

§171.1(c)(H) ENVIRONMENTAL ASSESSMENT

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4.0 DESCRIPTION OF THE PROPOSED ACTION

4.1 REQUEST APPROVAL

Approval is requested for the use of acidified sodium chlorite (ASC) solutions for the processing of excised, external poultry parts to reduce the numbers of pathogenic microorganisms on their surfaces. Alcide's prior related FAP 4A4433 and FAP 8A459 1, and the resulting modifications of 21 CFR § 173.325, which regulation covers the use of acidified sodium chlorite solutions during the processing of whole poultry carcasses for a similar purpose. The present petition relates to alternate processing options, *i.e.*, the removal and disinfection of whole poultry parts, such as necks, wings, and legs, either (a) prior to chilling of the parts, or (b) during the chilling of the parts. In all cases of the petitioned alternate uses of the ASC solutions, neither the poultry carcasses nor the external parts thereof will have sustained, or will sustain a previous, or subsequent exposure to the disinfecting ASC solution. Thus, as a result of these alternate treatment options, no additional quantities of ASC solutions **will** be introduced into the environment of a poultry processing facility above those initially projected in the FAP's supporting the current CFR regulation, § 173.325.

There are two components used to create these solutions, the food-grade acid and the sodium chlorite. The ASC solutions will be produced and used at one of two different stages of the poultry processing operation, (a) immediately following the evisceration stage, **after** removal of the external parts (e.g., legs, wings, necks) and application thereto, or (b) as a component of chiller waters, to reduce the temperature of the excised poultry parts and eliminate pathogenic and spoilage organisms on their surfaces and/or resulting from contamination by the cooling waters. When the solutions are applied to the parts before they enter a chiller bath, the sodium chlorite concentrations will be in the 500 to 1200 parts per million (**ppm**) range, and adjusted to **pH** 2.3 to 2.9 with a GRAS acid. When used in chiller water solutions, the sodium chlorite will be in the 50 to 150 ppm concentration range, at a **pH** from 2.8 to 3.2. These concentrations and **pH**'s are identical with the current regulated uses of acidified sodium chlorite solutions, under 21CFR § 173.325, for processing of whole

poultry carcasses, either as **prechiller** or chiller applications.

A) **Pre-Dip or Spray Application**

For this use of the ASC antimicrobial system, the liquid formulation is created and applied to the intact, excised external poultry parts following passage of the carcass through the evisceration operation and subsequent excision of the parts. The application may be made by either spraying the parts, for example in a suitable wire mesh container, or by their immersion in a dip tank containing the treatment liquid. In the case of a spray application, the acidified chlorite solution may be applied from a sprayer in which (a) two streams of the chlorite and the acid solutions are mixed at, or immediately before, the spray nozzle, or (b) a single stream of acidified chlorite is directed to the spray nozzle from a premixed solution. The latter may be prepared up to 8-hours prior to spraying, preferably in cold water, so long as the chlorite and acid levels have been analytically determined to be within acceptable levels. Following application of the ASC treatment, the parts are directed to a chilling bath containing no ASC solution.

B) **Application**

For this use of the ASC system, the liquid formulation is created by individual introduction of the chlorite and the acid into the chiller tank, which contains waters at temperatures of $\leq 40^{\circ}\text{F}$ ($\sim \leq 5^{\circ}\text{C}$). The excised poultry parts, in an suitable container, are generally moved through the chilling waters by mechanical means, in a direction countercurrent to the movement of fresh water being introduced at the opposite end of the tank. The residence time in the chiller tank will depend on the size and quantity of the parts exposed; the purpose of the chiller being to reduce tissue temperatures so as to minimize tissue degradation. The sodium chlorite and

acid components are added independently, in order to achieve optimum levels of both materials in the chiller waters. Additional factors which influence the level and rate of degradation of the chlorite in the tank waters include the amount of organic matter, the **pH** of the waters and the temperature. Factors which determine the level and rate of consumption of the acidifier are the alkalinity of the water, the alkalinity associated with the technical grade sodium chlorite, and the rate of consumption of the chlorite (specifically the chlorous acid formed therefrom).

4.2 NEED FOR THE ACTION

Supplementing the approval of ASC solutions for whole carcass poultry processing, under 21 CFR §173.325, the petitioned ASC applications are intended to further supplant the currently-used, USDA-approved chlorine disinfectant, which can form undesirable, mutagenic chloroorganic compounds by reaction with poultry components in the processing waters. The formation of such mutagens has been associated with the use of chlorine in water disinfection generally, and specifically in chlorinated poultry chiller waters'. The author of this paper refers to six other technical publications where the chlorination of waters containing organic materials has been shown to result in the production of mutagenic substances. Because of the great reactivity of chlorine with the many organic substances that are present in poultry processing waters, the treatment of such waters requires relatively high levels of chlorine to effectively control their microbial populations. The organic material in poultry chiller waters contains lipids, proteins and related substances, and exists in both dissolved and dispersed particular forms. Filtration of the particles will **lower** the chlorine demand, but the soluble **organics** are a major source of this chlorine consumption.

Even with the use of chlorine in such waters, at levels up to 50 parts per million, the fact still remains that the use of the chlorine disinfectant has not been totally sufficient to reduce the number of pathogenic microbes on processed poultry carcasses, including external parts such as necks, wings, and legs, to a safe level. The percentage of birds

contaminated with Salmonella after processing has changed (reduced) significantly in recent years but still remains at concern with respect to food safety. Similar arguments can be made for other pathogens, such as *Campylobacter* and *Listeria* spp. also present in poultry.

In comparison the oxychlorine compounds, such as those associated with acidified chlorite systems, have been found to produce minimal levels of chlorinated organic substances*, and this has been the motivation for replacing chlorine in drinking water disinfection with alternate **antimicrobials**. The latter include chlorine dioxide, an **oxychlorine** material closely-related to the acidified chlorite being petitioned for use herein. Robinson³ *et al.* in 1981 treated poultry with chlorine dioxide and found very low concentrations of chloroform (<20 parts per billion) in the tissues, with the small amounts present presumably resulting from the use of chlorine (hypochlorite) that was used to generate the ClO₂. Chloroform is a recognized carcinogen in rats, so its presence in foods is of significant concern.

The importance of the replacement of chlorine with acidified chlorite solutions can be put into proper perspective by considering the following: Approximately 7.5 billion broiler chickens and 200 million turkeys are raised in the United States annually. The United States Department of Agriculture (USDA) has developed comprehensive guidelines for processing these poultry to ensure their wholesomeness and quality. One requirement is that carcasses must be cooled to 4.4°C (40°F) or lower, in a defined limit of time which depends on the weight of the carcass. The cooling is generally accomplished by immersing the carcasses in cold water in long flow-through tanks (chillers). The buildup of microbial populations and solids is minimized by maintaining a low temperature and a controlled overflow of 1/2-gallon (1.89 liters) of water per chicken, or 1-gallon (3.78 liters) of water per turkey. This water is eventually returned to the environment, either *via* company-owned holding and treatment facilities or by treatment and disposal in municipal water purification operations. In both cases the treated waters must meet specific standards in the company's discharge permits.

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Without reuse of this water (to be discussed later), the quantity of **overflow water** from chicken and turkey chillers amounts to 2.7 billion gallons annually. This is but a small part of the total water (generally chlorinated) that is consumed in the many other operations of poultry processing (e.g., scalding, evisceration, washing of carcasses and contact surfaces). In fact it is estimated that *ca.* 5 gallons of water are used for each chicken processed, of which 0.5 gallons is consumed in the chilling operation. Approximately **one-half** of that water is chlorinated to some degree. Proportionate quantities of water are used for processing the other varieties of poultry, *i.e.*, turkeys, ducks and geese. Turkeys represent one-quarter of the quantity (by weight) of chickens consumed in the United States, and the remaining fowl are about one-fifth of that.

There has been an increasing interest in the reuse of poultry processing waters because of the large amounts of potable water presently consumed, particularly processing waters that have been cooled or heated (because of the additional energy savings involved). Both filtration and chemical treatment (e.g., chlorination) have been evaluated as means of controlling microbial populations in order to reuse poultry processing waters. The Food Safety and Inspection Service (FSIS) of the USDA permits (9CFR §38.1.66 March 13, 1984) the use of reconditioned waters that achieve at least a 60% reduction in total microorganisms and a light transmission $\geq 60\%$ of the fresh water supply. Despite this allowance, the use of reprocessed poultry waters is quite limited at the present time.

4.3 LOCATIONS WHERE PRODUCTS WILL BE PRODUCED

The compositions and the two components of the ASC solutions already approved under 21 CFR § 173.325 for poultry processing waters are identical with those now proposed for expanded application to excised, external poultry parts; i.e., the sodium chlorite and the acidifier required to achieve the desired pH. The acidifier will be any one of a variety of FDA-approved GRAS acids, including phosphoric, sulfuric, **malic** and citric. These are all materials of very high volume usage, and of many current diverse applications, and their projected volumes of use as an activator of sodium chlorite are much below a fractional

percentage of the other applications. Thus the sites of production of these different acids is not considered relevant to this environmental assessment.

Sodium chlorite is currently being used as a ClO_2 source in water treatment, as well as an industrial bleaching agent in a number of industries (primarily pulp and paper), in cleaning applications for the **electronics** industry, as a biocide in the food processing industry, and in various applications in the oil industry. The size of the North American market in 1992 was 18 million lb. per year, and with a demand for chlorite growing (at the expense of chlorine) at a rate of 8% to 9% per year, reached approximately 25 million lb. per year by 1996^(a). The major production source has been Olin Chemical's 13.5 million lb. per year Niagara Falls manufacturing site. It is marketed by Vulcan Chemicals, Birmingham, Alabama. Vulcan's new 18 million lb. per year facility in Wichita, Kansas will result in the closing of the Niagara Falls plant. Sterling Chemicals, of Houston, Texas has acquired Tenneco's production facility in Richmond, Virginia, to add to its 8 million lb. per year sodium chlorite manufacturing plant in Buckingham, Quebec. Foreign production sites for sodium chlorite, which may be accessed if quality and economics are appropriate, include that of France's Atochem, S.A., the world's largest producer, and Energia Industrias Aragonesas, Madrid, Spain.

4.4 LOCATIONS WHERE THE PRODUCTS WILL BE USED

Once the pending FAP is accepted as a modification of the current regulation, the ASC antimicrobial solution will become available to all poultry processors, an increasing number of which are now carrying out whole carcass disinfection with the ASC solutions (*ca.* 6% of all US plants, as of this writing). A generalized overview of poultry processing sites can be obtained by reference to the article appearing in Broiler Industry, which provided a year-end industry report for 1990, and which has not changed appreciably since that time. Of the 54 U.S. broiler companies surveyed, the range of percentages of total

(a) Resurgence in Demand Reviving Market for Sodium Chlorite", in Chemical and Engineering News, p. 11,12
March 22, 1993.

production was from 20.0% (for No. 1 ranked Tyson Foods, Inc.) to 0.10% (for No. 54 ranking). The following survey data (for year 1990) may be useful in identifying where the ASC antimicrobial solutions will find application.

- The largest four companies had 41.2% of the volume; this was accomplished in 58 primary processing plants.
- The largest eight companies had 56.6% of the volume; this was accomplished in 80 primary processing plants.
- The largest 20 companies had 79.3% of the volume; this was accomplished in 127 processing plants.

The names, and base of operation of the 20 largest broiler processors are provided below. These locations are generally central to the varying processing plants of the companies.

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|-----|--|------------------------|
| 1) | Tyson Foods, Inc. | Springdale, Arkansas |
| 2) | ConAgra, Inc. | Omaha, Nebraska |
| 3) | Gold Kist, Inc. | Atlanta, Georgia |
| 4) | Perdue Farms, Inc. | Salisbury, Maryland |
| 5) | Pilgrims's Pride Corp. | Pittsburgh, Texas |
| 6) | Wayne Poultry Divn.
Continental Grain, Inc. | Duluth, Georgia |
| 7) | Hudson Foods, Inc. | Rogers, Arkansas |
| 8) | Seaboard Farms, Inc. | Bogart, Georgia |
| 9) | Townsend's, Inc. | Millsboro, Delaware |
| 10) | Foster Farms, | Livingston, California |
| 11) | Showell Farms, Inc. | Showell, Maryland |
| 12) | Fieldale Farms, Inc. | Baldwin, Georgia |

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|-----|--------------------------------|---------------------------------|
| 13) | Wampler-Longacre Chicken, Inc. | Hinton , Virginia |
| 14) | Allen Family Foods, Inc. | Seafood, Delaware |
| 15) | McCarty Farms, Inc. | Magee , Mississippi |
| 16) | Cagle's Inc. | Atlanta, Georgia |
| 17) | Simmons Industries, Inc. | Siloam Springs, Arkansas |
| 18) | Herider Farms, Inc. | Camden, New Jersey |
| 19) | Sanderson Farms, Inc. | Laurel, Mississippi |
| 20) | B. C. Rogers, Inc. | Morton, Mississippi |

Turkey processors are located in the same general areas as the chicken processors, and often are components of the above companies. For example, Conagra (#2), Foster Farms (#10), Wampler-Longacre (#13) and Simmons Industries (#17) have significant turkey processing facilities. It is anticipated that a disproportionately large share of turkey processors will be opting for use of the ASC solutions on excised, external poultry parts, rather than applying them to the **full** carcasses. To the extent that such application will be made to excised, pre-chiller turkey parts rather than to the **full** carcasses, such use would lower the anticipated ASC volume of use as originally projected in Alcide's initial FAP for ASC solutions in poultry processing.

5. IDENTIFICATION OF CHEMICAL SUBSTANCES THAT ARE SUBJECT OF THE PROPOSED ACTION:

5.1 CHEMICAL NAMES AND PHYSICAL PROPERTIES

5.1.1 Sodium Chlorite

CAS Reg. No.: 7758-19-2
Color (37% Solution) Colorless to light green
Specific Gravity: 1 . 2 1
Viscosity (@25°C): 1.62 cps
pH: 12.33

5.1.2 Acidifiers (GRAS) (representative)

Phosphoric Acid-

CAS Reg. No.: 7664-38-2
Conforms with 21CFR § 182.1073 as a Multiple Purpose-GRAS Food Substance

Citric Acid

CAS Reg. No.: 77-92-9 (anhydrous)
5949-29-1 (monohydrate)
Conforms with 21CFR § 182.1033 as a Multiple Purpose GRAS Food Substance

Hydrochloric Acid

CAS Reg. No.: 7647-0 1-0
Conforms with 21 CFR § 182.1057 as Multiple Purpose **GRAS** Food Substance

Malic Acid

CAS Reg. No.: 617-48-1 DL mixture
97-67-6 L isomer

Conforms with 21CFR §184.1069 as a Specific Substance Affirmed as GRAS, with respect to the following l/k-

- (a) description
- (b)** specifications
- (c) use as **pH** control agent
- (d) maximum use level

Sulfuric Acid

CAS Reg. No.: 7664-93-9

Conforms with 21CFR § 184.1095 as a Specific Substance Affirmed as GRAS, with respect to the following ¶s-

- (a) description
- (b) specifications
- (c) use as **pH** control agent
- (d) maximum use level

The subject of this food additive petition (FAR) is the system comprised of aqueous ASC solutions for use as an antimicrobial agent to reduce pathogenic microorganisms on the surfaces of excised, external poultry parts during processing. The composition and concentration of the system depends on the mode and site of application of the antimicrobial formulation during the procession operation (*i.e.*, **prechiller** spray or dip, chill-tank immersion). The germicidal activity of this antimicrobial system derives from the degradation of chlorous acid (HClO₂) [CAS No. 13898-47-O] which will form as a predictable fraction of the total chlorite species (ClO₂⁻) in the solution. The degree to which chlorous acid forms will depend on the hydrogen ion concentration (*i.e.*, **pH**) in the solution.

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Chlorous acid, an unstable material, can exist in equilibrium with the chlorite ion in aqueous systems with a stability proportionate to its total concentration; the lower the concentration the slower the rate of degradation.

Chlorous acid has a **pKa** of 1.1×10^{-2} , and from this constant the relative amount of chlorous acid can be calculated for the **pH** range of intended application of this acidified sodium chlorite system (2.3 – 3.2), as follows:

<u>pH</u>	<u>% Chlorite as HClO₂</u>
2.3	32.0
2.4	27.0
2.5	22.2
2.6	18.1
2.7	15.0
2.8	12.3
2.9	10.0
3.0	8.5
3.1	7.0
3.2	5.6

The ability to provide sustained antimicrobial activity based on the presence of chlorous acid relies on the presence of reservoirs of chlorite and hydrogen ions in the solution. As the chlorous acid is consumed, through interaction with microorganisms and certain other organic matter in solution, re-equilibration will occur to produce more of the **acidic** chlorous acid. As chlorous acid degrades it produces a series of transient oxidants, including hypochlorous acid and **dichlorine** dioxide; and ultimately chlorine dioxide (ClO₂)[10049-04-4] if the intermediates are not consumed through a **redox** interaction with such materials as microorganisms. The ClO₂ that forms may further combine with free chlorite (ClO₂⁻) to form the **acidic** oxidant Cl₂O₄.

The $[H^+]$ ion source can be any **protic** acid which, for this application, must be a GRAS material. Three such acids, covering a range of strengths, are sulfuric acid [7664-93-9], phosphoric acid [7664-38-2] and citric acid [77-92-9], although these are representative rather than restrictive of the GRAS acids which may be employed as suitable acidifiers of the chlorite ion.

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6.0 INTRODUCTION OF SUBSTANCES INTO THE ENVIRONMENT

6.1 PRODUCTION RELEASES

As noted above in Format Section 4, the acidified sodium chlorite solution will be produced on site in the poultry processing plant. This will be either immediately prior to chilling as a spray or dip application to the still-warm carcasses, or during separate addition of the chlorite and acid concentrates to the chiller tank. In both cases the introduction of the two concentrates will be into cool tap water, where the acidified chlorite will not create levels of free chlorine dioxide that are expected to exceed ca. 1 ppm. No other substances will be formed, at the production stage, that can enter the environment.

6.2 USE RELEASES

The key areas of potential concern are listed as follows:

WATER AND AIR RELEASES

6.2.1 The components of the acidified **chlorite/chlorous** acid solution are the GRAS acid, of high purity, and the sodium chlorite (of a technical grade) which has sodium chloride and sodium chlorate as significant impurities. Upon acidification the chlorite, through chlorous acid, will slightly transform to chlorine dioxide and chlorate. At the level of use of these components, the amount of chlorine dioxide formed will not immediately exceed *ca.* 1 ppm and, being a highly reactive compound, will be quickly reduced by reaction with organic matter and microorganisms, either on the carcass parts or in the chiller waters. The reduction will be to even smaller quantities of chlorite and chloride ions, with an even lesser amount of chlorate being formed.

When the acidified sodium chlorite solution is used as a prior-to-chilling application, the residual liquid on the carcass that is then carried into the chiller, **will** be $\leq \frac{1}{2}$ oz. Since the water:carcass ratio in the chiller is set at $\frac{1}{2}$ gallon (64 **oz.)/bird**, the carry-over chlorite solution will be diluted by a factor of 128 upon entering the chiller. To simplify the following discussion, consider the following. The maximum level of chlorite petitioned for pre-chiller application is 895 ppm (as the chlorite ion); that for the chiller is 112 ppm as chlorite ion. Since the pre-chiller application **will** be immediately diluted 128 fold, *i.e.*, **from** 895 ppm chlorite to 7 ppm, which **is** less than the maximum 112 ppm in the chiller, subsequent considerations of **water** releases will be **confined** to the more-conservative chiller tank usage.

As the initially-introduced chlorite remains in, and moves with the chiller water to the exit end of the chiller tank, it is (conservatively) estimated that its level drops to approximately half its original value, both through reaction (in its **chlorous** acid form) and by **dilution** with make-up water. The chlorite reduces primarily to chloride, but some chlorate may be expected.

An estimate of the amount of chlorate which may be present, can be obtained from the following. The technical grade sodium chlorite, containing *ca.* 80%; pure material, will have no more than 4% sodium chlorate. The ratio of chlorite to chlorate ion initially, therefore, will be ≥ 20 : 1. A final estimate of chlorate in the solution can be obtained **from** the residue data provided in page 141 of the petition, where carcass rinsings of birds immersed for one hour in a simulated chiller and then removed for one hour showed an average 0.54 ppm of chlorite and **<0.0** 19 ppm of chlorite (a ratio; 128: 1). Based on these considerations, a summary of the maximum levels of oxychlorine species in the chiller water, at the exit of the tank, is as follows:

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Chlorite ion:	56 ppm
Chlorate ion:	≤2 ppm
Chlorine dioxide:	≤1 ppm

Chloride ion is of no consequence, it being a small fraction (*ca.* 0.1) of the original chlorite, and a larger molar fraction (*ca.* ½) of the reacted chlorite (reduced by its lower weight ratio [35.5/67.5] to *ca.* 1/4 of the reacted chlorite on a weight basis).

The levels of acid used to achieve the requisite initial **pH's** of 2.5 - 3.2 (for both pre-chiller spray and chiller treatment), for some of the representative acids listed earlier in the FAP, are as follows:

Sulfuric acid-	10.005%	(≤50 ppm)
Phosphoric acid-	0.01 - 0.02%	(≤100 - 200 ppm)
Malic acid-	0.02 - 0.04%	(≤200 - 400 ppm)

As in the case of the chlorite in the pre-chiller spray application, a dilution of the acid volume from *ca.* L/-ounce to 1/8 gallon per carcass reduces the acidity it might contribute to the chiller tank to levels markedly below those required for addition for chlorite acidification therein.

Levels of materials in releases:

6.2.1.a **Water Releases**

The “worst case” concentrations of chlorite, chlorate and chlorine dioxide discharged to Publicly Owned Treatment Works (**POTWs**), from treatment of chiller water with acidified **chlorite/chlorous acid**, can be approximated from the estimate that 10% of the total water discharged from

a poultry processing plant is chiller water^(b). Thus, the levels of chlorite, chlorate and chlorine dioxide entering the POTWs from chiller water use, based on the figures shown in the previous section, are:

chlorite-	5.6 ppm
chlorate-	≤0.2 ppm
chlorine dioxide-	10.1 ppm

In a “worse case” scenario when these species derive only from use in a pre-chiller carcass application, they would be 1/16 of the above levels (i.e., [7 ppm/112 ppm maximum chlorite;] from the 128-fold dilution in chiller water), i.e.,

chlorite-	350 ppb
chlorate-	≤12.5 ppb
chlorine dioxide-	≤6.3 ppb

The latter is the primary intended mode of application of the acidified sodium chlorite treatment, consistent with the recent requirements of the USDA’s Food Safety and Inspection Service (FSIS)^(c) for the use of at least one antimicrobial treatment of the poultry carcass prior to chilling.

With respect to the “worst-case” discharge of food-grade acidifiers; using the 10% factor relating chiller water to total water discharge, the figures for the representative acids shown earlier reduce to the following maxima:

(b) Observations in typical poultry processing plants.

(c) Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems- Federal Register, Vol. 60, No. 23 1995-02-03

sulfuric acid-	5 ppm
phosphoric acid-	20 ppm
malic acid-	40 ppm

Again, for pre-chiller application only, these figures would be significantly lower.

The contribution of industrial discharges to POTWs is further diluted by discharges **from** non-industrial sources. An approximation of the **further** dilution by these other sources **can** be made **from** information made available in an EPA- sponsored study by Consulting Engineers⁴ of discharge sources which have a negative impact on the operation of POTWs. The POTWs studied included a representative cross-section of U.S. municipal treatment facilities serving industrial and non-commercial dischargers. In the 29 Case Study Reports provided in the survey, 26.3% of the **influent** wastewater to these facilities derived **from** industrial sources.

A single industrial discharge source to a particular **POTW**, such as a poultry processing plant, can be conservatively estimated to represent an upper limit of 50% of the total industrial discharge to a single POTW. Thus a water flow percentage contributed by a single poultry processor to a POTW is 26.3% x **50%**, or 13.2% of the total water processed. On that basis the maximum approximate chlorite, chlorate and chlorine dioxide levels which enter an average POTW would be:

chlorite;	5.6 ppm x 13.2% = 739 ppb
chlorate;	≤ 0.2 ppm x 13.2% = ≤ 26 ppb
chlorine dioxide,	≤ 0.1 ppm x 13.2% = 113 ppb

For pre-chiller treatment, the anticipated major application of acidified **chlorite/chlorous** acid solutions, the levels would be:

chlorite;	4.6 ppb
chlorate;	11.6 ppb
chlorine dioxide;	≤0.8 ppb

For the representative food grade acids, the figures are:

sulfuric acid;	0.66 ppm
phosphoric acid;	2.64 ppm
malic acid;	5.28 ppm

Alcide Corporation does not believe that the above-indicated concentrations of oxychlorine species or food acids will have a negative impact on the operation of **POTWs**, for the following reasons:

- 1) Neither chlorite, chlorate nor chlorine dioxide is listed as an Interfering Substance in **POTWs**, as provided in Appendix A (Page 125) of the **Wetzel** document. These interfering substances, as contained in certain industrial discharges, can cause “a **POTW's** noncompliance with its permit or inability to lawfully use or dispose of its sludge.” Chloride was listed as a potentially interfering substance, but at a level significantly higher (180 ppm) than its presence either as an impurity in the technical grade chlorite or if all the oxychlorines were converted to chloride. Acidity is also listed as a potential interference in **POTW** operation, but the levels contributed by this application would not have a measurable impact on **pH**.

- 2) None of the species present at the levels indicated can interfere with the microbiological treatment systems. Chlorine dioxide, a recognized antimicrobial, will have no effect at the maximum ppb levels calculated; neither can the chlorite, a much weaker source of activity, at the 0.35 ppm calculated.
- 3) “(M)ost interference problems at **POTWs** are related to intermittent discharges of high-strength conventional wastes which overload a **POTW's** organic capacity, causing plant upset,” according to an **EPA reporter**⁵. The organic contribution of these systems is minimal, and the other common causes of plant interference are not a factor here:

low pH [corrosion]
 solids or viscous **pollutants**.....[flow obstruction]
 high volatiles [explosion or fire hazard]
 heated discharges [altered biological activity]
 toxic discharges [inhibited biological activity]

6.2.1.b Air Releases

The only volatile material resulting from the use of the acidified sodium chlorite solutions is chlorine dioxide, which exists at a level of ≤ 1 ppm in the treatment media. From partial pressure considerations, and assuming the Ideal Gas Law (see calculations in Addendum I), this would correspond to a maximum equilibrium air level of ca. $\leq 0.044 \text{ mg/M}^3$, or ≤ 0.013 ppm. The OSHA TLV for chlorine dioxide, for continuous 8-hour exposure by a worker, is 0.3 mg/M^3 (0.1 ppm), which significantly exceeds any possible level of chlorine dioxide that could exist in the air of a poultry processing plant employing the acidified chlorite/chlorine dioxide antimicrobial.

6.2.2. RELATION OF PLANT WATER RELEASES TO TOTAL PUBLICLY OWNED TREATMENT WORKS QUANTITIES

The industrial discharges, such as from plants which process the poultry parts, to local Publicly Owned Treatment Works (POTWs) are further diluted by discharges from other industrial as well as from non-industrial sources. The relationship of such plant discharges to total POTW intakes is discussed in Sub-section 6.2 1 .a of Section H. Reference was made to an EPA-sponsored study which provided guidance in minimizing the discharge effects on these POTWs. In that report it was shown that the average **influent** waste water **from** industrial sources was 26.3% of the total intake. That information was used to estimate the projected impact of the poultry-processing facilities using ASC treatments.

Since -50% of the poultry processing used in this country is consumed as parts such as necks, wings, and legs, it **can** be presumed that none of the various facilities which will be using the petitioned ASC solutions will approach the volume usage characteristic of the various primary carcass processors. Thus the subsequent dilution of effluents from down-the-line poultry processors can be expected to result in lower oxychlorine discharges to the POTWs than from those from the carcass processors. If the contribution from a carcass processor to its handling POTW is a maximum 12 parts per billion (**ppb**), the contribution from a down-the-line processor should be less than that. A similar analogy holds for the food-grade acids used for ASC activation, where the acid contribution to POTW facilities would be *de minimus*.

On the **basis** of these discussions, Alcide corporation does not believe that the above-indicated concentrations of oxychlorine species or food acids will have a negative impact on the operation of POTW, for the following reasons:

- a) The levels of oxychlorines, *i.e.*, chlorite, chlorate, and chlorine dioxide, that would reach the **POTW's**, is at the ppb level, at most. Neither chlorite, chlorate nor chlorine dioxide is listed as an Interfering Substance in **POTW's**, as provided in a document listing Interferences at **POTW's**⁴. These interfering substances, as contained in certain industrial discharges, can cause “a **POTW's** noncompliance with its permit or inability to lawfully use or dispose of its sludge.” Acidity is also listed as a potential interference in POTW operation, but the levels contributed by this application would not have a measurable impact on **pH**.
- b) None of the species present at the levels indicated can interfere with the microbiological treatment systems. Chlorine dioxide, a recognized antimicrobial, will have no effect at the calculated ppb level; neither will the chlorite, a much weaker source of activity, at the minuscule levels possibly present.

6.2.3 COMPLIANCE WITH EMISSION REQUIREMENTS

Alcide is not aware of any federal, state or local water or air emission regulations applicable to chlorite, chlorate or chlorine dioxide. Alcide fully anticipates that any poultry processor who intends to use the acidified sodium chlorite solutions will obtain appropriate permits and approvals for discharging process water containing chlorite, chlorate and chlorine dioxide to **POTW's**. It should be noted that sodium chlorite, used in preparation of these solutions, is an **EPA**-registered pesticide product. It is Alcide's current intention to use one of three EPA registered sodium chlorite products for the proposed application (or the equivalent): Vulcan Chemicals' 79% Technical Sodium Chlorite, Technical Sodium Chlorite Solution 3 1.25, and 3 1% Active Sodium Chlorite Solution. Copies of the Labels, Technical Data Sheets and Material Safety Data Sheets for these products are provided in Addendum II. Alcide intends to request that Vulcan Chemicals include

label copy which mandates that users of the sodium chlorite must discharge the solutions in accordance with the requirements of the facility's NPDES permit. Any warning statements on the labels concerning the hazard of the products to organisms that may be exposed to it in the environment will also be on labels for the **FDA-**regulated use.

Alcide has carried out a number of evaluations in pilot and commercial plants of the acidified sodium chlorite solutions for chiller and pre-chiller application, on the basis of which it does not anticipate any compliance problems resulting from the use of these solutions in poultry processing.

6.2.4. COMPLIANCE STATUS

Sodium chlorite has a number of commercial uses, primarily as a source of chlorine dioxide, e.g., pulp and paper bleaching, drinking water treatment, as a **slimicide** in cooling towers, as a food disinfectant, and as a cleaning agent in the electronics industry. The current U.S. production of sodium chlorite is close to 25 million pounds. If all of the 7.0 billion chickens processed in the U.S. per year were to be exposed to the maximum pre-chiller concentration of acidified **chlorite/chlorous** acid treatment, total sodium chlorite consumed would be 0.27 million pounds. Use in the chiller tank would consume greater amounts, but this is considered to be a less-frequent application. On that basis an annual maximum consumption of sodium chlorite for this application is not expected to exceed 0.5 million lbs. This is 2% of the total sodium chlorite consumed annually. Accordingly Alcide does not believe that approval for the proposed use will affect **current compliance** by sodium chlorite producers with environmental regulations.

Use of the food grade acid activators is significantly **less**, of a larger total commercial utilization, and a similar conclusion is drawn for these materials as well.

7.0 FATE OF EMITTED SUBSTANCES IN THE ENVIRONMENT

Sodium chlorite, sodium chlorate and chlorine dioxide released into the environment will likely undergo reduction in contact with organic matter, and/or microbial degradation wherein microorganisms can use the oxychlorines as an oxygen source when present at sublethal levels. Ultimately the oxychlorines will be reduced to the chloride ion, **Cl⁻**.

8.0 ENVIRONMENTAL EFFECTS OF RELEASED SUBSTANCES

8.1 EFFECTS ON AQUATIC ORGANISMS

A variety of studies that have been carried out on the acute toxicity of technical grade sodium chlorite and sodium chlorate to both freshwater and marine species form the base set of data which the U.S. EPA uses for evaluation purposes. Apparently no such data set is available *on* chlorine dioxide. For the latter material, the rapidity of degradation by organic matter and the resulting minimal releases, (as discussed in Section 6), eliminates aquatic toxicity of C 10₂ releases from consideration.

The data show that, for sodium chlorate, the LC₅₀ for 48-96 hour exposure for freshwater and marine fish, the Eastern oyster, shrimp and *Daphnia magna* is consistently >1000 ppm. Sodium chlorate, then, is of no concern since anticipated releases from use of acidified chlorite solutions are ≤26 ppb.

<u>Test</u>	<u>Sodium Chlonte</u>	<u>Sodium Chlorate</u>
Bluegill Sunfish	100 ppm (96 hr LC ₅₀)	>1000 ppm (96 hr LC ₅₀)
Rainbow Trout	41 ppm (96 hr LC ₅₀)	>1000 ppm (96 hr LC ₅₀)
<i>Daphnia magna</i>	161 ppm (48 hr LC ₅₀)	>1000 ppm (48 hr LC ₅₀)
Mysid Shrimp	650 ppm (96 hr LC ₅₀)	> 1000 ppm (96 hr LC ₅₀)
Eastern Oyster	129 ppm (96 hr LC ₅₀)	> 1000 ppm (96 hr LC ₅₀)
Sheepshead Minnow	105 ppm (96 hr LC ₅₀)	> 1000 ppm (96 hr LC ₅₀)

The aquatic toxicity (LC₅₀) of sodium chlorite to the fish and oyster species studies ranged from 41 to 149 ppm, and 650 ppb and 161 ppb to Mysid shrimp and *Daphnia mgna*, resp. Because of the latter toxicity to *Daphnia magna*, the U.S. EPA has determined that sodium chlorite is toxic to fish:

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8.2. EFFECTS ON TERRESTRIAL ORGANISMS

A broad variety of toxicological studies have been carried out on the oxychlorine species chlorite, chlorate and chlorine dioxide, in connection with the worldwide use of chlorine dioxide in the disinfection of potable water. The ClO_2 has been found to produce virtually no chlorinated hydrocarbons as potential mutagens, as does chlorine. On a concentrated basis, the oxychlorines have been found to cause oxidative changes to erythrocytes, both in loss of structural integrity and formation of methemoglobin. However at the ppm levels and below where these materials may be found in poultry plant effluents, the data obtained in connection with drinking water levels of the oxychlorines are more relevant.

On an acute basis, the following is a summation of exposure to high levels of dissolved chlorite and chlorate.

LD₅₀ Values for Chlorite and Chlorate in Mammals*

SPECIES	ROUTE		CHLORITE	CHLORATE
	ORAL	I.P.	----- mg/kg -----	
Mouse	X		350	
		X		596
Rat	X		350	1200
Dog	X			700
Cat	X			1350
Guinea pig	X		300	
Rabbit	X			8000

* - Source of data; TOXNET

With respect to the acute toxicity of chlorine dioxide, an LD₅₀ of 500 ppm was found for 15 minutes air exposure by rats. In man, a 5 ppm level in the air was found to be an irritant to the respiratory and G. I. tracts. Such levels would not be found in poultry

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processing plants, where any sub-ppm levels of **C10₂** formed in the chiller water would be rapidly destroyed by organic matter. With respect to **ingestion** at subacute levels, Bianchine, *et al.*⁶ report on two adults who ingested 250 ml of chlorine dioxide in water containing a concentration of 40 **mg/L** (**≈142 mg/kg** for 70 kg person). Within 5 minutes of ingestion, sudden headache, nausea, abdominal discomfort and lightheadedness occurred, which disappeared after 5 minutes.

For sodium chlorite ingestion at subacute levels, Lubbers, *et al.*⁷ gave 10 male volunteers sodium chlorite in drinking water in two separate phases. In the first phase, subjects drank 1 liter of chlorite-containing water for 6 days, with 2 days intervening between each exposure day. The first day, the concentration of sodium chlorite was 0.01 **mg/L**, and this was increased each exposure day to a **final** concentration of 2.4 **mg/L** (0.034 **mg/kg/day**). Group mean values were determined for 2 days following each exposure for all investigated effects, including many serum chemistries and blood-cell counts as well as ECG analysis and physical examinations. All parameters measured were within normal ranges, and no trends or interactions judged to be of clinical significance were found. In the second phase, 10 volunteers drank 500 ml of water containing 5 **mg/L** sodium chlorite daily for 12 weeks (average 0.034 **mg/kg/day**). Significant (**p<0.05**) group-time interaction was found in the case of group mean corpuscular hemoglobin; however linear regression analysis did not show a significant trend, and the physiological significance of this interaction was doubted. Similar controlled clinical investigations on human volunteers ingesting chlorite or **chlorate**^{7,8}, and subsequent statistical evaluation of the **data**^{9,10} gave similar results.

A recently completed rodent **90-day** study, considered to be the, “most **definitive** and comprehensive study of chlorite undertaken and . . . considered.. . the most relevant basis for risk assessment”” was used, in conjunction with the earlier studies to calculate a NOEL (no observed effect level) for chlorite in drinking water of **5/mg/kg/day**. This corresponds to 350 mg intake for a 70 kg individual. Applying a **100-fold** safety factor, this reduces to a recommended maximum intake of **3.5 mg/day** for that individual. In the same publication a NOEL for chlorate is recommended of **78 mg/kg/day**, which translates to a maximum

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intake of 54.6 mg of chlorate per day for a 70 kg person, including the 100 fold safety factor. For chlorine dioxide, the NOEL of 3.5 **mg/kg/day** is recommended, translating to an intake of 245 mg for the 70 kg individual.

On the basis of the oxidative tendency of these oxychlorine species to be chemically reduced by organic matter in both the poultry chiller waters and subsequent municipal water treatment facilities, the levels of the three oxychlorine species are anticipated to be significantly lower than the levels calculated to be of minimal risk to individuals.

8.3 ENVIRONMENTAL BENEFITS

The use of acidified sodium chlorite systems in poultry processing offers several environmental benefits:

8.3.1. ELIMINATION OF MUTAGENS AND CARCINOGENS

The formation of mutagens and carcinogens by chlorine which is in current use in poultry processing waters has been reviewed in earlier sections of this FAP. Further information on the lack of trihalomethane formation (THM) resulting from the substitution of chlorine dioxide for chlorine in drinking water disinfection (where chlorite and chlorate are created) may also be referred to⁶. Many of the THM's are now acknowledged by the EPA to be **carcinogenic**^(d).

8.3.2. REDUCTION IN AQUATIC TOXICITY

The proposed acidified chlorite solutions are expected to replace or reduce the chlorine currently used in poultry processing. Chlorine, when dissolved in water, converts to hypochlorite, with the following aquatic **toxicity**^(e).

(d) See U.S. EPA's "Proposed Rule for Disinfectants and Disinfectant By-Products: 58 Fed. Reg. Pgs. 38668-38829, July 29, 1994.

(e) See Reregistration Eligibility Document for sodium and Calcium Hypochlorite Salts, February, 1992. NTIS Report No. 540/RS-92-193.

These data indicated that **chlorine/hypochlorite** is much more toxic to both cold and warm freshwater fish than is chlorite or chlorate, and generally slightly more toxic to the *Daphnia magna* invertebrate. When considering that the primary application of the acidified chlorite solution shall be prior to the chiller tank, where the maximum anticipated chlorite in the POTWs will be 46 ppb, the overall effect is that the partial or complete replacement of chlorine in poultry processing should significantly reduce the risk to aquatic species.

9.0 USE OF RESOURCES AND ENERGY

The solutions are intended to replace the currently-used, USDA-approved chlorine disinfectant; consequently, an increase in the energy required to produce our product will be offset by a decrease in energy required for the production of chlorine. No minerals will be used in the preparation or production of the subject additive. Environmental releases of chlorite, chlorate, chlorine dioxide and any of the GRAS acid activators are not expected to adversely affect threatened or endangered species nor impact historic structures.

The bactericidal effectiveness of acidified chlorite solutions are intrinsically greater than chlorine solutions, both of which rely on their oxidative action to destroy microorganisms. The chlorite undergoes a 4-electron change (from Cl^{+3} to Cl^{-1}) during this process, in comparison to chlorine's 1-electron change (Cl^0 to Cl^{-1}) when oxidatively destroying microorganisms. Each chlorite molecule therefore is electronically more efficient as a **cidal** agent than is chlorine (actually 2-times more so as compared with Cl). This effect is parallel to the greater **efficiency** of chlorine dioxide (Cl^{+4} to Cl^{-1}) than chlorine, where the greater oxidizing capacity allows for *ca.* 7-fold lower levels of use of the **oxychlorine**^(f). The studies that have been carried out thus far with the acidified chlorite solutions were directed to achieving more efficient organism kills on poultry carcasses than are currently available with chlorine, where pathogen problems are still very significant^(g). As a result, the (lower) quantities of chlorite that would be needed to reduce microorganism levels to only those attained with chlorine have not been determined. Thus, a direct comparison of chlorite and chlorine parity levels is not possible. However, for the primary intended use of the acidified chlorite solutions as pre-chiller treatments, the maximum levels that would transfer **from** the carcasses to the chiller immediately thereafter would be 7 ppm. This can be compared with the 50 ppm chlorine currently allowed in chillers, and the practical maximum level of *ca.* **20**

(f) "Effect on Broiler Carcasses and Water of Treating Chiller Water with Chlorine or Chlorine Dioxide," Lillard, H.S., Poultry Science, 1980, Vol. 59, pags. 1761-I 766. Levels of Chlorine and Chlorine Dioxide of Equivalent Bactericidal Effect in Poultry Processing Water," Lillard, H.S., Poultry Science, 1979, Vol. 44, pgs. 1594-1597.
(g) Salmonellosis control: Estimated economic costs." Roberts, T., Poultry Science, 1988, Vol. 67, pgs. 936-943. Preliminary Estimates of Costs of Foodborne Disease in the United States," Todd, E.C.D.. J. Food Prot. Vol. 52, pgs. 595-60 1.

ppm (based on odor/irritation problems). With the FDA's recent drive to treat carcasses with an antimicrobial prior to chiller tank immersion, the acidified **chlorites** would minimize or eliminate the use of chlorine in chiller tanks

10.0 MITIGATION MEASURES

No adverse environmental effects are anticipated from residual “worst-case” levels of chlorine dioxide as a result of any aspect of use of the subject additive, if this petition is approved. Therefore, no mitigation measures are required.

11.0 ALTERNATIVES TO PROPOSED ACTION

Inasmuch as no potential adverse environmental effects are expected to occur, no mitigation alternative actions are necessary.

12.0 PREPARER

This Environmental Assessment was prepared by Robert D. Kross, Ph.D. of Kross-Link Laboratories. Dr. Kross has an educational background in physical chemistry, analytical chemistry and physics, and has consulted in the fields of oxychlorine chemistry, food & nutrition, biochemistry, microbiology, toxicology and environmental analysis. He was an intervenor in the siting of the **Shoreham** Nuclear Power Plant of the Long Island Lighting Corporation.

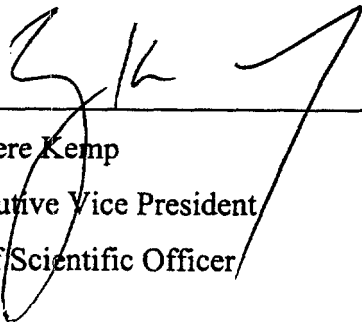
13.0 CERTIFICATION

The undersigned official certifies that the information presented is true, accurate and complete to the best knowledge of the firm.

Date:

November 12, 1999

Signature:



Name:

G. Kere Kemp

Title:

Executive Vice President/
Chief Scientific Officer

14.0 APPENDICES

Appendix 1. Sodium Chlorite Technical Data Sheets and Materials Safety Data Sheets.