



To contact us, please visit our WebSite :
<http://www.rohmhaas.com/ionexchange/pharmaceuticals>
to find the address, phone and fax of the nearest local subsidiary
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CAUTION

Ion exchange resins and polymeric adsorbents, as produced, contain by-products resulting from the manufacturing process. The user must determine the extent to which organic by-products must be removed for any particular use and establish techniques to assure that the appropriate level of purity is achieved for that use. The user must ensure compliance with all prudent safety standards and regulatory requirements governing the application. Except where specifically otherwise stated, Rohm and Haas Company does not recommend its ion exchange resins or polymeric adsorbents, as supplied, as being suitable or appropriately pure for any particular use. Consult your Rohm and Haas technical representative for further information. Acidic and basic regenerant solutions are corrosive and should be handled in a manner that will prevent eye and skin contact. Nitric acid and other strong oxidising agents can cause explosive type reactions when mixed with ion exchange resins.

Proper design of process equipment to prevent rapid buildup of pressure is necessary if use of an oxidising agent such as nitric acid is contemplated. Before using strong oxidising agents in contact with ion exchange resins, consult sources knowledgeable in the handling of these materials.

Rohm and Haas Company makes no warranties either expressed or implied as to the accuracy or appropriateness of this data and expressly excludes any liability upon Rohm and Haas arising out of its use. We recommend that the prospective users determine for themselves the suitability of Rohm and Haas materials and suggestions for any use prior to their adoption. Suggestions for uses of our products or the inclusion of descriptive material from patents and the citation of specific patents in this publication should not be understood as recommending the use of our products in violation of any patent or as permission or license to use any patents of the Rohm and Haas Company.

Material Safety Data Sheets outlining the hazards and handling methods for our products are available on request.

Rohm and Haas Company maintain a policy of continuous development and reserve the right to amend any specification. To get updated product information, please consult your nearest Rohm and Haas office.

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ION EXCHANGE RESINS FOR PHARMACEUTICAL FORMULATIONS





PRINCIPAL AMBERLITE™ IRP and DUOLITE™ API43 Ion Exchange Resins

BULK PHARMACEUTICAL CHEMICALS FOR FINISHED DOSAGE FORMS

Compendial Name	Commercial Name	Function in the Dosage Form	Matrix	Functionality	Ionic Form
		Active			
		Excipient			
Polacrilex Resin ⁽¹⁾	AMBERLITE™ IRP64	<ul style="list-style-type: none"> • Taste masking agent • Drug stabilising agent • Nicotine 	Methacrylic acid divinylbenzene polymer	Weak acid -COO ⁻	Hydrogen
Polacrilin Potassium	AMBERLITE™ IRP88	<ul style="list-style-type: none"> • Tablet desintegrant • Taste masking agent 	Methacrylic acid divinylbenzene polymer	Weak acid -COO ⁻	Potassium
Sodium Polystyrene Sulfonate	AMBERLITE™ IRP69	<ul style="list-style-type: none"> • Potassium reduction • Sustained release • Drug stabilising agent • Taste masking agent 	Styrene-divinylbenzene polymer	Strong acid -SO ₃ ⁻	Sodium
Cholestyramine Resin ⁽²⁾	DUOLITE™ API43	<ul style="list-style-type: none"> • Cholesterol reduction • Sustained release • Drug stabilising agent • Taste masking agent 	Styrene-divinylbenzene polymer	Strong base -N ⁺ (R) ₃	Chloride

⁽¹⁾ Refers to Nicotine Polacrilex monograph
⁽²⁾ Cholestyramine resin is available in several grades which vary only in their particle size

Detailed information is available in product data sheets which can be provided upon request.

If you have any specific requests in terms of particle size or other polymer characteristics then please contact your regional Ion Exchange Resin office as Rohm and Haas is interested in expanding its product line in partnership with pharmaceutical companies.

Regulatory Compliance and Support

Rohm and Haas is committed to manufacturing bulk pharmaceutical chemicals of consistent and uniform quality in compliance with current good manufacturing practice (cGMP) standards and complying with the latest requirements of the regulatory authorities.

The processing, packaging, labelling and control operations in the production of all our pharmaceutical grade resins are carried out by Rohm and Haas France SAS at the facility located in Chauny (France).

- FDA inspected in 1995, 1997 and 2001
- ISO 9001 certified
- ISO14001 certified
- ISO18001 certified
- AFSSAPS (2006)

Assistance is also provided to customers with preparing regulatory submissions. Chemistry, Manufacturing and Controls (CMC) Documentation is available for each of our pharmaceutical grade resin for your review and /or inclusion in your Marketing Authorisation Applications.

For US applications, Rohm and Haas has filed with the Food and Drug Administration appropriate Drug Master Files (Type II and Type IV DMF).

Letters of Authorisation and CMC will be issued and provided upon request.

