Mallinckrodt Baker

Mallinckrodt Baker, Inc.
222 Red School Lane
Phillipsburg, NJ 08865

Tel: 908-859-2151
Fax: 908-859-9370
www.mallbaker.com

Sodium Bicarbonate

Product Regulatory Data Sheet

Section 1 – Product Information

Products Covered

J.T. Baker	3509	Sodium Bicarbonate, Powder, U.S.P. - F.C.C.
J.T. Baker	3510	Sodium Bicarbonate, Powder, USP, Multi-Compendial
Mallinckrodt	7396	Sodium Bicarbonate, Powder, U.S.P. - F.C.C.
Mallinckrodt	7749	Sodium Bicarbonate, Powder, USP - GenAR®
Mallinckrodt	7903	Sodium Bicarbonate, Granular, U.S.P.

Section 2 – Manufacturing, Packaging and Release Site Information

A number of the cGMP produced products that are sold by Mallinckrodt Baker, Inc. 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 the International Pharmaceutical Excipients Council (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 Q&A Center of the customer support section of our web site or by directly linking to www.AskMBI.com Keyword: Manufacturer Code.

Section 3 – Physical/Chemical Information

CAS #: 144-55-8

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.mallbaker.com

DMF: Mallinckrodt Baker, Inc. 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 wheat, rye, oats, barley, spelt, malt, triticale, gluten, other grains, corn, soy, eggs, yeast, canola, dairy products, seafood products, nut products, seed products, natural grape products, natural flavors, artificial flavors, celery, lactose, sulfites, elemental sulfur, preservatives, 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.

Residual Metallic Catalysts: No metallic catalysts, as defined by EMEA Guideline on the Specification Limits for Residues of Metal Catalysts (CPMP/SWP/QWP/4446/00), are used in the production of the above subject materials.

Kosher/Halal Status: Please refer to the customer support section of our website for our most up to date listing of Kosher and Halal products. (www.AskMBI.com Keyword: Kosher)

Gras Status: The United States Food and Drug Administration (FDA) have acknowledged that the chemical listed in Section 1 is a substance Generally Recognized as Safe (GRAS) in foods when used in accordance with the requirements and limitations per 21 CFR parts 184.1736.

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Section 5 – Miscellaneous Product Information

Lot Numbering System and Batch Description

Please refer to the customer support section of our website for information concerning our lot numbering system. (www.AskMBI.com Keyword: Lot Number)

Shelf Life Information

If a product has an assigned expiration 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.AskMBI.com Keyword: Expiration)

Section 6 – Revision History

Rev. 0; Oct. 1, 2007 – IPEC EIP format
Rev. 1; Oct. 22, 2008 – Section 4: updated residual solvents information
Rev. 2; Jan. 29, 2010 – Entire document: new letterhead and changed all references of “Solv IT Center” to “AskMBI.”; Section 7: updated TS manager info. Section 4: added Residual Metallic Catalysts and GRAS information. (KES

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Section 7 – Contact Information

POSITION/TITLE	PHONE NUMBER
Research & Technology: Director of R & T	908-859-9425
Assistant Director of R & T	908-859-9337
Production: Director of Manufacturing	908-859-9345
Phillipsburg Plant Manager	908-859-9456
Paris Plant Manager	859-987-9400
Packaging: Senior Packaging Engineer	908-859-9668
Quality Control/Quality Assurance: Director of QA & Regulatory Affairs	908-859-9420
Quality Manager, Phillipsburg Plant	908-859-6926
Quality Manager, Paris Plant	859-987-9459
Regulatory Affairs Manager	908-859-9466
Other Key Personnel: EH&S Phillipsburg Plant	908-859-9437
EH&S Paris Plant	859-987-9423
Director of Customer Service	908-859-9413
Manager, Technical Support	908-329-9915