

PRODUCT DECLARATION

Purolite[®] C115KMR

This declaration was prepared by Purolite Corporation
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Prepared by:
Doina Florea –
Quality & Regulatory Manager

Cosmin Catanas –
Quality Assurance Engineer

Victoria, Romania February, 2019

PUROLITE S.R.L.

Str. Aleea Uzinei, Nr.11, 505700
Victoria, Jud. Braşov, România
T: +40 268 243 004 to 243 010
F: +40 268 243 002 and 243 003
office@purolite.ro
www.purolite.com
Nr. Reg. Com.: J08/446/1995
Cod Fiscal: RO 6039433

PRODUCT INFORMATION**General**

Product Name:	Purolite® C115KMR
Manufacturer Code:	90635
Product Type:	Excipient
Principal Applications:	Tablet disintegrant, Polacrilin potassium
Manufacturer Site:	SC Purolite SRL
Chemical Name:	2-propenoic acid, 2-methyl-, potassium salt, polymer with diethenylbenzene
Ph. Eur. Name:	Not in Ph. Eur.
USP/NF Name:	Polacrilin Potassium
JP Name [JP 16]:	Not in JP
CAS Number:	65405-55-2

Regulatory status

- Drug Master File (DMF) registered in the United States of America.

Certifications / Approvals

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

Material origin:

- Purolite® C115KMR 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® C115KMR [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® C115KMR is manufactured through chemical synthesis;
- Purolite® C115KMR is manufactured as per a systematic [Manufacturing Process](#);
- Purolite® C115KMR batch size:

1000 kg for 25 kg drums;
1000 kg for 50 kg drums.

Packaging details

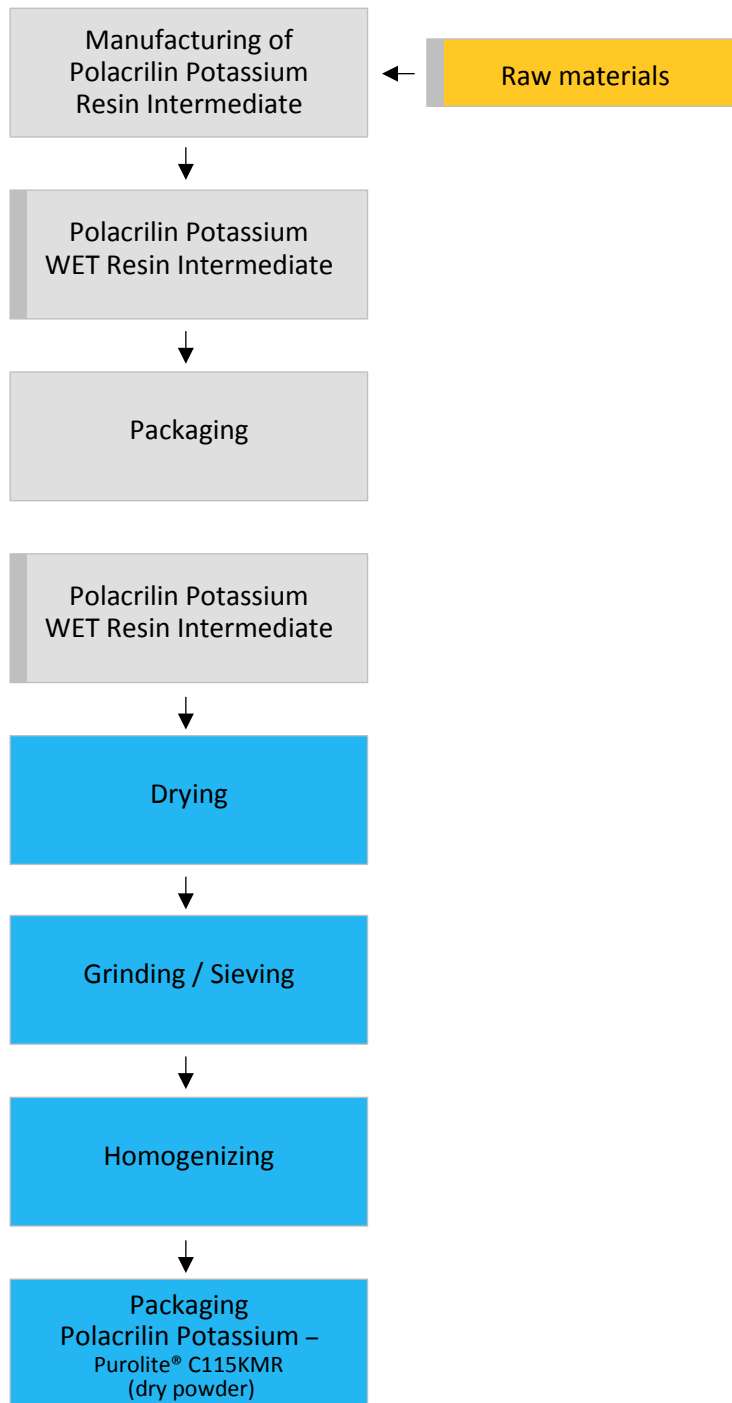
- Purolite® C115KMR is packed in double polyethylene lined fibre drums; the internal liner is tie sealed and the outer one is heat sealed. The fibre drum is sealed.

Pharmaceutical fibre drums		
DRUM TYPE	DIMENSIONS cm (in)	QUANTITY / NET WEIGHT
Small	40.5 x 65 (16 x 25.6)	25 kg; 50 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® C115KMR 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
Polacrilin Potassium – Purolite® C115KMR



Date issued: **February 2019****DECLARATION**

Component Name:	Purolite® C115KMR, Polacrilin Potassium
Manufacturer Catalogue No.:	90635
Component Grade:	USP / NF

Purolite certifies that:

- Purolite® C115KMR is a powdered, fully synthetic, acrylic cation exchange resin in potassium form, fully conforming to the NF / USP monograph of Polacrilin Potassium;
- Purolite® C115KMR 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® C115KMR:**

- 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 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 a result, the product is melamine free and glycerol material free.

Doina FLOREA

Quality and Regulatory Manager

Americas

150 Monument Road
 Bala Cynwyd, PA
 19004
 T +1 800 343 1500
 T +1 610 668 9090
 F +1 484 384 2751
 americas@purolite.com

EMEA

Purolite Ltd
 Unit D
 Llantrisant Business Park
 Llantrisant, Wales, UK
 CF72 8LF
 T +44 1443 229334
 F +44 1443 227073
 emea@purolite.com

Asia Pacific

Room 707, C Section
 Huanglong Century Plaza
 No.3 Hangda Road
 Hangzhou, Zhejiang, China 310007
 T +86 571 876 31382
 F +86 571 876 31385
 asiapacific@purolite.com

FSU

Purolite Ltd
 Office 6-1
 36 Lyusinovskaya Str.
 Moscow, Russia
 115093
 T +7 495 363 5056
 F +7 495 564 8121
 fsu@purolite.com



Algeria
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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.

