APPLICATION INFORMATION

FOOD ADDITIVE PETITION FOR THE USE OF HYDROGEN PEROXIDE IN THE MANUFACTURE OF WHEY PROTEIN CONCENTRATES

February 19, 2010

Cover Letter

Office of Food Additive Safety (HFS–200),
Center for Food Safety and Applied Nutrition,
Food and Drug Administration,
5100 Paint Branch Pkwy.,
College Park, MD 20740.

Dear Sirs:

The undersigned, Burdock Group, as agent for the undersigned, Fonterra Inc., submits this petition pursuant to section 409(b)(1) of the Federal Food, Drug, and Cosmetic Act with respect to hydrogen peroxide for use as an antimicrobial treatment of whey protein concentrate (WPC) in commercial processing plants. The use of hydrogen peroxide is intended to significantly decrease the potential for human pathogens or their toxins in/on specific food products; therefore, we request an expedited review of this food additive petition.[1]

Attached hereto, in triplicate, and constituting a part of this petition are the following:

A. The name and all pertinent information concerning the food additive, including chemical identity and composition of the food additive, its physical, chemical, and biological properties, and specifications prescribing the minimum content of the desired component(s) and identifying and limiting the reaction byproducts and other impurities.

B. The amount of the food additive proposed for use and the purposes for which it is proposed, together with all directions, recommendations, and suggestions regarding the proposed use.

C. Data establishing that the food additive will have the intended physical or other technical effect or that it may reasonably be expected to become a component, or to affect the characteristics, directly or indirectly, of food and the amount necessary to accomplish this.

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[1] Pusuent to the guidance for industry and CFSAN staff for Food Additive Petition Expedited Review, January 4, 1999.
http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodIngredientsandPackaging/ucm091735.htm; site visited February 15, 2010.

D. A description of practicable methods to determine the amount of the food additive in the raw, processed, and/or finished food and of any substance formed in or on such food because of its use. The test proposed shall be one that can be used for food-control purposes and that can be applied with consistent results by any properly equipped and trained laboratory personnel.

E. Full reports of investigations made with respect to the safety of the food additive, or references to existing food additive regulations stated for hydrogen peroxide.

The safety of hydrogen peroxide for its intended use as an antimicrobial treatment of WPC in commercial processing plants was partially determined based on published, peer-reviewed safety studies obtained from the scientific literature, as well as uses currently available *via* existing food additive regulations. As a result, full reports were not available for those studies obtained from the scientific literature or from FDA.

F. A proposed regulation.

G. Statement of categorical exclusion from preparation of an environmental assessment.

Sincerely,

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FOOD ADDITIVE PETITION FOR THE USE OF HYDROGEN PEROXIDE IN THE MANUFACTURING PROCESS OF WHEY PROTEIN CONCENTRATE

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FOOD ADDITIVE PETITION FOR THE USE OF HYDROGEN PEROXIDE IN THE MANUFACTURING PROCESS OF WHEY PROTEIN CONCENTRATE

Executive Summary

This document describes the safe use of hydrogen peroxide (H_2O_2; CAS Reg. No. 7722-84-1) as an antimicrobial treatment at a concentration of up to 400 ppm for whey protein manufactured *via* the ultrafiltration methodology. This petition requests a change to current FDA regulations outlining the use of hydrogen peroxide in the manufacture of whey protein manufactured *via* electrodialysis methodology. This request is not expected to result in an increase in the consumption of whey protein, but would be a substitute process which also ensures no residual hydrogen peroxide in the whey protein product.

A comprehensive search was conducted by Burdock Group of the scientific literature in the public domain as of December 2009 for safety and toxicity information on hydrogen peroxide and related substances. The articles resulting from that literature search, and other materials deemed appropriate or necessary, were employed to construct this critical safety review, which demonstrates that the use of hydrogen peroxide at up to 400 ppm, is safe for the conditions of intended use described herein.

SECTION A-D: Chemistry Section

Chemistry (TOC)

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Section A: Identity

Hydrogen peroxide (H_2O_2, CAS Reg. No. 7722-84-1; also known as hydrogen dioxide, peroxide, dihyrogen dioxide, hydrogen oxide, and hydroperoxide) is a colorless liquid with a bitter taste and a molecular weight of 34, a boiling point of 150.2°C and a melting point of -0.43ºC. Hydrogen peroxide is very soluble in water, soluble in diethyl ether, and insoluble in petroleum ether (IARC, 1985). Hydrogen peroxide can be produced by several different methods including those stated in Title 21 of the US Code of Federal Regulations (CFR) as follows: (1) the electrolytic oxidation of sulfuric acid or a sulfate to persulfuric acid or a persulfuric acid salt

with subsequent hydrolysis and distillation of the hydrogen peroxide formed; (2) by decomposition of barium peroxide with sulfuric or phosphoric acid; (3) by hydrogen reduction of 2-ethylanthraquinone, followed by the oxidation with air, to regenerate the quinine and produce hydrogen peroxide and; (4) by electrical discharge through a mixture of hydrogen, oxygen, and water vapor.[2] The resulting hydrogen peroxide must meet the specifications of the Food Chemicals Codex, 3rd edition (FCC, 1981) and be of food grade quality, usually having a concentration between 30% and 50%. Heavy metals (as lead) and tin must not be present at more than 10 mg/kg, with iron at not more than 0.5 mg/kg and phosphate at not more than 0.005%.

Section B: Use

The current document requests that "ultrafiltration" be added as a alternate manufacturing process to the existing regulation governing the use of hydrogen peroxide in the production of whey (21 CFR § 184.1366). This request does not expand the number or types of foods being manufactured under the current regulation, nor does it increase the concentration of hydrogen peroxide utilized. As proposed, it would only add the ultrafiltration manufacturing process as an option to the electrodialysis procedure, which is the only manufacturing process mentioned in the existing regulation. The whey protein concentrate produced from this ultrafiltration manufacturing process is not expected to increase the total amount of whey consumed, but would replace existing whey sold in the market, which likely has been manufactured through a process that also used hydrogen peroxide.

As allowed by law now, hydrogen peroxide would be used as an antimicrobial in the production of whey protein concentrate (WPC) at up to 0.04% of the weight of the whey when the WPC is produced through an ultrafiltration process (*i.e.* the hydrogen peroxide is removed from the WPC by means of ultrafiltration).

The regulatory status of hydrogen peroxide as a food ingredient in the United States is summarized in Table 1. Federal regulations indicate that hydrogen peroxide for food use must meet the specifications of the Food Chemicals Codex (FCC, 1981), and that residual hydrogen peroxide be removed by appropriate physical and chemical means (such as evaporation and drying) during the processing of food. (21 CFR § 184.1366(b) and (d))

There is a long history of hydrogen peroxide use in the manufacture of food in the United States, and specifically, in whey production. The regulation governing the production of whey protein concentrate was the subject of a rulemaking initiated in 1979 entitled "Whey and Whey Products, Hydrogen Peroxide; Affirmation of GRAS Status as Direct Human Food Ingredients" (Proposed Rule, 44 Fed. Reg. 36416, June 22, 1979; FDA, 1979). The proposed rule was to affirm the GRAS status of whey and whey products as direct human food ingredients, and of hydrogen peroxide for use as an antimicrobial agent in cheese making and whey processing. At that time, procedures for the production of soluble whey protein concentrates included dialysis,

[2] Title 21 of the US Code of Federal Regulations (CFR), section 184.1366, 2008

electrodialysis, precipitation, ion exchange, filtration, ultrafiltration, chemical extraction, or a combination of two or more of these methods. Hydrogen peroxide was included in this proposed rule as an antimicrobial at an amount that would not exceed 0.04% for whey processing, with the additional use of catalase to effectively remove any residual hydrogen peroxide from the WPC product.

When finalizing this rule, the Food and Drug Administration (FDA) affirmed that "whey and certain modified whey products are generally recognized as safe (GRAS) as direct human food ingredients, and that hydrogen peroxide is GRAS for use as an antimicrobial agent in cheese making and whey processing". (GRAS Status of Whey, Whey Products and Hydrogen Peroxide, 46 Fed. Reg. 44434-44442, Sept. 4, 1981; FDA, 1981). FDA noted that hydrogen peroxide decomposes rapidly, and catalase enzymes are added to destroy any residual hydrogen peroxide. The agency concluded that "the projected level of hydrogen peroxide in either the processed whey or in the subject cheeses, although not analytically detectable, may approach the intracellular level reported to be in the liver of rats (and supposedly humans) and is so low that the two uses of hydrogen peroxide in cheese making and whey manufacture can be affirmed as GRAS." (GRAS Status of Whey, Whey Products and Hydrogen Peroxide, 46 Fed. Reg. 44434 - 44442, Sept. 4, 1981; FDA, 1981).

During the rulemaking regarding whey production, FDA addressed public comments, one of which was that the proposed regulation failed to list all the methods used to prepare the modified whey, such as reverse osmosis, ultrafiltration and other membrane technology. The comments "…. expressed concern that the listed methods were the only ones that would be permitted." FDA made it clear that it understood many different processes were used to manufacture whey, and stated that:

> The agency does not intend to limit the processing methods that may be used, and does not object to the use of newly developed physical separation techniques, if there are no new toxicants introduced as a result of use of these techniques, and if these techniques do not result in a concentration of natural toxicants in whey products. FDA believes that such results can be avoided by the use of good manufacturing practices and by the establishment of specifications for heavy metals. Therefore, the agency has used the term "prepared by physical separation techniques *such as* precipitation, filtration, or dialysis (emphasis added) to describe briefly the methodologies that have been reviewed and at the same time to avoid eliminating other acceptable methods" (GRAS Status of Whey, Whey Products and Hydrogen Peroxide, 46 Fed. Reg. 44434 at 44437, Sept. 4, 1981).

When publishing the final regulations in 1981, however, FDA did not limit the governing regulation to only the "electrodialysis" method in either the whey or the hydrogen peroxide rule. For some reason, however, that restriction was added later, as discussed below.

Following the rulemaking on whey and hydrogen peroxide stated above, FDA conducted a comprehensive safety review of human food ingredients classified as GRAS or subject to a prior sanction,[3] under which the safety of hydrogen peroxide was re-evaluated. At this time, the agency proposed to affirm the GRAS status of hydrogen peroxide with certain limitations (Hydrogen Peroxide: Proposed Affirmation if GRAS Status as a Direct Human Food Ingredient with Specific Limitations, 48 Fed. Reg. 52323, Nov. 17, 1983; FDA, 1983). As part of this rulemaking, FDA reviewed various safety and toxicity reports on the preclinical and clinical evaluation of the safety of hydrogen peroxide in the report provided by Select Committee on GRAS Substances (SCOGS) (1979).[4] The Committee had evaluated data on any potential changes to the nutritional quality and wholesomeness of peroxide-treated milk, and concluded the following:

> The Select Committee concludes that no evidence in the available information on hydrogen peroxide demonstrates or suggests reasonable grounds to suspect a hazard to the public when it is used at levels that are now current and in the manner now practiced. However, the Select Committee also states that it is not possible to determine, without additional data, whether a significant increase in consumption would constitute a dietary hazard. The Select Committee further concludes that there is no evidence in the available information on hydrogen peroxide that demonstrates or suggest reasonable grounds to suspect a hazard to the public when it is used in cotton and cotton fabrics for dry food packaging at levels that are now current or that might reasonable be expected in the future. (SCOGS Report No. 113, available at http://www.accessdata.fda.gov/scripts/fcn/fcnDetailNavigation.cfm?rpt=scogsListing&id=153)

FDA concurred with the Select Committee, and concluded that hydrogen peroxide should be affirmed as GRAS with certain, specific limitations placed on it. (Hydrogen Peroxide: Proposed Affirmation if GRAS Status as a Direct Human Food Ingredient with Specific Limitations, 48 Fed. Reg. 52323 at 52330, Nov. 17, 1983; FDA, 1983)

FDA also independently evaluated longstanding uses of hydrogen peroxide in food, specifically whey, and noted that it had:

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[3] Substances Prohibited From Use In Food, 38 Fed. Reg. 20040 (July 26, 1973). An evaluation of the health aspects of hydrogen peroxide as a food ingredient was conducted for the FDA by the Life Sciences Research Office (LSRO) Select Committee of GRAS Substances (SCOGS) of the Federation of American Societies for Experimental Biology (FASEB) in 1979. The SCOGS concluded that "Toxic effects in animals by all routes studied occurred only at levels several orders of magnitude greater than man's possible exposure from food sources or packaging materials. There is no evidence that hydrogen peroxide is carcinogenic, teratogenic, or mutagenic at levels present in foods treated with hydrogen peroxide during processing" (SCOGS, 1979).

[4] The agency noted several safety studies conducted in rodents on the oral consumption of hydrogen peroxide added to drinking water, which did not directly evaluate the safety of foods treated with hydrogen peroxide and subsequent removal of any remaining hydrogen peroxide.

> …affirmed the GRAS status, based on current good manufacturing practice conditions of use, of the use of hydrogen peroxide as an antimicrobial agent in the manufacture of certain cheeses and in certain aspects of whey processing. The antimicrobial use of hydrogen peroxide in cheeses had been permitted under 21 CFR Part §133 of the agency's standards of identity even before the passage in 1958 of the Food Additives Amendment to the act. FDA has affirmed that the use of hydrogen peroxide in whey is GRAS on the basis of data presented in petitions to affirm the GRAS status of this use. However, a provision of the regulation stipulated that 'this regulation is issued before the completion of the general evaluation of the use of this ingredient in order to affirm as GRAS the specific use named' (21 CFR §184.1366(e)).
>
> On the basis of its general evaluation of hydrogen peroxide, FDA has tentatively concluded that the uses of this substance should be affirmed as GRAS with specific limitations. Therefore, the agency is modifying §184.1366 to remove the reference to use of the ingredient at "levels not to exceed good manufacturing practice in accordance with §184.1(b)(1)" and to include a reference to use under §184.1(b)(2). The agency believes that the results from the general safety review, together with the agency's concerns expressed in the final rule establishing §184.1366 (46 FR 44434), provide an adequate basis for this change. (Hydrogen Peroxide: Proposed Affirmation if GRAS Status as a Direct Human Food Ingredient with Specific Limitations, 48 Fed. Reg. 52323 at 52331, Nov. 17, 1983).

In evaluating the petitioned uses of hydrogen peroxide, the agency estimated exposure to this substance based only on the petitioned uses, as the petition contained "good information about the levels of use and effective removal of hydrogen peroxide from the products involved." The agency expressed concerns that the specific approval for the use of hydrogen peroxide as an antimicrobial in whey processing and cheese making could be expanded to encompass its use as an antimicrobial agent in other foods at much higher levels and without proper measures to ensure its removal.[5] Therefore, the agency has concluded that specific limitations on the use of hydrogen peroxide in food, including its use as an antimicrobial agent in whey processing and cheese making, are necessary to ensure its continued safe use." (Hydrogen Peroxide: Proposed Affirmation if GRAS Status as a Direct Human Food Ingredient with Specific Limitations, 48 Fed. Reg. 52323 at 52331, Nov. 17, 1983). However, for some reason not discussed during the rulemaking, FDA added "electrodialysis" as the only listed processing methodology for the production of whey. This petition merely requests that the ultrafiltration process be added to this

[5] Concerning additional uses, the agency stated: In order for the agency to consider additional uses of hydrogen peroxide, it will be necessary to have a description of the technical effect; the specific food (rather than food category) treated by hydrogen peroxide as either a bleaching or processing agent; the levels and strength at which hydrogen peroxide is employed; and either the levels of residues or the method used for removing any residues. (48 Fed. Reg. 52323 at 52331, Nov. 17, 1983). No additional uses are being proposed here.

regulation as a substitute manufacturing process for whey using hydrogen peroxide for exactly the same use.

Concerning limitations for any additional uses, the agency did not propose to modify the maximum treatment level, technical effect or method of removal for the approved uses, as the safety-in-use within these conditions was already established by the information submitted to the agency. The current regulatory status of hydrogen peroxide use as a food ingredient in the United States is provided in Table 1, below.

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Table 1. Regulatory status of hydrogen peroxide in the United States as a direct food ingredient

Agency	Food	Use limits and permitted functionality	Reference
FDA	Milk, intended for use during the cheese making process as permitted in the appropriate standards of identity for cheese and related cheese products under part 133 of this chapter	Maximum treatment level in food at 0.05% as an antimicrobial agent as defined in 170.3 (o)(2) of this chapter.	21 CFR §184.1366
	Whey, during the preparation of modified whey by electrodialysis methods	Maximum treatment level in food at 0.05% as an antimicrobial agent as defined in 170.3 (o)(2) of this chapter.	
	Dried eggs, dried egg whites, and dried egg yolks as in 160.105, 160.145, and 160.185 of this chapter	Amount sufficient for the purpose as an oxidizing and reducing agent as defined in 170.3 (o)(22) of this chapter.	
	Tripe	Amount sufficient for the purpose as a bleaching agent.	
	Beef feet	Amount sufficient for the purpose as a bleaching agent (Hydrogen peroxide may be in the form of a compound salt, sodium carbonate peroxide).	
	Herring	Amount sufficient for the purpose as a bleaching agent.	
	Wine	Amount sufficient for the purpose as an oxidizing and reducing agent as defined in Section 170.3 (o) (22) of this chapter.	
	Starch	Maximum treatment level in food at 0.15% as an antimicrobial agent as defined in 170.3 (o)(2) of this chapter to produce thermophile-free starch; Remove sulfur dioxide from starch slurry following steeping and grinding operations of corn refining.	
	Instant tea	Amount sufficient for the purpose as a bleaching agent.	
	Corn syrup	Maximum treatment level in food at 0.15% as an antimicrobial agent as defined in 170.3 (o)(2) of this chapter to reduce sulfur dioxide levels in the finished corn syrup.	
	Colored (annatto) cheese whey	Maximum treatment level in food at 0.05% as a bleaching agent.	
	Wine vinegar	Amount sufficient for the purpose to remove sulfur dioxide from wine prior to fermentation to produce vinegar.	
	Emulsifiers containing fatty acid esters	Maximum treatment level in food at 1.25% as a bleaching agent.	
FDA	Substance migrating to food from cotton and cotton fabrics used in dry food packaging		21 CFR §182.70

CFR = Code of Federal Regulations; FDA = US Food and Drug Administration

In addition to the discussion above, the Joint FAO/World Health Organization (WHO) Expert Committee on Food Additives (JECFA) initially evaluated the available data on the safety of hydrogen peroxide (used as an antimicrobial or bleaching agent) in 1965 in contemplation of determining an acceptable daily intake (ADI), but stated that "because of the instability of the compound in contact with food, it is not possible to allocate to it a meaningful acceptable daily intake for man. However, in circumstances where more acceptable methods of milk preservation are not available, hydrogen peroxide may be used for this purpose." JECFA again reviewed new and existing data in 1973 and again concluded that no ADI could be allocated, but that "hydrogen peroxide is to be used only where better methods of milk preservation are not available" (JECFA, 1974). JECFA noted that "when hydrogen peroxide is used as an agent to reduce the number of bacteria in dairy products or other foodstuffs, the excess is destroyed." JECFA concluded that "toxicological considerations, therefore, apply only to the possible interference with the nutritional value of treated foodstuffs or the formation of toxic substances, but not to residual hydrogen peroxide."

Hydrogen peroxide is also approved for the sanitation of drinking water by the National Sanitation Foundation (NSF/ANSI 60 standard, 2009).

Section C: Intended Technical Effect

The intended technical effect of hydrogen peroxide in this petition is as an antimicrobial substance added to milk whey during the separation and concentration of whey-based protein, according to 21 CFR §184.1979(c): Whey protein concentrate (FDA, 2009) *via* ultrafiltration separation techniques. Ultrafiltration methodology has been used in the United States dairy industry and worldwide for over thirty years (Kosikowski, 1973). The general method for whey filtration processing passes the raw whey through a membrane, after which it is evaporated and spray dried to produce a range of whey products, including whey protein concentrate (WPC) and whey protein isolate (WPI) (Fonterra, 2008a). Hydrogen peroxide is added to the liquid whey stream during processing at a treatment level of not greater than 0.04% (400 ppm) for control of microbial growth. Hydrogen peroxide has been utilized in dairy processing for decades as a preservative in milk and milk products (Luck, 1956; Luck, 1962).

Section D: Analytical and Filtration Methodology

The whey protein manufacturing process utilized by Fonterra initially obtains whey produced from either the manufacture of cheese or casein, to which hydrogen peroxide is added at up to 5 ppm into the raw whey stream to ensure microbial stability of the whey during subsequent holding steps. A storage holding stage enables any casein fines to agglomerate to enable them to be removed. Whey is then clarified to remove any solids (*e.g.*, aggregated casein fines) which would foul the membrane during the ultrafiltration process. Whey is then stored in a heat hold stage for up to 12 hours. The time is necessary for some whey types to allow for the minerals in the whey to reach equilibrium to minimize fouling of the filtration membranes and to

assist in maintaining membrane performance. Whey is then filtered through an ultra filtration (UF) membrane[6] (Koch Membrane Systems, 2009) to remove undesirable substances, including hydrogen peroxide. The ultrafiltration process concentrates the whey proteins which are retained by the membrane in what is termed "retentate." Any residual microbes present are too large to pass through the membrane, and are also concentrated in the retentate by this process. Water, the peroxide and some of the lactose and minerals pass through the membrane as a "permeate."

The retentate from the ultrafiltration process is then partially evaporated to remove some of the water content, and hydrogen peroxide at up to 5 ppm is added into the evaporated stream to keep down the bacterial count in the drier buffer tanks. Buffer tanks are holding tanks utilized to even out variations in flow rate between the evaporator and dryer. The retentate is then taken through a spray drying process, removing residual water and hydrogen peroxide. The final product is then tested to confirm that there is no hydrogen peroxide present (Fonterra, 2009a).

The cleaning of the ultrafiltration apparatus occurs after run lengths up to 20 hours depending on operating temperature and whey quality. The cleaning regimen of the ultrafiltration plant involves rinses and chemical steps using caustic, acid and/or sanitizer procedures. Time, temperature, flows and chemical strengths are important to ensure sufficient cleaning has taken place and is monitored. Cleaning effectiveness is also monitored by microbial testing. Cleaning regimens are run in accordance with recommendations of the membrane suppliers for edible applications.

In summary, in the membrane ultrafiltration process, hydrogen peroxide (at a molecular weight of 34 Da) passes readily through the membrane, with up to 90% removal of any hydrogen peroxide added to the whey. Any remaining hydrogen peroxide will be removed during the evaporation and drying process. The final whey product is analyzed for the absence of residual hydrogen peroxide (Fonterra, 2009b). The membrane process is used to decrease mineral and small molecule content in the whey, and several different driving forces may be used to separate the substances *via* the membrane, including pressure, concentration gradients, or electric potential. The ultrafiltration process uses transmembrane pressure against small-pore, uncharged membranes to remove minerals, lactose, water, and small molecules from the whey, forming the whey concentrate. A process flow diagram of whey protein product production and the use of hydrogen peroxide in this process is provided in Figure 1. A representation of an ultrafiltration plant is provided in Figure 2. Fonterra produces whey products under ISO9001:2000 standards and HACCP plans (Fonterra, 2008b; Fonterra, 2008c). Von Bockelmann *et al.* (1975) investigated the influence of processing time, temperature and degree of concentration on microbial growth in whey, as well as on the solubility of whey proteins during the ultrafiltration process in whey production, and found that total counts of bacteria in untreated whey varied, ranging from 200 – 1,000,000 bacteria *per* ml, with an average of 10,000 bacteria *per* ml. The increase in bacteria during processing was dependent on processing time and temperature.

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[6] http://www.kochmembrane.com/mktapp_dairy.html; Koch membrane systems for ultrafiltration; site visited December 22, 2009

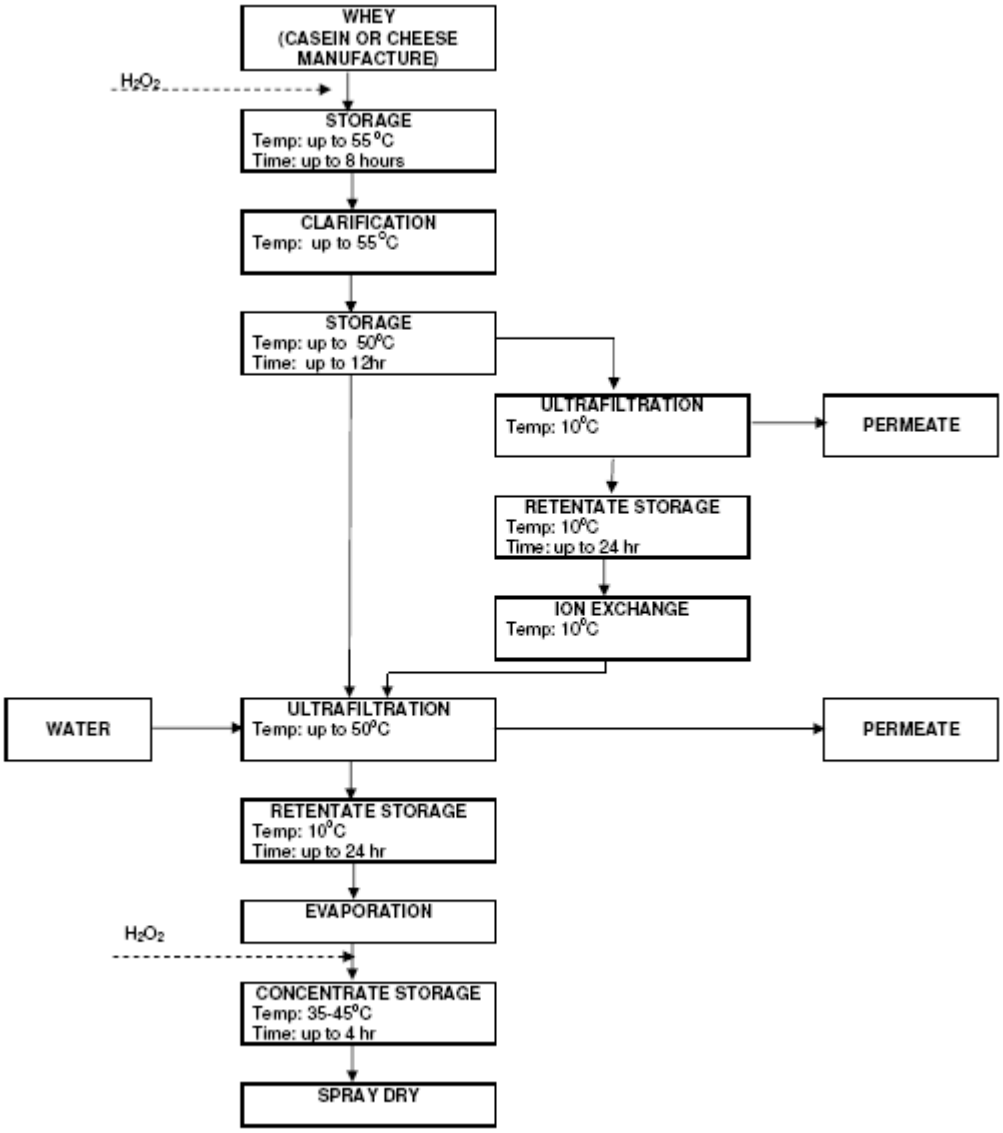
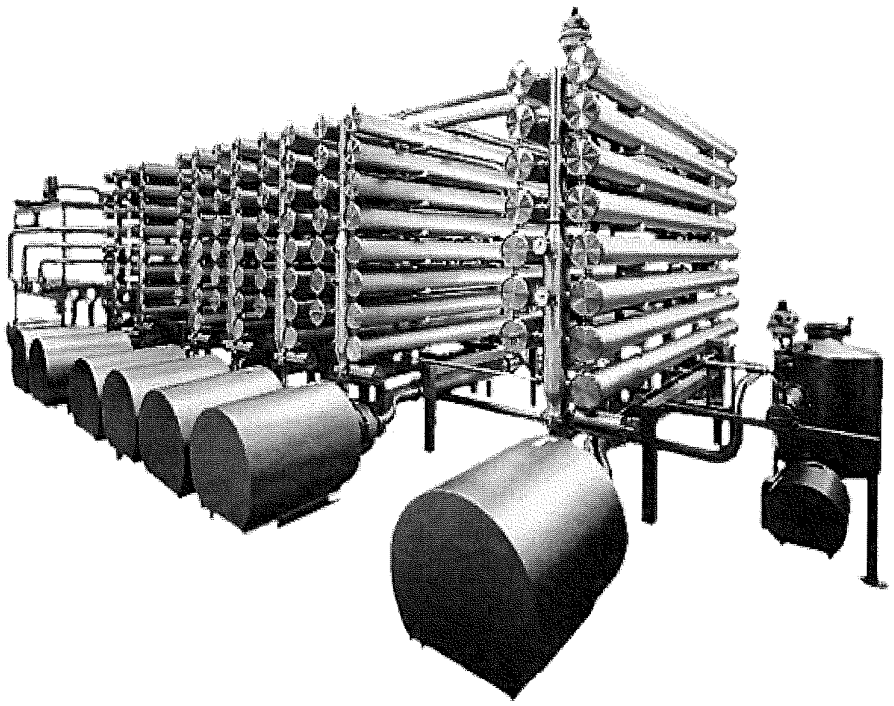


Figure 1. Whey protein products process flow diagram

TYPICAL ULTRAFILTRATION PLANT



Taken from:

http://www.tetrapak.com/products_and_services/processing_equipment/dairy_equipment/filtration/pages/default.aspx

Figure 2. Ultrafiltration plant

The level of hydrogen peroxide remaining in the final WPC product is determined by utilizing a commercially available test strip, and is semi-quantitative in nature. In principle, the peroxide test detects inorganic and organic substances which contain a peroxide or a hydroperoxide group (Fonterra, 2009b). The apparatus utilized are the following:

(1) a balance weighing to 0.1g;
(2) a screw-topped bottle, 250 mL, *e.g.*, Schott or an equivalent;
(3) a 100 ml measuring cylinder;
(4) a water bath controlled at 60 ± 2ºC;
(5) a peroxide test strip, *e.g.*, Merckoquant® (Cat. No. 100111, 100 strips, 0 – 25 mg/l H_2O_2) or an equivalent.

The procedure is completed as follows:

(1) weigh 10.0 ± 0.1 g of sample into a 250 ml screw-topped bottle;
(2) add 90 ml water and screw on the top;
(3) place the bottle in a 60ºC water bath for 20 minutes, inverting until the sample is dissolved;
(4) cool to room temperature (approximately 20 minutes);
(5) dip the test strip in the solution (about 1 second), shake off the excess solution and compare the strip with the color scale on the strip container after 15 seconds (any coloration detected within three minutes can be interpreted as a positive reaction);
(6) record the result obtained from the scale. The commercial test strip method and test color card (Merck, 2008; Merck, 2009).

Intake Estimate

Because the safety of any substance is based on exposure, an understanding of the aggregate consumption of hydrogen peroxide is key to any food safety risk assessment process. This aggregate consumption is the estimated daily intake (EDI) from all sources. Oral exposure to hydrogen peroxide may occur *via* food in certain vegetables at levels of 3-7 ppm and through the use of toothpaste and other consumer products. The Joint FAO/WHO Expert Committee on Food Additives (JECFA) evaluated the use of hydrogen peroxide in dairy applications or other foodstuffs as an agent to reduce bacterial counts and concluded that the excess hydrogen peroxide is destroyed. The conclusions provided by the JECFA review indicate that hydrogen peroxide added to whey protein will be destroyed during the processing. In the unlikely event that residual hydrogen peroxide is retained in food during processing, small amounts of hydrogen peroxide administered orally are rapidly decomposed by peroxidases in the saliva or by catalases formed by the intestinal cells (Desesso *et al.*, 2000). As part of the quality control process, Fonterra analyzes for residual hydrogen peroxide in the whey protein product. The limit of detection by the test method (Merck, 2008) for hydrogen peroxide contained in the Fonterra WPC product is 0.5 mg hydrogen peroxide *per* liter whey product (equivalent to 0.0005% or 0.5 ppm). The following discussion will analyze the amount of hydrogen peroxide if present at the level of detection.

A typical serving of WPC, based on suggested consumer serving sizes of various WPC and whey protein isolate products, is approximately 30 g (EnergyFirst, 2007). Therefore, if the WPC was consumed as a single ingredient, consumption of the WPC product that would contain up to 0.5 mg hydrogen peroxide *per* liter product would contain 0.015 mg hydrogen peroxide *per* serving. Consumption of one serving *per* day would result in a consumption of 0.00025 mg hydrogen peroxide *per* kg bodyweight, based on a 60 kg person. Based on the information provided by Fonterra, ingestion of the WPC final product would result in the consumption of negligible levels of hydrogen peroxide. Sato (1990) noted that the Japanese Ministry of Health allows the use of hydrogen peroxide provided that the hydrogen peroxide is decomposed or removed from the final products although hydrogen peroxide was found to be clastogenic *in vitro* and carcinogenic *in vivo* at high concentrations, as there is probably insignificant intake by humans consuming hydrogen peroxide-treated food products.

The SCOGS committee (1979) noted that the quantity of hydrogen peroxide used in foods in 1975 was equivalent to a *per capita* daily "intake" of 8 mg, but the committee stated that this value was an "illusory value, for only traces, if any, of the added hydrogen peroxide

would survive food processing. The ingestion of hydrogen peroxide from foods is almost certainly miniscule" (SCOGS, 1979).

The use of hydrogen peroxide in the production of WPC *via* electrodialysis methods is currently regulated under 21CFR §184.1366. The production of WPC *via* ultrafiltration is not expected to add to the amount of WPC or hydrogen peroxide consumed in the United States, only replace WPC that is currently sold. Hydrogen peroxide is not detected in the final WPC product.

Studies

Hydrogen peroxide utilized in the production of whey protein concentrate through the ultrafiltration process does not remain in the whey protein concentrate after processing. Hydrogen peroxide is removed from the whey by rapid breakdown on reaction with the whey components, loss through the membrane, and through the evaporation and drying process. APPENDIX 1 contains batch/lot data on the analysis for hydrogen peroxide residual levels remaining in the whey protein product produced *via* the ultrafiltration process using hydrogen peroxide. The limit of detection for the method of hydrogen peroxide analysis is 0.5 mg/L, as determined utilizing a commercial test system according to Fonterra standard operating procedures (Marks *et al.*, 2001; Merck, 2009; Fonterra, 2009b).

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Safety Reports

This assessment is based on a review of the relevant safety studies on hydrogen peroxide. A review of the literature, including abstracts of publications available at PubMed®, ToxLine®, and Scopus®[7] sites, and other relevant data and information available to Burdock Group, was evaluated for safety information relevant to the safe use of hydrogen peroxide as a food ingredient. Hydrogen peroxide is an oxidizing agent that may cause toxicity at extremely high doses through three different mechanisms: corrosive damage, gas (*i.e.*, oxygen) formation and lipid peroxidation. However, none of these effects would be seen in the WPC that is the subject of this petition because of the low concentration of hydrogen peroxide utilized in this manufacturing process (below the 40 ppm level already established in the regulations for WPC manufacturing *via* electrodialysis) and that any hydrogen peroxide utilized in the manufacture of WPC is removed during the manufacturing process, as verified by standard WPC lot analysis for residual hydrogen peroxide.

In 1983, FDA published a Federal Register document (FDA, 1983) outlining the modification of the proposed affirmation of GRAS status of hydrogen peroxide as a direct human food ingredient to limit the use of hydrogen peroxide to certain whey production processes. Included in this document was a summary of toxicity and carcinogenicity studies that indicated potential toxicity from the consumption of hydrogen peroxide, as outlined in the SCOGS opinion report released in 1979 (SCOGS, 1979). These studies will be summarized below, as well as later

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studies summarized by IARC (1985) and ECETOC (1993), in addition to other studies relevant to the determination of safe use of hydrogen peroxide as a component in the manufacture of WPC.

Studies

In general, concentrated hydrogen peroxide (*e.g.*, greater than 30% solutions) is caustic and tissue exposure may result in local tissue damage when consumed alone. Hydrogen peroxide readily breaks down to hydrogen and oxygen gas, and therefore ingestion of large volumes of concentrated (>35%) hydrogen peroxide may result in substantial levels of oxygen formation (Watt *et al.*, 2004). If the decomposition of hydrogen peroxide occurs in the bloodstream and exceeds the maximum solubility in blood, venous or arterial gas embolism may occur. Arterial gas embolism may result in central nervous system damage *via* an embolism with a subsequent brain infarction. The rapid generation of oxygen may also cause a rapid mechanical distension of closed body cavities, causing pain and potential tissue damage. Hydrogen peroxide is also directly cytotoxic *via* lipid peroxidation.

No studies on the toxicity of foodstuffs or food components treated with hydrogen peroxide were found in the literature. Analysis of the potential for compositional changes of proteins treated with hydrogen peroxide is discussed below, with summaries of studies on the toxicity of hydrogen peroxide provided.

Genetic Toxicity Studies

Hydrogen peroxide has been extensively tested for genotoxicity using bacterial and mammalian *in vitro* assays. These studies have been reviewed in detail by the SCOGS (1979), European Centre for Eco-toxicology and Toxicology of Chemicals (ECETOC, 1993) and IARC (1999) committees and concluded that there were no adverse events when hydrogen peroxide was added to food; therefore, the effect of hydrogen peroxide on genotoxicity studies will only be summarized briefly here.

SCOGS (1979) cited several genotoxicity studies conducted with hydrogen peroxide (see below) and noted the fact that hydrogen peroxide has been shown to be mutagenic to various microorganisms and to mouse ascites tumors, specifically stating that "DNA degradation, cell damage, and increase in mutants were reported under the specific conditions of the experiments, usually involving the addition of hydrogen peroxide to the media." The exposure to hydrogen peroxide on DNA solutions and bacterial cells has also been shown to cause DNA strand breakage, believed to be caused by the formation of hydroxyl free radicals (Dickey *et al.*, 1949). Thacker and Parker (1976) (cited by SCOGS (1979)) reported that inactivation and mutation by hydrogen peroxide led to respiratory deficiency induction in yeast cells, in which they theororized that a majority of this effect was probably due to a selection of pre-existing mutants in log phase populations.

Schoneich (1967) conducted a study to evaluate the effect of hydrogen peroxide injections on several lines of mouse ascites tumors. The S2 sarcoma, Erlich ascites carcinoma, and sarcoma 180 were grown in the mouse strain ABJena Gat., after which hydrogen peroxide (1

ml of a 0.1 M solution, approximately equivalent to 170 mg/kg) was injected (*i.p.*) 48 hours after tumor implantation. Spontaneous chromatid aberrations occurred in less than 1% of the cells of untreated tumors, but 4 – 44.7% of the examined tumor cells in the hydrogen peroxide-treated animals had chromatid aberrations. Although the frequency of aberrations varied considerably, there was a consistent increase with increasing HP concentrations.

The IARC monograph (1985) summarized genotoxicity data concerning hydrogen peroxide, noting that hydrogen peroxide was mutagenic in a substantial number of *in vitro* assays (Table 2).

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Table 2. Mutagenicity and other short-term *in vitro* tests cited by IARC (IARC, 1985)

***In vitro* test system**	**Finding**	**Reference**
Salmonella typhimurium TA92	Mutagenic	Ames *et al.* (1981)
S. typhimurium TA102	Mutagenic	Levin *et al*. (1982)
S. typhimurium SV50	Positive in forward mutation assay	Xu *et al.* (1984)
S. typhimurium TA100	Mutagenic	Norkus *et al.* (1983)
S. typhimurium TA100	Not mutagenic	Stich *et al.* (1978)
S. typhimurium TA98	Not mutagenic	Yamaguchi and Yamashita (1980)
Micrococcus aureus	Mutagenic	Clark (1953); Stich *et al.* (1978)
Haemophilus influenzae	Mutagenic	Kimall and Hirsch (1975)
Bacillus subtilis	Mutagenic	Sacks and MacGregor (1982)
Escherichia coli	Mutagenic	Demerec *et al.* (1951)
Saccharaomyces cerevisiae	Mutagenic	Thacker (1976); Thacker and Parker (1976)
Neurospora crassa	Mutagenic	Dickey *et al.* (1949); Jensen *et al*., (1951)
Aspergillus chevalieri	Mutagenic	Nanda *et al*. (1975)
Streptomyces griseoflavus	Not mutagenic	Mashima and Ikeda (1958)
Drosophila melanogaster	No induction of sex-linked recessive lethal mutations	DiPaolo (1952)
V79-4 Chinese hamster cells	Induction of single-strand DNA breaks	Brakley *et al*. (1979)
V79-4 Chinese hamster cells	Lack of DNA-DNA or DNA-protein crosslinking	Bradley *et al.* (1979)
Cultured human fibroblasts	Increased induction of unscheduled DNA synthesis	Stich *et al*. (1978); Coppinger *et al.* (1983)
Chinese hamster ovary cells	Induction of sister chromatid exchanges	MacRae and Stich (1979); Wilmer and Natarajan (1981)
V79 Chinese hamster cells	Induction of sister chromatid exchanges	Bradley *et al*. (1979); Speit *et al*. (1982)
Chinese hamster ovary cells	Induction of chromosomal abberations	Hanham *et al.* (1983)
Chinese hamster DON-6 cells	Induction of chromosomal abberations	Sasaki and Sagimura (1977)
Primary Syrian hamster embryo cell cultures	Induction of chromosomal abberations	Tsuda (1981)
newborn Balb/c mouse back-skin cells	Induction of chromosomal abberations	Tsuda (1981)
Cultured human cells	Induction of sister chromatid exchanges	Estervig and Wang (1979)
human fibroblast cell line	Induction of chromosomal abberations	Parshad *et al.* (1980)
Human fibroblast and adenocarcinoma cell lines	Induction of single-strand DNA breaks	Hoffmann and Meneghini (1979); Taylor *et al.* (1979); Wang *et al.*, (1980)

However, it must be kept in mind that specific features inherent to the *in vitro* systems must be taken into account as they are likely to influence any test results, as discussed by DeSesso *et al.* (2000) below, who have offered valid reasons why these *in vitro* mutagenicity assays are likely showing "false positive" responses, and posed the hypothesis that hydrogen peroxide is not mutagenic when used in the manufacture of food products. As indicated above and in review documents, the majority of *in vitro* mutagenicity assays for hydrogen peroxide have used prokaryotic cells, which lack distinct, membrane-bound nuclei (genetic material in

prokaryotic cells lies in the cytoplasm as a continuous loop of "naked" DNA), and therefore prokaryotic DNA is extremely vulnerable to xenobiotic insult. In eukaryotic cells, there are several distinct differences from prokaryotic cells that provide protection from xenobiotic insult: (1) the genetic material is located within the double membrane of the nuclear envelope, (2) the DNA is protected by histone proteins that bind to the DNA, and (3) the cytoplasm surrounding the nucleus contains antioxidant protective enzymes and membrane-bound organelles (which are absent in prokaryotic cells). These factors make prokaryotic cells much more susceptible to DNA damage by xenobiotics, and therefore a mechanistic insight is of critical importance when assessing the relevance of *in vitro* genotoxicity studies with prokaryotic cells. As reviewed in ECETOC (1993), hydrogen peroxide has been reported mutagenic in bacterial assays without metabolic activation, with the highest mutagenic response measured in bacterial strains sensitive to oxidative damage. The addition of antioxidant enzymes (*e.g.*, S9 liver fractions, exogenous catalase, or exogenous SOD) to bacterial assay systems, or the induction of endogenous catalase levels, has reduced or eliminated the observed mutagenic responses, indicating that the presence of normal mammalian protective mechanisms eliminates the mutagenic response of bacteria to hydrogen peroxide treatment.

DeSesso *et al.* (2000) also evaluated the relevance of *in vitro* mammalian cell systems for determining genotoxicity after oral consumption of various substances. Genotoxicity systems that utilize mammalian cells must also be analyzed carefully for actual relevance to the production of genotoxicity *in vivo* by food ingredients. Of primary importance is the fact that *in vitro* cell systems do not take into account the absorption, distribution, and excretion of xenobiotics. In addition, the majority of the *in vitro* assays use permanent and transformed cell lines, with the majority already having abnormal chromosomes. The transformed cell lines also typically have a reduced capability for metabolizing the xenobiotic to a non-mutagenic metabolite, or express significantly lower levels of endogenous antioxidant enzymes. Finally, many of the *in vitro* studies use extremely high concentrations of the substance, many times inducing cytotoxicity at the same concentration that mutagenicity is reported (Desesso *et al.*, 2000).

DeSesso *et al.* (2000) further described *in vivo* mammalian studies using hydrogen peroxide. In one study, Chinese hamsters were administered hydrogen peroxide at a daily oral dose of 70 mg hydrogen peroxide/kg bw/day, five days/week for 15 weeks and six months (Li *et al.*, 1993). The bone marrow cells obtained from the control and hydrogen peroxide-treated animals were isolated at the end of the study and examined for SCE frequencies, an indicator of genotoxicity. The frequency of SCE induction in hydrogen peroxide-treated animals was not different from control animals. Adam-Rodwell *et al.* (1994) reported that administration of an "oral dentifrice" containing 10% urea peroxide (approximately equivalent to 3.5% hydrogen peroxide) administered by oral gavage at doses of 100 to 1000 mg/kg/day to Sprague-Dawley rats for five consecutive days did not increase the incidence of bone marrow cell SCEs over control values. In addition, Regnier *et al.* (1996) administered C57BL/6N mice with 6000 ppm hydrogen peroxide solution as the sole source of drinking water (mean daily intakes of 536 and 774 mg/kg for male and female mice, respectively), and evaluated the formation of micronuclei in bone marrow erythroblasts. In a separate study, Regnier *et al.* (1996) injected (*i.p.*) Swiss OF1 mice with 250, 500 and 1000 mg hydrogen peroxide/kg bw and also evaluated micronuclei

formation in bone marrow erythroblasts. In both experiments, hydrogen peroxide did not induce genotoxicity.

In summary, *in vitro* studies have been conducted to analyze the genetic potential of hydrogen peroxide; however, the biological relevance of the *in vitro* studies is doubtful, as these studies do not take into account the specific protective features typical of mammalian cells that have been reduced in performance or eliminated from the prokaryotic and mammalian cells utilized in these *in vitro* studies, and the lack (or reduction) in metabolic capability of these cells and the surrounding medium to disassociate hydrogen peroxide into hydrogen and oxygen. The *in vivo* studies conducted to date indicate that hydrogen peroxide does not increase genotoxicity in mammalian systems, inasmuch as the animals have maintained appropriate mechanisms to metabolize and eliminate hydrogen peroxide.

Acute Toxicity Studies

The acute toxicity of oral hydrogen peroxide is readily understood. The European Chemicals Bureau (ECB, 2003) indicated the results of several acute oral toxicity studies on hydrogen peroxide, as part of an overall evaluation of hydrogen peroxide toxicity. The following studies (Table 3) have been included in this petition to exemplify the oral toxicity and the relevant doses of hydrogen peroxide as a solitary substance. There were no acute toxicity studies that indicated that food treated with hydrogen peroxide, that did not contain significant residual levels of hydrogen peroxide, resulted in any acute toxicity.

Table 3. Acute oral toxicity of hydrogen peroxide in preclinical toxicity studies (ECB, 2003)

Hydrogen peroxide (%)	LD_{50} (mg/kg)/Strain	Effect	Reference
Rat			
9.6%	1517 (M) 1617 (F) / Wistar JCL	Decreased locomotion as the only symptom of toxicity; deaths occurred within 24 hours	Ito *et al*. (1976)
10%	>5000 (M and F) / Sprague Dawley	Hemorrhagic stomach and intestinal lesions were noted at necropsy.	FMC (1989)
35%	1193 (M) 1270 (F) / Sprague Dawley	Predominant clinical signs were tremors, decreased locomotion, prostration, oral, ocular and nasal discharge; pathological signs: reddened lungs, hemorrhagic white stomachs, blood-filled intestines	FMC (1983)
50%	>225 / Sprague Dawley	Decreased locomotion, abdominogenital staining, lacrimation, red nasal discharge. All symptoms resolved in 72 hours.	FMC (1986)
60%	872 (M) 801 (F) / Wistar	Decreased locomotion; hemorrhagic stomachs at necropsy	Mitsubishi (1981)
70%	75 (M) / strain unknown	No further data*	FMC (1979)

*Unreliable data as use concentration is corrosive; F=female; M=male

Short Term Toxicity Studies between 14 Days and 28 Days

To determine potential toxicity from milk protein treated with hydrogen peroxide, groups of ten male rats were fed 9% milk protein or cheese protein produced from pasteurized milk treated with 0, 0.1, 0.2 and 0.5% hydrogen peroxide in a six-week study (Teply *et al.*, 1958). The biological value of the proteins was not altered, with the exception of a slightly depressed value for milk treated with 0.5% hydrogen peroxide at 160ºF. No abnormalities were found on autopsy at study termination. There were no significant differences in feed efficiency among the groups. The authors concluded that there were no marked changes in the composition or nutritional value of milk treated with 0.1, 0.2 or 0.5% hydrogen peroxide, or in the cheese or whey obtained from that milk.

The SCOGS committee (1979) summarized several short-term studies in mice and rats. In a 35-week study, mice were provided 0.15% hydrogen peroxide *ad libitum* for their source of drinking water. The hydrogen peroxide-treated mice had no visible abnormalities during the study, but degenerative changes were observed in the liver and kidney, with the stomach wall being inflamed, irregular and slightly necrotic. The lymphatic tissue of the small intestinal wall was hypertrophic. However, hydrogen peroxide solutions in excess of 1% (more than 1000 mg/kg/day) caused pronounced weight loss and death of the mice within two weeks (Teply *et al.*, 1958). Romanowski *et al*. (1960) conducted a 20-week study in which he replaced the drinking water of rats with solutions of 0.25 – 10% hydrogen peroxide. All rats that consumed 2.5% or higher hydrogen peroxide solutions died within 43 days. Only one rat died in the 0.25% dose group, and two rats died in the 0.5% dose group, but the weight gain in these dose groups were less than the controls (tap water). The summary indicated that the daily hydrogen peroxide intakes for these two groups were approximately 250 and 500 mg/kg, respectively.

Hankin (1958) gave a 0.45% hydrogen peroxide solution as drinking water to a group of male Osborne-Mendel rats for three weeks. Fluid intake and body weight gain parameters in the hydrogen peroxide treatment group were significantly less than the control group. When the fluid intake in the control group was restricted to the levels consumed by the 0.45% hydrogen peroxide group, there were no significant differences in body or organ weights between treated and control groups. The daily consumption was approximately 500 mg hydrogen peroxide *per* kg body weight. In addition, three female rats were given 0.45% hydrogen peroxide as drinking water for five months, then switched to tap water and mated with males consuming tap water. Normal litters were produced. Male rats from these litters were then given 0.45% hydrogen peroxide solution as drinking water for nine months and compared with littermates receiving tap water. The only stated difference was a decreased weight gain in the hydrogen peroxide treatment group.

As summarized by SCOGS (1979), a study was conducted in male Holtzman rats given 0, 0.5, 1.0, and 1.5% hydrogen peroxide (approximately equivalent to 0, 500, 1000 and 1500 mg/kg/day, respectively) for eight weeks (Shapiro *et al.*, 1960). Growth was significantly and dose-dependently reduced in all hydrogen peroxide groups, with 7 out of 24 rats in the 1.5% hydrogen peroxide dose group dying during the study. All surviving rats in the 1.5% dose group and 15 of the 24 rats in the 1% dose group had extensive carious lesions and pathological changes in the periodontium. In the 0.5% dose group, 7 out of 24 rats had mild caries, but no

periodontal changes. The SCOGS committee (1979) summarized a study by Kawasaki *et al.* (1969) who reported that no adverse effects were seen in male Wistar rats that received up to 30 mg hydrogen peroxide/kg/day by gastric intubation, although 60 mg/kg/day hydrogen peroxide resulted in significantly decreased growth rates after 20 days, with decreased hematocrit, plasma protein, and plasma catalase activities after 100 days. When the same amount of hydrogen peroxide (60 mg/kg/day) was administered in the feed, no harmful effects were noted.

Subchronic Toxicity Studies 90 Days

Weiner *et al.* (2000) conducted a 13-week subchronic toxicity study of hydrogen peroxide when administered continuously in the drinking water of catalase-deficient (C57BL/6N) male and female mice (15/sex/group) at 0, 100, 300, 1000 or 3000 ppm (approximately equivalent to 0, 0.01, 0.03, 0.1, and 0.3%, respectively), for a mean hydrogen peroxide consumption of 0, 26, 76, 239 and 547 mg/kg/day by the males, and 0, 37, 103, 328 and 785 mg/kg/day by the females, respectively. Five mice/sex/group were administered distilled water during a subsequent six-week recovery period. Mice consuming 3000 ppm hydrogen peroxide had decreased water and food consumption and body weight ($P<0.05$). Female mice at the 1000 ppm dose level had reduced water consumption, but this did not affect body weight. Administration of hydrogen peroxide did not produce mortality, adverse clinical signs, hematological effects or organ weight effects on adrenals, brain, heart, kidneys, liver, spleen, or testes. The male 3000 ppm dose group had significantly reduced total protein and globulin during the treatment period, which was reversible during the recovery period. Mild to minimal duodenal mucosal hyperplasia was noted in the 1000 and 3000 ppm male and female dose groups, and one male receiving 300 ppm hydrogen peroxide for the 13-week study. The duodenal hyperplasia was reversible during the six-week recovery period. Based on the duodenal mucosal hyperplasia, Weiner *et al.* (2000) stated the no-observed-adverse-effect level (NOAEL) at 100 ppm in drinking water or 26 and 37 mg/kg/day hydrogen peroxide for male and female mice, respectively.

Chronic Toxicity/Carcinogenicity Studies between 6 Months and 2 Year

Ito *et al.* (1981; 1982; 1984) conducted several studies analyzing the potential carcinogenic effect of hydrogen peroxide, which were summarized by IARC (1985). Ito *et al.* (1981) administered hydrogen peroxide at 0, 0.1 and 0.4% in distilled water as drinking water to male and female C57BL/6J mice for 100 weeks. One adenoma of the duodenum was noted in control animals. At the 0.1% dose level, six adenomas and one carcinoma of the duodenum were noted, while two adenomas and five carcinomas of the duodenum were noted at the 0.4% dose ($P<0.05$).

Ito *et al.* (1982) also conducted a 630-day study in which male and female C57BL/6N mice were treated with 0.4% hydrogen peroxide in the drinking water, with groups of 5-17 mice killed sequentially at 30-day intervals up to 210 days, then every 60, 70 or 90 days up to the 630-day time point. The experiment was terminated on Day 700, with the evaluation of the 29 remaining mice. The authors noted gastric erosions and duodenal ‘plaques’ (round, flat, avillous areas) present at the first 30-day time point and throughout the remainder of the study. Hyperplastic lesions, adenomas and carcinomas were reported in both the duodenum and

stomach samples from 90 days until the end of the experiment (but were absent at the Day 210 and Day 360 time points in the stomach). Atypical hyperplasia appeared in the stomach and duodenum late in the experiment, with 5% of the animals developing duodenal adenocarcinoma in the treated animals, but no such carcinoma was noted in the controls. In groups of mice treated with 0.4% hydrogen peroxide for 120, 140, 150 or 180 days and allowed a recovery period of 10-30 days, noted stomach lesions regressed completely, irrespective of the length of treatment, although some of the duodenal lesions persisted (Ito, 1982).

In a separate experiment, male and female DBA/2N, BALB/CAnN and C57BL/6N mice were administered 0.4% hydrogen peroxide in distilled water as drinking water, and examined from 90 to 210 days of treatment to determine if there are strain differences in the development of gastric or duodenal hyperplastic lesions, adenomas or carcinomas (Ito, 1982). Duodenal nodules were noted at 90 days in all three strains. The incidences of gastric nodules were 2/22 (mice), 1/39, and 12/34 and those of duodenal nodules were 14/22, 7/39 and 22/34 in DBA, BALB/c and C57BL mice, respectively.

An additional experiment was conducted to analyze the effects of hydrogen peroxide in mouse strains that have known differences in catalase activities in the duodenal mucosa (Ito *et al.*, 1984). Hydrogen peroxide at 0.4% in the drinking water was administered to groups of C3H/HeN, C57BL/6N, B6C3F1 and hypocatalasemic C3H/Cbs mice for six to seven months. Catalase activities (10-4 k/mg protein) in the duodenal mucosa were 5.3, 1.7, 0.7, and 0.4 in C3H, B6C3F1, C57BL and C3H/Cbs mice, respectively. The catalase activity inversely correlated with the incidences of duodenal tumor formation. The authors concluded that the incidence of duodenal tumor induction by hydrogen peroxide is dependent on the individual mouse strain and the catalase activity of that strain (Ito *et al.*, 1984).

In a recent review of the potential of hydrogen peroxide to produce carcinogenic effects when consumed, Desesso *et al*. (2000) noted that although hydrogen peroxide is a potential source of damage to mammalian cells due to the highly reactive hydroxyl radical released during decomposition, hydroxyl radicals are short lived, and typically react within one millionth of a second in biological fluids, or within a few nm from their site of production. Due to this high reactivity, it is highly unlikely that hydroxyl radical would cross biological membranes or even travel to different areas of a cell. DeSesso *et al.* (2000) conducted a literature review of the potential carcinogenicity of hydrogen peroxide, and found that only four studies by one laboratory (Ito *et al.*, 1981; Ito, 1982; Ito *et al.*, 1984; Ito *et al.*, 1986) concluded that hydrogen peroxide is carcinogenic. DeSesso *et al*. (2000) pointed out several important features that should be considered when evaluating these studies:

> First, carcinomas were only observed in the proximal duodenum; no carcinomas occurred in the oral cavity, esophagus, forestomach or glandular stomach as a result of exposure to H_2O_2. Secondly, the incidence and average number of duodenal lesions drastically decreased or fell to zero when the H_2O_2 treatment was stopped for 10-30 days after 150-210 days of exposure (Ito, 1982), indicating reversibility. Thirdly, the type of duodenal lesions and their sequential development are typical of those seen following exposure of rapidly regenerating tissues to corrosive/cytotoxic agents acting on tissues.

Finally, the C57BL mouse strain used in many of the experiments is deficient in catalase (Ito *et al.*, 1984), a key protective enzyme in the degradation of H_2O_2.

In addition, antioxidant substances (*e.g.*, ascorbic acid, glutathione and α-tocopherol) are readily available to detoxify hydroxyl radicals through reduction to water. Catalases and peroxidases are cellular enzymes present in most mammalian cells and catalyze the reduction of hydrogen peroxide to water and oxygen (Deakins, 1941). Humans have catalases in their saliva that metabolize hydrogen peroxide in the oral cavity, and the human stomach is a relatively large single-chambered organ that retains a watery fluid at a resting pH of approximately 2.0. The acidity of the stomach inactivates salivary peroxidase, but the irregular contractions and body temperature potentiate chemical decomposition of any remaining hydrogen peroxide (Desesso *et al.*, 2000, Marino & Gorelick, 2003).

In preclinical studies evaluating the effects of hydrogen peroxide in mice, hydrogen peroxide has typically been provided in the drinking water, which decreases the residence time of hydrogen peroxide in the oral cavity, thereby decreasing the significant breakdown of hydrogen peroxide by salivary peroxidases (Desesso *et al.*, 2000). In addition, the rodent stomach differs from the human stomach in both structure (is relatively small compared to the human stomach, and does not contain the crescentic folds, but is relatively smooth) and contents (the human stomach contains a watery fluid that may dilute consumed hydrogen peroxide, while the mouse stomach contains thick, pasty contents with a rich population of microorganisms that may become abrasive without an adequate water supply). Desesso *et al.* (2000) noted that several preclinical studies utilizing hydrogen peroxide in the drinking water reported decreased fluid intake, which would decrease the fluidity of the stomach contents, making the pasty chyme coarse enough to irritate and abrade both the gastric and duodenal mucosa, resulting in cell loss that would lead to regenerative hyperplasia.

Human Clinical Studies

No clinical studies were located in the published literature or conducted by Fonterra that evaluated the toxicity of whey proteins treated with hydrogen peroxide, as no toxicity from this treatment is expected, based on the fact that no hydrogen peroxide is present in the finished product. This is consistent with the conclusions by FDA that allowed the use of hydrogen peroxide *via* electrodialysis manufacturing processes in the production of WPC.

Nutrition Studies

Studies have been conducted that analyzed the effect of hydrogen peroxide on the amino acid composition of the proteins contained in evaporated milk and whey processed from cheese (Koning and van Rooijen, 1972). Whey protein powder was treated with hydrogen peroxide, with the hydrogen peroxide concentration at 400 ppm in the whey powder immediately after production. The samples were stored for two months at room temperature and contained 24 ppm hydrogen peroxide at the end of the two-month period. Treatment with hydrogen peroxide did not alter the amino acid composition of the cheese-derived whey (Table 4). From their studies, the authors concluded

"that treatment of cheese whey and evaporated milk with hydrogen peroxide in a concentration of 0.02 and 0.05% (w/v) respectively did not appear to have any effect on the amino acid composition of the proteins. In addition, a concentration of 0.05% hydrogen peroxide is too low to demonstrate any possible difference in the susceptibility to oxidation between the sedimented casein and the whey protein fraction as isolated from evaporated milk" (Koning and van Rooijen, 1972).

Table 4. Effect of hydrogen peroxide on the amino acid composition of the proteins from cheese whey (g amino acid/100 g protein)[1] (Koning and van Rooijen, 1972)

Amino Acid	After treatment with hydrogen peroxide	Without treatment with hydrogen peroxide
Aspartic acid	11.72	11.58
Threonine[2]	7.41	7.5
Serine[3]	6.15	6.17
Glutamic acid	19.74	19.71
Proline	5.91	6.15
Glycine	2.18	2.17
Alanine	5.25	5.22
Half-cystine[4]	2.62	2.54
Valine	6.57	6.49
Methionine	2.08	2.09
Isoleucine	6.43	6.42
Leucine	12.02	11.84
Tyrosine	3.72	3.7
Phenylalanine	6377	3.66
Lysine	10.38	10.36
Histidine	2.07	2.1
Ammonia	1.74	1.79
Arginine	3.09	3.09

[1]These samples of whey powder were stored for two months at room temperature and contained 24 ppm of hydrogen peroxide. Immediately after production of the whey powder the hydrogen peroxide concentration was 400 ppm; [2]A correction of 3% was made to compensate for losses during hydrolysis; [3]A correction of 10% was made to compensate for losses during hydrolysis

Slump and Schreuder (1973) analyzed protein samples for damage to sulfur-containing amino acids from milk casein, and evaluated the biological utilization of the oxidized products. Casein was oxidized by the addition of 30% hydrogen peroxide at a temperature of 30ºC for a total of two hours, stored overnight at room temperature, then filtered, washed, and dried. The concentrations of methionine sulfone, methionine sulfoxide, and cysteic acid in proteins were then measured. The results indicated that "practically all methionine bound in proteins of casein and fish meal was oxidized by the pretreatment with hydrogen peroxide." In casein, the methionine was oxidized to methionine sulfoxide and methionine sulfone. Slump and Schreuder (1973) also evaluated the net protein utilization and true digestibility of hydrogen peroxide-treated casein, and found that the net protein utilization, true digestibility, and biological value were not different from untreated *vs.* treated casein samples, in terms of net protein utilization (Table 5). The authors noted that if methionine sulfoxide is nutritionally available, the losses of available S-amino acids would be approximately 33% in hydrogen peroxide-treated casein,

which correlates with their experimental findings. If the methionine sulfoxide was not nutritionally available, the loss in protein utilization would have been 97%. The authors concluded that "peptide-bound methionine sulfoxide is as available as peptide-bound methionine" (Slump and Schreuder, 1973).

Table 5. Nutritive value of casein before and after treatment with hydrogen peroxide (Slump and Schreuder, 1973)

Nutritive value	Casein	
	Untreated	Treated with hydrogen peroxide (30%)
Net protein utilization	79	55[a]
True digestibility	97	96
Biological value	81	57

[a]Addition of 0.2% of *DL*-methionine to a diet containing 10% protein as hydrogen peroxide-treated casein in crease the net protein utilization to 93

Other Studies

SCOGS (1979) stated that "hydrogen peroxide has a selective action on bacteria in milk, destroying most of the facultative anaerobic types that are associated with common defects in cheese, while the desirable aerobic acid-forming species are more resistant to the peroxide treatment." A summary of work by Jasewicz and Porges stated that a concentration of 0.02 *percent* hydrogen peroxide had a preservative effect on cheese whey, which lasted for up to 10 days. When the whey was "grossly" contaminated (*i.e.*, 2.8 x 10^7 microorganisms *per* ml), 0.02 *percent* hydrogen peroxide had a 97% destruction rate within one hour, with 99% destruction after 24 hours. The effect of hydrogen peroxide addition to milk was evaluated by Tepley *et al*. (1958) who added hydrogen peroxide to milk at 49ºC at 0.1, 0.2 or 0.5% in the milk, held at temperature for 10 minutes and then cooled. Some of the milk was further processed to whey or cheese. There was no significant effect in milk or whey on levels of thiamin, riboflavin, niacin, pyridoxine, pantothenic acid, folic acid, vitamin B12, vitamin A or β-carotene. There was no significant reduction in protein efficiency ratios when milk, whey or cheese treated with hydrogen peroxide was fed for six weeks to Sprague Dawley rats as the sole source of protein.

Hydrogen peroxide at 50 and 100 ppm added to milk significantly (P<0.01) decreased standard plate counts and coliform counts during the first 24 hours of storage, compared to untreated samples, as indicated in Table 6 (Das *et al.*, 2006). Hydrogen peroxide (100 ppm) extended the shelf-life to 42 and 119 hr at ambient and chill temperatures, respectively, while the milk was organoleptically acceptable when treated with hydrogen peroxide at levels up to 100 ppm.

Table 6. Effect of spiking level and storage on quality and stability of hydrogen peroxide-treated milk (Das *et al.*, 2006)

Parameter	AT, 0 hr	AT, 24 hr	CT, 24 hr	AT, 48 hr	CT, 48 hr
Hydrogen peroxide, 50 ppm (HP1)					
Acidity (%)	0.09 ± 0.006^{A}	0.14 ± 0.01^{BC}	0.11 ± 0.01^{AB}	N/A	0.17 ± 0.011^{C}
pH at 25ºC	6.8 ± 0.02^{A}	6.2 ± 0.01^{D}	6.5 ± 0.02^{C}	N/A	6.1 ± 0.02^{E}
SPC, $\log_{10}$cfu/g	5.6 ± 4.06^{E}	5.4 ± 3.89^{D}	5.4 ± 3.98^{D}	N/A	5.6 ± 4.21^{E}
SA, $\log_{10}$cfu/g	1.4 ± 0.9^{BCD}	1.8 ± 1.04^{D}	1.3 ± 0.48^{BC}	N/A	1.6 ± 1.00^{CD}
CF, $\log_{10}$cfu/g	2.8 ± 1.81^{D}	2.6 ± 1.46^{C}	2.6 ± 1.53^{C}	N/A	2.6 ± 1.34^{C}
Hydrogen peroxide, 100 ppm (HP2)					
Acidity (%)	0.09 ± 0.004^{A}	0.1 ± 0.006^{AB}	0.09 ± 0.005^{A}	0.27 ± 0.01^{D}	0.12 ± 0.008^{AB}
pH at 25ºC	6.8 ± 0.03^{A}	6.6 ± 0.02^{B}	6.7 ± 0.01^{A}	5.4 ± 0.02^{F}	6.5 ± 0.01^{C}
SPC, $\log_{10}$cfu/g	5.1 ± 3.86^{BC}	5.0 ± 3.79^{B}	4.9 ± 3.08^{A}	5.4 ± 3.86^{D}	5.1 ± 3.19^{C}
SA, $\log_{10}$cfu/g	ND^{A}	1.8 ± 0.95^{D}	ND^{A}	1.7 ± 0.78^{D}	0.9 ± 0.3^{B}
CF, $\log_{10}$cfu/g	2.4 ± 1.41^{B}	2.1 ± 1.2^{A}	2.3 ± 1.23^{AB}	2.2 ± 1.56^{AB}	2.3 ± 1.41^{AB}

AT=Ambient temperature (27 ± 4ºC); CF=coliform count; CT=chill temperature (7 ± 2ºC); hr = hours; HP=hydrogen peroxide; N/A=not analyzed; ND=not detectable; SA=*Staphylococcus aureus* count; SPC=standard plate count; Shelf life: 26.3 ± 2.5 hr at AT and 97.3 ± 4.1 hr at CT for HP1 and 42.3±1.2 hr at AT and 119.3 ± 4.4 hr at CT for HP2; Mean ± SD values with different superscripts in a row for a parameter differ significantly ($P < 0.01$); $n = 8$

Hydrogen peroxide-containing oral health care products have been used for more than 100 years and have been considered safe by the FDA (Li, 1996). Hydrogen peroxide is routinely added to toothpastes and other oral health products, and current tooth-whitening products may contain hydrogen peroxide at up to six *percent*, with the only adverse events reported as minor chemical irritation of the oral soft tissues (Walsh, 2000; Collins *et al.*, 2004). Ingestion of concentrated hydrogen peroxide (>30%) may cause irritation of the gastrointestinal tract with nausea, vomiting, hematemesis and foaming at the mouth; the resulting foam may obstruct the respiratory tract or may be aspirated into the lungs. Blistering of the mucosa and oropharyngeal burns may occur after ingestion of highly concentrated hydrogen peroxide solutions. However, these effects have not been reported to occur at hydrogen peroxide levels (0.04%) utilized as a food ingredient.

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SECTION F & G: Administrative Section

Administrative TOC

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Section F: Proposed Tolerance

Section G: Proposed Regulation

This petition is to request an additional manufacturing process to be added to the existing regulation under Title 21, Part 184, Section 184.1366 Hydrogen peroxide, to include the manufacturing method of ultrafiltration for the use of hydrogen peroxide in the preparation of modified whey. The appropriate section of the regulation would be stated as follows:

21CFR§184.1366 (c) In accordance with §184.1 (b) (2), the ingredient is used to treat food only within the following specific limitations:

Food: Whey, during the preparation of modified whey by electrodialysis and ultrafiltration methods.

Maximum treatment level in food (*percent*): 0.04

Functional use: Antimicrobial agent as defined in §170.3 (o) (2) of this chapter.

This proposed regulation will only add the ultrafiltration methodology to the current regulation allowing the use of hydrogen peroxide in the manufacture of whey during the preparation of modified whey by electrodialysis methods. The original regulation is stated below:

Sec. 184.1366 Hydrogen peroxide.

(a) Hydrogen peroxide (H2O2, CAS Reg. No. 7722-84-1) is also referred to as hydrogen dioxide. It is made by the electrolytic oxidation of sulfuric acid or a sulfate to persulfuric acid or a persulfuric acid salt with subsequent hydrolysis and distillation of the hydrogen peroxide formed; by decomposition of barium peroxide with sulfuric or phosphoric acid; by hydrogen reduction of 2-ethylanthraquinone, followed by oxidation with air, to regenerate the quinone and produce hydrogen peroxide; or by electrical discharge through a mixture of hydrogen, oxygen, and water vapor.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d ed. (1981), pp. 146-147,1which is incorporated by reference.

(c) In accordance with 184.1(b)(2), the ingredient is used to treat food only within the following specific limitations:

Food	Maximum treatment level in food (percent)	Functional use
Milk, intended for use during the cheesemaking process as permitted in the appropriate standards of identity for cheese and related cheese products under part 133 of this chapter	0.05	Antimicrobial agent as defined in 170.3 (o)(2) of this chapter
Whey, during the preparation of modified whey by electrodialysis methods	0.04	do.
Dried eggs, dried egg whites, and dried egg yolks as in 160.105, 160.145, and 160.185 of this chapter	Amount sufficient for the purpose	Oxidizing and reducing agent as defined in 170.3 (o)(22) of this chapter
Tripe	do	Bleaching agent.
Beef feet	Amount sufficient for the purpose. (Hydrogen peroxide may be in the form of a compound salt, sodium carbonate peroxide)	Bleaching agent.
Herring	Amount sufficient for the purpose	do.
Wine	do	Oxidizing and reducing agent as defined in 170.3 (o)(22) of this chapter.
Starch	0.15	Antimicrobial agent as defined in 170.3 (o)(2) of this chapter, to produce thermophile-free starch;
		Remove sulfur dioxide from starch slurry following steeping and grinding operations of corn refining.
Instant tea	Amount sufficient for the purpose	Bleaching agent.
Corn syrup	0.15	Reduce sulfur dioxide levels in the finished corn syrup.
Colored (annatto) cheese whey	0.05	Bleaching agent.
Wine vinegar	Amount sufficient for the purpose	Remove sulfur dioxide from wine prior to fermentation to produce vinegar.
Emulsifiers containing fatty acid esters	1.25	Bleaching agent.

(d) Residual hydrogen peroxide is removed by appropriate physical and chemical means during the processing of food where it has been used according to paragraph (c) of this section.

(e) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

SECTION H: Environmental Section

Environmental TOC

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Environmental Assessment

Categorical Exclusion

Consistent with prior petitions and commissioner reviews on the regulation for the use of hydrogen peroxide in the production of WPC, Fonterra is requesting a categorical exclusion for the proposed action, pursuant to 21 CFR §25.32 (f)(Affirmation of a food substance as GRAS for humans or animals on FDA's initiative or in response to a petition, under parts 182, 184, 186, or 582 of this chapter, and establishment or amendment of a regulation for a prior-sanctioned food ingredient, as defined in 21 CFR §170.3(1) and §181.5(a) of this chapter, if the substance or food ingredient is already marketed in the United States for the proposed use).

Hydrogen peroxide is to be utilized in the production of whey by ultrafiltration methods. Hydrogen peroxide is added at a maximum treatment level in food at 0.04%. Hydrogen peroxide is already regulated as a food ingredient in the production of whey by electrodialysis methods at this use level. The inclusion of ultrafiltration methods in the use of hydrogen peroxide in the production of whey is not expected to increase the amount of hydrogen peroxide released into the environment, as a previous discussion by the FAO/WHO Expert Committee on Food Additives (JECFA, 1980) has indicated that "most of the added H_2O_2 likely to be used for preservation is split into water and oxygen immediately after addition due to the action of catalase. In addition, residual H_2O_2 is likely to disappear during processing or manufacturing as a result of agitation and heating."

Analysis of the effluent released into the environment after the use of hydrogen peroxide in the ultrafiltration process indicates that hydrogen peroxide released from this manufacturing process ranges from 0 – 2 mg/L, with an average of 0.7 mg/L (see Studies below). This effluent stream is further processed from this point prior to being released into the environment. In general, hydrogen peroxide has been reported in rainwater, with levels varying according to the concentration of atmospheric hydrogen peroxide washed out by precipitation or formed in clouds independent of contamination (Kok, 1983). Hydrogen peroxide concentrations in rainwater range from undetectable to 2.6 mg/L (Zika and Saltzman, 1982; Zika *et al.*, 1982), while surface-water hydrogen peroxide concentrations have been reported at 51 – 231 mg/L (Draper and Crosby, 1983). ECETOC (1993) stated that at concentrations ≤200 mg/L in waste water, hydrogen peroxide does not affect the performance of biological treatment systems, and may even

stimulate biodegradation in these systems. However, at concentrations ≥200 mg/L, hydrogen peroxide becomes toxic to microorganisms in biological treatment systems (ECETOC, 1993).

Studies

Fonterra has analyzed the permeate stream released during the manufacture of whey protein concentrate for residual hydrogen peroxide content (Table 7), utilizing a commercial test system according to Fonterra standard operating procedures (Marks *et al.*, 2001; Merck, 2009; Fonterra, 2009a). The limit of detection of hydrogen peroxide for this method is 0.5 mg hydrogen peroxide *per* liter whey product (approximately equivalent to 0.0005%). The amount of hydrogen peroxide released into the waste stream from the production of WPC is provided in Table 7.

Table 7. Concentration of hydrogen peroxide in waste permeate (Fonterra, 2009b)

Sample number	Hydrogen peroxide (mg/L)*
1	0
2	0
3	0.5
4	0
5	0
6	0
7	0
8	1
9	2
10	2
11	1
12	2
13	2
14	0.5
15	0
16	0.5
17	0.5
18	0.5

*Hydrogen peroxide level after ultrafiltration manufacture; the effluent stream from the manufacture of whey is further processed in other manufacturing processes within the facility prior to being released

Hydrogen peroxide is naturally produced in the environment, generally produced in surface water by a photochemical process involving molecular oxygen and dissolved light-absorbing organic matter (Zika and Saltzman, 1982; ECB, 2003). Hydrogen peroxide is also found in the gaseous state in the earth's lower atmosphere (a product of atmospheric photochemical reactions) and is subsequently washed *via* the rain into fresh and saltwater bodies. Hydrogen peroxide concentrations in rain-water ranged from undetectable to 2.6 mg/l (Zika *et al.*, 1982). As summarized in the International Agency for Research on Cancer (IARC) monograph (IARC, 1985), surface-water concentrations vary between 51-231 mg/l, and were

found to increase relative to sunlight exposure and the presence of dissolved organic matter (Draper and Crosby, 1983). The levels of hydrogen peroxide released into the water after WPC production is well below the surface-water concentrations (Draper and Crosby, 1983). Hydrogen peroxide has been found to be decomposed by enzymatic action and does not accumulate in cell systems. Decomposition in water and soil takes minutes to several hours, depending on the mineral content and microbial content, as at low hydrogen peroxide concentrations (typically <10 mg/l), aerobic microbes living in water and soil ecosystems are able to utilize catalases to convert hydrogen peroxide to water and oxygen (ECB, 2003). A summary in an assessment of hydrogen peroxide as a commodity chemical indicated that hydrogen peroxide at up to 200 mg/l in waste water does not affect the performance of biological treatment plants (ECB, 2003). The above information indicates that the potential level of hydrogen peroxide released from the production of WPC that utilizes hydrogen peroxide is not of a sufficient quantity to affect the amount of hydrogen peroxide currently found in the environment; therefore, an environmental assessment is not necessary and a categorical exclusion does apply, as stated under 21 CFR25.32(r)[8]: Approval of a food additive petition, color additive, GRAS affirmation petition, or allowing a notification submitted under 21 U.S.C. 348(h) to become effective for a substance that occurs naturally in the environment, when the action does not alter significantly the concentration or distribution of the substance, its metabolites, or degradation products in the environment.

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APPENDIX 1

Table 8. Whey protein concentrate analysis for hydrogen peroxide residue levels (Fonterra, 2009a)

Batch	Batch/ Cypher	Unit	Date	Product	Product Description	Test	Test Description	Result
41+08/4281	AS04	DAILY COMP	8/5/2008	41+0811323017502	WPC 80 Sul A132 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/4282	AS04	DAILY COMP	8/5/2008	41+0811323017502	WPC 80 Sul A132 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/5497	AS07	DAILY COMP	8/8/2008	41+0811633017510	WPC 80 Sul A163 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/5650	AS08	DAILY COMP	8/9/2008	41+0811633017510	WPC 80 Sul A163 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/5913	AS09	DAILY COMP	8/10/2008	41+0811633017510	WPC 80 Sul A163 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/6246	AS10	DAILY COMP	8/11/2008	41+0811633017510	WPC 80 Sul A163 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/6661	AS12	DAILY COMP	8/13/2008	41+0811633017510	WPC 80 Sul A163 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/6975	AS13	DAILY COMP	8/14/2008	41+0811633017510	WPC 80 Sul A163 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/7232	AS14	DAILY COMP	8/15/2008	41+0811633017510	WPC 80 Sul A163 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/7437	AS15	DAILY COMP	8/16/2008	41+0811633017510	WPC 80 Sul A163 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/7598	AS16	DAILY COMP	8/17/2008	41+0811633017510	WPC 80 Sul A163 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/7777	AS17	DAILY COMP	8/18/2008	41+0811633017510	WPC 80 Sul A163 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/8119	AS18	DAILY COMP	8/19/2008	41+0811633017510	WPC 80 Sul A163 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/8186	AS19	DAILY COMP	8/19/2008	41+0811633017510	WPC 80 Sul A163 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/8485	AS20	DAILY COMP	8/21/2008	41+0811633017510	WPC 80 Sul A163 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/9043	AS22	DAILY COMP	8/23/2008	41+0811633017510	WPC 80 Sul A163 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs

Batch	Batch/ Cypher	Unit	Date	Product	Product Description	Test	Test Description	Result
41+08/9350	AS23	DAILY COMP	8/24/2008	41+08116430175 10	WPC 80 Sul A164 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/9535	AS24	DAILY COMP	8/25/2008	41+08116430175 10	WPC 80 Sul A164 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/9770	AS25	DAILY COMP	8/25/2008	41+08116430175 10	WPC 80 Sul A164 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/10231	AS26	DAILY COMP	8/27/2008	41+08116430175 10	WPC 80 Sul A164 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/10543	AS27	DAILY COMP	8/28/2008	41+08116430175 10	WPC 80 Sul A164 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/10783	AS28	DAILY COMP	8/29/2008	41+08116430175 10	WPC 80 Sul A164 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/10964	AS29	DAILY COMP	8/30/2008	41+08116330175 10	WPC 80 Sul A163 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/11171	AS30	DAILY COMP	8/31/2008	41+08116430175 10	WPC 80 Sul A164 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/11436	AS31	DAILY COMP	9/1/2008	41+08116430175 10	WPC 80 Sul A164 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/11741	BS01	DAILY COMP	9/2/2008	41+08116330175 10	WPC 80 Sul A163 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/11901	BS02	DAILY COMP	9/2/2008	41+08116330175 10	WPC 80 Sul A163 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/12443	BS03	DAILY COMP	9/4/2008	41+08116330175 10	WPC 80 Sul A163 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/12724	BS04	DAILY COMP	9/5/2008	41+08116330175 10	WPC 80 Sul A163 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/12964	BS05	DAILY COMP	9/6/2008	41+08116330175 10	WPC 80 Sul A163 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/13184	BS06	DAILY COMP	9/7/2008	41+08116330175 10	WPC 80 Sul A163 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/13462	BS07	DAILY COMP	9/8/2008	41+08116330175 10	WPC 80 Sul A163 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/13734	BS08	DAILY COMP	9/8/2008	41+08116330175 10	WPC 80 Sul A163 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/14262	BS09	DAILY COMP	9/10/2008	41+08116330175 10	WPC 80 Sul A163 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs

Batch	Batch/ Cypher	Unit	Date	Product	Product Description	Test	Test Description	Result
41+08/14448	BS10	DAILY COMP	9/11/2008	41+08116330175 10	WPC 80 Sul A163 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/14783	BS11	DAILY COMP	9/12/2008	41+08116330175 10	WPC 80 Sul A163 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/14997	BS12	DAILY COMP	9/13/2008	41+08116330175 10	WPC 80 Sul A163 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/15174	BS13	DAILY COMP	9/14/2008	41+08116330175 10	WPC 80 Sul A163 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/15388	BS14	DAILY COMP	9/15/2008	41+08116330175 10	WPC 80 Sul A163 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/15943	BS15	DAILY COMP	9/16/2008	41+08116330175 10	WPC 80 Sul A163 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/16124	BS16	DAILY COMP	9/17/2008	41+08116330175 10	WPC 80 Sul A163 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/16282	BS17	DAILY COMP	9/17/2008	41+08116330175 10	WPC 80 Sul A163 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/16829	BS18	DAILY COMP	9/19/2008	41+08116330175 10	WPC 80 Sul A163 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/16863	BS19	DAILY COMP	9/19/2008	41+08116330175 10	WPC 80 Sul A163 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/17012	BS20	DAILY COMP	9/20/2008	41+08116330175 10	WPC 80 Sul A163 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/17221	BS21	DAILY COMP	9/21/2008	41+08116330175 10	WPC 80 Sul A163 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/17850	BS22	DAILY COMP	9/23/2008	41+08116330175 10	WPC 80 Sul A163 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/18165	BS23	DAILY COMP	9/24/2008	41+08116330175 10	WPC 80 Sul A163 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/18425	BS24	DAILY COMP	9/25/2008	41+08116330175 10	WPC 80 Sul A163 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/18696	BS25	DAILY COMP	9/26/2008	41+08116330175 10	WPC 80 Sul A163 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/18912	BS26	DAILY COMP	9/27/2008	41+08116330175 10	WPC 80 Sul A163 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/19198	BS27	DAILY COMP	9/28/2008	41+08113230175 02	WPC 80 Sul A132 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs

Batch	Batch/ Cypher	Unit	Date	Product	Product Description	Test	Test Description	Result
41+08/19461	BS28	DAILY COMP	9/29/2008	41+08113330175 02	WPC 80 Sul 1333 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/19795	BS29	DAILY COMP	9/30/2008	41+08113330175 02	WPC 80 Sul 1333 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/19892	BS30	DAILY COMP	9/30/2008	41+08125630175 12	WPC 80 Sul A256 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/20207	CS01	DAILY COMP	10/1/2008	41+08116430175 10	WPC 80 Sul A164 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/20438	CS02	DAILY COMP	10/2/2008	41+08116430175 10	WPC 80 Sul A164 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/20706	CS03	DAILY COMP	10/4/2008	41+08116430175 10	WPC 80 Sul A164 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/20933	CS04	DAILY COMP	10/5/2008	41+08116430175 10	WPC 80 Sul A164 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/21042	CS05	DAILY COMP	10/5/2008	41+08116430175 10	WPC 80 Sul A164 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/21609	CS06	DAILY COMP	10/7/2008	41+08116430175 10	WPC 80 Sul A164 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/21813	CS07	DAILY COMP	10/8/2008	41+08116430175 10	WPC 80 Sul A164 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/21896	CS08	DAILY COMP	10/8/2008	41+08100880181 79	WPC80Sul A152 LTG Ksh 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/22204	CS09	DAILY COMP	10/10/2008	41+08100880181 79	WPC80Sul A152 LTG Ksh 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/22422	CS10	DAILY COMP	10/11/2008	41+08100880181 79	WPC80Sul A152 LTG Ksh 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/22633	CS11	DAILY COMP	10/12/2008	41+08100880181 79	WPC80Sul A152 LTG Ksh 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/22873	CS12	DAILY COMP	10/13/2008	41+08100880181 79	WPC80Sul A152 LTG Ksh 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/23150	CS13	DAILY COMP	10/13/2008	41+08100880181 79	WPC80Sul A152 LTG Ksh 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/23517	CS14	DAILY COMP	10/15/2008	41+08100880181 79	WPC80Sul A152 LTG Ksh 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/23760	CS15	DAILY COMP	10/16/2008	41+08100880181 79	WPC80Sul A152 LTG Ksh 25kgMBG	C5200-02	Hydrogen Peroxide	Abs

Batch	Batch/ Cypher	Unit	Date	Product	Product Description	Test	Test Description	Result
41+08/24052	CS16	DAILY COMP	10/17/2008	41+0810088018179	WPC80Sul A152 LTG Ksh 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/24288	CS17	DAILY COMP	10/18/2008	41+0810088018179	WPC80Sul A152 LTG Ksh 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/24490	CS18	DAILY COMP	10/19/2008	41+0811333017502	WPC 80 Sul 1333 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/24491	CS18	DAILY COMP	10/19/2008	41+0810088018179	WPC80Sul A152 LTG Ksh 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/24765	CS19	DAILY COMP	10/20/2008	41+0811333017502	WPC 80 Sul 1333 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/25386	CS20	DAILY COMP	10/21/2008	41+0811333017502	WPC 80 Sul 1333 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/25473	CS21	DAILY COMP	10/21/2008	41+0811333017502	WPC 80 Sul 1333 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/26013	CS22	DAILY COMP	10/23/2008	41+0811333017502	WPC 80 Sul 1333 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/26485	CS23	DAILY COMP	10/25/2008	41+0811333017502	WPC 80 Sul 1333 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/26487	CS24	DAILY COMP	10/25/2008	41+0811333017502	WPC 80 Sul 1333 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/26665	CS25	DAILY COMP	10/26/2008	41+0811323017502	WPC 80 Sul A132 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/27005	CS26	DAILY COMP	10/28/2008	41+0812563017512	WPC 80 Sul A256 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/27628	CS29	DAILY COMP	10/30/2008	41+0812563017512	WPC 80 Sul A256 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/27963	CS30	DAILY COMP	10/31/2008	41+0812563017512	WPC 80 Sul A256 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/28153	CS31	DAILY COMP	11/1/2008	41+0812563017512	WPC 80 Sul A256 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/28482	DS01	DAILY COMP	11/2/2008	41+0812563017512	WPC 80 Sul A256 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/29521	DS05	DAILY COMP	11/6/2008	41+0812563017512	WPC 80 Sul A256 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/29654	DS06	DAILY COMP	11/6/2008	41+0811620017508	WPC 80 Sul A162 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs

Batch	Batch/ Cypher	Unit	Date	Product	Product Description	Test	Test Description	Result
41+08/30076	DS07	DAILY COMP	11/8/2008	41+0811620017508	WPC 80 Sul A162 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/30331	DS08	DAILY COMP	11/9/2008	41+0811620017508	WPC 80 Sul A162 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/30560	DS09	DAILY COMP	11/10/2008	41+0811620017508	WPC 80 Sul A162 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/30755	DS10	DAILY COMP	11/10/2008	41+0811620017508	WPC 80 Sul A162 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/31227	DS11	DAILY COMP	11/11/2008	41+0811620017508	WPC 80 Sul A162 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/31495	DS12	DAILY COMP	11/12/2008	41+0811620017508	WPC 80 Sul A162 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/31927	DS13	DAILY COMP	11/14/2008	41+0811620017508	WPC 80 Sul A162 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/32146	DS14	DAILY COMP	11/15/2008	41+0811620017508	WPC 80 Sul A162 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/32527	DS15	DAILY COMP	11/16/2008	41+0811323017502	WPC 80 Sul A132 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/32671	DS16	DAILY COMP	11/17/2008	41+0811323017502	WPC 80 Sul A132 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/32996	DS17	DAILY COMP	11/17/2008	41+0811323017502	WPC 80 Sul A132 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/33382	DS18	DAILY COMP	11/19/2008	41+0811323017502	WPC 80 Sul A132 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/33537	DS19	DAILY COMP	11/19/2008	41+0811323017502	WPC 80 Sul A132 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/33792	DS20	DAILY COMP	11/21/2008	41+0811323017502	WPC 80 Sul A132 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/34057	DS21	DAILY COMP	11/22/2008	41+0811323017502	WPC 80 Sul A132 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/34477	DS23	DAILY COMP	11/24/2008	41+0812563017512	WPC 80 Sul A256 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/34948	DS24	DAILY COMP	11/25/2008	41+0812563017512	WPC 80 Sul A256 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/35197	DS25	DAILY COMP	11/26/2008	41+0812563017512	WPC 80 Sul A256 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs

Batch	Batch/ Cypher	Unit	Date	Product	Product Description	Test	Test Description	Result
41+08/35488	DS26	DAILY COMP	11/27/2008	41+0812563017512	WPC 80 Sul A256 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/35790	DS27	DAILY COMP	11/28/2008	41+0812563017512	WPC 80 Sul A256 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/36010	DS28	DAILY COMP	11/29/2008	41+0812563017512	WPC 80 Sul A256 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/36235	DS29	DAILY COMP	11/30/2008	41+0812563017512	WPC 80 Sul A256 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/36344	DS30	DAILY COMP	11/30/2008	41+0812563017512	WPC 80 Sul A256 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/37041	ES01	DAILY COMP	12/2/2008	41+0811323017502	WPC 80 Sul A132 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/37344	ES02	DAILY COMP	12/3/2008	41+0811323017502	WPC 80 Sul A132 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/37608	ES03	DAILY COMP	12/4/2008	41+0811323017502	WPC 80 Sul A132 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/37855	ES04	DAILY COMP	12/5/2008	41+0811323017502	WPC 80 Sul A132 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/38246	ES05	DAILY COMP	12/6/2008	41+0811323017502	WPC 80 Sul A132 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/38494	ES06	DAILY COMP	12/7/2008	41+0811323017502	WPC 80 Sul A132 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/38916	ES08	DAILY COMP	12/9/2008	41+0818301017542	WPC 80 Chs 8300 LOL 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/39438	ES09	DAILY COMP	12/10/2008	41+0818301017542	WPC 80 Chs 8300 LOL 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/40084	ES11	DAILY COMP	12/12/2008	41+0818301017542	WPC 80 Chs 8300 LOL 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/40086	ES11	DAILY COMP	12/12/2008	41+0818301017542	WPC 80 Chs 8300 LOL 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/40401	ES12	DAILY COMP	12/13/2008	41+0818301017542	WPC 80 Chs 8300 LOL 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/40560	ES13	Daily Comp	12/14/2008	41+0813423017510	WPC 80 Sul A322 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/40763	ES14	Daily Comp	12/15/2008	41+0813423017510	WPC 80 Sul A322 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs

Batch	Batch/ Cypher	Unit	Date	Product	Product Description	Test	Test Description	Result
41+08/41192	ES15	Daily Comp	12/16/2008	41+0813423017510	WPC 80 Sul A322 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/41493	ES16	Daily Comp	12/17/2008	41+0813423017510	WPC 80 Sul A322 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/42227	ES19	DAILY COMP	12/19/2008	41+0811620017508	WPC 80 Sul A162 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/42417	ES20	DAILY COMP	12/20/2008	41+0811620017508	WPC 80 Sul A162 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/42882	ES21	DAILY COMP	12/22/2008	41+0811620017508	WPC 80 Sul A162 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/43348	ES22	DAILY COMP	12/23/2008	41+0811620017508	WPC 80 Sul A162 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/43661	ES23	DAILY COMP	12/24/2008	41+0811620017508	WPC 80 Sul A162 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/43903	ES24	DAILY COMP	12/25/2008	41+0811620017508	WPC 80 Sul A162 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/44072	ES25	DAILY COMP	12/26/2008	41+0811620017508	WPC 80 Sul A162 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/44203	ES26	DAILY COMP	12/27/2008	41+0811620017508	WPC 80 Sul A162 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/44418	ES27	DAILY COMP	12/28/2008	41+0811620017508	WPC 80 Sul A162 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/44620	ES28	DAILY COMP	12/29/2008	41+0811333017502	WPC 80 Sul 1333 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/44902	ES29	DAILY COMP	12/29/2008	41+0811333017502	WPC 80 Sul 1333 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/45399	ES30	DAILY COMP	12/31/2008	41+0811333017502	WPC 80 Sul 1333 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/45664	ES31	DAILY COMP	1/1/2009	41+0811333017502	WPC 80 Sul 1333 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/45946	FT01	DAILY COMP	1/2/2009	41+0811333017502	WPC 80 Sul 1333 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/46249	FT02	DAILY COMP	1/3/2009	41+0811333017502	WPC 80 Sul 1333 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/46480	FT03	DAILY COMP	1/4/2009	41+0811333017502	WPC 80 Sul 1333 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs

Batch	Batch/ Cypher	Unit	Date	Product	Product Description	Test	Test Description	Result
41+08/47271	FT05	DAILY COMP	1/6/2009	41+0811333017502	WPC 80 Sul 1333 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/48168	FT07	DAILY COMP	1/8/2009	41+0811333017502	WPC 80 Sul 1333 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/48400	FT08	DAILY COMP	1/8/2009	41+0811333017502	WPC 80 Sul 1333 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/48822	FT09	DAILY COMP	1/10/2009	41+0818301017542	WPC 80 Chs 8300 LOL 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/49145	FT11	DAILY COMP	1/11/2009	41+0818301017542	WPC 80 Chs 8300 LOL 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/49457	FT11	DAILY COMP	1/12/2009	41+0818301017542	WPC 80 Chs 8300 LOL 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/49746	FT12	DAILY COMP	1/13/2009	41+0818301017542	WPC 80 Chs 8300 LOL 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/50241	FT14	DAILY COMP	1/14/2009	41+0818301017542	WPC 80 Chs 8300 LOL 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/50526	FT15	DAILY COMP	1/15/2009	41+0818301017542	WPC 80 Chs 8300 LOL 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/51028	FT16	DAILY COMP	1/17/2009	41+0818301017542	WPC 80 Chs 8300 LOL 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/51244	FT17	Daily Comp	1/18/2009	41+0810121022118	WPC 80 Sul Tr 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/51630	FT18	Daily Comp	1/19/2009	41+0810121022118	WPC 80 Sul Tr 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/51753	FT19	Daily Comp	1/19/2009	41+0810121022118	WPC 80 Sul Tr 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/52003	FT20	Daily Comp	1/20/2009	41+0810121022118	WPC 80 Sul Tr 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/52529	FT21	Daily Comp	1/22/2009	41+0810121022118	WPC 80 Sul Tr 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/52907	FT22	Daily Comp	1/23/2009	41+0810121022118	WPC 80 Sul Tr 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/53025	FT23	Daily Comp	1/23/2009	41+0810121022118	WPC 80 Sul Tr 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/53350	FT24	Daily Comp	1/25/2009	41+0810121022118	WPC 80 Sul Tr 25kgMBG	C5200-02	Hydrogen Peroxide	Abs

Batch	Batch/ Cypher	Unit	Date	Product	Product Description	Test	Test Description	Result
41+08/53564	FT25	DAILY COMP	1/26/2009	41+0811333017502	WPC 80 Sul 1333 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/53656	FT26	DAILY COMP	1/26/2009	41+0811333017502	WPC 80 Sul 1333 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/54449	FT27	DAILY COMP	1/28/2009	41+0811333017502	WPC 80 Sul 1333 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/54655	FT28	DAILY COMP	1/29/2009	41+0811333017502	WPC 80 Sul 1333 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/54890	FT29	DAILY COMP	1/30/2009	41+0810088018179	WPC80Sul A152 LTG Ksh 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/55148	FT30	DAILY COMP	1/31/2009	41+0810088018179	WPC80Sul A152 LTG Ksh 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/55476	GT01	DAILY COMP	2/1/2009	41+0810088018179	WPC80Sul A152 LTG Ksh 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/55937	GT02	DAILY COMP	2/3/2009	41+0810088018179	WPC80Sul A152 LTG Ksh 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/56256	GT03	DAILY COMP	2/4/2009	41+0810088018179	WPC80Sul A152 LTG Ksh 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/56918	GT04	Daily Comp	2/5/2009	41+0810121022118	WPC 80 Sul Tr 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/57102	GT05	Daily Comp	2/6/2009	41+0810121022118	WPC 80 Sul Tr 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/57375	GT06	Daily Comp	2/7/2009	41+0810121022118	WPC 80 Sul Tr 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/57600	GT07	Daily Comp	2/8/2009	41+0810121022118	WPC 80 Sul Tr 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/57818	GT08	Daily Comp	2/9/2009	41+0810121022118	WPC 80 Sul Tr 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/58356	GT09	Daily Comp	2/10/2009	41+0810121022118	WPC 80 Sul Tr 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/58594	GT11	Daily Comp	2/11/2009	41+0810121022118	WPC 80 Sul Tr 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/59077	GT12	Daily Comp	2/13/2009	41+0810121022118	WPC 80 Sul Tr 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/59384	GT13	Daily Comp	2/14/2009	41+0810121022118	WPC 80 Sul Tr 25kgMBG	C5200-02	Hydrogen Peroxide	Abs

Batch	Batch/ Cypher	Unit	Date	Product	Product Description	Test	Test Description	Result
41+08/59750	GT15	Daily Comp	2/15/2009	41+08101210221 18	WPC 80 Sul Tr 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/60239	GT16	Daily Comp	2/17/2009	41+08101210221 18	WPC 80 Sul Tr 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/60575	GT18	Daily Comp	2/18/2009	41+08101210221 18	WPC 80 Sul Tr 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/60742	GT19	Daily Comp	2/19/2009	41+08101210221 18	WPC 80 Sul Tr 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/61120	GT20	Daily Comp	2/20/2009	41+08101210221 18	WPC 80 Sul Tr 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/62166	GT23	Daily Comp	2/24/2009	41+08101210221 18	WPC 80 Sul Tr 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/62447	GT24	Daily Comp	2/25/2009	41+08101210221 18	WPC 80 Sul Tr 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/62665	GT26	Daily Comp	2/26/2009	41+08101210221 18	WPC 80 Sul Tr 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/63114	GT28	Daily Comp	2/28/2009	41+08101210221 18	WPC 80 Sul Tr 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/63702	HT01	DAILY COMP	3/3/2009	41+08183010175 42	WPC 80 Chs 8300 LOL 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/63703	HT02	DAILY COMP	3/3/2009	41+08183010175 42	WPC 80 Chs 8300 LOL 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/64248	HT04	DAILY COMP	3/5/2009	41+08183010175 42	WPC 80 Chs 8300 LOL 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/64900	HT06	DAILY COMP	3/7/2009	41+08183010175 42	WPC 80 Chs 8300 LOL 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/65544	HT08	DAILY COMP	3/9/2009	41+08183010175 42	WPC 80 Chs 8300 LOL 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/65914	HT09	DAILY COMP	3/11/2009	41+08101160216 97	PL WPC 80 Sul 25kg MBG	C5200-02	Hydrogen Peroxide	Abs
41+08/66029	HT11	DAILY COMP	3/11/2009	41+08183010175 42	WPC 80 Chs 8300 LOL 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/66478	HT12	DAILY COMP	3/13/2009	41+08113330175 02	WPC 80 Sul 1333 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/67074	HT14	DAILY COMP	3/15/2009	41+08113330175 02	WPC 80 Sul 1333 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs

Batch	Batch/ Cypher	Unit	Date	Product	Product Description	Test	Test Description	Result
41+08/67277	HT15	DAILY COMP	3/16/2009	41+0811333017502	WPC 80 Sul 1333 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/67767	HT17	DAILY COMP	3/18/2009	41+0812563017512	WPC 80 Sul A256 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/67963	HT18	DAILY COMP	3/19/2009	41+0812563017512	WPC 80 Sul A256 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/68503	HT20	DAILY COMP	3/21/2009	41+0812563017512	WPC 80 Sul A256 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/68822	HT21	DAILY COMP	3/22/2009	41+0812563017512	WPC 80 Sul A256 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/69396	HT23	DAILY COMP	3/23/2009	41+0812563017512	WPC 80 Sul A256 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/69782	HT24	DAILY COMP	3/25/2009	41+0812563017512	WPC 80 Sul A256 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/69950	HT25	DAILY COMP	3/25/2009	41+0812563017512	WPC 80 Sul A256 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/70455	HT26	DAILY COMP	3/27/2009	41+0818301017542	WPC 80 Chs 8300 LOL 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/70476	HT27	DAILY COMP	3/27/2009	41+0812563017512	WPC 80 Sul A256 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/70781	HT28	DAILY COMP	3/29/2009	41+0812563017512	WPC 80 Sul A256 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/71133	HT29	DAILY COMP	3/30/2009	41+0812563017512	WPC 80 Sul A256 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/71393	HT30	DAILY COMP	3/31/2009	41+0812563017512	WPC 80 Sul A256 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/71805	HT31	DAILY COMP	3/31/2009	41+0812563017512	WPC 80 Sul A256 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/72129	IT01	DAILY COMP	4/2/2009	41+0812563017512	WPC 80 Sul A256 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/72504	IT02	DAILY COMP	4/3/2009	41+0812563017512	WPC 80 Sul A256 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/73019	IT04	DAILY COMP	4/5/2009	41+0818301017542	WPC 80 Chs 8300 LOL 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/73215	IT05	DAILY COMP	4/6/2009	41+0818301017542	WPC 80 Chs 8300 LOL 25kgMBG	C5200-02	Hydrogen Peroxide	Abs

Batch	Batch/ Cypher	Unit	Date	Product	Product Description	Test	Test Description	Result
41+08/73959	IT08	DAILY COMP	4/8/2009	41+08183010175 42	WPC 80 Chs 8300 LOL 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/74669	IT10	DAILY COMP	4/11/2009	41+08183010175 42	WPC 80 Chs 8300 LOL 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/75028	IT13	DAILY COMP	4/13/2009	41+08101220221 30	WPC 80 Sul 1333 K Tr 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/75422	IT14	DAILY COMP	4/15/2009	41+08183010175 42	WPC 80 Chs 8300 LOL 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/75795	IT15	Daily Comp	4/16/2009	41+08101210221 18	WPC 80 Sul Tr 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/76163	IT18	Daily Comp	4/18/2009	41+08101210221 18	WPC 80 Sul Tr 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/76835	IT20	Daily Comp	4/21/2009	41+08101210221 18	WPC 80 Sul Tr 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/77497	IT22	DAILY COMP	4/23/2009	41+08113330175 02	WPC 80 Sul 1333 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/78215	IT25	DAILY COMP	4/26/2009	41+08113330175 02	WPC 80 Sul 1333 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/79063	IT29	DAILY COMP	4/30/2009	41+08113330175 02	WPC 80 Sul 1333 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/79173	JT01	DAILY COMP	5/1/2009	41+08113330175 02	WPC 80 Sul 1333 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/79319	JT02	Daily Comp	5/2/2009	41+08101210221 18	WPC 80 Sul Tr 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/80047	JT05	Daily Comp	5/6/2009	41+08101210221 18	WPC 80 Sul Tr 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+08/80263	JT07	Daily Comp	5/8/2009	41+08101210221 18	WPC 80 Sul Tr 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+09/2919	AT01	Daily Comp	8/2/2009	8.13423E+11	WPC 80 Sul A322 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+09/3344	AT04	Daily Comp	8/4/2009	8.13423E+11	WPC 80 Sul A322 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+09/3505	AT05	Daily Comp	8/5/2009	8.13423E+11	WPC 80 Sul A322 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+09/4235	AT08	DAILY COMP	8/8/2009	8.11633E+11	WPC 80 Sul A163 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs

Batch	Batch/ Cypher	Unit	Date	Product	Product Description	Test	Test Description	Result
41+09/4236	AT08	DAILY COMP	8/8/2009	8.11633E+11	WPC 80 Sul A163 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+09/4973	AT10	DAILY COMP	8/11/2009	8.11633E+11	WPC 80 Sul A163 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+09/5277	AT11	Daily Comp	8/12/2009	8.13423E+11	WPC 80 Sul A322 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+09/6000	AT14	DAILY COMP	8/15/2009	8.11633E+11	WPC 80 Sul A163 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+09/6380	AT16	DAILY COMP	8/17/2009	8.11633E+11	WPC 80 Sul A163 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+09/6559	AT17	DAILY COMP	8/18/2009	8.11633E+11	WPC 80 Sul A163 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+09/6837	AT18	DAILY COMP	8/19/2009	8.11633E+11	WPC 80 Sul A163 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+09/6838	AT19	DAILY COMP	8/19/2009	8.11633E+11	WPC 80 Sul A163 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+09/8633	AT21	DAILY COMP	8/25/2009	8.11633E+11	WPC 80 Sul A163 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+09/8634	AT22	DAILY COMP	8/25/2009	8.11633E+11	WPC 80 Sul A163 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+09/8635	AT23	DAILY COMP	8/25/2009	8.11633E+11	WPC 80 Sul A163 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+09/8721	AT24	DAILY COMP	8/25/2009	8.11643E+11	WPC 80 Sul A164 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+09/8724	AT20	DAILY COMP	8/25/2009	8.11633E+11	WPC 80 Sul A163 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+09/9060	AT25	DAILY COMP	8/27/2009	8.11643E+11	WPC 80 Sul A164 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+09/9061	AT26	DAILY COMP	8/27/2009	8.11643E+11	WPC 80 Sul A164 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+09/9554	AT28	DAILY COMP	8/28/2009	8.11643E+11	WPC 80 Sul A164 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+09/9855	AT28	DAILY COMP	8/29/2009	8.11633E+11	WPC 80 Sul A163 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+09/10224	AT30	DAILY COMP	8/31/2009	8.11633E+11	WPC 80 Sul A163 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs

Batch	Batch/ Cypher	Unit	Date	Product	Product Description	Test	Test Description	Result
41+09/10534	AT31	DAILY COMP	9/1/2009	8.11633E+11	WPC 80 Sul A163 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+09/10678	AT31	DAILY COMP	9/1/2009	8.11633E+11	WPC 80 Sul A163 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+09/10814	BT01	DAILY COMP	9/2/2009	8.11633E+11	WPC 80 Sul A163 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+09/11590	BT03	DAILY COMP	9/4/2009	8.11633E+11	WPC 80 Sul A163 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+09/12371	BT04	DAILY COMP	9/5/2009	8.11633E+11	WPC 80 Sul A163 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+09/12372	BT04	DAILY COMP	9/5/2009	8.11633E+11	WPC 80 Sul A163 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+09/12547	BT05	DAILY COMP	9/6/2009	8.11633E+11	WPC 80 Sul A163 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+09/12784	BT06	DAILY COMP	9/7/2009	8.11633E+11	WPC 80 Sul A163 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs
41+09/13285	BT07	DAILY COMP	9/8/2009	8.11633E+11	WPC 80 Sul A163 K 25kgMBG	C5200-02	Hydrogen Peroxide	Abs

Batch = lab system assigned sample number; batch/cipher=manufacturing lot number; unit=unit number being tested or composite (="daily comp"); date = date of product manufacture; product=product code; product desc = product description; test = lab system test code; test desc=description of test; result=(Abs=Absent; Pres = Present);
*Limit of detection is 0.5mg/L