

## CERTIFICATE OF COMPLIANCE

**DATE:** May 12, 2025  
**SUBJECT:** REGULATORY COMPLIANCE FOR VALUE PLASTICS PRODUCTS  
**PART AFFECTED:** ALL VALUE PRODUCTS WITH SUFFIX OF -J2A or -20  
**MATERIAL TYPE:** Kynar 740 Natural PVDF  
**SUPPLIER:** ARKEMA <http://www.arkema-inc.com/index.cfm>

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](mailto: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**  
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
		Y	N	N/A	See Comment	
1	Allergens (Global Food)	Y				Based upon the food allergenic substance listings – a specific list of allergens which are not present are available upon request.
2	Corn / Plant / Vegetable			N/A		The manufacturer of this material has indicated this product is manufactured from plant-based raw materials but is corn-free.
3	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.

4	<p><b>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)</b></p>	Y				<p><b>21 CFR 177.2510, 177.2600, 177.1520 (Food Contact):</b> Intended for repeated use applications only and provided that the food contact article in its finished form meets the extractive requirements of paragraph (b). Extraction testing to verify compliance with this section is the responsibility of the finished article manufacturer. Further, paragraph (c) requires that in accordance with good manufacturing practice, finished food-contact articles containing the polyvinylidene fluoride resins shall be thoroughly cleansed prior to their first use in contact with food.</p>
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5	<b>3-A Sanitary Standards</b>			N/A		This material has not been tested against these standards to our knowledge.
6	<b>AD-DSL (the AeroSpace &amp; Defence Declarable)</b>				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.
7	<b>Animal Derived Materials</b>	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	<b>Aromatic Amines</b>	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.
9	<b>ASTM D3222</b>			N/A		Our Supplier has not indicated if this material meets these standards.

10	<b>ASTM F963 Standard Consumer Safety for Toy Safety</b>			N/A		Our Supplier has not indicated if this material meets these standards.
11	<b>biocides</b>	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.
12	<b>Biocompatibility</b>	Y				Components have been tested by the raw material manufacturer under USP Class VI and ISO 10993 standards LISTED BELOW.
13	<b>Bioterrorism Act of 2002</b>			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.

14	<b>BISPHENOL A (BPA)</b>	Y				Not used in the manufacture or formulation of this product.
15	<b>BSE/TSE</b>	Y				Based on a review of the product composition, this product is not known or expected to contain substances which are animal derived or associated with BSE/TSE infectivity.
16	<b>California Prop 65</b>	Y				Based on the final product composition this product does not contain any components or chemicals currently known to the State of California to cause cancer, birth defects or reproductive harm at levels which would be subject to Proposition 65.
17	<b>Canadian WHMIS INGREDIENT DISCLOSURE LIST, Canadian Domestic Substance List (DSL), AND OTHER APPLICABLE REGULATIONS</b>	Y				Canadian Domestic Substances List (DSL) DSL All components of this product are on the Canadian DSL.
18	<b>Chemicals of High Concern to Children (CHCC) Maine, Vermont, Washington</b>	Y				To the best of our knowledge, this product does not contain chemicals at levels which require reporting under this statute.
19	<b>China RoHS</b>	Y				Based on a review of the final product composition, there are no listed substances known to be present above the reporting threshold.

20	Clean Air Act, 40 CFR	Y			<p>Under the Clean Air Act, US EPA is required to regulate emissions of hazardous air pollutants (HAPs). This original list included 189 pollutants. Since 1990, EPA has modified the list through rulemaking to include This assessment is based on the 187 substances identified by the EPA as hazardous air pollutants including the general class of glycol ether substances as defined by the Toxic Release Inventory (TRI) (EPA 745-R-00- 004).</p> <p>Based on the final product composition, this product is not known or expected to contain US HAPs as defined by the regulation.</p>
21	Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) - Reportable Quantity (RQ):	Y			<p>The components in this product are either not CERCLA regulated, regulated but present in negligible concentrations, or regulated with no assigned reportable quantity.</p>
22	CONEG	Y			<p>Model Toxics in Packaging Legislation (also referred to as CONEG) concerns restrictions on the use of certain hazardous substances in packaging or packaging components (including printing inks used in packaging), and restricts the sum of the incidental concentration levels of lead, mercury, cadmium and hexavalent chromium present in the product to a level equal to or less than 100 parts per million by weight</p> <p>Based on a review of the final product composition, this product is not known to contain CONEG substances at or above the 100 ppm reporting threshold.</p>

23	<b>Conflict Minerals</b>	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.
24	<b>Consumer Product Safety Improvement Act of 2008 (CPSIA)</b>	Y				To the best of our knowledge This product is not manufactured or formulated with lead, di-(2-ethylhexyl) phthalate (DEHP), dibutyl phthalate (DBP), or benzyl butyl phthalate (BBP). Our supplier has indicated that it does not contain these materials above the limits set in the Consumer Product Safety Improvement Act of 2008, Title 1, Sections 101 and 108.
25	<b>Drug Master File</b>			N/A		To the best of our knowledge this Material is not Listed.

26	<b>Endotoxins</b>				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.
27	<b>EU 200/53/EC &amp; 2002/525/EC - END-OF-Life Vehicles Regulation</b>			N/A		Our Supplier has not indicated if this material meets these standards.
28	<b>EU Commission Decision 2009/251/EC – Dimethylfumarate</b>	Y				To the best of our knowledge: This product does not use the biocide Dimethyl fumarate in its formulation or manufacture.
29	<b>EU Directive 2002/16/EC</b>			N/A		Our Supplier has not indicated if this material meets these standards.

30	<b>EU Directive 2003/11/EC</b>			N/A		Our Supplier has not indicated if this material meets these standards.
31	<b>EU Directive 76/769 EEC and Regulation EC 1907/2006 - Hexabromo Cyclododecane (HBCDD) and Hexachlorobenze (HCB) –</b>			N/A		Our Supplier has not indicated if this material meets these standards.
32	<b>EU Directive 90/128 and subsequent amendments</b>			N/A		Our Supplier has not indicated if this material meets these standards.
33	<b>EU MDR</b>	Y				Based on review of the final product composition, substances listed in the EU Regulation 2017/745 on medical devices, Chapter II, Section 10.4.1, regarding the absence of substances above 0.1% which are (a) carcinogenic, mutagenic, or toxic to reproduction (“CMR”) of category 1A or 1B, and (b) substances having endocrine-disrupting properties for which there is scientific evidence of probable serious effects to human health, are not known to be present above the declaration threshold.
	<b>EU-Food Contact</b>				See Comment	In the area of food contact materials, plastics materials and articles are regulated by a specific measure harmonized at EU level by Regulation (EU) 10/2011. Some materials such as but not limited to coatings, adhesives, printing inks, silicones, rubbers, are not covered by Regulation (EU) No 10/2011 and do not have such specific EU harmonized legislation. These materials are nevertheless subject to the general requirements of EU framework Regulation (EC) 1935/2004 and where existing, to the relevant national legislations. In such case, this statement and any information provided herein does not constitute a legally binding obligation for Nordson or it’s supplier and provided for your guidance only.

34						<p>This product is manufactured according to the Good Manufacturing Practices, as defined by the specific requirements of Article 3 of Framework Regulation (EC) No 1935/2004.</p> <p>Particular measures have been implemented to confirm the compliance of the raw materials and to assure a good level of traceability of this product, in accordance with the requirements of Articles 16 and 17 of Framework Regulation (EC) No 1935/2004.</p>
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35	<b>EU-Pharmacopeia (7th Edition)</b>			N/A		Our Supplier has not indicated if this material meets these standards.
36	<b>European Directive (94/62/EC) (Article 11), (2004/12/EC), and its amendments Packaging and Packaging Waste</b>			N/A		Our Supplier has not indicated if this material meets these standards.
37	<b>European Regulation (EC) No. 1895/2005 (BADGE, BFDGE, NOGE)</b>			N/A		Our Supplier has not indicated if this material meets these standards.
38	<b>Formaldehyde</b>	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.
39	<b>Genetically Modified Organism Free</b>	Y				Not intentionally added during manufacture or formulation of this product.

40	<b>GHS</b>	Y				Meets the requirements for classification and labeling as hazardous under GHS requirements.
41	<b>Gluten-Free</b>	Y				Not intentionally added during manufacture or formulation of this product.
42	<b>ILFI – Red List Chemicals The International Living Future Institute</b>	Y				This product is not known to contain substance(s) identified as ILFI Red List Chemicals above the reporting threshold.
43	<b>In Vitro Hemocompatibility Assay (ISO)</b>			N/A		This material has not been tested against these standards to our knowledge.



44	<b>International Inventories</b>	Y				AS far as our knowledge this product is Not listed/Not regulated.
45	<b>ISO 10993-1</b>			N/A		This material has not been tested against these standards to our knowledge.
46	<b>ISO 10993-10</b>			N/A		This material has not been tested against these standards to our knowledge.
47	<b>ISO 10993-11</b>			N/A		This material has not been tested against these standards to our knowledge.
48	<b>ISO 10993-12</b>			N/A		This material has not been tested against these standards to our knowledge.
49	<b>ISO 10993-18, EXTRACTABLES TESTING</b>			N/A		This material has not been tested against these standards to our knowledge.
50	<b>ISO 10993-2</b>			N/A		This material has not been tested against these standards to our knowledge.
51	<b>ISO 10993-3</b>			N/A		This material has not been tested against these standards to our knowledge.
52	<b>ISO 10993-4</b>	Y				Modified ASTM Hemolysis (Direct Contact Method) Tested on Human Blood. Result: Pass Modified ASTM Hemolysis (Extract Method) Extracted in Phosphate Buffered Saline at 50°C for 72 hours. Tested with Human Blood. Result: Pass.
53	<b>ISO 10993-5</b>	Y				Cytotoxicity (MEM Elution) Extract tested on L-929 Mouse Fibroblast cells for 72 hours. Result: Pass.
54	<b>ISO 10993-6</b>			N/A		This material has not been tested against these standards to our knowledge.

55	<b>Kosher</b>		N			Supplier does not certify this resin to be Kosher or in compliance with Kosher requirements.
56	<b>Lactose</b>	Y				Not used in the manufacture or formulation of this product.
57	<b>Latex</b>	Y				Not used in the manufacture or formulation of this product.
58	<b>MA Right to Know Extraordinarily Hazardous Substance List</b>	Y				To the best of our knowledge, this product does not contain chemicals at levels which require reporting under this statute.

59	<b>Melamine</b>	Y				Not intentionally used in the manufacture or formulation of this product.
60	<b>Natural Rubber</b>	Y				Not used in the manufacture or formulation of this product.
61	<b>Nitrosamines</b>	Y				To the best of our knowledge, none of the following substances are intentionally added during manufacturing or formulation of this product: - Nitrosatable substances, - Nitrosating agent that may form nitrosamines, and/or - Nitrosamines. Therefore, no nitrosamines are expected in the final product.
62	<b>NJ Right to Know Regulated Chemicals</b>	Y				To the best of our knowledge, this product does not contain chemicals at levels which require reporting under this statute.
63	<b>Nanoparticles</b>	Y				To the best of our knowledge, the above-mentioned products are not intentionally manufactured or formulated with this compound or substance.
64	<b>NSF-61</b>				See Comment	See <a href="https://www.nsf.org/certified-products-systems">https://www.nsf.org/certified-products-systems</a> for reference.
65	<b>NSF-14</b>				See Comment	See <a href="https://www.nsf.org/certified-products-systems">https://www.nsf.org/certified-products-systems</a> for reference.
66	<b>NSF-51</b>				See Comment	See <a href="https://www.nsf.org/certified-products-systems">https://www.nsf.org/certified-products-systems</a> for reference.

67	Other Substance/compounds				<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, Azodyes, 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, Hexabomocyclododecane, Iridium, Iron, Isocyanate, Jatropa, 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,</p>
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					<p> Zinc, C10-rich (DIDP)68515-49-1, 1,2-Benzenedicarboxylic acid, di-C9-11-branched alkyl esters, C10-rich (DINP), 68515-48-0, Benzyl butyl phthalate (BBP) 85-68-7, Bis(2-ethyl-1-hexyl) tetrabromophthalate 26040-51-7, Bis(2-ethylhexyl)phthalate (DEHP) 117-81-7, Bis(2-methoxyethyl) phthalate 117-82-8, Bisphenol A (BPA) 80-05-7, Bisphenol AF 1478-61-1, Bisphenol B 77-40-7, Bisphenol F (BPF) 620-92-8, Bisphenol F (BPF) 87139-40-0, Bisphenol S 80-09-, Dibutyl phthalate (DBP) 84-74-2, Dicyclohexyl phthalate 84-61-7, Diethyl phthalate 84-66-2, Diisobutyl phthalate 84-69-5, Diisodecyl phthalate (DIDP) 26761-40-0, Diisohexyl phthalate (DIHxP) 71850-09-4, Diisononyl phthalate (DINP) 28553-12-0, Diisopentylphthalate 605-50-5, Di-n-hexyl phthalate (DNHP) 84-75-3, Di-n-octyl phthalate (DNOP) 117-84-0, Di-n-pentyl phthalate 131-18-0, Mono-n-butyl phthalate 131-70-4, Phthalic anhydride, 2-Methoxyethanol 0.001 109-86-4 , Butyldiglycol 112-34-5 , Diethylene glycol dimethyl ether (DEGDME) 111-96-6, Diethylene glycol methyl ether (DEGME) 111-77-3, Ethyldiethyleneglycol 111-90-0, Ethylene glycol dimethyl ether (EGDME) 110-71-4, Ethylene glycol ethyl ether acetate (EGEEA) 111-15-9, Ethylene glycol methyl ether acetate (EGMEA) 110-49-6, Ethylene glycol monobutyl ether (EGBE) 111-76-2, Ethylene glycol monoethyl ester 0.001 110-80-5, Triethylene glycol dimethyl ether (TEGDME) 112-49-2, cis 1,4 Polyisoprene, Natural Rubber, Polyisoprene, cis, Epichlorohydrin, Polybrominated Biphenyls (PBBs),Polybrominated diphenylethers (PBDEs), </p>
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						<p>Polybrominated Diphenyl Ethers (PBDEs and DecaBDE), Polybrominated Terphenyls (PBTs), Polychlorinated biphenyls (PCB), Polychlorinated naphthalenes (PCN), Polychlorinated terphenyls (PCT), Short Chain Chlorinated paraffins (SCCP), Tris(2-chloroethyl) phosphate 0.005, Novolac glycidyl ethers (NOGE), Bis(hydroxyphenyl)methane bis(2,3-epoxypropyl)ethers (BFDGE) (CAS: 39817-09-9), 2,2-bis(4-hydroxyphenyl)propane bis(2,3-epoxypropyl) ether (BADGE) (CAS: 1675-54-3) and some of its derivatives:- BADGE.H2O (CAS: 76002-91-0)- BADGE.2H2O (CAS: 5581-32-8)- BADGE.HCl (CAS: 13836-48-1)- BADGE.2HCl (CAS: 4809-35-2)- BADGE.H2O.HCl (CAS: 227947-06-0).</p>
68	<b>Ozone Depleting Substances</b>	9				Based on the product composition this product is not known or expected to contain Ozone Depleting Substances as defined by the regulation.
69	<b>PA Right to Know Regulated Chemicals</b>				See Comment	Ethene, 1,1-difluoro-, homopolymer 24937-79-9.
70	<b>Persistent Organic Pollutants (POP)</b>	Y				Does not intentionally use substances listed in Annexes I, 11, III and IV of Regulation (EU) No 2019/1021 and its amendments for the manufacture of the above-mentioned product. Therefore, such substances are not expected to be present.
71	<b>PFAS (Per and Polyfluoroalkyl substances)</b>	Y				Not used in the manufacture or formulation of this product.
72	<b>PFCA (Perfluoroalkyl carboxylic acid)</b>	Y				Not used in the manufacture or formulation of this product.
73	<b>PFOA (perfluorooctanoic acid)</b>	Y				Not used in the manufacture or formulation of this product.
74	<b>PFOS (Perfluorooctanoate sulfonate)</b>	Y				Not used in the manufacture or formulation of this product.

75	<p><b>Phthalates: Dibutyl phthalate</b>  <b>Diethyl phthalate (DEHP) Di-</b>  <b>isononyl phthalateDimethyl</b>  <b>phthalate DMP</b>  <b>CAS# 131-11-3</b>  <b>Diethyl phthalate DEP</b>  <b>CAS# 84-66-2</b>  <b>Diallyl phthalate DAP</b>  <b>CAS# 131-17-9</b>  <b>Di-n-propyl phthalate DPP</b>  <b>CAS# 131-16-8</b>  <b>Di-n-butyl phthalate DBP</b>  <b>CAS# 84-74-2</b>  <b>Diisobutyl phthalate DIBP</b>  <b>CAS# 84-69-5</b>  <b>Butyl cyclohexyl phthalate BCP</b>  <b>CAS# 84-64-0</b>  <b>1,2-bis(2-methoxyethyl)ester</b>  <b>DMEP</b>  <b>CAS# 117-82-8</b>  <b>[bis(2-methoxyethyl) phthalate]</b>  <b>Di-n-pentyl phthalate DNPP</b>  <b>CAS# 131-18-0</b>  <b>1,2-Benzenedicarboxylic acid,</b>  <b>dipentyl ester branched</b>  <b>and linear</b>  <b>CAS# 84779-61-3</b>  <b>Dicyclohexyl phthalate DCP</b>  <b>CAS# 84-61-7</b>  <b>Butyl benzyl phthalate BBP</b>  <b>CAS# 85-68-7</b>  <b>Di-n-hexyl phthalate DnHP</b>  <b>CAS# 84-75-3</b></p>	Y				Not intentionally added during the manufacture or formulation of this product.
76	REACH	Y				Our supplier confirms that substances defined by Article 57 in Regulation (EC) No. 1907/2006 (REACH) and published on the most current candidate list according to Annex XIV at the ECHA website, SVHC issued January 21, 2025 (cumulative), or chemical substances restricted for specific applications listed in Annex XVII or chemicals listed in the substance of very high concern identification list are not known to be present in the product above the declaration threshold.

77	<b>RoHS / RoHS 2 / RoHS 3</b>	Y			As defined in the RoHS Directive 2011/65/EU & 2015/863-EU and/or amendments restricting the use of Heavy Metals, PBB's, PBDE's, and phthalates. Based on a review of the final product composition, there are no RoHS substances known to be present above the reporting threshold.
78	<b>SARA (311,312) Hazard Class</b>	Y			Non-hazardous under Section 311/312.
79	<b>SARA 313 Regulated Chemicals</b>	Y			This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.
80	<b>SARA Title III – Section 302 Extremely Hazardous Chemicals:</b>	Y			The components in this product are either not SARA Section 302 regulated or regulated but present in negligible concentrations.
81	<b>Transport Classification</b>	Y			Not regulated as hazardous for shipment.
82	<b>TSCA</b>	Y			This material is in compliance with TSCA Inventory requirements for commercial purposes. Under the U.S. Environmental Protection Agency (EPA) Toxic Substances Control Act (TSCA), as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, EPA issued final rules to reduce exposures to certain chemicals that are persistent, bioaccumulative and toxic (PBT). EPA is prohibiting either the manufacture (including import), processing, and/or distribution in commerce unless use is specifically exempted in the final rule for the substance. Arkema is providing the information about the presence of these PBTs in the product(s) to aid its customers. Customers should consult the final rules in docket EPA-HQ-OPPT-2019-0080 for their specific situation. Based on a review of the product composition, this product is not known to contain TSCA Section 6(h) PBTs.

83	<b>Unactivated Partial Thromboplastin Time Assay (ISO)</b>			N/A		This material has not been tested against these standards to our knowledge.
84	<b>US Pharmacopoeia Class VI</b>	Y				<p>Acute Systemic Injection Test Extracted in Normal Saline, Alcohol in Saline, PEG 400 and Vegetable oil (Cottonseed or Sesame oil) at 50°C, for 72 hours. Injected in Mouse. Result: Pass</p> <p>Intracutaneous Irritation Test Extracted in Normal Saline, Alcohol in Saline, PEG 400 and Vegetable oil (Cottonseed or Sesame oil) at 50°C, for 72 hours. Tested with Rabbit. Result: Pass</p> <p>Intramuscular Implantation Test Implanted in Rabbit for 1 week. Result: Pass</p>
85	<b>USDA</b>				See Comment	For use in process or storage area to contact with meat or poultry food products.
86	<b>USP 381 (Elastomeric Closures for injection)</b>			N/A		This material has not been tested against these standards to our knowledge.
87	<b>USP 643 (Total Organic Carbon)</b>			N/A		This material has not been tested against these standards to our knowledge.
88	<b>USP 661</b>			N/A		This material has not been tested against these standards to our knowledge.
89	<b>USP 665 (Single-use systems (SUS) &amp; the risk associated with extractable &amp; leachables (E&amp;L))</b>			N/A		This material has not been tested against these standards to our knowledge.
90	<b>USP 85 (Endotoxin)</b>			N/A		This material has not been tested against these standards to our knowledge.
91	<b>USP 851 (Static Sorption Study of Phenol)</b>			N/A		This material has not been tested against these standards to our knowledge.
92	<b>USP 87 (L929 MEM Elution)</b>			N/A		This material has not been tested against these standards to our knowledge.
93	<b>USP 88</b>			N/A		This material has not been tested against these standards to our knowledge.
94	<b>Volatile Organic Compounds (VOCs)</b>	Y				Not used in the manufacture or formulation of this product.



95	WEEE			N/A	<p>The WEEE Directive 2012/19/EU 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.</p> <p>However, for the above-mentioned products the supplier confirms that they do not contain any substances listed in Annex II of this directive (2002/96/EC) as an intentional ingredient.</p>
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