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## Food-grade Lube Formulators Draw from a More Colorful Palette

SPECIFICATIONS

## New ACEA Sequences Make Their Debut

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#### SPOTLIGHT on Food-grade Lubricants

Food-grade lubricants must adequately protect valuable food manufacturing equipment, while also being safe for incidental food contact. Lanxess and Zschimmer & Schwarz offer products that fit the bill.



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# FOOD-GRADE FORMULATORS

DRAW FROM A MORE COLORFUL PALETTE



By Trevor Gauntlett

**While COVID-19 brought contraction to certain markets, the options for formulators of incidental food contact lubricants expanded significantly in 2020, despite some administrative hurdles. Trevor Gauntlett looks at some of the benefits formulators can reap.**

**T**he number of components available to formulators of food-grade lubes has grown significantly over the past five years, with an annual average of more than 100 base oils and additives receiving HX-1 registration from NSF International.

Mike Peters of the London-based distributor SIP Speciality Oils and Fluids, told *Lubes'n'Greases*, "In the past couple of years, we have seen new NSF HX-1-registered products coming onto the market, such as hydrocarbon-based viscosity modifiers, high-viscosity-index products derived from natural products and ashless anti-wear and friction reducing additives. Many of these products are also suitable for use in environmentally friendly lubricants and are on the Lubricant Substance Classification list, so there is genuine interest from lubricants blenders." The LuSC list is a list of substances and finished products that meet the criteria of the European Union Ecolabel.

Some of these new materials have yet to appear on the registrant's website, but there could be an advantage for formulators who are quick off the mark to request samples.

Many new HX-1 components are analogues of componentry that was already available. Some examples include graphite, white oils, esters,



polyalphaolefins, polyglycols or polytetrafluoroethylene. Some offer benefits to the formulator, including a wider range of viscosities or particle sizes relative to those previously available.

Procurement colleagues may also relish access to a wider variety of suppliers, which could offer price and supply security benefits, subject to the finished formulations all being H1 registered.

However, it is the genuinely new materials that catch the eye. Paul Savage was Shell's technology manager for the Cassida brand—now owned by Fuchs—in the early 2000s and explained to *Lubes'n'Greases* why the new materials are notable. "Formulators at that time took great pride in creating something new from a very small set of approved components, but it was difficult," Savage said. "Essentially you had clays, white oils, PAOs, polybutenes, perfluoropolyethers, a few esters and a limited number of performance additives from one or two suppliers. Traditional extreme pressure or antiwear additives usually contain sulfur and/or phosphorus. Only a few had suffi-

ciently low toxicity to be used in food lubes at levels at which they were effective."

### Making a Registration

According to NSF's Orsi Dezsi, a manufacturer must independently verify that its lubricants or lubricant components meet the requirements of the Guidelines of Security Code of Federal Regulations Title 21, §178.3570. The most effective way to do this is by registering their products and their components under the H1 (lubricants) or HX-1 (lubricant components) categories of non-food compounds.

"It is possible for a lubricant's formulation to meet H1 registration requirements even if components are not HX-1 registered," Dezsi told *Lubes'n'Greases*, hinting at some underlying complexity. "The components in question must meet the appropriate sections of 21 CFR, such as being generally recognized as safe (GRAS) or has a food contact notification with the U.S. FDA. It is also possible for a lubricant not to meet H1 requirements even if the lubricant is composed completely of HX-1 registered ingredients because the

components used are at levels that exceed the limitations present in 21 CFR §178.3570."

There are three different types of lists and three different processes for registration of potential ingredients.

- The list of substances—with Chemical Abstract Service numbers—on 21 CFR §178.3570 is found on the FDA website. Probably by design, the web page looks like a list typed onto paper.
- Substances that are GRAS can be found on two other pages on the FDA website, one titled Substances Generally Recognized as Safe (21 CFR 182), the other Direct Food Substances Generally Recognized as Safe (21 CFR 184).
- HX-1 substances are listed by the bodies that facilitate registration, currently 2Probity and NSF. Each maintains a separate website.

The registration processes introduce more complexity.

- A supplier of a component that is listed on 21 CFR §178.3570 could make a self-declaration that its product meets the criteria. In practice, most suppliers seek a

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## Food-grade Lubricant and Component Registration

Ann Arbor, Michigan-based NSF International ([www.nsf.org](http://www.nsf.org)) has been the de facto body for more than 20 years for registering lubricants and their components, heat transfer fluids and solvents as fit to be used for incidental food contact. The website where these materials and others are listed is referred to as the NSF White Book.

Lubricants were originally approved by the United States Department of Agriculture, with approval contingent on the lubes being formulated from components that were listed by the United States Food and Drug Administration in accordance with the Guidelines of Security Code of Federal Regulations Title 21, §178.3570.

Listing and validations were outsourced to NSF in the late 1990s. In 2009, United Kingdom-based InS Services also began registering

H1 lubricants. The company was acquired by NSF in 2019.

Coincident with NSF's acquisition of InS, a new organization based in Gothenburg, Sweden, 2Probity, began offering H1 and HX-1 registrations. CEO Sofia Öberg said, "I looked into the lubricant industry and services linked to registrations in early 2018 and saw that I could contribute with my competence" in audit and management system implementation.

"So, we decided to start 2Probity in 2019," Öberg said. "We want to support the industry in achieving a sustainable development linked to safe food for everyone. HX-1 registrations and additives play an important role in this." 2Probity offers a secure, fully digital platform for registrations with multilingual telephone or email support ([2probity.eu](http://2probity.eu)).

third-party letter, often from a law firm.

- Suppliers of substances that are GRAS or are food-grade additives must have persuaded experts—third parties for GRAS or the FDA for additives—that they are safe under the conditions of intended use.
- New substances for HX-1 must be registered using a food contact notification through either 2Probioty or NSF.

### A Wealth of New Materials

Three suppliers whose new components have become available in the past 18 months exemplify the multidirectional approach. Green Frix S.A., a technology startup based in Blandain, Belgium, made its own registrations with NSF. The company developed technology to modify the chemistry of plant-based oils for use as lubricant additives. The process, called voltolization or electro-ionization, deliberately uses electric discharges to modify organic molecules.

Frederic Danneaux, technology and development manager for Green Frix, told *Lubes'n'Greases*, "Once we understood the reaction [see Page 16 of the *Lubes'n'Greases* May 2021 issue], we registered the products on REACH. The underlying ecotoxicology and toxicology studies for the REACH registration showed the necessary non-toxicity and biodegradability for HX-1."

REACH—Registration, Evaluation, Authorisation and Restriction of Chemicals—is the European Union's main regulation for chemical safety.

While Green Frix was able to point to pre-existing food contact use for similar materials developed in the second quarter of the 20th century—also by Belgian companies—their products are new and derived from vegetable oils, while other products use mineral oils as solvents. "There is no risk of mineral oil saturated hydrocarbons [MOSH] or mineral oil aromatic hydrocarbons [MOAH] in our

products," Danneaux said.

With viscosities ranging from 68 to 6,000 centistokes at 40°C, customer inquiries and sampling have covered a wide variety of applications. "We have registered products as HX-1 only as customers have requested them, so not all products are currently covered," Danneaux said. "We are aware of our customers testing in hydraulics, greases, gear oils and sprays for food-based applications."

Green Frix has been focusing on the rheological behavior of its ColFadol and SunFadol range. It also has evidence to support friction reduction and oxidative stability claims.

Another company, Indianapolis, United States-based Biosynthetic Technologies, received confirmation of the HX-1 registrations for several of its estolides in December 2020. A food lube formulator accessing its products may be using their demonstrated oxidative or hydrolytic stability, high viscosity index, low volatility, friction reducing or antiwear properties, all in an ashless product. Estolides have been shown to add benefits in many industrial lubricants, and they offer potential in many food lube applications. Matt Kriech, chief technology officer with Biosynthetic Technologies, told *Lubes'n'Greases*, "Our HX-1 process was managed by Keller and Heckman Law," who provided "the legal opinion that was used to certify our products through NSF."

"We generated almost all the data required internally and filled any gaps with certified third-party labs where required," Kriech continued. Using a third-party letter of opinion "has dramatically reduced the time to commercialize new products and obtain the proper certifications from a regulatory standpoint."

Gelita, headquartered in Eberbach, Germany, is a supplier of lubricant additives based on gelatin. Its Novotec products have demonstrated excellent EP, antiwear, friction reduction and heat transfer performance in oil- and water-based systems, such

as metalworking fluids. Because they are based on gelatin, Novotec products are considered foods. Matthias Reihmann, head of global product management at Gelita, said, "Gelatin has been granted GRAS status by the FDA. This includes gelatin hydrolysate," which is found in Gelita's Novotec products.

The fact that Gelita's products are GRAS can lead to some misunderstandings with potential customers, though. "We understand that since Novotec products are food, a listing as HX-1 and H1 would not be possible," Reihmann said, referring to NSF registration. This has led to confusion with some potential customers believing that Gelita's products could not be used in formulating H1 lubricants because they were not HX-1 registered.

### There's Value in HX-1

An increasing number of suppliers of lubricant additives have taken steps over the past five years to register their products for use in H1 lubricants. Some have shouldered the administrative burden themselves, while some have outsourced to an expert group.

But could the process be simpler in the future? Sofia Öberg, CEO of 2Probioty, thinks so. "We had a discussion at the [European Lubricating Grease Institute]'s Food Working Group meeting in May regarding how the industry can simplify and strengthen the H1 and HX-1 registration," Öberg said. "However, it will require great cooperation and coordination from all." ♠



#### TREVOR GAUNTLETT

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