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Understanding Food Grade Lubricants

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Food Safety

Health and safety are priorities for food, drink and drug manufacturers. Standards of cleanliness and hygiene are as important on the shop room floor as in hospital operating rooms. But when it comes to production equipment, lubrication keeps the business of feeding and healing the nation on track.

Lubricant leakages and maintenance are an inevitable part of all industries. Lubricants do not discriminate against the materials with which they come into contact. So the food-processing and pharmaceutical industries have additional challenges in selecting the right lubricants to do the job. This article looks at the previous, current and future standards relating to lubrication in this industry.



What is a Food-Grade Lubricant?

Food-grade lubricants must perform the same technical functions as any other lubricant: provide protection against wear, friction, corrosion and oxidation, dissipate heat and transfer power, be compatible with rubber and other sealing materials, as well as provide a sealing effect in some cases.

In addition, different applications within the food and drugs business demand that lubricants resist degradation from food products, chemicals and water/steam, must exhibit a neutral behavior toward plastics and elastomers, and have the ability to dissolve sugars. These oils must also comply with food/health and safety regulations, as well as be physiologically inert, tasteless, odorless and internationally approved.

Lubricants can be subjected to intense environmental contaminants. A corn-milling environment generates significant dust. Although not as hard as silica-based 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. Some plants experience as much as 15 percent by volume of water in their gear oils.

Another aspect of lubrication contamination that poses a risk to food-grade lubricants is the growth of microorganisms such as bacteria, yeast and fungi. While these can be a risk in industrial environments, the opportunity for contamination in the food-production environment is even greater.

Food-Grade Categories

The United States Department of Agriculture (USDA) created the original food-grade designations H1, H2 and H3. The approval of a new lubricant and its registration in one of these categories depends on the list of the ingredients.

- H1 lubricants are food-grade lubricants used in food-processing environments where there is the possibility of incidental food contact.
- H2 lubricants are nonfood-grade lubricants used on equipment and machine parts in locations where there is no possibility of contact.
- H3 lubricants are food-grade lubricants, typically edible oils, used to prevent rust on hooks, trolleys and similar equipment.

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

Approval and Compliance

Approval and compliance was, in the past, the responsibility of the USDA. The agency is considered an internationally renowned authority on consumer safety issues with regard to the food-processing industry. Its efforts essentially covered federally inspected meat and poultry facilities, but were rapidly adopted by other sectors such as fisheries and retail food operations.

To gain USDA approval, lubricant manufacturers had to prove that all the ingredients in the formulation were allowable substances. Allowable substances, in this instance, are those listed by the United States Food and Drug Administration (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.

However, since September 30, 1998, the USDA has no longer been issuing registration of food-grade lubricants or reviewing federally inspected meat and poultry process facilities.



The Future of Food-Grade Approval

Registrations granted prior to this date will remain in effect, and as before, USDA H1 and H2 still stand as a recognized approval for food and drug suitability. In fact, many lubricant manufacturers still aspire to the USDA H1 and H2 categories and approval process, and supply certification from their boards of directors to guarantee that claim.

However, efforts chaired by Klüber Lubricants of Germany, led to the creation of a new standard, DIN V 0010517, 2000-08 (Food-Grade Lubricants - Definitions and Requirements). This standard has since been approved at a higher DIN level.

The German Institute for Standardization (DIN) has submitted this German standard as a draft to International Organization for Standardization (ISO) in Geneva. It may take up to three years from the date the application is accepted for an international standard to be released.

The National Sanitary Foundation (NSF) has evolved globally to succeed the USDA. NSF International, The Public Health and Safety Company™, is an independent, nonprofit organization that has been committed to public health, safety and protection of the environment for more than 55 years. NSF has earned the Collaborating Center designations by the World Health Organization (WHO) for both food safety and for drinking water safety and treatment. It is conceived and administered as a public service organization, serving as an independent and neutral body to resolve issues between regulatory bodies, business, industry and the public.

NSF has basically adopted the DIN Standard V 0010517, 2000-08 as its own guideline for a registration of food-grade lubricants. Using the former USDA H1 and H2 classifications, NSF has submitted its draft standard, NSF 116-2000 (nonfood compounds used in food-processing facilities - food-grade lubricants) to the American National Standards Institute (ANSI). The draft standard covers the former USDA H1 and H3 categories.

The DIN standard V 0010517, 2000-08 has also been adopted by the European Lubricating Grease Institute (ELGI) and National Lubricating Grease Institute (NLGI) as their guideline.

NSF 116-2000 Draft Standard in Detail

The purpose of the standard is to establish food safety evaluation criteria for food-grade lubricants used in food-processing, packaging, handling and storage. It provides a mechanism for the validation of a manufacturer's claims and labeling, but does not provide a mechanism for demonstrating this through laboratory testing. The scope does not cover evaluation of product performance or operational criteria inside food-processing facilities. However, it does specify definitions and requirements for food-grade lubricants in lubrication, heat transfer, load transmission and corrosion protection of machinery and equipment in food-manufacturing and processing facilities. Because the scope is food-grade lubricants, only H1 and H3 are covered in this draft standard.

The requirements section of the draft standard covers labeling and formulation. More specifically in labeling, the name of the product, the manufacturer's name (or name of the company marketing the product), category code and directions regarding use must be displayed. The directions for use must state the minimum required

amount to achieve the product's required purpose or technical effect. All references to the company name on the labels must be in complete agreement with the disclosure information on formulation.

Formulation Guidelines

With respect to formulation requirements, the draft standard states the product shall not contain intentionally added heavy metals, and shall not contain ingredients classified as carcinogens, mutagens or teratogens. A carcinogen is a substance that when ingested, may cause cancer. A mutagen is a substance which causes mutation. A teratogen is an agent which raises the incidence of congenital malformations. For certain types of lubricants, these shall be neutral in taste and odor, and in addition, should be selected according to the use such that the lubricant withstands temporal, chemical, biological, thermal or mechanical stresses without premature degradation or impact to its neutral state.

The evaluation criteria cover three main aspects: food-grade lubricants, evaluation requirements and ingredients. The food-grade lubricants must comply with the requirements of the draft standard as well as CFR Title 21 §178.3570, and more specifically, sections 172.860 for vegetable oils and 172.878 for mineral oils. Ingredients and/or compounds must comply with 21 CFR parts 182 and 184.

Evaluation requires that the manufacturer or supplier disclose the product name, a qualitative/quantitative identification of all constituents, the Chemical Abstract Service (CAS) number where applicable, the chemical ingredient names based on the International Union of Pure and Applied Chemistry (IUPAC) rules, suppliers or sources of each ingredient, any prior product approval from a state or country regulatory authority, and any appropriate FDA regulatory reference for each ingredient.

In terms of the ingredients, any separate confirmation issued by the FDA or USDA should be provided and should not be mentioned in any list of nonallowable substances.

What Does All This Mean?

For the manufacturer and supplier, a new standard potentially exists by which their lubricants can be categorized and approved. Because the same categories and requirements exist within the USDA, although with some modifications, continuity of supply and safety can be assured.

For the end-user, selection of lubricants per the original H1, H2 and H3 categories remain. Compliance and regulation are now potentially assured by the NSF draft standard.

Consumers can be assured that the lubricant manufacturers and food and drugs industries are maintaining strict standards with regard to our health and safety.



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