Purolite® Life Sciences

Regulatory Information

Chromalite® Chromatography Resins

Lifetech™ Enzyme Carriers

Lifetech™ Immobilized Enzymes

Purolite® PAD and Macronet Adsorbents

Purolite® Life Sciences

Global Solutions

Purolite is a global leader in resin technology, and one of the world's largest developers and manufacturers of high-quality chromatographic resins, enzyme carriers, ion exchange resins, APIs, adsorbents and specialty resins. All Purolite Life Sciences products are of premium quality and are produced in our ISO-certified production facilities in the UK, Romania, China and the USA.

For over 35 years, Purolite has supplied specialty resin technology to industries within complex regulatory environments including biotechnology, pharmaceutical, food, fine chemical and electric power generation. Purolite complies with required national and international regulations, as well as many voluntary specialty certifications. These include:

- Part II of the EU GMP Guide
- US FDA Current Good Manufacturing Practice (CGMP) regulations
- US FDA CFR - Code of Federal Regulations including Title 21
- GMO/TSE/BSE free
- ResAP(2004)3
- NSF/ANSI 61/WRAS standards
- REACH regulations
- ISO 9001:2015 quality system specifications,
- ISO 14001:2015 Environmental Management System requirements
- OHSAS18001:2007
- RoHS Directive 2011/65/EU
- Halal and Kosher requirements

We also hold Drug Master Files with the US FDA, Japan, Canada and EU.

- 100% focused on resin technology.
- Global manufacturing facilities
- Secure global supply
- 25+ years of regulatory experience, including FDA inspected facility for APIs
- Over 35+ years of experience in solving advanced R&D and purification challenges.

Purolite Life Sciences Regulatory Support

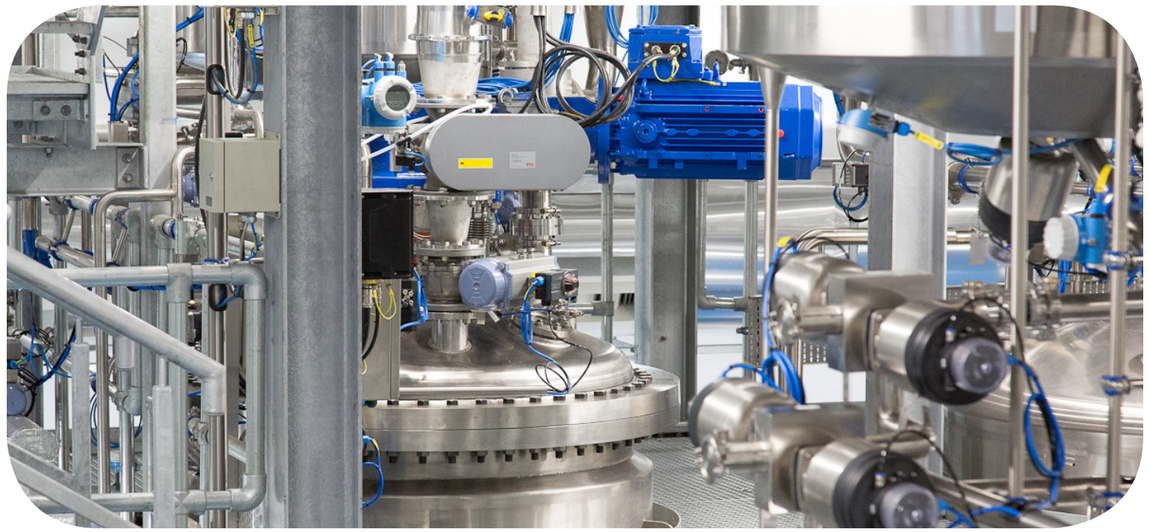
The regulatory environment is ever changing, driven by increasing regulatory requirements, increasing development costs and times, and market pressures impacting pharma and food industries. Regulatory issues influence decision-making throughout the product life cycle - at every stage of development, distribution, marketing and post-market monitoring. Consequently, regulatory management has a role in many business-critical functions, including organizational and scorporate strategy, technology assessment, research and development, and legal issues.

Regulatory expertise throughout the product life-cycle is essential to identify regulatory options for product development, optimize 'speed to market' and produce a product that meets customer needs. Purolite implements control documentation and processes at every level to ensure regulatory support to customers using our products. Our raw material suppliers are selected and qualified from leading manufacturers and are part of our network supplier program. Raw materials suppliers and partners are routinely audited for compliance to quality standards. Critical raw materials are managed through a globally coordinated inventory system to ensure security of supply. Additionally, a quality control protocol is in place for testing new batches/lots of raw materials to confirm product specifications and lot-to-lot consistency.

Global ISO 9001: 2015 standards ensure consistent operating practices across each of our plants. Compliance is monitored and maintained through a quality assurance and regulatory team who conduct internal audits to ensure operations meet the guidelines and protocols for equipment and procedures. Additionally, our production team is given continual training on quality processes to ensure batch-to-batch consistency. Quality certificates for our sites are available, and we welcome customer visits and host numerous audits each year to make sure we meet and comply with user and regulatory expectations.

Products are shipped in compliant containers and under controlled conditions, as applicable. Certificates of analysis (CoA) and conformance of materials records are available for all Purolite Life Sciences products. These document compliance with product release criteria, certify animal-free origin, or show wetted materials are in conformance with USP class VI.

For Life Sciences products, Regulatory Support Files (RSF) are available. Regulatory Support Files provide direct and detailed information on performance, stability, extractable compounds, and analytical methods for each resin.



Contents

Chromalite®

CGA/CGC Resins

Chromalite CGA and CGC chromatographic ion exchange resins for small organic and inorganic compound separation and purification.

Chromalite CGA and CGC resins are spherical, unifom and highly purified resins, made from styrene cross-linked with divinylbenzene.

They are offered in three different particle sizes - 50, 100 and 200 µm.

Table 1: Regulatory Compliance for Chromalite® CGA/CGC Resins

Product Name	Shipped as	Compliant with							
		21CFR173.25	21CFR173.65	21CFR177.2710	ResAP(2004)3	Halal	Kosher	GMO Free	TSE/BSE Free
CGA50x2	Wet resin (water)	Yes	-	-	Yes	Yes	Yes	Yes	Yes
CGA100x2	Wet resin (water)	Yes	-	-	Yes	Yes	Yes	Yes	Yes
CGA200x2	Wet resin (water)	Yes	-	-	Yes	Yes	Yes	Yes	Yes
CGA50x4	Wet resin (water)	Yes	-	-	Yes	Yes	Yes	Yes	Yes
CGA100x4	Wet resin (water)	Yes	-	-	Yes	Yes	Yes	Yes	Yes
CGA200x4	Wet resin (water)	Yes	-	-	Yes	Yes	Yes	Yes	Yes
CGA50x8	Wet resin (water)	Yes	-	-	Yes	Yes	Yes	Yes	Yes
CGA100x8	Wet resin (water)	Yes	-	-	Yes	Yes	Yes	Yes	Yes
CGA200x8	Wet resin (water)	Yes	-	-	Yes	Yes	Yes	Yes	Yes
CGC50x2	Wet resin (water)	Yes	-	-	Yes	Yes	Yes	Yes	Yes
CGC100x2	Wet resin (water)	Yes	-	-	Yes	Yes	Yes	Yes	Yes
CGC200x2	Wet resin (water)	Yes	-	-	Yes	Yes	Yes	Yes	Yes
CGC50x4	Wet resin (water)	Yes	-	-	Yes	Yes	Yes	Yes	Yes
CGC100x4	Wet resin (water)	Yes	-	-	Yes	Yes	Yes	Yes	Yes
CGC200x4	Wet resin (water)	Yes	-	-	Yes	Yes	Yes	Yes	Yes
CGC50x8	Wet resin (water)	Yes	-	-	Yes	Yes	Yes	Yes	Yes
CGC100x8	Wet resin (water)	Yes	-	-	Yes	Yes	Yes	Yes	Yes
CGC200x8	Wet resin (water)	Yes	-	-	Yes	Yes	Yes	Yes	Yes

Table 2: Regulatory Compliance for Chromalite® PCG Resins

Product Name	Shipped as	Compliant with							
		21CFR173.25	21CFR173.65	21CFR177.2710	ResAP(2004)3	Halal	Kosher	GMO Free	TSE/BSE Free
PCG600F	Dry resin in 20% EtOH	-	Yes	-	Yes	-	Yes	Yes	Yes
PCG600M	Wet resin (water)	-	Yes	-	Yes	Yes	Yes	Yes	Yes
PCG600C	Wet resin (water)	-	Yes	-	Yes	Yes	Yes	Yes	Yes
PCG900F	Dry resin in 20% EtOH	-	Yes	-	Yes	-	Yes	Yes	Yes
PCG900M	Wet resin (water)	-	Yes	-	Yes	Yes	Yes	Yes	Yes
PCG900C	Wet resin (water)	-	Yes	-	Yes	Yes	Yes	Yes	Yes
PCG1200F15	Dry resin in 20% EtOH	-	Yes	-	Yes	-	Yes	Yes	Yes
PCG1200F	Dry resin in 20% EtOH	-	Yes	-	Yes	-	Yes	Yes	Yes
PCG1200M	Wet resin (water)	-	Yes	-	Yes	Yes	Yes	Yes	Yes
PCG1200MHEMA	Dry resin	-	No	-	Yes	Yes	Yes	Yes	Yes
PCG1200C	Wet resin (water)	-	Yes	-	Yes	Yes	Yes	Yes	Yes

Table 3: Regulatory Compliance for Chromalite® A860/5952

Product Name	Shipped as	Compliant with							
		21CFR173.25	21CFR173.65	21CFR177.2710	ResAP(2004)3	Halal	Kosher	GMO Free	TSE/BSE Free
A860/5952	Wet resin (water)	-	-	-	Yes	Yes	Yes	Yes	Yes

A860/5952 is a macroporous polyacrylic resin, crosslinked with divinylbenzene with application in the food industry for isolation of proteins, especially for proteins from milk and dairy products.

Chromalite®

PCG Resins

Chromalite PCG resins are macroporous hydrophobic polystyrene adsorbents intended for use in high, medium- and low pressure reverse-phase chromatography, and adsorption of medium/large molecules.

Made from divinylbenzene, they are characterized by both mechanical and chemical robustness. Three different porosities enable Chromalite PCG resins to accommodate a variety of molecule sizes.

Depending on particle size, they are manufactured using either Purolite's proprietary Jetting technology or classical suspension polymerization.

Chromalite®

MN, GN & AD

Chromalite MN, GN and AD products are small particle size resins manufactured using unique seeding technology developed by Purolite.

This technology results in highly uniform particle size beads with a very narrow particle size distribution (UC <1.1) and sizes from 3 to 70 µm.

This production method produces close to monodispersed beads with applications in HPLC chromatography (Chromalite AD and MN) or calibrations (Chromalite GN).

Chromalite MN, GN and AD products are made from styrene and divinylbenzene.

Table 4: Regulatory Compliance for Chromalite® MN

Product Name	Shipped as	Compliant with							
		21CFR173.25	21CFR173.65	21CFR177.2710	ResAP(2004)3	Halal	Kosher	GMO Free	TSE/BSE Free
5MN	Wet resin (water)	-	Yes	-	Yes	Yes	Yes	Yes	Yes
10MN	Dry resin in 20% EtOH	-	-	Yes	Yes	-	Yes	Yes	Yes
15MN	Dry resin in 20% EtOH	-	-	Yes	Yes	-	Yes	Yes	Yes
70MN	Dry resin	-	-	Yes	Yes	Yes	Yes	Yes	Yes

Table 5: Regulatory Compliance for Chromalite® GN Resins

Product Name	Shipped as	Compliant with							
		21CFR173.25	21CFR173.65	21CFR177.2710	ResAP(2004)3	Halal	Kosher	GMO Free	TSE/BSE Free
3GN6	Dry resin	-	-	Yes	Yes	Yes	Yes	Yes	Yes
5GN6	Dry resin	-	-	Yes	Yes	Yes	Yes	Yes	Yes
6GN6	Dry resin	-	-	Yes	Yes	Yes	Yes	Yes	Yes
6GN8	Dry resin	-	-	Yes	Yes	Yes	Yes	Yes	Yes
8GN6	Dry resin	-	-	Yes	Yes	Yes	Yes	Yes	Yes
8GN8	Dry resin	-	-	Yes	Yes	Yes	Yes	Yes	Yes
10GN8	Dry resin	-	-	Yes	Yes	Yes	Yes	Yes	Yes
20GN4	Dry resin	-	-	Yes	Yes	Yes	Yes	Yes	Yes
20GN6	Dry resin	-	-	Yes	Yes	Yes	Yes	Yes	Yes
30GN6	Dry resin	-	-	Yes	Yes	Yes	Yes	Yes	Yes
29GN3	Dry resin	-	-	Yes	Yes	Yes	Yes	Yes	Yes
32GN6	Dry resin	-	-	Yes	Yes	Yes	Yes	Yes	Yes

Table 6: Regulatory Compliance for Chromalite® AD Resins

Product Name	Shipped as	Compliant with							
		21CFR173.25	21CFR173.65	21CFR177.2710	ResAP(2004)3	Halal	Kosher	GMO Free	TSE/BSE Free
5AD1	Dry resin in 20% EtOH	-	Yes	-	Yes	-	Yes	Yes	Yes
5AD2	Dry resin in 20% EtOH	-	Yes	-	Yes	-	Yes	Yes	Yes
10AD1	Dry resin in 20% EtOH	-	Yes	-	Yes	-	Yes	Yes	Yes
10AD2	Dry resin in 20% EtOH	-	Yes	-	Yes	-	Yes	Yes	Yes
15AD1	Dry resin in 20% EtOH	-	Yes	-	Yes	-	Yes	Yes	Yes
15AD2	Dry resin in 20% EtOH	-	Yes	-	Yes	-	Yes	Yes	Yes
15AD2Q	Dry resin in 20% EtOH	-	Yes	-	Yes	-	Yes	Yes	Yes

Chromalite®

MN, GN & AD

Chromalite MN, GN and AD products are small particle size resins manufactured using unique seeding technology developed by Purolite.

This technology results in highly uniform particle size beads with a very narrow particle size distribution (UC <1.1) and sizes from 3 to 70 µm.

This production method produces close to monodispersed beads with applications in HPLC chromatography (Chromalite AD and MN) or calibrations (Chromalite GN).

Chromalite MN, GN and AD products are made from styrene and divinylbenzene.

Lifetech™
ECR Resins

The Lifetech range of products include resins for enzyme immobilization (ECR) and ready-to-use immobilized enzymes.

The range includes resins for covalent, adsorption and ionic immobilization of enzymes. Resins are made of either a methacrylic hydrophilic backbone or more hydrophobic backbone by using styrene and divinybenzene.

Resins are manufactured in different particle sizes and different functional groups to cover a wide range of applicatons in the food, pharma and chemical industry.

Table 7: Regulatory Compliance for Lifetech™ ECR Resins

Product Name	Description	Compliant with								
		21CFR173.25	21CFR173.65	21CFR177.2710	ResAP(2004)3	Halal	Kosher	GMO Free	TSE/BSE Free	**FCN**
ECR1090F	Macroporous styrene	-	Yes	-	Yes	Yes	Yes	Yes	Yes	-
ECR1090M	Macroporous styrene	-	Yes	-	Yes	Yes	Yes	Yes	Yes	-
ECR1091M	Macroporous styrene	-	-	Yes	Yes	Yes	Yes	Yes	Yes	-
ECR8204F	Epoxy Methacrylate	-	-	-	Yes	Yes	Yes	Yes	Yes	-
ECR8204M	Epoxy Methacrylate	-	-	-	Yes	Yes	Yes	Yes	Yes	-
ECR8209F	Epoxy Methacrylate	-	-	-	Yes	Yes	Yes	Yes	Yes	-
ECR8209M	Epoxy Methacrylate	-	-	-	Yes	Yes	Yes	Yes	Yes	-
ECR8215F	Epoxy Methacrylate	-	-	-	Yes	Yes	Yes	Yes	Yes	FCN1685
ECR8215M	Epoxy Methacrylate	-	-	-	Yes	Yes	Yes	Yes	Yes	FCN1685
ECR8285	Epoxy/butyl meth-acrylic	-	-	-	Yes	Yes	Yes	Yes	Yes	-
ECR8304F	Amino C2 Methacrylate	-	-	-	Yes	Yes	Yes	Yes	Yes	-
ECR8304M	Amino C2 Methacrylate	-	-	-	Yes	Yes	Yes	Yes	Yes	-
ECR8404F	Amino C2 Methacrylate	-	-	-	Yes	Yes	Yes	Yes	Yes	-
ECR8404M	Amino C2 Methacrylate	-	-	-	Yes	Yes	Yes	Yes	Yes	-
ECR8309F	Amino C2 Methacrylate	-	-	-	Yes	Yes	Yes	Yes	Yes	-
ECR8309M	Amino C2 Methacrylate	-	-	-	Yes	Yes	Yes	Yes	Yes	-
ECR8315F	Amino C2 Methacrylate	-	-	-	Yes	Yes	Yes	Yes	Yes	FCN1685
ECR8315M	Amino C2	-	-	-	Yes	Yes	Yes	Yes	Yes	FCN1685
ECR8409F	Methacrylate	-	-	-	Yes	Yes	Yes	Yes	Yes	-
ECR8409M	Amino C2 Methacrylate	-	-	-	Yes	Yes	Yes	Yes	Yes	-
ECR8415F	Amino C2 Methacrylate	-	-	-	Yes	Yes	Yes	Yes	Yes	
ECR8415M	Amino C2 Methacrylate	-	-	-	Yes	Yes	Yes	Yes	Yes	
ECR8806F	Octadecyl Methacrylate	-	-	-	Yes	Yes	Yes	Yes	Yes	-
ECR8806M	Octadecyl Methacrylate	-	-	-	Yes	Yes	Yes	Yes	Yes	-
ECR1030M	DVB/ Methacrylate	-	-	-	Yes	Yes	Yes	Yes	Yes	-
ECR1508	Styrene tertiary amine	Yes	-	-	-	Yes	Yes	Yes	Yes	-
ECR1504	Styrene tertiary amine	Yes	-	-	-	Yes	Yes	Yes	Yes	-
ECR1604	Styrene quaternary amine	Yes	-	-	-	Yes	Yes	Yes	Yes	-
ECR1640	Styrene quaternary amine	Yes	-	-	-	Yes	Yes	Yes	Yes	-

Table 8: Regulatory Compliance for Lifetech™ Immobilized Enzymes

Product Name	Description	Shipped as	Compliant with									
			21CFR173.25	21CFR173.65	21CFR177.2710	ResAP(2004)3	Halal	Kosher	GMO Free	TSE/BSE Free	JECFA (FAO/ WHO)	USP/FCC
Calb immo Plus	Immobilized enzyme	Dry resin	-	-	-	Resin only	Yes	-	Yes	Yes	-	-
CalB immo Plus Food Grade	Immobilized enzyme	Dry resin	-	-	-	Resin only	Yes	-	Yes	Yes	Yes	Yes
Calb immo 8806	Immobilized enzyme	Dry resin	-	-	-	Resin only	Yes	-	Yes	Yes	-	-
Calb immo 8285	Immobilized enzyme	Dry resin	-	-	-	Resin only	Yes	-	Yes	Yes	-	-
Calb immo 5587	Immobilized enzyme	Dry resin	-	-	Resin only	Resin only	Yes	-	Yes	Yes	-	-
Calb immo 1090	Immobilized enzyme	Dry resin	-	Resin only	-	Resin only	Yes	-	Yes	Yes	-	-
Calb immo 5872	Immobilized enzyme	Dry resin	-	-	Resin only	Resin only	Yes	-	Yes	Yes	-	-
CalB immo KIT	KIT of immobilized enzymes	Dry resin	-	-	-	-	Yes	-	Yes	Yes	-	-
Lipase immo KIT	KIT of immobilized enzymes	Dry resin	-	-	-	-	-	-	-	-	-	-

Lifetech™

Immobilized Enzymes

CalB immo Plus™ is a highly hydrophobic, high-performance immobilized CalB Preparation immobilized on ECR1030M, for applications in cosmetic, chemical and pharma industries.

For food applications CalB immo Plus™ Food Grade is also available. CalB immo KIT and Lipase immo KIT are sceening kits offering the possibility to screen different resins and different enzymes to find the optimal during process development. All resins used for enzyme immobilization belong to the Lifetech ECR range.

Purolite®

PuroSorb & Macronet

PuroSorb™ PAD polymeric adsorbents are synthetic polymers that are highly cross linked and have a highly porous structure as part of the polymer matrix. These adsorbents in many cases may replace carbon, a common generic adsorbent. Unlike carbon which must be regenerated off site, PuroSorb adsorbents can be regenerated in situ.

Macronet® adsorbents have macropores to provide rapid access to the internal surfaces within the resin bead, and micropores to provide a high surface area. They can be functionalized to provide high capacities and selectivity, in order to enhance purification and separation performance.

Table 9: Regulatory Compliance for Purolite Macronet® and PuroSorb™ Resins

Product Name	Compliant with							
	21CFR173.25	21CFR173.65	21CFR177.2710	ResAP(2004)3	Halal	Kosher	GMO Free	TSE/BSE Free
PAD350	-	-	Yes	Yes	Yes	Yes	Yes	Yes
PAD550	-	-	Yes	Yes	Yes	Yes	Yes	Yes
PAD600	-	Yes	-	Yes	Yes	Yes	Yes	Yes
PAD400	-	Yes	-	Yes	Yes	Yes	Yes	Yes
PAD900	-	Yes	-	Yes	Yes	Yes	Yes	Yes
PAD1200	-	Yes	-	Yes	Yes	Yes	Yes	Yes
MN200	-	-	Yes	Yes	Yes	Yes	Yes	Yes
MN202	-	-	Yes	Yes	Yes	Yes	Yes	Yes
MN250	-	-	Yes	Yes	Yes	Yes	Yes	Yes
MN270	-	-	Yes	Yes	Yes	Yes	Yes	Yes
PAD610	-	-	-	Yes	Yes	Yes	Yes	Yes
PAD950	-	-	-	Yes	Yes	Yes	Yes	Yes
PAD428	-	-	-	-	Yes	Yes	Yes	Yes
MN100	Yes	-	-	Yes	Yes	Yes	Yes	Yes
MN102	Yes	-	-	Yes	Yes	Yes	Yes	Yes
MN500	Yes	-	-	Yes	Yes	Yes	Yes	Yes
MN502	Yes	-	-	Yes	Yes	Yes	Yes	Yes

Table 10: Glossary: Common Regulatory Legislation		
Name	Description	Comment
21CFR173.25	Secondary direct food additives permitted in food for human consumption/ion exchangers	Different copolymers and can be functionalized. It can also include acrylics. Must meet the extractable and operating conditions as defined in the CFR. See FDA.
21CFR173.65	Secondary direct food additives permitted in food for human consumption/divinylbenzene co-polymer	Very pure coplymer. Very high purity divinylbenzene to produce polymer. Almost any porogen is acceptable, permitted that extractable levels are met. Must meet extractable and operating conditions as defined in the CFR. See FDA.
21CFR177.2710	Substances for use only as components of articles intended for repeated use/styrene-divinylbenzene, cross-linked resins	Same base as styrene/DVB for 173.25. Must meet the extractable and operating conditions as defined in the CFR. See FDA
21CFR182.3640	Substances generally recognized as safe	Includes Potassium sorbate
21 CFR 173.357	Materials used as fixing agents in the immobilization of enzyme preparations.	Includes Glutaraldehyde
ISO 10993-17:2002	Specifies the determination of allowable limits for substances leachable from medical devices.	Not applicable to devices that have no patient contact (e.g. in vitro diagnostic devices).
ISO 10993-5	Required for all types of medical devices, presents a number of test methods designed to evaluate the cytotoxicity, i.e. acute adverse biological effects of extractables from medical device materials.	Mammalian cells, usually of mouse or human origin are used in this test.
ISO 9001:2015	The ISO 9000 series of certifications addresses various aspects of quality management	
ISO 14001:2015	The ISO 14000 series of certifications address various aspects of environmental management	

Glossary

Common Regulatory Terms

Table 11: Glossary: Common Regulatory Terms		
Name	Description	Comment
AFNOR test	Association française de normalisation (AFNOR) is an organization which has a recognised test to evaluate extractable and leachable from an article	
Antifoams used in manufacturing	Kosher approved antifoams	
Audit	An Audit is a review by a customer, supplier certifying body or government agency. This usually included a site visit	
Biocompatibility	Biocompatibility refers to materials being biologically compatible	See ISO 10993-17:2002
BSI	The British Standards Institution (BSI) is a business standards company that helps organizations attain and maintain ISO accreditation	
cGMP	Current Good Manufacturing Practice cGMP) regulations provide systems that assure proper design, monitoring, and control of manufacturing processes and facilities	
CIP	Clean-in-place (CIP) is a method of cleaning the interior surfaces of pipes, vessels, process equipment, filters and associated fittings, resins without disassembly	
CLP	Classification, Labelling and Packaging (CLP) is an international globally harmonised system for classification and labelling of chemicals	
CoA	Certificate of Analysis	
Cytotoxicity	Is the ability of a substance or article to be toxic to cells	See ISO 10993-5
EU GMP Guide	The minimum standard that a medicines manufacturer must meet in their production processes.	
Extractable	An extractables is a substance in an article which can be recovered and identified using conditions such as strong solvents, and elevated temperatures	
FCN	Food Contact Notification (FCN) number assigned to FCS by FDA	See FCS
FCS	A Food Contact Substance (FCS) is one which has demonstrated to be safe for their intended food use	
FDA	The US Food and Drug Administration (FDA) oversees Medical Products and Tobacco and Food regulations	
FDA Polymer Exemption Process	Is a set of rules administrated by the EPA which assess if a particular polymer is exempt from TSCA declarations	See also FCN
Food grade	A term used to describe ingredients, packaging and equipment that are of a quality sufficient to be used for food production	
Gamma radiation	Gamma radiation is an energetic form of electromagnetic radiation, with a very short wavelength used to sterilize articles and or their components. As an example, a methacrylate product can typically be sterilized up to 20 kGy	Specific limits are set for Total Microbial Count (CFU/ml max) and Bacterial Endotoxins (LAL)
Gelatine used in manufacturing	Kosher approved fish gelatine	
Glutaraldehyde	Additive for enzyme immobilization	See 21CFR.173.357
GMO free	Product does not contain any GMOs or modified genetic material	
GRAS	A food is Generally Recognized as Safe (GRAS) when is generally recognized, among qualified experts, as having been adequately shown to be safe under the conditions of its intended use	
Halal	Products certified, manufactured plant and raw materials audited by Ifanca. Raw materials free of porcine, alcohol, blood, etc.	
HTS codes	The Harmonized Tariff Schedule (HTS) sets out the tariff rates for various import categories applied to most world trade in goods	
Ifanca	Islamic Food and Nutrition Council of America	
ISO 9001:2015	The ISO 9000 series of certifications addresses various aspects of quality management	
ISO 14001:2015	The ISO 14000 series of certifications address various aspects of environmental management	
JECFA (FAO/WHO) and USP/FCC	Meets the JECFA/FCC/WHO general specifications for enzyme preparations used in food processing	
Kosher	Products certified, manufactured plant and raw materials certified and audited for orthodox compliance. Raw materials free of porcine, alcohol, blood, etc.	
Leachable	A leachable is a substance in an article that naturally exude under normal conditions of exposure over the lifespan of the article	
NSF/ANSI 61	USA National standards relating to water treatment	
OHSAS 18001:2007	British standard for occupational health and safety management systems	
Opinion letter	Letter provided by an industry expert as to the suitability of the product in contact with specific foods. Often used in lieu of a FCN or other food contact compliance information	
Pareve	Made without milk, meat or their derivatives	All products comply with Pareve

Glossary

Common Regulatory Terms

Table 11: Glossary: Common Regulatory Terms (Continued...)		
Name	Description	Comment
Passover	Free from fermented products of wheat, rye, spelt, barley and oats	None of the Purolite products are certified for Passover
Pesach	see Passover	
Pharmaceutical grade	Article that is described in the Pharmacopoea	
Pharmacopeia	Book containing directions for the identification of compound medicines, and published by the authority of a government or a medical or pharmaceutical society	
REACH	Registration, Evaluation and Authorisation of Chemicals (REACH) is a regulation of the European Union, and lists all existing substances manufactured, processed, or imported in the Europe. Unless that substance is exempt from REACH	
ResAP(2004) 3	EU Resolution on ion exchange and adsorbents resins used in the processing of food stuffs	Must meet the extractable and operating conditions as defined in the ResAP(2004) 3 as per AFNOR.
RoHS Directive 2011/65/EU	EU Directive restricting the use of certain hazardous substances in electrical and electronic equipment	
RSF	The purpose of a Regulatory Support File (RSF) is to provide assistance with respect to process development of clinical and commercial purification processes, manufacturing validation, Quality control tests, Standard Operating Procedure (SOP) for cleaning in place (CIP) and sanitization, application for various regulatory licenses or compliance and plant and document audits	
Sanitisation	Sanitisation of a resin is a cleaning/minimising the level of microbial contamination to non-harmful levels. Sanitisation of resins with NaOH is not routinely considered as sterilisation because it will not remove 100% of the microbial contamination in all situations, since it does not affect some spores and viruses	
SDS	A safety data sheet (SDS), or material safety data sheet (MSDS), describes occupational safety and health, and spill-handling procedures for an article	
SOP	A standard operating procedure, or SOP, is a set of step-by-step instructions compiled to help workers carry out complex routine operations	
Steam sterilization	Sterilization is achieved by heating an article with saturated steam at high temperatures (121°C to 134°C). Effective for all microorganisms including spores	Specific limits are set for Total Microbial Count (CFU/ml max) and Bacterial Endotoxins (LAL)
Sterilization	Sterilization is using a method to kill or inactivate all disease-causing bacteria, spores, fungi and viruses	Specific limits are set for Total Microbial Count (CFU/ml max) and Bacterial Endotoxins (LAL)
TSCA	The Toxic Substances Control Act (TSCA) Chemical Substance Inventory lists all existing chemical substances manufactured, processed, or imported in the United States. Unless that substance is exempt from TSCA	
TSE/BSE free	TSE/BSE free - The product has been manufactured without the use or inclusion of any animal products which carry a TSE/BSE risk	
USDA	United States Department of Agriculture	
TDS	Technical Data Sheet	

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