ADM
Quality Center of Excellence
4666 Faries Parkway Decatur, IL 62526
217.424.5200 | www.adm.com

Sodium Citrate Dihydrate – Fine Granular, USP-NF/FCC (Excipient / Food Use) Product Code 042420

Technical Information

Product Description

Sodium Citrate Dihydrate is derived from citric acid. It is odorless and freely soluble in water but is insoluble in alcohol. Sodium Citrate Dihydrate is the most broadly used emulsifying salt in sliced processed cheese products. It is commonly used as a buffering agent in combination with citric acid to provide precise pH control required in many food and beverage applications. In meat products, it is used as an anticoagulant of fresh livestock blood and as a curing accelerator. The detergent-building and rapid biodegradability characteristics of Sodium Citrate enable its use as an environmentally acceptable phosphate substitute in a variety of household cleaning products

Specification

UCharacteristics	
Formula	$Na_3C_6H_5O_7 \cdot 2H_2O$
Appearance	White, fine, translucent granules
Odor	None
Taste	Mild, cool saline taste
Molecular Weight	294.11
pH (5g/100ml at 25°C)	7.5 - 9.0
Solubility (g/100ml @ 25°C)	71 in Water / Insoluble in Alcohol

Standard Specifications	
Identification	Meets USP-NF/FCC
Assay (Anhydrous Basis)	99.0 – 100.5%
Water	10.0 – 13.0%
Alkalinity	Meets USP-NF/FCC
Tartrate	Meets USP-NF
Heavy Metals (as lead)	Maximum 10.0 ppm
Lead	Maximum 2.0 ppm

Other Information

Labelling
Sodium Citrate Dihydrate

Identification
CAS No: 6132-04-03

Regulatory Data
Country of Origin: United States
GRAS Affirmation: 21 CFR 184.1751

Granulation

On 30 USS Mesh	1% maximum
Through 100 USS Mesh	10% maximum

Lot Numbering Information
SYMMDDB (Ex: S308261 – 8-26-23)
S – Manufacturing location (Southport, NC)
Y – Last digit of year
MM – Month
DD – Day of month

Storage and Shelf Life

Sodium Citrate should be stored below 75°F and 55% relative humidity inside a tightly sealed container. The shelf life or “best by” date is 36 months or 1095 days.

Availability

ADM Sodium Citrate is available in 50 lb. bags, 25 kg bags, and 275 lb. drums.

Regulatory Status

This food additive complies with all of the compendial requirements of the U.S.. Pharmacopeia, Food Chemical Codex, Code of Federal Regulations, European Pharmacopoeia, British Pharmacopoeia, Japanese Pharmacopoeia, and W.H.O. / F. A. O. Food Addition specification.

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Nutrition Information

Nutrition

Nutrient	/100g
Total Calories, Kcal*	159
Total Fat	0 g
Saturated Fat	0 g
Trans Fat	0 g
Polyunsaturated Fat	0 g
Monounsaturated Fat	0 g
Cholesterol	0 mg
Total Carbohydrates	64.5g
Total Sugars	0 g
Sugar Alcohols	0 g
Added Sugars	0 g
Other Carbohydrates	0 g
Dietary Fiber	0 g
Soluble Fiber	0 g
Insoluble Fiber	0 8
Protein	0 g
Calcium	0.3 mg
Iron	0.1 mg
Sodium	23,450 mg
Potassium	24 mg
Moisture	12 g

Other Essential Vitamin & Mineral	/100g
Thiamine	0 mg
Riboflavin	0 mg
Niacin	0 mg
Vitamin D	0 mg
Vitamin E	0 mg
Vitamin B_6	0 mg
Folic Acid	0 mg
Vitamin B_{12}	0 mg
Phosphorus	0 mg
Iodine	0 mg
Magnesium	0 mg
Zinc	0 ppm
Copper	0 mg
Biotin	0 mg
Pantothenic Acid	0 mg
Vitamin A	0 µg RAE
Vitamin C	0 mg

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Allergen Information

Allergen Information

The following table lists all the major food allergens recognized under the US Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA) and other regional definitions. This product is not manufactured with equipment that comes in contact with the listed allergens, nor do we have these allergens within the process areas. Sulfur dioxide, which is considered a sensitizer, can be used in the manufacture of this product, but residual levels will be less than 10 ppm.

	US	CAN	EU	AUS NZ	JPN	Present in Final Product	Present in Production Line	Present in Production Facility	Cross Contamination Possible
Celery and celeriac		●	●			No	No	No	No
Cereals with Gluten, such as wheat, rye, barley, oats, spelt, buckwheat and triticale	●	●	●	●	●	No	No	No	No
Crustacean shellfish	●	●	●	●	●	No	No	No	No
Egg and egg products	●	●	●	●	●	No	No	No	No
Fish and fish products	●	●	●	●	●	No	No	No	No
Fruits and fruit products such as orange, kiwi, banana, peach, apple, mango, tomato					●	No	No	No	No
Gelatin and gelatin products					●	No	No	No	No
Latex and latex products						No	No	No	No
Lupin and lupin products			●	●		No	No	No	No
Meat and meat products such as beef, chicken, pork					●	No	No	No	No
Milk and dairy	●	●	●	●	●	No	No	No	No
Mulluscan Shellfish	●	●	●	●	●	No	No	No	No
Mustard and mustard products		●	●			No	No	No	No
Matsutake mushrooms					●	No	No	No	No
Peanut and Peanut products	●	●	●	●	●	No	No	No	No
Sesame and sesame products	●	●	●			No	No	No	No
Soy or Soy products	●	●	●	●	●	No	No	No	No
Sulphur dioxide & Sulfites (>10ppm)	●	●	●	●	●	No	Yes	Yes	Yes
Tree nuts such as almond, brazil nut, cashew, hazelnut (filbert), macadamia, pecan, pine nut, pistachio and walnut	●	●	●	●	●	No	No	No	No
Yam and yam products					●	No	No	No	No

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Product Information

BSE (*Bovine Spongiform Encephalopathy*) and TSE (*Transmissible Spongiform Encephalopathy*)

ADM Sodium Citrate does not contain and is not processed, stored, packaged, or delivered with any animal products, by-products, or animal derived products.

Drug Substance

ADM Sodium Citrate is not manufactured with, nor does it contain, narcotics, psychotropic drugs or aggressive substances.

Gluten

ADM Sodium Citrate is considered to be gluten free and is not stored with any gluten containing products.

Pesticides and Residuals

ADM performs a monitoring program on pesticide residues for its acidulant products. The analyses are done on a periodic basis by an accredited laboratory and to date; results have been below limit of quantification (LOQ). The monitoring results are in line with the FDA Guidelines as well as European Regulation (EC) No 396/2005 and all subsequent amendments.

Chlorates and chlorate compounds: Chlorine or chlorates are not directly added during the production of Sodium Citrate. The presence of chlorate in the product may result from drinking water use in the process or chlorine disinfectant use on equipment. Some foods can show tendencies for chlorate accumulation which can cause higher chlorate presence. The use of chlorine disinfectants and chlorinated water within the process is in compliance with all local requirements and an eventual accumulation and chlorate presence is unavoidable. This is in compliance with Annex III, Regulation (EU) No. 396/2005 as no other chlorate contamination source is utilized in the process. ADM is monitoring levels through regular testing to keep the accumulation within the ALARA principle.

Chlorpyrifos and Chlorpyrifos-methyl: ADM Sodium Citrate is in compliance with Regulation (EU) No 396/2005 for Chlorpyrifos and Chlorpyrifos-methyl. Test results show that levels are below the limit of detection (LOD) of 0.01mg/kg, the defaulted MRL.

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Product Information

Proposition 65

The Safe Drinking Water and Toxic Enforcement Act of 1986 in Title 27 of the California Code of Regulations, commonly known as "Proposition 65", requires businesses to provide a "clear and reasonable" warning when they knowingly and intentionally cause an exposure to an OEHHA listed chemical, and prohibits the discharge of listed chemicals into sources of drinking water. Its purpose is to protect the state's drinking water sources and provide California residents assistance in making informed decisions regarding exposure to listed chemicals that cause cancer or reproductive effects in purchased products and at physical sites. After review of its acidulants, it is ADM's position that a Proposition 65 warning label is not required for these products as none contain listed chemicals at levels above "no significant risk."

Ready to Eat (RTE)

The Food and Drug Administration (FDA) defines a ready-to-eat (RTE) food in 21 CFR 117.3 as "any food that is normally eaten in its raw state or any other food, including a processed food, for which it is reasonably foreseeable that the food will be eaten without further processing that would significantly minimize biological hazards."

ADM is not passing on any hazards that require a preventative control. However, following the guidelines laid out by the Food Safety Modernization Act (FSMA), Sodium Citrate is not considered a RTE food since ADM markets and labels it as a business to business product, and it is not considered readily foreseeable that Citric Acid will be consumed without further processing. ADM therefore recommends you conduct a risk assessment of the ingredient and determine if additional processing is required, by you the customer, in order to use for your finished RTE application.

Residual Solvents

ADM certifies that, based on our knowledge of the manufacturing process, storage, and shipping and handling procedures, Sodium Citrate complies with the established Compendia standards for Residual Solvents.

Source Material

ADM Sodium Citrate is derived from various carbohydrate sources and is manufactured in the US.

Miscellaneous Exclusionary Statement

ADM Sodium Citrate is produced following the U.S. Food and Drug Administration current Good Manufacturing Practice guidelines. The following compounds are not knowingly introduced directly or through processing aids during production, storage, or shipment. These compounds are not expected to be present, and therefore are not specifically tested for presence or absence.

- Additives
- Animal Products
- Animal By-products
- Animal derived products
- Antibiotics
- Dyes
- Ethylene Oxide (ETO)
- Irradiation/Radioactivity
- (Iso)paraffin, mineral oil, and petrolatum
- Latex
- Melamine (or cyanuric acid)
- Monosodium Glutamate
- Nanotechnology
- Nitrosamines
- Paraben or Paraben-related compounds
- Phenylalanine
- Phthalates
- Perfluorinated Compounds (PFCs):
- Preservatives
- Partially Hydrogenated Oils / Trans Fats
- Sewage and Sludge
- Sulfates

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Food Safety and Quality Information

Letter of Guarantee

ADM hereby warrants and guarantees that the above listed product sold to you has been approved by the US Food and Drug Administration for its use in foods or are Generally Recognized As Safe (GRAS), or exempt from the provisions of the 1958 Additives Amendment to the Federal Food, Drug and Cosmetic Act, and are allowed for sale in Canada.

We further guarantee that none of the foregoing products comprising any shipment or other delivery now in transit or hereafter made to you is, as of the date of shipment or delivery, adulterated or misbranded within the meaning of the Federal Food, Drug and Cosmetic Act or any practically similar state or municipal law, or is an article which many not under Section 404 or 505 of said Act, be introduced into interstate commerce. All of the foregoing is a continuing guarantee, subject to revocation upon written notice.

FDA Bioterrorism Registration

ADM facilities that manufacture, process, pack, or hold acidulant products or facilities within our distribution network are fully compliant with this registration requirement. The US Public Health Security and Bioterrorism Preparedness Response Act of 2002 requires registration with the US Food and Drug Administration of facilities that manufacture, process, pack, or hold food for human or animal consumption in the United States. The 2010 Food Safety Modernization Act requires a re-registration of these facilities prior to December 31, 2010 and biennially thereafter.

Food Safety Modernization Act (FSMA) Compliance

Food Safety Modernization Act (FSMA) compliance dates for the following programs are in affect for ADM. ADM has enacted programs to comply with the requirements.

- Preventative Controls for Human Food
- Preventative Controls for Animal Food
- Reportable Food Registry Notification (RFR)
- Sanitary Transportation Guidelines
- Foreign Supplier Verification

Current Good Manufacturing Practices and GFSI

ADM certifies that Sodium Citrate is manufactured following current Good Manufacturing Practices (cGMP) as defined by FDA 21 CFR Part 117. Our programs have been audited and are currently FSSC22000 certified. Our quality program includes, but is not limited to the following procedures and guidelines.

- Allergen Control
- Auditing Procedures
- Calibration Procedures
- CAPA Program
- cGMP Requirements
- Chemical Control Program
- Cleaning Procedures
- Glass, Brittles, & Plastic Program
- Food Safety Plan / HACCP
- In-Process Controls
- Incoming Good Requirements
- Internal Auditing
- Isolation of Rejected Materials
- Issuance of Certificate of Analysis
- Issuance of Product Specifications
- Laboratory Technician Training
- Management of Change
- Master Manufacturing Plan
- Out-of-Specification Handling
- Outsourced Services
- Personnel Training
- Pest Control
- Pre-requisite Programs
- Preventative Maintenance
- Product Withdrawal and Recall
- Recording of Sampling Data
- Records Retention
- Release of Finish Goods
- Retain Samples
- Significant Change Notification
- Site Security
- Specification Requirements Review
- Supplier Management
- Traceability & Mock Recall

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Food Safety & Quality Information

HACCP Summary and Flow Diagram

Food Safety Plans are an integral piece of our quality and food safety systems. ADM acidulant products are produced in the US. A cross-functional team of colleagues have reviewed annually, at a minimum, manufacturing hazard analysis and risk assessments to ensure accuracy and adequacy.

Biological Risk Summary

The risk of pathogenic bacteria and organisms in the process is minimal, mainly because of the physical properties of acidulants.

Physical Risk Summary

ADM acidulants are passed through verified metal detectors..

Chemical Risk Summary

ADM acknowledges mycotoxins (e.g., aflatoxins and fumonisins), pesticides and cyanide can be of concern in commercially grown corn. Milling and further production is efficient in mycotoxin removal. It is not expected that these toxins and chemicals would be present in acidulant products.

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Social Programs

Animal Testing

ADM ingredients have and continue to be predominantly used in food and/or feed products, but also have use in cosmetic and/or household products. We do not animal test ingredients to determine safety or efficacy for cosmetic uses.
In our food ingredients business, we occasionally work with animals to evaluate the nutritional value and safety of ingredients intended for human and/or animal consumption. This work is intended to help us meet standards set by regulatory authorities. ADM works closely either with universities or with contractors whose work is closely evaluated by review boards charged with ensuring that animal trials are safe, humane and ethically designed and conducted.

California Transparency in Supply Chains Act and UK Modern Slavery Act

A critical component of ADM's efforts to enrich lives around the world is our commitment to creating positive impacts for the people throughout our value chain, and the communities in which we live and work. As part of that commitment, ADM is proud to disclose its efforts to eliminate slavery and human trafficking in product supply chains, in compliance with the California Transparency in Supply Chains Act of 2010 and the UK Modern Slavery Act of 2015.

ADM, its subsidiaries and its joint ventures strongly support human rights, and we expect our business partners to treat their employees with dignity and respect. We will never knowingly use suppliers who employ or exploit legally underage workers or forced labor, and will not condone such practices. In order to enforce these strict standards, we have implemented multiple programs and policies related to our human rights commitments. For more information, please visit https://www.adm.com/sustainability/downloads .

Code of Conduct

ADM has long maintained a Code of Conduct to help our company achieve the right results, the right way. The Code establishes high standards of honesty and integrity for all ADM colleagues and business partners, and sets forth specific policies to help ensure that our company conducts business fairly and ethically at all times, everywhere we operate. The Code also offers guidance on the appropriate handling of situations in which personal and business interests have the potential to conflict. We invite you to explore the ADM Code of Conduct by visiting: https://www.adm.com/our-company/the-adm-way/code-of-conduct .

Conflict Minerals

In July 2010, the United States Securities and Exchange Commission adopted the Dodd-Frank Reform and Consumer Protection Act (herein referred to as the "Act"). This Act requires U.S. companies to disclose, on an annual basis, whether any "Conflict Minerals" are necessary to the functionality or production of any of their products (see §1502 of the Act). A "Conflict Mineral" is considered to be any of the following minerals or their derivatives originating in the Democratic Republic of the Congo (the "DRC") or any of the adjoining countries with which the DRC shares a recognized international border: tin (cassiterite), tantalum (columbite-tantalite), tungsten (wolframite), and gold.

ADM complies with all national and other applicable laws and regulations. We are committed to keeping our supply chain free from conflict minerals which are covered by laws and regulations concerning the sourcing of minerals from conflict areas. Based on currently available information, ADM does not use conflict minerals originating in the Democratic Republic of the Congo and its adjoining countries.

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Social Programs

National Bioengineered Food Disclosure Statement

On December 21, 2018, the Agricultural Marketing Service, USDA released the final rule establishing the new mandatory National Bioengineered Food Disclosure Standard (NBFDS). The NBFDS requires food manufacturers, importers, and other entities that label foods for retail sale to disclose information about bioengineered (BE) food and BE food ingredients. This rule is intended to provide a mandatory uniform national standard for disclosure of information to consumers about the BE status of foods. This rule is effective from February 19, 2019 and has an implementation date of January 1, 2020. The mandatory compliance date for BE labeling is January 1, 2022.

Under 7 CFR 66.1 Bioengineered Food is defined as a "*a food that contains genetic material that has been modified through in vitro recombinant deoxyribonucleic acid (rDNA)"* 7 CFR 66.6 contains a List of Bioengineered Foods for which bioengineered versions have been developed. Requirements for disclosure and non-disclosure need to be followed for listed foods. This list is maintained and updated by AMS and contains:

Alfalfa, apple (Arctic varieties), canola, corn, eggplant (BARI Bt Begun varieties), papaya (ringspot virus-resistant varieties), pineapple (pink flesh), potato, salmon (AquaAdvantage), soybean, squash (summer), and sugar beet.

NBFDS only applies to human food and drinks except distilled spirits, wines and malt beverages. The rule does not apply to animal feed/food.

Natural Classification

There is no formal FDA definition for the term "natural" except as it is defined for "natural flavors" under 21 CFR 101.22. This food ingredient does not fit the definition of "flavor". Additionally, the FDA is not restricting the use of the term "natural" except as it applies to 21 CFR 101.22. ADM does not provide labeling advice with use of this product. We advise that you consult legal counsel.

Organic Classification

ADM Sodium Citrate is not organic certified.

Sustainability

ADM believes there is a direct relationship between the health of the planet and our natural resources, and the health of our business and communities in which we operate. More and more, consumers around the world expect their food and drink to come from sustainable ingredients, produced by companies they trust. ADM has a complete sustainability website to share our vision, actions, and accomplishments: https://www.adm.com/sustainability .

Vegan / Vegetarian

ADM Sodium Citrate is considered suitable for vegetarian and vegan diets. No materials used in the manufacturing of Acidulants contain any components of animal origin. All processing equipment used in the manufacturing of ADM Acidulants is dedicated, and has no contact with ingredients of animal origin. The packaging components do not contain ingredients of animal origin.