Global Lifescience Solutions

An NSF International Company

April 30, 2007

Chem Fresh Inc.
Attn: Karan Khurana
16117 Covello Street
Van Nuys, CA 91406

RE: GRAS Status of Oxcide™ and Oxcide+™

Dear Mr. Khurana,

Chem Fresh Incorporated (hereafter identified as the client) has requested that Global Lifescience Solutions, LLC (hereafter identified as GLS) conduct a regulatory review of their Oxcide™ and Oxcide+™ products (0.05% sodium hypochlorite) to determine whether it is currently approved under an applicable section of 21 CFR for food contact or is the subject of a current GRAS regulation.

Under the Federal Food, Drug and Cosmetic Act and Title 21, Code of Federal Regulations (21 CFR), food additives must be shown to be safe under their intended conditions of use before they can be intentionally added to food. The definition of a food additive as defined by the Federal Food, Drug, and Cosmetic Act is any substance for which the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food unless such substance is generally recognized as safe (GRAS) by qualified experts or is prior sanctioned for its intended end use. A substance may be considered GRAS if it meets the following requirements: there must be general recognition among qualified experts that the particular substance is safe and the basis of the safety determination must be either on publicly available scientific data or the fact that the substance was commonly used in foods prior to January 1, 1958. A list previously affirmed GRAS substances is provided in 21 CFR under Parts 182, 184, and 186. If a substance or its end use is not the subject of a current GRAS regulation under 21 CFR Parts 182, 184, or 186, a

substance can be marketed for a specific use without FDA review and approval, if that substance has been evaluated under the GRAS self affirmation process. The data and information that is used to establish the safety of the specific end use of a potential GRAS substance must be generally available (e.g., through publication in the scientific literature) and there must be a basis to conclude that there is consensus among qualified experts regarding the safety of the substance for its intended use.

If a substance and its specific end use is not affirmed as GRAS, it may be considered a food additive. Under the Act, food additives require premarket approval by the FDA and publication of a regulation authorizing their end use. A food additive may not be legally marketed for the petitioned use until FDA publishes an authorizing regulation. However, if a substance used in a food contact article migrates into food, or is expected to migrate into food, at levels that are below the threshold of regulation (21 CFR 170.39), the substance will be exempted from regulation as a food additive.

Food additives generally fall in one of two categories; those added directly to food, and those added indirectly through the contact with packaging materials, processing equipment, or other contact materials, as codified in 21 CFR Parts 174-178. Additionally, there is a third category of additives that are considered secondary additives, and are codified in 21 CFR Part 173. These are substances that are required during the processing or manufacture of food and are normally removed from the final food product.

Generally, for a new food additive to comply with the Federal Food, Drug and Cosmetic Act the manufacturer must submit a Food Contact Notification (FCN) and/or a Food Additive Petition (FAP). Both indirect food additives and secondary additives require the submission of an FCN, whereas direct food additives require the submission of an FAP. The information used to support a FCN or FAP can include both publicly available data as well as data that is not publicly available.

Authorization of a FAP requires the submission of chemical, technological, toxicological, and environmental data and information. If the petition is filed, the FDA publishes a notice in the Federal Register announcing the filing of the petition. Data and information submitted in a FAP are available for public disclosure once a filing notice for the petition has been published. Once, a petition is filed, FDA has up to 180 days to respond to the petition.

The information contained in the FCN must support the notifier's determination of the food contact substances safety. The FDA has 120 days from the date of receipt of the notification to object and thereby, to prevent marketing of the substance. If the agency does not object to the notification within the 120 days, the substance may be legally marketed for the notified use. Once the notification becomes effective, FDA will include it in a list of effective notifications, which can be found on its Web site at: http://vm.cfsan.fda.gov/dms/opa-fcn.html.

Approved Uses of Sodium Hypochlorite as a Food Additive

Sodium hypochlorite is approved for use as a food additive in a number of sections of 21 CFR. These sections of 21 CFR are provided below.

21 CFR 172.892 Food starch-modified

Food starch-modified as described in this section may be safely used in food. The quantity of any substance employed to effect such modification shall not exceed the amount reasonably required to accomplish the intended physical or technical effect, nor exceed any limitation prescribed. To insure safe use of the food starch-modified, the label of the food additive container shall bear the name of the additive ``food starch-modified" in addition to other information required by the Act. Food starch may be acid-modified by treatment with hydrochloric acid or sulfuric acid or both. Chlorine, as sodium hypochlorite, shall not to exceed 0.0082 pound of chlorine per pound of dry starch. The finished food starch-modified is limited to use only as a component of batter for commercially processed foods.

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21 CFR 178.1010 Sanitizing solutions

Sodium hypochlorite may be used in a sanitizing solution used on food-processing equipment and utensils, and on other food-contact articles when the use of the sanitizing solution is followed by adequate draining, before contact with food.

21 CFR 177.2800 Textiles and textile fibers

Textiles and textile fibers may safely be used as articles or components of articles intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food, subject to the provisions of this section.

21 CFR 173.315 Chemicals used in washing or to assist in the peeling of fruits and vegetables

Sodium hypochlorite may be used in the washing or to assist in the lye peeling of fruits and vegetables.

21 CFR 175.105 Adhesives

Adhesives may be safely used as components of articles intended for use in packaging, transporting, or holding food in accordance with the following prescribed conditions:
The adhesive is either separated from the food by a functional barrier or used subject to the following additional limitations:

(i) In dry foods. The quantity of adhesive that contacts packaged dry food shall not exceed the limits of good manufacturing practice.

(ii) In fatty and aqueous foods. (a) The quantity of adhesive that contacts packaged fatty and aqueous foods shall not exceed the trace amount at seams and at the edge exposure between packaging laminates that may occur within the limits of good manufacturing practice.

(b) Under normal conditions of use the packaging seams or laminates will remain firmly bonded without visible separation.

(b) To assure safe usage of adhesives, the label of the finished adhesive container shall bear the statement ``food-packaging adhesive".

21 CFR 176.170 Components of paper and paperboard in contact with aqueous and fatty foods

Substances identified in this section may be safely used as components of the uncoated or coated food-contact surface of paper and paperboard intended for use in producing, manufacturing, packaging, processing, preparing, treating, packing, transporting, or holding aqueous and fatty foods, subject to the provisions of this section. Components of paper and paperboard in contact with dry food of the type identified under Type VIII of table 1 in paragraph (c) of this section are subject to the provisions of Section 176.180.

21 CFR 173.325 Acidified sodium chlorite solutions

Sodium chlorite is approved for use in food processing facilities for multiple end uses as outlined in 21 CFR 173.325. Although sodium hypochlorite is not specifically listed for use under 21 CFR 173.325, when in solution, sodium chlorite dissociates into sodium hypochlorite and sodium chlorate. Because sodium chlorite dissociates into sodium hypochlorite in solution, 21 CFR 173.325 applies to sodium hypochlorite in addition to sodium chlorite. In an email dated 4/26/2007, the FDA confirmed that sodium hypochlorite would also fall under 21 CFR 173.325 and could be used under the same end use conditions as specified within this section of 21 CFR. These specific end use conditions are specified below.

Acidified sodium chlorite solutions may be safely used in accordance with the following prescribed conditions:

(a) The additive is produced by mixing an aqueous solution of sodium chlorite (CAS Reg. No. 7758-19-2) with any generally recognized as safe (GRAS) acid.

(b)(1) The additive is used as an antimicrobial agent in poultry processing water in accordance with current industry practice under the following conditions:

(i) As a component of a carcass spray or dip solution prior to immersion of the intact carcass in a prechiller or chiller tank;

(ii) In a prechiller or chiller solution for application to the intact carcass;

(iii) As a component of a spray or dip solution for application to poultry carcass parts;

(iv) In a prechiller or chiller solution for application to poultry carcass parts; or

(v) As a component of a post-chill carcass spray or dip solution when applied to poultry meat, organs, or related parts or trim.

(2) When used in a spray or dip solution, the additive is used at levels that result in sodium chlorite concentrations between 500 and 1,200 parts per million (ppm), in combination with any GRAS acid at a level sufficient to achieve a solution pH of 2.3 to 2.9.

(3) When used in a prechiller or chiller solution, the additive is used at levels that result in sodium chlorite concentrations between 50 and 150 ppm, in combination with any GRAS acid at levels sufficient to achieve a solution pH of 2.8 to 3.2.

(c) The additive is used as an antimicrobial agent in accordance with current industry practice in the processing of red meat, red meat parts, and organs as a component of a spray or in the processing of red meat parts and organs as a component of a dip. Applied as a dip or spray, the additive is used at levels that result in sodium chlorite concentrations between 500 and 1,200 ppm in combination with any GRAS acid at levels sufficient to achieve a solution pH of 2.5 to 2.9.

(d)(1) The additive is used as an antimicrobial agent in water and ice that are used to rinse, wash, thaw, transport, or store seafood in accordance with current industry standards of good manufacturing practice. The additive is produced by mixing an aqueous solution of sodium chlorite with any GRAS acid to achieve a pH in the range of 2.5 to 2.9 and diluting this solution with water to achieve an actual use concentration of 40 to 50 parts per million (ppm) sodium chlorite. Any seafood that is intended to be consumed raw shall be subjected to a potable water rinse prior to consumption.

(2) The additive is used as a single application in processing facilities as an antimicrobial agent to reduce pathogenic bacteria due to cross-contamination during the harvesting, handling, heading, evisceration, butchering, storing, holding, packing, or packaging of finfish and crustaceans; or following the filleting of finfish; in accordance with current industry standards of good manufacturing practice. Applied as a dip or spray, the additive is used at levels that result in

a sodium chlorite concentration of 1,200 ppm, in combination with any GRAS acid at levels sufficient to achieve a pH of 2.3 to 2.9. Treated seafood shall be cooked prior to consumption.

(e) The additive is used as an antimicrobial agent on raw agricultural commodities in the preparing, packing, or holding of the food for commercial purposes, consistent with section 201(q)(1)(B)(i) of the act, and not applied for use under section 201(q)(1)(B)(i)(I), (q)(1)(B)(i)(II), or (q)(1)(B)(i)(III) of the act, in accordance with current industry standards of good manufacturing practice. Applied as a dip or a spray, the additive is used at levels that result in chlorite concentrations of 500 to 1200 parts per million (ppm), in combination with any GRAS acid at levels sufficient to achieve a pH of 2.3 to 2.9. Treatment of the raw agricultural commodities with acidified sodium chlorite solutions shall be followed by a potable water rinse, or by blanching, cooking, or canning.

(f) The additive is used as an antimicrobial agent on processed, comminuted or formed meat food products (unless precluded by standards of identity in 9 CFR part 319) prior to packaging of the food for commercial purposes, in accordance with current industry standards of good manufacturing practice. Applied as a dip or spray, the additive is used at levels that result in sodium chlorite concentrations of 500 to 1200 ppm, in combination with any GRAS acid at levels sufficient to achieve a pH of 2.5 to 2.9.

(g) The additive is used as an antimicrobial agent in the water applied to processed fruits and processed root, tuber, bulb, legume, fruiting (i.e., eggplant, groundcherry, pepino, pepper, tomatillo, and tomato), and cucurbit vegetables in accordance with current industry standards of good manufacturing practices, as a component of a spray or dip solution, provided that such application be followed by a potable water rinse and a 24-hour holding period prior to consumption. However, for processed leafy vegetables (i.e., vegetables other than root, tuber, bulb, legume, fruiting, and cucurbit vegetables) and vegetables in the Brassica [Cole] family, application must be by dip treatment only, and must be preceded by a potable water rinse and followed by a potable water rinse and a 24-hour holding period prior to consumption. When used in a spray or dip solution, the additive is used at levels that result in sodium chlorite concentrations between 500 and 1,200 ppm, in combination with any GRAS acid at a level sufficient to achieve a solution pH of 2.3 to 2.9.

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GRAS Status of Sodium Hypochlorite

Although sodium hypochlorite is approved for use as a food additive under the end use conditions as provided in the Sections of 21 CFR listed above, it is not currently specifically the subject of a GRAS regulation as provided in 21 CFR Parts 182, 184, or 186. However, sodium chlorite is the subject of a GRAS regulation under 21 CFR 186.1750. When in solution, sodium chlorite dissociates into sodium hypochlorite and sodium chlorate. Because sodium chlorite dissociates into sodium hypochlorite in solution, the GRAS regulation for sodium chlorite also applies to sodium hypochlorite. 21 CFR 186.1750 states that sodium chlorite can be used at levels ranging from 125 to 250 parts per million as a slimicide in the manufacture of paper and paperboard that contacts food. Therefore, sodium hypochlorite is considered GRAS when used as a slimicide in the manufacture of paper and paperboard that contacts food at levels from 125 to 250 ppm. In an email dated 4/3/2007, the FDA confirmed that sodium hypochlorite would also fall under 21 CFR 186.1750, and could be considered GRAS when used as a slimicide in the manufacture of paper and paperboard that contacts food. There are no other specific end-uses for which sodium hypochlorite is currently considered GRAS under a specific section of 21 CFR.

Upon request, GLS can evaluate a specific end use of sodium hypochlorite to determine whether it can be affirmed as GRAS. Prior to affirming its GRAS status, the client would need to indicate a specific end use or end uses for their sodium hypochlorite product. This type of GRAS evaluation requires conducting a literature search to determine the extent and type of toxicity data that is publicly available, review of the data to determine whether the specific end use(s) of sodium hypochlorite would be considered GRAS, compilation of the data into a GRAS affirmation dossier, and review of the GRAS affirmation dossier by a scientific panel of experts. A GRAS affirmation does not require FDA review or approval. However, if the client would like to pursue FDA review following the self-affirmation process, there is a GRAS Notification program under which the FDA does review the GRAS affirmation documentation. The costs associated with self affirming GRAS status can range from $25,000 to $70,000 depending on the extent of data and end uses being evaluated.

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Summary of FDA Compliance

Sodium hypochlorite is considered to be compliant with the FDA when used in compliance with the following sections of 21 CFR:

- 21 CFR 172.892 Food starch-modified
- 21 CFR 178.1010 Sanitizing solutions
- 21 CFR 177.2800 Textiles and textile fibers
- 21 CFR 173.315 Chemicals used in washing or to assist in the peeling of fruits and vegetables
- 21 CFR 175.105 Adhesives
- 21 CFR 176.170 Components of paper and paperboard in contact with aqueous and fatty foods
- 21 CFR 173.325 Acidified sodium chlorite solutions (for use in food processing facilities)
- 21 CFR 186.1750 Sodium Chlorite (for use as a slimicide in the manufacture of paper and paperboard in contact with food)

Respectfully Submitted,

Mark Jackson
Senior Scientist
Global Lifescience Solutions, LLC