



# Registar Corp

144 Research Drive, Hampton, Virginia 23666 USA

Phone: +1-757-224-0177 \* Fax: +1-757-224-0179 \* Email: [info@registrarcorp.com](mailto:info@registrarcorp.com) \* Website: [www.registrarcorp.com](http://www.registrarcorp.com)

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October 09, 2013

Purolite S.R.L.

Str Aleea Uzinei, Nr. 11

Victoria, Judetul Brasov, Brasov RO-505700

Romania

Re: U.S. FDA Drug Establishment Registration Renewal Certificate

Good Day,

We enclose the Certificate of Registration issued by Registar Corp verifying that your firm's drug establishment registration has been electronically updated with FDA for Fiscal Year 2014 (FY 2014).

We advise that FDA has changed its requirement for annual registration. The Food and Drug Administration Safety and Innovation Act of 2012 ("FDASIA"), which was signed into law on July 9, 2012, requires that all registrants renew their Drug Establishment Registrations between October 1 and December 31 of each year. To comply with this statutory requirement, we submitted your registration during this period. Your next renewal period will be October 1 to December 31, 2014. You will be sent documents to verify the accuracy of your information again at that time.

Registar Corp will send you color copies of your certificates by email. You may wish to use the electronic version to forward copies of your company's certificates to your customers and suppliers so they are aware that your company has complied with FDA's registration requirements. Please note that pursuant to 21 CFR § 207.39, "Registration of a drug establishment or drug wholesaler, or assignment of a registration number or assignment of a NDC number does not in any way denote approval of the firm or its products. Any representation that creates an impression of official approval because of registration or possession of a registration number or NDC number is misleading and constitutes misbranding." This means that the enclosed certificate does not denote endorsement or approval by the U.S. FDA, and it should not be used to suggest such an inference.

As your U.S. Agent and Registrant Contact, Registar Corp will continue to serve as a communications link between the U.S. FDA and your company for your electronic submissions. If we receive any correspondence from the U.S. FDA for your company regarding your electronic submissions, we will notify you by fax, email, or phone. In addition, we will be pleased to complete electronic submissions for any drug products not already listed with the U.S. FDA which you may introduce to market.

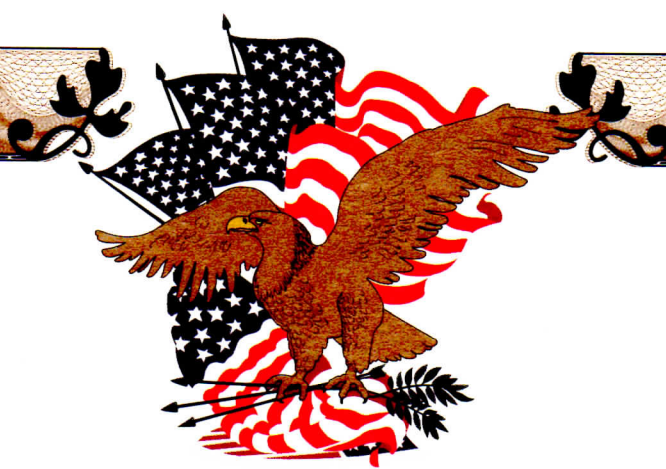
Please contact us if you have any questions or need additional help with FDA compliance.

Sincerely,

David Lennarz

Vice President

Registar Corp. is a private registration agent not affiliated with the U.S. Food and Drug Administration.



FY2014

## CERTIFICATE OF REGISTRATION

*This certifies that:*

**Purolite S.R.L.**  
**Str Aleea Uzinei, Nr. 11**  
**Victoria, Judetul Brasov, Brasov RO-505700**  
**Romania**

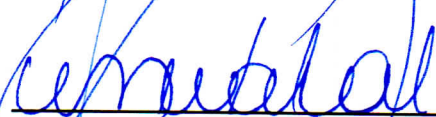
is registered with the U.S. Food and Drug Administration for the statutory filing period applicable to U.S. FY 2014 pursuant to part 207 of Title 21, U.S. Code of Federal Regulations.

DUNS Number: **565718892**  
Labeler Code: **68444**  
FEI: **3004201705**  
U.S. Agent/Registrant Contact: **Registrar Corp**  
144 Research Drive, Hampton, Virginia, 23666, USA  
Telephone: +1-757-224-0177 • Fax: +1-757-224-0179

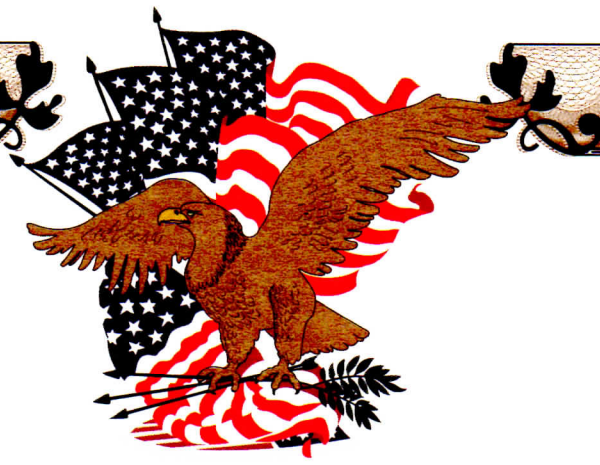
*Filing was performed during the October 1 - December 31, 2013 statutory period, and renewal is not required until the next statutory period of October 1- December 31, 2014. Registrar Corp will confirm that such registration remains effective upon request and presentation of this certificate, until the end of the year stated above, unless terminated after issuance of this certificate. Registrar Corp makes no other representations or warranties, nor does this certificate make any representations or warranties to any person or entity other than the named certificate holder, for whose sole benefit it is issued. Registrar Corp assumes no liability to any person or entity in connection with the foregoing. Registration of a drug establishment or drug wholesaler, or assignment of a registration number, or assignment of a NDC number does not in any way denote approval of the firm or its products by the U.S. Food and Drug Administration. Any representation that creates an impression of official approval because of registration or possession of registration number or NDC number is misleading and constitutes misbranding. The U.S. Food and Drug Administration does not issue a certificate of registration, nor does the U.S. Food and Drug Administration recognize a certificate of registration. Registrar Corp is not affiliated with the U.S. Food and Drug Administration.*

**Registrar Corp** ★

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\_\_\_\_\_  
Russell K. Statman  
Executive Director  
Registrar Corp

Dated: October 9, 2013



2013

## CERTIFICATE OF API PRODUCT LISTING

*This certifies that:*

**Purolite, S.R.L.**  
**Str Aleea Uzinei, Nr. 11,**  
**Victoria, Judetul Brasov RO-505700**  
**Romania**

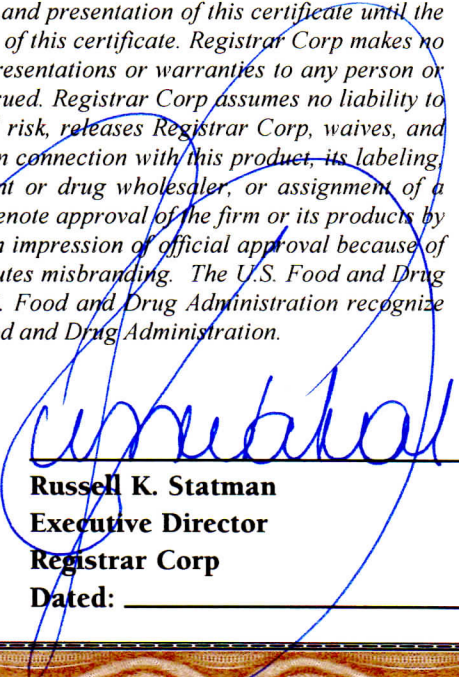
has listed the referenced API product with the U.S. Food and Drug Administration pursuant to part 207 of Title 21, US Code of Federal Regulations, such listing having been verified as currently effective on the date hereof by Registrar Corp:

Product Trade Name:	<b>Cholestyramine Resin A430 MR U.S.P.</b>
Labeler Code:	<b>68444</b>
Product Code:	<b>0001</b>
Package Code:	<b>0</b>
NDC Number:	<b>68444-0001-0</b>
U.S. Agent /	<b>Registrar Corp</b>
Registrant Contact:	<b>144 Research Drive, Hampton Virginia, 23666 USA</b> <b>Telephone: +1-757-224-0177 • Fax: +1-757-224-0179</b>

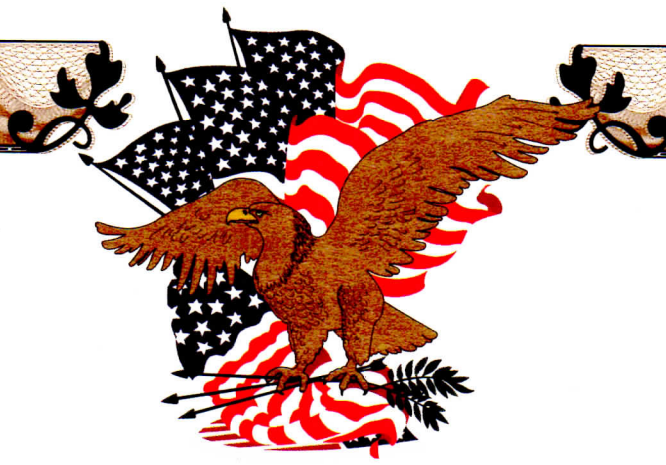
*Registrar Corp will confirm that such listing remains effective upon request and presentation of this certificate until the expiration of one year from the date hereof, unless terminated after issuance of this certificate. Registrar Corp makes no other representations or warranties, nor does this certificate make any representations or warranties to any person or entity other than the named certificate holder, for whose sole benefit it is issued. Registrar Corp assumes no liability to any person or entity in connection with the foregoing. Holder assumes all risk, releases Registrar Corp, waives, and will hold harmless and indemnify Registrar Corp from any and all claims in connection with this product, its labeling, FDA drug listing, commerce or use. Registration of a drug establishment or drug wholesaler, or assignment of a registration number, or assignment of a NDC number does not in any way denote approval of the firm or its products by the U.S. Food and Drug Administration. Any representation that creates an impression of official approval because of drug listing or the assignment of an NDC number is misleading and constitutes misbranding. The U.S. Food and Drug Administration does not issue certificates of drug listing, nor does the U.S. Food and Drug Administration recognize certificates of drug listing. Registrar Corp is not affiliated with the U.S. Food and Drug Administration.*

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**Russell K. Statman**  
**Executive Director**  
**Registrar Corp**

**Dated:** \_\_\_\_\_



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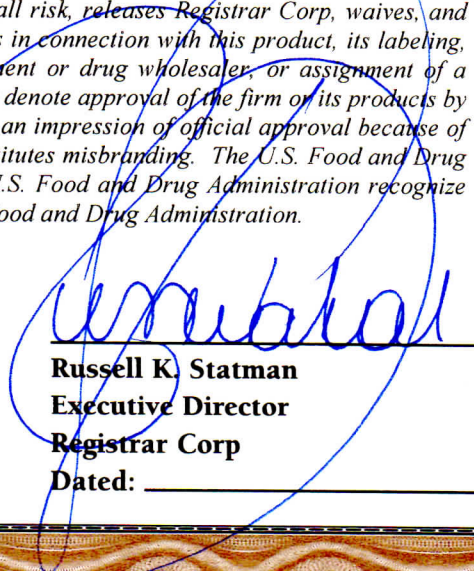
has listed the referenced API product with the U.S. Food and Drug Administration pursuant to part 207 of Title 21, US Code of Federal Regulations, such listing having been verified as currently effective on the date hereof by Registrar Corp:

Product Trade Name:	<b>Polacrilin Potassium, NF</b>
Labeler Code:	<b>68444</b>
Product Code:	<b>0003</b>
Package Code:	<b>0</b>
NDC Number:	<b>68444-0003-0</b>
U.S. Agent /	<b>Registrar Corp</b>
Registrant Contact:	<b>144 Research Drive, Hampton Virginia, 23666 USA</b> <b>Telephone: +1-757-224-0177 • Fax: +1-757-224-0179</b>

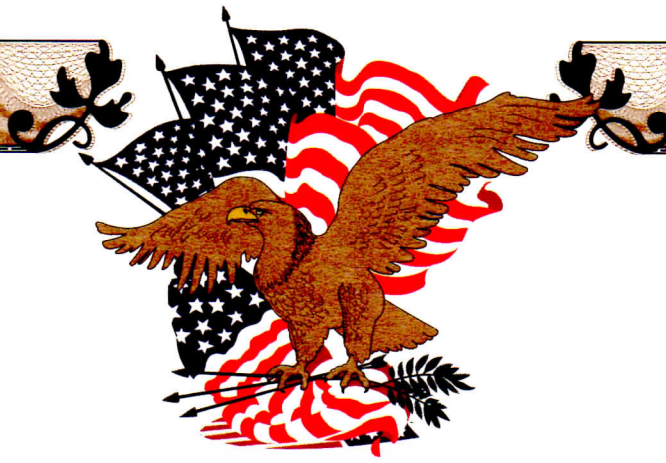
*Registrar Corp will confirm that such listing remains effective upon request and presentation of this certificate until the expiration of one year from the date hereof, unless terminated after issuance of this certificate. Registrar Corp makes no other representations or warranties, nor does this certificate make any representations or warranties to any person or entity other than the named certificate holder, for whose sole benefit it is issued. Registrar Corp assumes no liability to any person or entity in connection with the foregoing. Holder assumes all risk, releases Registrar Corp, waives, and will hold harmless and indemnify Registrar Corp from any and all claims in connection with this product, its labeling, FDA drug listing, commerce or use. Registration of a drug establishment or drug wholesaler, or assignment of a registration number, or assignment of a NDC number does not in any way denote approval of the firm or its products by the U.S. Food and Drug Administration. Any representation that creates an impression of official approval because of drug listing or the assignment of an NDC number is misleading and constitutes misbranding. The U.S. Food and Drug Administration does not issue certificates of drug listing, nor does the U.S. Food and Drug Administration recognize certificates of drug listing. Registrar Corp is not affiliated with the U.S. Food and Drug Administration.*

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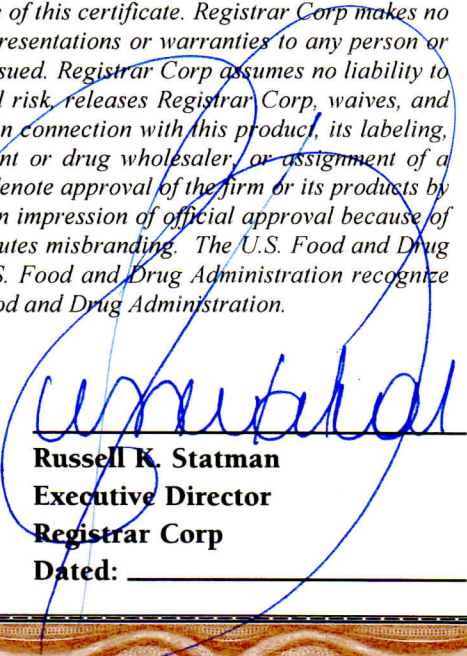
has listed the referenced API product with the U.S. Food and Drug Administration pursuant to part 207 of Title 21, US Code of Federal Regulations, such listing having been verified as currently effective on the date hereof by Registrar Corp:

Product Trade Name:	<b>C 100 MR NS</b>
Labeler Code:	<b>68444</b>
Product Code:	<b>0002</b>
Package Code:	<b>0</b>
NDC Number:	<b>68444-0002-0</b>
U.S. Agent /	<b>Registrar Corp</b>
Registrant Contact:	<b>144 Research Drive, Hampton Virginia, 23666 USA</b> <b>Telephone: +1-757-224-0177 • Fax: +1-757-224-0179</b>

*Registrar Corp will confirm that such listing remains effective upon request and presentation of this certificate until the expiration of one year from the date hereof, unless terminated after issuance of this certificate. Registrar Corp makes no other representations or warranties, nor does this certificate make any representations or warranties to any person or entity other than the named certificate holder, for whose sole benefit it is issued. Registrar Corp assumes no liability to any person or entity in connection with the foregoing. Holder assumes all risk, releases Registrar Corp, waives, and will hold harmless and indemnify Registrar Corp from any and all claims in connection with this product, its labeling, FDA drug listing, commerce or use. Registration of a drug establishment or drug wholesaler, or assignment of a registration number, or assignment of a NDC number does not in any way denote approval of the firm or its products by the U.S. Food and Drug Administration. Any representation that creates an impression of official approval because of drug listing or the assignment of an NDC number is misleading and constitutes misbranding. The U.S. Food and Drug Administration does not issue certificates of drug listing, nor does the U.S. Food and Drug Administration recognize certificates of drug listing. Registrar Corp is not affiliated with the U.S. Food and Drug Administration.*

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