# Incidental contact lubricants for the food industry

*Start your ounce of prevention with the right formulation and processes.*

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**KEY CONCEPTS**

Incidental contact lubricants for the food industry must perform well with a smaller set of allowed ingredients and strict maximum limits on contact with food.

Lubricant leaks can contaminate thousands of pounds of food, cause significant down time and repairs and damage a company's reputation.

The U.S. government is making more formal its use of sustainable, biodegradable products, including those used in food-related operations.

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**No one wants to** eat food that tastes funny or makes them sick. However, on the journey from farm to fork, food touches or comes close to conveyor belts, slicers, extruders, gearboxes, bearings, pumps and drive mechanisms—and the lubricants that keep them running smoothly. Using specifically formulated incidental-contact lubricants anywhere there is any possibility of the lubricant coming into contact with the food can ensure that the final food product is safe to eat.

Incidental contact lubricants present their own particular challenges, says STLE-member John Sander, vice president for research and development for Lubrication Engineers, Inc., in Wichita, Kan. These lubricants should provide the same pumpability, chemical stability and tribologi-

'You could self-certify, but no end-user would accept that.'

cal performance as their more general counterparts. However, they must be made from ingredients that won't harm the end-user and, even then, contact between lubricant and food must be strictly minimized. "If you have an oil leak, you still have to make the repairs," explains Andreas Adam, sales director for Germany-based FRAGOL, AG.

**Registration and certification**

In the U.S., federal regulations govern the ingredients that are approved for use in incidental contact lubricants and limit the amounts used or the maximum exposure to the food product. NSF (formerly the National Sanitation Foundation) registration guidelines for incidental contact (H1) lubricants are modeled on 21 CFR 178.3570,[1] but lubricant formulators also can get H1 approval for components that fall under the FDA's designation of "generally recognized as safe" (GRAS) *(see Terminology)*. Manufacturers submit their formulations to NSF, which checks the ingredients against their list of allowable compounds[2] or a list of GRAS compounds.[3] Approved formulations receive a registration number, which appears along with the NSF logo on the product label. The manufacturer is responsible for guaranteeing that they adhere to the registered formula and that nothing goes into the vessels that isn't on the list of approved chemicals, says Sander.

"You could self-certify a finished lubricant, without going through NSF or InS (in Europe), but no end-user would accept that," says STLE-member Wayne Mackwood, global application technology head of detergents and grease for LANXESS Canada Co.; Lubricant Additives Business Unit. "They are looking for NSF/InS registration and/or ISO certification."

Certification goes beyond registration, Sander explains. NSF and several other organizations certify incidental contact lubricants using the ISO 21469:2006 standard.[4] This standard spells out hygiene requirements for the "formulation, manufacture, use and handling" of incidental contact lubricants for "products and packaging used in the food, food-processing, cosmetics, pharmaceutical, tobacco or animal-feeding-stuffs industries." Certification requires annual onsite audits where an inspector walks through the plant to see if there is any possibility of a non-H1 ingredient getting into the lubricant batch. The inspec-

## Terminology

Incidental contact lubricants are approved for use in operations where food products might be exposed to as much as 10 ppm of lubricant (1 ppm for silicone oils), not intentionally, but as an unavoidable result of normal operations. The USFDA has found no reported toxicological effects for mineral oil exposures below 10 ppm. Above that level, any lubricant present in a food product is considered a contaminant and must be treated as such.[A]

Although the term "food-grade lubricant" is commonly used, it can be misleading. Very few performance lubricants, some vegetable oil release agents for example, are true full-contact products.

Incidental contact lubricants are those that have been deemed acceptable by USDA for use in food processing equipment, applications and plants. The USDA turned over registration responsibility to NSF in 1999. In July 2019, NSF acquired the UK-based registration organization InS Services, and products currently registered by InS will be listed in the NSF White Book beginning in 2020.[B] Under the NSF registration system, oils and greases are categorized based on their likelihood of coming into contact with food:

- **H1 lubricants** are used where there is some possibility of incidental food contact.
- **H2 lubricants** may only be used in areas of food-processing plants where there is no possibility that the lubricant or lubricated surface will contact food, and it is preferable to avoid them altogether.
- **H3 corrosion preventives** (soluble oils) are used to clean and prevent rust on hooks, knives, trolleys and similar equipment during storage. H3 is not an incidental contact lubricant classification, and these materials must be cleaned off of the equipment before it is put into use.
- **3H oils** are pharmaceutical-grade white oils, defined as food additives, and their maximum levels in food are defined under 21 CFR 172.[C]

NSF designates lubricant additive HX classifications corresponding to the lubricants for which they are used (i.e., HX-1 additives are used in H1 lubricants). Approved additives can be found in the NSF White Book.[2]

ISO 21469 is an international certification program that verifies compliance with H1 formulations, and also requires periodic inspections of the manufacturing and handling processes used for lubricant production.[4]

A. Housel, T., "The History and Future of Food Processing Lubricants," Reliable Plant 2016 Conference Proceedings. Available at **https://directory.lubesngreases.com/media/B0C23952-9885-1913-A58A-BE5908EA7599.pdf**.

B. NSF International Acquires UK-based InS Services, NSF press release, July 24, 2019. Available at **www.nsf.org/newsroom/nsf-international-acquires-uk-based-ins-services.**

C. Food Additives Permitted for Direct Addition to Food for Human Consumption, 21CFR172. Available at **www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=172.**

tor also looks at the formulation and raw materials, as well as the accompanying documents.

**Formulations and functions**

Although 21 CFR 178.3570 currently lists fewer than 50 compounds, NSF has registered a wide variety of formulations made from these compounds. H1-approved base oils include white oils (highly refined mineral oils), PAOs, PAGs, several silicone oils, polybutenes, alkylated naphthalenes, synthetic esters and PFPE (perfluoropolyether).[1]

Cory MacLeod, technical service manager for LANXESS Solutions US Inc.; Lubricant Additives Business Unit, explains the limitations that H1 compliance places on allowable additives. Many commonly used sulfur- and zinc-based EP and antiwear additives are not approved for applications where they could come into contact with food products, MacLeod says.

LANXESS has one antiwear additive in its portfolio, an amine-neutralized phosphate ester, that is designated for incidental contact use, as well as one corrosion inhibitor. They have several aminic and phenolic antioxidants to choose from, but even these have limits on permissible levels of exposure set by NSF and based on FDA toxicology studies. LANXESS also uses several HX-1-approved esters as base oils or lubricity additives. For some additives, NSF specifies using the "minimum level required to achieve technical effect," which requires formulators to use as little as possible to get the performance they need, he adds.

Incidental contact greases are sometimes referred to as white greases because of the whiteners (titanium oxide or other compounds) added to the formulation. In some applications, this whitener might benefit the grease's performance, says Sander, but often it just serves an aesthetic function, providing a connotation of cleanliness.

Lithium thickeners are the most commonly used for general industrial grease formulations, but they aren't allowed under H1, Sander says. An ingredient not allowed under H1 might be safe to use, but if it hasn't been through the approval process, it can't be used in incidental contact lubricants, he adds.

The number of H1-approved grease thickeners is limited, says Mackwood. Historical H1-approved grease thickeners include aluminum complex, simple calcium, some polyurea materials and clay, as well as PTFE- and silica-based dispersion-type thickeners, he says.

Calcium sulfonate complexes have emerged as promising high-performance grease thickeners, gaining H1 status in 2001. "The value that we saw when we were getting approval is that it has antiwear, EP and corrosion resistance built right into the thickener, so you don't need to use other additives," Mackwood explains. "All you really need is an antioxidant, and the ones available work very well. It hasn't replaced everything, but it opens up a possibility for formulating H1 [products] in applications where grease is used." This type of thickener can be used with a variety of base oils to produce greases for use under corrosive conditions, under high loads and across a wide range of temperatures, from freezers to baking ovens.

**Most major international food-based producers, including Europe, strictly follow USDA categories.**

Mackwood notes that because general-use industrial lubricants have access to a broader range of base oils and additives than do the H1 lubricants: "There's no way that the two can perform similarly given the treatment allowances and the limited number of components available." Thus, much of the onus has been on engineers to design food processing equipment that requires less lubricant, operates better with approved lubricants and reduces the likelihood of incidental contact. Otherwise, operators must replace parts and lubricants more frequently to make up for the limitations in H1 lubricant performance.

"The H1 lubricants, especially if based on synthetic technology, have greatly closed the performance gap in the last 10 years. We still see a push toward equality, but we're not there yet," says Cindy Cleves, owner of Interlube Corp., in a 2017 interview.[5] In the same article, Sander noted that manufacturers will continue to pay more for H1 lubricants than they do for general-purpose (H2) lubricants because of the cost of the raw ingredients and the added expense of registration or certification. However, he says that this cost is small compared to the price of a mistake that results in a product recall.

Food processing operations should rely on reputable suppliers, Adam says. Restrictions on the types of allowable ingredients need not limit performance, but "you need to know the limitations of the products and you need to have a knowledgeable sales representative."

**Special requirements**

"Food touches on various areas of all our daily lives," Sander says, adding that some customers' dietary requirements can prohibit the use of certain allergens or religiously prohibited substances. For instance, many persons who practice the Jewish and Muslim religions observe Kosher and Halal dietary restrictions, and lubricants used in plants that produce these foods require special approvals.

Kosher and Halal are true certification processes, requiring annual inspections of the plant and handling procedures as well as verifying the formulations and raw material suppliers. Inspectors look at the cleanliness of the plant to ensure that no open doors can let in dirt and dust, and that there are no insects, birds or reptiles inside the plant. They also check finished products to ensure that the Kosher or Halal logos are being used properly on the product labeling. Kosher or Halal inspectors are required to conduct educational sessions for plant personnel to explain the rationale and importance of the certification requirements.

Not all lubricants approved under NSF/ISO standards for incidental contact meet the requirements for Halal or Kosher and vice versa. Thus, formulators of these products must operate within the overlap between these two areas. The allowable ingredients are very similar for both Kosher and Halal, so many of the same lubricant formulations can be used to meet the requirements for both, Sander says. ▶

Allergens are a growing area of concern, says Mackwood. Because exposure to a very small amount of an allergen can trigger a reaction, food producers are scrambling to eliminate any potential sources of these materials. "It seems like every month, there's a new ingredient that they are asking about. The allergen list is quite lengthy now," he says. Common allergens include peanuts and tree nuts, milk and egg products, fish and seafood, wheat, sesame seeds, soy products and some food dyes. Mackwood explains that additive levels in a lubricant can be less than 1%, and that food exposure to the fully formulated lubricant must be kept below 10 ppm, so potential exposure levels are very low. "But customers just want to know whether the allergen is there," he says.

Mackwood explains that, as much as possible, LANXESS simply avoids the use of potential allergens on its plant sites. The company maintains documentation on its handling equipment, tank flushing and cleaning procedures that specifies the steps taken to avoid cross-contamination from batches of other formulations. They also specify that operators must practice proper hygiene and wear proper personal protective equipment to ensure that contamination from their meals does not transfer to the equipment or product.

Even pet food plants have begun adding incidental contact designations, Sander says. Because many of these plants also make feed for livestock that produce meat, milk and other products for human consumption, customers want to know that the food they eat conforms to their dietary requirements. "Keeping up with all the food equipment lubricant requirements from regulators, OEMs and customers can be daunting, but that's what makes them a higher-value product compared with conventional industrial lubricants," Sander says.

### Thinking globally

The major foodstuff producers in many parts of the world, including Europe, follow the USDA categories strictly, says Adam. Compliance is mandatory in the U.S., he adds, but European legislation doesn't specify any categories, and they have no rulings on lubricants. European countries use advisable daily intakes as guidelines for maximum exposure to highly refined mineral oils, he explains, but they only state that lubricant use must be as little as technically feasible *(see MOSH and MOAH)*.

STLE-member Salvatore Rea, technical service manager, North American Sales, LANXESS Solutions US Inc.; Lubricant Additives Business Unit, notes that in the U.S., the federal government is codifying and making more formal its drive toward requiring that government agencies use sustainable, biodegradable products and this extends to lubricants for food-related operations. In Europe, the EU Ecolabel is given to products that meet high environmental standards for raw material extraction, production, distribution and disposal. These programs place even further restraints on the list of allowable components, he says.

### Compliance planning

Modern plant equipment is designed to minimize contact between lubricants and food products during processing and packaging. This makes it easier to keep incidental contact exposure below the allowable limit.[6] "A huge food-processing factory probably uses about 5,000 liters of lubricants a year, and this includes routine oil changes and maintenance, not just leaks," Adam says. "In the food industry, you want to have zero leakages, so the oil consumption is extremely low."

The most practical way to check for lubricant contamination is to check machine oil levels daily. If the level is down, and the oil is not on the floor, it's probably in the food, Adam says. Quantifying how much oil has been lost and how much food has been processed since the last time the operator checked allows the operator to calculate how much oil went into how much food and determine

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### MOSH and MOAH

One area of controversy, especially in Europe, is the use of mineral oil saturated hydrocarbons (MOSH) and mineral oil aromatic hydrocarbons (MOAH). Several advocacy organizations are pushing for a ban on MOSH and MOAH compounds in the food industry. Implementing such a ban is likely to prove impractical, says Andreas Adam, sales director for Germany-based FRAGOL, AG, and the human health benefits are doubtful.

The mineral oils used in the food and beverage industries are so-called white oils—highly refined products that are hypoallergenic and have a high degree of chemical inertness. The petroleum refining process removes 3- to 7-ring polyaromatic hydrocarbons (PAHs), and 40 years of scientific evidence shows that the remaining 1- and 2-ring PAHs don't cause cancer.[D]

These mineral oils are approved not only as incidental contact lubricants for foods and beverages, Adam adds, but also as ingredients for cosmetic and skin care products like hand creams and lip balms.

D. Mineral oils are safe for human health? CONCAWE report, Oct. 18, 2018. Available at **www.concawe.eu/publication/mineral-oils-safe-human-health/.**

whether the contamination is under 10 ppm for mineral oils or 1 ppm for silicone oils (*see Tracking the Source*).

Companies looking to implement or improve procedures for minimizing incidental contact can establish a hazard analysis of critical control points (HACCP) plan. This involves going through the entire production and packaging chain to document points where the product could face incidental exposure to a lubricant product *(see Seven HACCP Plan Principles.*

Where possible, H1 lubricants should be used from start to finish along the production chain to minimize the chance of accidentally using the wrong lubricant or contaminating one part of the production line with H2 lubricant from another part. In some cases, H2 lubricants may be used downstream of areas where incidental contact could occur, but they must be kept strictly segregated from upstream areas.

A reputable lubricant supplier can help a food company set up and implement an HACCP plan. The supplier can offer guidance on maintaining documentation, minimizing lubricant usage without decreasing performance and putting control procedures in place. The plan should include procedures for verifying and documenting product registrations. A multi-level control procedure includes checking product names before usage and implementing numbering systems or color codes that provide a convenient way of matching a lubricant to its application point. Dedicated lubrication and filling equipment also should be color coded or otherwise visibly designated to prevent cross-contaminating various lubricants.

### Diligence

Reducing contamination requires process control at all stages, Mackwood says: selecting raw materials and suppliers and using dedicated equipment and plants. It also requires diligence in cleaning and inspection, air handling systems, hygiene plans and training the operators.[7]

However, a single product recall can involve thousands of pounds of food, significant down time and repairs and damage to a company's reputation. Thus, good process control is well worth the investment of time and effort.

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### Tracking the source

Hydrocarbon compounds in food products can come from mineral oil lubricants, but they also can come from nature, air pollution or a host of other sources. Andreas Adam, sales director for Germany-based FRAGOL, AG, cites several examples of these sources:

- Broccoli from one particular farm near an airfield has a higher than normal MOAH content because of the crop's exposure in the field to aircraft exhaust gases.
- About three years ago, reported contamination put a dent in Christmas season chocolate sales in Europe. Part of the contamination was traced to an oil compound used to soften the jute bags used for harvesting cocoa beans.
- Coconut oil is naturally high in some of the same aromatic hydrocarbon compounds that are present in mineral oils.

The only way to identify a food processing plant lubricant as the source of these compounds, Adam says, is to test the food before and after processing.

### Seven HACCP Plan Principles[E]

1. Analyze hazards
2. Identify critical control points (CCPs)
3. Establish critical limits for each CCP
4. Monitor CCPs
5. Establish corrective actions
6. Keep good records
7. Verify that the plan is effective.

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