#### United States Department of Agriculture Agricultural Marketing Service | National Organic Program Document Cover Sheet https://www.ams.usda.gov/rules-regulations/organic/national-list/petitioned

Document Type:

### ⊠ National List Petition or Petition Update

A petition is a request to amend the USDA National Organic Program's National List of Allowed and Prohibited Substances (National List).

Any person may submit a petition to have a substance evaluated by the National Organic Standards Board (7 CFR 205.607(a)).

Guidelines for submitting a petition are available in the NOP Handbook as NOP 3011, National List Petition Guidelines.

Petitions are posted for the public on the NOP website for Petitioned Substances.

#### □ Technical Report

A technical report is developed in response to a petition to amend the National List. Reports are also developed to assist in the review of substances that are already on the National List.

Technical reports are completed by third-party contractors and are available to the public on the NOP website for Petitioned Substances.

Contractor names and dates completed are available in the report.



Kemin Industries 1900 Scott Avenue Des Moines, Iowa 50317, USA +1 800-777-8307 www.kemin.com

August 7, 2020

National Organic Standards Board Agricultural Marketing Service Room 2510 – So, Ag Stop 0268 PO Box 96456 Washington, D.C. 20090-6456

Dear Sir or Madam:

Please find the attached official amended petition to have a substance evaluated by the National Organic Standards Board pursuant to 7 CFR §205.607(a). We petition to have Phosphoric Acid's inclusion on the NOSB National List of Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as "organic" or "made with organic (specified is or food groups)" be amended to additionally include use as a pH adjuster. As mentioned in the application, phosphoric acid has a long use in organic production, already approved as a pH adjuster in manufacture of soil amendments and fertilizers. Additionally, phosphoric acid is also approved as a cleaning substance within organic production.

We request the following terminology be added to §205.605(b)(22)'s listing for Phosphoric Acid:

Phosphoric acid – cleaning of food-contact surfaces and equipment, <u>and as an acidifier to</u> <u>adjust pH of an extraction solvent to extract antioxidants or other target molecules from</u> <u>lamiaceae</u> plants, provided the amount of acid used shall not exceed the minimum needed to lower pH to 2.5.

Your time and consideration is greatly appreciated in this matter.

Respectfully submitted,

Dr. William D. Schroeder, Ph.D. Vice President, Food Safety and Quality Kemin Food Technologies



# Phosphoric Acid Processing

#### **Identification**

<b>Chemical Names:</b>	phosphoric acid	CAS Numbers:	7664-38-2
<b>Other Names:</b>	Orthophosphoric acid; also	<b>Other Codes:</b>	None
	metaphosphoric acid and		
	pyrophosphoric		

# **Recommendation**

Synthetic/Non- synthetic	National List	Suggested Annotation
Synthetic (consensus)	<ul> <li>95%+ = Allowed, provided</li> <li>phosphoric acid is not greater than or</li> <li>equal to 5% of the nonorganic</li> <li>components.</li> <li>50%+ = Allowed, provided</li> <li>phosphoric acid is not greater than or</li> <li>equal to 5% of the final formula</li> <li>weight.</li> </ul>	ACS or USP-grade orthophosphoric acid may be used as an acidifier during extraction of antioxidants or other target molecules from lamiaceae plants.

# **Characterization**

# **Composition**

# **Properties:**

Phosphoric acid is a colorless, odorless solution that complies with the Food Chemical Codex spec and is 75-85% by weight in all commercial strengths with an approximate Molarity of 14.7M to 15.2M. It is further diluted to different concentrations depending upon usage applications. Strongly acidic. Corrosive to concrete, most metals, and fabrics.

# Method of Manufacture:

Phosphoric acid can be made in two ways, either the wet process or the thermal (furnace) process. In the wet process, mined phosphate ore is treated with sulfuric acid and then the resulting phosphoric acid is separated from the calcium sulfate crystals produced. The chemical reaction is the following:

 $(PO_4)_2Ca_3 + 3H_2SO_4 + 6H_2O --> 3SO_4Ca \cdot 2H_2O + PO_4H_3$ 

This process conserves most of the impurities found in the ore (and is therefore mostly used for fertilizer production), but the product can then be purified further for technical and food-grade phosphoric acid. Thermal acid is made from elemental phosphorus and is considerably more expensive and purer than the wet process acid. The pure phosphorus is burned in excess air and the resulting phosphorus pentoxide is then hydrated, cooled, and the acid mist is collected.

# Specific Uses:

Phosphoric Acid is currently used in manufacturing organically-listed products for use as plant



or soil amendments. There, Phosphoric Acid is used as a pH adjuster and is currently on the National List as a synthetic and allowed in plant or soil amendments under §205.601(j)(7): *Liquid fish products – can be pH adjusted with sulfuric, citric or phosphoric acid. The amount of acid used shall not exceed the minimum needed to lower the pH to 3.5.* Phosphoric Acid is also currently used as an equipment cleaner and sanitizer for food contact surfaces in organically-produced products under Synthetic allowed at §205.605(b)(22): *Cleaning of food-contact surfaces and equipment only.* In the recommendation above, we intend to use the suggested annotation to extract target molecules, including antioxidants, from various plant species of the lamiaceae family. As further described below, pH of the water during extraction is a critical factor in the ability to extract these target compounds.

Oxidation, a chain reaction that occurs in the presence of oxygen, is responsible for deterioration in food quality and can lead to possible off-flavors or off-odors. Oxidation can be affected by processing, packaging, storage methods, or even ingredients within a food product. Fortunately though, antioxidants are common food ingredients today used to help prevent oxidant and thereby preserve freshness to help ensure consumers have the most appealing and fresh food. Multiple synthetic antioxidants have commonly been used throughout history, but data has shown similar effects can come from the power of plants. These plant-based antioxidants are acceptable to consumers, Consumers not only expect a product to taste fresh through its shelf life, but also demand use of ingredients they feel good about, including those that are plantbased and organic compliant. Consumers have a wide range of expectations, meaning food ingredient manufacturers must offer a wide range of product solutions, including the antioxidants or other target molecules mentioned in this petition. Disallowing use of organic compliant ingredients like antioxidants, coupled with consumers turning away from and no longer purchasing food with comparable synthetic sources, could result in unnecessary spoilage and waste.

Therefore, we request the National List be amended to reflect the following for §205.605(b)22):

"Phosphoric acid – cleaning of food-contact surfaces and equipment, and adjusting pH provided the amount of acid used shall not exceed the minimum needed to lower pH to 2.5.

# Action:

In order to prepare the proper extraction solvent, tap water will be adjusted with phosphoric acid to lower pH. This low pH is required to extract certain target molecules, some of which may include but not be limited to antioxidants, from plants because low pH conditions can inhibit enzymatic oxidation that would otherwise destroy target molecules.<sup>1</sup> Without the acid to lower extraction pH, there would be no protective effect for the antioxidants or other target molecules that are extracted into the aqueous media.

<sup>&</sup>lt;sup>1</sup> Eddine *et al.*, Solvent pH extraction effect on phytochemical composition and antioxidant properties of Alergian Matricaria Pubescens, J Pharm Res, Vol. 10 Issue 2, Feb. 2016



#### <u>Status</u>

### <u>OFPA</u>

The substance is used in handling and is necessary for the handling of agricultural product because of the unavailability of wholly natural substitute products (7 USC 6517(c)(l)(A)(u)).

#### **Regulatory**

FDA has affirmed phosphoric acid as GRAS according to 21 CFR 182.1073, when used up to GMP levels.

#### Status among Certifiers

Phosphoric Acid is already approved for use in organic plant or soil amendment production as a pH adjuster and is currently on the National List for that purpose in §205.601(j)(7). It is also used in cleaning food-contact surfaces and equipment in organic production and is currently on the National List for that purpose in §205.605(b)22).

#### Historic Use

The National List of Allowed and Prohibited Substances does not specifically regulate individual acidifying agents.

### International Not mentioned in IFOAM standards.

# **OFPA Criteria**

Pursuant to §6518(m) of the Organic Food Production Act (OFPA), when evaluating a petitioned substance for amendment of the National List, the NOSB shall consider:

1. <u>The potential of the substance for detrimental chemical interactions with other</u> <u>materials used in organic farming systems;</u>

Phosphoric Acid itself combines readily with many other chemicals and no known detrimental interactions within organic farming systems is known.

2. <u>The toxicity and mode of action of the substance and of its breakdown products or</u> <u>any contaminants, and their persistence and areas of concentration in the</u> <u>environment;</u>

In the process of phytochemical extraction, Phosphoric Acid combines with water to form an acidified extraction solution. Phosphoric acid in its original form will break down quickly in the environment, so there are no toxicity issues directly related to its breakdown products. In this process, phosphoric acid will be partially neutralized by the plant components , and after extraction, the matrix has a pH of about 5.0-6.0. Consequently, the phosphoric acid will no longer exist in its acid form and the resulting liquid will not be corrosive. Therefore, while raw and concentrated phosphoric acid might be toxic to aquatic environments, the process mitigates contaminant persistence and/or concentration in the environment.



3. <u>The probability of environmental contamination during manufacture, use, misuse or disposal of the substance;</u>

There could be numerous potential environmental consequences from the manufacture, misuse or disposal of phosphates in general, and these cannot be separated out for Phosphoric Acid alone. There can be extreme environmental impacts from the mining of phosphate ore, which occurs in many parts of the world. Therefore, worker safety is of prime concern in the wet-process acid and elemental phosphorous used in thermal process because of high acidity, heat released upon neutralization and toxic gases released. Thus, Manufacturing plants are equipped with proper safety procedures and equipment to deal with these issues

Regarding use, about 90% of all phosphate consumption is for use in fertilizer products while 4.5% is used in laundry detergents.

4. <u>The effect of the substance on human health;</u>

Inorganic phosphates are not hazardous to ingest and are in fact essential mineral nutrients for proper human health. At low concentrations, Phosphoric Acid is not a health hazard. There could be minor nutritional benefits from low-level ingestion of the material.

Phosphoric Acid is Generally Regarded As Safe (GRAS) by the FDA when used in accordance with Good Manufacturing Practices (GMP), and contains no residues of heavy metals or other contaminants in excess of tolerances established by the FDA.

The Select Committee on GRAS Substances submitted a final report to the FDA in 1980 discussing how Phosphoric Acid should continue its GRAS status with no limitations other than GMP's.

Undiluted Phosphoric Acid can be hazardous and should be handled with caution. Phosphoric Acid is corrosive and should not come into contact with skin or eyes. Phosphoric Acid can produce corrosive toxic gases when heated and care should be taken to provide ventilation and protective clothing should be worn by workers.

5. <u>The effects of the substance on biological and chemical interactions in the</u> agroecosystem, including the physiological effects of the substance on soil organisms (including the salt index and solubility of the soil), crops, and livestock;

When stored, used and disposed of appropriately, Phosphoric acid use during phytochemical extraction will have no negative interactions with soil organisms, crops, or livestock.

6. <u>The alternatives to using the substance in terms of practices or other available</u> <u>materials; and</u>

Non-synthetic acids such as citric and lactic acid are available as Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products. Synthetic acids



such as alginic acid and ascorbic acid are also allowed. However, these acids are generally not used as pH adjusters because they are corrosive and much more volatile than Phosphoric Acid. Phosphoric Acid is preferred because of its low corrosiveness and low volatility in low concentrations in which it is effective for reducing pH. Citric, lactic, alginic, and ascorbic are effective in some situations and could possibly be used but are much weaker acids and would not be feasible for use because of the very high inclusion rates required to achieve the necessary pH adjustment.

Phosphoric Acid is being utilized as a pH adjuster in this instance. For this purpose, there may or may not be traces of the material entering into the final food product, depending on the care with which it is used in the processing line. Again, fortunately though, the FDA has already affirmed Phosphoric Acid entering the final food product as GRAS at GMP levels.

7. Its compatibility with a system of sustainable agriculture.

Since reducing pH is a desired processing step in phytochemically extracting targeting molecules created by plants in sustainable agricultural practices, Phosphoric Acid appears to be among the best and safest of the acids products being used for pH reduction. The material is compatible with organic production-or processing system being employed in the U.S.A and abroad.

From there, synthetic substances petitioned for use in organic processing are evaluated pursuant to additional criteria in 7 C.F.R. § 205.600(b):

# 1. <u>The substance cannot be produced from a natural source and there are no organic</u> <u>substitutes;</u>

Other acids which involve less environmental impact and/or human health hazard are organic acids such as citric, gluconic, tartaric, or acetic acids; these materials must also be used with care though, some more than others, depending on their respective concentrations. Such alternatives may or may not be as effective as phosphoric acid.

Other strong acid agents that could be used as acidifying agents in this process include hydrochloric (muriatic), hydrofluoric, sulfamic, sulfuric, and nitric acids. Nitric and sulfuric acids are so corrosive that they are not generally used phytochemical extraction. Hydrofluoric acid is very unstable and dangerous to handle and also extremely corrosive. Hydrochloric acid is very effective at descaling metals but produces highly toxic fumes in the form of hydrogen chloride gas. Phosphoric acid is preferred because it is the lowest in corrosiveness at the low concentrations which are effective and there conducive to successful extraction methods.

Phosphoric acid is sometimes used in the food processing industry as a disinfectant or microbial control for fresh produce, by addition of it to flume or rinse water such as in the processing of oranges and other citrus fruits). In this case, there may or may not be traces of the material entering into the final food product, depending on the care with which it is used in the processing



line. As a food additive, phosphoric acid has a long history of safe use as an acidulating agent<sup>2</sup>, to which there are several possible natural and/or organically-produced alternatives, which as previously stated would be less effective.

# 2. <u>The substance's manufacture, use, and disposal do not have adverse effects on the environment and are done in a manner compatible with organic handling</u>

There are many environmental consequences from the manufacture, misuse and disposal of phosphates in general and these cannot be separated out for phosphoric acid in particular. In figures from world phosphorus consumption in 1980, about 90% of phosphate consumption is for fertilizer, while 4.5% is for all detergents including other cleaners such as trisodium phosphate.<sup>3</sup> There are extreme environmental impacts from mining of phosphate ore which occurs in many parts of the world. Worker safety is of prime concern in the wet-process acid and elemental phosphorous used in the thermal process because of high acidity, heat released upon neutralization and toxic gases released. Plants will be equipped with proper safety procedures and equipment to deal with these issues.

The issues of phosphate pollution from disposal are discussed above, but in general the dilution of phosphoric acid will minimize disposal problems in the food processing or livestock facility.

3. <u>The nutritional quality of the food is maintained when the substance is used, and the substance itself, or its breakdown products do not have an adverse effect on human health as defined by applicable Federal regulations.</u>

Undiluted phosphoric acid is a hazard to living organisms, and as such, must be handled with caution. Phosphoric acid is extremely corrosive and should not come into contact with skin or eyes. The acid can produce corrosive toxic gases when heated and care should be taken to provide ventilation and protective clothing for workers. Inorganic phosphates are not hazardous to ingest and are in fact essential mineral nutrients.

At low concentrations ingestion is not a health hazard. There could be minor nutritional benefit from low-level ingestion of this material, although the actual commercial formulation in which it is found (i.e. in combination with other materials) may negate such benefit. Assuming that basic GMP's are followed, phosphoric acid would not appear in foodstuffs in a concentration which would be deleterious to human health.

<sup>&</sup>lt;sup>2</sup> Considered GRAS under FDA's Code of Federal Regulations at Section 182.1073. Also listed in USDA FSIS Directive 7120.1 as a "Safe and Suitable Ingredient used in the Production of Meat, Poultry and Egg Products" for adjusting pH in processing water in meat and poultry products.

<sup>&</sup>lt;sup>3</sup> Becker, *Phosphates & Phosphoric Acid – Raw Materials*, Technology & Economics of the Wet Process, 2<sup>nd</sup> edition. Marcel Dekker, Inc., 1989.



4. <u>The substance's primary use is not as a preservative or to recreate or improve flavors, colors, textures, or nutritive value lost during processing, except where the replacement of nutrients is required by law</u>

The use of phosphoric acid is only to acidify the extraction solution to optimize phytochemical extraction of target molecules. Phosphoric acid does not serve as a preservative or attempt to recreate or impact flavors, colors, textures, or nutritive value lost during processing, except where the replacement of nutrients is required by law.

5. <u>The substance is listed as generally recognized as safe (GRAS) by the Food and Drug</u> <u>Administration (FDA) when used in accordance with FDA's good manufacturing</u> <u>practices (GMP) and contains no residues of heavy metals or other contaminants in</u> <u>excess of tolerances set by FDA.</u>

In 1980, the final report to the FDA from the Select Committee on GRAS Substances indicated that Phosphoric Acid should continue its GRAS status with no limitations other than GMP's.<sup>4</sup> Furthermore, this GRAS affirmation was published under 21 CFR §182.1073, again with the only limitation being use at GMP levels.

Some technical grades of phosphoric acid can have impurities related to their recovery processes. When properly used with GMPs as pH adjuster, all phosphoric acid will be converted into its respective conjugate base.

6. <u>The substance is essential for the handling of organically produced agricultural products.</u>

Since effective extraction is a critical step in the ability to use biomolecules, the ultimately benefit of the applicable organic management program, and since phosphoric acid appears among the best and safest pH adjusters, this material seems compatible with an organic production and processing system.

<sup>&</sup>lt;sup>4</sup> Winter, R. *A Consumer's Dictionary of Food Additives*. New York Crown Trade Paperbacks, 1994.