

Food Allergens

Regarding: Bioprocess Single-Use Consumables and Filtration Products

Background

A food allergy is a hyper-response of a body's immune system to food. Allergy symptoms can range from mild to severe, and millions of sensitive individuals suffer from food allergies every year.

The United States (US) Food Allergen Labeling and Consumer Protection Act (FALCPA) was created in 2004 to improve food labeling information for the millions of individuals who suffer from food allergies. FALCPA states that eight major foods or food groups—milk, eggs, fish, Crustacean shellfish, tree nuts, peanuts, wheat, and soybeans—account for 90 percent of food allergies.

Regulation (EU) No 1169/2011 also addresses labeling of foods that are known to cause allergic reactions in individuals. Substances or products causing allergies or intolerances are listed in Annex II of this Regulation.

Cytiva's bioprocess single-use consumables and filtration products are not intended to be food, ingredients in food, or direct components in food.


Statement

It is hereby stated that the food allergens noted in the regulations above are not primary raw materials, nor are they intentionally added during the manufacturing process of Cytiva's bioprocess single-use and filtration products. To the best of our knowledge, these food allergens are not present in the materials we purchase from our suppliers, with one exception, which is described below.

Some products contain a red cap (product number 87940020) that may or may not be removed during operation. This cap contains soybean or soybean-derived components. The products containing the red cap are as follows:

- All WAVE and M*bag products
- Additional products from the ReadyCircuit™, ReadyToProcess™, and Xcellerex™ lines listed in Appendix 1

Cytiva appreciates the opportunity to serve our valued customers and is dedicated to improving our capabilities to manufacture and deliver products and services that meet or exceed your needs consistently.

Signature: 	DocuSigned by:	Date: 17 JUNE 2021
Name: Susan Boucher	5300EF5718844C1...	Title Regulatory Support Manager

The information herein is provided to the best of our knowledge and belief, based on the information we have been given and the information available to us at the time that this document was issued. The information may change as additional facts come to light, or as the circumstances warrant. Your use hereof is hence at your own risk and does not relieve you of your own responsibility for checking the suitability of our products for your intended use.

Appendix 1

ReadyCircuit Assemblies

Product Numbers	Description
29399663	XDR-500L Fortem™ Microbial Bag
888-1902	100L Custom Storage Bag
RC2010-0015	20L, Custom Assembly
RC2010-0016	10L NFF, Custom
RC2010-0017	5L NFF, Custom
RC2010-0021	5L NFF, Custom
RC2011-0003	10L NFF Custom
RC2011-0006	10L Cell Harvest Assembly
RC2011-0007	20L Cell Harvest Assembly
RC2011-0008	50L Cell Harvest Assembly
RC2011-0011	Hollow Fiber Circuit
RC2011-0023	5L CFF Custom
RC2011-0031	Process Bag, CFF
RC2011-0034	1L CFF Custom
RC2011-0060	500ml Manifold
RC2011-0110	10L Recirculation Bag Assembly
RC2011-0112	Recovery Bag Assembly
RC2011-0113	Buffer Condition Assembly
RC2011-0114	Process Feed Assembly
RC2011-0163	10L, Custom, NFF
RC2012-0030	5L, Custom Assembly
RC2012-0032	5L Recirculation Bag Assembly
RC2012-0043	10L, Custom Assembly
RC2012-0055	10L, Custom Assembly
RC2012-0056	5L, Custom Assembly
RC2012-0058	10L, Custom Assembly
RC2012-0060	5L Manifold, Custom
RC2012-0061	1L Manifold, Custom
RC2012-0062	5L Manifold, Custom
RC2012-0063	1L Manifold, Custom
RC2012-0064	20L Manifold, Custom

Product Numbers	Description
RC2012-0065	50L Manifold, Custom
RC2012-0066	20L Manifold, Custom
RC2012-0067	50L Manifold, Custom
RC2012-0068	500mL Manifold, Custom
RC2012-0085	1L Custom Assembly
RC2012-0086	5L Custom Assembly
RC2012-0087	10L, Custom Assembly
RC2012-0088	20L, Custom Assembly
RC2012-0112	50L, Custom Assembly
RC2012-0129	250mL Custom Assembly
RC2012-0130	500mL Custom Assembly
RC2012-0138	20L, Custom Assembly
RC2012-0144	20L, Custom Assembly
RC2012-0067	50L Manifold, Custom
RC2012-0068	500mL Manifold, Custom
RC2012-0152	50L, Custom Assembly
RC2012-0153	50L, Custom Assembly
RC2013-0001	5L Custom Manifold
RC2013-0007	10L, Custom
RC2013-0034	250mL, Custom Assembly
RC2013-0035	10L, Custom Assembly
RC2013-0036	5L, Custom Assembly
RC2013-0037	1L, Custom Assembly
RC2013-0041	20L, Custom Assembly
RC2013-0043	50L, Custom Assembly
RC2013-0049	NFF Jumper Assembly, Custom
RC2013-0071	5L, Custom Assembly
RC2013-0076	5L, Custom Assembly
RC2013-0077	1L, Custom Assembly

Product Numbers	Description
RC2013-0078	1L Custom Assembly
RC2014-0011	5L, Custom Assembly
RC2014-0012	20L, Custom Assembly
RC2014-0013	50L, Custom Assembly
RC2014-0032	250ml, Custom Assembly
RC2014-0033	500ml, Custom Assembly
RC2014-0043	5L, Custom Assembly
RC2014-0044	50L, Custom Assembly
RC2014-0051	100L, Custom Assembly
RC2014-0052	200L, Custom Assembly
RC2014-0089	20L, Custom Assembly
RC2014-0090	10L, Custom Assembly
RC2014-0100	20L, Custom Assembly
RC2014-0101	200L, Custom Assembly
RC2014-0107	10L, Custom Assembly
RC2014-0108	20L, Custom Assembly
RC2014-0132	1L, Custom Assembly
RC2015-0003	20L, Custom Assembly
RC2015-0004	5L, Custom Assembly
RC2015-0005	500mL, Custom Assembly
RC2015-0006	5L, Custom Assembly
RC2015-0008	20L, Custom Assembly
RC2015-0021	250mL, Custom Manifold
RC2015-0022	1L, Custom Assembly
RC2015-0025	10L, Custom Assembly
RC2015-0029	20L, Custom Assembly
RC2015-0066	20L Custom Assembly
RC2015-0089	Jumper Assembly, Custom
RC2015-0103	10L, Custom Assembly

Appendix 1, Continued

ReadyCircuit Assemblies, Continued

Product Numbers	Description
RC2015-0104	50L, Custom Assembly
RC2015-0122	250mL Custom Assembly
RC2015-0126	Manifold Assembly, Custom
RC2015-0127	10L, Custom Assembly
RC2015-0128	Jumper Assembly, Custom
RC2015-0130	50L, Custom Assembly
RC2016-0013	1L, Custom Assembly
RC2016-0020	1L, Custom Assembly
RC2016-0031	20L Custom Assembly
RC2016-0032	50L Custom Assembly
RC2016-0036	20L, Custom Assembly
RC2016-0047	5L Custom Assembly
RC2016-0054	5L Custom Assembly
RC2016-0092	20L Custom Assembly
RC2016-0129	Jumper Assembly, Custom
RC2016-0162	Jumper Assembly, Custom
RC2016-0165	1L, Custom Assembly
RC2017-0005	20L, Custom Assembly
RC2017-0007	Manifold Assembly, Custom
RC2017-0014	10L Custom Assembly
RC2017-0015	50L Custom Assembly
RC2017-0021	50L Custom Assembly
RC2017-0030	50mL Assembly, 20 Pack, Custom
RC2017-0037	Jumper Assembly, Custom
RC2017-0056	5L Custom Assembly
RC2017-0073	10L, Custom Assembly
RC2017-0074	20L, Custom Assembly
RC2017-0075	10L, Manifold, Custom
RC2017-0076	Manifold Assembly, Custom

Product Numbers	Description
RC2017-0102	Jumper Assembly Clave, Custom
RC2017-0106	1L, Custom Manifold
RC2017-0107	Manifold Assembly, Custom
RC2017-0108	Manifold Assembly, Custom
RC2017-0127	20L Custom Assembly
RC2017-0132	250mL Custom Assembly
RC2017-0139	Jumper Assembly, Custom
RC2017-0153	20L Custom Assembly
RC2017-0163	250mL, Manifold Assembly, Custom
RC2017-0164	Manifold Assembly, Custom
RC2017-0172	5L, Custom Manifold
RC2018-0023	500mL Custom Assembly
RC2018-0023NS	500mL Custom Assembly
RC2018-0067	Jumper Assembly, Custom
RC2018-0075	5L, Custom Assembly
RC2018-0076	20L, Custom Assembly
RC2018-0077	20L, Custom Assembly
RC2018-0079	10L, Custom Assembly
RC2018-0137	Jumper Assembly, Custom
RC2018-0173	Jumper assembly, custom
RC2018-0197	10L Custom Assembly
RC2018-0208	5L Custom Assembly
RC2019-0036	1L Custom Assembly
RC2019-0140	50ml Assembly, Custom
RC2019-0143	10L Assembly, Custom
RC2019-0164	10L Assembly, Custom
RC2019-0171	10L Cell Harvest Assembly
RC2019-0249	5L Custom Assembly
RC2019-0250	10L Custom Assembly

Product Numbers	Description
RC2019-0251	20L Custom Assembly
RC2019-0252	50L Custom Assembly
RC2020-0079	5L, Custom Assembly
RC2020-0080	10L, Custom Assembly
RC2020-0081	20L, Custom Assembly
RC2020-0082	50L, Custom Assembly
RC2020-0287	20L, Custom Assembly
RC2020-0296	5L Assembly, Custom
RC2020-0339	50L Custom Assembly
RC2019-0251	20L Custom Assembly
RC2019-0252	50L Custom Assembly
RC2020-0079	5L, Custom Assembly
RC2020-0080	10L, Custom Assembly

Appendix 1, Continued

ReadyToProcess (RTP) Products

Product Numbers	Description
29344947	RTP XL Bin 3D 50L Fortem™ Bag 2 Port with ReadyMate™
29345483	RTP XL Bin 3D 100L Fortem Bag 2 Port with ReadyMate
29345484	RTP XL Bin 3D 200L Fortem Bag 2 Port with ReadyMate
29345485	RTP XL Bin 3D 500L Fortem Bag 2 Port with ReadyMate
29345686	RTP XL Bin 3D 1000L Fortem Bag 2 Port with ReadyMate
29348287	RTP XL Bin 3D 50L Fortem Bag 3 Port with ReadyMate
29348288	RTP XL Bin 3D 100L Fortem Bag 3 Port with ReadyMate
29348289	RTP XL Bin 3D 200L Fortem Bag 3 Port with ReadyMate
29348290	RTP XL Bin 3D 500L Fortem Bag 3 Port with ReadyMate
29348291	RTP XL Bin 3D 1000L Fortem Bag 3 Port with ReadyMate

Product Numbers	Description
29374836	RTP XL Bin 3D 50L Fortem Bag 2 Port with Aseptiquik®
29374837	RTP XL Bin 3D 100L Fortem Bag 2 Port with Aseptiquik
29374838	RTP XL Bin 3D 200L Fortem Bag 2 Port with Aseptiquik
29374839	RTP XL Bin 3D 500L Fortem Bag 2 Port with Aseptiquik
29374840	RTP XL Bin 3D 1000L Fortem Bag 2 Port with Aseptiquik
29374841	RTP XL Bin 3D 50L Fortem Bag 3 Port with Aseptiquik
29374842	RTP XL Bin 3D 100L Fortem Bag 3 Port with Aseptiquik
29374843	RTP XL Bin 3D 200L Fortem Bag 3 Port with Aseptiquik
29374844	RTP XL Bin 3D 500L Fortem Bag 3 Port with Aseptiquik
29374845	RTP XL Bin 3D 1000L Fortem Bag 3 Port with Aseptiquik

Product Numbers	Description
29619321	RTP XL Bin 3D 50L Fortem Bag 3 Port with TC
29619322	RTP XL Bin 3D 50L Fortem Bag 2 Port with TC
29619323	RTP XL Bin 3D 100L Fortem Bag 3 Port with TC
29619324	RTP XL Bin 3D 100L Fortem Bag 2 Port with TC
29619325	RTP XL Bin 3D 200L Fortem Bag 3 Port with TC
29619326	RTP XL Bin 3D 200L Fortem Bag 2 Port with TC
29619327	RTP XL Bin 3D 500L Fortem Bag 3 Port with TC
29619328	RTP XL Bin 3D 500L Fortem Bag 2 Port with TC
29619330	RTP XL Bin 3D 1000L Fortem Bag 3 Port with TC
29619331	RTP XL Bin 3D 1000L Fortem Bag 2 Port with TC

Appendix 1, Continued

Xcellerex™ Assemblies

Product Numbers	Description
29053753	XDM-50L Plus Bag
29053761	XDM-100L Bag
29053767	XDM-100L Plus Bag
29053771	XDM-200L Bag
29053773	XDM-200L Plus Bag
29053775	XDM-500L Bag
29053777	XDM-500L Plus Bag
29053779	XDM-1000L Bag
29053926	XDM-1000L Plus Bag
29058020	XDM-50L Bag
29084737	XDM-100L Plus Bag with ReadyMates
29084738	XDM-200L Plus Bag with ReadyMates
29084772	XDM-500L Plus Bag with ReadyMates
29084773	XDM-1000L Plus Bag with ReadyMates
29084775	XDM-50L Plus Bag with ReadyMates
29117422	XDM-100L Bag with ReadyMates
29117545	XDM-200L Bag with ReadyMates
29117547	XDM-500L Bag with ReadyMates
29117549	XDM-1000L Bag with ReadyMates
29117551	XDM-50L Bag with ReadyMates
29278691	XDM-50L Fortem Plus Bag
29280674	XDM-100L Fortem Plus Bag
29282860	XDM-200L Fortem Plus Bag
29296403	XDM-1000L Fortem Plus Bag
29297664	XDM-1000L Fortem Bag
29299915	XDM-200L Fortem Bag
29300460	XDM-50L Fortem Bag
29301053	XDM-2500L Fortem Plus Bag
29301275	XDM-100L Fortem Bag
29302484	XDM-2500L Fortem Bag

Product Numbers	Description
29304524	XDM-500L Fortem Bag
29305463	XDM-500L Fortem Plus Bag
29394998	XDM-50L Fortem Bag with ReadyMate
29394999	XDM-50L Fortem Plus Bag with ReadyMate
29395000	XDM-100L Fortem Bag with ReadyMate
29395001	XDM-100L Fortem Plus Bag with ReadyMate
29395002	XDM-200L Fortem Bag with ReadyMate
29395003	XDM-200L Fortem Plus Bag with ReadyMate
29395004	XDM-500L Fortem Bag with ReadyMate
29395005	XDM-500L Fortem Plus Bag with ReadyMate
29395007	XDM-1000L Fortem Plus Bag with ReadyMate
29395008	XDM-2500L Fortem Bag with ReadyMate
29395009	XDM-2500L Fortem Plus Bag with ReadyMate
29395105	XDM-50L Fortem Bag with AseptiQuik
29395106	XDM-50L Fortem Plus Bag with AseptiQuik
29395107	XDM-100L Fortem Bag with AseptiQuik
29395108	XDM-100L Fortem Plus Bag with AseptiQuik
29395109	XDM-200L Fortem Bag with AseptiQuik
29395110	XDM-200L Fortem Plus Bag with AseptiQuik
29395111	XDM-500L Fortem Bag with AseptiQuik
29395112	XDM-500L Fortem Plus Bag with AseptiQuik
29395113	XDM-1000L Fortem Bag with AseptiQuik
29395114	XDM-1000L Fortem Plus Bag with AseptiQuik

Product Numbers	Description
29395115	XDM-2500L Fortem Bag with AseptiQuik
29395116	XDM-2500L Fortem Plus Bag with AseptiQuik
29399648	XDR-10L Fortem™ Pro Bag
29399649	XDR-10L Fortem Plus Bag
29399651	XDR-50L Fortem Dev Bag
29399652	XDR-50L Fortem Pro Bag with Readymate
29399653	XDR-50L Fortem Pro Bag with Aseptiquik
29399654	XDR-50L Fortem Microbial Bag
29399655	XDR-50L Fortem MC Bag
29399656	XDR-200L Fortem Dev Bag
29399657	XDR-200L Fortem Pro Bag with Readymate
29399658	XDR-200L Fortem™ Pro Bag with Aseptiquik
29399659	XDR-1000L Fortem Microbial Bag with Kleenpak
29399660	XDR-200L Fortem MC Bag
29399661	XDR-500L Fortem Pro Bag with Readymate
29399662	XDR-500L Fortem Pro Bag with Aseptiquik
29399664	XDR-1000L Fortem Pro Bag with Readymate
29399665	XDR-1000L Fortem Pro Bag with Aseptiquik
29399666	XDR-2000L Fortem Pro Bag with Readymate
29399667	XDR-2000L Fortem Pro Bag with Aseptiquik
29484311	XDM-100L Fortem Plus Bag with AseptiQuik-CN
29484313	XDM-100L Fortem Bag with ReadyMate-CN

Appendix 1, Continued

Xcellerex Assemblies, Continued

Product Numbers	Description
29484568	XDM-100L Fortem Plus Bag with ReadyMate-CN
29484569	XDM-100L Fortem Bag with AseptiQuik-CN
29484570	XDM-200L Fortem Plus Bag with ReadyMate-CN
29484571	XDM-200L Fortem Plus Bag with AseptiQuik-CN
29484572	XDM-200L Fortem Bag with AseptiQuik-CN
29484573	XDM-200L Fortem Bag with ReadyMate-CN
29484574	XDM-500L Fortem Plus Bag with ReadyMate-CN
29484575	XDM-500L Fortem Bag with ReadyMate-CN
29484576	XDM-500L Fortem Bag with AseptiQuik-CN
29484577	XDM-500L Fortem Plus Bag with AseptiQuik-CN
29484578	XDM-1000L Fortem Plus Bag with ReadyMate-CN
29484579	XDM-1000L Fortem Bag with ReadyMate-CN
29484580	XDM-1000L Fortem™ Bag with AseptiQuik-CN
29484581	XDM-1000L Fortem Plus Bag with AseptiQuik-CN
29487808	XDM-100L Fortem Bag-CN
29487810	XDM-200L Fortem Bag-CN
29487811	XDM-500L Fortem Bag-CN
29487813	XDM-1000L Fortem Bag-CN
29503130	XDM-100L Fortem Plus Bag-CN
29503131	XDM-200L Fortem Plus Bag-CN
29503132	XDM-500L Fortem Plus Bag-CN
29503133	XDM-1000L Fortem Plus Bag-CN

Product Numbers	Description
29506472	XDM-500L Fortem Plus Bag with AseptiQuik and SU pH sensor
29506481	XDM-1000L Fortem Plus Bag with AseptiQuik and SU pH sensor
29594867	XDR-50L VDMAX SIP BAG, Non Sterile
29616929	XDM-50L Fortem Bag with TC
29616930	XDM-50L Fortem Plus Bag with TC
29616931	XDM-100L Fortem Bag with TC
29616932	XDM-100L Fortem Plus Bag with TC
29616933	XDM-200L Fortem Bag with TC
29616934	XDM-200L Fortem Plus Bag with TC
29616935	XDM-500L Fortem Bag with TC
29616936	XDM-500L Fortem Plus Bag with TC
29616937	XDM-1000L Fortem Bag with TC
29616938	XDM-1000L Fortem Plus Bag with TC
29616939	XDM-2500L Fortem Bag with TC
29616940	XDM-2500L Fortem Plus Bag with TC
29621080	XDM-1000L Fortem Plus Bag with ReadyMate, Kleenpak
29623173	XDM-500L Fortem Plus Bag with ReadyMate, Kleenpak
29624413	XDM-1000L Fortem Plus Bag with TC, MPX, Filter
29626023	XDM-1000L Fortem Plus Bag with AseptiQuik, Filter
29626833	XDM-500L Fortem Plus Bag with AseptiQuik, Filter
29627969	XDM-100L Fortem Plus Bag with Readymate
29628934	XDM-50L Fortem Bag with ReadyMate, Pump Tubing

Product Numbers	Description
29629608	XDM-50L Fortem Plus Bag with AseptiQuik, Kleenpak, Pump Tubing
29630214	XDM-100L Fortem Plus Bag with AseptiQuik, Kleenpak, Pump Tubing
29631589	XDM-200L Fortem Plus Bag with AseptiQuik, Kleenpak, Pump Tubing
29631847	XDM-500L Fortem Plus Bag with AseptiQuik, Kleenpak, Pump Tubing
29631851	XDM-1000L Fortem Plus Bag with AseptiQuik, Kleenpak, Pump Tubing
29640034	XDM-500L Fortem Bag with ReadyMate, Pump Tubing
29641212	XDM-200L Plus Bag with ReadyMates
29642678	XDM-50L Plus Bag with ReadyMates
29643035	XDM-100L Plus Bag with ReadyMates
29643504	XDM-500L Plus Bag with ReadyMates
29643507	XDM-1000L Plus Bag with ReadyMates
29646239	XDM-50L Bag
29646244	XDM-50L Bag with ReadyMates
29646248	XDM-50L Plus Bag
29646249	XDM-100L Bag
29646261	XDM-100L Bag with ReadyMates
29646597	XDM-100L Plus Bag
29647053	XDM-200L Bag
29647062	XDM-200L Bag with ReadyMates
29647064	XDM-200L Plus Bag
29647868	XDM-500L Bag

Appendix 1, Continued

Xcellerex Assemblies, Continued

Product Numbers	Description
29647872	XDM-500L Bag with ReadyMates
29647890	XDM-500L Plus Bag
29648264	XDM-1000L Bag
29648268	XDM-1000L Bag with ReadyMates
29648270	XDM-1000L Plus Bag
29651324	XDM-2500L Fortem Plus Bag with AseptiQuik, Filter
29651945	XDM-1000L Fortem Plus Bag with ReadyMate
29652837	XDM-500L Fortem Plus Bag with ReadyMate
29658307	XDM-500L Fortem Plus Bag with TC, Reducer
29658310	XDM-1000L Fortem Plus Bag with TC, Reducer