Polyalkylene Glycol Monobutyl Ether (PGME)

Handling/Processing

Identification of Petitioned Substance

Chemical Names:
Poly (ethylene glycol-ran-propylene glycol) monobutyl ether

Other Name:
Polyethylene-propylene glycol, monobutyl ether
Poly (ethylene glycol-co-propylene glycol) monobutyl ether
Oxirane, methyl-, polymer with oxirane, monobutyl ether
Oxirane, methyl-, polymer with oxirane, monobutyl ether
PAGMBE
Propylene oxide ethylene oxide polymer monobutyl ether

Trade Names:
JEFFOX WL-660 (Huntsman)
JEFFOX WL-5000 (Huntsman)
UCON ™ 50-HB-660 (Dow)
UCON™ 50-HB-3520 (Dow)
UCON™ HTF 14 (Aldrich)
Aldrich 438189
Teritol™ XD Surfactant

CAS Numbers:
9038-95-3

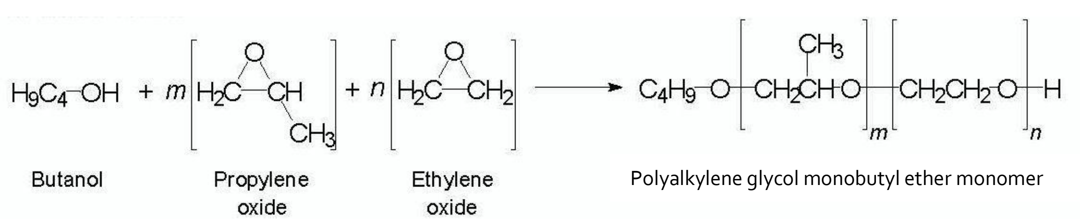
Other Codes:
MDL Number MFCD00198079
PubChem Substance ID 248899946

Summary of Petitioned Use

The petitioner requests addition of polyalkylene glycol monobutyl ether (PGME) to the USDA National Organic Program's National List (7 CFR 205.605) as a non-agricultural substance. PGME is a polymeric synthetic boiler additive with unique solubility properties (inverse solubility). It is used to improve boiler steam quality. Steam is used as a conditioner for animal feed pellet production. The petitioner requests to restrict the use of PGME products with molecular weight greater than 1500.

Characterization of Petitioned Substance

<u>**Composition of the Substance:**</u>
The substance is composed of high molecular weight (>1500) polymers of polyalkylene glycol monobutyl ether, an aliphatic diether of polypropylene glycol. It is synthesized from butanol, propylene oxide and ethylene oxide. The molecular formula of the monomer is $C_9H_{24}O_5$. Its molecular weight is 212.28386. The structural formula for the polyalkylene glycol monobutyl ether is:



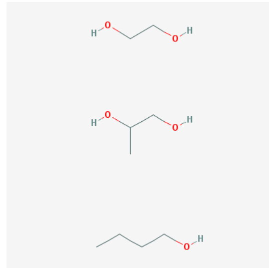


Fig 1. 2D Structure

Source or Origin of the Substance:

Polyalklylene glycol monobutyl ether (PGME) was developed during World War II by the Union Carbide Corporation and first marketed by them in 1959 as a synthetic functional fluid. Union Carbide has been well known as a purchaser and producer of ethylene, a basic building-block chemical, from components of crude oil and natural gas. Their products usually began with the conversion of ethylene to polyethylene or reacting ethylene with oxygen to produce ethylene oxide, the precursor for many of their products, e.g. ethylene glycol and hundreds of solvents, alcohols, surfactants, amines and specialty products. Union Carbide is now a wholly owned subsidiary of the Dow Chemical Corporation.

PGME is a lubricant, but also has the unusual combination of properties of complete solubility (dissolving easily) in cold water and insolubility at temperatures greater than 40°C (104°F). At this temperature, called the cloud point, PGME is completely, insoluble in water. This property is called inversed solubility.

The predominant uses for polyalkylene glycol monobutyl ether polymers are as automotive transmission, brake and hydraulic fluid, heat transfer fluid and as an inert solvent for processing operations. Polyalkylene glycol monobutyl ether polymers are manufactured by Dow at their facility in Charleston, West Virginia. Similar products called JEFFOX WL-660 and JEFFOX WL-5000 are produced by the Huntsman Petrochemical Corporation. There are also several international manufacturers.

Properties of the Substance:

High molecular weight (>1500) polyalkylene glycol monobutyl ether polymers are colorless to yellow liquids with a mild odor and low volatility (do not evaporate easily at room temperature). Individual products vary in their average molecular weight and viscosity. Depending on the product's molecular weight, they are water-soluble at temperatures below 51-60°C (123.8-140°F), but completely insoluble at higher temperatures. PGME polymers do not readily lose their viscosity (shear stable), do not hydrolyze in the presence of acid, neutral, or base solutions, and do not become rancid during storage. They show good oxidation resistance up to 500°F; are non-corrosive to common metals, have little or no effect on most rubber compounds and are miscible in hydrocarbon oils. Table 1 provides a list of popular polyalkylene glycol monobutyl ether polymer products and their respective physical properties.

PGME polymers have a low degree of toxicity. Toxicity by ingestion is low, but highest for lower molecular weight products. Toxicity by skin contact is low for all PGME species. Higher molecular weight PGME polymers have been found to be toxic in animals upon inhalation of mechanically generated mists. The products of thermal degradation are also toxic. Eye injury is possible only for the lowest molecular weight species.

Because they are generally non-toxic, PGME polymers have been approved for a variety of uses where the surfaces or water treated has the potential to come into contact with food including use in lubricants to manufacture and otherwise process food (21 CFR 178.3570) and in a variety of foam control applications. In these applications, only a potential exposure is assumed, i.e. PGME will be washed off surfaces before they contact food and is not volatile, thus under normal conditions is not introduced into steam that contacts food.

Ready biodegradability is measured according to the Organization for Economic Cooperation and Development Guideline using the modified Sturm test (OECD 301B). This method measures evolved CO_2 over a 28 day period. For PGME polymers with molecular weights ranging from 520-3930, biodegradation generally ran from 90% for the lowest molecular weight to 7 % for the highest molecular weight product (Table 1). Toxicity to fish, aquatic invertebrates and bacteria is low (Table 1).

Specific Uses of the Substance:

The petitioned use for polyalkylene glycol monobutyl ether polymeric fluid is as an additive for water used in the production of steam for manufacturing organic animal feed pellets. It is added to water at very low concentrations to prevent boiler foaming and subsequent introduction of liquid water into steam. Most often the product UCON Lubricant 50-HB 5100 is used at concentrations of 0.15 to 0.35 parts per million (ppm)—seldom over 1.7 ppm. Introduction of antifoam can be done intermittently or continuously. Although not part of the petition, PGME can also be used as part of a boiler maintenance regimen since it dissolves greases, and oils at low temperatures and removes them as precipitates during boiler blowdowns. In both cases PGME, interacts with substances in boiler water that cause foam and prevents it from occurring. Prevention of boiler foaming and carryover of liquid water into steam (see action of the substance), improves both steam uniformity and quality by making it drier and potentially hotter if it is superheated. Uniform, high quality steam provides the operator with more control over the heat and moisture introduced to the pellet conditioner. PGME is non-volatile and precipitates at boiler temperatures. Thus, it is not delivered with steam, but stays in the boiler as a precipitate until the boiler cools below the cloud point. Practically, PGME does not contact food. Precipitated PGME may be removed during boiler blow-down.

Steam conditioning with uniform, high quality steam brings natural oils present in the mash to the surface lubricating and extending the longevity of the pellet mill dies. Friction is defined in pelleting making as the difference in temperature between mash entering the pellet die and mash extruded from the pellet die. Reducing friction by steam conditioning generally results in increased production efficiency, and reduced fuel or electrical costs.

Polyalkylene glycol monobutyl ether polymers are inert lubricative functional fluids, making them useful in a variety of other applications that include, chemical intermediates – for the manufacture of resins, plasticizers, modifiers, and surfactants; compressor lubricants – as base fluids in compressor lubricant formulations; antifoam agents – in boiler water and fermentation processes; personal-care products – as an emollient (softening agent), solvent or viscosity modifier for moisturizing body lotions, self-tanning products, eye-makeup remover formulations, skin toner, and hair treatment/shampoo formulations; rubber lubricants – as anti-stick agents for uncured rubber, machining lubricants for hard rubber, mold lubricants, and lubricants for rubber packings, O-rings, and seals and textile-fiber lubricants – for high-speed, high-temperature, synthetic-fiber manufacturing processes such as false-twist texturing.

Approved Legal Uses of the Substance:

Title 21 CFR 173.310 from the FDA provides for the use of polyalkylene glycol monobutyl ether polymeric fluids with molecular weight greater than 1500, as a boiler water additive in the preparation of steam that will contact food. Title 21 CFR 177.1632 from the FDA provides that polyalkylene glycol monobutyl ether polymeric fluid may be added safely at a concentration of less than 1% as an adjuvant to poly (phenyleneterephthalamide) resins for finishes that may repeatedly contact food. Title 21 CFR 178.010 from the FDA provides for the use of polyalkylene glycol monobutyl ether polymeric fluids as a generally recognized as safe added component of a sanitizing solutions that can be safely used on food-processing equipment and utensils, and on other food-contact articles followed by adequate draining, before contact with food. Title 21 CFR 178.3570 provides that polyalkylene glycol monobutyl ether polymeric fluids may be used as a lubricant with incidental food contact at a concentration of less than 10 parts per million. Title 40 CFR 180.960 provides that polyalkylene glycol monobutyl ether polymeric fluid (CAS 9038-95-3) meets the definition of a polymer, and the criteria specified for defining a low-risk polymer in 40 CFR 723.250, as an inert ingredient in a pesticide chemical formulation, including antimicrobial pesticide chemical formulations, are exempted from the requirement of a tolerance under FFDCA section 408, if such use is in accordance with good agricultural or manufacturing practices. Because polyalkylene glycol monobutyl ether polymeric fluids are water-soluble and non-toxic at low concentrations they are considered environmentally friendly compounds with respect to petroleum based lubricants that are not water soluble.

Action of the Substance:

During production, animal feed pellets require the addition of moisture, binding agents and the addition of heat to enable starches in the pellet mix to gelatinize and proteins to denature. This is called conditioning. Steam produced by a boiler is often used to provide both the moisture and heating sources. Boiler water and boiler design affect the quality of steam leaving the boiler. Excessive concentrations of certain components of the boiler water such as mineral solids, high alkalinity and certain organic contaminants can cause "foaming." Foaming is caused by bubbles collecting as a layer of foam on the surface of the water in the boiler. The bubbles can invade the active steam separation section of the boiler. If this happens, masses of bubbles can be mixed with the steam resulting in carryover of the foam into the steam. Slow collapsing bubbles result in very undesirable wet steam. Antifoam agents (polyalkylene glycol monobutyl ether polymers) are used specifically to speed up the collapse of steam bubbles and thereby minimize the tendency for foam to accumulate in any part of the boiler. Antifoam treatment is often effective in preventing carryover caused by uncontrollable feed water contamination or by high concentrations of boiler water solids, which for physical or economic reasons cannot be adequately controlled by normal blow-down. Antifoam may be beneficial by producing a higher quality boiler water that is ideal for uniform steaming and by encouraging steam bubbles to collapse with the greatest possible speed. It also can minimize the carryover effects of mechanical or operating factors for which there is no immediately practical or economic remedy. Of course, the best approach to problems of this nature is through physical changes, which correct the difficulty at its source.

Combinations of the Substance:

Polyalkylene glycol monobutyl ether is a boiler chemical. It is used in combination with other boiler chemicals that prevent damage to boilers, remove unwanted dissolved gasses such as oxygen or carbon dioxide, prevent scale, condition boiler water, and provide a cleaner boiler environment. There are already examples of boiler chemicals on the National List at section 205.605(b). All are synthetics used to prevent corrosion of boiler equipment and distribution lines. Calcium hydroxide and sodium hydroxide are approved without restrictions applying to their use in boilers producing steam likely to have contact with food. Three volatile amines: diethylaminoethanol, octadecylamine, and cyclohexylamine are approved for use only in producing steam to sterilize packaging for organic products.

PGME is not only useful to prevent foaming and carryover of liquid in steam. PGME is a polymeric compound comprised of long, complex molecules that attach to impurities and prevent them from sticking to boiler metal to form scale. The action of PGME creates total dissolved solids that are removed via blow down. Blow down is the process used in boiler operation to reduce the concentration of boiler impurities.

Status

Historic Use:

Polyalkylene glycols are one of many important industrial chemicals developed during World War II. As part of a team from the Union Carbide Chemical Company, H.R. Fife and R.F. Holden developed the polyalkylene glycols primarily for use as lubricants. The first use was in water based hydraulic fluids for military aircraft. The product called UCON hydrolube was formulated from water and ethylene glycol and useful because it was not flammable. PGME was introduced by the Union Carbide Corporation in June 1959 as a functional fluid. The compound, an aliphatic diether of polypropylene glycol was synthetically produced from petroleum chemicals: ethylene oxide and propylene oxide. PGME polymers are efficient antifoam agents in many aqueous and non-aqueous foaming systems. They have proven successful in boiler water, latex processing and compounding, low-foam washing solutions, paints and coatings, adhesives, fermentation processes, Benfield gas treating operations, and salt water flash evaporators, as well as other applications where foam control is important. PGME functional fluids often exhibit synergistic effects when used with other antifoams or surface, active agents. PGME fluids function as antifoams in boilers at steam producing temperatures. They are insoluble in aqueous solutions at temperatures above 50°C (122°F). The insoluble particulate material can be removed by filtration and not carried over in steam. For non-aqueous systems, PGME fluids have also proven especially successful as antifoams in salt water flash evaporators used to produce drinking water from sea water or brackish water sources. The EPA Office of Water has approved a number of PGME fluids as foam control agents in the desalination of sea water. The complete water solubility of the some PGME fluids at low temperature allows for accurate and uniform solutions. In addition, high molecular weight PGME polymers are substances identified in FDA Regulation 21 CFR 173.310 governing boiler water additives, including antifoams, used in food processing.

Organic Foods Production Act, USDA Final Rule:

Polyalkylene glycol monobutyl ether is not included in the Organic Foods Production Act, the USDA final rule (7 CFR Part 205) or any NOP guidance document. There are five boiler additives listed in 7 CFR 205.605. The use of all five synthetic substances is predominantly to inhibit boiler and pipe corrosion. Two are the alkali salts, calcium hydroxide, and sodium hydroxide, which may be used in boiler water because they are relatively nonvolatile, mostly stay in the boiler, and have limited contact with the certified organic product. Both sodium and calcium ions formed when these alkaline salts dissolve in water have limited solubility in steam. The volatile amines: diethylaminoethanol, octadecylamine, and cyclohexylamine are approved for use only in packaging sterilization, because they may persist in steam that has contact with the organic product. A technical advisory panel report submitted to the NOSB by the Organic Materials Review Institute in 2001 entitled "Steam Generation in Organic Food Production Systems" reviewing these volatile amines recommended against their use as boiler water additives due to their known volatility and toxicity. However, they are permitted for use in organic packaging sterilization, and would need to be removed or prevented from entering boiler water in cases where steam could contact food. Prior to addition of the volatile amines to the National List, the NOSB cited FDA's guidance in a 1995 recommendation that residues of boiler water additives must be prevented from contacting organically produced food by the use of steam without entrained water, steam filtering, or other means.[1]

International

Canada - Canadian General Standards Board Permitted Substances List –

The Canada General Standards Board Permitted Substance List (CAN/CGSB-32.311-2006) does not have a reference to any boiler additives, including polyalkylene glycol monobutyl ether. Culinary steam is defined by the Canadian Food Inspection Agency as steam used in direct contact with milk and dairy products. Examples include any heating application where appreciable amounts of steam contact the product. Source of water must be potable and acceptable to the Canadian regulatory agency. Feed waters may be treated, as necessary, but ion exchange or other acceptable methods are preferred, to the use of water conditioners. Compounds such as ammonium hydroxide, cyclohexylamine, octadecylamine and diaminoethanol are not permitted. A clean, dry saturated steam is considered necessary for proper equipment operation. The specification is explicit that boilers and steam generation equipment shall be operated in such a manner as to prevent foaming, priming, carryover, and excessive boiler water entrainment into steam. A culinary steam piping assembly design for steam infusion or injection and a dual trap culinary steam piping assembly for airspace heating and defoaming is provided. Thus, foaming in the boiler is prevented by a mechanical piping design.

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labeling and Marketing of Organically Produced Foods (GL 32-1999) -

[1] The National Organic Standards Board Final Recommendation Addendum Number 7, Organic Good Manufacturing Practices adopted April 25, 1995 in Orlando, Florida section (g) Boiler Water Additives [refer to 21 CFR Part 173.310 (a)]

The objective of the Codex Alimentarius Committee's (CAC) Code of Practice on Good Animal Feeding (CAC/RCP 54-2004) is to help ensure the safety of food for human consumption through adherence to good animal feeding practice at the farm level and good manufacturing practices (GMPs) during the procurement, handling, storage, processing, and distribution of animal feed and feed ingredients for food producing animals. In section 4.5.3 of this document, undesirable substances are discussed. It states, the presence in feed and feed ingredients of undesirable substances such as industrial and environmental contaminants, pesticides, radionuclides, persistent organic pollutants, pathogenic agents and toxins such as mycotoxins should be identified, controlled and minimized. The risks of each undesirable substance to consumers' health should be assessed and such assessment may lead to the setting of maximum limits for feed and feed ingredients or the prohibition of certain materials from animal feeding. Manufacturing procedures should be used to avoid cross-contamination (for example flushing, sequencing and physical clean-out) between batches of feed and feed ingredients containing restricted or otherwise potentially harmful materials (such as certain animal by-product meals, veterinary drugs). These procedures should also be used to minimize cross-contamination between medicated and non-medicated feed and other incompatible feed. Both sections 4.4.1.3 of the CAC Code of Hygienic Practice for Low and Acidified Low Acid Canned Foods (cac/rcp 23-1979) and 4.3.12.4 of the Code of Hygienic Practice for Precooked and Cooked Foods in Mass Catering (cac/rcp 39-1993) indicate that steam used in direct contact with food or food contact surfaces should contain no substance which may be hazardous to health or may contaminate the food. Tables 3 and 4 from Annex 2 of the (CAC) organic guideline's permitted substances list do not provide for boiler additives such as PGME. The Codex guidelines provide an indicative list of permitted substances, and as stated in the guidelines, are not intended to be all inclusive or exclusive. Substances included in the Codex guidelines for organic labeling must meet the following criteria:

i) it is consistent with principles of organic production as outlined in these Guidelines;
ii) it is necessary/essential for its intended use;
iii) its manufacture, use and disposal does not result in, or contribute to, harmful effects on the environment;
iv) it has the lowest negative impact on human or animal health and quality of life; and
v) approved alternatives are not available in sufficient quantity and/or quality.

Furthermore, if they are used as additives or processing aids in the preparation or preservation of the food, these substances are used only if it has been shown that, without having recourse to them, it is impossible to produce the food. In the absence of other available technologies, satisfying the Codex guidelines then those substances that have been chemically synthesized may be considered for inclusion in exceptional circumstances. Their use must maintain the authenticity of the product. The consumer will not be deceived concerning the nature, substance, and quality of the food produced because of the addition. The additives and processing aids do not detract from the overall quality of the product. In the evaluation process of substances for inclusion on lists, all stakeholders should have the opportunity to be involved.

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008

European Economic Community (EEC) Council Regulation, EC No. 834/2007 has set forward in Title 1 the inclusion of feed in its scope: the feeding of livestock with organic feed composed of agricultural products from organic farming. Processing of organic feed is further restricted to keeping the use of feed additives and processing aids to a minimum and only in the case of essential technological or zoo-technical needs or for particular nutritional purpose with the use of biological, mechanical and physical methods. Article 18 of Chapter 3 specifies that any feed materials used or processed in organic production shall not have been processed with the aid of chemically synthesized solvents. The use of steam is described for disinfection of equipment used for husbandry and processing.

Japan Agricultural Standard (JAS) for Organic Production—
http://www.ams.usda.gov/nop/NOP/TradeIssues/JAS.html

Although, MAFF has a stringent process for the introduction of non-agricultural synthetic substances into organic feed, the standard does not explicitly mention prohibiting the use of any boiler chemicals for the production of animal feed.

International Federation of Organic Agriculture Movements (IFOAM)

http://www.ifoam.org/standard/norms/cover.html

IFOAM approves the use of steam for disinfection of manufacturing equipment; however, steam traps and filters should be used to remove non-volatile boiler water additives. All components of additives and processing aids should be declared. Product labels should identify all ingredients, processing methods, and all additives and processing aids. Furthermore, non-organic substances listed contain only ionic compounds, acids, bases and substances derived from natural products. PGME is not included in any IFOAM list, but would considered be a non-volatile water additive that is not likely to be entrained in steam.

Table 1 Published Data for polyalkylene glycol monobutyl ether (PGME) products

MSDS, Sample Name	Viscosity, cSt				Pour Point, °F	Flash Point COC °F	Specific Gravity @20/20°C	Water/Oil Solubility	Cloud Point, °C, 1% Aq.Soln.	Mol. Wt. Mn	Sturm Biodegradtion (% in 28 days)	Est. Concentration (mg/L)*		
	60°F	100°F	150°F	210°F								96 fathead minnow, LC 50	48 hour Daphnia magna, EC 50	Bacterial Inhibition IC 50
UCON(TM) 50-HB-660 Personal Care Grade (Dow)	-	25.6	-	25.6	-34.4	444	1.051	w	56	1590	45	24, 500	21,000	32,000
UCON(TM) 50-HB-3520 Personal Care Grade (Dow)	-	700	-	117	-28.9	235.4	1.056	w	51	3380	7	11,900	17,000	10,000
Aldrich 438189	3600	-	-	-	-27	235	1.056	w	-	3900	-	-	-	-
Tergitol™ XD		-	-	-	1	480	1.041	w	-	2990	-	-	-	-
JEFFOX WL-660 (Huntsman)	471	158	60	27	-30	445	1.05	w	60	1800	-	-	-	-
JEFFOX WL-5000 (Huntsman)	3556	1107	409	182	10	475	1.06	w	53	4365	-	-	-	-

*LC50 = median lethal concentration (expected 50% mortality), EC50 = median effect concentration (expected 50% Loss of mobility), IC = median. inhibition concentration (expected 50% loss off respiration)

Evaluation Questions for Substances to be used in Organic Handling

Evaluation Question #1: Describe the most prevalent processes used to manufacture or formulate the petitioned substance. Further, describe any chemical change that may occur during manufacture or formulation of the petitioned substance when this substance is extracted from naturally occurring plant, animal, or mineral sources (7 U.S.C. § 6502 (21)).

PGME is manufactured from ethylene oxide. Ethylene oxide is a toxic material with an OSHA time-weighted average for 8 hours of exposure of 1 ppm and a short-term permissible limit of 5 ppm in a 15 minute period. It is highly flammable and has a wide flammable range in air of 3-100 %. It can explosively decompose if exposed to an ignition source. The flammability is accentuated by its boiling point of 10.4^{o}C, making it a gas at room temperature. Similar hazards also exist with propylene oxide and butylene oxide.

The first commercial scale syntheses of PGME were performed at the Union Carbide production facility in Charleston, WV and are similar to those used today. A nitrogen gas filled stainless steel autoclave is fed an epoxide mix of ethylene oxide, propylene oxide and the sodium salt of butanol. The autoclave has a controlled environment which permits heating and cooling to maintain 100-120^{o}C at high pressure (60 psig). Cooling is necessary to prevent the heat of fusion of the reaction from igniting the unreacted ethylene oxide vapor. Pure ethylene oxide vapor can explosively decompose upon exposure to an ignition source. A sufficient amount of nitrogen present before the initiation of the epoxide feed ensures that the vapor phase does not reach the flammable limit at any time during the run. It is critical to keep the inventory of unreacted oxide in the reactor at a level such that the heat of polymerization (20 kcal/mol) can be removed by the cooling system. A critical factor in keeping the oxide concentration low is the reactor temperature. If pressure is the control mechanism, a low temperature in the reactor will allow the oxide to build to potentially unsafe concentrations. Unrestricted, concentration of unreacted, epoxides has been the cause of the greatest number of reactor failures. The problem becomes larger with propylene oxide and especially butylene oxide, where the vapor pressure of the oxide is not a reliable indication of liquid phase concentration. The reactor should have a safety relief device sized to handle such runaway reactions due to loss of cooling in order to prevent catastrophic events, i.e. a high-pressure cell catastrophically destroyed, with the autoclave top thrown many hundreds of feet caused by inadvertent feeding of ethylene oxide at a low temperature. This error allowed the accumulation of a large inventory of ethylene oxide at a low temperature, but proved uncontrolled as polymerization heated up the vessel. However, in spite of tight temperature control, keeping the temperature close to the boiling point is essential to the reaction rate and polymerization of the unreacted epoxides.

In order to avoid exposure of personnel to unreacted ethylene oxide, it is necessary to hold the reactor contents at the reaction temperature after the feed of starting materials is completed and the level of unreacted epoxides drops to an acceptable level. This is called a "cook out" or digestion. It is necessary because liquid is formed as the reaction proceeds compressing the nitrogen used to prevent ignition and slowing the reaction. Nitrogen gas can also be vented as the liquid level rises. Union Carbide has added several measures to make the process safer e.g., crude fluids were diluted with water, acidified with carbon dioxide, extracted with hot water and then stripped of water at high temperatures. When the reaction is completed the final product is decolorized with activated charcoal. The resulting functional fluid forms the backbone for the Dow Chemical Company's UCON line of products.

The starting materials for this product are all chemically derived from petroleum, natural gas or other hydrocarbon source. The processes are proprietary and unique to this particular product. No alternative production method utilizing organic practices have been defined at this time.

Evaluation Question #2: Discuss whether the petitioned substance is formulated or manufactured by a chemical process, or created by naturally occurring biological processes (7 U.S.C. § 6502 (21)). Discuss whether the petitioned substance is derived from an agricultural source.

PGME is manufactured by a chemical process. It is produced from three highly reactive chemicals that are derived from hydrocarbon compounds: ethylene oxide, propylene oxide and butylene oxide. Ethylene oxide is produced by direct silver catalyzed oxidation of ethylene, a hydrocarbon that is produced by the steam cracking process in petroleum refining. Ethylene oxide is extremely flammable and explosive; therefore, it is commonly handled and shipped as a refrigerated liquid. Ethylene is also naturally produced by all parts of all plants. Ethylene is included in 7 CFR 205.605. Propylene oxide is produced from propylene a product of petroleum refining. Propylene oxide is produced by oxidation of propylene with hydrogen peroxide. Butanol is also used in the synthesis of PGME; although, sodium *tert*-butoxide is another chemical that can be used in the synthetic process. PGME is synthetically produced from these petroleum derived starting materials by the Dow Chemical Company and the Huntsman Chemical Company.

Evaluation Question #3: If the substance is a synthetic substance, provide a list of nonsynthetic or natural source(s) of the petitioned substance (7 CFR § 205.600 (b) (1)).

PGME fluids and lubricants include a wide range of formulated products that differ significantly from petroleum, animal, and vegetable oils. These polyalkylene glycol (PAG)-based synthetic products can be varied and controlled in formulations and used to a degree not possible with natural oils or lubricants. They are used in applications from hydraulic fluids to quenchants, and from machinery, gear and bearing lubricants, to compressor lubricants. There are two main manufacturers, Dow Chemical Company and Huntsman Chemical Company. There are no natural sources for PGME.

Evaluation Question #4: Specify whether the petitioned substance is categorized as generally recognized as safe (GRAS) when used according to FDA's good manufacturing practices (7 CFR § 205.600 (b)(5)). If not categorized as GRAS, describe the regulatory status.

PGME is absent from the Department of Human Health Services, Food and Drug Administration list of substances GRAS, the list of food substances affirmed as GRAS, the list of indirect food substances affirmed as GRAS and the GRAS Notice Inventory. Title 21 CFR 173.310 from the FDA provides for the use of polyalkylene glycol monobutyl ether polymeric fluids with molecular weight greater than 1500, as a boiler water additive in the preparation of steam that will contact food. Title 21 CFR 177.1632 from the FDA provides that polyalkylene glycol monobutyl ether polymeric fluid may be added safely at a concentration of less than 1% as an adjuvant to poly (phenyleneterephthalamide) resins for finishes that may repeatedly contact food. Title 21 CFR 178.010 from the FDA provides for the use of polyalkylene glycol monobutyl ether polymeric fluids as a generally recognized as safe added component of a sanitizing solutions that can be safely used on food-processing equipment and utensils, and on other food-contact articles followed by adequate draining, before contact with food. Title 21 CFR 178.3570 provides that polyalkylene glycol monobutyl ether polymeric fluids may be used as a lubricant with incidental food contact at a concentration of less than 10 parts per million.

Evaluation Question #5: Describe whether the primary technical function or purpose of the petitioned substance is a preservative. If so, provide a detailed description of its mechanism as a preservative (7 CFR § 205.600 (b)(4)).

PGME has many uses in food processing, but is being petitioned for use only as a boiler water additive in organic processing. It will be used as a boiler additive to reduce boiler foam and subsequently lower delta temperature (less die friction), amperage, and motor load for pellet mills used to produce organic livestock feed. Addition of PGME to boilers producing steam for pellet production has been found to improve quality and increase production rate. This suggests that a pellet mill could decrease energy cost without decreasing tons of feed produced. Although not intended as a preservative, PGME addition to boiler water improves steam quality which improves pellet hardness. Improved pellet hardness increases pellet stability and shelf life. There are currently three volatile boiler additives listed in 7 CFR 205.605. These are octadecylamine, diethylaminoethanol and cyclohexylamine. These chemicals are used to prevent boiler corrosion, but, since they are volatile, have the potential to carry-over into steam.

Evaluation Question #6: Describe whether the petitioned substance will be used primarily to recreate or improve flavors, colors, textures, or nutritive values lost in processing (except when required by law)

and how the substance recreates or improves any of these food/feed characteristics (7 CFR § 205.600 (b)(4)).

PGME is not used primarily to recreate or improve flavors, colors, textures, or nutritive values lost in processing. The purpose of PGME in animal feed pellet manufacturing is to prevent foaming in steam boilers that produce culinary steam. Steam is added to pellets as a source of moisture, serves to increase the extent to which feed carbohydrates are gelatinized and proteins denatured, and provides lubrication to reduce friction inasmuch as the pellet mash flows easier through dies used to form pellets. Foaming increases the amount of water that is carried over from the boiler making the steam wetter, whereas drier steam is preferable. Drier, hotter steam gives the producer more control over both the degree of gelatinization, denaturation and the amount of heat and moisture added to the pellet. A number of scientific studies have found that both protein denaturation and the correct amount of moisture result in higher nutrition pellets. PGME has another important characteristic that makes it useful in the production of culinary steam. At high temperatures characteristic of culinary steam boiler operating temperatures, PGME solubility in water is significantly reduced. Thus, there is little carryover of PGME from boiler water to steam and negligible transfer of PGME to food.

<u>Evaluation Question #7</u>: Describe any effect or potential effect on the nutritional quality of the food or feed when the petitioned substance is used (7 CFR § 205.600 (b)(3)).

PGME is used as an antifoam treatment in boiler water. Exclusive of PGME, foaming can be prevented in other ways involving boiler or steam generator design and feed water quality. Steam used by feed processors is called "culinary," "sanitary" or "clean" steam. Any additives in culinary steam must meet all applicable FDA and USDA requirements for human or animal consumption. For organic foods, and products steam must also meet guidance provided by the National Organic Program. For some products, to meet specific regulations and for boilers that are not subject to foaming, the addition of PGME to boiler water may not be necessary or desirable. However, under normal boiler operating conditions, PGME is not present in the steam produced from a treated boiler and this steam would not be any different from steam produced by a boiler that was not treated with PGME.

Modern conditioning systems for pellet manufacture include the use of steam. In feed manufacture, steam is directly injected into the product with a tubular apparatus called a conditioner. This heat, plus water, pressure, and time to a physical state facilitates compaction of the feed mash into pellets. The process increases production capacity and positively affects the physical, nutritional, and hygienic quality of the produced feed. Pelleting with steam offers the manufacturer and the feeder other advantages that justify using additional energy for steam pelleting. While dry pelleting is done at 40^{o}C, 250 and 275% production rate increases result from the use of steam increasing temperatures respectively, to 65 and 78°C. Production rate increased only 9% when the conditioning temperature was raised from 65 to 80°C. Steam conditioning also decreases fixed costs such as labor. Die and roller replacements are also a major cost of pelleting. The temperature increase of mash pressed through the pellet die and the electrical energy used to pellet showed that steam conditioning decreased mechanical friction. A decrease in friction increases both die and roller life. Thus, the main contribution to nutrition of the pellets is derived from the additional moisture added by steam to the mash through conditioning. However, the contribution of steam conditioning to productivity is also significant.

<u>Evaluation Question #8:</u> List any reported residues of heavy metals or other contaminants in excess of FDA tolerances that are present or have been reported in the petitioned substance (7 CFR § 205.600 (b)(5)).

PGME is a chemically derived polymeric compound the production of which results in polymers of various sizes. The lower molecular polymers (<1500) have been determined to be toxic.[2] Thus, the FDA has restricted the use of PGME in sanitizing solutions that may contact surfaces that contact foods to a 0.05% aqueous solution of polymers that have an average molecular weight of 2,400-3,300 and a cloud-point of 90-100^{o}C. In this application, large PGME polymers engulf (micellize) oils and smaller particulates that are

[2] http://yosemite.epa.gov/oppts/epatscat8.nsf/ReportSearchView/612615DD19EBC8E085256930004CD868

subsequently precipitated at temperatures of 90-100^{o}C. The product is provided as a >99% pure liquid. The starting materials for the synthetic process are gaseous at production temperatures and are unlikely to contain heavy metal contaminants. Data was not found to substantiate the presence of detectable heavy metal contamination in this product.

<u>Evaluation Question #9:</u> Discuss and summarize findings on whether the manufacture and use of the petitioned substance may be harmful to the environment or biodiversity (7 U.S.C. § 6517 (c) (1) (A) (i) and 7 U.S.C. § 6517 (c) (2) (A) (i)).

PGME is relatively non-toxic on an acute basis for fish (LC50 > 100 mg/L— LC50 = median lethal concentration (expected 50% mortality), Table 1). For organisms with higher sensitivity, PGME has an LC50, an EC50—median effective concentration (expected 50% loss of mobility), an EL50 —median effective lifespan reduction (expect 50% reduction of lifespan), and an LD50—median lethal dose (expect 50% mortality) greater than 100mg/L. Supporting experimental data include: a static LC50 determination in fathead minnows (*Pimephales promelas*), where the fish received 3,170-11,900 mg/L of PGME for 96 hours; an EC50 determination with water flea (*Daphnia magna*), where immobilized organisms were exposed to 17,000-19,000 mg/L for 48 hours, and a static EC50 determination with bacteria with concentration 10,000 mg/L for 16 hours (Table 1).

PGME polymers with a molecular weight of > 2000 are inherently, but not readily biodegradable. The Organization for Economic Cooperation and Development (OECD) has adopted several tests for screening chemicals for ready biodegradability in an aerobic aqueous medium (OECD 301). Two of these tests have been used to evaluate biodegradability of PGME: OECD 301 B, the Sturm biodegradability test (CO_2 evolution) and OECD 301 C, the Ministry of International Trade and Industry, Japan (MITI) method (respirometry: oxygen consumption). Pass levels for readily biodegradability in both tests are 60-70%. A substance has inherent biodegradability if there is evidence of biodegradation in any of the OECD 301 tests.

Under laboratory conditions, PGME is only moderately biodegradable under aerobic conditions. PGME was not biodegraded after 28 days in the OECD 301C test for biodegradability. High molecular weight polymers are not expected to bioaccumulate to any great extent, while no data was available for bioaccumulation in soil. Although its transport is unregulated, PGME should not be dumped in sewers or any body of water. PGME (CAS. 9038-95-3) is listed as item number 3493 in the EPA document entitled Inert Ingredients permitted for use in nonfood pesticide products, last update April, 2011. This list has been superseded by 40 CFR Part 180. PGME is manufactured from ethylene oxide, propylene oxide and butanol which are chemical products of petroleum industry. Each of these chemicals is extremely toxic.

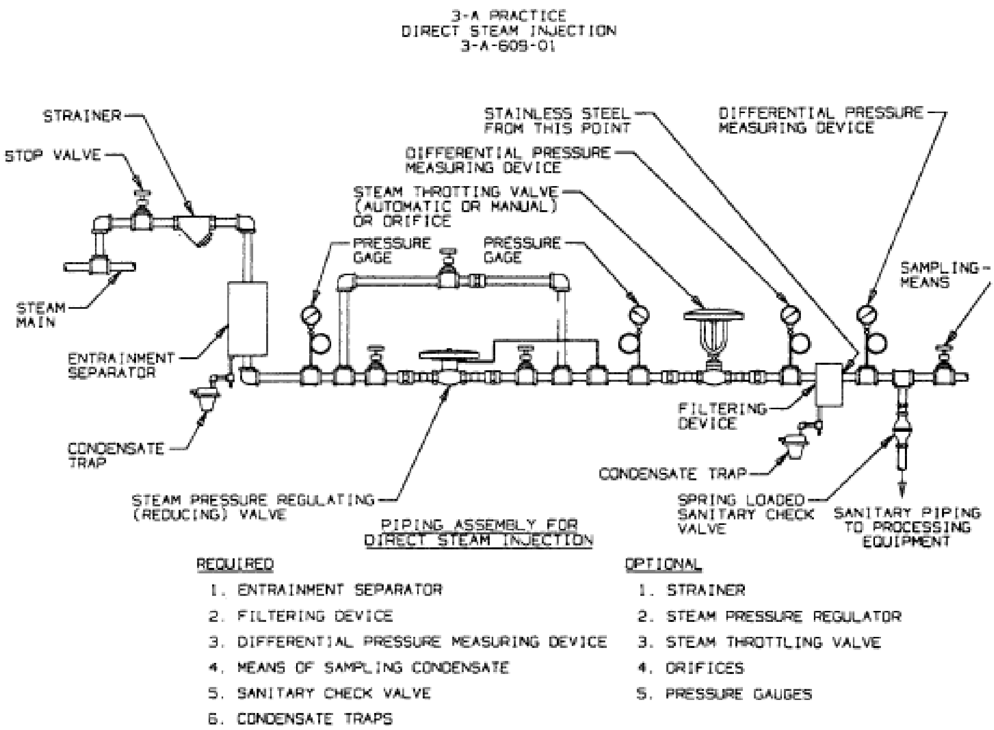
<u>Evaluation Question #10:</u> Describe and summarize any reported effects upon human health from use of the petitioned substance (7 U.S.C. § 6517 (c) (1) (A) (i), 7 U.S.C. § 6517 (c) (2) (A) (i)) and 7 U.S.C. § 6518 (m) (4)).

There have been no reported effects of PGME on human health. However, data from toxicity studies performed in appropriate animal species provides information on potential human toxicity. PGME polymers with molecular weight greater than 1500, have limited acute toxicity by the oral (LD50, Rat, 8630 mg/kg) and dermal (LD50, Rabbit, >8,000 mg/kg) routes, while toxicity of the high molecular weight products through inhalation is increased (LC50, 4 hours, Rat, > 5mg/kg). Oral and dermal toxicity in general increases with lower molecular weight products. This product has not been evaluated for genetic, developmental, or reproductive toxicity. PGME is not known to be an irritant or an allergen. It has many uses in the cosmetic industry. PGME is used in boilers at concentrations ranging from 0.15 to 0.35 mg/kg (ppm). In extreme circumstances, it may be used at concentrations as high as 1.7 mg/kg (ppm). The FDA has approved PGME as a boiler chemical if used according to this concentration schedule. 21 CFR 173.310 covers the use of PGME in boilers used to generate steam that will contact food. 21 CFR 173.340 covers the use of PGME as a defoaming agent in the processing of beet sugar. Because it is used as an antifoam or chemical scavenger in boilers, the application of PGME can be continuous or intermittent. Several studies have been performed to evaluate the effects of aerosol, intraperitoneal and oral administration of high doses of PGME in animals. These studies in rats, mice and dogs elucidated toxic effects with dosages as low as 147 mg/kg, although toxicity appeared to be species dependent. Pulmonary inflammation resulted in some case with aerosol administration of higher molecular weight products and convulsions or death occurred in some animals with intraperitoneal or oral administration of products with molecular weights less than 1500. No effect was seen with the intraperitoneal or oral administration of the high molecular weight product.

<u>Evaluation Question #11:</u> Describe any alternative practices that would make the use of the petitioned substance unnecessary (7 U.S.C. § 6518 (m) (6)).

Although it has been shown through a large number of scientifically based studies that feeding animals pelleted feed is advantageous, producers can chose alternatively to feed their animals, natural fodder such as whole or cracked grains for poultry or grasses for cattle. Pelleting feed and improving pellet quality requires a significant investment. Pellet hardness, lack of fines and high throughput are very important pellet characteristics enhanced by steam conditioning. In addition to ensuring that pellet formulations are appropriate fodder for the animals to which they are provided, feed producers have focused on steam conditioning to improve pellet quality and optimize production in order to maximize their return on investment. Steam required for conditioning is produced by a boiler system. Boiler systems vary in their engineering, design, purpose, quality of input water and quality of steam produced. The quality of steam produced is influenced by the quality of water entering the boiler, correct operation, cross-contamination, the level of chemicals used and adherence to a water treatment management program. Of particular importance for organic production is the potential of contaminants and chemical water treatments to be carried over from boiler water to steam that comes in contact with food. Carryover into steam of substances present in boiler water is caused both by entrainment of small droplets of water in the steam leaving the boiler drum and by volatilization of salts that are dissolved in the steam. Mechanical entrainment, which can occur in all steam generators, can be minimized through mechanical or operational changes. Mechanical entrainment can be divided into three categories: priming, foaming, and equipment failure. Priming usually results from a sudden reduction in boiler pressure caused by a rapid increase in the steam load. This causes steam bubbles to form throughout the mass of water in the steam drum, flooding the separators or dry pipe. Priming may also result from excessively high water levels. Priming results in a violent "throwing" of large slugs of boiler water into the steam. The problem can usually be minimized by changes in operation. Foaming is the buildup of bubbles on the water surface in the steam drum. This reduces the steam release space, and, by various mechanisms, causes mechanical entrainment. Foaming is almost always the result of improper chemical conditions in the boiler water, including alkalinity, suspended solids, dissolved solids, and organic surfactants and detergents. Boiler blow down is a way to dilute dissolved solids and reduce foaming; however, increased blow down frequency reduces boiler efficiency. The 3-A Accepted Practices for a method of producing steam of culinary quality, Number 609-01 provides a system of producing steam that is free from entrained contaminants, and is relatively free from water in liquid form. This type of steam is generally suitable for use in dairy and some food processing applications. The device is constructed of stainless steel, to resist corrosion and contains both 10 and 2 micron filters to remove particulates (Fig 1.) Steam entering this system is mechanically treated to remove entrained water and filtered to remove particulate contamination. Valves are conveniently located to allow cleaning and service of components. Prerequisite for culinary steam production is a supply of clean, dry steam. Boilers and steam generation equipment for this application still need to be operated to prevent foaming, priming, carryover, and excessive entrainment of boiler water into the steam. Thus, boiler blow-down must be monitored, so that over-concentration of boiler water solids and foaming are avoided. In most cases, boiler feed water will also still need to be treated to prevent corrosion and scale in boilers and facilitate sludge removal for proper boiler care and operation. This treatment may include PGME and must be under the supervision of personnel certified in industrial water conditioning who are informed that the steam is to be used for culinary purposes. Water-treatment programs including the use of PGME to control the chemistry of the boiler water, with appropriate monitoring, can be practical and reasonably safe, but will not eliminate every possibility of potential boiler chemical carryover into steam. Producers may choose to use an intermittent boiler chemical treatment program where chemicals not on the National List are absent from boiler water during organic pellet production runs. The safest approach for the production of clean steam is to use a steam generation system designed to eliminate the potential of volatile or carryover contamination. Here, steam from a primary boiler is used to heat water in a secondary steam generator where feed water quality and purity are carefully controlled and free of chemicals. Design is very important and feed water must be filtered free of contaminants and degassed prior to instruction into the generator. It is still possible to have water droplets contaminating steam in this type of system. The use of the water separators can resolve this issue and steam produced by this type of system will be free of chemical contaminants. Because steam generators require additional equipment, the cost effectiveness of their introduction into feed pellet production may become a factor in their use.

Fig. 1



<u>Evaluation Question #12:</u> Describe all natural (non-synthetic) substances or products which may be used in place of a petitioned substance (7 U.S.C. § 6517 (c) (1) (A) (ii)). Provide a list of allowed substances that may be used in place of the petitioned substance (7 U.S.C. § 6518 (m) (6)).

For pellet producers, pure high quality uniform steam is essential. Studies have shown that precise moisture and heat addition to mash in the steam conditioner results in a desirable lubricative effect. Foaming causes steam to lose quality reducing the lubricative effect. Foaming in boilers is directly related to the presence of impurities in the boiler feed water and the construction of the boiler. Factors affecting foaming are total dissolved solids in boiler water, finely divided solids in suspension, and colloidal material. Pure water does not foam. In most systems, the presence of a surface-active agent or surfactant is necessary for foaming to occur. Foaming of boiler water can be controlled by either de-concentration (blowing down the boiler) or by the addition of antifoam chemicals to the boiler. Boiler blow down merely dilutes the boiler water with fresh water. The role of antifoam such as PGME is to depress the effect of surfactants in boiler water. In cold water, PGME is soluble, and may promote foaming. At high temperatures above the cloud point, PGME becomes insoluble and particulate depositing on bubbles as sites of low surface tension, dispersing the bubbles and foam. Because of its insolubility in water at high temperatures, PGME does not carryover in the steam used to condition pellet mash. Thus, in properly operating boilers, PGME is neither a component or has a direct effect on the pellet mash or the pellet. The use of antifoam chemicals increases the permissible, overall degree of concentration of the boiler water and is justified by the resulting savings in fuel and water. There are not many natural antifoam chemicals for boilers. Castor oil is a natural compound that has been used to prevent foam in boilers. If castor oil is used, care must be taken to condition boiler water so that it is not alkaline. In the case of alkaline boiler water, castor oil will undergo hydrolysis to form the sodium soap of ricinoleic acid. Although not toxic, this soap may exacerbate foaming in the boiler. In addition to castor oil and depending upon the specific boiler conditions other natural oils may be used such as lard, lard burning, soybean, corn, maize, cod liver, cottonseed, olive, sunflower, safflower, peanut, ground nut, grape seed, linseed, poppy seed castor and palm oil. Carnauba and peat waxes also have been used as boiler antifoams. As a note, none of these natural chemicals is as effective or has the performance and characteristics provided by PGME. Extensive water treatment is also an alternative to using antifoam chemicals. Water can be treated using reverse osmosis filtration or ion exchange resins to reduce dissolved solids.

In addition to the use of boiler additives such as PGME, it is also possible to reduce friction during the pelleting process with addition of glycerin to the mash. It has been shown that the addition of up to 6% glycerin lowered the delta temperature at the pelleting die, reduced friction, amperage and motor load. Glycerin is on the National List. For livestock production (see 205.603(a)(12)), Glycerin is allowed as a livestock teat dip, and must be produced through the hydrolysis of fats or oils. Glycerin is also allow for handling, (see 205.605(b)) and must be produced by hydrolysis of fats and oils. Organic glycerin may be also be available for inclusion in livestock feed pellets. These changes result in a cost effective change in production. Furthermore, glycerin addition improved pellet quality. The conditioning temperature with and without glycerin did not change, because the conditioning temperature is dependent upon required conditions for starch gelatinization and protein denaturation. It is possible other natural humectants are available that can be used to reduce friction in pellet manufacture, but data for these was not available.

<u>Evaluation Information #13:</u> Provide a list of organic agricultural products that could be alternatives for the petitioned substance (7 CFR § 205.600 (b) (1)).

The process of pelleting animal food requires a conditioning step. The conditioning step includes adding moisture and heat to the mash containing the feed ingredients. Heat and moisture are customarily added by addition of steam, where the steam condensate provides moisture. Although, it is possible to produce pellets without steam, this is already the normal procedure used in manufacturing. Steam production requires specialized equipment and energy. Both add expense to animal feed pellet production. Steam quality is dependent on both the design of the producing boiler and the water used to feed the boiler. The addition of steam to the pellet mash prior to its introduction to the pelleting die, reduces the friction produced at the die. Friction influences pellet mill power cost, die wear and production throughput. Thus, any substance that reduces friction can act in place of substances such as PGME, which directly influences the quality of steam produced by a boiler. Concerning, boiler chemicals, there are very few natural substitutes that have antifoam properties. A number of oils such as lard, lard burning, soybean, corn, maize, cod liver, cottonseed, olive, sunflower, safflower, peanut, ground nut, grape seed, linseed, poppy seed castor and palm oil are organically produced and may work as antifoams, but may also work as mash additives to reduce friction. Very little data on the use of these oils is available.

The addition of glycerin to the mash has been shown to reduce friction. Organic glycerin may be available. However, studies have shown that addition of glycerin to the mash does not remove the requirement for the steam conditioning. Given a reduction in friction, and increases in production efficiency and pellet quality, more frequent boiler blowdowns may be justified to reduce dissolved solid concentration in the boiler water, so that foam is controlled and high quality steam is available. Glycerin has humective properties that make it useful for this type of application. Other organically produced polyhedric alcohols, may theoretically be used as additives in this process, although data supporting this use was not found.

The following substances are included in 7 CFR 205.605, and may be used in boilers: ascorbic acid, citric acid, potassium carbonate, potassium hydroxide, sodium bicarbonate, sodium carbonate (soda ash), sodium hydroxide (caustic soda). In addition, cyclohexylamine (CAS # 108-91-8), diethylaminoethanol (CAS # 100-37-8) and octadecylamine (CAS # 124-30-1) are permitted for use only as a boiler water additive for packaging sterilization. Oxygen scavenging compounds such as sodium sulfite, ethylenediaminetetraacetic acid (EDTA), nitriloacetic acid (NTA) that react with free oxygen and precipitate out of the boiler water are considered materials that do not carry over into the steam. These are not on the National List.

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