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1 855 282 6867
www.avantorsciences.com

Boric Acid

Product Regulatory Data Sheet

Section 1 – Product Information

Products Covered

Brand	Product Code	Product Description	MOC* code
J.T.Baker®	0091	Boric Acid, Granular N.F.	R
J.T.Baker®	0092	Boric Acid, Granular, N.F. Multi-Compendial	R
J.T.Baker®	0096	Boric Acid, Granular Multi-Compendial	R
J.T.Baker®	1394	Boric Acid, Granular N.F.	R
J.T.Baker®	7905	Boric Acid N.F., A.C.S.	R
Macron Fine Chemicals™	7779	Boric Acid, Granular NF - GenAR®	R

*MOC = Management of Change

Section 2 – Manufacturing, Packaging and Release Site Information

The products in Section 1 are manufactured according to current Good Manufacturing Practices (cGMPs) as set forth by International Pharmaceutical Excipients Council (IPEC) guidelines.

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.askavantor.com Keyword: Manufacturer Code.

Section 3 – Physical/Chemical Information

CAS #: 10043-35-3

Manufacturing Process: Synthesis , Recrystallization

Raw Material Origin: Chemical

Section 4 – Regulatory Information

Compendial Compliance: Please see the current product specifications at 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

Allergen/Hypersensitivities Information: The products listed do not contain cereals containing gluten (i.e. wheat, rye, oats, barley, spelt, kamut or their hybridized strains), malt, triticale, gluten, other grains, corn, soy, soybeans, eggs, yeast, canola, milk, dairy products, fish, crustacean shellfish, seafood products, tree nuts, peanuts, nut products (i.e. Almond (Amygdalus communis L.), Hazelnut (Corylus avellana), Walnut (Juglans regia), Cashew (Anacardium occidentale), Pecan nut (Carya illiniesis (Wangenh.) K. Koch), Brazil nut (Bertholletia excelsa), Pistachio nut (Pistacia vera), Macadamia nut and Queensland nut (Macadamia ternifolia)), seed products (sesame seeds and products thereof), natural grape products, natural flavors, artificial flavors, celery, mustard, lactose, sulfites, elemental sulfur, preservatives, lupine and products thereof, MSG, disodium guanylate/inosinate, artificial sweeteners, phenylalanine, additives, colorants, dyes, or natural rubber (latex). These products are manufactured using cGMP guidelines which provide controls that allow no potential for cross contamination of any allergens or other 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.

Kosher Status: The subject materials are not Kosher Certified. Please refer to the customer support section of our website for our most up to date listing of Kosher products. (www.askavantor.com Keyword: Kosher)

Halal Status: The subject materials are not Halal Certified. Please refer to the customer support section of our website for our most up to date listing of Halal products. (www.askavantor.com Keyword: Halal)

GRAS Status: The United States Food and Drug Administration (FDA) have acknowledged that Boric Acid is a Substance Generally Recognized as Safe (GRAS) as an additive in foods when used in accordance with the requirements and limitations per 21 CFR parts 181.30.

Section 5 – Miscellaneous Product Information

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 effective April 30, 2012. For example, the Manufactured Date for October 1, 2012 would be reported as 2012/10/01.

Prior to ERP implementation, the Release Date on the C of A was reported as MM/DD/YYYY. For example, the Release Date for October 1, 2012 would have been reported as 10/01/2012.

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.askavantor.com Keyword: Lot Number)

Batch Definition: A "batch" is a homogeneous unit of production; each batch of is from one single batch of the source supplier.

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.askavantor.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.askavantor.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).

Storage Requirements: Please refer to the product Certificate of Analysis/Product Specifications. In the absence of specific storage conditions listed on the Avantor specification sheet or certificate of analysis, our products are to be stored in ambient conditions of temperature and humidity. We do not formally tie any specific temperature or humidity range with the 'ambient' storage designation, but an example of a common temperature interpretation is 15-30°C. Our products are also packaged to protect from the normal variation in humidity during storage and shipment. Further handling and storage information may be found in Section 7 of the product SDS sheet.

Section 6 – Revision History

Rev. 0; Oct. 1, 2007 – IPEC EIP format
Rev. 1; Oct. 3, 2008 – Section 4: updated residual solvents information
Rev. 2; March 18, 2010– Entire document: new letterhead and changed all references of "Solv IT Center" to "AskMBI."; Section 7: updated TS manager info. GRAS statement added.
Rev. 3; July 25, 2011 –Entire document: new letterhead, and changed all references of "AskMBI" to "AskAvantor." Updated website links for new website; Section 1: Mallinckrodt brand name updated to Macron; added MOC codes; Section 2: added GMP statement; Section 4: expanded Allergens list; added Residual Metallic Catalysts; Section 7: updated contact information; minor formatting. (PH/MCH)

Rev. 4; Dec. 11, 2014 – HDQ address change. Section 1: added code 7905; Section 4: added add'l allergens as listed in EU Directive 2003/89/EC; updated Residual Metallic Catalysts statement; separated Kosher/Halal status and added certification statement Section 5: added Management of Change information; Added COA Date Format statement; Section 7: removed contact list table and added CS/TS contact information. (MCH).
Rev. 5; November 02, 2017 - Update document to new format. Section 4: added Elemental Impurity Statement (PT).
Rev. 6; January 13, 2020 - Entire document: New format and letterhead (company name & headquarters address). Updated email and website address from avantorinc.com to avantorsciences.com. Added website link for AskAvantor; Section 1: Typographical error for code 0096 product name corrected; Section 4: GRAS Status statement changed from "not assessed" to applicable regnum per the FDA website; Section 5: Certificate of Analysis Date Format statement updated. (KH)

This electronic document is valid without a signature.

Section 7 – Contact Information

Customer Service

Phone: 1-855-282-6867
1-610-573-2600 (outside U.S.)
Fax: 1-610-573-2650
CS.Specialist@avantorsciences.com

Technical Service

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The most current revision of this document is maintained on our website. Reviews and revisions are performed as warranted due to product changes or as part of the supplier audit cycle

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Material Name: Boric Acid **Product codes**: : 0091, 0092, 1394, 7779, 7905 **Date**: June 2, 2017
Source/Type of Excipient: ☐ Mineral; ☐ Mineral derived; ☐ Plant; ☐ Plant derived; ☒ Synthetic; ☐ Fermentation derived
Other (explain):

Elemental Impurity		Class	Likely to be Present			If Known, Please Identify the Expected Concentration /Units (or Range)	Analytical Method Used (and Limit of Detection if Available)	Comments regarding source of information (i.e.; number of lots tested, frequency of testing, process understanding, etc.)
Arsenic (inorganic)	As	1	Yes ☐	No ☒	Unknown ☐	<0.1 ppm	ICP-OES (MRL=0.1 ppm)	> 3 batches – testing provided by supplier
Cadmium	Cd	1	Yes ☐	No ☒	Unknown ☐	<0.1 ppm	ICP-OES (MRL=0.1 ppm)	> 3 batches – testing provided by supplier
Mercury (inorganic)	Hg	1	Yes ☐	No ☒	Unknown ☐	<0.1 ppm	ICP-OES (MRL=0.1 ppm)	> 3 batches – testing provided by supplier
Lead	Pb	1	Yes ☐	No ☒	Unknown ☐	<0.2 ppm	ICP-OES (MRL=0..2 ppm)	> 3 batches – testing provided by supplier
Cobalt	Co	2A	Yes ☐	No ☒	Unknown ☐	<0.2 ppm	Atomic Absorption (MRL=0..2 ppm)	> 3 batches – testing provided by supplier
Nickel	Ni	2A	Yes ☐	No ☒	Unknown ☐	<0.2 ppm	ICP-OES (MRL=0..2 ppm)	> 3 batches – testing provided by supplier
Vanadium	V	2A	Yes ☐	No ☒	Unknown ☐	<0.1 ppm	ICP-OES (MRL=0.1 ppm)	> 3 batches – testing provided by supplier

Elemental Impurity		Class	Likely to be Present			If Known, Please Identify the Expected Concentration /Units (or Range)	Analytical Method Used (and Limit of Detection if Available)	Comments regarding source of information (i.e.; number of lots tested, frequency of testing, process understanding, etc.)
Silver	Ag	2B	Yes ☐	No ☒	Unknown ☐	<0.1 ppm	Atomic Absorption (MRL=0.1 ppm)	> 3 batches – testing provided by supplier
Gold	Au	2B	Yes ☐	No ☒	Unknown ☐	Not applicable	Not applicable	Not tested, not added to process
Iridium	Ir	2B	Yes ☐	No ☒	Unknown ☐	<0.1 ppm	ICP-OES (MRL=0.1 ppm)	> 3 batches – testing provided by supplier
Osmium	Os	2B	Yes ☐	No ☒	Unknown ☐	<0.1 ppm	ICP-OES (MRL=0.1 ppm)	> 3 batches – testing provided by supplier
Palladium	Pd	2B	Yes ☐	No ☒	Unknown ☐	<0.1 ppm	ICP-OES (MRL=0.1 ppm)	> 3 batches – testing provided by supplier
Platinum	Pt	2B	Yes ☐	No ☒	Unknown ☐	<0.1 ppm	ICP-OES (MRL=0.1 ppm)	> 3 batches – testing provided by supplier
Rhodium	Rh	2B	Yes ☐	No ☒	Unknown ☐	<0.1 ppm	ICP-OES (MRL=0.1 ppm)	> 3 batches – testing provided by supplier
Ruthenium	Ru	2B	Yes ☐	No ☒	Unknown ☐	<0.1 ppm	ICP-OES (MRL=0.1 ppm)	> 3 batches – testing provided by supplier
Selenium	Se	2B	Yes ☐	No ☒	Unknown ☐	Not applicable	Not applicable	Not tested, not added to process
Thallium	Tl	2B	Yes ☐	No ☒	Unknown ☐	Not applicable	Not applicable	Not tested, not added to process
Barium	Ba	3	Yes ☐	No ☒	Unknown ☐	0.1 ppm	Ion Chromatography (MRL=0.1 ppm)	> 3 batches – testing provided by supplier
Chromium	Cr	3	Yes ☐	No ☒	Unknown ☐	<0.2 ppm	ICP-OES (MRL=0.2 ppm)	> 3 batches – testing provided by supplier
Copper	Cu	3	Yes ☐	No ☒	Unknown ☐	<0.4 ppm	ICP-OES (MRL=0.4 ppm)	> 3 batches – testing

Elemental Impurity		Class	Likely to be Present			If Known, Please Identify the Expected Concentration /Units (or Range)	Analytical Method Used (and Limit of Detection if Available)	Comments regarding source of information (i.e.; number of lots tested, frequency of testing, process understanding, etc.)
								provided by supplier
Lithium	Li	3	Yes ☐	No ☒	Unknown ☐	<0.1 ppm	Ion Chromatography (MRL=0.1 ppm)	> 3 batches – testing provided by supplier
Molybdenum	Mo	3	Yes ☐	No ☒	Unknown ☐	<0.2 ppm	ICP-OES (MRL=0.1 ppm)	> 3 batches – testing provided by supplier
Antimony	Sb	3	Yes ☐	No ☒	Unknown ☐	<0.1 ppm	Atomic Absorption (MRL=0.1 ppm)	> 3 batches – testing provided by supplier
Tin	Sn	3	Yes ☐	No ☐	Unknown ☒	Not expected to be present	Not applicable	Not tested, not added to process

Reference: ICH Q3D Guideline for Elemental Impurities, Step 4 version, September 2014

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