

---

# Sodium Carbonate Anhydrous Granular

---

---

## Product Data Sheet

---

### Section 1 – Product Information

#### Products Covered

Brand	Product Code	Name	Grade	Compendia
Macron Fine Chemicals™	H660-02	Sodium Carbonate Anhydrous Granular	IP	IP
Macron Fine Chemicals™	H660-06	Sodium Carbonate Anhydrous Granular	IP	IP
Macron Fine Chemicals™	H680-02	Sodium Carbonate Anhydrous Granular	NF	NF
Macron Fine Chemicals™	H680-06	Sodium Carbonate Anhydrous Granular	NF	NF
Macron Fine Chemicals™	H690-02	Sodium Carbonate Anhydrous Granular	Multi	NF/BP/EP/JP
Macron Fine Chemicals™	H690-06	Sodium Carbonate Anhydrous Granular	Multi	NF/BP/EP/JP

---

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

The **USP/NF and Multicompendial** grade products in Section 1 are manufactured according to current Good Manufacturing Practices (cGMPs) as set forth by International Pharmaceutical Excipients Council (IPEC) guidelines.

The **IP** grade products in Section 1 are manufactured according to current Good Manufacturing Practices (cGMPs) as set forth in the Drugs and Cosmetics Rules, 1945, Government of India Ministry of Health and Family Welfare.

---

### Section 3 – Physical/Chemical Information

**CAS #:** 497-19-8

**Manufacturing Process:** Synthesis

**Raw Material Origin:** Chemical

---

---

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

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

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

**BSE/TSE Status:** To the best of our knowledge, 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.

**Allergen/Hypersensitivities Information:** This product has not yet been evaluated for allergen information.

**GMO Information:** To the best of our knowledge, the subject materials, including any raw materials and processing aids, are NOT subject to genetic modification.

**Residual Solvents/Organic Volatile Impurities (OVI) Information:** To the best of our knowledge, 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.

**Residual Metallic Catalysts:** No metal catalysts or metal reagents, as defined by EMA Guideline EMEA/CHMP/SWP/4446/2000, are used in the production of this material.

---

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

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

---

## ***Section 6 – Revision History***

Rev. 0; Effective Date: August 30, 2013(TLS/MCH)

Rev. 1; May 19, 2014 – Section 1: Updated compendia designation for H690 (MCH)

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

Technical Service Department  
Avantor™ Performance Materials, Inc.  
3477 Corporate Parkway Suite #200  
Center Valley, PA 18034  
1-800-669-8230

OR

Mail-ID: [pharma.india@avantormaterials.com](mailto:pharma.india@avantormaterials.com)  
Phone No. +91-129-4267019

---

Avantor™ Performance Materials, Inc provides the information contained herein in good faith but makes no representations or warranties, either expressed or implied, including without limitation any warranties of merchantability or fitness for a particular purpose with respect to the information set forth herein or the product(s) to which the information refers. Accordingly, Avantor™ Performance Materials, Inc will not be responsible for damages resulting from the use of or reliance upon this information.

Trademarks are owned by Avantor Performance Materials, Inc. or its affiliates unless otherwise noted.  
© 2014 Avantor Performance Materials, Inc.