

GRAS Notice (GRN) No. 316

<http://www.fda.gov/Food/FoodIngredientsPackaging/GenerallyRecognizedasSafeGRAS/GRASListings/default.htm>

GR



**ORIGINAL SUBMISSION**

000001

**BLANK PAGE(S) INSERTED FOR CORRECT PAGINATION**

COMPUTER TECHNOLOGY SERVICES, INC.

000002-  
000003

# COVINGTON & BURLING LLP

1201 PENNSYLVANIA AVENUE NW  
WASHINGTON, DC 20004-2401  
TEL 202 662 6000  
FAX 202.662 6291  
WWW COV.COM

BEIJING  
BRUSSELS  
LONDON  
NEW YORK  
SAN DIEGO  
SAN FRANCISCO  
SILICON VALLEY  
WASHINGTON

**MIRIAM J. GUGGENHEIM**  
TEL 202.662 5235  
FAX 202 778 5235  
MGUGGENHEIM@COV.COM

December 17, 2009

VIA FEDERAL EXPRESS

Office of Food Additive Safety (HFS-200)  
Center for Food Safety and Applied Nutrition  
Food And Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740-3835

Re: GRAS Notification for Sodium Potassium Hexametaphosphate

Dear Sir/Madam:

Enclosed please find three copies of the Generally Recognized as Safe (GRAS) notification for the use of Sodium Potassium Hexametaphosphate (SKMP), filed on behalf of ICL Performance Products LP, along with supporting documentation.

Please do not hesitate to contact me if you have any questions regarding this submission.

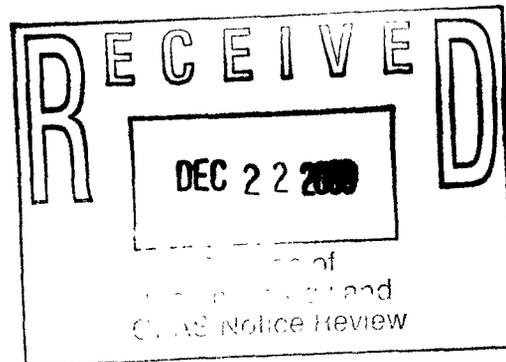
Respectfully submitted,

(b) (6)

Miriam J. Guggenheim 

Enclosures

000004



**GENERALLY RECOGNIZED AS SAFE (GRAS) NOTIFICATION  
FOR THE USE OF SODIUM POTASSIUM HEXAMETAPHOSPHATE  
AS A FOOD INGREDIENT**

Submitted on behalf of

ICL Performance Products LP

622 Emerson Road, Suite 500  
St. Louis, MO 63141

Communications regarding this document  
should be addressed to:

Miriam J. Guggenheim  
Covington & Burling LLP  
1201 Pennsylvania Avenue, N.W.  
Washington, D.C. 20004  
Email: [mguggenheim@cov.com](mailto:mguggenheim@cov.com)

000005

I. CLAIM OF GRAS STATUS

ICL Performance Products LP (ICL) hereby submits this notification, pursuant to proposed 21 C.F.R. 170.30,<sup>1</sup> that it considers the use of the food grade compound Sodium Potassium Hexametaphosphate (SKMP) to be generally recognized as safe (GRAS) based on scientific procedures, and therefore exempt from the premarket approval requirements of the Federal Food, Drug, and Cosmetic Act (FDCA). This conclusion is based on the report of the Select Committee on GRAS Substances (SCOGS or Select Committee) entitled, "Evaluation of the Health Aspects of Phosphates as Food Ingredients," prepared for the Food and Drug Administration (FDA) by the Life Sciences Research office of the Federation of American Societies for Experimental Biology, 1975,<sup>2</sup> and FDA's letter (dated October 10, 2003) regarding the GRAS determination of phosphates specified in this SCOGS report<sup>3</sup>, including the scientific information underlying both documents.

A. Name and address of Notifier:

ICL Performance Products LP  
622 Emerson Road, Suite 500  
St. Louis, MO 63141

through its attorney,

Miriam J. Guggenheim,  
Covington & Burling LLP  
1201 Pennsylvania Avenue, N.W.  
Washington, D.C. 20004

B. Common or usual name: Sodium Potassium Hexametaphosphate (SKMP)

C. Conditions of use: In food generally, as a multi-purpose food ingredient.

---

<sup>1</sup> 62 Fed. Reg. 18938 (April 17, 1997).

<sup>2</sup> "Evaluation of the Health Aspects of Phosphates as Food Ingredients," prepared for FDA by the Life Sciences Research office of the Federation of American Societies for Experimental Biology, SCOGS Report 32, NTIS Accession # PB-262-651; 1975. (Copy attached at Tab A.)

<sup>3</sup> Letter from U.S. Food and Drug Administration, from L. Highbarger to C. Ely, regarding the GRAS determination of phosphates specified in the SCOGS Report, dated October 10, 2003. (Copy attached at Tab B.)

- D. Levels of use: This food grade phosphate may be used up to the limits of good manufacturing practice.
- E. Purpose: This food grade phosphate is useful as a multi-functional food ingredient. Due to its lower sodium content, in comparison with Sodium Hexametaphosphate, this ingredient is useful in reduced-sodium foods for certain health considerations.
- F. Basis for GRAS determination: Scientific Procedures.

The SCOGS report on phosphates includes evaluation of the relevant scientific literature and exposure information of both the sodium salt and the potassium salt of hexametaphosphate (also known as polyphosphate), and concluded that these phosphates were GRAS. FDA evaluated this report and utilized these findings as the basis for allowance of the GRAS determination of these individual phosphates. This compound is a mixed salt (sodium and potassium) hexametaphosphate, which has the same functionality as the individual salt forms of this phosphate, but provides an increased-potassium / reduced-sodium alternative for healthier foods in which this phosphate provides functionality. This mixed cation hexametaphosphate was not evaluated in the SCOGS report, since it has only recently been developed as a food ingredient to address the need in the food industry for reduced sodium food products.

- G. Availability of data and information: The data and information supporting the GRAS status of the food grade sodium and potassium hexametaphosphate compounds may be found in the scientific literature review prepared for FDA by the Franklin Institute Research laboratories and the SCOGS report. ICL hereby incorporates all information supporting the GRAS status of food grade phosphates from FDA's proposed rule, Phosphates; Proposed Affirmation of and Deletion From GRAS Status as Direct and Human Food Ingredients,<sup>4</sup> into this notification. Any information not currently in FDA's files will be made available to the Agency upon request. ICL acknowledges that FDA more recently published a notice of its intent to withdraw this proposed rule<sup>5</sup> for lack of follow-up action. This does not, however, evidence any reason to believe FDA has changed its position on the GRAS status of food grade phosphates.

---

<sup>4</sup> 44 Fed. Reg. 74845 (December 18, 1979); FDA Docket No. 78N-0272.

<sup>5</sup> 68 Fed. Reg. 19766, April 22, 2003.

In consideration of the data and information summarized or provided in this document or incorporated by reference, ICL Performance Products LP submits that the described uses of sodium potassium hexametaphosphate are exempt from the premarket approval requirements of the FDCA because such uses are GRAS.

Respectfully submitted,

ICL PERFORMANCE PRODUCTS LP

By: \_\_\_\_\_  
Miriam J. Guggenheim  
Covington & Burling LLP  
Counsel for ICL Performance Products LP

## II. DESCRIPTION OF THE SUBSTANCE

### A. Nomenclature

1. Common names: Sodium Potassium Hexametaphosphate, SKMP, Sodium Potassium Phosphate, Glassy Metaphosphoric Acid, Sodium Potassium Salt, Glassy Sodium Potassium Phosphate
2. Chemical Names: Same as above
3. Trade name: Benephos™ (ICL Performance Products LP)
4. CAS Reg. No. 67183-30-6

### B. Empirical Formula

$(\text{Na}, \text{K})_{(n+2)} \text{P}_n \text{O}_{(3n+1)}$ , where  $n \cong 14$

### C. Structural Formula

Amorphous glass with Mole Ratio:  $\text{K} / (\text{Na} + \text{K}) \cong 0.70$

### D. Molecular Weight

A mixture of straight chain polymeric compounds, with Average MW  $\cong 1670$

### E. Method of Manufacture

An aqueous solution is prepared from the following food grade raw materials: phosphoric acid, potassium hydroxide, and sodium hydroxide or sodium carbonate. The mole ratios in this solution are:

$$[(\text{Na} + \text{K}) / \text{P}] = 0.9 - 1.3 \quad \text{and} \quad [\text{K} / (\text{Na} + \text{K})] \leq 0.8$$

The solution is heated in a furnace to evaporate water and form a high-temperature melt. This melt is then chilled to form a solid (amorphous glass). The glass is then milled and screened to obtain the appropriate granule size for use as a food ingredient.

### F. Characteristic Properties

- SKMP occurs as colorless or white granules. It is an amorphous, glassy, water-soluble polyphosphate composed of linear chains of metaphosphate units ( $\text{NaPO}_3$ )

or  $KPO_3$ ), and terminated by phosphate groups  $[(Na \text{ or } K)_2PO_4]$ , according to the empirical formula listed above.

- The average chain length of this linear polyphosphate is  $n \cong 14$ .
- SKMP is very soluble in water: 30 – 50g / 100 g solution @ 25°C.
- The bulk density of SKMP is 1.2 – 1.3 g/cc.
- Sodium reduction: On a molar basis, approximately 70% of the cations in this mixed cation hexametaphosphate are potassium, and 30% are sodium. This provides significant sodium reduction when compared to the Sodium Hexametaphosphate food ingredient which is commonly used in foods and is listed in 21 C.F.R. 182.6760 as GRAS.
- Typical nutrient levels in SKMP:
  - Phosphorus: 26.2 – 27.1 %
  - Potassium: 23 - 26 %
  - Sodium: 5 - 8 %

#### **G. Specifications for Food Grade Material\***

P <sub>2</sub> O <sub>5</sub> Content (Assay)	59.0 – 62.0 %
pH, 1% Solution	6.0 – 8.0
Water Insolubles, %	2.0 %, Maximum
Arsenic (as As), mg/kg	3 mg/kg, Maximum
Fluoride (as F), mg/kg	50 mg/kg, Maximum
Lead (as Pb), mg/kg	2 mg/kg, Maximum

\*Scientific methods and test procedures used to determine these specifications are consistent with those available in the current edition of the Food Chemicals Codex (FCC).

### III. FUNCTIONALITY AND USE OF SKMP

Food grade phosphates have been used as direct and indirect food ingredients for many years. The use of SKMP would be the same as the uses for its full sodium and full potassium counterparts (sodium hexametaphosphate and potassium polymetaphosphate, respectively). The level of use of SKMP as a food ingredient would also be consistent with levels that are now current or might reasonably be expected in the future, according to the limits of good manufacturing practice.

SKMP provides several important technical functions as a food ingredient in many types of food systems, and particularly in beverage and dairy formulations. Some of these functionalities are listed below:

- Metal complexing or sequestration: SKMP is able to complex calcium, magnesium, iron, and other ions, and prevent them from interacting with other formulation components in a negative way. For example, sequestration of calcium and magnesium from water sources helps to maintain the clarity and uniformity of beverages such as tea, fortified water, and flavored drinks, by preventing the formation of undesirable precipitates due to the interaction of metal ions with other formulation components.
- Emulsification: SKMP provides protein modification typical for polyphosphates, in processed cheese products to maintain the emulsion of fat in the protein-water matrix, to prevent syneresis in cheese sauces, and to protect the protein in milk and cheese powders during spray drying processes.
- Protein interaction: SKMP interacts with proteins to stabilize them in food systems. For example, SKMP aids in whey processing through stabilization, suspension, and dispersion of the protein. It also stabilizes protein films in milk-based foams, which inhibits drainages and increases the aeration, or whipping efficiency, of these foams.
- Increased rate of solution: SKMP goes into solution up to twice as fast as its full sodium counterpart. A faster rate of solution provides the opportunity for process optimization, or shorter batch cycles, in food processing.
- Sodium reduction / potassium addition: The important functionality of a water-soluble hexametaphosphate can be utilized, with a reduced level of sodium contribution to the overall food formulation, as well as providing a dietary source of potassium from its increased level in the formulation.

#### IV. SAFETY AND ADVERSE EFFECTS

ICL incorporates by reference the safety review conducted by SCOGS, as well as FDA's discussion of the SCOGS review. This SCOGS report reviewed the safety of a number of phosphate salts, including the full sodium (sodium hexametaphosphate) and the full potassium (potassium polyphosphate) counterparts to SKMP. ICL has reviewed the SCOGS report, and has determined that the conclusions regarding the GRAS status of these food grade phosphates remain valid.

The SCOGS report also evaluated the relevant toxicity studies on phosphates, with a focus on studies utilizing the oral administration of these compounds. While many of those studies were done using sodium salts, the presence of other cations, such as potassium, is not expected to affect these results. The Select Committee felt that "it is

improbable that the effects of the ammonium and potassium moieties of the salts, in the amounts used in foods, would be significantly different from the sodium salts and has no reports that indicate otherwise.”<sup>6</sup>

It is important to note that the use of SKMP as a food ingredient is not expected to increase the overall consumption of phosphate, since it likely will be used to replace sodium hexametaphosphate (SHMP) in reduced-sodium food applications. The phosphate functionality of SKMP is the same as that for SHMP, so that the technical applications in food will be the same. While the potassium consumption may increase very slightly due to replacement of some of the SHMP in certain food applications, this increase should be considered a source of dietary potassium, which should be beneficial to the diet of most healthy people. Although the recommended intake for potassium is 4700 mg/day<sup>7</sup>, it has been found that currently the dietary intake of potassium by all groups in the United States and Canada is considerably lower than this level.<sup>8</sup>

Based on the toxicity information evaluated in the SCOGS report, the Select Committee states “None of the [food grade phosphates relevant here] is intrinsically harmful and their use in foods does not present a hazard when the total amount of phosphorous ingested and the intakes of calcium, magnesium, vitamin D, and other nutrients are satisfactory.”<sup>9</sup> The report goes on to state the conclusions of the Select Committee that “there is no evidence in the available information on [the relevant food grade phosphates] that demonstrates or suggests reasonable grounds to suspect a hazard to the public when they are used at levels that are now current or might reasonably be expected in the future.”<sup>10</sup>

---

<sup>6</sup> SCOGS Report, p. 13.

<sup>7</sup> “Dietary Guidelines for Americans, 2005,” Chapter 8: Sodium and Potassium (Published by U.S. Department of Health & Human Services, and U.S. Department of Agriculture) (<http://www.health.gov/dietaryguidelines/dga2005/document/html/chapter8.htm>).

<sup>8</sup> “Dietary Reference Intakes for Water, Potassium, Sodium, Chloride, and Sulfate,” Institute of Medicine of the National Academies, The National Academies Press: Washington, DC, 2005, p. 187.

<sup>9</sup> SCOGS Report, p. 26.

<sup>10</sup> SCOGS Report, p. 26.

V. CONCLUSION

Based on the information underlying the conclusions of FDA and the Select Committee, and in accordance with those conclusions regarding sodium hexametaphosphate and potassium polymetaphosphate, ICL has determined that sodium potassium hexametaphosphate is GRAS when used as a direct and indirect food ingredient, in accordance with the limits of good manufacturing practice.

A

000014

Pages 000015 - 000057 have been removed in accordance with copyright laws. Please see appended bibliography list of the references that have been removed from this request.

B

000058



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
College Park, MD 20740

October 10, 2003

Clausen Ely, Jr.  
Covington & Burling  
1201 Pennsylvania Ave.  
P.O. Box 7566  
Washington, D.C. 20044-7566

Dear Mr. Ely:

The Food and Drug Administration (FDA) is responding to the notice, dated August 6, 2003, that you submitted as an agent, on behalf of the International Food Additives Council (IFAC) in accordance with the agency's proposed regulation, proposed 21 CFR 170.36 (62 FR 18938; April 17, 1997; Substances Generally Recognized as Safe (GRAS)). The notice states that the IFAC has determined that potassium phosphate (mono-, di-, and tribasic), calcium hexametaphosphate, calcium pyrophosphate, tetrapotassium pyrophosphate, potassium tripolyphosphate, sodium hexametaphosphate, tetrasodium pyrophosphate, and sodium tetrphosphate are GRAS for use in food generally, as multi-purpose food ingredients, up to the limits of good manufacturing practice.

Some of the substances that are listed in the GRAS notice that you submitted are presently regulated under 21 CFR 182, substances generally recognized as safe. Specifically: calcium hexametaphosphate is regulated under 21 CFR 182.6203; calcium pyrophosphate is regulated under 21 CFR 182.8223; sodium hexametaphosphate is regulated under 21 CFR 182.6760; sodium pyrophosphate is regulated under 21 CFR 182.6787; tetrasodium pyrophosphate is regulated under 21 CFR 182.6789 (the agency notes that sodium pyrophosphate and tetrasodium pyrophosphate are the same compound); dipotassium phosphate is regulated under 21 CFR 182.6285. The remaining substances, tetrapotassium pyrophosphate, potassium tripolyphosphate, potassium phosphate (mono- and tribasic), and sodium tetrphosphate are not explicitly regulated under parts 182 or 184 (direct food substances affirmed as generally recognized as safe), however, these phosphate compounds have been reviewed by the Select Committee on GRAS Substances (SCOGS) and were determined to be GRAS for their intended use. The agency has no reason to question the GRAS determination performed by the SCOGS when used in accordance with good manufacturing practice.

000059

Page 2 - Mr. Ely

If you have any further questions concerning this matter, please do not hesitate to contact me at (202)-418-3032 or lhighbar@cfsan.fda.gov.

Sincerely,

(b) (6)

  
Lana A. Hightarger  
Division of Biotechnology  
And GRAS Notice Review  
Office of Food Additive Safety  
Center for Food Safety  
And Applied Nutrition

000060

COVINGTON & BURLING LLP

1201 PENNSYLVANIA AVENUE NW  
WASHINGTON, DC 20004-2401  
TEL 202 662 6000  
FAX 202 662.6291  
WWW COV COM

BEIJING  
BRUSSELS  
LONDON  
NEW YORK  
SAN DIEGO  
SAN FRANCISCO  
SILICON VALLEY  
WASHINGTON

MIRIAM J. GUGGENHEIM  
TEL 202 662 5235  
FAX 202.778 5235  
MGUGGENHEIM@COV.COM

January 7, 2010

VIA FEDERAL EXPRESS

Robert L. Martin, Ph.D.  
Office of Food Additive Safety (HFS-200)  
Center for Food Safety and Applied Nutrition  
Food And Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740-3835

RECEIVED  
JAN - 8 2010  
BY: RLM

Re: GRAS Notification for Sodium Potassium Hexametaphosphate

Dear Dr. Martin:

In follow-up to our conversation this morning, I am writing to confirm that ICL Performance Products LP does intend its Generally Recognized as Safe (GRAS) notification for the use of Sodium Potassium Hexametaphosphate (SKMP), submitted on December 17, 2009, to encompass the use of SKMP in meat and poultry products. Accordingly, I have attached another copy of that GRAS notification for you to forward to USDA's Food Safety and Inspection Service (FSIS).

Additionally, I attach an original and 2 extra copies of the signed signature page for the GRAS submission, which I regret was erroneously not included in our original submission. The additional full copy of the GRAS notification for FSIS contains a copy of the signed signature page.

Please let me know if you need any additional information from me or from ICL Performance Products LP in order for you and FSIS to complete the review of this GRAS notification.

Very truly yours,

(b) (6)

Miriam J. Guggenheim

Enclosures

000061

In consideration of the data and information summarized or provided in this document or incorporated by reference, ICL Performance Products LP submits that the described uses of sodium potassium hexametaphosphate are exempt from the premarket approval requirements of the FDCA because such uses are GRAS.

Respectfully submitted,

ICL PERFORMANCE PRODUCTS LP

(b) (6)

By:

Miriam J. Guggenheim  
Covington & Burling LLP  
Counsel for ICL Performance Products LP

000062

RECEIVED  
JAN - 8 2010  
(b) (6)  
BY \_\_\_\_\_

SUBMISSION END

000063

## *Reference List for Industry Submission, GRN 000316*

<i>Pages</i>	<i>Author</i>	<i>Title</i>	<i>Publish Date</i>	<i>Publisher</i>	<i>BIB_Info</i>
000015 - 000057	Life Sciences Research Office	Evaluation of the Health Aspects of Phosphates as Food Ingredients	1975	National Technical Information Service	NA

*NA- Not applicable*

**Harry, Molly \***

---

**From:** Guggenheim, Miriam [mguggenheim@cov.com]  
**Sent:** Monday, June 14, 2010 10:02 AM  
**To:** Harry, Molly \*  
**Cc:** Martin, Robert L  
**Subject:** GRAS Notice No. 316

Dear Ms. Harry,

In follow-up to my telephone conversation with you and Dr. Martin regarding GRAS Notice No. 316, regarding Sodium Potassium Hexametaphosphate (SKMP), I am writing to confirm that a review has been conducted of the relevant literature and safety data regarding SKMP and related polyphosphates since the SCOGS report on phosphates in 1975. That review has confirmed that no additional or subsequent data or information has raised questions about the safety or GRAS status of SKMP.

Please let me know if there is any further information we can provide regarding this GRAS notification.

Sincerely,

Miriam

**Miriam J. Guggenheim**

Covington & Burling LLP

1201 Pennsylvania Avenue, NW

Washington, DC 20004

Tel: (202) 662-5235

Fax: (202) 778-5235

mguggenheim@cov.com

**Harry, Molly \***

---

**From:** Guggenheim, Miriam [mguggenheim@cov.com]  
**Sent:** Monday, June 21, 2010 2:52 PM  
**To:** Harry, Molly \*  
**Cc:** Martin, Robert L; Gaynor, Paulette M  
**Subject:** RE: GRAS Notice No. 316

Dear Ms. Harry,

ICL confirmed that they have done literature searches several times over the last five or six years. A major search was done in 2006, and additional searches have been conducted several times since that time as well, including in the fall of 2009. After your June 10, 2010, inquiry, ICL again checked to see whether any additional information had been published. No new information was discovered at that time that would impact the safety data for sodium or potassium polyphosphates, including SKMP.

Best,  
Miriam

**Miriam J. Guggenheim**  
Covington & Burling LLP  
1201 Pennsylvania Avenue, NW  
Washington, DC 20004  
Tel: (202) 662-5235  
Fax: (202) 778-5235  
mguggenheim@cov.com

---

**From:** Harry, Molly \* [mailto:Molly.Harry@fda.hhs.gov]  
**Sent:** Monday, June 14, 2010 1:39 PM  
**To:** Guggenheim, Miriam  
**Cc:** Martin, Robert L; Gaynor, Paulette M  
**Subject:** RE: GRAS Notice No. 316

Dear Ms. Guggenheim,

Thank you for your e-mail responding to FDA's question on June 10, 2010. We would like clarification regarding the end date for ICL's literature search. For example, please specify the last date ICL searched the literature for safety data on SKMP and related polyphosphates prior to submission of GRN 000316.

Sincerely,

Molly Harry

---

**From:** Guggenheim, Miriam [mailto:mguggenheim@cov.com]  
**Sent:** Monday, June 14, 2010 10:02 AM  
**To:** Harry, Molly \*  
**Cc:** Martin, Robert L  
**Subject:** GRAS Notice No. 316

Dear Ms. Harry,  
In follow-up to my telephone conversation with you and Dr. Martin regarding GRAS Notice No.

316, regarding Sodium Potassium Hexametaphosphate (SKMP), I am writing to confirm that a review has been conducted of the relevant literature and safety data regarding SKMP and related polyphosphates since the SCOGS report on phosphates in 1975. That review has confirmed that no additional or subsequent data or information has raised questions about the safety or GRAS status of SKMP.

Please let me know if there is any further information we can provide regarding this GRAS notification.

Sincerely,  
Miriam

**Miriam J. Guggenheim**

Covington & Burling LLP

1201 Pennsylvania Avenue, NW

Washington, DC 20004

Tel: (202) 662-5235

Fax: (202) 778-5235

[mguggenheim@cov.com](mailto:mguggenheim@cov.com)