



## INNOPHOS, INC.

### PHOSPHATE-BASED PRODUCTS\*

# GENERAL QUALITY & REGULATORY STATEMENTS

|   |          |
|---|----------|
| <b>PHOSPHATES-BASED PRODUCT LIST*</b>                   | <b>2</b> |
| <b>ANIMAL ORIGIN / NO ANIMAL INGREDIENT</b>             | <b>3</b> |
| <b>ANIMAL TESTING</b>                                   | <b>3</b> |
| <b>BSE-TSE</b>  | <b>3</b> |
| <b>IMPURITIES/ CONTAMINANTS/ INGREDIENTS OF CONCERN</b> | <b>3</b> |
| <b>IRRADIATION/ ETHYLENE OXIDE (ETO)/ SEWAGE SLUDGE</b> | <b>4</b> |
| <b>NANOTECHNOLOGY</b>                                   | <b>4</b> |
| <b>NON-BIOENGINEERED (BE)</b>                           | <b>4</b> |
| <b>NON-GENETICALLY MODIFIED ORGANISM (GMO)</b>          | <b>5</b> |
| <b>PROPOSITION 65 (PROP 65)</b>                         | <b>5</b> |
| <b>RADIOLOGICAL HAZARDS</b>                             | <b>6</b> |
| <b>READY-TO-EAT (RTE)</b>                               | <b>6</b> |
| <b>RESIDUAL SOLVENT</b>                                 | <b>7</b> |
| <b>VEGETARIAN-VEGAN</b>                                 | <b>7</b> |
| <b>WADA</b>   | <b>7</b> |
| <b>ADDITIONAL PRODUCT INFORMATION</b>                   | <b>8</b> |

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DATE: February 09, 2024

CRAN-QRGS-0001 V08

[259 Prospect Plains Road Bldg. A, Cranbury, NJ 08512, USA](https://www.innophos.com) ♦ [1-800-243-5052](tel:1-800-243-5052) ♦ [www.innophos.com](http://www.innophos.com)

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## Phosphates-Based Product List\*

|  |  |
|--|--|
| ACTIF•8®   | Monoammonium Phosphate Powder with TCP             |
| Ajax® (Monocalcium Phosphate Monohydrate)              | Monoammonium Phosphate                             |
| A-TAB® (Dicalcium Phosphate Anhydrous Granular)        | Monopotassium Phosphate                            |
| BAC-N-FOS®   | Monosodium Phosphate                               |
| BL-60®   | OptiBalance™                                       |
| B.P. PYRO® (Sodium Acid Pyrophosphate)                 | OptiBalance 200                                    |
| Calipharm T® (Tribasic Calcium Phosphate)              | OPTIBALANCE™ 300                                   |
| Calipharm® A Dicalcium Phosphate Anhydrous             | Optibind™  |
| Calipharm® D Dicalcium Phosphate Dihydrate             | PERFECTION® (Sodium Acid Pyrophosphate)            |
| Cal-Rise®  | Phosphoric Acid (All concentrations)               |
| Cal-Rise® 100  | Regal Bake™  |
| Colorsure™   | Regal Rise™  |
| Curafos® (Sodium Tripolyphosphate)                     | REGENT 12XX® (Monocalcium Phosphate Monohydrate)   |
| CURAVIS® 250   | SAPP #4® (Sodium Acid Pyrophosphate)               |
| CURAVIS® (FORMULA 350)                                 | SAPP #4® Blend (Sodium Acid Pyrophosphate)         |
| CURAVIS® So-Lo 93                                      | SAPP 40  |
| Diammonium Phosphate Powder with TCP                   | Sodium Trimetaphosphate                            |
| Diammonium Phosphate                                   | STPP (Sodium Tripolyphosphate)                     |
| Dicalcium Phosphate (Anhydrous)                        | STABILCOLOR™ (Trisodium Pyrophosphate)             |
| Dicalcium Phosphate (Dihydrate)                        | SUPERBIND® HB-CT                                   |
| Dipotassium Phosphate                                  | TATERFOS® (Sodium Acid Pyrophosphate)              |
| Dipotassium Phosphate Liquid - 50% Solution            | TKPP (Tetrapotassium Pyrophosphate)                |
| Disodium Phosphate Anhydrous Powder                    | Tetrapotassium Pyrophosphate Liquid - 60% Solution |
| Disodium Phosphate Anhydrous Granular                  | TSPP (Tetrasodium Pyrophosphate)                   |
| Disodium Phosphate, Duohydrate                         | TEXTUR-BIND® OB525                                 |
| DI-TAB® (Unmilled Dicalcium Phosphate, Dihydrate)      | TEXTUR-MELT® LS85                                  |
| DONUT PYRO® (Sodium Acid Pyrophosphate)                | TEXTUR-MELT® WM86                                  |
| Expandia R® (Tribasic Calcium Phosphate)               | TEXTUR-MELT® WS80                                  |
| KASAL™ (Sodium Aluminum Phosphate Basic)               | Tricalcium Phosphate                               |
| Kena® Formula 22-4 (Sodium Polyphosphate Blend)        | Trisodium Phosphate, Dodecahydrate                 |
| KENA® (Formula FP-28)                                  | Tetrasodium Pyrophosphate                          |
| LEMOFOS® (Phosphate/Lemon Juice Blend)                 | TRI-TAB® (Tricalcium Phosphate Anhydrous)          |
| LEVAIR® (SALP - Sodium Aluminum Phosphate, Acidic)     | V-90® (Monocalcium Phosphate, Anhydrous)           |
| LEVAIR® FT-01  | VersaCAL® Clear                                    |
| LEVAIR® ST-01  | VersaCAL® MP (Tricalcium Phosphate)                |
| LEVAIR® ST-02  | VICTOR CREAM® (Sodium Acid Pyrophosphate)          |
| LEVAIR® Select (SE-01)                                 | Victor® D.F. Dicalcium Phosphate Dihydrate         |
| MCP-A (Monocalcium Phosphate, Anhydrous)               | VITRAFOS® Sodium Hexametaphosphate                 |
| MCP-M (Monocalcium Phosphate, Monohydrate)<br>Granular |  |
| MCP-A (Monocalcium Phosphate, Anhydrous)               |  |

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## **ANIMAL ORIGIN / NO ANIMAL INGREDIENT**

Innophos, Inc.'s phosphate products are made from inorganic mined materials. They are not derived from an animal starting material.

## **ANIMAL TESTING**

Innophos, Inc. has not conducted animal testing on its phosphate products since 1992 except for requests by government entities for the purpose of registration and/or safety of our product, Cal-Rise<sup>®</sup>. In connection with the government entities' request, limited animal testing was performed on Calcium Acid Pyrophosphate, a component of Cal-Rise<sup>®</sup>, in 2011.

## **BSE-TSE**

Innophos, Inc.'s inorganic phosphate products do not contain animal derived materials in either their raw materials, processing aids or in the process used in their manufacture. In addition, these products do not come in direct contact with animal products during storage or transportation. Therefore, our inorganic phosphate products cannot be a source of Bovine Spongiform Encephalitis (BSE) or Transmissible Spongiform Encephalitis (TSE).

## **IMPURITIES/ CONTAMINANTS/ INGREDIENTS OF CONCERN**

Refer to the Does Not Contain – Do Not Test Statement located on the Innophos website:  
<https://www.innophos.com/customer-center>.

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## IRRADIATION / ETHYLENE OXIDE (ETO)/ SEWAGE SLUDGE

None of Innophos, Inc.'s phosphate products are irradiated, treated with Ethylene Oxide (ETO), or produced from sewage sludge.

## NANOTECHNOLOGY

Innophos, Inc.'s Phosphate products do not meet the definition of nanomaterial according to the European Commission's Recommendation of 10 June 2022 on the definition of nanomaterial (2022/C 229/01). The Recommendation defines "Nanomaterial" as follows:

"Nanomaterial" means a natural, incidental, or manufactured material consisting of solid particles that are present, either on their own or as identifiable constituent particles in aggregates or agglomerates, and where 50 % or more of these particles in the number-based size distribution fulfil at least one of the following conditions:

- a) One or more external dimensions of the particle are in the size range 1 nm to 100 nm.
- b) The particle has an elongated shape, such as a rod, fiber, or tube, where two external dimensions are smaller than 1 nm and the other dimension is larger than 100 nm.
- c) The particle has a plate-like shape, where one external dimension is smaller than 1 nm and the other dimensions are larger than 100 nm. In the determination of the particle number-based size distribution, particles with at least two orthogonal external dimensions larger than 100 µm need not be considered.

However, a material with a specific surface area by volume of < 6 m<sup>2</sup> /cm<sup>3</sup> shall not be considered a nanomaterial."

## NON – BIOENGINEERED (BE)

Based on the United States' National Bioengineered Food Disclosure Standard, Innophos, Inc.'s inorganic Phosphate products are not derived from or manufactured with ingredients that have been bioengineered (genetically modified through modern biotechnology), except for LEM-O-FOS® Sodium Tripolyphosphate with lemon juice concentrate, which contains a botanically derived ingredient (lemon juice concentrate) that may be bioengineered.

Contact us if you have any questions about this product.

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## NON – GENETICALLY MODIFIED ORGANISM (GMO)

Innophos, Inc.'s Inorganic Phosphate products do not contain genetically modified organisms in accordance with EC regulations 1829/2003 and 1830/2003 as well as the Directive 2001/18/EC and do not require additional labelling in relation to the presence or use of GMO, except for LEM-O-FOS® Sodium Tripolyphosphate with lemon juice concentrate, which contains a botanically derived ingredient (lemon juice concentrate) that may be GMO.

Contact us if you have any questions about this product.

## PROPOSITION 65 (PROP 65)

Regulations implementing California's Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65) state in part "...that the warning language...will be associated only with consumer products which contain, or which the business connected with the exposure reasonably believe to contain, significant levels of listed chemicals in excess of these levels which are naturally occurring".

A review of the lists being considered and/or adopted by the California Health and Welfare Agency leads us to conclude that none of the listed substances are present in any of Innophos, Inc.'s phosphate products as added substances or at levels deemed to be significant such that warning language would be required for consumer products containing the substance. Naturally occurring trace elements may be present in our products, e.g., arsenic, lead, cadmium, and mercury, but these substances are naturally occurring and thus exempt from exposure considerations under the Act and, therefore, not included within the scope of California's Proposition 65 initiative.

Proposition 65 is a law that applies to products (finished products) marketed and sold to consumers in California. The limits for dangerous chemicals in the law are expressed in daily

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intake or dose. Innophos, Inc. manufactures and sells products as bulk raw materials. These products are not manufactured or labeled for direct sale to consumers.

## **RADIOLOGICAL HAZARDS**

Innophos, Inc. products are manufactured under Code of Federal Regulations, Title 21, Part 117, Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food, including section 117.130, which pertains to the identification and addressing of preventive controls of potential radiological hazards. Hazard Analyses are regularly performed on all phosphate food grade and excipient products.

To the best of our knowledge, Innophos, Inc.'s products, and its raw ingredients, are not sourced from or manufactured in areas that contain radiological hazards, have experienced an accidental release of radiation, or are affected by nuclear accidents or incidents.

## **READY-TO-EAT (RTE)**

Based on the FDA's definition of Ready-To-Eat (RTE) Foods, Innophos, Inc.'s phosphate products are not considered Ready to Eat (RTE). The FDA defines RTE food 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.

Our phosphate food grade products are in compliance with all applicable FSMA rules, including the Preventive Controls Rule for Human Food. These products may be used in the manufacture of an RTE product when utilized under Good Manufacturing Practices (GMP) conditions and at GMP levels in accordance with applicable food regulations. The nature of these products (due to pH, inorganic origin, water activity) does not promote microbial growth. These items are manufactured under current Good Manufacturing Practices for the Manufacturing, Processing, Packaging and Holding of Human Food. However, these products are not considered sterile

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although they are processed at temperatures which could significantly reduce or eliminate biological hazards.

## RESIDUAL SOLVENT

Please be advised that Innophos, Inc. phosphate products theoretically comply with the requirements for Residual Solvents in excipients per the current editions of United States Pharmacopeia (USP) General Chapter <467> Residual Solvents, General Chapter 5.4 of the European Pharmacopoeia, and the International Conference of Harmonization (ICH) Q3c Residual Solvent (Organic Volatile Impurities) Guideline. These products are not manufactured with Class 1, Class 2 or Class 3 solvents listed in the aforementioned sources.

Based on knowledge of the manufacturing processes and raw materials, other organic solvents are not likely to be present. Therefore, Innophos does not routinely test these products for the presence of residual solvents.

## VEGETARIAN – VEGAN

Phosphate products supplied by Innophos, Inc. do not contain animal ingredients, animal by-products, or their derivatives and its manufacturing processes use no animal ingredients, animal by-products, or their derivatives.

## WADA

As of the date of this statement none of the substances appearing on the current prohibited lists published by the World Anti-Doping Agency (WADA) or the National Football League

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Players Association (NFL-NFLPA) are used in the manufacturing of our products. In addition, none of these substances are manufactured, packed, or stored in our facilities.

## ADDITIONAL PRODUCT INFORMATION:

Located on the Innophos website: <https://www.innophos.com/customer-center>.

- Allergen Statements
  - Halal Certificates
  - Kosher Certificates
  - Nutrition Information
  - Product Data Sheets
  - Safety Data Sheets
  - Additional Regulatory Information
  - Plant Certificates and 3<sup>rd</sup> Part Audit Certificates
- <https://www.innophos.com/who-we-are/about-us/our-locations>

### INNOPHOS-CHICAGO HEIGHTS

CH ISO 9001:2015

<https://www.innophos.com/-/media/innophos-com/customer-center-files/phosphates/public/shared/certificates/chicago-heights-iso-certificate.pdf>

CH BRC (GFSI CERT/ 3RD PARTY AUDIT CERT)

<https://www.innophos.com/-/media/innophos-com/customer-center-files/phosphates/public/shared/certificates/chicago-heights-brc-certificate.pdf>

### INNOPHOS-GEISMAR

GE BRC (GFSI CERT/ 3RD PARTY AUDIT CERT)

<https://www.innophos.com/-/media/innophos-com/customer-center-files/phosphates/public/shared/certificates/geismar-brc-certificate.pdf>

### INNOPHOS-NASHVILLE

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NV BRC (GFSI CERT/ 3RD PARTY AUDIT CERT)

<https://www.innophos.com/-/media/innophos-com/customer-center-files/phosphates/public/shared/certificates/nashville-brc-certificate.pdf>

NV ISO 9001:2015

<https://www.innophos.com/-/media/innophos-com/customer-center-files/phosphates/public/shared/certificates/nashville-iso-certificate.pdf>

#### INNOPHOS-WATERWAYS

WW BRC (GFSI CERT/ 3RD PARTY AUDIT CERT)

<https://www.innophos.com/-/media/innophos-com/customer-center-files/phosphates/public/shared/certificates/waterway-brc-certificate.pdf>

#### INNOPHOS-PORT MAITLAND

PM BRC (GFSI CERT/ 3RD PARTY AUDIT CERT)

<https://www.innophos.com/-/media/innophos-com/customer-center-files/phosphates/public/shared/certificates/port-maitland-brc-certificate.pdf>

PM ISO 9001:2015

<https://www.innophos.com/-/media/innophos-com/customer-center-files/phosphates/public/shared/certificates/port-maitland-iso-certificate.pdf>

#### INNOPHOS-COATZACOALCOS

CZ BRC (GFSI CERT/ 3RD PARTY AUDIT CERT)

<https://www.innophos.com/-/media/innophos-com/customer-center-files/phosphates/public/shared/certificates/coatzacoalcos-brc-certificate.pdf>

CZ ISO 9001:2015

<https://www.innophos.com/-/media/innophos-com/customer-center-files/phosphates/public/shared/certificates/coatzacoalcos-iso-certificate.pdf>

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Quality and Regulatory Team

[QualityAssurance@Innophos.com](mailto:QualityAssurance@Innophos.com)

| REVISION HISTORY |   |              |             |
|------------------|---|--------------|-------------|
| Version No.      | Description of Change   | Date         | Revised by: |
| 08               | Added BE section, adjusted the pages  | Feb 09, 2024 | A.Sadiq     |
| 07               | Added Levair® Select SE 01  | Jan.22, 2024 | B Kirkland  |
| 06               | Updated Nanoparticle Statement according to latest EU Regulation  | Jan 02, 2024 | A. Sadiq    |
| 05               | Updated Nanoparticle Statement  | Jun 21, 2023 | A. Sadiq    |
| 04               | Added new LEVAIR products and deleted obsolete products.  | Jul 27, 2022 | J. Abadiano |
| 03               | Deleted Page 1, added title to page 2, added Radiological Statement<br><br>Revised Nanotechnology Statement according to latest EU Regulation | Feb 03, 2022 | J. Abadiano |
| 02               | Added Residual Solvent statement and Ready-To Eat statement   | Sep 27, 2021 | J. Abadiano |
| 01               | Initial template, combined individual product statements at Table of Contents list.   | Aug 27, 2021 | J. Abadiano |

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