Richard C Theuer, Ph.D. 7904 Sutterton Court Raleigh, NC 27615-2534 Tel. 1-919-844-5843 <rtheuer@bellsouth.net>

October 26, 2012

Lisa M. Brines, Ph.D. National List Manager USDA/AMS/NOP, Standards Division 1400 Independence Ave. SW Room 2648-So., Ag Stop 0268 Washington, DC 20250-0268

Dear Dr. Brines,

Enclosed with this cover letter is a petition to add the substance ammonium hydroxide as a boiler water additive to the National List at §205.605.

If you have any questions or require additional information or clarification, please let me know. My contact information is given above.

Sincerely,

Richard Theuer

Petition

Item A – Petition for inclusion of ammonium hydroxide at § 205.605 with the annotation "boiler water additive."

Ammonium hydroxide is a synthetic non-agricultural (non-organic) GRAS substance permitted as a boiler water additive by FDA, USDA, and the Pasteurized Milk Ordinance. Ammonium hydroxide passes into steam as ammonia to neutralize carbon dioxide in steam, forming ammonium carbonate when the steam condenses to water and preventing "acid attack." The ammonium carbonate formed in this reaction would be the actual substance "in or on processed products labeled as 'organic' or 'made with organic (specified ingredients)'" if ammonium hydroxide is used as a boiler water additive.

Ammonium carbonate is currently on the National List at §205.605 as a permitted ingredient in processed products labeled as "organic" or "made with organic (specified ingredients)."

Item B – Information on Ammonium Hydroxide

1. Name of the substance

The petitioned substance is known by the chemical name "ammonium hydroxide" and has the molecular formula NH_4OH . It is a solution of ammonia in water and is made by passing ammonia gas – NH_3 – into water. Water – H_2O or HOH – can be considered to be "hydronium hydroxide": (H)⁺ (OH)⁻. The hydronium ion (H)⁺ of the water reacts with ammonia – NH_3 – forming the ammonium ion (NH_4)⁺, thus 'producing' ammonium hydroxide: (NH_4)⁺ (OH)⁻. Ammonium hydroxide is commonly referred to as "ammonia water."

The strength of an ammonium hydroxide solution can be expressed as its percentage of ammonia or as its ammonia concentration expressed in parts per million (PPM). Concentrated ammonium hydroxide is a common laboratory reagent. It contains 27% to 30% ammonia, or 270,000 to 300,000 PPM. Household ammonia water currently available in the supermarket contains 3% (30,000 PPM) to not more than 5% (50,000 PPM) free ammonia. In years past, household ammonia contained up to 10% ammonia (100,000 PPM). However, the Consumer Product Safety Commission now regulates ammonia water sold to consumers. Any preparation containing free or chemically uncombined ammonia in a concentration of 5 percent or more is classified as a poison under the Federal Caustic Poison Act and requires the label to bear the signal word "poison" (16 CFR 1500.129).

Ammonium hydroxide is added to boiler water to provide a level of ammonia in the steam that will neutralized any carbon dioxide in the steam when the steam condenses. The required concentration of ammonia in the steam is a few PPM to about 25 PPM free ammonia, depending upon the concentration of carbon dioxide. Good Manufacturing Practice requires measuring the carbon dioxide level in steam condensate in order to determine how much ammonium hydroxide is required to neutralize the carbon dioxide to pH 8.5 to 9.0, a pH where the carbon dioxide is sequestered as ammonium carbonate.

The reaction of 22 PPM of ammonia (45 PPM of ammonium hydroxide) with carbon dioxide would yield about 60 PPM of ammonium carbonate in the condensate (water), a 0.006% solution.

2. Names, addresses, telephone numbers, and other contact information of manufacturers of ammonium hydroxide.

Food grade concentrated ammonium hydroxide food grade is produced by many reputable chemical suppliers. Two major suppliers are listed below.

Mallinckrodt Baker, Inc.	Fisher Scientific
222 Red School Lane	One Reagent Lane
Phillipsburg, NJ 08865	Fair Lawn, NJ 07410
908-859-2151	201-796-7100

Boiler water additive solutions containing ammonium hydroxide are available from several suppliers, including WET USA, Inc., 316 Roma Jean Parkway, Streamwood, IL 60107; telephone 630-540-2113; URL www.wet-usa.com.

3. Intended Use of Ammonium Hydroxide

Ammonium hydroxide is currently used in conventional dairy processing and is petitioned for use in organic food processing as a boiler additive to neutralize carbon dioxide in order to prevent "acid attack" in steam condensate lines.

4. Handling Activities for which the ammonium hydroxide will be used

Ammonium hydroxide is a substance affirmed as generally recognized as safe (GRAS), at 21 CFR 184.1139. FDA permits it use as a leavening agent, a pH control agent, a surface-finishing agent, and as a boiler water additive. The petitioned annotation restricts it solely for use as a boiler water additive, to neutralize carbon dioxide in steam condensate.

Steam is used in a food processing plant for CIP (Clean-In-Place) heat exchangers, pasteurizers, whey dryers, and tank heating, as well as for other processes. Relatively few of these applications involve use of steam "in or on food," but the technical need for boiler additives applies to all applications.

The technical term for steam used "in or on food" is "culinary steam." There are two main uses of culinary steam in a food plant:

- Food contact surface sanitation or sterilization, including packaging sterilization.
- Direct steam injection, including creating a vacuum by injecting steam into the headspace of a container immediately prior to sealing it.

Sanitizing a food contact surface can be accomplished by applying steam to a clean food contact surface. This destroys most human pathogens and reduces the number of other vegetative micro-organisms to a safe level. Packaging sterilization is required as part of good manufacturing practices in certain food processing applications. For example, passage through a steam tunnel sterilizes bottle caps just before they are put on juice bottles.

The most common form of direct steam injection is injecting a puff of steam into the headspace of a can or jar just before sealing. When the steam condenses to water, it creates a vacuum that keeps the jar lid on during processing and makes the "pop-up" safety feature of the lid operational. The "pop-up" lid of a jar or bottle and the depressed end of a canned food under vacuum give the consumer visible and even audible assurance of the bacteriological safety of the packaged food.

"Direct steam injection" is a particularly efficient method of heating liquid foods. For example, direct steam injection is used to heat the milk in a latte or cappuccino.

Drinking water normally contains minerals like silica, iron, and the carbonates and bicarbonates of calcium and magnesium that contribute hardness and alkalinity, and dissolved gases, like oxygen and carbon dioxide. The minerals in the water deposit on the surface of the boiler as scale. Scale acts as an insulator that reduces heat transfer, causing a decrease in boiler efficiency and excessive fuel consumption.

lon exchange softening of the feed water can be an effective means of reducing the rate of scale formation. Scale formation can be prevented by boiler water additives that chelate the minerals and thus keep them soluble. Most of the boiler water additives used to prevent scale are not volatile, so they remain behind in the boiler water when steam is generated.

Carbon dioxide is responsible for "acid attack." Carbonate alkalinity in the water is converted to carbon dioxide gas (CO_2) by the heat and pressure of the boilers. Acid attack can happen in the boiler when the pH of the boiler water drops below 8.5, which is why alkali is added to boiler water to maintain the pH between 9 and 11.

Acid attack is much more of a problem in steam condensate lines because gaseous CO_2 carries over in the steam. When the steam condenses, the CO_2 dissolves in the condensate (water) to form carbonic acid (H_2CO_3). As little as 1 PPM of carbon dioxide¹ in the steam will reduce the pH below neutrality, to pH 5.5. Condensate can have a pH as low as 3.8 or less. The carbonic acid in condensate corrodes condensate lines. Preventing acidity in condensate requires volatile alkalinity that will pass into the steam and be there when the steam condenses so it can neutralize the carbonic acid to a safe pH of 8.2 to 9.2.

Ammonium hydroxide is a desirable neutralizer of carbonic acid for several reasons. Ammonium hydroxide is a substance affirmed as GRAS. The reaction product of carbon dioxide and ammonium hydroxide is ammonium carbonate, a GRAS substance currently listed on the National List at §205.605. The ammonium ion is a biochemical intermediate in our bodies.

The level of ammonium hydroxide² required in steam depends upon the level of carbon dioxide in the steam. The level of 1 PPM of carbon dioxide³ in the steam, which reduces the pH of the condensate below neutrality, to pH 5.5, is neutralized by less than 1 PPM of ammonia in the steam.

5. Manufacturing process

21 CFR 184.1139 describes the simple process for making ammonium hydroxide: "produced by passing ammonia gas into water." The 2001 TAP for ammonium hydroxide¹ has the following description of how ammonia is produced.

"Ammonia is produced by a number of different processes. Historically, one of the oldest, and the basis for most currently used methods, is the Haber-Bosch process, where natural gas is used to convert atmospheric nitrogen to ammonia (Budavari, 1996). This can be characterized as: $N_2 + 3H_2 \rightarrow 2NH_3$

"Industrial-scale production (of ammonia) requires the maintenance of high temperatures, generally in the range of 700°K to 900°K (427°C - 627°or 800°F - 1,160°F). Processes generally involve the direct reaction of dissociated hydrogen and nitrogen atoms over a catalytic surface coated with a metallic iron. Ammonium hydroxide is produced by the addition of the resulting ammonia to water."

¹ Expressed as calcium carbonate – CaCO3, molecular weight = 100.

² Expressed as ammonia – NH_3 , molecular weight = 17.

³ Expressed as calcium carbonate – $CaCO_3$, molecular weight = 100. Steam containing 1 PPM of free ammonia will neutralize about 3 PPM of carbon dioxide expressed as calcium carbonate.

According to the Hazardous Substances Data Bank, ammonium hydroxide is produced by direct reaction of hydrogen and nitrogen over a catalytic surface based on metallic iron, followed by addition of the resulting ammonia to water.

Some organisms produce ammonia from atmospheric nitrogen by enzymes called nitrogenases. The overall process is called nitrogen fixation. Biological nitrogen fixation has not been commercialized as a source of ammonia, despite intensive research.

6. Previous reviews

Ammonium hydroxide was subjected to a full safety review by the Select Committee on GRAS Substances (SCOGS), an independent committee of the Federation of American Societies for Experimental Biology (FASEB) that reported its findings to FDA in 1974. See Item B-7.

A TAP Review of ammonium hydroxide was prepared by OMRI⁴ for the NOP in 2001. Certain statements in this report were later challenged by this petitioner as part of a review of the TAP Review authorized by NOP. Both documents are referred to or are included in Appendix A. At the NOSB meeting in October 2001, the NOSB recommended addition of ammonium hydroxide to the National List with the annotation "For use as boiler water additive only, removal from the list October 21, 2005." Note that the use of ammonium hydroxide as a boiler water additive was not restricted solely to packaging sterilization.

Ammonium hydroxide never made it to the National List. In the Federal Register of September 11, 2006, NOP explained its reasoning for not implementing the NOSB's ammonium hydroxide recommendation. According to this notice, most commenters supported the inclusion of ammonium hydroxide on the National List and requested that the expiration date be amended to acknowledge the three years that the NOSB had intended to allow the use of the substance. Other commenters expressed the view that ammonium hydroxide should not be added to the National List. They asserted that processors had managed without use of the substance in the past four years and suggested that there are a number of alternatives to ammonium hydroxide for boiler maintenance. The NOP said that they took into account the concerns of the commenters. However, because the expiration date recommended by the NOSB for the use of ammonium hydroxide had lapsed (because of NOP inaction related to the Harvey case), NOP decided not to add ammonium hydroxide to the National List. NOP wrote that, for ammonium hydroxide to be reconsidered for inclusion on the National List, the

⁴ <u>http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5066965&acct=nosb</u> accessed 26 October 2012.

NOSB will have to submit a new recommendation to the Secretary to amend the National List to permit the use of this substance.

The purpose of this petition is to solicit a new recommendation from the NOSB.

The European Union allows ammonium hydroxide in the production of organic gelatin⁵.

Ammonium carbonate is a permitted food additive in the EU, Canadian, and U.S. organic regulations.

7. Regulatory status

FIFRA Requirements: Residues of ammonium hydroxide are exempted from the requirement of a tolerance when used as a solvent, co-solvent, neutralizer, or solubilizing agent in accordance with good agricultural practices as inert (or occasionally active) ingredients in pesticide formulations applied to growing crops or to raw agricultural commodities after harvest. [40 CFR 180.1001(c) (7/1/97)]

CERCLA Reportable Quantities: Persons in charge of vessels or facilities are required to notify the National Response Center (NRC) immediately, when there is a release of this designated hazardous substance, in an amount equal to or greater than its reportable quantity of 1000 lb. or 454 kg. The toll free number of the NRC is (800) 424-8802; In the Washington D.C. metropolitan area (202) 426-2675. The rule for determining when notification is required is stated in 40 CFR 302.4 (section IV. D.3.b). [40 CFR 302.4 (7/1/97)].

Clean Water Act Requirements: Designated as a hazardous substance under section 311(b)(2)(A) of the Federal Water Pollution Control Act and further regulated by the Clean Water Act Amendments of 1977 and 1978. These regulations apply to discharges of this substance. [40 CFR 116.4 (7/1/88)]

FDA affirmed ammonium hydroxide as GRAS in 1974 after extensive review of the scientific literature and a rulemaking process. It is codified at 21 CFR 184.1139. Ammonium hydroxide was one of 235 substances that were subjected to a full safety review by the Select Committee on GRAS Substances (SCOGS), an independent committee of the Federation of American Societies for Experimental Biology (FASEB) that reported its findings to FDA. The SCOGS report to FDA concluded that:

"Ammonia and the ammonium ion are integral components of normal metabolic processes and play an essential role in the physiology of man.... the Select Committee concludes that: There is no evidence in the available information

⁵ Authorized under Regulation (EEC) No 2092/91 and carried over by Article 21(2) of Regulation (EC) No 834/2007.

on.... ammonium hydroxide..... that demonstrates, or suggests reasonable grounds to suspect, a hazard to the public when [it is] used at levels that are now current or that might reasonably be expected in the future." Select Committee on GRAS Substances (SCOGS) Review, Report No. 34, 1974.

Ammonium hydroxide is included in the USDA's list of Safe and Suitable Ingredients Used in the Production of Meat, Poultry, and Egg Products (FSIS Directive 7120.1, Revision 2; last revised 4/12/10). It is used as a pH control agent in brine solutions for meat products, and as an antimicrobial agent for beef carcasses (in hot boxes and holding coolers) and boneless beef trimmings.

Ammonia gas (anhydrous ammonia) is also used as an antimicrobial agent for lean finely textured beef. An informative article on the safety benefit of this use is available on the Cornucopia Institute website⁶.

The reaction products of ammonium hydroxide and carbon dioxide are the affirmed GRAS direct food substances ammonium carbonate (21 CFR 184.1137) and ammonium bicarbonate (21 CFR 184.1135). At the desired safe pH of steam condensate, pH of 8.2 to 9.2, little ammonium bicarbonate is present in the solution.

8. Chemical Abstract Service (CAS) Numbers and Product Label

The CAS Number of ammonium hydroxide is 1336-21-6. The INS Number of ammonium hydroxide is 527. The CAS Number of ammonium carbonate is 8000-73-5.

A product label and a Product Bulletin for WET-1133, a boiler water additive distributed by WET-USA, Inc., that contains ammonium hydroxide, are attached as Appendix B.

9. Physical properties and chemical mode of action

Ammonium hydroxide, concentrated, is a colorless liquid with an intense pungent suffocating odor and an acrid taste. Ammonium hydroxide is infinitely soluble in water. The specific gravity of a 28% NH4OH solution is 0.9 at 25 °C. It has a strong alkaline reaction and dissolves copper and zinc. Solutions of ammonium hydroxide have an alkaline pH: 1.0N solution (3.5% NH4OH) pH 11.6; 0.1 N solution (0.35% NH4OH) pH 11.1; 0.01 N solution (0.035% NH4OH or 170 PPM ammonia) pH 10.6. Fumes are formed when ammonia water (ammonium hydroxide) is brought near volatile acids. It has an exothermic reaction with sulfuric acid. Ammonium hydroxide boils at about 36°C

⁶ What's Wrong With Pink Slime? <u>http://www.cornucopia.org/2012/03/whats-wrong-with-pink-slime/</u> Accessed October 22, 2012.

(97°F) (body temperature) and melts at -72°C (-98°F). It is stable under ordinary conditions of use and storage and produces low temperatures by its own evaporation.

Ammonium hydroxide is useful as a boiler water additive because it gives rise to ammonia which is volatile and carried over in the steam and thus is available to neutralize carbon dioxide (which also is volatile and carried over in the steam) when the steam condenses. Neutralizing the carbon dioxide prevents "acid attack" in steam lines and in steam condensate return lines.

(a) Chemical interactions with other substances, especially substances used in organic production;

Ammonium hydroxide reacts with copper and zinc and dissolves these two metals.

The ammonia in ammonium hydroxide reacts with chorine sanitizers, such as bleach, to produce toxic vapors. The primary toxic chemical formed by the reaction is chloramine vapor.

(b) toxicity and environmental persistence;

The Animal Toxicity Studies section from the NCBI Hazardous Substance Data Bank is reproduced in Appendix C.

(c) environmental impacts from its use and/or manufacture;

The major hazards encountered in the use and handling of ammonium hydroxide stem from its toxicological properties. Toxic by all routes (i.e., inhalation, ingestion, and dermal contact), exposure to this colorless, intensely pungent-smelling liquid may occur from its use in fertilizers, dyes, explosives, plastics, cleansing agents, fibers, and resins. Effects from exposure may include extreme irritation of the eyes and mucous membranes, contact burns to the skin and eyes, and life-threatening pulmonary edema. In activities and situations where over-exposure is possible, wear a self-contained breathing apparatus, and protective clothing (including full face protection). If contact should occur, immediately flush affected skin or eyes with running water for at least 15 minutes, and remove contaminated clothing and shoes at the site. While ammonium hydroxide does not ignite easily, it can burn with the production of irritating or poisonous gases. Fires involving ammonium hydroxide may be extinguished with dry chemical, CO2, Halon, water spray, fog, or standard foam.⁷

Ammonium hydroxide may be shipped via air, rail, road, and water, in containers bearing warning labels that differ depending upon the density, specific gravity, and percent composition of the solution being shipped. Consult the regulatory requirements of the US Department of Transportation before shipping. Ammonium hydroxide should be stored in cool, well-ventilated areas, in strong glass, plastic, or rubber stoppered

⁷ Hazards Summary, Hazard Substances Data Bank.

bottles, away from heavy metals, acids, and combustibles (e.g., wood, paper, oil). For small spills of ammonium hydroxide, first isolate the spill area, then take up with sand or other noncombustible absorbent and place into a container for later disposal. Large spills should be diked far ahead of the spill, taking care to stay out of low areas. Before implementing land disposal of waste ammonium hydroxide, consult with environmental regulatory agencies for guidance.

(d) effects on human health;

Ammonia is toxic at high concentrations. Adverse reactions to free ammonia in food occur at 500 to 1500 PPM, which is fifteen to forty times greater than the human limit of sensory detection (34 PPM). Concentrated ammonium hydroxide, a common laboratory reagent, contains 25% to 30% free ammonia – 250,000 to 300,000 PPM. Eye damage is known to occur very quickly at 90,000 to 440,000 PPM (9% to 44% solutions) and a pH > 12. The Human Health Effects section from the NCBI Hazardous Substance Data Bank is reproduced in Appendix D. EPA classifies concentrated ammonium hydroxide as an extremely hazardous substance.

The Consumer Product Safety Commission regulates ammonia water. Household ammonia water currently available in the supermarket can contain 3% to not more than 5% (50,000 PPM) free ammonia. In years past, household ammonia contained up to 10% ammonia (100,000 PPM). Any preparation containing free or chemically uncombined ammonia in a concentration of 5 percent or more is classified now as a poison under the Federal Caustic Poison Act and requires the label to bear the signal word "poison" (16 CFR 1500.129).

The 2001 Technical Advisory Panel Report on ammonium hydroxide for use as a boiler water additive referred to a product recall of packaged milk contaminated with high levels of ammonia. However, this incident had absolutely nothing to do with the use of ammonium hydroxide as a boiler water additive. It was the result of the rupture of a refrigerant line in the finished product storage area of a dairy.

The refrigeration process in many food plants is based on ammonia compression and expansion. In the product recall referred to above, contamination of the recalled milk cartons resulted when liquid ammonia from a ruptured refrigerant line sprayed on milk cartons for "an unspecified number of hours." The Centers for Disease Control and Prevention (CDC) report describing the incident and the attendant product recall is available at http://www.cdc.gov/mmwr/preview/mmwrhtml/00000726.htm .

The milk containers subject to this recall contained up to 1524 PPM ammonia, with 23% of containers examined having levels of 530 PPM or greater. Of the approximately 520 children exposed to the contaminated milk, 3.9% had case-specific adverse reactions, suggesting that the adverse effects on health were associated with free ammonia levels in excess of 1000 PPM.

Refrigerant grade anhydrous ammonia is a clear, colorless liquid or gas. It is at least 99.95% pure ammonia (999,950 PPM ammonia) and cannot contain more than 33 PPM of water. In stark contrast, steam condensate in food processing plants generally would contain no more than 22 PPM ammonia and not less than 99.95% water.

A food heated by direct steam injection would contain much less than this amount of "ammonia" if the boiler water has ammonium hydroxide added to it. Steam condensate physically cannot amount to more than 20% of the weight of a food product, so any "ammonia" in the condensate would be diluted by a factor of five or more. A five-fold dilution would yield an "ammonia" level in the food product of around 5 PPM or less due to use of steam produced under current good manufacturing practice.

Even more significantly from a health perspective, this "ammonia" would be in the form of ammonium carbonate and would not be free ammonia.

(e) effects on soil organisms, crops, or livestock.

Most microorganisms can utilize the ammonium ion as a nitrogen source. Aqueous solutions of ammonia (ammonium hydroxide) ranging from 16% to 25% ammonia are used in the fermentation industry as a source of nitrogen for microorganisms and to adjust pH during fermentation.

In conventional agriculture, anhydrous ammonia is an efficient and widely used source of nitrogen fertilizer. Ammonia increases yields of field crops such as corn and wheat.

The Animal Toxicity Studies section from the NCBI Hazardous Substance Data Bank is reproduced in Appendix C. Fish are particularly vulnerable since ammonium hydroxide can significantly increase the pH of the water.

10. Safety information

A Material Safety Data Sheet (MSDS) for the boiler water additive product containing ammonium hydroxide designated WET-1133 and produced by WET-USA, Inc., is attached as Appendix E. Human Health Effects information from the Hazardous Substance Data Bank is provided in Appendix D.

11. Research information and contrasting positions

In the Federal Register of September 11, 2006, NOP mentioned the view of some commenters who believed ammonium hydroxide should not be added to the National List. These commenters asserted that processors had managed without use of this substance in the prior four years and suggested that there are a number of alternatives to ammonium hydroxide for boiler maintenance. Other commenters expressed the view that ammonium hydroxide should not be added to the National List because processors

had managed without use of the substance in the past four years and that there are a number of alternatives to ammonium hydroxide for boiler maintenance.

The USDA General Specifications for Dairy Plants Approved for USDA Inspection and Grading Service at 7 CFR 58.127(d) state that "Culinary steam used in direct contact with milk or dairy products shall be free from harmful substances or extraneous material and only those boiler water additives that meet the requirements of 21 CFR 173.310 shall be used, or a secondary steam generator shall be used in which soft water is converted to steam and no boiler compounds are used."

Those individuals opposed to adding ammonium hydroxide to the National List several years ago correctly stated that processors were able to manage by using alternatives. However, the alternatives entail extra expense and extra effort that increase the cost of organic foods for the consumer. Examples of these alternatives are:

- Replacement of steam lines with stainless steel piping;
- Extensive water treatment of the feed water to soften, deionize, filter and otherwise purify it;
- Physical and chemical deaeration;
- Interruption of boiler water treatment prior to organic processing;
- "Bleed runs" [product flush and discard];
- More frequent "blow-downs" [removal and disposal of treated boiler water as waste water];
- Dismantling and cleaning the system prior to organic food handling;
- Steam-to-steam heat exchangers;
- Use of heat exchangers instead of direct steam injection for product heating;
- A separate secondary boiler to generate steam for direct food contact applications, as suggested in the USDA General Specifications for Dairy Plants.

Each of these alternatives has economic, environmental, and/or safety downsides. Irregular boiler operation shortens the life of the boiler and increases the risk of catastrophic events. Extensive water treatment increases the discharge of chemicals into the waste stream. "Bleed runs" can consign nutritious, expensive organic food to the sewer or dumpster.

As boiler water is converted to steam, the levels of minerals and boiler additives increase in the remaining boiler water. The main form of maintenance and downtime for a boiler is "blowdown," a periodic or continuous water removal process that limits the concentration of impurities in boiler water and controls the buildup of dissolved (soluble) solids in the boiler water. "Blowdown" is required whether volatile chemical treatments are used or not, but more frequent "blow-downs" increase the discharge of boiler chemicals into the waste stream and thus the environment.

Boilers, heat exchangers, and other equipment are expensive; the Petition Justification Statement in the 2000 petition for the volatile amine diethylaminoethanol cited the cost of a new boiler at \$200,000.

12. Petition Justification Statement

Ammonium hydroxide should be included on the National List at 205.605(b) for the following reasons:

Permit avoidance of synthetic volatile amines by concerned processors

The National List currently includes three volatile synthetic amines as boiler water additives to prevent acid attack in steam condensate lines: **cyclohexylamine** and **diethylaminoethanol**, two neutralizing amines, and **octadecylamine**, a filming amine. These synthetic substances permitted as food additives can be replaced by ammonium hydroxide. Unlike the three volatile amines, ammonium hydroxide is not a "boiler water additive" listed at 21 CFR 173.310. It is a "direct food substance affirmed by FDA as Generally Recognized As Safe" (GRAS) listed at 21 CFR 184.1139. Moreover, the form of "ammonium hydroxide" in steam condensate is ammonium carbonate, a substance currently on the National List. In contrast, the three synthetic amines retain their identity in the steam condensate and thus persist into the processed food as such.

Create consistency and uniformity with other U.S. regulations

FDA, the Pasteurized Milk Ordinance, and USDA, in its General Specifications for Dairy Plants Approved for USDA Inspection and Grading Service, each regulates boiler water additives. Their regulations are consistent with each other but not with the organic regulation, in two regards. What they allow is not permitted by the Organic regulation. What the Organic regulation allows is not permitted for all uses by the other regulations.

The Organic regulation currently allows use of **cyclohexylamine**,

diethylaminoethanol, and **octadecylamine** as boiler water additives and thus in culinary steam. The FDA regulation 21 CFR 173.310 that permits these three volatile amines for use in culinary steam has the provision "*excluding use of such steam in contact with milk and milk products*."

The Pasteurized Milk Ordinance (PMO) requires that in culinary steam "only compounds complying with 21 CFR 173.310 may be used to prevent corrosion and scale in boilers, or to facilitate sludge removal." It continues: "Boiler compounds containing **cyclohexylamine**, morpholine, **octadecylamine**, **diethylaminoethanol**, trisodium nitrilotriacetate, and hydrazine *shall not be permitted for use in steam in contact with milk and milk products*."

The USDA General Specifications for Dairy Plants Approved for USDA Inspection and Grading Service state at 7 CFR 58.127(d) that "*Culinary steam used in direct contact*

with milk or dairy products shall be free from harmful substances or extraneous material and only those boiler water additives that meet the requirements of 21 *CFR 173.310 shall be used*, or a secondary steam generator shall be used in which soft water is converted to steam and no boiler compounds are used."

The converse is true. Ammonium hydroxide is permitted by FDA, the PMO, and the USDA for use as a boiler water additive, at levels not to exceed current good manufacturing practice without restriction except for good manufacturing practices (GMP), but the Organic regulation currently does not allow it.

Allowing ammonium hydroxide as a boiler water additive will begin to harmonize the Organic regulation with FDA, PMO, and USDA regulations.

Allow use of a safer, less "unnatural" boiler water additive

The three boiler additives currently on the National List are 'unnatural' substances (i.e., they are not found in nature). Unlike these three volatile amines, the ammonium ion is found in nature. Our bodies actually convert the amino acid glutamine into glutamic acid and ammonium ions by splitting off ammonia (ammonium ions at physiological pH). Our kidneys produce ammonia to balance the excretion of acid and keep our urine from becoming too acidic. Individuals with severe acidosis can produce and excrete as much as 5 grams of ammonia a day in the urine.

Because the nitrogen of the ammonium ion is nutritionally available, the extremely small amount of ammonium ion present in food as ammonium carbonate contributed by steam condensate is not harmful. In 1973, FDA determined that the concentrations of ammonia and ammonium compounds normally present in food do not suggest a health risk and recognized that ammonia and ammonium ions are integral components of normal metabolic processes. Ammonium hydroxide is added to a boiler only to the degree necessary to neutralize the carbonic dioxide carried over in the steam by forming ammonium carbonate.

The reaction product of carbon dioxide and ammonium hydroxide is ammonium carbonate, a substance currently on the National List as a leavening agent. FDA permits use of ammonium salts in many processed foods. For example, maximum allowable levels are 0.04–3.2% ammonium bicarbonate in baked goods, grain, snack, foods and reconstituted vegetables; 2.0% ammonium carbonate in baked goods, gelatins and puddings; and 0.6–0.8% ammonium hydroxide (equivalent to 300 to 400 PPM of ammonia) in baked goods, cheeses, gelatins and puddings.

13. Confidential Business Information Statement

This petition contains no Confidential Business Information (CBI) or confidential commercial information.

Ammonium Hydroxide as a Boiler Water Additive

¹¹ <u>http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5066965&acct=nosb</u> accessed 26 October 2012

Appendix A

TAP Review of ammonium hydroxide prepared by OMRI in 2001. Available at http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5066965&acct=nosb Accessed 26 October 2012.

Cover letter dated August 13, 2001, from R. Theuer to Ms. Kim Burton, Chair, Materials Committee, National Organic Standards Committee. (enclosed)

Deferred Material Review - Boiler Water Additives. Report of R. Theuer dated August 8, 2001. (enclosed)

Richard C Theuer, Ph.D. Theuer Research & Consulting 7904 Sutterton Court Raleigh, NC 27615 Tel. 1-919-844-5843 Fax 1-919-845-2754 <theuer@worldnet.att.net>

August 13, 2001

Ms. Kim Burton Chair, Materials Committee National Organic Standards Committee Speedway Avenue Chico, CA 95926

Dear Kim,

I have completed the task outlined in your letter of July 30, 2001. Enclosed is my report. You will note that it is accompanied by a copy of a May 2, 1986, article on ammonia contamination of school milk cartons in Wisconsin published by the Centers for Disease Control (CDC). The relevance of this CDC article is discussed in my report.

I hope that you find my report fully responsive to the National Organic Standards Board request to review critically the petitions and TAP reviews for the boiler additives ammonium hydroxide, cyclohexylamine, diethylaminoethanol, morpholine, and octadecylamine.

I am retaining the files that Mr. Robert Pooler of the National Organic Program sent to me. I am also sending him a copy of my report and the CDC article.

I enjoyed investigating the subject of boiler water additives and learning more about it.

Sincerely,

Richard C Theuer, Ph.D.

 cc: Robert Pooler, Agricultural Marketing Specialist USDA/AMS/TM/NOP, Room 2510-South, Ag Stop 0268 P.O. Box 96456 Washington, DC 20090-6456

Creating better foods for babies . . . for over 30 years

Deferred Material Review - Boiler Water Additives

My intentional order of review was as follows:

A. Requirements Petition requirements TAP Review against NOP work agreement statement TAP Review against NOSB and NOP criteria
B. Document Review Steam generation in organic food processing systems Cyclohexylamine Octadecylamine Morpholine Diethylaminoethanol

Ammonium Hydroxide

Document: Creation:	Steam generation in organic food processing systems. NOSB TAP Review Compiled by OMRI
Date:	15 Feb 2001
General Comment:	A very useful review with a few minor chemical inaccuracies that organizes, simplifies and summarizes the subject so it is easy to grasp. With respect to volatile amine compounds, the document lacks discussion of a critical issue: dairy plant practice (see point 2 below).

Specific Comments:

- 1. Steam is used to heat food by "direct steam injection." The injected steam condenses to water in the process. [The consumer model is the frothy hot milk used to make cappuccino. The milk is diluted and the volume of the "milk" increases by the amount of water condensed from the steam.] The water introduced into the food in this manner should NOT be assumed to be subject to the drinking water standards. [This assumption is specifically indicated on page 1 of the document.]
- 2. The most significant question in my mind is raised by the FDA regulation on boiler water additive use [21 CFR 173.310; specifically paragraph (d)] as it relates to dairy plants. Dairy plants use steam extensively, for both indirect heating with heat exchangers and direct heating by steam injection. 21 CFR 173.310(d) has identical wording for the usage limitations for cyclohexylamine, diethylaminoethanol, morpholine and octadecylamine: "excluding use of such steam in contact with milk and milk products." The reference document should describe how dairy plants manage to do without these volatile amines.
- 3. My initial and tentative conclusion on the use of toxic volatile amines in boiler water to produce steam for "direct contact with" (read "condensation into") organic food is that if dairy plants can manage without them, organic food plants can do likewise.

The included literature references covered general aspects of steam generation. They did not provide any information on dairy plant operation and dairy plant steam generation and use. They do refer to stainless steel systems that resist corrosion.

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Deferred Material Review - Boiler Water Additives

Material:	cyclohexylamine
Document: Opinion:	Petition Justification Statement Incomplete. Ammonium hydroxide is cited as an acceptable amine- based compound for dairy product use but it is ignored as an alternative to toxic volatile organic amines for use in non-dairy food plants
Att. C-3	An incorrect chemical structure of cyclohexylamine is given. [One TAP reviewer also noted this error.]
Document: Opinion:	Petition (other than Petition Justification Statement) Complete.
Document: Aspect: Opinion:	TAP Report Evaluation against the statement of work agreement. Complete with inclusion of reviewer comments. The identification of alternatives in the base document was incomplete in itself but the TAP reviewers (especially Reviewer 3) enumerated a further range of alternatives to use of toxic volatile organic amines in steam that contacts organic food (but excluded consideration of ammonium hydroxide).
Document: Aspect: Opinion:	TAP Report Evaluation against NOSB Requirements. Complete.

Richard C T	heuer 10 August 2001 Deferred Material Review - Boiler Water Additives
Material:	octadecylamine
Document: Opinion:	Petition Justification Statement Incomplete. The justification simply states that octadecylamine is one of several substances available to prevent corrosion of steam lines. None of these other substances are identified.
Document: Opinion:	 Petition (other than Petition Justification Statement) Incomplete. 1. The "manufacturing process" may be incorrect ["nitride" should be "nitrile" or "amide"?]. The "method of manufacturing" description cites "nitrile". The description is very sketchy and does not satisfy the criterion of "detailed." 2. The comprehensive research reviews and bibliographies are illegible and fragmented.
Document: Aspect: Opinion: Document: Aspect: Opinion:	 TAP Report Evaluation against the statement of work agreement. Complete with inclusion of reviewer comments. No information was given on the environmental persistence of octadecylamine. One cited use of the substance is as an antistripping agent in asphalt emulsions for highways, so some data on its environmental persistence must exist. The identification of alternatives in the base document was incomplete. Reference to the "Steam Paper" is inadequate by itself but TAP reviewers 2 and 3 discuss a further range of alternatives to use of toxic volatile organic amines in steam that contacts organic food (but did not consider ammonium hydroxide). TAP Report Evaluation against NOSB Requirements.

Richard C Theuer

Deferred Material Review - Boiler Water Additives

Material: morpholine

Document: Petition Justification Statement

Opinion: Incomplete. Ammonium hydroxide is **cited** as an acceptable aminebased compound for steam in direct contact with dairy products but its use as an alternative to toxic volatile organic amines for use in steam in direct contact with food in non-dairy food plants is not discussed.

Document: Petition (other than Petition Justification Statement)

Opinion: Very complete. The citation of morpholine as a component of protective coatings applied to fresh fruits and vegetables does not create a presumption of safety since morpholine is volatile. More information on this application would be informative. The ethylene glycol MSDS is irrelevant.

Document: TAP Report

Aspect: Evaluation against the statement of work agreement.

Opinion: Complete with inclusion of reviewer comments. The identification of alternatives in the base document was incomplete. Reference to the "Steam Paper" is inadequate in itself but all three TAP reviewers discuss a range of alternatives to use of toxic volatile organic amines in steam that contacts organic food (but they did not consider ammonium hydroxide).

Document: TAP Report

Aspect: Evaluation against NOSB Requirements.

Opinion: Complete.

Richard C Th	neuer 10 August 2001 Deferred Material Review - Boiler Water Additives
Material:	diethyaminoethanol
Document: Opinion:	Petition Justification Statement Incomplete. Ammonium hydroxide is cited as an acceptable amine- based compound for steam in direct contact with dairy products but its use as an alternative to toxic volatile organic amines for use in steam in direct contact with food in non-dairy food plants is not discussed.
Document: Opinion:	Petition (other than Petition Justification Statement) Complete.
Document: Aspect: Opinion:	TAP Report Evaluation against the statement of work agreement. Complete with inclusion of reviewer comments. The identification of alternatives in the base document was incomplete. Reference to the "Steam Paper" is inadequate in itself but all three TAP reviewers discussed a broader range of alternatives to use of volatile organic amines in steam that contacts organic food. They did not consider ammonium hydroxide as an alternative.
Document: Aspect: Opinion:	TAP Report Evaluation against NOSB Requirements. Complete.

Richard C Theu	er	10 August 2001
	Deferred Material Review - Boiler Water Additiv	'es

Material:	ammonium hydroxide
Note:	Food GRAS citation is 21 CFR 184.1139 (not 21 CFR 582.1139)

Document: Petition Justification Statement Opinion: Complete.

Document: Petition (other than Petition Justification Statement)

Opinion: Incomplete. The method of manufacture of ammonia is not disclosed. Ammonium hydroxide is "ammonia water" so the manufacturing method for ammonia is required. The environmental impact of the manufacture of ammonia is not discussed either. The CFR citation of GRAS for human food use is incorrect.

Document: TAP Report

Aspect: Evaluation against the statement of work agreement.

Opinion: Complete. The TAP Report has a complete description of the ammonia production process. The TAP reviewers adequately discussed a range of alternatives to the use of ammonium hydroxide in steam that contacts organic food.

Document: TAP Report

Aspect: Evaluation against NOSB Requirements.

Opinion: Deficient – Nutritional Quality, Available Alternatives.

Nutritional Quality Requirement

"3. If the nutritional quality of the food is maintained and the material itself or its breakdown products do not have adverse effects on human health as defined by applicable Federal regulations."

NOSB Requirement 3 asks if the nutritional quality of the food is maintained and the material itself or its breakdown products do not have adverse effects on health. I interpret this question to focus on the levels of the material and/or its breakdown products in food as allowed by Federal regulation and when the material is used according to current good manufacturing practice.

The discussion of the effect of the ammonium hydroxide used a boiler water additive on the nutritional quality of food in the TAP Review is incomplete and misleading. For example, consider the report of the "accidental release of ammonia." Most food processing facilities possess refrigeration systems to maintain food quality by keeping perishable foods cold. Most of these refrigeration systems are based on ammonia compression and expansion. Virtually every "accidental release of ammonia" at food plants is related to compressor failure or leaky ammonia lines in the refrigeration system. (The ammonia is under pressure.) Virtually none are due to ammonium hydroxide used in boiler water. The TAP Review discussion gives a false impression that the case of milk contaminated with ammonia and children becoming ill (CDC citation) was related to use of steam containing ammonia. This was not the case. To quote the CDC report (this report is available on the Internet and a copy is attached):

"An investigation into the source of the milk determined that, 5 days previously, the milk processor had noted an ammonia leak in one of its cooling chambers, where approximately 250,000 half-pint milk containers with an expiration date of 11/9 were stored. The liquid ammonia, used to cool the tanks and stored under pressure, had sprayed about the storage tank for an undetermined number of hours."

It is misleading to cite this situation as an example of "incidents and indications that ammonia can have documented adverse effects on human health at relatively low levels, not far above the levels at which workers and consumers could potentially be exposed" in a section dealing with the impact of ammonium hydroxide as a boiler additive.

The TAP Review declares that the threshold for detection of ammonia in water is about 35 PPM. The milk in the above situation contained up to 1524 PPM, with 23% of containers examined having ammonia levels of 530 PPM or greater. The level of ammonia in the contaminated milk was fifteen to forty times the cited detection threshold. Of the approximately 520 children exposed to the contaminated milk, only 3.9% had case-specific adverse reactions, suggesting that the adverse effects on health were associated with ammonia levels in excess of 1000 PPM.

The most prejudicial statement in this section is that "it (ammonia or ammonium hydroxide) has **minimal adverse effects on human health if used as intended**." The fact is that FDA has **affirmed** ammonium hydroxide as GRAS. The FDA does not affirm substances as GRAS if the substance "has minimal adverse effects on human health if used as intended." The FDA has defined "safe" in 21 CFR 170.3(i) as "a reasonable certainty . . that **the substance is not harmful under the intended conditions of use**." It is worthwhile to insert the entire definition for the sake of completeness.

21 CFR 170.3

"(i) *Safe* or *safety* means that there is a reasonable certainty in the minds of competent scientists that the substance is not harmful under the intended conditions of use. It is impossible in the present state of scientific knowledge to establish with complete certainty the absolute harmlessness of the use of any substance. Safety may be determined by scientific procedures or by general recognition of safety. In determining safety, the following factors shall be considered:

(1) The probable consumption of the substance and of any substance formed in or on food because of its use.

Deferred Material Review - Boiler Water Additives

- (2) The cumulative effect of the substance in the diet, taking into account any chemically or pharmacologically related substance or substances in such diet.
- (3) Safety factors which, in the opinion of experts qualified by scientific training and experience to evaluate the safety of food and food ingredients, are generally recognized as appropriate."

The TAP Review similarly raises fears of metal toxicity related to the fact that ammonia is a good solvent for certain metals. So is citric acid. This concern is too speculative.

The TAP Review correctly states that ammonium hydroxide is used as a boiler water additive to neutralize carbonic acid (carbon dioxide) in the boiler water condensate. When ammonium hydroxide neutralizes carbon dioxide, the compounds formed are ammonium bicarbonate and ammonium carbonate. These latter substances are commonly used in food as leavening agents. Ammonium carbonates are on the National List as leavening agents in baked goods but also as alternative yeast food. Human beings are similar to yeast in that they can utilize the nitrogen in ammonia ("non-protein nitrogen"), at least at low levels, for amino acid and protein synthesis.

The fact that ammonium hydroxide is affirmed as GRAS (21 CFR 184.1139) with no upper limit specified other than "current GMP" is evidence that the FDA is confident that no manufacturer will add an excessive amount of ammonia via steam condensate because the consumer-perceived quality of the product will suffer.

The TAP Review should have included a listing of the levels of ammonia exposure that produced each effect or "no-effect" to put its fears into perspective. Thus, eye damage occurs at 90,000 to 440,000 PPM (and a pH of > 12), adverse reactions to ammonia in food occur at 500 to 1500 PPM (probably at levels greater than 1000 PPM), and the limit of detection for ammonia in water is 34 PPM. A food heated by steam injection would contain much less "ammonia" when the boiler water has ammonium hydroxide added to it. Reviewer 1 states that "since there are no FDA limitations on its use, the potential for excessive use exists resulting in high concentrations of ammonia in the steam (i.e., greater than 25 PPM)."

Steam condensate cannot account for more than 20% of the weight of a food product, so any "ammonia" in the steam would be diluted by a factor of at least five. A five-fold dilution would yield an "ammonia" level in the food product of 5 PPM or less due to use of steam produced under current good manufacturing practice. Note that at the pH of most food products (rarely higher than pH 8, normally between pH 7 and pH 3.5) there is no "ammonia"; there's only the ammonium ion.

6. The alternatives to using the substance in terms of practices or other available materials. Enough information must be provided with the TAP reviews to ensure that the alternatives are achievable, feasible, and the supply is available to the entire organic industry. If the alternative will create an economic impact to the industry then information should be provided to the board as to cost of the alternative.

The three TAP Reviewers and the "Steam paper" cite some alternatives to the use of carbonic acid scavengers for avoiding corrosion:

- Stainless steel piping;
- Extensive water treatment of the feed water to soften, deionize, filter and otherwise purify it;
- Physical and chemical deaeration;
- Interruption of boiler water treatment during organic processing;
- "Bleed runs" [product flush and discard];
- Frequent "blow-downs" [removal of treated boiler water];
- Dismantling and cleaning the system prior to organic food handling;
- Steam-to-steam heat exchangers;
- Use of heat exchangers instead of direct steam injection;
- Secondary boiler for steam for direct food contact applications.

The reviewers concede that these measures have economic cost. Irregular boiler operation shortens the life of the boiler and increases the risk of catastrophic events. Frequent "blow-downs" increases the discharge of boiler chemicals into the waste stream. Extensive water treatment also increases the discharge of chemicals into the waste stream. "Bleed runs" can consign nutritious, expensive organic food to the dumpster. Equipment is expensive; the Petition Justification Statements for cyclohexylamine, etc. cited the cost of a new boiler at \$200,000.

The reviewers consider ammonia [actually "ammonium hydroxide"] in this specific use to be toxic rather than GRAS as the FDA concluded. They cite ammonium hydroxide as "a toxic boiler additive" and a "cheap toxic chemical." However, ammonium hydroxide is not in the same class as the highly toxic volatile organic amines (cyclohexylamine, diethylaminoethanol, morpholine and octadecylamine). Ammonium hydroxide is a direct food substance <u>affirmed as</u> <u>Generally Recognized As Safe</u> [21 CFR 184.1139] by the Food and Drug Administration. Moreover, the ammonium ion is a normal component of cell metabolism in microorganisms, plants and animals, including humans.

The FDA has drawn a clear distinction between the toxic volatile amines on the one hand and ammonium hydroxide on the other. As I commented earlier, the most significant question in my mind with respect to the "Steam paper" was raised by the FDA limitation on boiler water additive use in dairy plants. 21 CFR 173.310(d) excludes the use of the toxic volatile amines (cyclohexylamine, diethylaminoethanol, morpholine and octadecylamine) to make steam that contacts milk and milk products but allows ammonium hydroxide with no limitation other

than current GMP. The TAP document and the TAP reviewers lumped them all together and considered all of them to be toxic. This is an error. In fact, certain reviewer comments in this regard should be construed as "personal opinions" rather than "technical comments."

For this former NOSB member, there is only one alternative to the use of the toxic volatile amines in boiler water treatment that meets the NOP requirements of "achievable, feasible, and the supply is available to the entire organic industry" and that also does not introduce a toxic material into organic food and thereby violate organic integrity and public trust. That alternative is the use of ammonium hydroxide. Allowance of ammonium hydroxide would put organic food handling plants in the same situation as dairy plants that manage to operate without the toxic volatile amines. If dairy plants can manage with ammonium hydroxide, organic food plants should be able to do so too.

Appendix B

Product Label: WET-1133 Condensate Treatment

Product Bulletin: WET-1133 Boiler Treatment. Revision Date September 1997

WET - 1133 CONDENSATE TREATMENT

INFOTRAC EMERGENCY NO. 1-800-535-5053

Attention:

This container is hazardous when empty. Empty containers retain product residues (vapor and liquid). All labeled precautions must be observed. Do not re-use empty container for any purpose until commercially cleaned and reconditioned. Store empty containers away from heat, sparks, and flame.

Health	3
Flammability	0
Reactivity	1
Personal Protection	J

CORROSIVE LIQUID, N.O.S., 8, UN2672, PG III

(Contains: Ammonia Solution

PG III)

WARNING — MATERIAL CAN CAUSE SEVERE BURNS TO EYES AND SKIN! In case of contact, speed in removing material from eyes and skin is of extreme importance. Flush eyes and skin with plenty of water for at least 15 minutes and then immediately obtain medical attention. Remove and isolate contaminated clothing and shoes, wash before reuse.

D.O.T. EMERGENCY RESPONSE GUIDE NUMBER 154

FIRE OR EXPLOSION: Some of these materials may burn, but none of them ignites readily. Flammable/poisonous gases may accumulate in tanks and hopper cars. Some of these materials may ignite combustibles (wood, paper, oil, etc.). HEALTH HAZARDS: Contact causes burns to skin and eyes. If inhaled, may be harmful. Fire may produce irritating or poisonous gases. Runoff from fire control or dilution water may cause pollution.

EMERGENCY ACTION: Keep unnecessary people away; isolate hazard area and deny entry. Stay upwind; keep out of low areas. Positive pressure self-contained breathing apparatus (SCBA) and structural firefighters' protective clothing will provide limited protection.

If water pollution occurs, notify the appropriate authorities.

FIRE: Small Fires: Dry chemical, CO_2 , water spray or regular foam. Some of these materials may react violently with water. Large Fires: Water spray, fog or regular foam. Move container from fire area if you can do it without risk. Apply cooling water to sides of containers that exposed to flames until well after fire is out. Stay away from end of tanks.

SPILL OR LEAK: do not touch or walk through spilled material: stop leek if you can do it without risk.

Small Dry Spills: With clean shovel place material into clean, dry container and cover loosely; move containers from spill area.

Small Spills: Take up with sand or other noncombustible absorbent material and place into containers for later disposal.

Large Spills: Dike far ahead of liquid spill for later disposal.

FIRST AID: In case of contact with material, immediately flush eyes with running water for at least 15 minutes. Wash skin with soap and water. Remove and isolate contaminated clothing and shoes at site.

APPROPRIATE HAZARD WARNINGS **HEALTH HAZARDS** □ REPRODUCTIVE TOXIN □ CORROSIVE □ CARCINOGEN □ HIGHLY TOXIC □ IRRITANT □ SENSITIZER П (Immediate & Delayed Target Organ Effects) □ HEPATOXINS: LIVER DAMAGE-JAUNDICE, LIVER HEMATOPOIETICS: BLOOD DAMAGE-CYANOSIS. CUTANEOUS HAZARDS: SKIN DAMAGE-RASHES. UNCONSCIOUSNESS ENLARGEMENT **IRRITATION. DEFATTING OF SKIN** PULMONARY DISFUNCTIONS: LUNG DAMAGE-SHORTNESS OF NEPHROTOXINS: KIDNEY DAMAGE-EDEMA, PROTEINURIA EYE HAZARDS: IMPAIRED VISION. BREATH, CHEST TIGHTNESS, COUGH CONJUNCTIVITIS, CORNEAL DAMAGE □ NEUROTOXINS: NERVOUS SYSTEM DAMAGE-NARCOSIS. REPRODUCTIVE TOXINS: BIRTH DEFECTS, STERILITY BEHAVIORAL CHANGES. DECREASE IN MOTOR FUNCTIONS **ROUTES OF ENTRY** □ INGESTION □ SKIN ABSORPTION □ INHALATION □ SKIN OR EYE CONTACT PHYSICAL HAZARDS COMBUSTIBLE LIQUID □ ORGANIC PEROXIDE □ UNSTABLE (REACTIVE) □ FLAMMABLE GAS □ FLAMMABLE LIQUID/SOLID □ COMPRESSED GAS □ WATER REACTIVE □ OXIDIZER □ EXPLOSIVE



WET-1133 BOILER TREATMENT

DESCRIPTION

WET-1133 Condensate Treatment is an aqueous blend of neutralizing amine. The active ingredient in WET-1133 is Ammonium Hydroxide. This product is designed for applications where steam can come in contact with dairy products.

BENEFITS

- Reduces corrosion in a condensate system by neutralizing carbonic acid
- Decreases insulating iron deposits on boiler tubes through lower condensate iron levels
- Special multi-component formulation protects initial, middle, and extended areas of the condensate system.
- Complies with FDA regulations where steam can come in contact with dairy products

APPLICATIONS

WET-1133 is a condensate corrosion inhibitor designed for use in steam and condensate systems. It may be used at boiler operating pressures up to 2,400 psig and temperatures up to 850°F.

DOSAGE

WET-1133 dosage varies according to percent make-up, carbon dioxide content of steam and desired condensate pH. Dosages should be adjusted to maintain a pH range of 8.2 - 9.2 in the condensate. The maximum dosage in plants subject to FDA regulations is not to exceed 45 ppm WET-1133 in the steam. In non-FDA applications where the steam will be used for humidification, the maximum dosage is not to exceed 50 ppm in the steam. For optimum protection of your system, see your WET representative for other recommendations.

FEEDING

WET-1133 can be fed neat or in any convenient dilution. Demineralized water or cooled (<90°F) condensate should be used for product dilution. The preferred feed point is the main steam header, but product can be fed directly to the boiler or into the feedwater line. When feeding WET-1133 to the steam header, a stainless steel retractable atomizing injector should be used. Do not feed WET-1133 ahead of the deaerator, as this will result in significant product loss through the deaerator vent.

WET-1133 should be fed on a continuous basis to help assure program performance.

Materials Compatibility - Suitable materials of construction for chemical feed tank, feed lines, and pump include polyethylene, mild steel, and stainless steel. Nonferrous materials such as copper, aluminum, and zinc should be avoided.

MATERIAL SAFETY DATA SHEET

For information concerning typical properties, health hazard, flammability, reactivity, handling & storage, please consult the MSDS.

PACKAGING

Available in 55, 30, 15, 5 gal drums, bulk shipments, and returnable 200 and 400 gallon tote containers.

TECHNICAL ASSISTANCE

Our technical staff is available to assist in the application of WET's products. You may request assistance through your sales representative or by contacting WET, Inc. at (877) 938-4621.

OTHER REMARKS

Improper application of this product will result in insufficient protection and/or potential damage to the system being treated. Please follow the recommendations of your WET representative.

The information and statements herein are believed to be reliable, but are not to be construed as warranty or representation for which we assume legal responsibility.

For Medical and Transportation Emergencies involving WET products call (24-hour response): (800)535-5053

Revision Date: September 1997

Appendix C

Hazardous Substances Data Bank - Animal Toxicity Studies:

AMMONIUM HYDROXIDE CASRN: 1336-21-6

Animal Toxicity Studies:

Non-Human Toxicity Excerpts:

... APPLICATION OF 28.5% AMMONIUM HYDROXIDE TO /RABBIT/ EYES FOR 2-20 SEC (BEFORE IRRIGATION WITH WATER) CAUSES INJURY RANGING FROM FAINT PERMANENT CORNEAL NEBULA TO PROFOUND CORNEAL OPACIFICATION & VASCULARIZATION PROPORTIONAL TO LENGTH OF EXPOSURE

[Grant, W.M. Toxicology of the Eye. 3rd ed. Springfield, IL: Charles C. Thomas Publisher, 1986., p. 87] **PEER REVIEWED**

SOLN AT PH 9-11.5 APPLIED CONTINUOUSLY TO GINGIVAL CREVICE OF MONKEYS CAUSED ULCERATIVE LESIONS SIMILAR TO THOSE SEEN IN ACUTE NECROTIZING ULCERATIVE GINGIVITIS, BUT GINGIVAL DESTRUCTION MAY HAVE BEEN DUE TO UNIONIZED AMMONIA LIBERATED FROM AMMONIUM SOLN.

[JANN RC ET AL; J S CALIF DENT ASS 41 (6): 485-8 (1973)] **PEER REVIEWED**

Using a (51)Chromium release assay, the cytotoxic potencies of 56 test substances were evaluated in corneal endothelial cell cultures. All of these substances were nonirritants. Ammonium hydroxide was one of the tested substances.

[Douglas WHJ, Spilman SD; Altern Methods Toxicol 1 (Prod Saf Eval): 205-30 (1983)] **PEER REVIEWED**

Acids and alkalies /ammonium hydroxide/ were instilled into the eyes of 2 groups of rabbits; the eyes of 1 group were washed with tap water 30 seconds after exposure. All the alkalies of pH 11.5-13.5 produced opacities and other ocular damage of different degrees depending upon the alkali and its concn. Acidity and alkalinity of the test material are not the only factors to be considered in relation to a substances' capacity to produce severe ocular injury. The concn of the test chemical and its period of contact with the eye prior to washing are also important. [Murphy JC et al; Toxicol 23 (4): 281-91 (1982)] **PEER REVIEWED**

... /IN STUDY/ OF PENETRATION OF AMMONIA INTO EYE ... /RABBIT EYES WERE/ EXPOSED ... TO 10% AMMONIUM HYDROXIDE SOLN, & ... /PENETRATION DETERMINED BY TESTING/ AQUEOUS HUMOR FOR AMMONIUM IONS WITH NESSLER'S REAGENT ... A VERY STRONG REACTION /WAS FOUND/ IN 10 MIN, & PERSISTENCE OF AMMONIUM IONS IN ANTERIOR CHAMBER FOR AT LEAST 2 HR /WAS OBSERVED/, BUT NONE WAS DISCOVERED INTHE VITREOUS. [Grant, W.M. Toxicology of the Eye. 3rd ed. Springfield, IL: Charles C. Thomas Publisher, 1986., p. 90] **PEER REVIEWED**

Appendix C

In carp the acute toxicity of total and unionized ammonia was determined in the 48 hr tests. Experiments were performed in aquariums (245 cu dm) under static conditions, ie without water flow; with the toxic solutions being replaced every 24 hr. Five ammonium cmpd were used as toxic agents. Eight experimental series were carried out; each series comprising of 5-7 ammonium concn and a control fish group. The 48 hr median lethal concn (LC50) and the 95% confidence interval were determined. The concn of unionized ammonia were calculated. The resulting values of 48 hr LC50 of total ammonia remained within the range of 6.6-109 mg/cu dm whereas the respective values of unionized ammonia amounted to 1.15-1.96 mg/cu dm. [Dabrowska H, Sikora H; Pol Arch Hydrobiol 33 (1): 121-8 (1986)] **PEER REVIEWED**

The effect of 0.13 mg/l ammonium hydroxide on Oncorhynchus kisutch (coho salmon) in a pH of 8.0 and temperature of 14.2 deg C for 72 hours was a critical level for the fish. /From table/ [USEPA; Ambient Water Quality Criteria Doc: Ammonia p.145 (1984) EPA 440/5-85-001] **PEER REVIEWED**

The effect of 0.04-0.11 mg/l ammonium hydroxide on Oncorhynchus tshawytscha (chinook salmon) at a pH of 7.6 and temperature of 15.3 deg C for 72 hours was a critical level for the fish. /From table/

[USEPA; Ambient Water Quality Criteria Doc: Ammonia p.145 (1984) EPA 440/5-85-011] **PEER REVIEWED**

The effect of 29.6 mg/l ammonium hydroxide on Salmo gairdneri (rainbow trout) in a pH of 9.42 and a temperature of 13.5 deg C for 3.5 hours was that activity ceased. /From table/ [USEPA; Ambient Water Quality Criteria Doc: Ammonia p.145 (1984) EPA 440/5-85-001] **PEER REVIEWED**

0.15 mg/l of ammonium hydroxide on Salmo trutta (brown trout) in pH 7.8 and a temperature of 11 deg C for 18 hr results in 36% mortality. /From table/ [USEPA; Ambient Water Quality Criteria Doc: Ammonia p.148 (1984) EPA 440/5-85-001] **PEER REVIEWED**

0.26-1.2 mg/l of ammonium hydroxide on Semotilus erythrophthalmus (creek chub) in pH of 8.3 and a temperature of 15-21 deg C for 24 hr resulted in a critical level. /From table/ [USEPA; Ambient Water Quality Criteria Doc: Ammonia p.150 (1984) EPA 440/5-85-001] **PEER REVIEWED**

Chronic effects of ammonia to rainbow trout (Salmo gairdneri) exposed to concn ranging from 0.01 to 0.07 mg/l at mean pH of 7.7 & temp of 9.3 deg C were studied in the lab over a 5 yr period. Parental fish were exposed for 11 mo, the first filial generation (F1) for 4 yr, & second filial generation (F2) for 5 mo. Parental fish spawned at all concn. F1 was manually spawned at 4 yr of age. There was no correlation between ammonia concn & egg reproduction, growth of progeny, or mortality of parents or progeny in any generation. Histopathological lesions were common in parental & F1 generation at blood ammonia non-ionized concn of 0.04 mg/l, & at 0.02 mg/l in F2 generation. The F2 generation incurred a severe protozoan infection at this concn.

[Thurston RV et al; Trans Am Fish Soc 113 (1): 56-73 (1984)] **PEER REVIEWED**

Non-Human Toxicity Values: LD50 Rat oral 350 mg/kg [Lewis, R.J. Sax's Dangerous Properties of Industrial Materials. 9th ed. Volumes 1-3. New York, NY: Van Nostrand Reinhold, 1996., p. 210] **PEER REVIEWED**

Ecotoxicity Values:

LC50 Lepomis macrochirus (bluegill) 0.024-0.093 mg/l/48 hr. /Conditions of bioassay not specified/

[USEPA; Ambient Water Quality Criteria Doc: Ammonia p.151 (1984) EPA 440/5-85-001] **PEER REVIEWED**

LC50 Ictalurus punctatus (channel catfish) 0.974 mg/liter/one week pH= 7.7 Temp= 21.1 degrees C. /Conditions of bioassay not specified/ [USEPA; Ambient Water Quality Criteria Doc: Ammonia p.150 (1984) EPA 440/5-85-001] **PEER REVIEWED**

LC50 Ictalurus punctatus (channel catfish) 1.27 mg/liter/one week pH= 7.8 Temp= 21.7 degrees C. /Conditions of bioassay not specified/ [USEPA; Ambient Water Quality Criteria Doc: Ammonia p.150 (1984) EPA 440/5-85-001] **PEER REVIEWED**

LC50 Ictalurus punctatus (channel catfish) 1.41 mg/liter/one week pH= 7.8 Temp= 22.8 degrees C. /Conditions of bioassay not specified/

[USEPA; Ambient Water Quality Criteria Doc: Ammonia p.150 (1984) EPA 440/5-85-001] **PEER REVIEWED**

LC50 Ictalurus punctatus (channel catfish) 1.97 mg/liter/one week pH= 8.0 Temp= 22.8 degrees C. /Conditions of bioassay not specified/ [USEPA; Ambient Water Quality Criteria Doc: Ammonia p.150 (1984) EPA 440/5-85-001] **PEER REVIEWED**

TLm Fathead minnow 8.2 mg/l/96 hr (hard water) /Conditions of bioassay not specified/ [Verschueren, K. Handbook of Environmental Data of Organic Chemicals. 2nd ed. New York, NY: Van Nostrand Reinhold Co., 1983., p. 195] **PEER REVIEWED**

LC50 Atlantic Salmon smolt 5 to 8 mg/l/24 hr /Conditions of bioassay not specified/ [Environment Canada; Tech Info for Problem Spills: Ammonia (Draft) p.85 (1983)] **PEER REVIEWED**

LC50 Perch 0.29 mg/l/7 days /Un-ionized ammonia/ /Conditions of bioassay not specified/ [Environment Canada; Tech Info for Problem Spills: Ammonia (Draft) p.85 (1983)] **PEER REVIEWED**

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TLm Bluegill 3.4 mg/l/96 hr /hard water, 20 deg C/ /Conditions of bioassay not specified/ [Environment Canada; Tech Info for Problem Spills: Ammonia (Draft) p.85 (1983)] **PEER REVIEWED**

LC50 Daphnia magna 0.66 mg/l/48 hr 22 deg C /Conditions of bioassay not specified/ [Environment Canada; Tech Info for Problem Spills: Ammonia (Draft) p.86 (1983)] **PEER REVIEWED**

TLm Diatom 420 mg/l/120 hr 50% growth reduction /hard water and soft water, 22 deg C//Conditions of bioassay not specified/

[Environment Canada; Tech Info for Problem Spills: Ammonia (Draft) p.86 (1983)] **PEER REVIEWED**

TLm Snail 90 mg/l/96 hr (soft water, 20 deg C) /Conditions of bioassay not specified/ [Environment Canada; Tech Info for Problem Spills: Ammonia (Draft) p.86 (1983)] **PEER REVIEWED**

TLm Striped bass 0.97 ug/l/96 hr (15 deg C); 0.73 ug/l/96 hr (23 deg C) /Unionized NH3/ /Conditions of bioassay not specified/ [Environment Canada; Tech Info for Problem Spills: Ammonia (Draft) p.87 (1983)] **PEER REVIEWED**

TLm Stickleback 96 hr 5.05 ug/l (15 deg C); 1.12 mg/l (23 deg C) (Unionized ammonia) /Conditions of bioassay not specified/ [Environment Canada; Tech Info for Problem Spills: Ammonia (Draft) p.87 (1981)] **PEER REVIEWED**

LC50 Salmo gairdnerii 8 ug/ml NH3/24 hr /Conditions of bioassay not specified/ [Fromm PO; Toxic Action of Water Soluble Pollutants on Freshwater Fish; EPA Water Pollution Control Research Series No. 18050 DST (1970)] **PEER REVIEWED**

TLm Goldfish 2 to 2.5 mg/l/24-96 hr /Conditions of bioassay not specified/ [Verschueren, K. Handbook of Environmental Data of Organic Chemicals. 2nd ed. New York, NY: Van Nostrand Reinhold Co., 1983., p. 195] **PEER REVIEWED**

LC50 Coho salmon 0.45 mg/l/96 hr, Flow-through bioassay [Verschueren, K. Handbook of Environmental Data of Organic Chemicals. 2nd ed. New York, NY: Van Nostrand Reinhold Co., 1983., p. 195] **PEER REVIEWED**

LC50 Guppy fry 74 mg/l/72 hr, Static bioassay [Verschueren, K. Handbook of Environmental Data of Organic Chemicals. 2nd ed. New York,

NY: Van Nostrand Reinhold Co., 1983., p. 195] **PEER REVIEWED**

LC50 Salmo clarki (cutthroat trout fry) flow-through bioassay 0.5-0.8 mg/l/96 hr; 0.56 mg/l/36 day 0.56 mg/l

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[Verschueren, K. Handbook of Environmental Data of Organic Chemicals. 2nd ed. New York, NY: Van Nostrand Reinhold Co., 1983., p. 195] **PEER REVIEWED**

LC50 Rainbow trout: (fertilized egg) > 3.58 mg/l/24 hr; alevin (0-50 days old) > 3.58 mg/l/24 hr; fry (85 days old) 0.068 mg/l/24 hr; adult 0.097 mg/l/24 hr, Static bioassay [Verschueren, K. Handbook of Environmental Data of Organic Chemicals. 2nd ed. New York, NY: Van Nostrand Reinhold Co., 1983., p. 195] **PEER REVIEWED**

LC50 Walking catfish 0.28 mg/l/48 hr, Static bioassay

[Verschueren, K. Handbook of Environmental Data of Organic Chemicals. 2nd ed. New York, NY: Van Nostrand Reinhold Co., 1983., p. 195] **PEER REVIEWED**

Non-Human Toxicity Excerpts:

... APPLICATION OF 28.5% AMMONIUM HYDROXIDE TO /RABBIT/ EYES FOR 2-20 SEC (BEFORE IRRIGATION WITH WATER) CAUSES INJURY RANGING FROM FAINT PERMANENT CORNEAL NEBULA TO PROFOUND CORNEAL OPACIFICATION & VASCULARIZATION PROPORTIONAL TO LENGTH OF EXPOSURE [Grant, W.M. Toxicology of the Eye. 3rd ed. Springfield, IL: Charles C. Thomas Publisher, 1986., p. 87] **PEER REVIEWED**

SOLN AT PH 9-11.5 APPLIED CONTINUOUSLY TO GINGIVAL CREVICE OF MONKEYS CAUSED ULCERATIVE LESIONS SIMILAR TO THOSE SEEN IN ACUTE NECROTIZING ULCERATIVE GINGIVITIS, BUT GINGIVAL DESTRUCTION MAY HAVE BEEN DUE TO UNIONIZED AMMONIA LIBERATED FROM AMMONIUM SOLN. [JANN RC ET AL; J S CALIF DENT ASS 41 (6): 485-8 (1973)] **PEER REVIEWED**

Using a (51)Chromium release assay, the cytotoxic potencies of 56 test substances were evaluated in corneal endothelial cell cultures. All of these substances were nonirritants. **Ammonium hydroxide** was one of the tested substances.

[Douglas WHJ, Spilman SD; Altern Methods Toxicol 1 (Prod Saf Eval): 205-30 (1983)] **PEER REVIEWED**

Acids and alkalies /ammonium hydroxide/ were instilled into the eyes of 2 groups of rabbits; the eyes of 1 group were washed with tap water 30 seconds after exposure. All the alkalies of pH 11.5-13.5 produced opacities and other ocular damage of different degrees depending upon the alkali and its concn. Acidity and alkalinity of the test material are not the only factors to be considered in relation to a substances' capacity to produce severe ocular injury. The concn of the test chemical and its period of contact with the eye prior to washing are also important. [Murphy JC et al; Toxicol 23 (4): 281-91 (1982)] **PEER REVIEWED**

.../IN STUDY/ OF PENETRATION OF AMMONIA INTO EYE .../RABBIT EYES WERE/ EXPOSED ... TO 10% AMMONIUM HYDROXIDE SOLN, & ... /PENETRATION DETERMINED BY TESTING/ AQUEOUS HUMOR FOR AMMONIUM IONS WITH NESSLER'S REAGENT ... A VERY STRONG REACTION /WAS FOUND/ IN 10 MIN, & PERSISTENCE OF AMMONIUM IONS IN ANTERIOR CHAMBER FOR AT LEAST 2 HR /WAS OBSERVED/, BUT NONE WAS DISCOVERED INTHE VITREOUS. [Grant, W.M. Toxicology of the Eye. 3rd ed. Springfield, IL: Charles C. Thomas Publisher, 1986., p. 90] **PEER REVIEWED** In carp the acute toxicity of total and unionized ammonia was determined in the 48 hr tests. Experiments were performed in aquariums (245 cu dm) under static conditions, ie without water flow; with the toxic solutions being replaced every 24 hr. Five ammonium cmpd were used as toxic agents. Eight experimental series were carried out; each series comprising of 5-7 ammonium concn and a control fish group. The 48 hr median lethal concn (LC50) and the 95% confidence interval were determined. The concn of unionized ammonia were calculated. The resulting values of 48 hr LC50 of total ammonia remained within the range of 6.6-109 mg/cu dm whereas the respective values of unionized ammonia amounted to 1.15-1.96 mg/cu dm. [Dabrowska H, Sikora H; Pol Arch Hydrobiol 33 (1): 121-8 (1986)] **PEER REVIEWED**

The effect of 0.13 mg/l ammonium hydroxide on Oncorhynchus kisutch (coho salmon) in a pH of 8.0 and temperature of 14.2 deg C for 72 hours was a critical level for the fish. /From table/ [USEPA; Ambient Water Quality Criteria Doc: Ammonia p.145 (1984) EPA 440/5-85-001] **PEER REVIEWED**

The effect of 0.04-0.11 mg/l **ammonium hydroxide** on Oncorhynchus tshawytscha (chinook salmon) at a pH of 7.6 and temperature of 15.3 deg C for 72 hours was a critical level for the fish. /From table/

[USEPA; Ambient Water Quality Criteria Doc: Ammonia p.145 (1984) EPA 440/5-85-011] **PEER REVIEWED**

The effect of 29.6 mg/l ammonium hydroxide on Salmo gairdneri (rainbow trout) in a pH of 9.42 and a temperature of 13.5 deg C for 3.5 hours was that activity ceased. /From table/ [USEPA; Ambient Water Quality Criteria Doc: Ammonia p.145 (1984) EPA 440/5-85-001] **PEER REVIEWED**

0.15 mg/l of **ammonium hydroxide** on Salmo trutta (brown trout) in pH 7.8 and a temperature of 11 deg C for 18 hr results in 36% mortality. /From table/ [USEPA; Ambient Water Quality Criteria Doc: Ammonia p.148 (1984) EPA 440/5-85-001] **PEER REVIEWED**

0.26-1.2 mg/l of **ammonium hydroxide** on Semotilus erythrophthalmus (creek chub) in pH of 8.3 and a temperature of 15-21 deg C for 24 hr resulted in a critical level. /From table/ [USEPA; Ambient Water Quality Criteria Doc: Ammonia p.150 (1984) EPA 440/5-85-001] **PEER REVIEWED**

Chronic effects of ammonia to rainbow trout (Salmo gairdneri) exposed to concn ranging from 0.01 to 0.07 mg/l at mean pH of 7.7 & temp of 9.3 deg C were studied in the lab over a 5 yr period. Parental fish were exposed for 11 mo, the first filial generation (F1) for 4 yr, & second filial generation (F2) for 5 mo. Parental fish spawned at all concn. F1 was manually spawned at 4 yr of age. There was no correlation between ammonia concn & egg reproduction, growth of progeny, or mortality of parents or progeny in any generation. Histopathological lesions were common in parental & F1 generation at blood ammonia non-ionized concn of 0.04 mg/l, & at 0.02 mg/l in F2 generation. The F2 generation incurred a severe protozoan infection at this concn.

[Thurston RV et al; Trans Am Fish Soc 113 (1): 56-73 (1984)] **PEER REVIEWED**

Non-Human Toxicity Values:

LD50 Rat oral 350 mg/kg [Lewis, R.J. Sax's Dangerous Properties of Industrial Materials. 9th ed. Volumes 1-3. New York, NY: Van Nostrand Reinhold, 1996., p. 210] **PEER REVIEWED**

Ecotoxicity Values:

LC50 Lepomis macrochirus (bluegill) 0.024-0.093 mg/l/48 hr. /Conditions of bioassay not specified/ [USEPA; Ambient Water Quality Criteria Doc: Ammonia p.151 (1984) EPA 440/5-

85-001] **PEER REVIEWED**

LC50 Ictalurus punctatus (channel catfish) 0.974 mg/liter/one week pH= 7.7 Temp= 21.1 degrees C./Conditions of bioassay not specified/ [USEPA; Ambient Water Quality Criteria Doc: Ammonia p.150 (1984) EPA 440/5-85-001] **PEER REVIEWED**

LC50 Ictalurus punctatus (channel catfish) 1.27 mg/liter/one week pH= 7.8 Temp= 21.7 degrees C. /Conditions of bioassay not specified/

[USEPA; Ambient Water Quality Criteria Doc: Ammonia p.150 (1984) EPA 440/5-85-001] **PEER REVIEWED**

LC50 Ictalurus punctatus (channel catfish) 1.41 mg/liter/one week pH= 7.8 Temp= 22.8 degrees C./Conditions of bioassay not specified/ [USEPA; Ambient Water Quality Criteria Doc: Ammonia p.150 (1984) EPA 440/5-85-001] **PEER REVIEWED**

LC50 Ictalurus punctatus (channel catfish) 1.97 mg/liter/one week pH= 8.0 Temp= 22.8 degrees C. /Conditions of bioassay not specified/

[USEPA; Ambient Water Quality Criteria Doc: Ammonia p.150 (1984) EPA 440/5-85-001] **PEER REVIEWED**

TLm Fathead minnow 8.2 mg/l/96 hr (hard water) /Conditions of bioassay not specified/ [Verschueren, K. Handbook of Environmental Data of Organic Chemicals. 2nd ed. New York, NY: Van Nostrand Reinhold Co., 1983., p. 195] **PEER REVIEWED**

LC50 Atlantic Salmon smolt 5 to 8 mg/l/24 hr /Conditions of bioassay not specified/ [Environment Canada; Tech Info for Problem Spills: Ammonia (Draft) p.85 (1983)] **PEER REVIEWED**

LC50 Perch 0.29 mg/l/7 days /Un-ionized ammonia/ /Conditions of bioassay not specified/ [Environment Canada; Tech Info for Problem Spills: Ammonia (Draft) p.85 (1983)] **PEER REVIEWED**

TLm Bluegill 3.4 mg/l/96 hr /hard water, 20 deg C/ /Conditions of bioassay not specified/ [Environment Canada; Tech Info for Problem Spills: Ammonia (Draft) p.85 (1983)] **PEER REVIEWED**

LC50 Daphnia magna 0.66 mg/l/48 hr 22 deg C /Conditions of bioassay not specified/

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[Environment Canada; Tech Info for Problem Spills: Ammonia (Draft) p.86
(1983)] **PEER REVIEWED**

TLm Diatom 420 mg/l/120 hr 50% growth reduction /hard water and soft water, 22 deg C/ /Conditions of bioassay not specified/

[Environment Canada; Tech Info for Problem Spills: Ammonia (Draft) p.86
(1983)] **PEER REVIEWED**

TLm Snail 90 mg/l/96 hr (soft water, 20 deg C) /Conditions of bioassay not specified/ [Environment Canada; Tech Info for Problem Spills: Ammonia (Draft) p.86 (1983)] **PEER REVIEWED**

TLm Striped bass 0.97 ug/l/96 hr (15 deg C); 0.73 ug/l/96 hr (23 deg C) /Unionized NH3/ /Conditions of bioassay not specified/ [Environment Canada; Tech Info for Problem Spills: Ammonia (Draft) p.87 (1983)] **PEER REVIEWED**

TLm Stickleback 96 hr 5.05 ug/l (15 deg C); 1.12 mg/l (23 deg C) (Unionized ammonia) /Conditions of bioassay not specified/

[Environment Canada; Tech Info for Problem Spills: Ammonia (Draft) p.87
(1981)] **PEER REVIEWED**

LC50 Salmo gairdnerii 8 ug/ml NH3/24 hr /Conditions of bioassay not specified/ [Fromm PO; Toxic Action of Water Soluble Pollutants on Freshwater Fish; EPA Water Pollution Control Research Series No. 18050 DST (1970)] **PEER REVIEWED**

TLm Goldfish 2 to 2.5 mg/l/24-96 hr /Conditions of bioassay not specified/ [Verschueren, K. Handbook of Environmental Data of Organic Chemicals. 2nd ed. New York, NY: Van Nostrand Reinhold Co., 1983., p. 195] **PEER REVIEWED**

LC50 Coho salmon 0.45 mg/l/96 hr, Flow-through bioassay [Verschueren, K. Handbook of Environmental Data of Organic Chemicals. 2nd ed. New York, NY: Van Nostrand Reinhold Co., 1983., p. 195] **PEER REVIEWED**

LC50 Guppy fry 74 mg/l/72 hr, Static bioassay [Verschueren, K. Handbook of Environmental Data of Organic Chemicals. 2nd ed. New York, NY: Van Nostrand Reinhold Co., 1983., p. 195] **PEER REVIEWED**

LC50 Salmo clarki (cutthroat trout fry) flow-through bioassay 0.5-0.8 mg/l/96 hr; 0.56 mg/l/36 day 0.56 mg/l [Verschueren, K. Handbook of Environmental Data of Organic Chemicals. 2nd ed. New York, NY: Van Nostrand Reinhold Co., 1983., p. 195] **PEER REVIEWED**

LC50 Rainbow trout: (fertilized egg) > 3.58 mg/l/24 hr; alevin (0-50 days old) > 3.58 mg/l/24 hr; fry (85 days old) 0.068 mg/l/24 hr; adult 0.097 mg/l/24 hr, Static bioassay [Verschueren, K. Handbook of Environmental Data of Organic Chemicals. 2nd ed. New York, NY: Van Nostrand Reinhold Co., 1983., p. 195] **PEER REVIEWED**

LC50 Walking catfish 0.28 mg/l/48 hr, Static bioassay

[Verschueren, K. Handbook of Environmental Data of Organic Chemicals. 2nd ed. New York, NY: Van Nostrand Reinhold Co., 1983., p. 195] **PEER REVIEWED**

Appendix D

Hazardous Substances Data Bank - Human Health Effects

AMMONIUM HYDROXIDE CASRN: 1336-21-6

Human Toxicity Excerpts:

... IN CASE IN WHICH 1 DROP OF **AMMONIUM HYDROXIDE** SOLN OF APPROX 9% CONCN WAS ACCIDENTALLY APPLIED TO PATIENTS EYE, & IRRIGATION WITH WATER ... STARTED WITHIN 10 SEC BECAUSE OF IMMEDIATE SEVERE PAIN & BLEPHAROSPASM, PH OF CONJUNCTIVA & CORNEA ... WITHIN 3 MIN ... RETURNED TO NORMAL, YET MOST OF CORNEAL EPITHELIUM WAS ALREADY LOST. [Grant, W.M. Toxicology of the Eye. 3rd ed. Springfield, IL: Charles C. Thomas Publisher, 1986., p. 87] **PEER REVIEWED**

IN SEVERE INJURIES, WHERE CONCN **AMMONIUM HYDROXIDE** SOLN ... HAS SPLASHED INTO EYE, OR FOLLOWING CONTACT WITH DIL SOLN, BUT WITH DELAY IN 1ST AID IRRIGATION, THROMBOSIS OF CONJUNCTIVAL & EPISCLERAL VESSELS, EVIDENT ON BIOMICROSCOPIC EXAM, MAY GIVE EARLY EYE UNNATURAL PALLOR & COOKED APPEARANCE.

[Grant, W.M. Toxicology of the Eye. 3rd ed. Springfield, IL: Charles C. Thomas Publisher, 1986., p. 87] **PEER REVIEWED**

... A CASE OF SEVERE CORNEAL & CONJUNCTIVAL ULCER WHICH DEVELOPED 10 DAYS AFTER AMMONIA WATER SPLASHED IN EYE /IS REPORTED/.

[Hamilton, A., and H. L. Hardy. Industrial Toxicology. 3rd ed. Acton, Mass.: Publishing Sciences Group, Inc., 1974., p. 207] **PEER REVIEWED**

AMMONIUM HYDROXIDE DIFFERS FROM OTHER ALKALIS IN ITS VOLATILITY; VAPOR (NH3) EVEN IN LOW CONCN IS EXTREMELY IRRITATING TO SKIN, EYES, & RESP PASSAGES. ... INGESTION OF AMMONIA SOLN PRODUCES EFFECTS SIMILAR TO OTHER CORROSIVE ALKALIS, NOTABLY CORROSIVE ESOPHAGITIS & GASTRITIS.

[Gosselin, R.E., R.P. Smith, H.C. Hodge. Clinical Toxicology of Commercial Products. 5th ed. Baltimore: Williams and Wilkins, 1984., p. III-22] **PEER REVIEWED**

The healing response of human volunteers was measured by monitoring the reestablishment of skin surface markings in unroofed blisters induced by brief exposure to a 1:1 aq soln of **ammonium hydroxide.** At all stages of repair, older individuals (ages 65-75 yr) as a group lagged behind young adults (ages 18-25 yr).

[Grove GL; Arch Dermatol Res 272 (3-4): 381-5 (1982)] **PEER REVIEWED** PubMed Abstract

An acute case /is described in/ which a tank of **ammonium hydroxide** overflowed and exposed a worker to a very high concentration of ammonia. Based on the **ammonium hydroxide** concentration and weather conditions, the ammonium concentration was estimated as 10,000 ppm. The patient immediately experienced cough and vomiting and had difficulty in breathing. The length of exposure was not stated, but he performed "small jobs" for the remaining 3 hours

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of work before he was seen at a clinic. At that time, his face was red and swollen, he had conjunctivitis, and his mouth and throat were red and raw. His voice was disappearing and he had labored breathing. The heart appeared to be normal, but while X-rays were being taken, the heart stopped. He was revived by massage and artificial respiration and was transferred to a hospital. Six hours after the accident his heart stopped again and he died. Autopsy showed marked inflammation of the respiratory tract. No pulmonary edema was present, but the tracheal epithelium was almost completely denuded.

[NIOSH; Criteria Document: Ammonia p.29-30 (1979) DHEW Pub. NIOSH 74-136] **PEER REVIEWED**

TOXIC BY INGESTION; BOTH LIQ & VAPOR EXTREMELY IRRITATING, ESP TO EYES.

[Sax, N.I. and R.J. Lewis, Sr. (eds.). Hawley's Condensed Chemical Dictionary. 11th ed. New York: Van Nostrand Reinhold Co., 1987., p. 64] **PEER REVIEWED**

ONE TEASPOONFULL (3 TO 5 ML) OF STRONG (28%) AMMONIA SOLN HAS BEEN RECORDED AS FATAL DOSE BUT RECOVERY HAS FOLLOWED AS MUCH AS 1 FLUID OZ ON SEVERAL OCCASIONS.

[Gosselin, R.E., R.P. Smith, H.C. Hodge. Clinical Toxicology of Commercial Products. 5th ed. Baltimore: Williams and Wilkins, 1984., p. III-22] **PEER REVIEWED**

A 54 year old man with a history of mild hypertension, adult onset diabetes, and heavy smoking was examined for possible ocular, upper airway, and pulmonary manifestations from chronic exposure to **ammonium hydroxide**. The patient was a custodian who daily, for 19 yr, had diluted a 28% solution of **ammonium hydroxide** with water for cleaning. This was his only contact with the chemical. A chest X-ray examination showed a reticular interstitial pattern, and a physical examination showed cataracts and fine inspiratory crackles over both lung fields. An exercise study demonstrated ventilatory restriction after the maximum oxygen consumption had been attained, and a transbronchial lung biopsy showed interstitial fibrosis with chronic inflammation. Fibrous obliteration of the small airways, bronchiectasis, and cataracts were previously described in relation to acute exposure to **ammonium hydroxide**. [Kollef MH; Ann Intern Med 107 (1): 118 (1987)] **PEER REVIEWED**

When ammonia is splashed or sprayed into the eyes, time is the most important consideration and the first 10 seconds are critical if blindness is to be prevented. [NIOSH; Criteria Document: Ammonia p.73 (1974) DHEW Pub. NIOSH 74-136] **PEER REVIEWED**

Swallowing of the liquid results in severe corrosive action to the mouth, throat, and stomach. [Braker W, Mossman A; Matheson Gas Data Book 6th ED p.24 (1980)] **PEER REVIEWED**

With **ammonium hydroxide** skin tests, older subjects had a shorter reaction time (MBT, minimal blistering time), whereas the time needed to develop a tense blister was longer ..., and longer time was needed for the resorption of a wheal elicited by saline injection. [Marzulli, F.N., H.I. Maibach. Dermatotoxicology 4th ed. New York, NY: Hemisphere Publishing Corp., 1991., p. 233] **PEER REVIEWED**

Skin, Eye and Respiratory Irritations:

Ammonium hydroxide causes extremely painful irritation of all mucous membranes. [Dreisbach, R.H. Handbook of Poisoning. 12th ed. Norwalk, CT: Appleton and Lange, 1987., p. 214] **PEER REVIEWED**

BOTH LIQ & VAPOR EXTREMELY IRRITATING, ESP TO EYES.

[Sax, N.I. and R.J. Lewis, Sr. (eds.). Hawley's Condensed Chemical Dictionary. 11th ed. New York: Van Nostrand Reinhold Co., 1987., p. 64] **PEER REVIEWED**

Medical Surveillance:

The following medical procedures should be made available to each employee who is exposed to ammonia at potentially hazardous levels: (1) A complete medical history and physical examination: the purpose is to detect existing conditions that might place the exposed employee at increased risk, and to establish a baseline for future health monitoring. Examination of the eyes and respiratory tract should be stressed. The skin should be examined for evidence of chronic disorders; (2) 14" x 17" chest roentgenogram: Ammonia causes human lung damage. Surveillance of the lung is indicated; (3) FVC and FEV (1 sec): Ammonia is a respiratory irritant. Persons with impaired pulmonary function may be at increased risk from exposure. Periodic surveillance is indicated. Medical examinations should be repeated on an annual basis, except that an X-ray is necessary only when indicated by the results of pulmonary function testing, or by signs and symptoms of respiratory disease. /Ammonia/ [Mackison, F. W., R. S. Stricoff, and L. J. Partridge, Jr. (eds.). NIOSH/OSHA – Occupational Health Guidelines for Chemical Hazards. DHHS(NIOSH)

Publication No. 81-123 (3 VOLS). Washington, DC: U.S. Government Printing

Office, Jan. 1981., p. 1] **PEER REVIEWED**

Appendix E

Material Safety Data Sheet: WET-1133 Condensate Treatment



WET-1133 CONDENSATE TREATMENT

EMERGENCY TELEPHONE 1-800-535-5053 (INFOTRAC)

DESCRIPTION

WET-1133		
CONDENSATE TREATMENT		
Health 3		
Flammability	0	
Reactivity	1	
Personal Protection	Н	
Corrosive, Ammonia Solutions, 8, UN2672, PGIII, RQ		
154		
	WET-1133 CONDENSATE TREATMENT Health Flammability Reactivity Personal Protection Corrosive, Ammonia Solutions, 8 154	

HAZARDOUS INGREDIENTS

Components	Cas #	%	OSHA PEL	ACGIH	Other
				TLV	Limits
Ammonium Hydroxide	1336216	<25.0	50 PPM	25 PPM	
Non-Hazardous Components		>75.0			
Total		100			

PHYSICAL DATA

Physical State	Clear Liquid
Appearance and Odor	Clear Liquid, Strong Ammonia Odor
pH	12+
Melting Point	N/A
Boiling Point	212°F
Vapor Pressure (mmHg)	N.I.A.
Vapor Density $(Air = 1)$	N.A.
Solubility in Water	Complete
Percent Volatile (By Weight)	100
Specific Gravity $(H_2O = 1)$	1.00
Evaporation Rate (($H_2O = 1$)	1.00
Water Reactive	No

FIRE and EXPLOSION DATA

Flash Point	Non-Flammable
Auto-Ignition Temperature	N/A
Lower Flammable Limits in Air (% by Volume)	N/A
Upper Flammable Limits in Air (% by Volume)	N/A
Fire Extinguishing Agents Recommended	Dry Chemical, CO ₂ , Water Spray
Special Fire Fighting Precautions	Wear self-contained breathing apparatus approved by NIOSH.
Unusual Fire and Explosion Hazards	None

WET-1133

REACTIVITY DATA

Stability	Stable
Decomposition Products	None
Hazardous Polymerization	Will Not Occur
Incompatibility	Avoid Strong Oxidizing Agents, any Reactive Materials, Acids
Conditions to Avoid	N/A
HEALTH HAZARD DATA	
Inhelation	Pamova to frach air
Initiatation	Remove to fresh an.
Ingestion	Do not induce vomiting. Dilute by giving large amount of
	water. Get immediate medical attention
Skin	Severe burns to skin.
	Flush skin with water for at least 15 minutes. If irritation
	persists, get medical attention
Eves	Severe hurns to ever
Lyes	Immediate flush eves with water for 15 minutes. Get medical
	attention immediately
Unusual Chronic Toxicity	None Known
Carcinogen Listed in	Not Listed
C C	

PRECAUTIONS FOR SAFE HANDLING AND USE

Leak and Spill Procedures	Absorb spill with paper towel or similar absorbent and place in dry garbage or flush to sewer or ground with large amounts of water.
Handling and Storing Procedures	Avoid contact with skin, eyes, or clothing. Store in cool, dry area away from any reactive materials.
Waste Disposal Methods	As per Local and Federal Regulations
Other Precautions	None.

SPECIAL PROTECTION INFORMATION

Respiratory Protection Protective Gloves Eye and Face Protection Ventilation Other Protective Equipment NIOSH Approved Respirator Rubber Gloves Chemical Splash Goggles and/or Face Shield Local Exhaust Rubber Apron, Eye Wash, and Quick Drench Shower.

SARA TITLE III REGULATORY INGREDIENT INFORMATION

Title III Section 302/304 Extremely Hazardous Substance List and/or CERCLA Hazardous Substance List.

Component	Ammonium Hydroxide
CAS #	1336216
Percent	<30
TPQ (lbs)	
RQ (lbs)	1,000

Title III Section 313 Toxic Chemical Annual Release Reporting Requirements (SARA Section 313 Toxic Chemical List).

Component	Ammonium Hydroxide
CAS #	1336216
Percent	<30

USER'S RESPONSIBILITY

The information and recommendations contained herein cannot cover all possible situations that the user may experience during processing. Each aspect of your operation should be examined to determine, if, or where, additional precautions may be necessary. All health and safety information contained in this bulletin should be provided to your employees or customers. It is your responsibility to use this information to develop appropriate work practice guidelines and employee instructional programs for your operations.

DISCLAIMER OF LIABILITY

As the conditions and methods of use are beyond our control, we do not assume any responsibility and expressly disclaim any liability for any use of this material. Information contained herein is believed to be true and accurate. All statements or suggestions are made without warranty, expressed or implied, regarding the accuracy of the information, the hazards connected with the use of the material or the results to be obtained from the use thereof. Compliance with all applicable federal, state, and local laws and regulations remains the responsibility of the user.

Revision Date: May, 2006