Avantor, Inc.
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Edetate Disodium

Product Regulatory Data Sheet

Section 1 – Product Information

Products Covered

Brand	Product Code	Product Description	MOC* code
J.T.Baker®	8994	Edetate Disodium U.S.P.	R
J.T.Baker®	8995	Edetate Disodium, U.S.P. Multi-Compendial	R
Macron Fine Chemicals™	1395	Edetate Disodium U.S.P.	R
Macron Fine Chemicals™	7565	Edetate Disodium USP - GenAR®	R
Macron Fine Chemicals™	7727	Edetate Disodium USP - GenAR®	R

*MOC = Management of Change

Section 2 – Manufacturing, Packaging and Release Site Information

The products in Section 1 listed 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 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.

For J.T.Baker® and Macron Fine Chemicals™ brand products, 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 the Avantor website. Instructions can be found by visiting the Ask Avantor link under the Resources tab or by directly linking to Ask Avantor Keyword: Manufacturer Code. Additional information on Avantor suppliers may be available under NDA. Please reach out to the support contact in Section 7 for additional supplier information inquiries.

Section 3 – Physical/Chemical Information

CAS #: 6381-92-6

Manufacturing Process: Synthesis. Additional manufacturing process information may be disclosed under NDA upon request from the support contact in Section 7.

Raw Material Origin: Chemical

Section 4 – Regulatory Information

DMF: Avantor may hold Master File(s) for specified product codes, dependent on the country of interest. Inquire with the support contact in Section 7 for additional details.

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: To the best of our knowledge, the allergens listed in the US FDA, EU Directive 2003/89/EC, and TG0-91/92 are not known additives, by products, intermediate parts, or otherwise intentionally added during the manufacturing processes of the product.

According to the Original Manufacturer of products 8994, 8995, 1395 and 7727, raw materials, including additives, that have origin in corn or corn derivatives, eggs, fish, gluten, grapefruits, milk, mustard, peaches, peanuts, pork, royal jelly, sesame seeds, shellfish, soybeans, sulfur dioxide, sunflowers, tomatoes, tree nuts, wheat or buckwheat, any species of grains including barley, wheat, kemut, oats, rye, corn, malt, tricale, other grains, and/or derivatives of these products. This product will be free of gluten, unrefined oil, sulfites, MSG, hydrolyzed vegetable or plant protein (HVP/HPP), colorings, spices, caffeine, animal and animal by-products, and yeast are not known additives, by products, intermediate parts, or otherwise intentionally added during the manufacturing processes of the product.

According to the Original Manufacturer of product 7565 celery, egg and egg products, milk and milk products, lactose, peanuts, all other nuts and nut oils, seafood e.g. shellfish, fish, seeds, e.g. poppy sesame, sunflower, soya and soy products, sulphites, cereal grains e.g. maize, rice, wheat and derivatives thereof, gluten, artificial flavors, phenylalanine from aspartame, colorants, antioxidants, preservatives, e.g. DMDM Hydantoin, Imidazolidinyl urea, glutamate added, latex, yeast and yeast extract, mold, lupin and products thereof, palm oil, fruits, e.g. apple, mustard and products thereof, parabens, as well as all the allergens listed in the cosmetics directive (European Regulation No. 1223/2009)are not known additives, by products, intermediate parts, or otherwise intentionally added during the manufacturing processes of the product.

Neither Avantor nor the Original Manufacturer produce any of the following types of products: antibiotics, aflatoxins, penicillin, semi-synthetic penicillins, cephalosporins, other beta-lactams, cytotoxins, steroids, medicated feeds, or pesticides.

This product is manufactured using cGMP guidelines which provide controls that allow no potential for cross contamination of any allergens or other contaminants. However, this product is not tested for

the presence of these or any other allergens by Avantor or the Original Manufacturer, therefore, we do not have confirmation for the absence of any allergens in the product.

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: For J.T.Baker® and Macron Fine Chemicals™ brand products, kosher certification is aligned to the Avantor packaging site as indicated on the product Certificate of Analysis. Please refer to the site-specific kosher certificate available on AskAvantor for our most up to date listing of kosher products at (Ask Avantor Keyword: kosher).

Halal Status: For J.T.Baker® and Macron Fine Chemicals™ brand products, halal certification is aligned to the Avantor packaging site as indicated on the product Certificate of Analysis. Please refer to the site-specific halal certificate available on AskAvantor for our most up to date listing of halal products at (Ask Avantor Keyword: halal).

GRAS Status: The United States Food and Drug Administration (FDA) have acknowledged that some chemicals may be considered Substances Generally Recognized as Safe (GRAS) in foods when used in accordance with the requirements and limitations per specific 21 CFR regnums. For the latest information on whether or not an Avantor product is considered GRAS, please visit the Electronic Code of Federal Regulations.

Section 5 – Miscellaneous Product Information

Certificate of Analysis Date Format: The Manufactured Date and Expiration/Retest Date on the Certificate of Analysis are reported as YYYY-MM-DD. For example, the Manufactured Date for October 1, 2021 would be reported as 2021-10-01.

Lot Numbering System and Batch Description: For J.T.Baker® and Macron Fine Chemicals™ brand products, please refer to Ask Avantor 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 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 reach out to the support contact in Section 7 for additional stability inquiries.

Management of Change: For J.T.Baker® and Macron Fine Chemicals™ brand products, please refer to Management of Change link under the Working with Avantor tab on the Avantor website.

Country of Origin Statement: Country of Origin is indicated on the product Certificate of Analysis. If you require further documentation, please reach out to the Trade Compliance support contact in Section 7.

Storage Requirements: Please refer to the product's Certificate of Analysis or Product Specifications. In the absence of specific storage conditions listed on its specification sheet or Certificate of Analysis, 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's SDS sheet.

Certificates of Analysis: For J.T.Baker® and Macron Fine Chemicals™ brand products, please see the current list of product specifications using the Certificate/SDS Search tool on our website here.

Safety Data Sheet: For J.T.Baker® and Macron Fine Chemicals™ brand products, please see the current product safety information using the Certificate/SDS Search tool on our website here.

Avantor Site Certifications: Please see the current Avantor site certifications on our website here.

Site Quality Overview: Avantor maintains a self-assessment modeled after IPEC guidelines which describes site and quality system information to support the manufacturing activities of this product. Please reach out to the support contact in Section 7 for a current copy of the Site Quality Overview.

Packaging Information: Please reach out to the support contact in Section 7 for current packaging specifications.

Section 6 – Revision History

Rev. 0; Oct. 1, 2007 – IPEC EIP format
Rev. 1; Oct. 13, 2008 – Section 4: updated residual solvents information
Rev. 2; Jan. 15, 2009- Section 4: added Residual Metallic Catalyst statement. Section 7: updated Customer Service Director telephone #. Entire Document: added keywords to Solv It Center links. (KES)
Rev. 3; June 17, 2011–Entire document: new letterhead, and changed all references of "Solv IT Center" or "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 7: updated contact information; minor formatting. PHMCH. Rev. 4; Oct 4, 2012– HDQ address change. Section 4: added add'l allergens as listed in EU Directive 2003/89/EC; updated Residual Metallic Catalysts statement; Section 5: added Management of Change information; Section 7: removed contact list table and added CS/TS contact information. (MCH)
Rev. 5; Dec. 20, 2016 – Section 4: separated Kosher/Halal status and added certification statement; Section 5: Added COA Date Format statement; (MCH).
Rev. 6: July 21, 2017 – Entire document: new letterhead, new format; Section 4: Replaced Residual Metallic Catalysts with Elemental Impurities statement. (MCH)
Rev. 7; November 14, 2018 - Entire Document: New Format. (EC)

Rev. 8; April 29, 2021 – Entire Document: Minor formatting. Update website and email addresses from avantorinc.com to avantorsciences.com; Section 4: Updated DMF and Allergen/Hypersensitivities Information statements. Update Elemental Impurities report. (KH)
Rev 9; August 16, 2024 – Entire Document: Minor Formatting; Section 4: Updated Kosher, Halal and GRAS Status statements; Section 5: Updated Certificate of Analysis Date Format, Shelf-Life Information, Management of Change, and Country of Origin statements. Added Certificates of Analysis, Safety Data Sheet, Avantor Site Certifications, Site Quality Overview and Packaging Information statements; Section 7: Updated Contact Information. (CR)
Rev.10; December 30, 2025 – Entire Document: Updated Ask Avantor hyperlinks; Section 4: Added Elemental Impurities report for product code 1395. (SP)

This electronic document is valid without a signature.

Section 7 – Contact Information

Technical Service

Phone: 1-855-282-6867 and 1-610-573-2600 (outside U.S.), select option 5
Email: Technical.Service@avantorsciences.com

Regulatory Support

Email: regulatory.support@avantorsciences.com

Trade Compliance

Email: fta@avantorsciences.com

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Material Name: Edetate Disodium **Product codes**: 7565, 8994, 8995, 7727 **Date**: November 28, 2018 (rev. 2)

Source/Type of Excipient: ☐ Mineral; ☐ Mineral derived; ☐ Plant; ☐ Plant derived; ☒ Synthetic; ☐ Fermentation derived

Other (explain):

No ICH Q3D elements are intentionally added to the production process.

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 ☐	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Cadmium	Cd	1	Yes ☐	No ☒	Unknown ☐	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Mercury (inorganic)	Hg	1	Yes ☐	No ☒	Unknown ☐	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Lead	Pb	1	Yes ☐	No ☒	Unknown ☐	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Cobalt	Co	2A	Yes ☐	No ☒	Unknown ☐	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Nickel	Ni	2A	Yes ☐	No ☒	Unknown ☐	<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.)
Vanadium	V	2A	Yes ☐	No ☒	Unknown ☐	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Silver	Ag	2B	Yes ☐	No ☒	Unknown ☐	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Gold	Au	2B	Yes ☐	No ☒	Unknown ☐	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Iridium	Ir	2B	Yes ☐	No ☒	Unknown ☐	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Osmium	Os	2B	Yes ☐	No ☒	Unknown ☐	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Palladium	Pd	2B	Yes ☐	No ☒	Unknown ☐	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Platinum	Pt	2B	Yes ☐	No ☒	Unknown ☐	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Rhodium	Rh	2B	Yes ☐	No ☒	Unknown ☐	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Ruthenium	Ru	2B	Yes ☐	No ☒	Unknown ☐	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Selenium	Se	2B	Yes ☐	No ☒	Unknown ☐	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Thallium	Tl	2B	Yes ☐	No ☒	Unknown ☐	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Barium	Ba	3	Yes ☐	No ☒	Unknown ☐	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Chromium	Cr	3	Yes ☐	No ☒	Unknown ☐	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Copper	Cu	3	Yes ☐	No ☒	Unknown ☐	<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.)
Lithium	Li	3	Yes ☐	No ☒	Unknown ☐	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Molybdenum	Mo	3	Yes ☐	No ☒	Unknown ☐	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Antimony	Sb	3	Yes ☐	No ☒	Unknown ☐	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Tin	Sn	3	Yes ☐	No ☒	Unknown ☐	<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

David L. Cugini, Sr. QA Analyst

Material Name: Edetate Disodium **Product codes**: 1395

Source/Type of Excipient: ☐ Mineral; ☐ Mineral derived; ☐ Plant; ☐ Plant derived; ☒ Synthetic; ☐ Fermentation derived

Other (explain):

No ICH Q3D elements are intentionally added to the production process.

avantor	Elemental Impurities Checklist for Customer	Attachment 3 to QI-14-17 Wydanie: 03 Strona 1/ stron 3

Product Name: Disodium Edetate

Product Number: 1395

Additional information: 2520206810: 2512706810; 2523806811; 1106-07-25; 1265-04-25; 1100-08-25

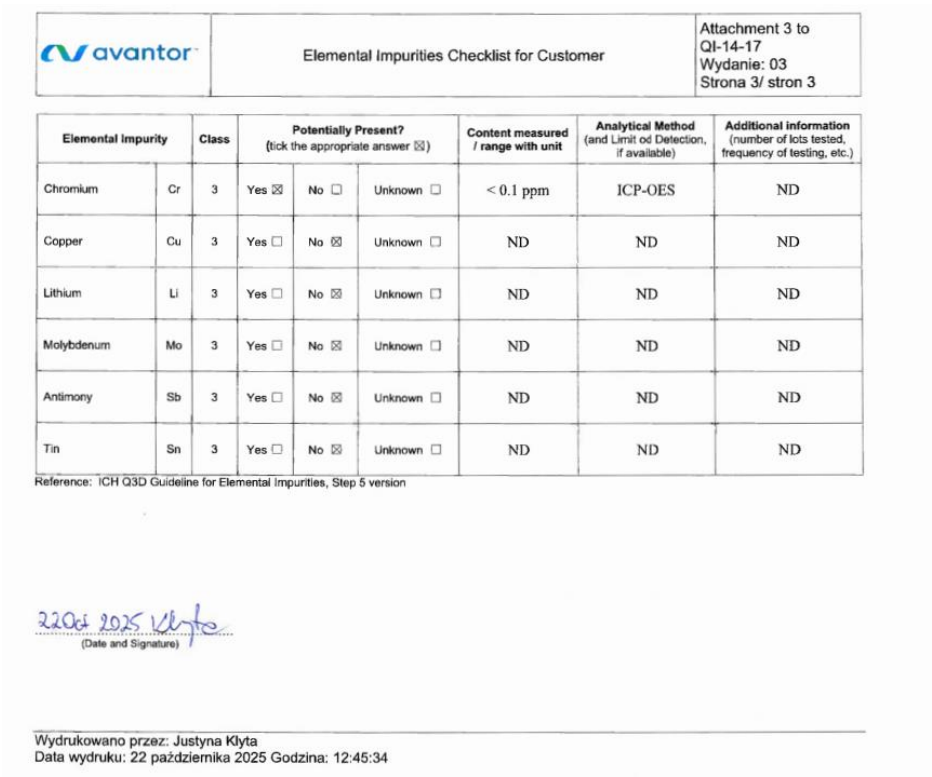
Elemental Impurity		Class	Potentially Present? (tick the appropriate answer ☒)			Content measured / range with unit	Analytical Method (and Limit od Detection, if available)	Additional Information (number of lots tested, frequency of testing, etc.)
Arsenic (inorganic)	As	1	Yes ☐	No ☒	Unknown ☐	ND	ND	ND
Cadmium	Cd	1	Yes ☐	No ☒	Unknown ☐	ND	ND	ND
Mercury (inorganic)	Hg	1	Yes ☐	No ☒	Unknown ☐	ND	ND	ND
Lead	Pb	1	Yes ☐	No ☒	Unknown ☐	ND	ND	ND
Cobalt	Co	2A	Yes ☐	No ☒	Unknown ☐	ND	ND	ND
Nickel	Ni	2A	Yes ☒	No ☐	Unknown ☐	< 0.1 ppm	ICP-OES	ND
Vanadium	V	2A	Yes ☐	No ☒	Unknown ☐	ND	ND	ND
Gold	Au	2B	Yes ☐	No ☒	Unknown ☐	ND	ND	ND

Wydrukowano przez: Justyna Klyta
Data wydruku: 22 października 2025 Godzina: 12:45:34

avantor	Elemental Impurities Checklist for Customer	Attachment 3 to QI-14-17 Wydanie: 03 Strona 2/ stron 3

Elemental Impurity		Class	Potentially Present? (tick the appropriate answer ☒)			Content measured / range with unit	Analytical Method (and Limit od Detection, if available)	Additional Information (number of lots tested, frequency of testing, etc.)
Iridium	Ir	2B	Yes ☐	No ☒	Unknown ☐	ND	ND	ND
Osmium	Os	2B	Yes ☐	No ☒	Unknown ☐	ND	ND	ND
Paliadium	Pd	2B	Yes ☐	No ☒	Unknown ☐	ND	ND	ND
Platinum	Pt	2B	Yes ☐	No ☒	Unknown ☐	ND	ND	ND
Rhodium	Rh	2B	Yes ☐	No ☒	Unknown ☐	ND	ND	ND
Ruthenium	Ru	2B	Yes ☐	No ☒	Unknown ☐	ND	ND	ND
Selenium	Se	2B	Yes ☐	No ☒	Unknown ☐	ND	ND	ND
Thallium	Tl	2B	Yes ☐	No ☒	Unknown ☐	ND	ND	ND
Silver	Ag	2B	Yes ☐	No ☒	Unknown ☐	ND	ND	ND
Barium	Ba	3	Yes ☐	No ☒	Unknown ☐	ND	ND	ND

Wydrukowano przez: Justyna Klyta
Data wydruku: 22 października 2025 Godzina: 12:45:34



avantor	Elemental Impurities Checklist for Customer	Attachment 3 to QI-14-17 Wydanie: 03 Strona 3/ stron 3

Elemental Impurity		Class	Potentially Present? (tick the appropriate answer ☒)			Content measured / range with unit	Analytical Method (and Limit od Detection, if available)	Additional information (number of lots tested, frequency of testing, etc.)
Chromium	Cr	3	Yes ☒	No ☐	Unknown ☐	< 0.1 ppm	ICP-OES	ND
Copper	Cu	3	Yes ☐	No ☒	Unknown ☐	ND	ND	ND
Lithium	Li	3	Yes ☐	No ☒	Unknown ☐	ND	ND	ND
Molybdenum	Mo	3	Yes ☐	No ☒	Unknown ☐	ND	ND	ND
Antimony	Sb	3	Yes ☐	No ☒	Unknown ☐	ND	ND	ND
Tin	Sn	3	Yes ☐	No ☒	Unknown ☐	ND	ND	ND

Reference: ICH Q3D Guideline for Elemental Impurities, Step 5 version

22 Oct 2025 Klyta
(Date and Signature)

Wydrukowano przez: Justyna Klyta
Data wydruku: 22 października 2025 Godzina: 12:45:34

Prepared by the Technical Service Department

Avantor™ Performance Materials, LLC