

# INNOPHOS, INC. PHOSPHATE-BASED PRODUCTS\* GENERAL QUALITY & REGULATORY STATEMENTS

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

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## **Phosphates-Based Product List\***

ACTIF•8®	Monoammonium Phosphate		
Ajax® (Monocalcium Phosphate Monohydrate)	Monopotassium Phosphate		
A-TAB® (Dicalcium Phosphate Anhydrous Granular)	Monosodium Phosphate		
BAC-N-FOS®	OptiBalance TM		
BL-60®	OptiBalance 200		
B.P. PYRO® (Sodium Acid Pyrophosphate)	OPTIBALANCE™ 300		
Calipharm T® (Tribasic Calcium Phosphate)			
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 <sup>™</sup>		
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)		
MCP-A (Monocalcium Phosphate, Anhydrous)	Victor® D.F. Dicalcium Phosphate Dihydrate		
MCP-M (Monocalcium Phosphate, Monohydrate) Granular	VITRAFOS® Sodium Hexametaphosphate		
Monoammonium Phosphate Powder with TCP			
Monoammonium Phosphate Powder with TCP			

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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®. In connection with the government entities' request, limited animal testing was performed on Calcium Acid Pyrophosphate, a component of Cal-Rise®, 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.

#### **N**ANOTECHNOLOGY

Innophos Inc.'s phosphate products do not meet the following definition of engineered nanomaterials according to the Commission Delegated Regulation (EU) No 1363/2013 of 12 December 2013 amending Regulation (EU) No 1169/2011:

"Any intentionally manufactured material, containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50 % or more of the particles in the number size distribution, one or more external dimensions is in the size range 1 nm to 100 nm."

## 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

REVISION HISTORY				
Version No.	Description of Change	Date	Revised by:	
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  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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