

PRODUCT DECLARATION

Purolite® C100MRNS

This declaration was prepared by Purolite Corporation
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Victoria, Romania February, 2019

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PRODUCT INFORMATION**General**

Product Name:	Purolite® C100MRNS
Manufacturer Code:	90822
Product Type:	Active Pharmaceutical Ingredient
Principal Applications:	Treatment of hyperkalemia
Manufacturer Site:	SC Purolite SRL
Chemical Name:	Styrene crosslinked with divinylbenzene, sulfonic acid, sodium form
Ph. Eur. Name:	Sodium Polystyrene Sulfonate
USP/NF Name:	Sodium Polystyrene Sulfonate
JP Name:	Sodium Polystyrene Sulfonate
CAS Number:	63182-08-1

Regulatory status

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

Certifications / Approvals

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

Material origin:

- Purolite® C100MRNS or 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® C100MRNS 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® C100MRNS is manufactured through chemical synthesis;
- Purolite® C100MRNS is manufactured as per a systematic [Manufacturing Process](#);
- Purolite® C100MRNS batch size:

1800 kg for 50 kg drums;
1440 kg for 90 kg drums.

Packaging details

- Purolite® C100MRNS is packed in double polyethylene lined fibre drums; the internal liner is tie sealed and the outer one is heat sealed. The fibre drum is sealed.

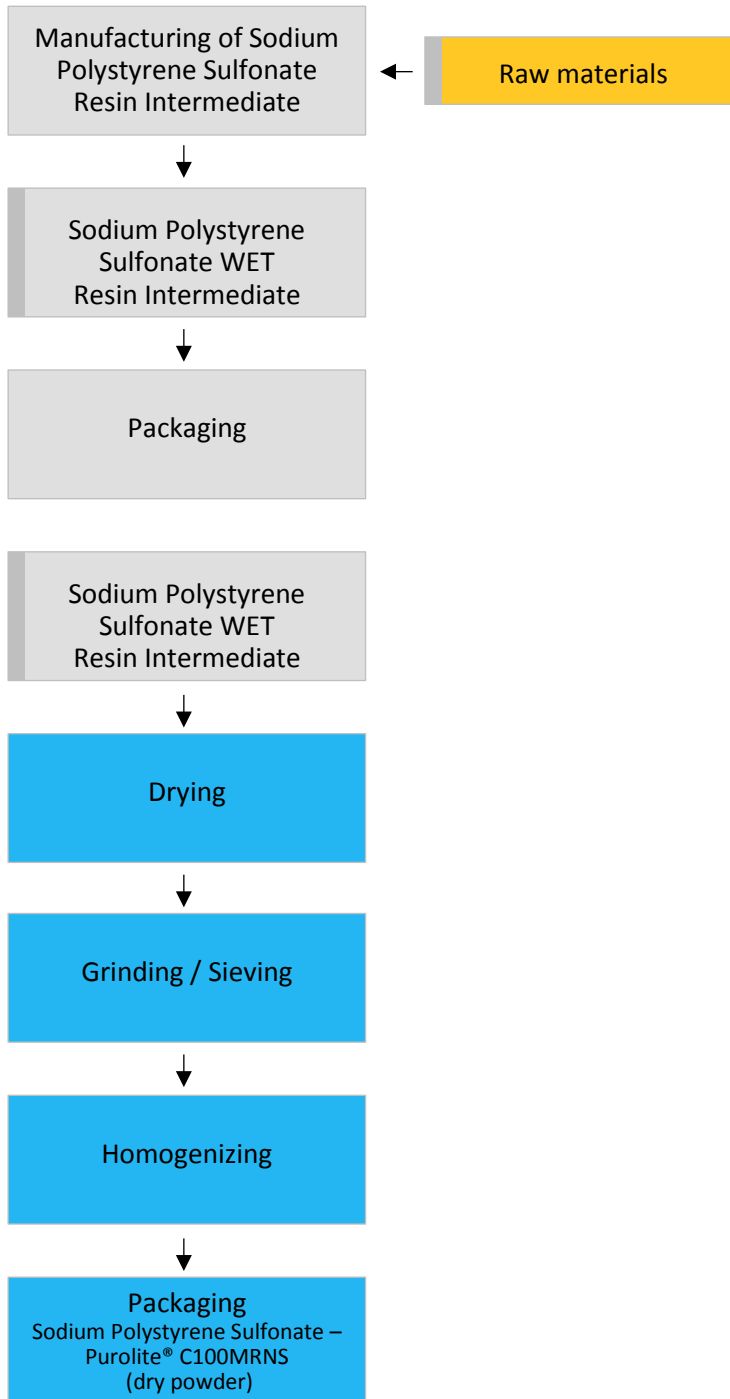
Pharmaceutical fibre drums		
DRUM TYPE	DIMENSIONS cm (in)	QUANTITY / NET WEIGHT
Small	40.5 x 65 (16 x 25.6)	50 kg
Medium	49 x 84.2 (19 x 33)	90 kg

Shelf-life and storage conditions

- When stored under proper storage conditions (in original packaging without extended exposure to temperature extremes or direct sunlight), Purolite® C100MRNS retains properties for a period of five (5) years from the date of manufacture;
- Purolite SRL has performed stability studies in order 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

Sodium Polystyrene Sulfonate – Purolite® C100MRNS



DECLARATION

Component Name:	Purolite® C100MRNS, Sodium Polystyrene Sulfonate
Manufacturer Catalogue No.:	90822
Component Grade:	USP / Ph. Eur. / BP

Purolite certifies that:

- Purolite® C100MRNS is a powdered, fully synthetic, polystyrenic, cation exchange resin in sodium form, fully conforming to the USP / Eu. Phar. / BP monograph of Sodium Polystyrene Sulfonate;
- Purolite® C100MRNS 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® C100MRNS:**

- 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 therefore 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 without solvent and no solvent is produced in the manufacturing process, and is therefore solvent free;
- Is manufactured without the use of metal catalysts; as a result, material is free of residual metals deriving from catalysts;
- Is compliant to ICH Guidelines Q3D on elemental impurities, to USP/NF chapter <232>, current version;
- Is not manufactured with compounds with genotoxic properties, and genotoxic compounds are not produced in 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.

