 2,4,6-Tris(tert-butyl)phenol (2,4,6-TTBP) • Hexachlorobutadiene (HCBD) • Pentachlorothiophenol (PCTP)
39	USP Class VI	Y				