2020 Product Certifications

Jost Calcium Carbonate

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

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

- 2,4,6-Tribromophenol (TBP)
- 2-Ethylhexanoic Acid (2-EHA)
- 3-MCPD (3-monochloropropane-1,2-diol)
- Acrylamide
- Added salt
- Added Sugar
- Alcohols
- Amino Acids
- Antibiotics
- Arachidic Fatty Acid
- Aromatic Amines
- Artificial Colour from Azo Dyes
- Artificial colours
- Artificial Flavors
- Artificial Sweeteners
- Asbestos
- Aspartame
- Azocolorants
- Barley / Derivatives
- Bee Pollen
- Beef / Derivatives
- Behenic Fatty Acid
- Benzo(a)pyrene
- Benzoic Acid
- Beta Lactams
- Biocides
- Bisphenol A
- Bisphenol A Compounds
- Bisphenol A Diglycidyl Ether (BADGE)
- Bisphenol F Diglycidyl Ether (BFDGE)
- Brominated Flame Retardants (BFRs)
- Butter
- Butylated Hydroxyaniseole (BHA)
- Butylated Hydroxytoluene (BHT)
- Butyric Fatty Acid
- Caffeine
- Capric Fatty Acid
- Caprylic Fatty Acid
- Caramel
- Carmine / cochineal
- Carproic Fatty Acid
- Celery and products thereof
- Cereal containing gluten and products thereof
- Cetoleic Fatty Acid
- Chicken / Derivatives
- Chlorofluorocarbons (CFCs)
- Cinnamon/ Extract
- Cocoa / Derivatives
Coconuts / Derivatives
Colorants
Colors
Conflict Minerals
Coriander
Cotton Seeds
Cyclopentylmethyleneether
Di-Acetyl
Diethylene Glycol
Dimethyl Fumarate
Dry Natural Rubber
Egg and products thereof
Emulsifiers
Enzymes
Erucic Fatty Acid
Ethoxyquin
Fatty Acids
Fish / Seafood and products thereof
Flavourings
Formaldehyde
Fragrances
Fructose g
Fruit / Derivatives
Garlic / Derivatives
Gelatin
GLA Fatty Acid
Glucose
Gluten
Glycerine
Glycoalkoloids
Gondoic Fatty Acid
Guaiacol
Halons
Heptadecenoic Fatty Acid
Herbicides
Hexabromocyclododecane (HBCD)
Histamine
Honey
Hormones
HVP (Hydrolysed vegetable protein)
Hydrochlorofluorocarbons (HCFCs)
Insecticides
Kamut / Kamut Derivatives
Lamb / Mutton / Derivatives
Latex
Lauric Fatty Acid
Leguminous Plants / pulses e.g. pea
Lignoceric Fatty Acid
Linoleic Fatty Acid
Long-chain (C9-20) perfluorocarboxyclic acids (PFCAs), their salts, and their precursors
Lupin and products thereof
Malt Extract
Maltodextrin
Margaric Fatty Acid
Mechanically Recovered Meat
Methylisothionate
Methylnaphthalenes (including 4-methylnaphthalene)
Methyltetrahydrofuran
Microbeads
Milk and products thereof
Mineral oil
Molluscs and products thereof
MSG (Monosodium glutamate) and other glutamates
Mushroom
Mustard and products thereof
Myristic Fatty Acid
Myristol Fatty Acid
Natural colours
Natural Flavors
Natural Rubber
Natural Rubber Latex
Nervonic Fatty Acid
Nitrosamine
Novalac Glycidyl Ether (NOGE)
Nucleotides
Nut oils / Derivatives
Nuts and products thereof
Oats / Derivatives
Oils (refined, bleached, deodorized (rbd), cold pressed, hydrogenated, & partially hydrogenated)
Oils of Seafood
Oleic Fatty Acid
Onion / Derivatives
Organic Acids
Other Animal Products / Derivatives
Other Artificial Sweeteners
PAHs (benz[a]anthracene, chrysene, benzo[b]fluoranthene and benzo[a]pyrene)
Palmitic Fatty Acid
Palmitoleic Fatty Acid
Parabens
Patulin
Peaches
Peanuts and products thereof
Penicillin
Pentachlorophenol (PCP)
Pentadecanoic Fatty Acid
Pentadecenoic Fatty Acid
Perfluorinated tensides (PFTs)
Perfluorooctanoic acid (PFOA), its salts and precursors
Pesticides
Petroleum
Phenylalaline
Plasticizers (adipates, ESBO, Phthalates e.g. BBP, DBP, DEHP, DnHP, DIDP, DINP, DNOP)
Polybrominated Biphenyl (PBB)
Polybrominated Diphenyl Ether (PBDE)
Polychlorinated bi- or terphenyls (PCB/PCT)
Polycyclic Aromatic Compounds (PACs)
Polycyclic aromatic hydrocarbons (PAH)
Polydextrose
Polyols
Polyphenols
Polyvinyl Chloride (PVC)
Poppy Seeds
Pork / Derivatives
Potato / Derivatives
Preservatives
Quinine
Rennet
Rye / Derivatives
Seed Derivatives
Seed oil / other Vegetable oils (excl sesame)
Seeds and Seed Products
Sesame and products thereof
Sewage Sludge
Shellfish or Crustaceans and products thereof
Short-Chain Chlorinated Paraffins (SCCPs)
Sialic Acid
Silicone
Siloxanes (D3, D4, D5, D6)
Sodium laureth sulfate
Sodium lauryl sulfate
Soybeans and products thereof
Spelt/ Derivatives
Sphingomyelin
Sucrose
Sugars
Sulfa
Tert-butanol
Tertiary Butylhydroquinone (TBHQ)
Tetra bromobisphenol A (TBBPA)
Thiurams
Tomatoes
Triglycerides
TVP (Texturised vegetable protein)
Umbelliferae / Derivatives
Vaccenic Fatty Acid
Vanilla
Vanillin
Vegetables / Derivatives
Vinegars
Vinyl Chloride
Volatile Organic Compounds (VOCs)
Wheat / Derivatives
Yeast / Extract (including autolyzed)
Yellow #5 (Tartrazine)
Yellow #6 (Sunset Yellow)

Allergen Free Certification

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

Jost Chemical Co. herein certifies that Calcium Carbonate 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

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

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

BSE / TSE / Animal Derivative Free Certification

Jost Chemical Co. herein certifies that Calcium Carbonate 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 Carbonate manufactured by Jost Chemical Co. should not be considered a vector for BSE or TSE.

Business Continuity Statement

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

Jost Chemical herein certifies that Calcium Carbonate 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

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

Contaminants Statement

Based on a knowledge of the raw materials used in manufacturing and a detailed understanding of the manufacturing process, Jost Chemical’s Calcium Carbonate 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

Jost Chemical hereby guarantees each shipment or delivery of Calcium Carbonate 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

Jost Chemical Co. herein certifies that Jost Calcium Carbonate is manufactured at the Jost Chemical Co. site located in St. Louis, Missouri, USA.
Cross Contamination Statement

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

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

Jost Chemical’s Calcium Carbonate is manufactured using high purity raw materials. Calcium Carbonate 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

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

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

1. Raw Materials
2. Controlled Reaction
3. Filtration
4. Crystal Isolation
5. Centrifugation
6. Drying
7. Blending
8. Sifting
9. Magnet
10. Packaging & Sampling
11. Testing
12. Release
Food Grade Certification

Jost Chemical Co. herein certifies that Calcium Carbonate 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

Jost Chemical Co. herein certifies that Calcium Carbonate 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

Jost Chemical Co. herein certifies that Calcium Carbonate 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 Carbonate should be considered non-Genetically Modified. This position is consistent with the directives outlined in EC 1830/2003 and EC 1829/2003.

Halal Certification

Please click the following link to Jost Chemical Co.’s website for the certificate: Halal Certification

Heat Treated Pallets Certification

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

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

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

Kosher Certification

Please click the following link to Jost Chemical Co.’s website for the certificate: Kosher Certification

Latex Free Statement

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

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

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

Metal Reagent / Metal Catalyst Statement

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

Nanomaterial Statement

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

Non Irradiation / ETO Statement

Jost Chemical’s Calcium Carbonate 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 Carbonate has not been treated with ETO (ethylene oxide) nor any other chemical sterilizing agent.
## Nutritional Certificate

<table>
<thead>
<tr>
<th>Nutrient</th>
<th>Dietary Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Fat</td>
<td>Not a dietary source</td>
</tr>
<tr>
<td>Saturated Fat</td>
<td>Not a dietary source</td>
</tr>
<tr>
<td>Trans Fat</td>
<td>Not a dietary source</td>
</tr>
<tr>
<td>Cholesterol</td>
<td>Not a dietary source</td>
</tr>
<tr>
<td>Total Carbohydrates (Digestible by difference)</td>
<td>Not a dietary source</td>
</tr>
<tr>
<td>Dietary Fiber</td>
<td>Not a dietary source</td>
</tr>
<tr>
<td>Added Sugars</td>
<td>Not a dietary source</td>
</tr>
<tr>
<td>Protein</td>
<td>Not a dietary source</td>
</tr>
<tr>
<td>Vitamin A</td>
<td>Not a dietary source</td>
</tr>
<tr>
<td>Thiamin</td>
<td>Not a dietary source</td>
</tr>
<tr>
<td>Riboflavin</td>
<td>Not a dietary source</td>
</tr>
<tr>
<td>Niacin</td>
<td>Not a dietary source</td>
</tr>
<tr>
<td>Vitamin C</td>
<td>Not a dietary source</td>
</tr>
<tr>
<td>Vitamin D</td>
<td>Not a dietary source</td>
</tr>
<tr>
<td>Calcium</td>
<td>38,400 – 41,000 mg / 100 grams</td>
</tr>
<tr>
<td>Iron</td>
<td>Not a dietary source</td>
</tr>
<tr>
<td>Potassium</td>
<td>Not a dietary source</td>
</tr>
<tr>
<td>Copper</td>
<td>Not a dietary source</td>
</tr>
<tr>
<td>Phosphorus</td>
<td>Not a dietary source</td>
</tr>
<tr>
<td>Magnesium</td>
<td>Not a dietary source</td>
</tr>
<tr>
<td>Manganese</td>
<td>Not a dietary source</td>
</tr>
<tr>
<td>Sodium</td>
<td>Not a dietary source</td>
</tr>
<tr>
<td>Strontium</td>
<td>Not a dietary source</td>
</tr>
<tr>
<td>Zinc</td>
<td>Not a dietary source</td>
</tr>
<tr>
<td>Calories</td>
<td>Not a dietary source</td>
</tr>
</tbody>
</table>

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

Non-Irradiated: See Non-Irradiation Statement herein.

No Sewage Sludge: Jost Chemical’s Calcium Carbonate 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

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 212°F and below.

Pesticide & Aflatoxin Free Certification

None of the raw materials used are agricultural products and none are treated with pesticides. Therefore, Calcium Carbonate 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

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

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

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

Quaternary Ammonium Compounds Statement

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

Residual Solvent Certification

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

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 Carbonate will comply with the USP <467>. 
Safety Data Sheet (SDS)

Please select the following link:  

- SDS - English (US)  
- SDS - English (EN)  
- SDS - German (DE)  
- SDS - French (FR)  
- SDS - Spanish (ES)  
- SDS - Polish (PL)  
- SDS – Belgian (BE)  
- SDS - Italian (IT)

Specification / Product Sheet

Please click the following link to Jost Chemical Co.’s website: Calcium Products

Stability & Storage Certification

Based on real-time stability studies, Jost Chemical recommends retesting Calcium Carbonate 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 Carbonate in a clean dry warehouse in the original unopened Jost Chemical packaging.

Substances of Very High Concern Statement

Jost Chemical’s Calcium Carbonate does not contain Substances of Very High Concern (SVHCs) from the ECHA Candidate List as an intentional or unintentional constituent at ≥ 0.1%.

Synthetically Produced Certification

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

2836.50.0000

Traceability Statement

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 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

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

W.A.D.A. Certification

Jost Chemical herein certifies that Jost Chemical products are manufactured without any substances listed in the January 2020 W.A.D.A. (World Anti-Doping Agency) Prohibited List.

Additionally, no January 2020 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 2020 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 2020 W.A.D.A. Prohibited List.

Water Source Statement

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.
Sincerely,

[Signature]

Michael Niehoff
Quality Assurance Specialist
Jost Chemical Co.
## REVISION HISTORY

<table>
<thead>
<tr>
<th>REVISION NUMBER</th>
<th>REVISION DATE</th>
<th>REVISED BY</th>
<th>REVISIONS</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>08/13/2018</td>
<td>Joel Kruse</td>
<td>Original</td>
</tr>
<tr>
<td>2</td>
<td>02/27/2020</td>
<td>Michael Niehoff</td>
<td>Updated W.A.D.A. Certification section to indicate compliance with the 2020 W.A.D.A. list, added additional substances to Absence Declaration section</td>
</tr>
</tbody>
</table>