

Acetic Acid

Product Regulatory Data Sheet

Section 1 – Product Information

Products Covered :

<u>Brand</u>	<u>Product Code</u>	<u>Product Description</u>	<u>MOC*</u>
J.T.Baker®	0321	Acetic Acid 80% Solution Biotech Reagent	R
Macron Fine Chemicals™	2488	Acetic Acid, 36% N.F. (Solution)	R
Macron Fine Chemicals™	2502	Acetic Acid, Glacial U.S.P., F.C.C., A.C.S.	R
Macron Fine Chemicals™	3121	Acetic Acid, Glacial U.S.P., F.C.C., A.C.S.	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 QA Center of the support section of our web site or by directly linking to Ask Avantor Keyword: Manufacturer Code.

Section 3 – Physical/Chemical Information

CAS #: 64-19-7

Manufacturing Process:

Synthesis- Continuous dedicated process

Raw Material Origin:

Chemical

Section 4 – Regulatory Information

Compendial Compliance: Please see the current product specifications at www.AvantorInc.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. Therefore the risk of BSE/TSE is considered negligible.

BSE/TSE Status Macron 2488: This product is not produced with using any bovine, ovine, or caprine tissue classified per EMA/410/01 rev.3; therefore, the risk of BSE/TSE risk is considered negligible.

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:

Macron 2502, 3121: The above acetic acid materials (all lots) comply with the requirements of the ICH Q3C Residual Solvents Guideline and USP<467>Residual Solvents. Only Class 3 Solvents are likely to be present. Residual concentration of all Class 3 Solvents is <0.5%.

J.T.Baker® 0321: The above acetic acid solution (all lots) has been prepared from glacial acetic acid and water. No Class 1, 2, 3 or other solvents are used or produced in the manufacturing or purification of the product.

Macron 2488: The above acetic acid materials (all lots) comply with the requirements of the ICH Q3C Residual Solvents Guideline and USP<467>Residual Solvents. Only the Class 3 Solvents acetone, isopropyl acetate, and propyl acetate are expected to be present. Residual concentration of all Class 3 Solvents combined is <0.1%.

Elemental Impurities:

Please see attached summary for Elemental Impurity information for listed products.

Aflatoxins:

compounds produced by certain strains of the fungi *Aspergillus flavus* and *A. parasiticus*. Under favorable conditions of temperature and humidity, these fungi grow on certain foods and feeds, resulting in the production of aflatoxins. The most pronounced contamination has been encountered in tree nuts, peanuts, and other oilseeds, including corn and cottonseed. Aflatoxicosis is poisoning that results from ingestion of aflatoxins in contaminated food or feed.

Avantor does not analyze the product(s) for the presence of aflatoxin content. However, we can confirm the subject materials do not contain, nor are they manufactured with any product commonly affected by aflatoxins. These include cereals (maize, sorghum, pearl millet, rice, wheat), oilseeds (peanut, soybean, sunflower, cotton), spices (chili peppers, black pepper, coriander, turmeric, ginger), and tree nuts (almond, pistachio, walnut, coconut, Brazil nut)

Kosher Status:

Certified Kosher – Pareve for year-round use.

Please refer to the customer support section of our website for our most up to date listing of Kosher products. (Ask Avantor 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. (Ask Avantor Keyword: Halal)

GRAS Status:

The United States Food and Drug Administration (FDA) have acknowledged that Acetic Acid is a Direct Food Substances Affirmed As Generally Recognized as Safe (GRAS) in foods when used in accordance with the requirements and limitations per 21 CFR parts 184.1005.

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

Lot Numbering System and Batch Description: Please refer to the customer support section of our website for information concerning our lot/batch numbering system. (Ask Avantor Keyword: Lot Number)

Batch Definition: A “batch” is a homogeneous unit of production; each batch of material 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. (Ask Avantor Keyword: Expiration)

Nutritional/Supplement Facts Labeling:

are to be processed, labeled, and/or repacked at a site other than where it’s originally processed or packed, are exempt from the Nutrient Content Evaluation and Nutrient Labeling Requirements. (21 CFR 101.9(j)(9))

Organic Status:

The products listed in Section 1 are not certified as organic. However, to the best of our knowledge, the product is not produced using Ionizing Radiation as described in 21 CFR 179.26 or Sewage Sludge as described in 7 CFR Section 205.2.

Management of Change: Please refer to the customer support section of our website for information concerning our Management of Change program. (Ask Avantor Keyword: MOC)

Country of Origin Statement: Country of Origin is indicated on the product Certificate of Analysis. Please contact our Trade Compliance Department if you require further documentation. (Trade.Compliance@AvantorInc.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; Jan. 2, 2008 – Section 1: Added product 0320; Section 4: Residual Solvents statement updated to mention “other” solvents and specifically reference USP chapter <467>. Added specific sentence for the acetic acid solutions listed in section 1; Section 7: updated telephone # for Customer Service Director; Entire Document: added keywords to Solv It Center links. (KES)

Rev. 2; Feb. 19, 2009- Section 1: Added product code 7711; Changed letterhead. (KES)

Rev. 3; Nov. 23, 2009 – Section 1: corrected brand for 0320, removed code 7711 b/c it’s discontinued; Section 4: separated residual solvents statement for glacial acetic acid and acetic acid solutions; Section 7: updated TS manager info; Entire document: changed reference from Solv-It Center to AskMBI. (JLW)

Rev. 4; July 8, 2011 – Entire document: new letterhead and changed all references of “AskMBI” to “AskAvantor.” Updated website links for new website; minor formatting; Section 1: omitted 0350, 0311 and 0321 (discontinued);

added MOC codes; Section 2: added GMP statement; Section 4: expanded Allergens list; added GRAS statement, removed typical residual solvent values; Section 5: added Nutrition and Organic statement; Section 7: updated contact information. (JLW/MCH)

Rev. 5; Oct 11, 2011 HDQ address change; Section 4: Kosher statement changed from AskMBI to AskAvantor; Section 7: Updated contact information. (JDR)

Rev. 6; February 9, 2012- Section 1: Replaced Macron 2504 with new code Macron 2502 per MOC-PROC-1431; Section 4: updated Residual Solvents statement to match Certificate of Analysis statement. Added Residual Metallic Catalysts statement; Section 7: updated contact information. (MCH)

Rev. 7; May 4, 2012- Section 4: updated Residual Solvents statement for Macron 2488. (MCH)

Rev. 8; Dec. 18, 2012 – 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. JDR

Rev. 9; March 13, 2013 – Section 4: updated Residual Metallic Catalysts statement. (MCH)

Rev. 10; March 19, 2015 – Section 1: Removed delisted code 0320, added code 0321; Section 4: updated Residual Solvents statement for Macron 2488, 2502, 3121 to more accurately reflect COA statement; added residual solvents statement for 0321. (MCH)

Rev. 11; April 14, 2015 – Section 4: Updated Residual Solvents statement per MOC-QUAL-7246 for code 2488. (MCH)

Rev. 12; October 8, 2015 – Section 4: Updated BSE/TSE statement for code 2488 to include reference to EMA guideline.(MCH)

Rev. 13; February 15, 2017- Entire document: new letterhead (company name & headquarters addresss); Section 4: Added Elemental Impurities information for applicable products, added Aflatoxin Statement; Section 5: Added Batch Definition,added storage requirements, and Country of Origin Statement. (CMG)

Rev. 14; May 18, 2017- Updated template to new Avantor Logo/Information. Section 4; removed residual metallic catalysts statement; added additional elemental impurities and summaries; Section 7: Updated contact information. (CMG)

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@AvantorInc.com

Technical Service

Phone: 1-855-282-6867

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

Fax: 1-610-573-2650

Technical.Service@AvantorInc.com



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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: Acetic Acid 80% **Product codes:** 0321 **Date:** May 18, 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 <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Testing of dilution components
Cadmium	Cd	1	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Testing of dilution components
Mercury (inorganic)	Hg	1	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Testing of dilution components
Lead	Pb	1	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Testing of dilution components
Cobalt	Co	2A	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Testing of dilution components
Nickel	Ni	2A	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Testing of dilution components

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.)
Vanadium	V	2A	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Testing of dilution components
Silver	Ag	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Testing of dilution components
Gold	Au	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Testing of dilution components
Iridium	Ir	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Testing of dilution components
Osmium	Os	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Testing of dilution components
Palladium	Pd	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Testing of dilution components
Platinum	Pt	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Testing of dilution components
Rhodium	Rh	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Testing of dilution components
Ruthenium	Ru	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Testing of dilution components
Selenium	Se	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Testing of dilution components
Thallium	Tl	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Testing of dilution components
Barium	Ba	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Testing of dilution components
Chromium	Cr	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Testing of dilution

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.)
								components
Copper	Cu	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Testing of dilution components
Lithium	Li	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Testing of dilution components
Molybdenum	Mo	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Testing of dilution components
Antimony	Sb	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Testing of dilution components
Tin	Sn	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Testing of dilution components

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



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Material Name: Acetic Acid 36% **Product codes:** : 2488 **Date:** June 30, 2016

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 <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Calculated from component glacial acetic acid and water
Cadmium	Cd	1	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Calculated from component glacial acetic acid and water
Mercury (inorganic)	Hg	1	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Calculated from component glacial acetic acid and water
Lead	Pb	1	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Calculated from component glacial acetic acid and water
Cobalt	Co	2A	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Calculated from component glacial acetic acid and water
Nickel	Ni	2A	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Calculated from component

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.)
								glacial acetic acid and water
Vanadium	V	2A	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Calculated from component glacial acetic acid and water
Silver	Ag	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Calculated from component glacial acetic acid and water
Gold	Au	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Calculated from component glacial acetic acid and water
Iridium	Ir	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Calculated from component glacial acetic acid and water
Osmium	Os	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Calculated from component glacial acetic acid and water
Palladium	Pd	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Calculated from component glacial acetic acid and water
Platinum	Pt	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Calculated from component glacial acetic acid and water
Rhodium	Rh	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Calculated from component glacial acetic acid and water
Ruthenium	Ru	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Calculated from component glacial acetic acid and water
Selenium	Se	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Calculated from component glacial acetic acid and water
Thallium	Tl	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Calculated from component glacial acetic acid and water
Barium	Ba	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Calculated from component glacial acetic acid and water

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.)
Chromium	Cr	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Calculated from component glacial acetic acid and water
Copper	Cu	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Calculated from component glacial acetic acid and water
Lithium	Li	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Calculated from component glacial acetic acid and water
Molybdenum	Mo	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Calculated from component glacial acetic acid and water
Antimony	Sb	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Calculated from component glacial acetic acid and water
Tin	Sn	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Calculated from component glacial acetic acid and water

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



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Material Name: Acetic Acid, Glacial **Product codes:** : 2502, 2504, 3121, 7711, 9522, 9523, 9526 **Date:** June 30, 2016

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 <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Cadmium	Cd	1	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Mercury (inorganic)	Hg	1	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Lead	Pb	1	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Cobalt	Co	2A	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Nickel	Ni	2A	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Vanadium	V	2A	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches

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 <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Gold	Au	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Iridium	Ir	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Osmium	Os	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Palladium	Pd	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Platinum	Pt	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Rhodium	Rh	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Ruthenium	Ru	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Selenium	Se	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Thallium	Tl	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Barium	Ba	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Chromium	Cr	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Copper	Cu	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Lithium	Li	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Molybdenum	Mo	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Antimony	Sb	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Tin	Sn	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches

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



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