

Avantor Performance Materials Poland Spółka Akcyjna  
Sowińskiego 11  
44-101 Gliwice  
Tel. 48 32 2392 000

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## SODIUM CHLORIDE, EP

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### Product Regulatory Data Sheet

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#### Section 1 – Product Information

##### Products Covered

<u>Brand</u>	<u>Product Code</u>	<u>Product Description</u>	<u>MOC* code</u>
Macron Fine Chemicals™	P135	Sodium Chloride, EP	RL

\*MOC = Management of Change

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#### Section 2 – Manufacturing, Packaging and Release Site Information

A number of the cGMP produced products that are sold by Avantor Performance Materials, LLC. may not be originally manufactured at our sites. However, we perform the analytical and stability testing for these products and repackage the products where applicable. With ISO and cGMP procedures in place at our facilities we can ensure, and take complete responsibility for, the traceability and quality of the finished, packaged product that we offer.

The original manufacturer and address will be referenced on the Certificate of Analysis as an alpha or alpha-numeric **manufacturer code** rather than listing the full name and address. This practice is compliant with both ICH Q7 Good Manufacturing Guidance for Active Pharmaceutical Ingredients (APIs) and IPEC guidelines and it meets cGMP requirements. For instructions to decipher the manufacturer reference code please consult our website. Instructions can be found in the Ask Avantor Q&A Center of the customer support section of our web site or by directly linking to [www.avantorsciences.com](http://www.avantorsciences.com) Keyword: Manufacturer Code.

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### ***Section 3 – Physical/Chemical Information***

**CAS #:** 7647-14-5

**Manufacturing Process:** Synthesis

**Raw Material Origin:** Chemical

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### ***Section 4 – Regulatory Information***

**Compendial Compliance:** Please see the current product specifications at [www.avantorsciences.com](http://www.avantorsciences.com)

**DMF:** Avantor Performance Materials, LLC does not carry a Drug Master File for these products.

**BSE/TSE Status:** The subject materials are manufactured from raw materials that contain NO animal parts, products, and/or by-products nor do they come in contact with animal parts, products, and/or by-products.

**GMO Information:** The subject materials, including any raw materials and processing aids, are NOT subject to genetic modification.

**Residual Solvents/Organic Volatile Impurities (OVI) Information:** The subject materials (all lots) comply with the requirements of the ICH Q3C Residual Solvents Guideline and USP<467>Residual Solvents. No Class 1, 2, 3 or other solvents are used or produced in the manufacturing or purification of the product.

**Elemental Impurities:** Please see attached summary for Elemental Impurity information for listed products.

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### ***Section 5 – Miscellaneous Product Information***

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**Certificate of Analysis Date Format:** The Manufactured Date and Expiration/Retest Date on the C of A are reported as YYYY/MM/DD from our ERP system. For example, the Manufactured Date for October 1, 2018 would be reported as 2018/10/01.

**Lot Numbering System and Batch Description:** Please refer to the customer support section of our website for information concerning our lot/batch numbering system. ([www.avantorsciences.com](http://www.avantorsciences.com) Keyword: Lot Number).

**Shelf Life Information:** If a product has an assigned expiration or retest period, the date will appear on the certificate of analysis. For products that do not have assigned dates please contact Technical Support through the customer support section of our website for our product stability profiles. ([www.avantorsciences.com](http://www.avantorsciences.com) Keyword: Expiration).

**Management of Change:** Please refer to the customer support section of our website for information concerning our Management of Change program. ([www.avantorsciences.com](http://www.avantorsciences.com) Keyword: MOC).

**Country of Origin Statement:** Country of Origin is indicated on the product Certificate of Analysis. Please contact our Trade Compliance if you require further documentation ([Trade.Compliance@avantorsciences.com](mailto:Trade.Compliance@avantorsciences.com)).

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## ***Section 6 – Revision History***

Rev. 0; November 15, 2013

Rev. 1; November 19, 2019

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***This electronic document is valid without a signature.***

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## ***Section 7 – Contact Information***

Customer Service

Phone: 1-855-282-6867

1-610-573-2600 (outside U.S.)

Avantor Performance Materials Poland Spółka Akcyjna  
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44-101 Gliwice  
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