Product Data Sheet

DuPont™ AmberLite™ IRP69 Ion Exchange Resin

Pharmaceutical Grade Cation Exchange Resin (Sodium Polystyrene Sulfonate, USP)

Description

DuPont™ AmberLite™ IRP69 [1] resin is an insoluble, strongly acidic, sodium form cation exchange resin supplied as a dry, fine powder. AmberLite™ IRP69 Resin is suitable for use in pharmaceutical applications, either as an active ingredient or as a carrier for basic (cationic) drugs. It can be used for sustained release applications with compatible coating technologies.

[1] The use of AmberLite™ pharmaceutical grade ion exchange resins as components of drug formulations is subject to the Food, Drug, and Cosmetic Act as amended.

Regulatory Status

A Drug Master File for AmberLite™ IRP69 is maintained with the United States Food and Drug Administration (DMF No. 12355). Letters of authorization granting access to the file by FDA in support of NDA and ANDA submittals will be provided upon request. Similar help can also be offered in support of the registration of formulations containing AmberLite™ IRP69 in many other countries world-wide. AmberLite™ IRP69 is manufactured in accordance with Good Manufacturing Practices (cGMP) for bulk pharmaceutical chemicals (e.g. Eudralex Vol. 4 Part II, ICH Q7) at the manufacturing site located in Chauny, France.

Typical Properties

AmberLite™ IRP69 complies with the compendial specifications for Sodium Polystyrene Sulfonate USP when tested in conformance to the compendial test methods presented in current USP/NF.

Physical Properties	
Copolymer	Styrene-divinylbenzene
Type	Strong acid cation
Functional Group	Sulfonic acid
Physical Form	Fine powder
Chemical Properties	
Ionic Form as Shipped	Na^+
Potassium Exchange Capacity [1]	110–135 mg/g, anhydrous basis
Water Content [1]	≤ 10.0%
Ammonia Salts [1]	Negative to litmus paper
Sodium Content [1]	9.4%–11.5%, anhydrous basis
Styrene Content [2]	1 ppm maximum
Particle Size [§]	
> 150 µm	≤ 1.0%
> 75 µm	10.0-25.0%
> 45 µm	≥ 40.0%

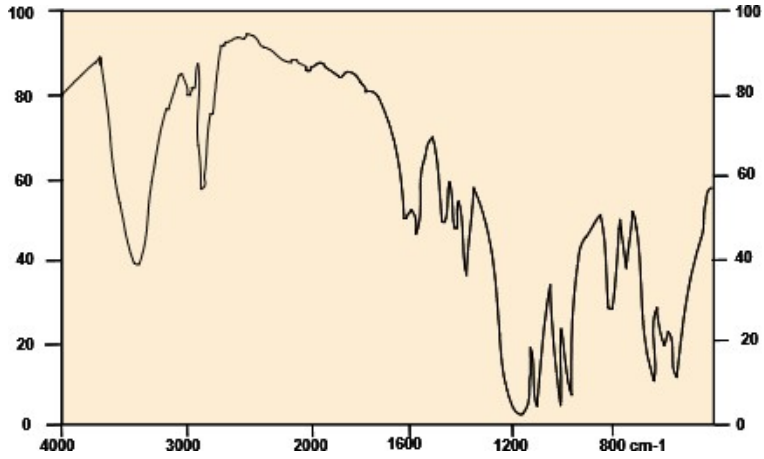
[§] For additional particle size information, please refer to the Particle Size Distribution Cross Reference Chart (Form No. 45-D00954-en).
[1] Appears in current USP/NF.
[2] If tested against the Ph. Eur. monograph for Sodium Polystyrene Sulfonate.

Form No. 45-D00961-en, Rev. 2
February 2023

Identification

DuPont™ AmberLite™ IRP69 can be identified by infrared spectroscopy, as shown in the example Figure 1.

Figure 1: AmberLite™ IRP69 Resin IR Spectrum



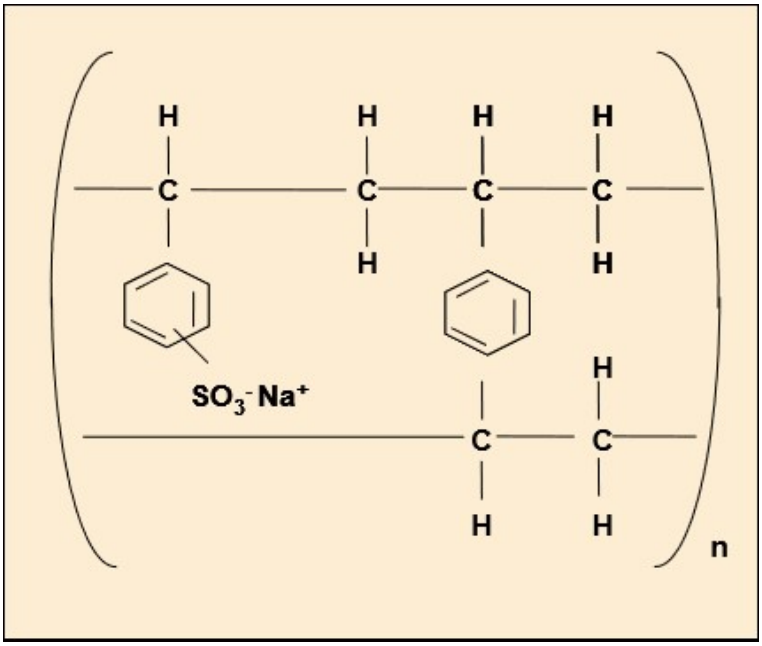
Chemical Properties

AmberLite™ IRP69 is derived from a sulfonated copolymer of styrene and divinylbenzene. The mobile, or exchangeable, cation is sodium; this can be exchanged for, or replaced by, many cationic (basic) species.

Since AmberLite™ IRP69 is an insoluble salt of a strong acid and a strong base, its ability to exchange ions is virtually independent of pH.

The chemical structure for AmberLite™ IRP69 is shown in Figure 2.

Figure 2: AmberLite™ IRP69 Resin IR Spectrum



Form No. 45-D00961-en, Rev. 2
February 2023

Applications

- Taste Masking
- Drug Stabilization
- Sustained Release
- Active Ingredient

When used as a drug carrier, DuPont™ AmberLite™ IRP69 provides a means for binding medicinal agents onto an insoluble polymeric matrix. This can afford an effective means for minimizing problems of taste and odor which may be associated with the drug substance. Controlled or sustained release properties can also be imparted to oral dosage formulations through the formation of resin-drug complexes (drug resinates). The drug is released from the resin in vivo as the drug reaches equilibrium with the high electrolyte concentrations which are typical of the gastrointestinal tract.

As an active ingredient, AmberLite™ IRP69 can be used as a therapeutic agent to lower potassium levels in the treatment of hyperkaliemia

Drug Loading

Batch equilibration is the preferred practice when loading a drug or other sorbate into finely divided ion exchange resin powders.

The total cation exchange capacity (~5 meq/g) represents the maximum achievable capacity for exchanging cations. The capacity which will be realized when loading a drug onto AmberLite™ IRP69 Resin will be less than this ideal; typically loadings will normally be between 5% and 75% of this maximum.

The actual amount of a drug loaded onto AmberLite™ IRP69 will be influenced by such factors as:

- the inherent selectivity of the sulfonic exchange groups for the drug.
- the drug’s concentration in the loading solution.
- the concentration of competing cations also present in the loading solution.
- the choice of solvent
- the molecular size of the drug

.The rate of loading will be affected by the activity of the drug and its molecular dimensions as well as the extent to which the polymer phase is swollen during loading.

When utilizing a batch or equilibrium contact to load a drug or other cationic sorbate onto AmberLite™ IRP69, complete transfer of the drug from the loading solution is not likely in a single equilibrium stage. Accordingly, more than one equilibration may be required in order to achieve the desired loading onto the resin. The use of two or more loading stages, separating the resin from the liquid phase between stages, is an effective means of achieving maximum loading of the drug onto the resin while maintaining minimum loss of drug from the liquid phase of the final stage.

Carefully controlled laboratory experiments are required to establish precise loading and elution conditions.

Form No. 45-D00961-en, Rev. 2
February 2023

Drug Loading (Cont.)

Drug Release

The rate and completeness of drug desorption in vivo will be affected by:

- The diffusion rate of the drug through the phase of the resin.
- The selectivity of the drug for the resin.
- The nature and concentration of electrolytes in the bulk phase during desorption.

More hydrophobic drugs will usually elute from the resin at a lower rate, owing to hydrophobic interactions with the aromatic structure of the cation exchange system.

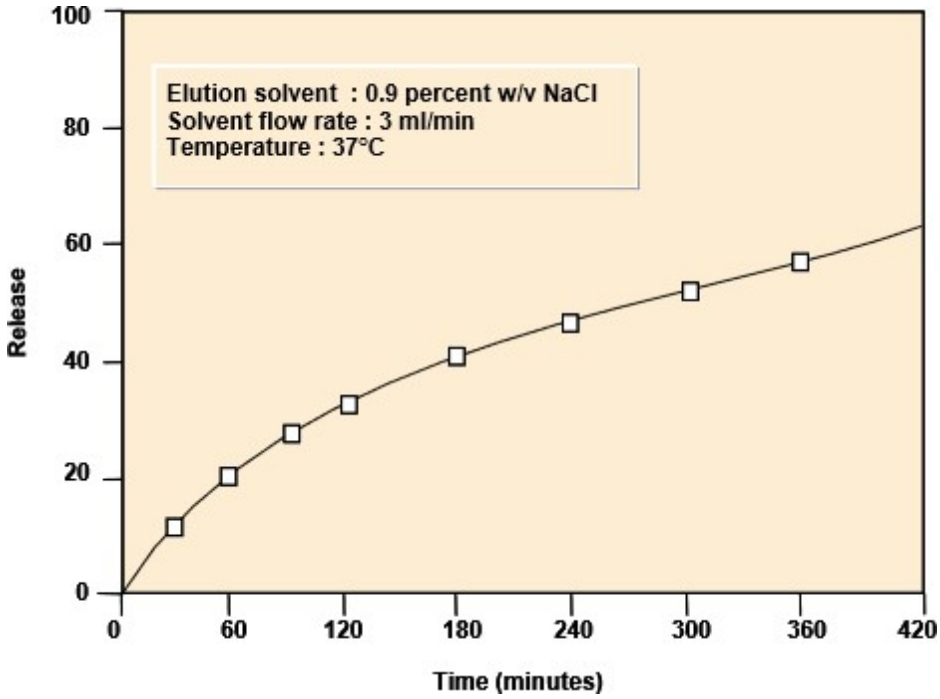
An example of this might be the presence of a transition metal in the structure of the sorbate molecule which can result in considerable selectivity through the formation of a coordination compound with the resin.

The following table and Figure 3 show the typical drug release properties for DuPont™ AmberLite™ IRP69 Resin.

Drug Release Characteristics of AmberLite™ IRP69 Resin

	% Drug released in 0.1N HCl			
Time, minutes	Phenylpropanolamine	Dextromethorphan	Pseudoephedrine	Ephedrine
15	82	21	64	63
30	88	43	66	66
60	92	60	67	68
90	95	71	68	69

Figure 3: Dextromethorphan Release from AmberLite™ IRP69 Resin (0.9% w/v NaCl)



Form No. 45-D00961-en, Rev. 2
February 2023

Controlled / Sustained Release Reference List

Amsel, L.P., O.N. Hinsvark, K. Rotenberg, and J.L. Sheumaker, 1983. recent advances in sustained release technology utilizing ion exchange polymers. Proc. Pharm Tech. Conf. ’83: 251-266.

Ferro, M.T., and F.C. Mondelo, 1987. Preparation of (-) eburnamenin-1,4(1,5H)-one resinates. Patent GB2,184,731.

Raghunathan, Y., 1980. Prolonged release pharmaceutical preparations. Patent US 4,221,778. Sriwongjanya, M., R. Bodmeier, 1997. Entrapment of drug-loaded ion-exchange particles within polymeric microparticles. Int. J. Pharm. 158: 29-38.

Sriwongjanya, M., R. Bodmeier, 1998. Effect of ion exchange resin on the drug release from matrix tablets. Eur. J. Pharm. Biopharm. 46: 321-327.

Jeong, S.H., and K. Park, 2008. Drug loading and release properties of ion- exchange resin complexes as a drug delivery matrix. Int. J. Pharm. 361:26-32.

Jeong, S.H., and K. Park, 2008. Development of sustained release fast- disintegrating tablets using various polymer-coated ion-exchange resin complexes. Int. J. Pharm. 353: 195-204.

Wilson, C.G., N. Washington, J.L. Greaves, C. Washington, I.R. Wilding, T. Hoadley, and E.E. Sims, 1991. Predictive modeling of the behavior of a controlled release buflomedil HCl formulation using scintigraphic and pharmacokinetic data. Int. J. Pharm. 72: 79-86.

Cheng, Y.H., P. Watts, M. Hinchcliffe, R. Hotchkiss, R. Nankervis, N.F. Faraj, A. Smith, S.S. Davis, and L. Illum, 2002. Development of a novel nasal nicotine formulation comprising an optimal pulsatile and sustained plasma nicotine profile for smoking cessation. J. Control. Release. 79: 243-254.

Applications Reference List

Raghunathan, Y., L.P. Amsel, O.N. Hinsvark, and W. Bryant, 1981. Sustained- release drug delivery system I: Coated ion exchange resin system for phenylpropanolamine and other drugs. J. Phar. Sci. 70 (4): 379-384.

Raghunathan, Y., 1983. Sustained-release liquid pharmaceuticals containing ionic components. Patent US 532,864.

Raghunathan, Y., 1989. Controlled release pharmaceutical preparations. Patent US 4,487,077

Sheumaker, J.L, 1988. Liquid prolonged release pharmaceutical formulations containing ionic constituents. Patent US 4,762,709.

Taste-Masking

Martel, J., J. Tessler, P. Girault, and P. Grandadam., 1981. Acid type ion exchange resins and their use as medicines and compositions containing them. Patent EP 27,768.

Quinlan, J. M., 1980. Diethylcarbamazine resinate and Strylpyridinium resinatediethylcarbamazine resinate edible anthelmintic tablets for companion animals. Patent GB 2,055,575.

Product Stewardship

DuPont has a fundamental concern for all who make, distribute, and use its products, and for the environment in which we live. This concern is the basis for our product stewardship philosophy by which we assess the safety, health, and environmental information on our products and then take appropriate steps to protect employee and public health and our environment. The success of our product stewardship program rests with each and every individual involved with DuPont products—from the initial concept and research, to manufacture, use, sale, disposal, and recycle of each product.

Customer Notice

DuPont strongly encourages its customers to review both their manufacturing processes and their applications of DuPont products from the standpoint of human health and environmental quality to ensure that DuPont products are not used in ways for which they are not intended or tested. DuPont personnel are available to answer your questions and to provide reasonable technical support. DuPont product literature, including safety data sheets, should be consulted prior to use of DuPont products. Current safety data sheets are available from DuPont.

Please be aware of the following:

- **WARNING:** Oxidizing agents such as nitric acid attack organic ion exchange resins under certain conditions. This could lead to anything from slight resin degradation to a violent exothermic reaction (explosion). Before using strong oxidizing agents, consult sources knowledgeable in handling such materials.

Have a question? Contact us at:

www.dupont.com/water/contact-us

All information set forth herein is for informational purposes only. This information is general information and may differ from that based on actual conditions. Customer is responsible for determining whether products and the information in this document are appropriate for Customer's use and for ensuring that Customer's workplace and disposal practices are in compliance with applicable laws and other government enactments. The product shown in this literature may not be available for sale and/or available in all geographies where DuPont is represented. The claims made may not have been approved for use in all countries. Please note that physical properties may vary depending on certain conditions and while operating conditions stated in this document are intended to lengthen product lifespan and/or improve product performance, it will ultimately depend on actual circumstances and is in no event a guarantee of achieving any specific results. DuPont assumes no obligation or liability for the information in this document. References to “DuPont” or the “Company” mean the DuPont legal entity selling the products to Customer unless otherwise expressly noted. NO WARRANTIES ARE GIVEN; ALL IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE ARE EXPRESSLY EXCLUDED. No freedom from infringement of any patent or trademark owned by DuPont or others is to be inferred.

© 2023 DuPont. DuPont™, the DuPont Oval Logo, and all trademarks and service marks denoted with ™, ℠ or ® are owned by affiliates of DuPont de Nemours Inc., unless otherwise noted.

Form No. 45-D00961-en, Rev. 2
February 2023