Acidified Sodium Chlorite

Handling/Processing

Identification of Petitioned Substance

Chemical Name:
Sodium chlorite

Synonym:
Chlorous acid, sodium salt

Other Names:
Acidified sodium chlorite (ASC)
Sanova® SANOVA®

CAS Number:
7758-19-2

Other Codes:
EINECS 231-836-6
RTECS No. VZ 4800000
UN No. 1496

Characterization of Petitioned Substance

Composition of the Substance:

The petitioned substance, acidified sodium chlorite (ASC) solution, is a binary composition that consists of sodium chlorite solution and citric acid.

Sodium chlorite solution is made with sodium chloride crystals or flakes and water, and available at various concentrations, such as SANOVA® Base (25%) and Sanova® Antimicrobial Food Additive Base (25%) containing 20-50% by weight of sodium chlorite ($NaClO_2$). While the chlorite ion (ClO_2^-) is stable in aqueous solution, under acidic conditions— the acidifier can be any one of food-grade acids, chlorite forms chlorous acid ($HClO_2$) (see Figure 1). Chlorous acid is unstable and dissociates back to chlorite ion. Other compounds like chlorine dioxide (ClO_2) and chlorate also generated. Ultimately, chlorous acid degrades to chloride (Cl^-).

$$ClO_2^- + H^+ \rightleftharpoons HClO_2$$

Chlorite Acid Chlorous acid

Figure 1. Formation of Chlorous Acid

Properties of the Substance:

Chemical and physical properties (FSANZ, 2003)

Color	White Crystalline Solid (80% Technical Grade) ; Solutions: Colorless to light green
Density/Specific Gravity	2.468 Crystal 1.176 Bulk, Packed, 80% Technical Grade 1.21 (25% aqueous solution)
Dissociation Constants	pK_a of chlorous acid ($HClO_2$) = 1.72 @ 25° C
Hydrolysis	Sodium chlorite reacts with hydrogen ions to form chlorous acid; pK_a of chlorous acid ($HClO_2$) = 1.72 @ 25° C
Melting/Crystallization Points (liquids)	-8° C (25% Solution)
Melting Point or Range (solids)	180—200° C, Decomposes
Molecular Weight	91.45
Odor	Slight chlorine-like
Oxidation Stability (air)	Stable to air oxidation
Photolysis	80% Technical Grade is stable to photolysis; Photolysis sodium chlorite solutions produces chlorine dioxide

Physical State	White Crystalline Solid, slightly hygroscopic (80% Technical)
Solubility in Organic Solvents	Not soluble in non-polar solvents; Sparingly soluble in polar solvents
Solubility in Water	43.6% @ 25° C
Thermal Stability	Decomposes at 180 — 200° C
Vapor Pressure	21.085 mm Hg (25% solution @ 25° C)
Viscosity (liquids)	1.851 cps @25° C (25% solution)

ASC solution is typically not constituted for application until immediately just prior to the actual time of use because of its unstable nature. Acidification of sodium chlorite results in partial conversion of chlorite to an unstable material, chlorous acid. Gordon, et al. stated that 100% chlorous acid solution decomposed to chloride and oxygen in one hour. Chlorous acid is the main active ingredient of ASC solution and is a very strong oxidizing agent. A Material Safety Data Sheet (MSDS) for chlorous acid (CAS No.13898-47-0) is not available; in addition, there is no USEPA registration number for chlorous acid.

Specific Uses of the Substance:

ASC solution is used as a processing aid in wash and/or rinse water, in accordance with the FDA limitation for using on direct food contact and indirect food contact:

- Direct Food Contact (Secondary Direct Food Additive) — Poultry carcass, organs and parts; red meat carcass, organs and parts, seafood (finfish and crustaceans), and fruits and vegetables (raw and further processed); processed, comminuted or formed meat products; and
- Indirect Direct Food Contact — Hard surface food contact sanitization.

Approved Legal Uses of the Substance:

1. The U.S. Food and Drug Administration (FDA) approved
   - ASC solution as an antimicrobial agent (21 CFR §173.325) under the Specific Usage Additives section of the Secondary Direct Food Additives Permitted in Food for Human Consumption. ASC solution is produced by mixing an aqueous solution of sodium chlorite with any generally recognized as safe (GRAS) acid, in accordance with current industry standards of good manufacturing practice, for use in red meat, poultry, seafood, and raw agricultural commodities.
   - as a sanitizing solution (21 CFR §178.1010 (b) (46)), which is an aqueous solution of oxy-chloro species generated by acidification of sodium chlorite, listed under the Substances Utilized to Control the Growth of Microorganisms of Indirect Food Additives: Adjuvants, Production Aids, and Sanitizers. In addition to use on food-processing equipment and utensils, this solution may be used on dairy-processing equipment.

2. The USDA Food Safety and Inspection Service (FSIS) identified the ASC, listed under Antimicrobials in Table of Safe and Suitable Ingredients on Attachment 1 of FSIS Directive 7120.1, for use in red meat and poultry products as processing aids.

3. The U.S. Environmental Protection Agency (EPA) approved oxy-chloro species generated by acidification of an aqueous solution of sodium chlorite, listed under 40 CFR §180.940 Tolerance exemptions for active and inert ingredients, for use in antimicrobial formulations (Food-contact surface sanitizing solutions). In addition, SANOVA® Base (25%) has the EPA Registration Number 1677-219.

Action of the Substance:

Chlorous acid exerts its antimicrobial activity by direct disruption of the cellular membrane and by oxidation of cellular constituents of microorganisms. ASC solution is considered a broad-spectrum oxidative antimicrobial, effective on pathogenic bacteria as well as viruses, fungi, yeast, molds, and some protozoa. The level of chlorous acid, which forms in acidic aqueous solution, depends on the hydrogen ion concentration (i.e. pH) of the mixed solution of sodium chlorite and acid. Sustained antimicrobial activity deriving from chlorous acid is based on reservoirs of chlorite and hydrogen ions in the solution. As chlorous acid is consumed through oxidation, interaction with microorganisms and other organic matter, re-equilibration from reservoir ions produces additional chlorous acid.

Status

United States:

1. The Food and Drug Administration (FDA) approved ASC solution as an antimicrobial agent (21 CFR §173.325), at specified levels of concentration (ppm) and pH, for treating on a variety of products, see Table 1; and as a sanitizing solution (21 CFR §178.1010 (b) (46)), at a range 100-200 ppm of sodium chlorite, for applying on food-processing equipment and utensils.

Table 1. Summary of 21 CFR §173.325 Acidified Sodium Chlorite Solutions

Food Product	Application	ASC Solution	
		ppm	pH
Poultry intact carcasses and parts, meat, organs, or related parts or trim	Spray or Dip	500-1200	2.3-2.9
Poultry intact carcasses and parts	Pre-chiller or Chiller Solution	50-150	2.8-3.2
Red meat, red meat parts, and organs	Spray or Dip	500-1200	2.5-2.9
Processed, comminuted or formed meat food products	Spray or Dip	500-1200	2.5-2.9
Seafood[1]	Water or Ice (use to rinse, wash, thaw, transport, or store)	40-50	2.5-2.9
Finfish and Crustaceans[2]	Spray or Dip Solution (in processing facilities)	1200	2.3-2.9
Raw Agricultural Commodities[3]	Spray or Dip	500-1200	2.3-2.9
Processed Fruits and Vegetables[4]	Spray or Dip	500-1200	2.3-2.9

2. The USDA Food Safety and Inspection Service (FSIS) identified the ASC for use in red meat and poultry products as processing aids (FSIS Directive 7120.1, Attachment 1). For poultry products, the pH and concentration levels of the solutions have been referred to 21 CFR §173.325. For red meat products, ASC solution applied as a spray or dip has the pH 5.0 - 7.5, in addition, the concentrations of sodium chlorite and chlorine dioxide are not exceed 1200 and 30 ppm, respectively.

3. The U.S. Environmental Protection Agency (EPA) approved oxy-chloro species (40 CFR §180.940) generated by acidification of an aqueous solution of sodium chlorite as a food-contact surface sanitizing solutions. The end-use concentration is not to exceed 200 ppm of chlorine dioxide.

International:

1. The Canada Food Inspection Agency, Meat Hygiene Directive listed ASC as an approved microbial control agent, in a range of 500-1200 ppm at pH 2.5-2.9, for use on poultry. (May 2001)
2. The Food Standards Australia New Zealand (FSANZ) approved ASC as a food processing aid for antimicrobial use. (October 2003)
3. The European Food Safety Authority (EFSA) endorsed ASC to clean chicken carcasses. (January 2006)
4. Codex Committee on Food Additives recommended that they consider adding ASC to the inventory of processing aids (IPA). (April 2008)

[1] Any seafood is intended to be consumed raw shall be subjected to a potable water rinse prior to consumption.
[2] Treated seafood shall be cooked prior to consumption.
[3] Treated product shall be followed by a potable water rinse, or by blanching, cooking, or canning.
[4] Treated product shall be followed by a potable water rinse and a 24-hour holding period prior to consumption.

Evaluation Questions for Substances to be used in Organic Handling

Evaluation Question #1: Is the petitioned substance formulated or manufactured by a chemical process? (From 7 U.S.C. § 6502 (21).)

In the petition, it states that ASC solutions are made on-site and on-demand by mixing a solution of sodium chlorite with natural citric acid. Sodium chlorite (25%) and citric acid (50%) solutions are stored separately in bulk on site. Both solutions are pumped by proportional pumps and a water dilution module to make the final use dilution product, which typically contains 0.1% sodium chlorite and 0.6% citric acid and 99.3% water.

Sodium chlorite is made by the reduction of chlorine dioxide, which is, in turn, from the reduction of sodium chlorate in the presence of sulfuric and hydrogen peroxide or sulfuric acid and sodium chloride. The resulting solution may be dried to a solid and the sodium chlorite content may be adjusted to about 80% by the addition of sodium chloride, sodium sulfate, or sodium carbonate. Sodium chlorite is marketed as a solid or an aqueous solution (such as 25% by weight).

The acid used to acidify sodium chlorite is natural citric acid, which is stated in the petition. However, there is no information in the petition regarding how the natural citric acid was manufactured.

Evaluation Question #2: Is the petitioned substance formulated or manufactured by a process that chemically changes the substance extracted from naturally occurring plant, animal, or mineral sources? (From 7 U.S.C. § 6502 (21).)

As mentioned above, ASC solution is formulated by mixing sodium chlorite solution with natural citric acid. However, the petitioner does not describe how the natural citric acid was made. Sodium chlorite solution and its precursor (sodium chlorite solid) are synthetic materials that are made by chemical processes, not extracted from naturally occurring plant, animal, or mineral sources.

ASC solution is produced by the addition of an acid (i.e. any GRAS acid in US/any food-grade acid in international community) to an aqueous solution of sodium chlorite. While the chlorite ion is stable in aqueous solution, under acidic conditions, chlorite forms a semi-stable intermediate, chlorous acid. Chlorous acid ultimately disintegrates to chloride.

Evaluation Question #3: Is the petitioned substance created by naturally occurring biological processes? (From 7 U.S.C. § 6502 (21).)

The petitioned substance is created by a chemical processes. Combination of sodium chlorite solution and acid results in partial conversion of chlorite to chlorous acid, which is the main active ingredient of ASC solution. Chlorous acid breaks down to form chlorate ion, chlorine dioxide, and chloride ion. The level of chlorous acid depends on the hydrogen ion concentration (i.e. pH) of the ASC solution. The hydrogen ion source for an ASC solution can be any food-grade, GRAS, acid. The quantity of GRAS acid required to achieve the appropriate pH (and level of chlorous acid) will depend upon the strength of the acid, the buffering capacity of the solution itself and, to a lesser extent, the alkalinity of the water used in the formulation. Weaker acid is needed in the approximate 0.20% to 1.20% concentration, while a stronger acid, such as phosphoric acid, is needed at approximate 0.04% to 0.10% concentration (FSANZ, 2003). Among the different applications, the highest concentration of chlorous acid is attained at a pH of 2.3 in 1200 ppm ASC solution. At a pH of 2.3, 2.9, and 3.2, approximately 31%, 10%, and 6% of chlorite (from sodium chlorite) are converted to chlorous acid, respectively (Rao, 2007).

Evaluation Question #4: Is there a natural source of the petitioned substance? (From 7 CFR § 205.600 (b) (1).)

There is no published literature to indicate that a natural source of ASC solution is available. ASC solution is prepared just prior to use because of its unstable natural. Once sodium chlorite solution and acid are mixed, the resulting solution is applied within one to two minutes (Rao, 2007).

Evaluation Question #5: Is there an organic agricultural product that could be substituted for the petitioned substance? (From 7 CFR § 205.600 (b) (1).)

There is no information available to suggest that an organic agricultural commodity or product could be substituted for the petitioned substance, ASC solution. However, on the NOP National List, there are some synthetic substances allowed, as disinfectant and sanitizer for using on food contact surfaces, listed under the 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))".

For example, peracetic acid, listed under 7 CFR §205.605(b), can be substituted for the ASC. Peracetic acid is a mixture of acetic acid and hydrogen peroxide. It is a very strong oxidizing agent and has a strong pungent acetic acid odor. The primary mode of action is oxidation the same as ASC. In addition, peracetic acid is considered environmentally safe. (For additional information, please see the NOP petitioned substances database.)

Evaluation Question #6: Are there adverse effects on the environment from the petitioned substance's manufacture, use, or disposal? (From 7 CFR § 205.600 (b) (2).)

ASC is manufactured by addition of acid (e.g. citric acid) to an aqueous solution of sodium chlorite. The indoor uses of sodium chlorite will not result in exposure to the environment (RED, Case 4023). ASC solution, once mixed, results in a chemical equilibrium containing chlorous acid, chlorite, and acid. During the antimicrobial process upon contact of ASC with the food surface, chloride is ultimately produced. Chloride is a normal constituent of all living organisms and waters; it is not expected to represent an environmental impact at the expected concentrations (SCHER et al., 2008).

FDA Environmental Review Group (ERG) have examined uses of ASC in poultry processing, fruit and vegetable processing, and for red meat and meat processing in Food Contact Notification 450, 644, 645, and 739. These reviews all indicate that the expected environmental concentrations of ASC will be lower than the lowest toxicity endpoints currently available due to the chemical degradation of chlorous acid to chloride (White, 2006).

Evaluation Question #7: Does the petitioned substance have an adverse effect on human health as defined by applicable Federal regulations? (From 7 CFR § 205.600 (b) (3).)

ASC solution is prepared prior to use by combining citric acid with sodium chlorite solution. According to the MSDSs submitted from the petitioner, citric acid is an irritant of the skin, eyes, and respiratory track; sodium chlorite solution is corrosive to skin, eyes, and respiratory systems. Sodium chlorite solution may cause burns to mouth, throat, and stomach, if it were swallowed.

Acidification of sodium chlorite results in conversion of chlorite to metastable chlorous acid, which can subsequently form a mixture with chlorite, chlorine dioxide, and chloride. Chlorous acid, the main active ingredient, is consumed by reacting with microorganisms and other organic matter found on the surface of the treated food and ultimately generated chloride. Chlorite that does not form chlorous acid may remain as chlorite ion in solution, or may react with water to produce chlorate. Chlorate is subsequently reduced to chloride, which is the major residue component of ASC solutions and appears toxicologically inert. Moreover, chloride occurs endogenously under normal physiological conditions in human body water (Rao, 2007). Chlorine dioxide appears extremely volatile and would be expected to evaporate from the food surface quickly. The toxicological impact of any chlorine dioxide generated in an ASC solution is minimal to the overall effects and/or final measurable concentrations of chlorite, chlorate, or chloride (FSANZ, 2003).

Evaluation Question #8: Is the nutritional quality of the food maintained when the petitioned substance is used? (From 7 CFR § 205.600 (b) (3).)

ASC is applied onto the surfaces of the food at low levels. The predominant chemical residue from the ASC solution is chloride. Chlorine dioxide can form in solution. However, chlorine dioxide is very volatile and is lost by evaporation or reduction to chlorite by oxidation of organic matter (e.g. bacteria). Consequently, it is not present as a residue of the treated food product. Moreover, if ASC is used according to good manufacturing practice (GMP), no residues of any of the oxy-chlorine species (e.g. chlorine dioxide, chlorite, and chlorate) should remain on the sprayed or dipped food product.

A number of studies (Rao, 2007) were performed and shown that no differences were identified in the amino acid and fatty acid distribution of ASC-treated poultry carcasses in comparison to untreated samples. The fatty acid profiles of ASC-treated red meat, seafood, and fish, also were comparable to untreated controls. The report concluded that no evidence of either oxidized or chlorinated organic residues, including lipids or amino acids and proteins, was found. In addition, a research conducted by Ruiz-Crus et al. demonstrated that shredded carrots sanitized with ASC retained higher levels of sugars, carotene, and antioxidant capacity.

Evaluation Question #9: Is the petitioned substance to be used primarily as a preservative? (From 7 CFR § 205.600 (b) (4).)

The petition request is to permit the use of ASC solution as a processing aid in organic handling. Its intended uses are for (a) direct food contact (secondary direct food additive) ─ poultry carcass, organs and parts; red meat carcass, organs and parts, seafood (finfish and crustaceans), and fruits and vegetables (raw and further processed); processed, comminuted or formed meat product; and (b) indirect direct food contact ─ hard surface food contact sanitization. There is no published information to suggest that the petitioned substance is being used primarily as a preservative.

Evaluation Question #10: Is the petitioned substance to be used primarily to recreate or improve flavors, colors, textures, or nutritive values lost in processing (except when required by law, e.g., vitamin D in milk)? (From 7 CFR § 205.600 (b) (4).)

There is no information to indicate that the petitioned substance is used to recreate or improve flavors, colors, textures, or nutritive values lost in processing. The petition request is to permit the use of ASC solution as a processing aid in wash and/or rinse water for direct food contact and indirect food contact.

Evaluation Question #11: Is the petitioned substance generally recognized as safe (GRAS) when used according to FDA's good manufacturing practices? (From 7 CFR § 205.600 (b) (5).)

The ASC solution is not listed as generally recognized as safe (GRAS). However, both sodium chlorite and citric acid, which are the components used in preparation of ASC solution, are approved by FDA as GRAS. In addition, both sodium chlorite and citric acid are listed under indirect and direct food substances affirmed as GRAS in 21 CFR §186.1750 and 21 CFR §184.1033, respectively.

Evaluation Question #12: Does the petitioned substance contain residues of heavy metals or other contaminants in excess of FDA tolerances? (From 7 CFR § 205.600 (b) (5).)47

Since ASC is a mixture of sodium chlorite solution and citric acid, any impurities in the resulting ASC solution are expected from both components. Currently there are no set purity criteria for ASC (Rao, 2007).

Sodium chlorite solution is commonly prepared by using technical-grade of sodium chlorite solid, which is comprised of 80% sodium chlorite, with sodium chloride, sodium carbonate, sodium hydroxide, sodium sulfate, and sodium chlorate making up the remainder of the compositions. In general, the manufacturing process employed in the production of sodium chlorite does not include any specific purification steps. Heavy metal, lead, may occur in the final product as a result of their occurrence in the starting material that are obtained from natural sources. Lead must be limited by the specifications indicating maximum levels of 5 mg/kg (Rao, 2007). In addition, the citric acid used to acidify sodium chloride solution must meet FDA specifications of its identity and purity.

There is no other published information to suggest that other heavy metals or contaminants may or may not be present in the petitioned substance.

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