



8150 Lackland Rd. St. Louis, MO 63114  
Tel. 314-428-4300 Fax 314-428-4366

**Jost Calcium Phosphate Tribasic**

# 2018 Product Certifications

**Jost Calcium Phosphate Tribasic**

Jost Chemical Co.  
8150 Lackland Road  
St. Louis, MO 63114 USA

## Contents

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Absence Declaration .....	4
Allergen Free Certification .....	5
Animal Testing Statement.....	5
Bisphenol A (BPA) Free Certification .....	5
BSE / TSE / Animal Derivative Free Certification .....	6
Business Continuity Statement.....	6
Carcinogenic, Mutagenic & Reproductive Toxicity Certification .....	6
Composition Statement.....	6
Contaminants Statement.....	7
Continuing Guarantee.....	7
Country of Origin Certification.....	7
Cross Contamination Statement.....	7
Debarment Statement.....	7
Dioxin & Polychlorinated Biphenyl (PCB) Free Certification .....	8
Environmental / Temperature Monitoring.....	8
FDA Audit Status / Registration & Bioterrorism .....	8
Flow Chart.....	9
Food Grade Certification.....	10
Gluten Free Certification .....	10
GMO Statement.....	10
Halal Certification .....	10
Heat Treated Pallets Certification.....	10
Homogeneity Statement.....	11
Ingredient Certification / Composition Statement .....	11
Kosher Certification .....	11
Latex Free Statement.....	11
Lot Number Explanation .....	11
Melamine Free Statement.....	12



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## Jost Calcium Phosphate Tribasic

Metal Reagent / Metal Catalyst Statement .....	12
Nanomaterial Statement .....	12
Non Irradiation / ETO Statement.....	12
Nutritional Certificate <sup>1</sup> .....	13
Organic Compliance Certification .....	14
Packaging Certification .....	14
Pesticide & Aflatoxin Free Certification.....	14
Phthalate Free Certification.....	15
Proposition 65.....	15
Purity Statement.....	15
Quaternary Ammonium Compounds Statement.....	15
Residual Solvent Certification .....	15
Safety Data Sheet (SDS) .....	16
Specification / Product Sheet .....	16
Stability & Storage Certification.....	16
Substances of Very High Concern Statement .....	16
Synthetically Produced Certification.....	16
Tariff Code .....	17
Traceability Statement.....	17
Vegan & Vegetarian Certification .....	17
W.A.D.A. Certification.....	17
Water Source Statement .....	17

## Absence Declaration

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Jost Chemical does not utilize as a raw material, starting material, processing aid, or deliberately add to Calcium Phosphate Tribasic the substances listed below. Jost Chemical does not specifically analyze Calcium Phosphate Tribasic for these substances as there is no reason to believe that they would be present.

2,4,6-Tribromophenol (TBP)	Formaldehyde
2-Ethylhexanoic Acid (2-EHA)	Halons
Acrylamide	Herbicides
Amino Acids	Hexabromocyclododecane (HBCD)
Antibiotics	Hormones
Aromatic Amines	Hydrochlorofluorocarbons (HCFCs)
Asbestos	Insecticides
Azocolorants	Latex
Biocides	Long-chain (C9-20) perfluorocarboxylic acids (PFCAs), their salts, and their precursors
Bisphenol A	Methylnaphthalenes (including 4-methylnaphthalene)
Bisphenol A Compounds	Natural Rubber
Bisphenol A Diglycidyl Ether (BADGE)	Natural Rubber Latex
Bisphenol A Diglycidyl Ether (BFDGE)	Novalac Glycidyl Ether (NOGE)
Brominated Flame Retardants (BFRs)	Pentachlorophenol (PCP)
Butylated Hydroxyanisole (BHA)	Perfluorinated tensides (PFTs)
Butylated Hydroxytoluene (BHT)	Perfluorooctanoic acid (PFOA), its salts and precursors
Chlorofluorocarbons (CFCs)	Pesticides
Colorants	Plasticizers (Adipates, ESBO, Phthalates e.g. BBP, DBP, DEHP, DnHP, DIDP, DINP, DNOP)
Conflict Minerals	Polybrominated Biphenyl (PBB)
Dimethyl Fumarate	Polybrominated Diphenyl Ether (PBDE)
Dry Natural Rubber	Polychlorinated bi- or terphenyls (PCB/PCT)
Ethoxyquin	Polycyclic Aromatic Compounds (PACs)
Fatty Acids	
Fatty Acids	



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## Jost Calcium Phosphate Tribasic

Polycyclic aromatic hydrocarbons (PAH)

Silicone

Polydextrose

Tertiary Butylhydroquinone (TBHQ)

Polyvinyl Chloride (PVC)

Tetrabromobisphenol A (TBBPA)

Preservatives

Thiurams

Sewage Sludge

Vinyl Chloride

Short-Chain Chlorinated Paraffins (SCCPs)

## Allergen Free Certification

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EU directive 1169/2011 annex II, FDA "Big Eight" Allergens & Others

Jost Chemical Co. herein certifies that Calcium Phosphate Tribasic does not contain as an ingredient and is not manufactured on processing equipment that comes in contact with any of the commonly recognized allergens, including but not limited to the following: cereals containing gluten and products thereof, crustaceans and products thereof, eggs and products thereof, fish and products thereof, peanuts and products thereof, soybeans and products thereof, milk and products thereof (including lactose), nuts and products thereof, celery and products thereof, mustard and products thereof, sesame seeds and products thereof, sulfur dioxide and sulfites, lupin and products thereof, mollusks and products thereof, artificial flavors, monosodium glutamate, wheat, buckwheat, animal derivatives, artificial colors, safflower, sesame, sunflower, cottonseed, poppy seed, rice, gelatin, soy, yeast, fruits and berries.

## Animal Testing Statement

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Jost Chemical does not perform, contract, or participate in animal testing with any of the Jost Chemical products manufactured by Jost Chemical or the raw materials used to manufacture Jost Chemical products.

## Bisphenol A (BPA) Free Certification

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BPA is not used as a raw material or as a packaging component in the manufacturing and packaging of Calcium Phosphate Tribasic.

## BSE / TSE / Animal Derivative Free Certification

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Jost Chemical Co. herein certifies that Calcium Phosphate Tribasic is not manufactured from, or with, any type of animal product nor any derivative of an animal product. Additionally, the Jost Chemical Co. facilities do not inventory any animal products or derivatives of animal products. As such, Calcium Phosphate Tribasic manufactured by Jost Chemical Co. should not be considered a vector for BSE or TSE.

## Business Continuity Statement

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Jost Chemical Co. has developed a detailed Business Continuity Plan to obviate any disruptions in the supply chain. Although many of the details are proprietary, the following can be shared:

- Jost Chemical Co. has approved / qualified alternate raw material suppliers to ensure an uninterrupted raw material supply.
- The Jost Chemical Co. operations are not unionized, which eliminates disruption resultant from labor disputes.
- Jost Chemical Co. employees are cross-trained thereby ensuring continuation of employee coverage in the event of unforeseen workforce disruptions (e.g. absences resultant from a flu pandemic).
- Jost Chemical Co. has multiple, identical manufacturing trains that are fully interchangeable so production can proceed if a disruption impacts part of the manufacturing site.
- The Jost Chemical Co. manufacturing site consists of four buildings. Two of these buildings are utilized for manufacturing. If one of the manufacturing buildings is impacted the other is available for manufacturing.
- Jost Chemical Co. has access to outside warehousing both in the USA and the EU. Safety stock can be established in these warehouses if requested by the customer.

## Carcinogenic, Mutagenic & Reproductive Toxicity Certification

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Jost Chemical herein certifies that Calcium Phosphate Tribasic does not contain any of the carcinogens, mutagens, or toxic for reproduction (CMR) substances referenced in Annex II of Council Directive 76/769/EEC.

## Composition Statement

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Jost Chemical's Calcium Phosphate Tribasic is a pure compound containing only Calcium Phosphate Tribasic. It does not contain any additives, carriers, excipients, flow conditioners, anti-caking agents, bulking agents, preservatives, anti-oxidants, flavorings, colorings, or additional ingredients of any type.

## Contaminants Statement

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Based on a knowledge of the raw materials used in manufacturing and a detailed understanding of the manufacturing process, Jost Chemical's Calcium Phosphate Tribasic should not be considered at risk for contamination with 3-MCPD (3-monochloropropane-1,2-diol or 3-chloropropane-1,2-diol) or any other chloropropanols.

## Continuing Guarantee

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Jost Chemical hereby guarantees each shipment or delivery of Calcium Phosphate Tribasic is not adulterated or misbranded within the meaning of the Federal Food, Drug, and Cosmetic Act and is not an article which may not, under the provisions of sections 404 or 505 of the Act, be introduced into interstate commerce and to be not adulterated or misbranded within the meaning of the statutes of any state of the United States in which the definition of adulteration and misbranding are substantially the same as set forth under the Federal Food, Drug, and Cosmetic Act. This guarantee shall apply to all shipments or other deliveries of the above indicated product, until revoked in writing.

## Country of Origin Certification

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Jost Chemical Co. herein certifies that Jost Calcium Phosphate Tribasic is manufactured at the Jost Chemical Co. site located in St. Louis, Missouri, USA.

## Cross Contamination Statement

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Jost Chemical implements a fully validated cleaning procedure to facilitate contamination prevention. The use of labels and isolated packaging suites equipped with dedicated air handling units further aid in keeping all material in its intended location.

## Debarment Statement

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Jost Chemical herein certifies that neither the Company nor any person employed by Jost Chemical has been convicted of any crime described in Section 306(a) and (b) of the Generic Drug Enforcement act of 1992. Jost Chemical does not, has not, and will not, use the services of any person debarred under Sections 306(a) or (b).

## Dioxin & Polychlorinated Biphenyl (PCB) Free Certification

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Jost Chemical's Calcium Phosphate Tribasic is manufactured using high purity raw materials. Calcium Phosphate Tribasic is not routinely tested for dioxins or PCBs. However, based on a detailed knowledge of the raw materials and processing conditions, dioxins and PCBs contamination is not considered a significant risk.

## Environmental / Temperature Monitoring

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All Jost products are manufactured and stored at ambient temperature. Due to the inherently stable nature of our products, temperature and humidity monitoring are not required.

## FDA Audit Status / Registration & Bioterrorism

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It is hereby certified that the Jost Chemical Co. facilities listed below are U.S. FDA registered as "Bulk Drug/API" manufacturing facilities and are subject to unannounced FDA current Good Manufacturing Practices (cGMP) compliance inspections on a regular basis.

**Manufacturing Plant:** Jost Chemical Co.

**Manufacturing Site Location:** 8110 / 8130 / 8150 / 8190 Lackland Rd., St. Louis, MO 63114, USA

**Jost Chemical FDA Drug Firm FEI:** 3001239108

**Data Universal Numbering System Number:** 147882294

**Bioterrorism Number:** 11389416366

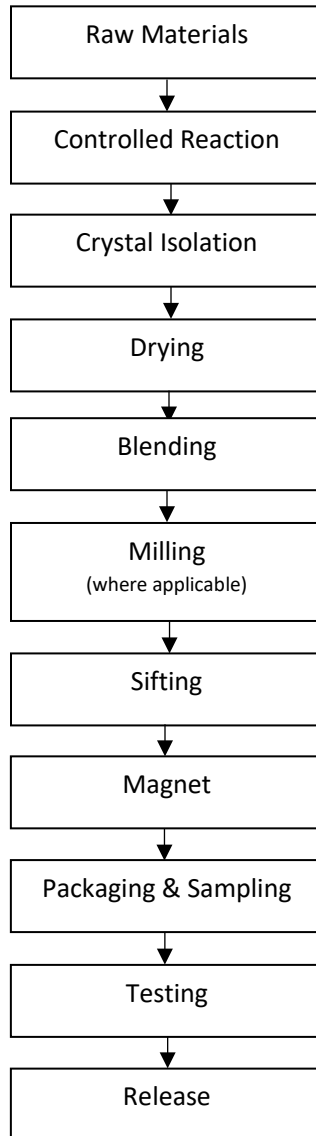
**Most Recent FDA Audit:** January 2018

**Audit Result:** No 483s issued.



## Flow Chart

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## Food Grade Certification

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Jost Chemical Co. herein certifies that Calcium Phosphate Tribasic under compendia titles (where applicable) USP, EP, BP, JP, FCC, NF, and Purified is Food Grade given that it is manufactured according to the principles and requirements of cGMPs and meets its defined microbiological requirements listed on the applicable Certificate of Analysis.

## Gluten Free Certification

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Jost Chemical Co. herein certifies that Calcium Phosphate Tribasic does not contain as an ingredient and is not manufactured on processing equipment that comes in contact with gluten or products containing gluten.

## GMO Statement

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Jost Chemical Co. herein certifies that Calcium Phosphate Tribasic is manufactured without the use of genetically modified organisms and without the use of raw materials or processing aids containing or derived from genetically modified material.

As such, Jost Chemical's Calcium Phosphate Tribasic should be considered non-Genetically Modified. This position is consistent with the directives outlined in EC 1830/2003 and EC 1829/2003.

## Halal Certification

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Please click the following link to Jost Chemical Co.'s website for the certificate: [Halal Certification](#)

## Heat Treated Pallets Certification

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Please be advised that Jost Chemical does not use chemically treated wood pallets. Jost Chemical pallets are heat-treated (HT) pallets bearing the IPPC logo. The IPPC heat-treatment or "HT" designation is clearly visible on the exterior of the pallets.

Jost Chemical wood pallets are purchased new and are stored indoors at Jost Chemical. The pallets are manufactured in the USA from USA hardwoods.

## Homogeneity Statement

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Jost Chemical hereby confirms that each lot is tested and released per our product specifications. Homogeneity is guaranteed by a validated blending procedure and associated testing.

## Ingredient Certification / Composition Statement

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Jost Chemical Co. herein certifies that Jost Calcium Phosphate Tribasic, contains only Calcium Phosphate Tribasic and no additional ingredients, additives, carrier, preservatives, or excipients.

## Kosher Certification

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Please click the following link to Jost Chemical Co.'s website for the certificate: [Kosher Certification](#)

## Latex Free Statement

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Jost Chemical Company does not warehouse, manufacture, or use latex in the manufacturing and packaging processes of Jost Chemical Products. Jost Chemical products are considered latex free.

## Lot Number Explanation

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Key:

First four digits = product and grade

Fifth digit = last digit of production year

Sixth, seventh, and eighth digits = consecutive lot produced in year indicated

Example: Lot 25603018

2560 = a Jost product code

3 = product produced in 2013

018 = the eighteenth lot of product code 2560 produced in 2013

Definitions: A "batch" is a discreet chemical reaction process. A "lot" is a uniform blend of multiple batches. The blending process has been validated for uniformity.

## Melamine Free Statement

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Calcium Phosphate Tribasic is not a source for protein, thus it is not considered “at risk” for intentional adulteration with melamine.

## Metal Reagent / Metal Catalyst Statement

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Jost Chemical’s Calcium Phosphate Tribasic does not utilize an elemental metal reagent and metal catalysts are not used in the production of Calcium Phosphate Tribasic at Jost Chemical.

## Nanomaterial Statement

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Jost Chemical does not employ the use of nanomaterials or nanotechnology in the manufacture of Jost Chemical finished products.

## Non Irradiation / ETO Statement

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Jost Chemical’s Calcium Phosphate Tribasic has not been irradiated per 7 CFR 205.105(f) requirements with the understanding that “irradiation” shall be defined as outlined in 21 CFR 179.26.

Jost Chemical’s Calcium Phosphate Tribasic has not been treated with ETO (ethylene oxide) nor any other chemical sterilizing agent.

## Nutritional Certificate<sup>1</sup>

Total Fat	Not a dietary source
Saturated Fat	Not a dietary source
Trans Fat	Not a dietary source
Cholesterol	Not a dietary source
Total Carbohydrates (Digestible by difference)	Not a dietary source
Dietary Fiber	Not a dietary source
Added Sugars	Not a dietary source
Protein	Not a dietary source
Vitamin A	Not a dietary source
Thiamin	Not a dietary source
Riboflavin	Not a dietary source
Niacin	Not a dietary source
Vitamin C	Not a dietary source
Vitamin D	Not a dietary source
Calcium	34,000 – 40,000 mg / 100 grams
Iron	Not a dietary source
Potassium	Not a dietary source
Copper	Not a dietary source
Phosphorus	18,497 mg / 100 grams
Magnesium	Not a dietary source
Manganese	Not a dietary source
Sodium	Not a dietary source
Strontium	Not a dietary source
Zinc	Not a dietary source
Calories	Not a dietary source
1. The above values should be considered typical nutritional values. Refer to the Certificate of Analysis for applicable lot specific analytical values. Nutritional values apply solely to USP, EP, BP, JP, FCC, NF, & Purified Grades where applicable.	

## Organic Compliance Certification

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**Non-Irradiated:** See Non-Irradiation Statement herein.

**No Sewage Sludge:** Jost Chemical's Calcium Phosphate Tribasic has not come into contact with sewage sludge per the requirements of 7 CFR 205.105(g).

**Non-GMO:** See GMO Statement herein.

## Packaging Certification

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Herein contains information concerning packaging used in the manufacturing of Jost Chemical's finished goods.

- The poly liners used are manufactured from virgin, FDA-approved, polyethylene that does not contain slip additives.
- The poly liners are not produced from materials engineered by nanotechnology.
- Per 21 CFR 177.1520, (c), 2.1, these liners are approved for use in the United States as an article or component of an article intended for use in contact with food, subject to the specific limitation that it may contact food only at temperatures of 212F and below.
- The primary packaging used complies with Regulations (EC) No. 1935/2004 of the European Parliament and of the council of 27 October 2004 on materials and articles intended to come into contact with food, Commission Regulation (EU) No. 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food, and Commission Regulation (EC) No. 2023/2006 of 22 December 2006 on good manufacturing practice for materials and articles intended to come into contact with food.

## Pesticide & Aflatoxin Free Certification

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None of the raw materials used are agricultural products and none are treated with pesticides. Therefore, Calcium Phosphate Tribasic is not routinely tested for pesticides or aflatoxins. Based on a detailed knowledge of the raw materials and processing conditions, pesticide and aflatoxin contamination is not considered a significant risk.

## Phthalate Free Certification

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Jost Chemical products and packaging used for said products are not manufactured using phthalates, and do not contain phthalates. This includes, but is not limited to, the following: DEHP, DINP, DNOP, DIDP, DBP, and BBP.

## Proposition 65

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Jost Chemical does not contribute, and is not the source of any Proposition 65 listed chemicals. The presence of any Prop 65 listed chemicals is due solely to the presence of the chemicals contained in raw materials used to manufacture a Jost Chemical finished product.

The California Office of Environmental Health Hazard Assessment (O.E.H.H.A.) of the California Environmental Protection Agency is the lead agency for Prop 65 implementation. The OEHHA website states the following:

*"It should be noted that under Proposition 65, there are no acceptable concentrations established for any prop 65 listed chemical in any given product. An exposure that causes a significant risk of harm from a listed chemical through the use of a product would trigger the warning requirement, not merely the fact that a listed chemical is present in a product."*

## Purity Statement

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Jost Chemical's Calcium Phosphate Tribasic is a pure compound containing only Calcium Phosphate Tribasic. It does not contain any other additional ingredients of any type.

## Quaternary Ammonium Compounds Statement

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Jost Chemical Co. products and packaging do not come into contact with Quaternary Ammonium Compounds.

## Residual Solvent Certification

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Jost Chemical Co. herein certifies that no organic solvents are used in the manufacture of Jost Calcium Phosphate Tribasic.

Additionally, based on a knowledge of the raw materials, the manufacturing process and the controlled handling, shipping and storage of said product, there is no significant potential for any of the ICH Q3C Class 1, Class 2 or Class 3 solvents or any other organic solvents to be present. If tested, Jost Calcium Phosphate Tribasic will comply with the USP <467>.

## Safety Data Sheet (SDS)

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Please select the following link: [SDS - English \(US\)](#)      [SDS - English \(EN\)](#)      [SDS – Belgian \(BE\)](#)  
[SDS - German \(DE\)](#)      [SDS - French \(FR\)](#)      [SDS – Netherlands \(NL\)](#)  
[SDS - Spanish \(ES\)](#)      [SDS - Polish \(PL\)](#)      [SDS - Italian \(IT\)](#)

## Specification / Product Sheet

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Please click the following link to Jost Chemical Co.'s website: [Calcium Products](#)

## Stability & Storage Certification

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Based on real-time stability studies, Jost Chemical recommends retesting Calcium Phosphate Tribasic three years from the labeled Date of Manufacture to ensure ongoing specification compliance. Three years from the Date of Manufacture represents a “Retest Date” and not an “Expiration Date”.

Store Jost Chemical Calcium Phosphate Tribasic in a clean dry warehouse in the original unopened Jost Chemical packaging.

## Substances of Very High Concern Statement

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Jost Chemical's Calcium Phosphate Tribasic does not contain Substances of Very High Concern (SVHCs) from the ECHA Candidate List as an intentional or unintentional constituent at  $\geq 0.1\%$ .

## Synthetically Produced Certification

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Jost Chemical's Calcium Phosphate Tribasic is manufactured by chemical synthesis. Due to the nature of the Jost Chemical proprietary production process (full chemical reaction), Jost Calcium Phosphate Tribasic should be considered as synthetic material manufactured by Jost Chemical Co. in St. Louis, MO USA.



## Tariff Code

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2835.26.0000

## Traceability Statement

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The Jost Chemical BPRs (Batch Production Records) allow for full traceability to raw materials used in manufacturing all finished lots, equipment used for manufacturing all finished lots, personnel responsible for manufacturing all finished lots, in-process lots, and controls for all finished lots and in-process testing results for all finished lots. The production records permit traceability to equipment usage. The laboratory records allow for all traceability to all testing activities. The cleaning records allow for traceability to all cleaning activities. The shipping and distribution records allow for full traceability to the “ship-to” location for every container comprising all finished lots. All of the above allows for full backwards and forward traceability. Jost Chemical performs mock recalls on a regular basis (2 times per year) and has repeatedly demonstrated full backwards and forwards traceability.

## Vegan & Vegetarian Certification

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Jost Chemical’s Calcium Phosphate Tribasic is suitable for vegetarians and vegans.

## W.A.D.A. Certification

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Jost Chemical herein certifies that Jost Chemical products are manufactured without any substances listed in the January 2018 W.A.D.A. (World Anti-Doping Agency) Prohibited List.

Additionally, no January 2018 W.A.D.A. Prohibited List substance is used as a processing aid in the manufacturing of any Jost Chemical product. None of the January 2018 W.A.D.A. Prohibited List substances comes into contact with any Jost manufacturing equipment and none of these Prohibited List substances are warehoused by Jost Chemical.

All Jost Chemical products comply with the January 2018 W.A.D.A. Prohibited List.

## Water Source Statement

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Jost Chemical’s source water is potable city water supplied by the City of St. Louis Water Division. This source water complies with all local, state, and federal regulations.



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## Jost Calcium Phosphate Tribasic

Sincerely,

A handwritten signature in black ink, appearing to read 'Joel Kruse', with a large, sweeping flourish at the end.

Joel Kruse  
Quality Assurance Manager  
Jost Chemical Co.