Peracetic Acid

Livestock

Identification of Petitioned Substance

Chemical Names:
Peracetic acid; Ethaneperoxoic acid (IUPAC name); Acetic peroxide; Monoperacetic acid; Peroxoacetic acid; Acetyl hydroperoxide

Other Name:
Peroxyacetic acid; PAA

Trade Names:
SaniDate® 5.0, OxyPure™ BIO (Europe)

CAS Numbers:
79-21-0
89370-71-8 (historic)

Other Codes:
EC Number 201-186-8; ICSC Number 1031; NIOSH Registry Number SD8750000; UN/ID Number 3105

Summary of Petitioned Use

Peracetic acid (PAA) is currently allowed under the National Organic Program (NOP) regulations for use in organic crop production, organic livestock production and in organic food handling. This report addresses the use of peracetic acid in organic livestock production. Peracetic acid is currently allowed for use in organic livestock production at 7 CFR 205.603(a)(19) for sanitizing facility and processing equipment.

Characterization of Petitioned Substance

Composition of the Substance:

Chemically, the term “peracetic acid” describes two substances. “Pure” peracetic acid, described in the Merck Index (Budavari 1996), has the chemical formula $C_2H_4O_3$ (alternatively written CH_3CO_3H). Anhydrous peracetic acid explodes violently upon heating. In contrast, solutions of peracetic acid used as sanitizers are created by combining aqueous mixtures of two substances: acetic acid (the acid in vinegar) and hydrogen peroxide. At cool temperatures, acetic acid and hydrogen peroxide react over a few days to form an equilibrium solution containing peracetic acid, acetic acid and hydrogen peroxide. This equilibrium solution is the substance sold commercially as the sanitizer “peracetic acid.” Adding a mineral acid catalyst accelerates the reaction.

Peracetic acid is an unstable oxidizing agent, which is why it is such an effective sanitizer. Most commercial peracetic acid solutions contain a synthetic stabilizer and chelating agent such as HEDP (1-hydroxyethylidene-1, 1-diphosphonic acid) or dipicolinic acid (2,6-dicarboxypyridine) to slow the rate of oxidation or decomposition. These and other additives are discussed in *Combinations of the Substance*.

Source or Origin of the Substance:

Pure anhydrous peracetic acid is prepared from acetaldehyde and oxygen in the presence of cobalt acetate, or by the auto-oxidation of acetaldehyde (Budavari 1996). Solutions of peracetic acid, hydrogen peroxide, acetic acid and water are produced by reacting glacial acetic acid with hydrogen peroxide, frequently in the presence of a catalyst such as a mineral acid (e.g., sulfuric acid). Specific grades are obtained by controlling the concentrations and amounts of hydrogen peroxide and acetic acid during the manufacturing process. Adding an acid or increasing the temperature during the manufacturing process can accelerate the establishment of the final equilibrium concentration (grade). Commercial grades are available in peracetic acid concentrations ranging from about 0.3 to 40 % by weight. Solutions with relatively low content of acetic acid and hydrogen peroxide can be produced by distillation of the equilibrium solutions. Based on the manufacturing process for sanitizing solutions of peracetic acid described above, it is evident that a pure peracetic acid solution is not produced or isolated when commercial peracetic acid solutions are manufactured.

A peracetic acid solution also can be generated *in situ* by dissolving an activator (tetra-acetyl ethylenediamine) and a persalt (sodium perborate or sodium percarbonate) in water (OECD 2008), or on site (within 1 minute) by adding sodium hydroxide to triacetin and hydrogen peroxide (Harvey and Howarth 2013).

Properties of the Substance:

Pure anhydrous peracetic acid is a colorless liquid with a strong, pungent acrid odor. It is an organic substance which is completely miscible with water (water solubility of 1000 g/L at 20 °C) and is also soluble in ether, sulfuric acid and ethanol. It is a strong oxidizing agent – stronger than chlorine or chlorine dioxide (Carrasco and Urrestarazu 2010). It is highly unstable and decomposes to its original constituents under various conditions of temperature, concentration and pH. Peracetic acid decomposes violently at 230ºF (110ºC). Peracetic acid diluted with 60% acetic acid, when heated to decomposition, emits acrid smoke and irritating fumes.

Pure peracetic acid is not commercially available because it is explosive. For this reason it is not technically possible to determine the melting point, boiling point and vapor pressure of pure peracetic acid experimentally. Estimates based on modeling have been reported as -42 °C for melting point, about 105 °C for boiling point and 32 hPa at 25 °C for vapor pressure. The properties of commercial peracetic acid solutions vary based on concentrations (ratios) of their components (peracetic acid, hydrogen peroxide, acetic acid and water) for different grades. The physical and chemical properties of commercial equilibrium grades of 5% - 35% PAA are generally consistent in composition. Their properties are shown in Table 1.

Table 1. Physical and Chemical Properties of Three Equilibrium Grades of PAA (adapted from JACC 2001).

Property	Value		
	5% PAA	15% PAA	35% PAA
Ratio of components: PAA:H_2O_2:HOAc:H_2O	5 : 22 : 10 : 63	15 : 20 : 15 : 50	35 : 7 : 40 : 18
Freezing/Melting point	-26 to -30 ºC	-30 to -50 ºC	-44 ºC
Boiling point	99 to 105 ºC	> 100 ºC	> 105 ºC
Density (g/cm^3) at 20 ºC	1.12	1.15	1.13
Vapor pressure at 20 ºC	21 to 21 hPa	25 hPa	17 hPa
Flash point (closed cup)	74 to 83 ºC	68 to 81 ºC	42 to 62 ºC
Self-accelerating decomposition	> 55 to > 65 ºC	> 50 ºC	> 55 ºC

Peracetic acid has a molecular weight of 76.05. Its dissociation constant (pKa) is 8.2 at 20 °C and, therefore, the substance is mainly present in the environment as peracetic acid at a neutral pH (pH = 7), while peracetate (the salt of peracetic acid) would mainly be present if the pH is significantly higher than 8.2 (OECD 2008). The pH of peracetic acid solutions is reported to range from < 1 to 1.8 (OECD 2008; U.S. National Library of Medicine 2012; NOAA 2015).

Specific Uses of the Substance:

Peracetic acid is listed for use in organic livestock production for sanitizing facility and processing equipment. This is consistent with the substance's primary use in the food industry as a bactericide and fungicide for sanitizing and disinfecting structures, equipment and hard surfaces. Sanitizers are described by both EPA and FDA as substances that reduce microorganisms to safe levels (U.S. EPA 2015). The FDA definition at 21 CFR 110.3(o) further identifies sanitizers as being effective in *destroying* vegetative cells of microorganisms of public health significance from food-contact surfaces, and without adversely affecting the product or its safety for the consumer. EPA defines disinfectants as substances used on hard inanimate surfaces and objects to destroy or irreversibly inactivate infectious fungi and bacteria but not necessarily their spores. Peracetic acid may be applied by spraying, fogging or immersing to kill bacteria, fungi and viruses (U.S. EPA 1993). Peracetic acid functions under cold conditions (-4 ºC) and is thus effective at reducing microbial levels on equipment normally held below ambient temperature (Pfuntner 2011). Peracetic acid may be used in livestock production in dairies – milking parlors, dairy production and transfer facilities and equipment – as well as in poultry premises, hatcheries, livestock quarters, stables, stalls, pens, cages, and on feeding and watering equipment. Application to livestock structures can include hard non-porous surfaces such as floors, walkways, walls, benches, countertops, shelves, racks, crates, utility carts, trailers, vehicles, conveyors, refrigerator exteriors, fan blades, drains, piping, process water transfer and handling systems, filter housings, vats, tanks, pumps, valves and systems. These applications can serve to control mold, mildew and odors (BioSafe Systems LLC 2015).

Peracetic acid can also remove biofilms. Biofilms are polysaccharides produced by microorganisms such as *E. coli*, *Salmonella spp.*, *Listeria spp.*, *Campylobacter spp.* and others. These biofilms facilitate attachment to almost any surface. Their build-up can serve as a host to other bacteria and can be a source of ongoing re-contamination (Pfuntner 2011).

There are other uses of peracetic acid in livestock production which are not permitted under NOP regulations. One study reports the effective treatment of digital dermatitis in cattle using peracetic acid in footbaths (Laven and Hunt 2002). Another patent describes the use of orally ingested peracetic acid to control microbial populations in the gastrointestinal tract of animals (McKenzie et al. 2003).

Significant use of peracetic acid also occurs in post-harvest handling and food processing. Refer to the Technical Reports on peracetic acid for Handling and Crops for further information on these uses. Peracetic acid has many other chemical uses in addition to that of sanitizer/disinfectant/microbial control. It serves as a reagent in the production of glycerol and caprolactam and for preparing epoxy compounds. It is a catalyst or co-catalyst for the polymerization of polyester resins. It is also a bleaching agent for textiles, paper, oil, wax and starch (California Air Resources Board 1997; National Center for Biotechnology Information 2015; U.S. EPA 2010). More recently peracetic acid has been employed in disinfecting municipal wastewater.

Regulatory Status and Approved Legal Uses of the Substance:

Peracetic acid is currently permitted in the NOP regulations for organic crop production, organic livestock production, and organic handling, with the annotations noted below. Sections 7 CFR 205.601(m) and 205.603(e) are also cited below because peracetic acid solutions contain certain inert ingredients that are essential for efficacy.

7 CFR 205.601 Synthetic substances allowed for use in organic crop production.

(a) As algicide, disinfectants, and sanitizer, including irrigation system cleaning systems.

(4) Hydrogen peroxide.

(6) Peracetic acid—for use in disinfecting equipment, seed, and asexually propagated planting material. Also permitted in hydrogen peroxide formulations as allowed in §205.601(a) at concentration of no more than 6% as indicated on the pesticide product label.

(i) As plant disease control.

(5) Hydrogen peroxide.

(8) Peracetic acid—for use to control fire blight bacteria. Also permitted in hydrogen peroxide formulations as allowed in §205.601(i) at concentration of no more than 6% as indicated on the pesticide product label.

(m) As synthetic inert ingredients as classified by the Environmental Protection Agency (EPA) for use with nonsynthetic substances or synthetic substances listed in this section and used as an active pesticide ingredient in accordance with any limitations on the use of such substances.

(1) EPA List 4 – Inerts of Minimal Concern

7 CFR 205.603 Synthetic substances allowed for use in organic livestock production.

(a) As disinfectants, sanitizer, and medical treatments as applicable.

(19) Peroxyacetic/peracetic acid (CAS #-79-21-0)—for sanitizing facility and processing equipment.

(e) As synthetic inert ingredients as classified by the Environmental Protection Agency (EPA) for use with nonsynthetic substances or synthetic substances listed in this section and used as an active pesticide ingredient in accordance with any limitations on the use of such substances.

(1) EPA List 4 – Inerts of Minimal Concern

7 CFR 205.605 Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))."

(b) Synthetics allowed: Peracetic acid/Peroxyacetic acid (CAS # 79-21-0)—for use in wash and/or rinse water according to FDA limitations. For use as a sanitizer on food contact surfaces.

Peracetic acid has a complex regulatory status because several federal agencies have their own specific areas of statutory jurisdiction. Each agency creates its own set of regulations for sanitizer use which can impact the permissible uses of peracetic acid in organic crop production, organic livestock production, and organic handling, including post-harvest handling.

The Organic Foods Production Act (OFPA) of 1990 at 7 USC 6519(c)(6) specifies that nothing in the OFPA shall alter the authority of the secretary of agriculture under the Federal Meat Inspection Act or under the Poultry Products Inspection Act, the authority of the Secretary of Health and Human Services under the Federal Food, Drug and Cosmetic Act, or the authority of the Administrator of the Environmental Protection Agency (EPA) under the Federal Insecticide, Fungicide and Rodenticide Act. Consequently, four federal agencies regulate peracetic acid used in handling organic foods after harvesting or slaughter (Theuer and Walden 2011).

- The National Organic Program (NOP) of Agricultural Marketing Service (AMS) of the U.S. Department of Agriculture (USDA)
- The Food Safety and Inspection Service (FSIS) of the USDA
- The Food and Drug Administration (FDA)
- The Environmental Protection Agency (EPA)

EPA, FDA, and FSIS have different approaches for implementing and codifying regulations, but the agencies closely coordinate their regulations to facilitate uniform compliance. AMS, FSIS, FDA, and EPA signed a memorandum of understanding (MOU 225-85-8400) in 1984 to promote more effective, efficient and coordinated federal regulatory activities concerning residues of drugs, pesticides and environmental contaminants that may adulterate food. Additional bilateral memorandums of understanding also ensure close harmony among the agencies' rules and regulations and define areas of responsibility. In 1971, EPA and FDA issued a memorandum of understanding (MOU 225-73-8010) that split the responsibility for pesticide materials used on agricultural products (other than meat). EPA is involved because peracetic acid is legally classified as a pesticide. This memorandum of understanding assigns the responsibility for processed fruit and vegetable products to FDA, and the responsibility for raw (unprocessed) fruit and vegetable products to EPA. FSIS is responsible for meat and poultry products. FSIS and FDA implemented a memorandum of understanding in January 2000.

FDA is responsible for exercising the authority of the secretary of health and human services under the Federal Food, Drug and Cosmetic Act. FDA regulates peracetic acid by enumerating the permissible ingredients in PAA solutions. FDA regulations relating to the use of PAA for the two handling uses allowed in 7 CFR 205.605(b) are codified in 21 CFR 173 and 178. Part 173 is titled "Secondary direct food additives permitted in food for human consumption" and includes two sections that specifically mention peroxyacetic acid: section 173.315 ("chemicals used in washing or to assist in the peeling of fruits and vegetables") and section 173.370 ("peroxyacids"). Part 178 is titled "Indirect food additives: adjuvants, production aids, and sanitizers," and includes one section specifically mentioning peroxyacetic acid:

section 178.1010 (sanitizing solutions). Section 178.1010 contains three paragraphs describing compositions of peroxyacetic acid solutions.

Five specific aqueous mixtures are described in 21 CFR 173 and 178, but there is redundancy in these mixtures, so there are only three generic PAA solutions of concern (Theuer and Walden 2011). These are described in detail below. In addition, FDA reviews petitions for new sanitizer compositions or new uses for existing compositions and issues "Food Contact Substance Notifications" (FCNs) for food contact substances that have been demonstrated to be safe for their intended uses. A database of these notifications is maintained online[1]. Entries in the FDA online database include the food contact substance, the manufacturer of the substance, the intended use, the limitations on the conditions of use and its specifications, and the effective date. Thirty FCNs relating to peracetic/peroxyacetic acid have been issued in the past six years[2].

EPA administers the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). Every pesticide product distributed in the United States must be registered with EPA. EPA approves the label and thus the permissible uses of every pesticide product. Peracetic acid is an antimicrobial substance and thus is a "pesticide" as defined by FIFRA.

EPA regulations for food disinfection and food contact surface sanitation relating to the use of peracetic acid for the uses allowed in 7 CFR 205.605(b) are codified in 40 CFR 180. In accordance with the regulatory practice of EPA, these regulations enumerate the permissible tolerance limits of active ingredients and inert ingredients in PAA solutions. Section 40 CFR 180.910 provides the list of inert (or occasionally active) ingredients used pre- and post-harvest in direct food contact, and the exemptions from the requirement of a tolerance of these ingredients on the food. Section 40 CFR 180.940 lists similar information for active and inert ingredients in antimicrobial formulations used to sanitize food contact surfaces. Section 40 CFR 180.950 lists common safe ingredients, such as glycerin (glycerol), that are exempt from a tolerance in any use. Sections 40 CFR 180.1196 and 180.1197 establish the conditions for an exemption from the requirement for a tolerance for peroxyacetic acid (peracetic acid) and hydrogen peroxide, respectively. For example, if the diluted solution applied to fruit contains less than 100 ppm of peracetic acid, the residue of peracetic acid on the fruit is exempt from a tolerance.

FSIS administers the Federal Meat Inspection Act (FMIA) and the Poultry Products Inspection Act (PPIA). Under the FMIA and the PPIA, FSIS is responsible for determining the suitability of FDA-approved substances in meat and poultry products. Pursuant to the memorandum of understanding signed in January 2000, FDA and FSIS work together to evaluate petitions requesting the approval of new substances or new uses of previously approved substances for use in or on meat and poultry products. FSIS inspectors enforce FSIS policy by implementing "FSIS Directives." FSIS Directive 7120.1 permits two peracetic acid solutions for direct food contact with red meat and poultry. These two solutions are among the same solutions allowed by FDA; however the allowance varies depending on use (USDA Food Safety and Inspection Service 2015).

Peracetic Acid Solutions Allowed by FDA and/or EPA and/or FSIS (For the purpose of this report, each PAA Solution is given a number which refers to one of the solutions listed below. More details on these solutions are described in *Combinations of the Substance.*)

PAA Solution #1 – An aqueous solution of peracetic acid prepared by reacting the substances acetic acid and hydrogen peroxide. The solution is stabilized with 1-hydroxyethylidene-1,1-diphosphonic acid (HEDP).

PAA Solution #1A – An aqueous solution of peracetic acid prepared by reacting the substances acetic acid, sulfuric acid and hydrogen peroxide. The solution is stabilized with HEDP.

[1] www.fda.gov/Food/FoodIngredientsPackaging/FoodContactSubstancesFCS/ucm116567.htm
[2] As of 1 November 2015.

PAA Solution #2 – An aqueous solution of peracetic acid and peroxyoctanoic acid prepared by reacting the substances acetic acid, octanoic acid and hydrogen peroxide. The solution is stabilized with HEDP. The food contact surface sanitizer version additionally contains the surface-active agent sodium 1-octanesulfonate.

PAA Solution #3 – An aqueous solution of peracetic acid prepared by reacting the substances acetic acid and hydrogen peroxide, optionally in the presence of sulfuric acid. The solution is stabilized with dipicolinic acid (DPA) and optionally HEDP.

PAA Solution #4 – An aqueous solution of peracetic acid prepared on site, either by adding sodium hydroxide to triacetin (glycerol triacetate) and hydrogen peroxide (Harvey and Howarth 2013), or by electrolysis and oxygenation of a sodium sulfate solution to produce sodium hydroxide and hydrogen peroxide, and then combining this with a solution of sulfuric acid and sodium acetate to produce peracetic acid (Buschmann and Del Negro 2012). No stabilizers are required.

The following tables describe which solutions are permitted for which uses by the responsible agencies.

Table 2: Post-Harvest Handling: Direct food contact – red meat and poultry.

PAA Solution	Agency	Status	References and Comments
#1	FSIS	permitted	Directive 7120.1
	FDA	permitted	FCN Nos. 323, 1144, 1236, 1247,1286, 1363, 1495, etc.
	EPA	permitted	Tolerance exemptions established in 40 CFR 180.910
	NOP	see comment	7 CFR 205.605(b) for use in wash and/or rinse water according to FDA limitations; May be permitted in accordance with FDA-approved FCNs
#1A	FSIS	permitted	Directive 7120.1
	FDA	permitted	FCN Nos. 951, 1093, 1094, 1132, 1394, 1419, 1490, 1501, 1522, etc.
	EPA	permitted	Tolerance exemptions established in 40 CFR 180.910
	NOP	see comment	7 CFR 205.605(b) for use in wash and/or rinse water according to FDA limitations; May be permitted in accordance with FDA-approved FCNs
#2	FSIS	permitted	Directive 7120.1
	FDA	permitted	21 CFR 173.370 ("Peroxyacids")
	EPA	permitted	Permitted in accordance with EPA registration, approved labeling, and FSIS approval
	NOP	see comment	Octanoic acid and peroxyoctanoic acid are not listed at 7 CFR 205.605(b). If either substance is labeled as an active ingredient, then the solution is not permitted.
#3	FSIS	permitted	Directive 7120.1 - Antimicrobial Update 10/21/15[3]
	FDA	permitted	FCN Nos. 1035, 1094, 1465, 1477, and 1522
	EPA	see comment	No tolerance exemptions for DPA but EPA has approved labels
	NOP	see comment	7 CFR 205.605(b) for use in wash and/or rinse water according to FDA limitations; May be permitted in accordance with FDA-approved FCNs
#4	FSIS	permitted[4]	No objection 15-ING-1043-N-A (FCN No. 1362) No objection 13-ING-0952-N-A (FCN No. 1384)
	FDA	permitted	FCN Nos. 1384 and 1362

[3]Pdf document available at http://www.fsis.usda.gov/wps/portal/fsis/topics/regulations/directives/7000-series/safe-suitable-ingredients-related-document. Accessed 19 November 2015.

[4] Food Safety and Inspection Service New Technology Information Table. Last Updates October 20, 2015; http://www.fsis.usda.gov/wps/wcm/connect/fsis-content/internet/main/topics/regulatory-compliance/new-technologies/new-technology-information-table. Accessed 21 November 2015.

	EPA	permitted	Tolerance exemptions established in 40 CFR 180.910, 180.950
	NOP	see comment	7 CFR 205.605(b) for use in wash and/or rinse water according to FDA limitations; May be permitted in accordance with FDA-approved FCNs

Table 3: Post-Harvest Handling: Direct food contact – fruits and vegetables.

PAA Solution	Agency	Status	References and Comments
#1	FDA	see comment	21 CFR 173.315(a)(5): for fruits and vegetables that are not raw agricultural commodities, subject to limitations
	EPA	permitted	Tolerance exemptions established in 40 CFR 180.910
	NOP	see comment	7 CFR 205.605(b) for use in wash and/or rinse water according to FDA limitations
#1A	FDA	permitted	FCN No. 1501
	EPA	permitted	Tolerance exemptions established in 40 CFR 180.910; Sulfuric acid is listed as GRAS at 21 CFR 184.1095
	NOP	see comment	7 CFR 205.605(b) for use in wash and/or rinse water according to FDA limitations; May be permitted in accordance with FDA-approved FCNs
#2	FDA	not permitted	21 CFR 173.370 permits use on meat and poultry only
	EPA	not permitted	No tolerance exemption for octanoic acid on growing crops or fruits and vegetables post-harvest at 40 CFR 180.910
	NOP	not permitted	7 CFR 205.605(b); Peroxyoctanoic acid is not listed in 7 CFR 205.605(b)
#3	FDA	permitted	FCN Nos. 1025 (not raw), 1426 (raw)
	EPA	see comment	No tolerance exemption for DPA in 40 CFR 180.910 but EPA has approved labels
	NOP	see comment	7 CFR 205.605(b) for use in wash and/or rinse water according to FDA limitations; May be permitted in accordance with FDA-approved FCNs
#4	FDA	permitted	FCN Nos. 1384 (both raw and not raw) and 1362 (not raw)
	EPA	see comment	Tolerance exemptions established in 40 CFR 180.910 and 180.950; May be permitted in accordance with EPA registrations (none have been registered as of November 1, 2015)
	NOP	see comment	7 CFR 205.605(b) for use in wash and/or rinse water according to FDA limitations; May be permitted in accordance with FDA-approved FCNs

Table 4: Sanitizer on food contact surfaces and equipment without an intervening event (e.g., no potable water rinse).

PAA Solution	Agency	Status	References and Comments
#1	FDA	permitted	21 CFR 178.1010(b)(30); Pasteurized Milk Ordinance
	EPA	permitted	40 CFR 180.940 and 180.910
	NOP	permitted	7 CFR 205.605(b)
#1A	FDA	permitted	21 CFR 178.1010(b) and 184.1095
	EPA	permitted	40 CFR 180.940 and 180.910
	NOP	permitted	7 CFR 205.605(b)
#2	FDA	permitted	21 CFR 178.1010(b)(45); Pasteurized Milk Ordinance
	EPA	permitted	40 CFR 180.940 and 180.910
	NOP	see comment	Peroxyoctanoic acid and octanoic acid are not listed in 7 CFR 205.605(b). If either substance is labeled as an active ingredient, then the solution is not permitted for use without

			an intervening event.
#3	FDA	permitted	21 CFR 178.1010(b)(38); Pasteurized Milk Ordinance
	EPA	permitted	40 CFR 180.940(b)
	NOP	permitted	7 CFR 205.605(b)
#4	FDA	see comment	Solutions are not specifically cited at 21 CFR 178.1010; May be permitted in accordance with FCNs (none have been approved as of November 1, 2015)
	EPA	see comment	40 CFR 180.910, 180.940, and 180.950; May be permitted in accordance with EPA registrations (none have been registered as of November 1, 2015)
	NOP	see comment	7 CFR 205.605(b); May be permitted in accordance with FDA-approved FCNs

Table 5: Crop Disease Control and Disinfection of Seed and Asexually Propagated Planting Material.

PAA Solution	Agency	Status	References and Comments
#1	EPA	permitted	Tolerances established at 40 CFR 180.910
	NOP	permitted	7 CFR 205.601(a)(4), (a)(6), (i)(5), (i)(8) and (m)(1)
#1A	EPA	permitted	Tolerances established at 40 CFR 180.910
	NOP	permitted	7 CFR 205.601(a)(4), (a)(6), (i)(5), (i)(8) and (m)(1)
#2	EPA	permitted	Tolerances established at 40 CFR 180.910
	NOP	see comment	Peroxyoctanoic acid and octanoic acid are not listed in 7 CFR 205.601. If either substance is labeled as an active ingredient, then the solution is not permitted.
#3	EPA	see comment	No tolerance exemption for DPA in 40 CFR 180.910 but EPA has approved labels
	NOP	not permitted	DPA is an EPA List 3 inert allowed solely as a component of passive pheromone dispensers [7 CFR 205.601(m)(2)]. Therefore, PAA Solution #3 is not permitted for the crop pesticide uses described in 7 CFR 205.601.
#4	EPA	see comment	40 CFR 180.910, 180.940, and 180.950; May be permitted in accordance with EPA registrations (none have been registered as of November 1, 2015)
	NOP	see comment	7 CFR 205.601(a)(4), (a)(6), (i)(5), (i)(8) and (m)(1) [all inerts on List 4]; May be permitted in accordance with EPA registrations

Action of the Substance:

Peracetic acid and other peroxy sanitizers disinfect via oxidation. Peracetic acid oxidizes the outer cell membrane of vegetative bacterial cells, endospores, yeast, and mold spores, making it an effective sanitizer against all microorganisms, including bacterial spores. The reason for the excellent and rapid antimicrobial effects of peracetic acid is its specific capability to penetrate the cell membrane. Once inside the cell, peracetic acid plays a role in denaturing proteins, disrupting cell wall permeability, and oxidizing sulfhydryl and sulfur bonds in enzymes and other proteins. PAA irreversibly disrupts enzyme systems, which destroys the microorganism. The end products of peracetic acid oxidation are acetic acid and water.

Numerous sources cite the efficacy of PAA even in the presence of organic matter (Ruiz-Cruz, Acedo-Felix, et al. 2007). However, it also has been reported that the organic load of a solution can diminish PAA's effectiveness. As the pH of a solution approaches neutrality, PAA loses activity (Pfuntner 2011). One study on the action of PAA against microbial spores concluded that its sporicidal activity may be due to organic radicals created by PAA acting as reducing agents (electron donors) for spores normally in a highly oxidized state, as well as being oxidizing agents (electron acceptors) that cause damage to vegetative cells

(Marquis et al. 1995). Peracetic acid has a higher oxidation potential than chlorine dioxide and bleach (sodium hypochlorite at pH greater than 10) and does not contribute chlorine.

Combinations of the Substance:

Peracetic acid solutions #1 – 3 discussed above are made by mixing the ingredients identified in Table 6. The resulting mixtures contain the "active ingredients" and "inert ingredients," as defined by EPA, identified in Table 7.

Table 6: Ingredients used to formulate PAA Solutions #1 – 3. The "+" symbol indicates that the ingredient is used in the formulation.

Ingredient	#1	#1A	#2	#3
Glacial acetic acid	+	+	+	+
Hydrogen peroxide	+	+	+	+
Octanoic acid			+	
Sodium 1-octanesulfonate			optional*	
Sulfuric acid		+		optional
HEDP	+	+	+	optional
Dipicolinic acid (DPA)				+

*only included in food contact surface sanitizer solutions; not included in solutions used in direct food contact

Table 7: Active or inert status of substances present in final PAA Solutions #1 – 3.

Substance Present in Final Solution	#1	#1A	#2	#3
Hydrogen peroxide	Active	Active	Active	Active
Peracetic acid	Active	Active	Active	Active
Octanoic acid			Active or Inert	
Peroxyoctanoic acid			Active	
Sodium 1-octane sulfonate			Inert	
Acetic acid	Inert	Inert	Inert	Inert
Sulfuric acid		Inert		Inert
HEDP	Inert	Inert	Inert	Inert
Dipicolinic acid (DPA)				Inert

PAA solution #4 can be generated on site in either of two ways. The first uses triacetin and hydrogen peroxide reacted with sodium hydroxide, and the end product contains hydrogen peroxide, glycerin and residual triacetin (13%). The alternative method using electrolysis yields the active ingredients peracetic acid and hydrogen peroxide; the inert ingredients are glycerin, residual triacetin, sodium sulfate, and sodium acetate, each of which is an EPA List 4A or List 4B inert.

Hydrogen peroxide is a synthetic substance. It is a Generally Recognized as Safe (GRAS) food ingredient (21 CFR 184.1366). Hydrogen peroxide itself is an antimicrobial used as a sanitizer. Sanitizing solutions of hydrogen peroxide are allowed in organic crop production at 7 CFR 205.601(a)(4) and (i)(5), in organic livestock production at 7 CFR 205.603(a)(13), and in organic handling at 7 CFR 205.605(b). See the Technical Report for hydrogen peroxide for additional information on this substance.

Sodium 1-octane sulfonate (CAS No. 5324-84-5) is a surface-active agent in food surface sanitizers. It is classified by EPA at 40 CFR 180.940 as an "inert ingredient" exempt from a tolerance for use in antimicrobial formulations (food contact surface sanitizing solutions). It is not permitted for direct food contact at 21 CFR 173.370.

Glacial acetic acid is essentially pure acetic acid, with a specification of 99.5% to 100.5% by weight of acetic acid (Wagner 2014). It has no direct antibacterial effects and thus is defined by EPA as an "inert ingredient."

Triacetin (CAS No. 102-76-1), referred to as "glycerol triacetate" by EPA at 40 CFR 180.910, is a synthetic triglyceride ("fat") created by reacting glycerin (glycerol) with acetic acid. Triacetin is soluble in 14 parts of water and has been used as an antifungal agent (Budavari 1996).
Sulfuric acid (CAS No. 7664-93-9), a mineral acid used to reduce pH, is frequently included in peracetic acid formulations to catalyze the formation of peracetic acid from acetic acid and hydrogen peroxide. Sulfuric acid is classified by EPA as a List 4 inert. It is added during the manufacturing process to accelerate the establishment of the final equilibrium concentration. Sulfuric acid is a GRAS food ingredient listed at 21 CFR 184.1095.

Peracetic acid preparations usually contain a synthetic stabilizer such as HEDP (1-hydroxyethylidene-1,1-diphosphonic acid) or dipicolinic acid (2,6-dicarboxy-pyridine) to slow the rate of oxidation or decomposition of peracetic acid (Kurschner and Diken 1997). These stabilizers are chelating agents that bind with metal ions and reduce their activity in solution. Synthetic stabilizers can be avoided if the peracetic acid solution is produced on site as described for PAA solution #4 in Evaluation Question 2. HEDP (CAS No. 2809-21-4) historically was classified by EPA as a List 4 inert. It is also exempt from the requirement of a tolerance when used as a stabilizer/chelator in antimicrobial pesticide formulations at not more than 1 percent (40 CFR 180.910).

Dipicolinic acid (DPA) (CAS No. 499-83-2) was classified by EPA as a List 3 inert in the past.

Octanoic acid (CAS No. 124-07-2), also known as caprylic acid, is an eight-carbon GRAS carboxylic acid (21 CFR 184.1025). It is a medium-chain fatty acid that occurs normally in various food fats, especially coconut oil, babassu oil and palm kernel oil. It is commercially prepared by oxidation of n-octanol or by fermentation and fractional distillation of the volatile fatty acids present in coconut oil.

Octanoic acid historically was on EPA List 4 as an inert ingredient but it may also be an active ingredient in certain formulations. In 2009, EPA published its determination (74 FR 30080) that "Caprylic (octanoic) acid is an antimicrobial pesticide that is used as a food contact surface sanitizer in commercial food handling establishments. It is also used as a disinfectant in health care facilities and as an algaecide in greenhouses and interiorscapes on ornamentals. In addition, caprylic (octanoic) acid is characterized by low toxicity, is biodegradable, and is found extensively in nature."

In the presence of hydrogen peroxide, octanoic acid is reversibly converted to peroxyoctanoic acid (POOA), CAS No. 33734-57-5. Octanoic acid and peroxyoctanoic acid have greater affinity for fatty tissues than acetic acid and peracetic acid do, and thus peroxyoctanoic acid solutions are particularly useful for disinfecting animal carcasses. A "peroxyacids" solution, referred to above as PAA solution #2, is manufactured by mixing acetic acid, hydrogen peroxide, octanoic acid, and HEDP, following prescribed relative proportions and order of addition at 13-27 °C. The mixture is allowed to equilibrate for about 7-13 days, whereby the acetic acid reacts in situ with hydrogen peroxide to form peroxyacetic acid, and the octanoic acid reacts in situ with the hydrogen peroxide to form peroxyoctanoic acid. These sanitizing mixtures are intended for washing of fruits, vegetables, meat, and poultry (Azanza 2004). The combination of peroxyoctanoic acid and peracetic acid has a synergistic effect and greatly enhanced antimicrobial activity when compared to peroxyoctanoic acid or peracetic acid alone, when used to control pathogens on plants (Hei et al. 2001; Oakes, Stanley, and Keller 1993).

Status

Historic Use:

Peracetic acid was first registered in the U.S. as a pesticide for use as a disinfectant, sanitizer and sterilant in 1985.

At its November 2000 meeting, the National Organic Standards Board (NOSB) reviewed the Technical Evaluation Reports for use of peracetic acid and recommended inclusion of this sanitizer at 7 CFR 205.601 (crop production), 205.603 (livestock production), and 205.605 (handling). On October 31, 2003, NOP published a final rule amending the National List to include peracetic acid at 7 CFR 205.601(a) for disinfecting equipment, seed and asexually propagated planting material, and at 7 CFR 205.601(i) for use to control fire blight bacteria (68 FR 61987).

On September 11, 2006, NOP published a final rule amending 7 CFR 205.605(b) to include peracetic acid with the current annotation: "Peracetic acid/Peroxyacetic acid (CAS No. 79-21-0) - for use in wash and/or rinse water according to FDA limitations. For use as a sanitizer on food contact surfaces" (71 FR 53299).

On December 12, 2007, NOP published a final rule amending 7 CFR 205.603(a) to include "Peroxyacetic/peracetic acid (CAS # -79-21-0) – for sanitizing facility and processing equipment" (72 FR 70479).

A 2008 petition to the NOSB requested that 7 CFR 205.601 be modified to recognize that some hydrogen peroxide sanitizers used in organic crop production, which had always contained some peracetic acid, required relabeling to meet a new EPA requirement. This minor amount of peracetic acid was now considered an active ingredient by EPA and thus must be labeled as such. In its November 2009 deliberations, the NOSB recommended that the peracetic acid annotation for crop production be amended to add the following proviso: "Peracetic acid—Also permitted in hydrogen peroxide formulations as allowed in §205.601(a) and (i) at concentration of no more than 6% as indicated on the pesticide product label." The final rule incorporating this change into 7 CFR 205.601(a)(6) and (i)(8) was published (78 FR 31815) on May 28, 2013.

Organic Foods Production Act, USDA Final Rule:

Peracetic acid is not specifically listed in the Organic Foods Production Act of 1990. It is listed in several parts of 7 CFR 205.601, 205.603, and 205.605(b) of the NOP regulations. Full regulatory text is included in *Regulatory Status and Approved Legal Uses of the Substance*.

International

Canada

Peracetic acid does not appear in paragraph 5.3 (Health Care Products and Production Aids) of the CAN/CGSB-32.311-2015 Permitted Substances List. It is, however, listed at paragraph 7.3 as a food-grade cleaner, disinfectant and sanitizer permitted without a mandatory removal event, with the following annotation: "On food and plants: peracetic acid may be used in wash or rinse water. Peracetic acid may also be used on food contact surfaces." This allowance is consistent with the NOP regulations at 7 CFR 205.603.

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)

The Codex Alimentarius Commission Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999) do not mention any permitted sanitizers. Peracetic acid also does not appear on Annex 2 (Permitted Substances for the Production of Organic Foods) in the guidelines.

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008

Peracetic acid is a permitted product for cleaning and disinfection of buildings and installations for animal production (EC No 889/2008 - Annex VII - Products for cleaning and disinfection referred to in Article 23). Peracetic acid and peroctanoic acid are permitted materials for cleaning and disinfection of equipment and facilities in the presence as well as in the absence of aquaculture animals (EC No 889/2008 - Annex VII point 2.2).

Japan Agricultural Standard (JAS) for Organic Production

The Japanese Agricultural Standard for Organic Livestock Products, Table 4, lists "Agents for cleaning or disinfecting of housing for livestock." Included on this list are "Hydrogen Peroxide Solution" and "Cleaning agents and disinfectants for milking equipment, rooms and buildings." Peracetic acid is not specifically mentioned.

IFOAM – Organics International (IFOAM)

The IFOAM norms permit use of peracetic acid for cleaning equipment and disinfecting equipment with no final rinse (IFOAM Appendix 4, Table 2), and for disinfection of livestock housing and equipment (IFOAM Appendix 5).

Evaluation Questions for Substances to be used in Organic Crop or Livestock Production

<u>**Evaluation Question #1: Indicate which category in OFPA that the substance falls under:**</u> **(A) Does the substance contain an active ingredient in any of the following categories: copper and sulfur compounds, toxins derived from bacteria; pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals; livestock parasiticides and medicines and production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleansers? (B) Is the substance a synthetic inert ingredient that is not classified by the EPA as inerts of toxicological concern (i.e., EPA List 4 inerts) (7 U.S.C. § 6517(c)(1)(B)(ii))? Is the synthetic substance an inert ingredient which is not on EPA List 4, but is exempt from a requirement of a tolerance, per 40 CFR part 180?**

(A) Peracetic acid is a production aid (7 USC 6517(c)(1)(B)(i)).
(B) Peracetic acid is not an inert ingredient.

<u>**Evaluation Question #2:**</u> **Describe the most prevalent processes used to manufacture or formulate the petitioned substance. Further, describe any chemical change that may occur during manufacture or formulation of the petitioned substance when this substance is extracted from naturally occurring plant, animal, or mineral sources (7 U.S.C. § 6502 (21)).**

Peracetic acid solutions used for sanitation are equilibrium mixtures of peracetic acid, acetic acid and hydrogen peroxide. Solutions of peracetic acid are most commonly produced by reacting glacial acetic acid with a hydrogen peroxide solution, as shown in Figure 1.

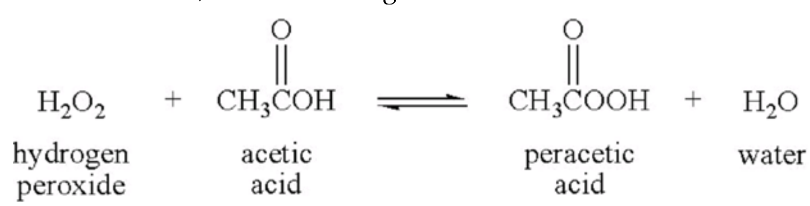

Figure 1. Production of peracetic acid (Buschmann and Del Negro 2012).

A mineral acid (e.g., sulfuric acid) may be added to catalyze the reaction, and increasing the temperature can accelerate the formation of PAA (National Center for Biotechnology Information 2015). If octanoic acid is included as a reactant, peroxyoctanoic acid also is created.

Peracetic acid solutions are usually made with synthetic acetic acid. The major routes for synthetic acetic acid production are methanol carbonylation, acetaldehyde oxidation, butane/naphtha oxidation, and methyl acetate carbonylation. Comparatively small amounts are generated by butane liquid-phase oxidation, direct ethanol oxidation, and synthesis gas. At present, methanol carbonylation using the Cativa (iridium catalyst) or Monsanto (rhodium catalyst) process is the main route. These processes produce glacial acetic acid, which is essentially pure acetic acid (Wagner 2014). Acetic acid is known as "vinegar acid." Vinegar is an aqueous solution containing about 4-12% acetic acid (Le Berre et al. 2014), a concentration too dilute to be practical in peracetic acid production.

Hydrogen peroxide (H_2O_2) is produced by autoxidation of an alkyl anthrahydroquinone. One way to achieve this is via the 2-ethyl derivative, in a cyclic continuous process in which the quinone formed in the oxidation step is reduced to the starting material by hydrogen in the presence of a supported palladium catalyst. Another method is the electrolytic processes in which aqueous sulfuric acid or acidic ammonium bisulfate is converted electrolytically to the peroxydisulfate, which is then hydrolyzed to form hydrogen peroxide. It may also be carried out by autoxidation of isopropyl alcohol (Lewis 1997) and by decomposition of barium peroxide with sulfuric acid or phosphoric acid.

PAA can reach concentrations of up to 40% in solution, with residual hydrogen peroxide from 5-25% and acetic acid from 10-40% (Malchesky 2001). However, concentrations of 5-15% peracetic acid are more typical in the food industry, and concentrations less than 6% are typical in crop pesticide solutions. Residual hydrogen peroxide and acetic acid levels can be reduced through distillation of the equilibrium solution. Stabilizers are generally added to chelate trace minerals and thereby retard PAA decomposition (Malchesky 2001).

PAA solution #4, described in the *Regulatory* section, can be generated on site in either of two ways. When a peracetic acid precursor (45 wt % triacetin and 55 wt % of 50% hydrogen peroxide) is reacted with sodium hydroxide, triacetin is converted to peracetic acid at an 87% efficiency level and yields hydrogen peroxide, glycerin and residual triacetin (13%) as inert ingredients. No stabilizers are required, allowing the solution to be used immediately upon generation and at higher concentrations (Harvey and Howarth 2013). The same solution can be made alternatively by the electrolysis and oxygenation of a sodium sulfate solution which generates sodium hydroxide and hydrogen peroxide. These are then combined with a solution of sodium acetate and/or triacetin to form peracetic acid (Buschmann and Del Negro 2012).

Several other PAA manufacturing processes exist, but do not appear to be commercially available sources based on the literature. One method is to produce peracetic acid by the oxidation of acetaldehyde (Budavari 1996). In another method, hydrogen peroxide is mixed with a carboxylic acid in a reactor in the presence of a sulfonic acid resin to form an aqueous PAA solution (Lokkesmoe and Oakes 1992). Still another method involves the dissolution of an activator such as tetra-acetyl ethylenediamine (TAED) and a persalt such as sodium percarbonate in water (Davies and Deary 1991).

<u>Evaluation Question #3:</u> Discuss whether the petitioned substance is formulated or manufactured by a chemical process, or created by naturally occurring biological processes (7 U.S.C. § 6502 (21)).

All of the commercial processes for making peracetic acid are chemical processes, as described in Evaluation Question 2. One source of naturally occurring peracetic acid reported in the literature is that which forms in the atmosphere through a series of photochemical reactions involving formaldehyde. However, this is not a commercial source. Another report describes the production of peracetic acid by the enzyme haloperoxidase produced by *Pseudomonas pyrrocinia* (Jacks et al. 2002). However, this also is not a commercial source.

<u>Evaluation Question #4:</u> Describe the persistence or concentration of the petitioned substance and/or its by-products in the environment (7 U.S.C. § 6518 (m) (2)).

Peracetic acid is highly soluble in water (1000 g/L at 20ºC) and is also a highly reactive oxidizer (OECD 2008). Based on its vapor pressure, PAA could be expected to exist primarily in the gas phase in the atmosphere (California Air Resources Board 1997). However, due to its solubility, it readily dissolves in clouds and is removed from the atmosphere through rain-out (U.S. National Library of Medicine 2012; California Air Resources Board 1997). PAA occurs, therefore, almost exclusively (99.95%) as a liquid in the environment.

In air the half-life of peracetic acid is 22 minutes. The abiotic degradation of peracetic acid increases with temperature and higher pH. At a temperature of 25 °C and at pH of 4, 7 and 9, the degradation half-life values were 48 hours, 48 hours and less than 3.6 hours, respectively (OECD 2008).

Peracetic acid exerts its oxidizing effect on contact with reducing materials (Massachusetts Department of Environmental Protection 2010), breaking down to water and acetic acid (Pfuntner 2011). Peracetic acid is also reported to have very low adsorption to soil (adsorption coefficient K_{oc} of 4) (PAN 2014b). Hydrogen peroxide, its co-active ingredient, also oxidizes on contact, breaking down into oxygen and water. Peracetic acid and hydrogen peroxide, therefore, degrade quickly and have low persistence in the environment and on food (JECFA 2004). The Technical Report for hydrogen peroxide may be referenced for further information on the persistence or concentration of hydrogen peroxide and its by-products in the environment.

Acetic acid, the by-product of PAA, is also highly soluble, has low adsorption to soil (adsorption coefficient K_{oc} of 117), and degrades in water into carbon dioxide and water. Its aerobic soil-half life is reported as an average of 0.05 days (PAN 2014a). Thus, it also has very low persistence in the environment. The residual amounts of acetic acid on food sanitized with peracetic acid solutions are expected to be within levels considered acceptable for antimicrobials (JECFA 2004).

Residual HEDP from peracetic acid solutions is generally estimated to remain on the surface of treated food at low levels (in the ppb range) (JECFA 2004).

<u>Evaluation Question #5:</u> Describe the toxicity and mode of action of the substance and of its breakdown products and any contaminants. Describe the persistence and areas of concentration in the environment of the substance and its breakdown products (7 U.S.C. § 6518 (m) (2)).

Peracetic acid and hydrogen peroxide are both strong oxidizers, meaning that they remove electrons from other chemical groups and are reduced in the process. This reaction can occur at the cell surface or with intercellular matter. High levels of oxidation can damage cells by disrupting membrane layers, inhibiting enzymes, impairing energy production, disrupting protein synthesis, and affecting oxygen scavengers, thiol groups and nucleosides. Oxidation can ultimately cause cell death. It has been suggested that oxidation by PAA increases cell wall permeability by disrupting sulfhydryl and sulfur bonds. One study specifically found PAA to be a powerful oxidant of amino acids, to fragment proteins, and to affect enzyme activity (Finnegan, et al. 2010).

EPA registered pesticide product labels for peracetic acid solutions state that they are toxic to birds, fish and aquatic invertebrates, and instruct users to use caution when applying indoors because pets may be at risk. These labels further instruct to not discharge effluent containing peracetic acid products into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of the National Pollution Discharge System (NPDES) permit and the permitting authority has been notified in writing prior to discharge.

Peracetic acid was readily biodegradable during a biodegradation test where its biocidal effect was prevented (OECD 2008). It was reported that peracetic acid will be degraded in a sewage treatment plant if the influent concentration is not extremely high (e.g., more than 100 ppm). If effluents generated during the production or use of peracetic acid are treated by a waste water treatment plant, no emission of peracetic acid to the aquatic environment is expected (OECD 2008). A different study found that urban wastewater treated with peracetic acid (not going through a water treatment plant) would show acute toxic effects on aquatic organisms (Crebelli et al. 2003). However, none of the uses permitted under NOP regulations involve direct application of PAA to effluent, and residual PAA from agricultural and food sanitizing applications is expected to be negligible due to its breakdown during oxidation.

<u>Evaluation Question #6:</u> Describe any environmental contamination that could result from the petitioned substance's manufacture, use, misuse, or disposal (7 U.S.C. § 6518 (m) (3)).

Peracetic acid is considered to be an environmentally friendly substance, with very little potential to cause contamination due to its rapid breakdown into benign substances already present in the environment. It has, however, been reported that peracetic acid in the atmosphere can react with photochemically produced hydroxyl radicals (reaction half-life of approximately 9 days) (U.S. National Library of Medicine 2012), with a suggested role in contributing to acid rain (Gaffney et al. 1987).

Both peracetic acid and hydrogen peroxide have been cited as potential contributors to acid rain. However, while peracetic acid and hydrogen peroxide can be involved in chemical reactions in the atmosphere that ultimately lead to acid rain, the literature does not cite them as being a significant contributor to or source of acid rain (Calvert and Stockwell 1983).

Peracetic acid has been found in some instances to have beneficial effects related to environmental contamination. One study reports peracetic acid to be effective in degrading toxic compounds benzo(*a*)pyrene and α-methylnaphthalene in lake sediments through oxidation of the parent compound (N'Guessan, Levitt and Nyman 2004).

<u>Evaluation Question #7:</u> Describe any known chemical interactions between the petitioned substance and other substances used in organic crop or livestock production or handling. Describe any environmental or human health effects from these chemical interactions (7 U.S.C. § 6518 (m) (1)).

Peracetic acid can react violently with acetic acid anhydride, metal chloride solutions (e.g., calcium chloride and potassium chloride), olefins (e.g., mineral oil) and organic matter (U.S. EPA 2010, National Center for Biotechnology Information 2015), thus presenting potential health hazards if proper safety measures are not employed. Manufacturers also recommend avoiding contact with strong bases, heavy metals, soft metals (e.g., copper, brass, bronze, zinc and aluminum), leather, paper, wood and oxidizable organics (EnviroTech 2014), as these will react with and accelerate the degradation of the peracetic acid. In practice, PAA has been used as an oxidizing agent to decompose humic materials in soils in order to study their composition (Schnitzer and Skinner 1974; Schnitzer and Hindle 1980). These reactions resulting in the degradation of PAA are not expected to have a significant effect on the environment.

As discussed earlier, peracetic acid is used almost exclusively in combination with hydrogen peroxide, acetic acid and stabilizers. The combination of peracetic acid and hydrogen peroxide has been reported to have synergistic effects as a bactericide, with that synergy being maintained over contact time (Alasri, et al. 1992). EPA registered pesticide product labels for peracetic acid/hydrogen peroxide disease controls instruct users to not mix or combine with other pesticide concentrations.

<u>Evaluation Question #8:</u> Describe any effects of the petitioned substance on biological or chemical interactions in the agro-ecosystem, including physiological effects on soil organisms (including the salt index and solubility of the soil), crops, and livestock (7 U.S.C. § 6518 (m) (5)).

Peracetic acid has been studied as an oxidizing agent of organic materials in soil. Schnitzer and Hindle (1980) looked at changes to the nitrogen profile of humic acid samples as a result of mild oxidation by peracetic acid and found decreases in amino acid-N and carbon, and increases in ammonia-N, nitrite-N and nitrate-N. As a bactericide, it can also impact soil microorganisms. However, nothing in the literature reviewed for this report suggests that the impact on soil microbiota is a concern when using PAA as a sanitizer, cleaner or in disease control applications. The reasons are likely due to the fact that the inhibitory effects of PAA on microorganisms are intended and/or ephemeral.

Peracetic acid is reported to have some phytotoxic properties. Little is known about the toxicity of peracetic acid to plants at levels expected in the environment (nanomolar to low micromolar concentrations in acidic precipitation) (Gaffney et al. 1987). However, direct application in combination with hydrogen peroxide as a disease control measure may cause some visible damage to treated plants. The label for one peracetic acid product, BioSafe Disease Control, states that "treatments may result in lesions on plant tissue. BioSafe Disease Control will oxidize parasitic organisms living in plant tissue that are not always visible to the naked eye. Resulting oxidative effects may include spotting, or drying of the plant tissue where organisms inhabited tissue."

Hydrogen peroxide can also cause cellular damage to plants and, although its adverse effects in the atmosphere have not been documented, scientists have noted the need to further study its impact on biota (Gaffney et al. 1987). Atmospheric H_2O_2 (from both anthropogenic and non-anthropogenic sources) is mostly removed from the atmosphere via dry deposition (Sakugawa, Kaplan and Shepard 1993). According to one study, gas phase peracetic acid is less likely to be taken up by plants via dry deposition than hydrogen peroxide (Wesely 1967).

<u>Evaluation Question #9:</u> Discuss and summarize findings on whether the use of the petitioned substance may be harmful to the environment (7 U.S.C. § 6517 (c) (1) (A) (i) and 7 U.S.C. § 6517 (c) (2) (A) (i)).

While peracetic acid is a hazardous substance with acute toxicity due to its strong oxidizing action, its use as a sanitizer is not likely to have significant adverse impacts on the environment. As a reactive chemical, it does have immediate impacts, but those impacts are short lived and not necessarily detrimental. There was no information in the literature reviewed for this report to suggest cumulative or persistent harm to the environment resulting from the permitted use of peracetic acid in organic agriculture and food processing.

<u>Evaluation Question #10:</u> Describe and summarize any reported effects upon human health from use of the petitioned substance (7 U.S.C. § 6517 (c) (1) (A) (i), 7 U.S.C. § 6517 (c) (2) (A) (i)) and 7 U.S.C. § 6518 (m) (4)).

Concentrated solutions of peracetic acid are strongly irritating to the skin, eyes, mucous membranes, and respiratory system (Budavari 1996). Skin contact can result in severe irritation and burns, as can eye contact, leading to eye damage (New Jersey Department of Health and Senior Services 2004). When using fully diluted sanitizing solutions, no special eye, hand, skin, or respiratory protective equipment is normally required (Budavari 1996). Ingestion can cause corrosion of the mucous membranes in the mouth, throat and esophagus (California Air Resources Board 1997). The probable human oral lethal dose may occur at a concentration of around 50-500 ppm (U.S. National Library of Medicine 2012), though EPA found no data on human lethality due to peracetic acid exposure in the literature (U.S. EPA 2010). Inhalation of PAA irritates the nose, throat and lungs, and causes coughing and/or shortness of breath. At high levels of inhalation exposure, one can experience pulmonary edema or a build-up of fluid in the lungs. High or repeated exposure may affect the liver or kidneys.

EPA considers concentrated solutions of peracetic acid to be in Toxicity Category I (highest toxicity category) for acute irritation to eyes and skin, and in Toxicity Category III for acute oral effects (U.S. EPA 1993). Hydrogen peroxide is considered to be much less toxic than peracetic acid (National Research Council 2010). Acetic acid is considered to be of low toxicity (PAN 2014a).

EPA has established Acute Exposure Guideline Levels (AEGLs) for peracetic acid, shown in Table 8 below. EPA reports that the effects of PAA exposure are more correlated with concentration than duration of exposure. And, because PAA is soluble in water, it is expected to be effectively scrubbed in the upper respiratory tract (U.S. EPA 2010).

Table 8. Acute Exposure Guideline Levels (AEGLs) for Peracetic Acid.

	10 min	30 min	60 min	4 hr	8 hr
AEGL 1[5]	0.52 mg/m3	0.52 mg/m3	0.52 mg/m3	0.52 mg/m3	0.52 mg/m3
AEGL 2[6]	1.6 mg/m3	1.6 mg/m3	1.6 mg/m3	1.6 mg/m3	1.6 mg/m3
AEGL 3[7]	60 mg/m3	30 mg/m3	15 mg/m3	6.3 mg/m3	4.1 mg/m3

The EPA Registration Eligibility Decision (RED) document for peracetic acid states that peroxy compounds pose essentially no risk to human health through dietary exposure, and the risks described above are minimized to applicators and mixers through the use of protective equipment, as required by product labeling. According to the report, EPA considers the risks posed to humans by the use of peroxyacetic acid to be negligible (U.S. EPA 1993).

An *in vitro* dermal penetration assay at 37ºC using 0.8% peracetic acid (8000 ppm) (non-corrosive) indicated a low dermal uptake of peracetic acid through the intact skin of pigs. When the skin of rats was exposed to a corrosive concentration of radiocarbon-labeled peracetic acid, a considerable uptake of radiocarbon was found but it is unknown if it was present as peracetic acid, acetic acid, or carbon dioxide. It is expected that corrosive concentrations of peracetic acid would compromise the normal barrier function of the skin (OECD 2008).

Two reliable in vitro studies, using different analytical methods, showed a rapid degradation of peracetic acid in rat blood. When rat blood was diluted 1000 times, the half-life of peracetic acid was less than five minutes. In undiluted blood the half-life is expected to be several seconds or less. For this reason the distribution of peracetic acid is probably very limited and it is not expected to be systemically available after exposure to peracetic acid (OECD 2008).

Evaluation Question #11: Describe all natural (non-synthetic) substances or products which may be used in place of a petitioned substance (7 U.S.C. § 6517 (c) (1) (A) (ii)). Provide a list of allowed substances that may be used in place of the petitioned substance (7 U.S.C. § 6518 (m) (6)).

Nonsynthetic alternatives to peracetic acid sanitizers include vinegar, natural alcohols, citric acid, lactic acid and sodium bicarbonate.

Reports indicate that vinegar may not be able to consistently replicate the antimicrobial efficacy of peracetic acid. One study reported that a 50% vinegar disinfectant had comparable effectiveness as an antimicrobial agent to an 80 ppm peracetic acid solution (Nascimento et al. 2003). Another study reported that undiluted vinegar showed antimicrobial activity against the Gram negative organisms *S. typhi* and *E. coli*; however, it was not effective against the Gram positive *S. aureus* (Parnes 1997). Unlike peracetic acid, vinegar is reported to have low efficacy in the presence of organic materials (Perry and Caveney 2011), but has been

[5] AEGL-1 is the airborne concentration of a substance above which it is predicted that the general population, including susceptible individuals, could experience notable discomfort, irritation or certain asymptomatic, non-sensory effects that are transient or reversible. For peracetic acid this is reported to be irritation to the upper respiratory tract.

[6] AEGL-2 is the airborne concentration of a substance above which it is predicted that the general population, including susceptible individuals, could experience irreversible or other serious, long-lasting adverse health effects or an impaired ability to escape. For peracetic acid, it is associated with slight to tolerable discomfort to nasal membranes and eyes for exposure durations up to 20 minutes.

[7] The AEGL-3 is the airborne concentration of a substance above which it is predicted that the general population, including susceptible individuals, could experience life-threatening health effects or death. These values for peracetic acid are adjusted from the highest concentrations at which no mortality was observed in exposed rats.

shown to have greater efficacy as a disinfectant than both lemon juice (citric acid) and baking soda (sodium bicarbonate) (Olson et al. 1994).

Alcohol is classified as an intermediate-level disinfectant for healthcare equipment. Like peracetic acid, it is fast acting. It is effective against *S. aureus*, *Salmonella*, *Streptococcus* and *Leptospira*. It leaves no residuals which is positive in terms of environmental impact, but limits the duration of its efficacy. Alcohols are also inactivated by organic material, whereas peracetic acid remains effective even in the presence of heavy organic loads (Perry and Caveney 2011).

There are also a number of synthetic substances allowed in the NOP regulations for use as disinfectants or sanitizers. These are: synthetic alcohols (ethanol and isopropanol), chlorine materials (including calcium hypochlorite, chlorine dioxide and sodium hypochlorite, electrolyzed water[8]), hydrogen peroxide, ozone, and sodium carbonate peroxyhydrate.

Evaluation Question #12: Describe any alternative practices that would make the use of the petitioned substance unnecessary (7 U.S.C. § 6518 (m) (6)).

Sanitization of facilities and process equipment is a crucial step in ensuring the health of organic livestock and the safety of their products for human consumption. Thus, other practices should be viewed as complementary to sanitization, not replacements. Everything from managing visitors and traffic control, to appropriately managing replacement animals, and also the storage and handling of feedstuffs and manure can help control pathogen spread. Using dedicated equipment to handle feed, for example, can help prevent transmission of pathogens from sick or dead animals or manure.

Livestock waste is a major source of pathogens and can also contain protozoa and viruses. Thus, best practices for manure management should be employed to help reduce the occurrence and minimize the spread of pathogenic organisms. These practices include appropriate animal management and housing, dietary modifications to add yeast or probiotics when determined necessary; appropriate production management, land application of manure and chemical and biological treatment of stored manure. Controlling flies and vermin can also reduce the spread of pathogens among animals (University of Minnesota Extension 2007).

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