Industrial Food-Grade Lubricants Guide

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Clarion Lubricants
1293 Eldridge Parkway
Houston, TX 77077

Phone: 832-486-4375
Fax: 832-486-1865
Email: info@clarionlubricants.com

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By Jim C. Fitch, Martin Williamson and Sabrin Gebarin, Noria Corporation

1. Introduction

The food processing industry presents unique challenges to lubricant formulation engineers, lubricant marketers, plant lubrication engineers, equipment designers and builders. While it is never desirable for lubricants to be allowed to contaminate raw materials, work-in-progress or finished product, the consequences of a lubricant-contaminated product is rarely more acute than in the food processing industry. As such, lubricants used in this industry have requirements, protocols and performance expectations that go well beyond typical industrial lubricants.

This paper provides a general overview of the unique challenges associated with food-grade lubricants, including recent revisions of the regulatory environment. The terminology commonly used by suppliers and clients of food-grade products will also be defined and discussed. So, too, will be machine applications common to certain sectors of the food processing industry and their unique requirements for food-grade lubricants.

2. The Food Processing Industry

Food-grade lubricants are significant in scope and application when you consider the size of the food processing industry. In the United States, food manufacturers represent a significant percentage of total manufacturing. According to the 1997 United States Census, approximately $485 billion in sales revenue was generated (about the same amount generated in the transportation manufacturing industry). This represents almost 13 percent of all manufacturing in the U.S. In 1997, approximately 28,000 manufacturing facilities employed 1.6 billion employees and produced 233 billion dollars in goods [1].

3. Current Registration Practices

Historically, the two U.S. government agencies primarily involved in food processing were the United States Department of Agriculture (USDA), which regulates meat, poultry and plants; and the U.S. Food and Drug Administration (FDA), which monitors other food and pharmaceutical manufacturing operations.

3.1. U.S. Regulations Prior to 1998

Prior to 1998, approval and compliance of food-grade lubricants was the responsibility of the USDA. The Food Safety and Inspection Services (FSIS), headed by the USDA, reviewed the formulations of maintenance and operating chemicals. FSIS required meat and poultry facilities to use only non-food compounds that were pre-approved by the USDA authorization program. However, these programs spread to other food market sectors such as fisheries and retail food operations [2].

To gain USDA approval, lubricant manufacturers had to prove that all of the ingredients in the formulation were allowable substances. Allowable substances, in this instance, are those listed by the FDA in accordance with the Guidelines of Security Code of Federal Regulations (CFR) Title 21, §178.3570. This did not include lubricant testing; rather, the approval was based primarily on a review of the formulation ingredients of the lubricant [2].

3.2. Changes in Food-Grade Lubrication Standards After 1998

Starting in February 1998, the FSIS significantly altered its program by implementing a system established by Hazard Analysis and Critical Control Point (HACCP) requiring the manufacturer to assess risk at each point in the operation where contamination might occur. The National Aeronautics and Space Administration (NASA) originally developed the HACCP system in the 1960s to prevent astronauts from receiving any food-borne illnesses. It established measures like minimum cooking temperatures for each control point and instituted procedures to monitor these measures and also provides corrective actions if critical limits are not met [3]. In essence, the manufacturer became responsible for reviewing and approving the chemical compositions of lubricants to decide whether they were safe or not as food-grade lubricants.

3.3. Third-Party Certifications

In response to the change in the approval process, several commercial organizations developed external certification programs. Three such organizations were the National Sanitation Foundation (NSF), Underwriters Laboratory (UL) and a joint effort by three recognized industry professional associations: the National Lubricating Grease Institute (NLGI), the European Lubricating Grease Institute (ELGI) and the European Hygienic Equipment Design Group (EHEDG).

NSF has developed a lubricant evaluation program that essentially mirrors the FSIS program by evaluating the candidate lubricant formulations to verify compliance with the various FDA Code of Federal Regulations (CFR). Each component in the formulation is submitted to NSF by the lubricant manufacturer along with other supporting documentation. This is then reviewed to verify it is within the FDA list of permitted substances [4]. NSF's Web site provides food processing manufacturers with a continually updated list of approved lubricants at www.nsfwhitebook.org (Figure 1).

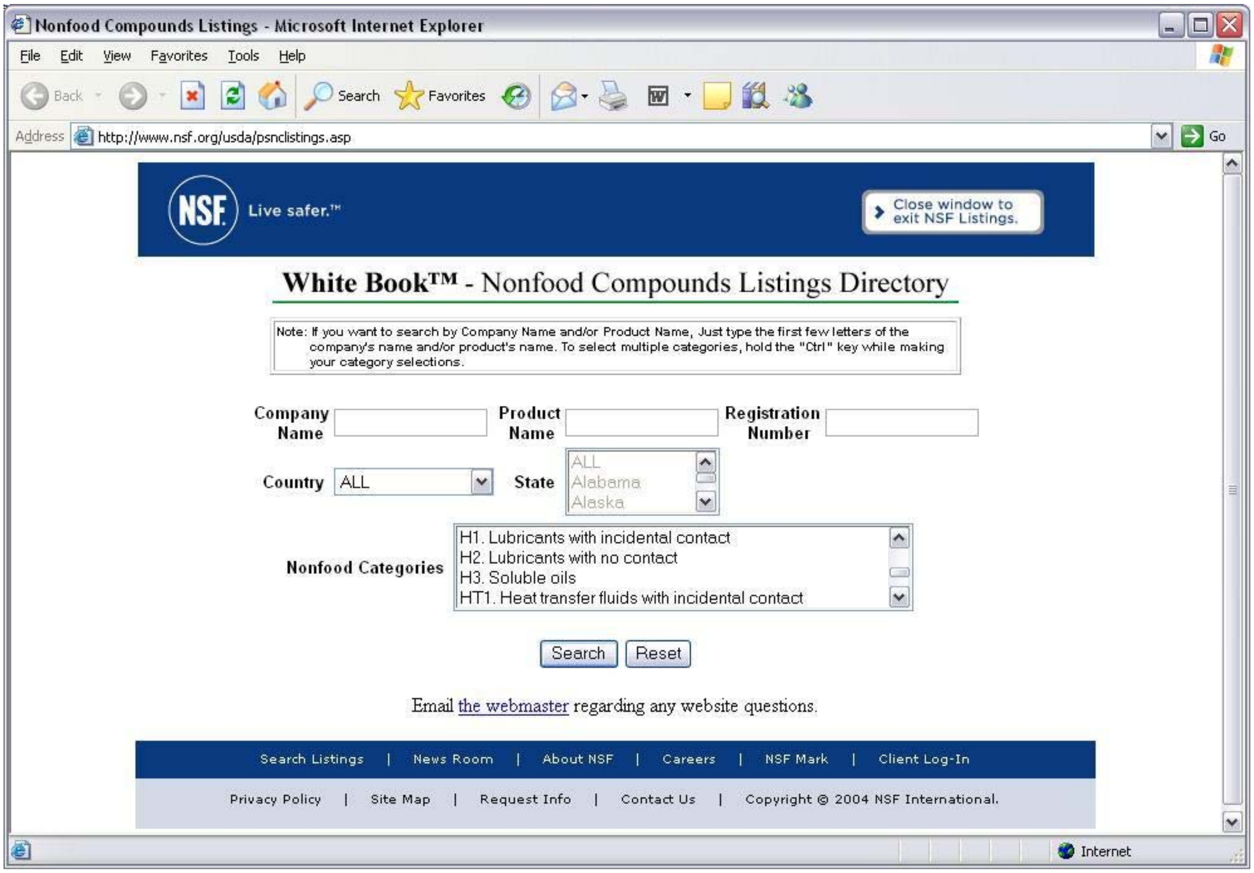

Figure 1. NSF's search engine of approved lubricants in H1, H2 and H3 applications.

UL is another organization that began third-party certification of food-grade lubricants but no longer is doing so. While they have not been as active as NSF in the area of food-grade lubricants, in the past, UL organized several informational meetings, inviting lubricant and chemical manufacturers to attend [5].

The NLGI / ELGI/ EHEDG Joint Food-grade Lubricants Working Group has been active in drafting an authorization program for food-grade lubricants. This group's program is also based on the former USDA/FSIS authorization program and CFR policies. Its plan is to develop a DIN standard in Germany and use the DIN standard to later develop an ISO (International Organization for Standardization) standard [5].

Not all countries use third-party certifications. Canada, New Zealand, Australia and Japan are some of the countries that federally regulate food-grade lubricants [1]. However the Canadian Food Inspection Agency (CFIA) is working on a food-grade lubricants approval system, and NSF will help with the CFIA review process. Also, the Australian Quarantine Inspection Service has approved approximately 50 food-grade lubricants based on NSF registration [6].

4. Challenges Facing Food-Grade Lubricants

Agricultural and animal substances go through a number of processes in a manufacturing plant, such as cleansing, sterilizing, blending, mixing, cooking, freezing, cutting, packaging, canning or bottling. Large-scale food processing requires machinery such as pumps, mixers, tanks, hoses and pipes, chain drives, and conveyor belts. Machinery used in food processing facilities face many of the same tribological and lubrication challenges found in other non-food processing plants. In that sense, lubricants must offer similar protection of internal surfaces to control friction, wear, corrosion, heat and deposits. They must also offer good pumpability, oxidation stability, hydrolytic stability and thermal stability where the application so requires. Many of the raw materials used to formulate lubricants that effectively address these challenges in conventional industrial applications are not permissible in food applications for safety reasons.

In addition, certain applications within the food and drug manufacturing facilities demand that lubricants resist degradation and impaired performance when in contact with food products, certain process chemicals, water (including steam) and bacteria. They must also exhibit neutral behavior toward plastics and elastomers and have the ability to dissolve sugars. In general, these lubricants must comply with food/health and safety regulations, as well as be physiologically inert, tasteless, odorless and internationally approved [7].

Lubricants in many food processing plants can be subjected to ingression and contend with an assortment of environmental contaminants. For instance, a corn-milling environment generates significant dust. Although not as hard as silica-based terrain dust, it still presents a problem for filtration. A meat plant requires stringent steam cleaning at all times, so the risk of water contamination is high. Water contamination in gear oils routinely exceeds 15 percent in some plants.

Another aspect of lubrication contamination that poses unique risk to food-grade lubricants is the growth of microorganisms such as bacteria, yeast and fungi. While these can also be challenging to conventional industrial lubricants, the opportunity for microbial contamination in the food-production industry is considerably greater.

5. Food-Grade Lubricants Defined by Category

Food-grade lubricants are either compounded or uncompounded products acceptable for use in meat, poultry and other food processing equipment, applications and plants. The lubricant types in food-grade applications are broken into categories based on the likelihood they will contact food. The USDA created the original food-grade designations H1, H2 and H3. The approval and registration of a new lubricant into one of these categories depends on the ingredients used in the formulation. The three designations are described as follows [2]:

H1 lubricants are food-grade lubricants used in food processing environments where there is some possibility of incidental food contact. Lubricant formulations must be composed of one or more approved basestocks, additives and thickeners (if grease) listed in 21 CFR 178.3750. Only the minimum amount of lubricant required should be used on the equipment.

H2 lubricants are lubricants used on equipment and machine parts in locations where there is no possibility that the lubricant or lubricated surface contacts food. Because there is not a risk of contacting food, H2 lubricants do not have a defined list of acceptable ingredients. They cannot, however, contain intentionally heavy metals such as antimony, arsenic, cadmium, lead, mercury or selenium. Also, the ingredients must not include substances that are carcinogens, mutagens, teratogens or mineral acids [4].

Lubricant Type	Regulations They Must Meet
Edible oils (corn oils, cottonseed oil, soybean oil)	21 CFR 172.860
Certain mineral oils	21 CFR 172.878
Generally Recognized as Safe (GRAS)	21 CFR 182 or 21 CFR 184

Table 1. H-3 Soluble Oil Approved Lubricants

H3 lubricants, also known as soluble or edible oil, are used to clean and prevent rust on hooks, trolleys and similar equipment. Equipment applied with H3 lubricants should be cleaned by washing or wiping the surface before putting the equipment in service. These lubricants can only consist of ingredients as shown in Table 1 [4].

Deciding whether there is a possibility of contact is tough, and many have erred on the side of safety with respect to selecting an H1 lubricant over an H2 lubricant.

6. Approved Lubricant Formulations in H1 Lubricants

As previously mentioned, the USDA/FSIS approvals are based on the various FDA Codes in Title 21 that dictate approval for ingredients used in lubricants that may have incidental contact with food. These are mentioned below:

- 21.CFR 178.3570 – Allowed ingredients for the manufacture of H1 lubricants
- 21.CFR 178.3620 – White mineral oil as a component of non-food articles intended for use in contact with food
- 21.CFR 172.878 – USP mineral oil for direct contact with food
- 21 CFR 172.882 – Synthetic isoparaffinic hydrocarbons
- 21.CFR 182 – Substances generally recognized as safe

Based on the Title 21 FDA regulations noted, the following paragraphs discuss the allowable basestocks, additives and thickeners in food-grade lubricants.

6.1. Acceptable Food-Grade Basestocks

Depending on whether the food-grade lubricant is H1 or H2, the list of approved basestocks will vary. H2 lubricant basestock guidelines are less restrictive and, consequently, allow a broader variety of basestocks. Many products used in industrial (non-food) plants are also used in food plants for H2 applications. H1 lubricants are much more limited since they are designed to allow for accidental exposure with the processed foods. The approved H1 lubricant basestocks can be either mineral or synthetic:

6.1.1. Petroleum-based lubricants

Mineral oils used in H1 food-grade lubricants are either technical white mineral or USP-type white mineral oils. White oils start as normal paraffinic petroleum stocks and are processed into pure branched paraffin stocks, stripped free of the majority of aromatic hydrocarbons, sulfur and nitrogen contaminants. They are highly refined and are colorless, tasteless, odorless and non-staining. Technical white oils meet the regulations specified in 21 CFR 178.3620. Based on the American Society for Testing Materials (ASTM) method D156-82, "Standard Test Method for Saybolt Color of Petroleum Products (Saybolt Chromometer Method)," the Saybolt color must be 20 minimum to be considered a technical white oil [8]. USP mineral oils are the purest of all white mineral oils and are the most oxidatively stable [5].

Historically, white mineral oils were first listed in the United States Pharmacopoeia (USP) in 1926. Later, a paper on the general principles of white oil manufacturing was written in 1935, followed by other papers [1].

6.1.2. Synthetic lubricants

Synthetic H1 lubricants are mainly polyalphaolefins (PAO). They were first introduced in 1981 by Gulf Research and Development Company [1]. Compared to white mineral oils, they have significantly greater oxidation stability and a greater range of operating temperatures. Another H1 synthetic lubricant used is polyalkylene glycols (PAG). These lubricants are more increasingly used in high-temperature applications.

Dimethylpolysiloxane (silicones) with a viscosity greater than 300 centistokes (cSt) [9] is also permitted for H1 lubricants. Sanction letters for the use of silicone fluids as defoaming agents show up as early as 1953. Silicones were not approved until soon after a petition filed by General Electric in 1965 [1]. Silicones have even higher thermal and oxidation stability than PAO and PAG base oils.

6.1.3. Differences among basestocks

Although synthetics are more expensive than mineral oils, tests performed on H1 PAO and white mineral oils on drive chains show that the useful life of PAOs is almost twice that of white oils. Testing has shown PAG base oils have a service life five times longer than white mineral oils [7]. In addition to longer service life, there is evidence that synthetic H1 oils do a better job of protecting metal surfaces from corrosion and wear and withstand greater temperature extremes required around freezers or ovens.

6.2. Acceptable Food-Grade Additives and Thickeners

Often, basestocks are not able to meet the severe demands required in food processing work environments. To improve the performance characteristics of base oils, additives are blended into the formulation. The types of antioxidants, corrosion inhibitors, anti-wear, extreme-pressure additives and concentration are limited by 21 CFR 178.3570.

Greases are lubricating oils that have a thickening agent added to the formulation. Approved grease thickeners include aluminum stearate, aluminum complex, organo clay and polyurea [10]. Aluminum complex is the most common H1 food-grade grease thickener. They can withstand high temperatures and are water resistant, which are important properties for food processing applications. Greases with calcium sulfonate thickeners have not been explored for approval by the USDA or FDA, but has been approved in Canada for incidental contact [11].

The list of approved base oils, additives and thickeners for H1 incidental contact with food is available in Table 2.

Table 2. Approved Substances for H1 Lubricants per 21 CFR 178.3570

Substance	Limitations
Aluminum stearoyl benzoyl hydroxide	For use only as a thickening agent in mineral oil lubricants at a level not to exceed 10 percent by weight of the mineral oil.
N,N-Bis(2-ethylhexyl)-ar-methyl-1H - benzotriazole-1-methanamine (CAS Reg. No. 94270-86-7)	For use as a copper deactivator at a level not to exceed 0.1 percent by weight of the lubricant.
BHA	
BHT	
[alpha]-Butyl-omega- hydroxypoly(oxyethylene) poly (oxypropylene) produced by random condensation of a 1:1 mixture by weight of ethylene oxide and propylene oxide with butanol; minimum molecular weight 1,500; Chemical Abstracts Service Registry No. 9038-95-3.	Addition to food not to exceed 10 parts per million.
[alpha]-Butyl-omega- hydroxypoly (oxypropylene); minimum molecular weight 1,500; Chemical Abstracts Service Registry No. 9003-13-8.	Addition to food not to exceed 10 parts per million.
Castor oil	Addition to food not to exceed 10 parts per million.
Castor oil, dehydrated	Addition to food not to exceed 10 parts per million.
Castor oil, partially dehydrated	Addition to food not to exceed 10 parts per million.
Dialkyldimethylammonium aluminum silicate (CAS Reg. No. 68953-58-2), weight 1, 6-hexanediol (CAS Reg. No. by weight of the mineral oil. 629-11-8), where the alkyl groups are derived from hydrogenated tallow fatty acids (C_{14}-C_{18}) and where the aluminum silicate is derived from bentonite.	For use only as a gelling agent in mineral oil lubricants; may contain up to 7 percent by level not to exceed 15 percent.
Dimethylpolysiloxane (viscosity greater than 300 centistokes).	Addition to food not to exceed 1 part per million.
Di (n-octyl) phosphite (CAS Reg. No. 1809-14-9).	For use only as an extreme-pressure antiwear adjuvant at a level not to exceed 0.5 percent by weight of the lubricant.
Disodium decanedioate (CAS Reg. No. 17265-14-4).	For use only:
	1. As a corrosion inhibitor or rust preventative in mineral oil-bentonite lubricants at a level not to exceed 2 percent by weight of the grease.

	2. As a corrosion inhibitor or rust preventative only in greases at a level not to exceed 2 percent by weight of the grease.
Disodium EDTA (CAS Reg. No. 139-33-3.	For use only as a chelating agent and sequestrant at a level not to exceed 0.06 percent by weight of lubricant at final use dilution.
Ethoxylated resin phosphate ester mixture consisting of the following compounds:	For use only as a surfactant to improve lubricity in lubricating fluids complying with this section at a level not to exceed 5 percent by weight of the lubricating fluid.
1. Poly(methylene-p-tert-butyl phenoxy) poly(oxyethylene) mixture of dihydrogen phosphate and monohydrogen phosphate esters (0 to 40 percent of the mixture). The resin is formed by condensation of 1 mole of p-tert-butylphenol with 2 to 4 moles of formaldehyde and subsequent ethoxylation with 4 to 12 moles of ethylene oxide.	
2. Poly(methylene-p-nonylphenoxy) poly(oxyethylene) mixture of dihydrogen phosphate and monohydrogen phosphate esters (0 -40 percent of the mixture). The resin is formed by condensation of 1 mole of p-nonylphenol with 2 to 4 moles of formaldehyde and subsequent ethoxylation with 4 to 12 moles of ethylene oxide.	
3. n-Tridecyl alcohol mixture of dihydrogen phosphate and monohydrogen phosphate esters (40 to 80 percent of the mixture; CAS Reg. No. 56831-62-0).	
Fatty acids derived from animal or vegetable sources, and the hydrogenated forms of such fatty acids.	
2-(8-Heptadecenyl)-4,5-dihydro-1H-	For use at levels not to exceed 0.5 percent by weight of the lubricant.
imidazole-1-ethanol (CAS Reg. No. 95-38-5).	
Hexamethylenebis(3,5-di-tert-butyl-4-	For use as an antioxidant at levels not to exceed 0.5 percent by weight of the lubricant.
hydroxyhydrocinnamate) (CAS Reg. No.	
35074-77-2).	
[alpha]-Hydro-omega-hydroxypoly (oxyethylene) poly(oxypropylene) produced by random condensation of mixtures of ethylene oxide and propylene oxide containing 25 to 75 percent by weight of ethylene oxide; minimum molecular weight 1,500; Chemical Abstracts Service Registry No. 9003-11-6.	Addition to food not to exceed 10 parts per million.
12-Hydroxystearic acid	
Isopropyloleate	For use only as an adjuvant (to improve lubricity) in mineral oil lubricants.
Magnesium ricinoleate.	For use only as an adjuvant in mineral oil lubricants at a level not to exceed 10 percent by weight of the mineral oil.
Mineral oil	Addition to food not to exceed 10 parts per million.
N-Methyl-N-(1-oxo-9-octadecenyl) glycine (CAS Reg. No. 110-25-8).	For use as a corrosion inhibitor at levels not to exceed 0.5 percent by weight of the lubricant.

N-phenylbenzenamine, reaction products with 2, 4, 4-trimethylpentene (CAS Reg. No. 68411-46-1).	For use only as an antioxidant at levels not to exceed 0.5 percent by weight of the lubricant.
Petrolatum	Complying with Sec. 178.3700. Addition to food not to exceed 10 parts per million.
Phenyl-[alpha]-and/or phenyl [beta]-naphthylamine.	For use only, singly or in combination, as an antioxidant in mineral oil lubricants at a level not to exceed a total of 1 percent by weight of the mineral oil.
Phosphoric acid, mono- and dihexyl esters, compounds with tetramethylnonylamines and C_{11-14} alkylamines.	For use only as an adjuvant at levels not to exceed 0.5 percent by weight of the lubricant.
Phosphoric acid, mono- and diisooctyl esters, reacted with tert-alkyl and (C_{12}-C_{14}) primary amines (CAS Reg. No.68187-67-7).	For use only as a corrosion inhibitor or rust preventative in lubricants at a level not to exceed 0.5 percent by weight of the lubricant.
Phosphorothioic acid, O, O, O-triphenyl ester, tert-butyl derivatives (CAS Reg. No. 192268-65-8).	For use only as an extreme-pressure antiwear adjuvant at a level not to exceed 0.5 percent by weight of the lubricant.
Polyurea, having a nitrogen content of 9 to 14 percent based on the dry polyurea weight, produced by reacting tolylene diisocyanate with tall oil fatty acid (C_{16} and C_{18}) amine and ethylene diamine in a 2:2:1 molar ratio.	For use only as an adjuvant in percent level not to exceed 10 mineral oil lubricants at a by weight of the mineral oil.
Polybutene (minimum average molecular weight 80,000).	Addition to food not to exceed 10 parts per million.
Polybutene, hydrogenated; complying with the identity prescribed under Sec. 178.3740.	Addition to food not to exceed 10 parts per million.
Polyethylene	Addition to food not to exceed 10 parts per million.
Polyisobutylene (average molecular weight 35,000-140,000 [Flory]).	For use only as a thickening agent in mineral oil lubricants.
Sodium nitrite	Use only as a rust preventive in mineral oil lubricants at a level not to exceed 3 percent by weight of the mineral oil.
Tetrakis [methylene(3,5-di-tert-butyl-4- hydroxyhydro-cinnamate)] methane (CAS Reg. No. 6683-19-8).	For use only as an antioxidant in lubricants at a level not to exceed 0.5 percent by weight of the lubricant.
Thiodiethylenebis (3,5-di-tert-butyl-4-hydroxyhydrocinnamate) (CAS Reg. No. 41484-35-9).	For use as an antioxidant at levels not to exceed 0.5 percent by weight of the lubricant.
Tri[2(or 4)-C_{9-10}-branched alkylphenyl]phosphorothioate (CAS Reg. No. 126019-82-7).	For use only as an extreme-pressure antiwear adjuvant at levels not to exceed 0.5 percent by weight of the lubricant.
Triphenyl phosphorothionate (CAS Reg. No. 597-82-0).	For use as an adjuvant in lubricants herein listed at a level not to exceed 0.5 percent by weight of the lubricant.
Tris(2,4-di-tert-butylphenyl) phosphite (CAS Reg. NO. 31570-04-4).	For use only as a stabilizer at levels not to exceed 0.5 percent by weight of the lubricant.
Thiodiethylenebis (3,5-di-tert-butyl-4- hydroxy-hydro-cinnamate) (CAS Reg. No. 41484-35-9).	For use as an antioxidant at levels not to exceed 0.5 percent by weight of the lubricant.
Zinc sulfide	For use at levels not to exceed 10 percent by weight of the lubricant.

Source: 21 CFR 3570 – Lubricants with incidental food contact. Retrieved online at www.access.gpo.gov/nara/cfr.index.asp.

7. Selecting What Machines Require Food-Grade Lubricants

Selecting whether to use an H1 or H2 lubricant can be challenging. As previously mentioned, H1 lubricants are permitted where incidental contact might be possible, while an H2 lubricant is only permitted where there is no possible contact with the food product. For example, a lubricant used on a conveyor system running over a food line must be an H1 category oil, while a conveyor system running underneath a food line may use either an H1 or H2 lubricant. Because H1 lubricants are limited by types of additives and in the past only used mineral oil basestocks, H1 lubricants in certain instances provided less protection and shorter lubricant life. Now that synthetics are used, some H1 lubricant performance can exceed non-food-grade lubricants. This is highly significant in allowing consolidation and avoiding accidentally cross-contamination of H1 and H2 oils, and contamination of H2 oils with food [7].

8. Selecting an H1 Food-Grade Supplier [13]

Finding the right lubricant supplier is as important as selecting the right lubricant. It is important to find a food-grade lubricant supplier that understands specific applications and requirements. Important qualities of a lubricant supplier are product consolidation, oil analysis, on-time delivery, speedy response to questions and an ability to tailor products to client needs.

9. Religious Organizations' Influence in Food-Grade Lubricants

The Muslim and Jewish religions further restrict the formulation of food-grade lubricants. Today, there are approximately 14 million Jews and 1.3 billion Muslims worldwide [14]. Both religions have rules covering aspects of food processing.

"Kosher for Pareve," or Kosher, is the term used to describe Jewish dietary laws. Kosher law is approved by several rabbinic orders. In the United States, the Orthodox Union and the Organized Kashrus Laboratories are major approval organizations active in the approval of food-grade lubricants. Kosher law outlaws the use of pork and pork by-products. Kosher law also prohibits any mixing of meats and dairy and eggs. Any equipment must be properly cleaned and left idle for 24 hours before and after making kosher foods [1].

Under Islamic law, "Halal" (meaning lawful or permitted in Arabic) laws are imposed on their food products. In the United States, the Islamic Food and Nutrition Council of America issues Halal certificates. Similar to Kosher laws, Halal foods exclude the use of pork and pork by-products. Also, Halal excludes the use of alcohol in its products, which potentially limits some of the additives used in food-grade lubricants [1].

10. Conclusions

The food and beverage processing industries with respect to food-grade lubricants have changed dramatically within the last few years. Understanding the differences between H1, H2 and H3 lubricants and making the proper lubricant selection is critical to food safety and machine reliability. As an additional source, NSF's Web site provides lubricant requirements for food-grade products and gives a free access listing of certified food-grade lubricants on their site at www.nsfwhitebook.org.

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Clarion Lubricants
1293 Eldridge Parkway
Houston, TX 77077

Phone: 832-486-4375
Fax: 832-486-1865
Email: info@clarionlubricants.com