Purell
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lyondellbasell
Advancing Possible

Advancing quality healthcare

Our *Purell* Service Concept makes modern healthcare solutions possible

The provision of safe and effective healthcare is one of the most important objectives of any society in the world today. As a consequence, LyondellBasell has developed a dedicated *Purell* service concept for customers in the healthcare industry.

Purell resins offer excellent aesthetic characteristics (clarity and gloss), outstanding organoleptic properties (low taste and odor), inertia to most chemicals and a full range of stiffness and mechanical resistance (even at low temperatures).

Customers regard these positive properties as the basis for the use of polyolefins in healthcare applications. Due to the complexity and tediousness of the approval processes (including e.g., expensive toxicological studies), pre-testing of material, pharmacopoeia compliance certificates, security of supply and consistency of formulation are also necessary preconditions for any raw material used.

As the original healthcare concept in the polyolefins industry, the *Purell* Service Concept addresses all these requirements. All products within the *Purell* range are compliant with European (Ph.Eur 3.1.4, 5, 6) and / or United States pharmacopoeia regulations and Drug Master Files (DMF) are filed with the US Food and Drug Administration (FDA).

The *Purell* Service Concept exemplifies the spirit of pharmaceutical GMP – awareness, change control and documentation and provides a series of benefits:

Purell Service Concept

Manufacturing and logistics

- Consistency of formulation
- Dedicated manufacturing and quality management procedures
- Dedicated cleaning procedures for silos, trucks, railcars and containers
- Customer-specific supply solutions
- Pest control and sanitation procedures

Regulations

- Meet EU and/or USP pharmacopeia, with a Drug Master File (DMF) listing
- Reference to ISO 10993 compliance available in regulatory documents
- Reference to ICH Harmonized Guideline Q3D covered in regulatory documentation
- Extractable profile available
- Long-term sample and documentation retention

Support

- Effective risk management procedures
- Minimum 2-year Notification of change
- Global asset base
- Dedicated Local sales and technical service teams in all regions of the world
- Access to over 40 years of application innovation in the industry
- Plant audits

Applications

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Purell polyolefins are widely used for the production of medical devices and pharmaceutical packaging. Increasingly they are being selected by converters for the replacement of other thermoplastics such as ABS, polycarbonate, polystyrene and PVC; as well as traditional materials such as metal and glass.

Purell high density polyethylene (HDPE) is used in the production of items such as closures, rigid bottles and ampoules, needle sheaths, plunger rods for single-use syringes, moldings to house diagnostic equipment, and collapsible tube shoulders. The applications for *Purell* low density polyethylene (LDPE) include items such as squeezable bottles and ampoules, blow-fill-seal products, collapsible tube bodies, and film for primary and secondary medical and pharmaceutical packaging.

Purell polypropylene (PP) is used in an exceptionally wide range of applications, the most important of which is 2 or 3-part syringes. Other applications where *Purell* PP is largely used due to unique technical properties include medical devices, labware, diagnostic equipment, drug delivery systems, inhalers, film, blow-fill-seal products, closures and many others.

Purell polybutene-1 (PB-1) is a high-molecular-weight plastomer obtained by polymerizing butene-1 and is based on LyondellBasell's proprietary technology. Due to its soft nature and excellent compatibility with PP, a full polyolefin solution is now available that may be considered for inter-material replacement of (soft) PVC and TPE for applications where good optical properties are required, like for instance flexible medical tubing, IV bags and blow-fill-seal applications.

Purell Polypropylene Resins

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This overview provides basic technical information about *Purell* polypropylene resins and their typical customer applications.
For detailed information, please contact your technical service representative as indicated on the last page of this brochure.

Properties	Physical	Mechanical/Thermal		Conversion Technology			Regulatory					Additivation						Further Description and Typical Applications
	MFR (230°C/ 2.16kgs) (g/10min)	Tensile Modulus (MPa)	Vicat Softening Temp (VST/A50) (°C)	IM	BM	FLM	Ph. Eur.	USP	ISO 10993	DMF		Nucleated	Clarified	Antistatic	Radiation resistant	Slip agent	Antiblocking	
Method	ISO1133	ISO527	ISO306															
Homopolymers (HOMO-PP)																		
Purell HP570M	7,5	1400	154	●		●	●	●	●	13038								Selected by customers for a wide variety of healthcare products such as medical devices, containers, closures and diagnostic equipment
Purell HP548N	11	1800	154	●			●	●	●	030482		●		●				Nucleated grade which also contains antistatic additivation, resulting in a balance of good stiffness properties and good flowability
Purell HP371P	18	1250	150	●				●	●	13038			●		●			Clarified grade with improved impact resistance compared to standard Homo PP; modified for radiation sterilization (subject to conditions); mainly used for empty 3-part-syringes, diagnostic and labware applications
Purell HP570R	23	1400	154	●			●	●	●	13038								Versatile material used in 3-part syringes, diagnostic applications, containers and drug delivery systems
Purell HP671T	55	1900	155	●				●	●	03304			●		●			A sterilizable, high fluidity PP resin used in injection molded medical applications, exhibiting very high stiffness, excellent transparency and an enhanced additive package offering increased resistance to gamma sterilization
Purell HP570U	75	1350	152	●			●	●	●	13038								High flow and high stiffness; used in diagnostics applications and other thin-wall injection molding that must be free from antistatic agents
Heterophasic Copolymers (HECO-PP)																		
Purell EP374M	7.5	1050	144	●			●	(*)	(*)	(*)		●						Excellent toughness with a good balance of physical and mechanical properties which can be used in containers, medical devices, packaging.
Purell EP274P	15	950	142	●			●	●	●	13038		●						Excellent balance of stiffness and low-temperature impact resistance; used for medical applications and healthcare products. It is used in medical containers, tubs, medical devices and packaging.
Purell EP370S	42	1250	147	●			●	●	●	03304		●						Excellent toughness with a good balance of physical and mechanical properties with a high flowability which can be used in medical devices, oral care, pharma packaging etc
Random Copolymers (RACO-PP)																		
Purell RP270G	1.8	1000	136	●	●	●	●	●	●	13038								Good balance of optical properties and toughness/softness (squeezability) for Blow Fill Seal applications requiring sterilization temperature of 121°C. Also it can be used in pharma packaging, IV bottles, ISBM etc.
Purell RP315M	8	1100	140	●		●	●	●	●	28195						●	●	Good balance of mechanical and optical properties. It contains slip and anti-blocking agents. Suitable for film applications; but also labware and caps/closures for pharma & cosmetic usage.
Purell RP373R	25	1000	130	●				●	●	13038			●			●		Clarified grade modified to provide improved impact and steam sterilization resistance; contains slip agent; mainly selected for empty disposable 2-part syringes
Purell RP374R	25	1000	130	●				●	●	13038			●					Clarified grade modified to provide improved impact and steam sterilization resistance; typically used in medical devices and empty disposable 3-part syringes
Purell RP375R	25	1100	134	●				●	●	03304			●		●			A very high fluid sterilizable PP resin with good transparency which can be used in labware, medical and pharma packaging, medical device components, syringes, injection pens etc
Purell RP378T	48	1100	130	●				●	●	13038			●	●				Clarified and contains antistatic; high-flow grade selected for applications requiring thin-walling and fast cycle times; used in a variety of medical applications and healthcare products such as inhalers and diagnostic devices

Remark: BM = Blow Molding IM = Injection Molding FLM = Film Extrusion IBM = Injection Blow Molding ISBM = Injection Stretch Blow Molding
(*) In progress

Note: Information related to relevant regulatory subjects is available in the Product Stewardship Bulletin (PSB) on the website:https://productsafety.lyondellbasell.com/

Purell Polyethylene resins

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This overview provides basic technical information about *Purell* polyethylene resins and their typical customer applications.
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Properties	Physical		Mechanical/Thermal			Conversion Technology			Regulatory				Further Description and Typical Applications
	MFR (190°C/ 2.16kgs) (g/10min)	Density (g/cm³)	Tensile Modulus (MPa)	DSC-Melting Point (°C)	ESCR (FNCT 2% Arcopal) (h)	IM	BM	FLM	Ph. Eur.	USP	ISO 10993	DMF	
Method	ISO1133	ISO1183	ISO527	ISO3146	ISO16770								
Low Density Polyethylene (LDPE)													
Purell PE 1810E	0.4	0,920	200	108		(●)	●	(●)	●	●	●	8412	Very flexible grade selected by customers for ampoules in BFS process
Purell PE 1840H ◊	1.5	0.919	200	108		(●)	●	(●)	●	●	●	8410	Very flexible grade selected by customers for ampoules and widely used in latest-generation BFS machines
Purell PE 3020D ◊	0.3	0.927	300	114		(●)	●	(●)	●	●	●	8413	Leading BFS grade used by customers in IV-bottles and ampoules
Purell PE 3040D	0.25	0.928	300	115		(●)	●	(●)	●	●	●	8700	Similar to Purell PE 3020D with slightly higher density for slightly increased sterilization opportunities
Purell PE 3220D ◊	0.4	0,930	430	117		(●)	●	(●)	●	●	●	19659	Current state of the art material in BFS allowing increased sterilization temperatures compared to standard BFS grades
Purell PE 3420F	0.9	0.933	520	119		(●)	●	(●)	●	●	●	23515	Latest-generation PE with high temperature resistance, enabling higher sterilization temperatures, offering significantly reduced cycle times compared to standard LDPE grades
Purell PE 2420F	0.75	0.923	260	111			(●)	●	●	●	●	21697	High purity film grade, well-established in the industry
Purell 2007H	1.5	0,920	200	108		●		(●)	●	●	●	15040	Soft PE with anti-block additive; often used for closures
Purell PE 3020K	4	0.928	300	114		●	(●)	●	●	●	●	29978	Non-additivated material with high rigidity, good opticals and good chemical resistance
Purell 2410T	36	0.924	280	112		●			●	●	●	18451	High flow material for fast times; often used for closures and seals
High Density Polyethylene (HDPE)													
Purell ACP 5531B	9.5[4]	0.954	1250	132	40[1]		●		●	●	●	27974	New grade with excellent combination of stiffness and stress crack resistance. Typically used by customers in light weight packaging applications, such as jerry cans, or as inner layer for coextruded industrial packaging, such as drums or IBCs
Purell PE GF4750	0.4	0,950	1000		15[1]	(●)	●		●	●	●	5654	Features a special additivation package for wide use in diagnostic and tube applications
Purell PE GF4760	0.4	0.956	1250		5[1]	(●)	●		●	●	●	5654	High barrier properties, offering protection for water sensitive fillings such as pills. Typically also converted in IBM process
Purell ACP 6031D	0.25	0,960	1350		7[1]	(●)	●		●	●	●	20343	Typical bottle grade from the latest-generation ACP technology, offering increased density and barrier properties. Also possible to convert in IBM processing
Purell ACP 6541A	1.5	0.954	1100		30[2]	●			●	●	●	19116	Typical cap grade from the latest-generation ACP technology, offering a combination of high ESCR and good flowability (comparable to an MFR 6 grade); often selected by customers for closures, seals and tube shoulders
Purell GC7260	8	0,960	1350		2,5[2]	●			●	●	●	5654	Predominantly used in closures, seals, tube shoulders
Purell GC7260G	8	0,960	1350		2,5[2]	●			●	●	●	5654	Higher additivated version of Purell GC7260 to enable broader processing conditions
Purell GB7250	10	0.952	1000		2,5[2]	●			●	●	●	5654	Predominantly used in closures, seals, tube shoulders
Purell GA7760	18	0.963	1350		1[3]	●			●	●	●	5655	High stiffness grade often selected for distortion-free moldings; typical applications include syringe plungers

Remark: BM = Blow Molding IM = Injection Molding FLM = Film Extrusion IBM = Injection Blow Molding ISBM = Injection Stretch Blow Molding
(●) conversion technology also used by customers but not the main one [1] 3.5MPa / 80°C [2] 6MPa / 50°C [3] 2.5MPa / 80°C [4] 190°C/21.6kg
Note: Information related to relevant regulatory subjects is available in the Product Stewardship Bulletin (PSB) at the website:https://productsafety.lyondellbasell.com/
◊ Grade currently also produced and available in the U.S.

Purell Polybutene -1 resins

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This overview provides basic technical information about *Purell* polybutene-1 resins and their typical customer applications.
For detailed information, please contact your technical service representative as indicated on the last page of this brochure.

Properties	Physical	Mechanical/Thermal		Conversion Technology				Regulatory				Further Description and Typical Applications
	MFR (190°C/ 2.16kgs) (g/10min)	Flexural Modulus (MPa)	Shore Hardness (Shore A)	IM	BM	FLM	EXT	Ph. Eur.	USP	ISO 10993	DMF	
Method	ISO1133	ISO178	ISO868									
Polybutene - 1												
Purell KT MR 07	1.3	< 10	60	●	●	●	●		●	●	032751	Owing to its excellent compatibility with Polypropylene (PP), thereby offering a full polyolefin solution that may be considered for inter-material replacement of PVC and TPE. This product blended and/or coextruded with PP enhances softness, flexibility, elastic recovery, elongation at break and impact resistance whilst improving transparency and reducing stress whitening. Particularly suitable for: flexible medical tubing, IV Bags and Blow Fill Seal applications

Remark: BM = Blow Molding IM = Injection Molding FLM = Film Extrusion IBM = Injection Blow Molding ISBM = Injection Stretch Blow Molding
(*) DMF in preparation

Note: Information related to relevant regulatory subjects is available in the Product Stewardship Bulletin (PSB) at the website:https://productsafety.lyondellbasell.com/

ABOUT US

LyondellBasell (NYSE: LYB) is one of the largest plastics, chemicals and refining companies in the world. Driven by its employees around the globe, LyondellBasell produces materials and products that are key to advancing solutions to modern challenges like enhancing food safety through lightweight and flexible packaging, protecting the purity of water supplies through stronger and more versatile pipes, improving the safety, comfort and fuel efficiency of many of the cars and trucks on the road, and ensuring the safe and effective functionality in electronics and appliances. LyondellBasell sells products into more than 100 countries and is the world's largest producer of polymer compounds and the largest licensor of polyolefin technologies.

For more information, visit lyb.com or please contact:

Europe
EU.Polymers@lyb.com

North America
NA.Polymers@lyb.com

South America
SA.Polymers@lyb.com

Africa, Middle East, India
AFMEI.Polymers@lyb.com

Asia
AP.Polymers@lyb.com

Australia/New Zealand
AU.Polymers@lyb.com

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