PRODUCT DECLARATION

Purolite® A430MR

This declaration was prepared by Purolite Corporation in February, 2019.

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Purolite® Life Sciences

Victoria, Romania February, 2019

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PRODUCT INFORMATION

General

Product Name:	Purolite® A430MR
Manufacturer Code:	90612
Product Type:	Active Pharmaceutical Ingredient
Principal Applications:	Reducing blood cholesterol levels
Manufacturer Site:	SC Purolite SRL
Chemical Name:	Poly(trimethylammoniomethyl styrene chloride- co-divinylbenzene) (x:y)
Ph. Eur. Name:	Cholestyramine
USP/NF Name:	Cholestyramine Resin
JPC Name:	Cholestyramine
CAS Number:	11041-12-6

Regulatory status

- Drug Master File (DMF) registered on various markets: USA, Europe, Japan, Canada Mexico, Australia, and New Zealand

Certifications / Approvals

- ISO 9001:2015 Certificate
- US-FDA Approval
- EU-GMP Certificate
- Kosher Certificate
- Halal Certificate

Material origin:

- Purolite® A430MR and any of its raw materials are of synthetic origin. It is manufactured using no raw materials or additives of human, animal and vegetal origin;
- Purolite® A430MR Comprehensive Declaration includes:
  - TSE/BSE free statement;
  - GMO free statement;
  - Allergens free statement;
  - Aflatoxin free statement;
  - Gluten free statement;
  - Residual solvents statement;
  - Residual metals statement;
  - Elemental impurities statement;
  - Genotoxic impurities statement;
  - Dioxins free statement;
  - Melamine and glycerol free statement.

Manufacturing

- Purolite® A430MR is manufactured through chemical synthesis;
- Purolite® A430MR is manufactured as per a systematic Manufacturing Process;
- Purolite® A430MR batch size: 1500 kg packed in 50 kg drums; 1440 kg packed in 90 kg drums.

Packaging details

- Purolite® A430MR is packed in double polyethylene lined fibre drums; the internal liner is tie sealed and the outer one heat sealed. Fibre drum is sealed.

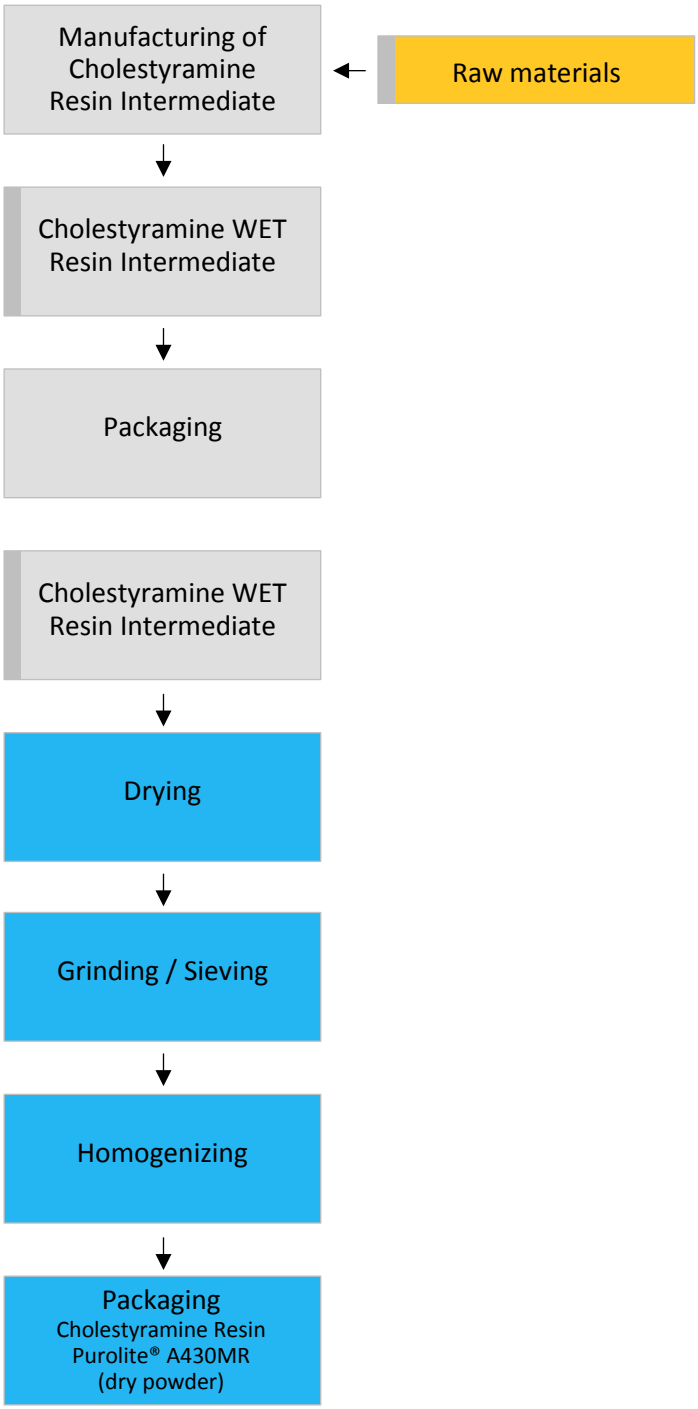
Pharmaceutical fibre drums		
DRUM TYPE	**DIMENSIONS cm (in)**	**QUANTITY / NET WEIGHT**
Medium	49 x 84.2 (19 x 33)	50 kg
Large	58.3 x 91.4 (23 x 36)	90 kg

Shelf-life and storage conditions

- When stored under proper storage conditions (in original packaging without extended exposure to temperature extremes or direct sunlight), Purolite® A430MR retains properties for a period of five (5) years from the date of manufacture;
- Purolite SRL has performed stability studies to establish the shelf life of the resin; stability data is available to support the assigned shelf life of five (5) years.

Manufacturing process flow chart

Cholestyramine – Purolite® A430MR



Date issued: **February 2019**

DECLARATION

Component Name:	**Purolite® A430MR, Cholestyramine**
Manufacturer Catalogue No.:	90612
Component Grade:	USP / Ph. Eur. / BP

Purolite certifies that:

- Purolite® A430MR is a powdered, fully synthetic, polystyrenic, strong base anion exchange resin in chloride form, fully conforming to the USP monograph of Cholestyramine and to the Eu. Phar. / BP monograph of Cholestyramine;
- Purolite® A430MR is produced by our subsidiary PUROLITE S.R.L. in their GMP certified manufacturing plant located in Victoria, Romania, which is FDA inspected and compliant;
- Purolite Company and Purolite S.R.L. operate a Quality Management System according to BS EN ISO 9001:2015 that is certified by BSI.

We also certify that **Purolite® A430MR:**

- Is manufactured using no raw materials or additives of human, animal and vegetal origin, and it is consequently BSE and TSE safe and aflatoxin free;
- Is manufactured using no genetically modified organisms or products, and is consequently GMO free;
- Is manufactured using NO raw materials or additives containing allergenic materials according to the ALBA list and the European Directive 2003/89/EC (gluten, crustaceans, eggs, fish, peanuts, soya beans, milk, nuts, celery, mustard and sesame seeds, and other products thereof), and is consequently allergen free;
- Is manufactured only with Methanol, a Class 2 Solvent; the residual methanol content of this product is much less than 1,000 ppm, well below 3,000 ppm allowed;
- Is manufactured without the use of any compound containing Class 1 or Class 2 metals, and neither Class 1 or Class 2 metals are produced in the production process; material is compliant with the ICH Q3D Guidelines on Elemental Impurities, to the USP/NF chapter <232>, current version;
- Is used as a catalyst compound of Fe, which is not classified; Fe content is quantified in routine analysis
- Is not manufactured with compounds with genotoxic properties, and genotoxic compounds are not produced during the production process. The use of divinylbenzene (DVB) is permitted by EC regulations for foodstuffs; by referring to bibliographic databases (HSDB), the genotoxic risk of the resin can be denied;
- Is not manufactured with dioxins, and dioxins are not created during the production process; as a result, the product is dioxin free;
- Is not manufactured with melamine and glycerol material and melamine and glycerol material is not created during the production process; as result, the product is melamine free and glycerol material free.

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Purolite—the leading manufacturer of quality ion exchange, catalyst, adsorbent and specialty high-performance resins—is the only company that focuses 100% of its resources on the development and production of resin technology.

We're ready to solve your process challenges.
For further information on Purolite® products and services, visit www.purolite.com or contact your nearest Technical Sales Office.

PSI-01-A430MR-Rev. 02 February 2019