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**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 5**

In the Matter of:)
)
BEHNKE LUBRICANTS, INC.) **COMPLAINANT'S INITIAL**
MENOMONEE FALLS, WISCONSIN) **PREHEARING EXCHANGE**
)
Respondent.)
) **Docket No. FIFRA-05-2007-0025**

COMPLAINANT'S REBUTTAL PREHEARING EXCHANGE

In accordance with the Prehearing Order issued by this Honorable Court on June 27, 2007, Complainant, the Director, Land and Chemicals Division¹, Region 5, United States Environmental Protection Agency (U.S. EPA, Complainant or Agency), through her undersigned attorneys, hereby files this Complainant's Rebuttal Prehearing Exchange pursuant to Section 22.19 of the Consolidated Rules of Practice Governing the Administrative Assessment of Civil Penalties, Issuance of Compliance or Corrective Action Orders, and the Revocation, Termination or Suspension of Permits (Consolidated Rules), codified at 40 C.F.R. § 22.19.

I. Additional Fact Witness

Complainant may also call the following individual to testify as a fact witness at the hearing in this matter:

Mr. Mark Hepp
Consumer Safety Officer
Division of Food Contact Notifications
Center of Food Safety and Applied Nutrition
United States Food and Drug Administration
College Park, Maryland

¹ The Land and Chemicals Division was formerly known as the Waste, Pesticides and Toxics Division. The Chemicals Management Branch was formerly known as the Pesticides and Toxics Branch, and the Pesticides/Toxics Compliance Section was formerly known as the Pesticides and Toxics Enforcement Section.

Mr. Hepp is a Consumer Safety Officer in the Division of Food Contact Notifications in the Center of Food Safety and Applied Nutrition (CFSAN) of the United States Food and Drug Administration (FDA). Mr. Hepp's testimony may include but may not be limited to the following:

Mr. Hepp may be called as a witness to testify that he has held his position as a Consumer Safety Officer since January of 1996. He may testify that he is responsible for managing the safety review of proposed new uses of food additives. He may testify that he is also responsible for responding to inquiries from the public regarding the federal regulation of food additives.

He may further testify that on April 4, 2007, the Division of Food Contact Notifications received a letter dated March 26, 2007, from Mr. Bruce McIlnay, an attorney for Behnke Lubricants, Inc. (Behnke). He may further testify that the letter requested FDA's opinion as to whether a lubricant containing a pesticide registered under FIFRA could be in compliance with 21 C.F.R. Section 178.3579.

He may further testify that on May 11, 2007, he spoke with Mr. McIlnay regarding Behnke's request for the FDA's opinion. He may further testify that during this telephone conversation, Mr. Hepp explained to Mr. McIlnay that he was only able to answer questions regarding FDA's regulatory authority and could not answer any questions relating to the applicability of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).

Mr. Hepp may further testify that he also explained to Mr. McIlnay that it is not unusual for certain substances that are regulated as food additives under the Federal Food, Drug and Cosmetic Act to also be registered by U.S. EPA as pesticides under

FIFRA. Further, he may testify that he suggested that Mr. McIlroy contact U.S. EPA if he had any questions regarding the applicability of FIFRA to any product. See Mr. Hepp's Declaration at Complainant's Exhibit (CX) 44.

II. Additional Expert Witness

Complainant may also call the following individual to testify as an expert witness at the hearing in this matter:

A member of the staff of the
Product Science Branch
Antimicrobials Division
Office of Pesticides Program
U. S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, D.C. 20640

A member of the Product Science Branch of the Antimicrobials Division of the Office of Pesticides Program at the U.S. EPA may testify regarding the matters set forth below. Complainant will provide this Honorable Court and Respondent with the specific name and curriculum vitae of the witness in a supplemental submission.

A member of the Product Science Branch may testify as to the role she or he plays in the Products Science Branch of the Antimicrobial Division. The witness may testify to her/his educational background and work experience in handling antimicrobial registration and testing of antimicrobial products coming in for registration.

This witness may be called as an expert witness to testify about the health hazards associated with pathogens such as Escherichia coli, (E. coli), Lysteria monocytogenes, (Lysteria), and Salmonella typhimurium, (Salmonella) (the pathogens against which Behnke claims its MICRONOX technology is effective). The witness may also testify about the requirements of efficacy testing for certain pesticides, including those

pesticides for which public health claims are made, such as claims that the product is effective against pathogenic bacteria or other microorganisms. The witness may also testify about the analyses used to determine the toxicity of pesticides, including antimicrobial pesticides.

The witness may also testify that she or he reviews antimicrobial pesticides for which public health claims are made. The witness may testify that, among other things, she/he is looking for particular efficacy data in such instances. The witness may further testify as to the significance of such data when public health claims are made.

This witness may also testify to additional opinions as necessary to respond to assertions or arguments raised by Respondent.

III. Seeking Clarification on the Following Matters

- a. Complainant requests that Respondent provide context for RX 54, including an explanation as to what the document is, who created it, when it was created, why it was created, to whom and when it was distributed, and why it was distributed.
- b. Complainant requests that Respondent specify the estimated amount of time needed to present its case-in-chief, as required by this Court's June 27, 2007, Prehearing Order.
- c. Complainant requests that Respondent submit a statement affirmatively stating whether Respondent intends to contest the amount of the proposed penalty, and if so, explaining in detail why and how Respondent believes the proposed penalty should be reduced or eliminated, as required by the June 27, 2007, Prehearing Order.
- d. Complainant renews its request for Respondent to either produce complete and reliable evidence of its actual gross sales, or expressly waive any objection to the penalty

based on the “size of business” statutory penalty factor. As an alternative, Respondent can stipulate that the amount of its annual gross sales exceeds one-million dollars (\$1,000,000).

e. Complainant requests that Respondent provide greater detail in its narrative summaries for its witnesses. In addition, Complainant does not believe that the described testimony of several of the witnesses identified in Respondent’s prehearing exchange is relevant to any issues relating to either liability or the amount of the penalty. Therefore, Complainant requests that Respondent explain how the testimony of each of the following witnesses relates to the alleged distribution or sale of unregistered products as set forth in the Complaint, or to any defenses or arguments concerning the proposed penalty.

- i. Mr. Carter Anderson
- ii. Ms. Patty Riek
- iii. Mr. Shaun Beauchamp

A follow-up Motion may be submitted regarding this matter.

f. Respondent identifies an expert witness who will testify to “background information regarding customer demands and requirements that lead [*sic*] to the investment in research and development of this technology including testing that demonstrated the antimicrobial properties of the additives.”

- i. Complainant does not believe that this proposed testimony, as described, is relevant to any issues relating to either liability or the amount of the penalty. Therefore, Complainant requests that Respondent explain how this testimony is relevant to the alleged distribution or sale of unregistered pesticides as set forth in the Complaint, or to any defenses or arguments concerning the proposed penalty.

- ii. In the event that such testimony is deemed relevant by this Court, Complainant requests that Respondent produce all of the testing data generated with respect to the “testing that demonstrated the antimicrobial properties of the additives” in the Behnke products at issue in the Complaint. Such testing data should include, but not be limited to, all laboratory analytical reports, all raw data, all test methods used, all Quality Assurance and Quality Control plans followed by the laboratory, all standard operating procedures followed by the laboratory, and all chain-of-custody forms. A follow up Motion may be submitted regarding this matter.
- g. Complainant requests that Respondent provide clarification on the relationship between Xact Fluid Solutions and Behnke.
- h. Complaint renews its Notice of Complaint’s Request For Voluntary Production of Information, which was filed on July 19, 2007. In the alternative, Complainant requests that Respondent withdraw the affirmative defenses set forth in its Answer to the Complaint, dated June 8, 2007. A follow up Motion for discovery or motion to strike affirmative defenses may be submitted regarding this matter.

IV. Additional Exhibits

- a. CX 44 Declaration of Mark Hepp
- b. CX 45 “Microbiological Considerations for Antimicrobial Food Additive Submissions – Draft Guidance” issued by the U.S. Food and Drug Administration, dated September, 2007. This document may be introduced into evidence at the time of hearing by Mr. Dennis Edwards, U.S. EPA.
- c. CX 46 Advertising Literature submitted by Behnke entitled “Food –Grade X FACTOR – DISCOVER THE X-FACTOR.” This document may be introduced into evidence at the time of hearing by Mr. Terence Bonace, U.S. EPA.

V. **Reservation of Rights**

Complainant respectfully reserves the right to supplement its list of witnesses and/or its list of exhibits upon reasonable notice to Respondent, or by order of this Honorable Court.

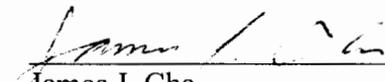
Complainant's Rebuttal Prehearing Exchange for *In the Matter of Behnke Lubricants, Inc.*, is hereby respectfully submitted.

Respectfully Submitted,



Nidhi K. O'Meara

11/15/07
Date



James J. Cha

11/15/07
Date

Associate Regional Counsels
U.S. EPA, Region 5

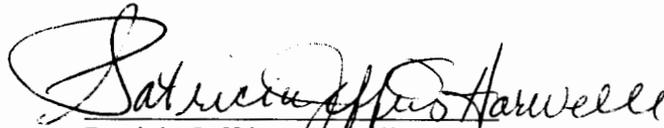
In the Matter of Behnke Lubricants, Inc.
Docket No. FIFRA-05-2007-0025

CERTIFICATE OF SERVICE

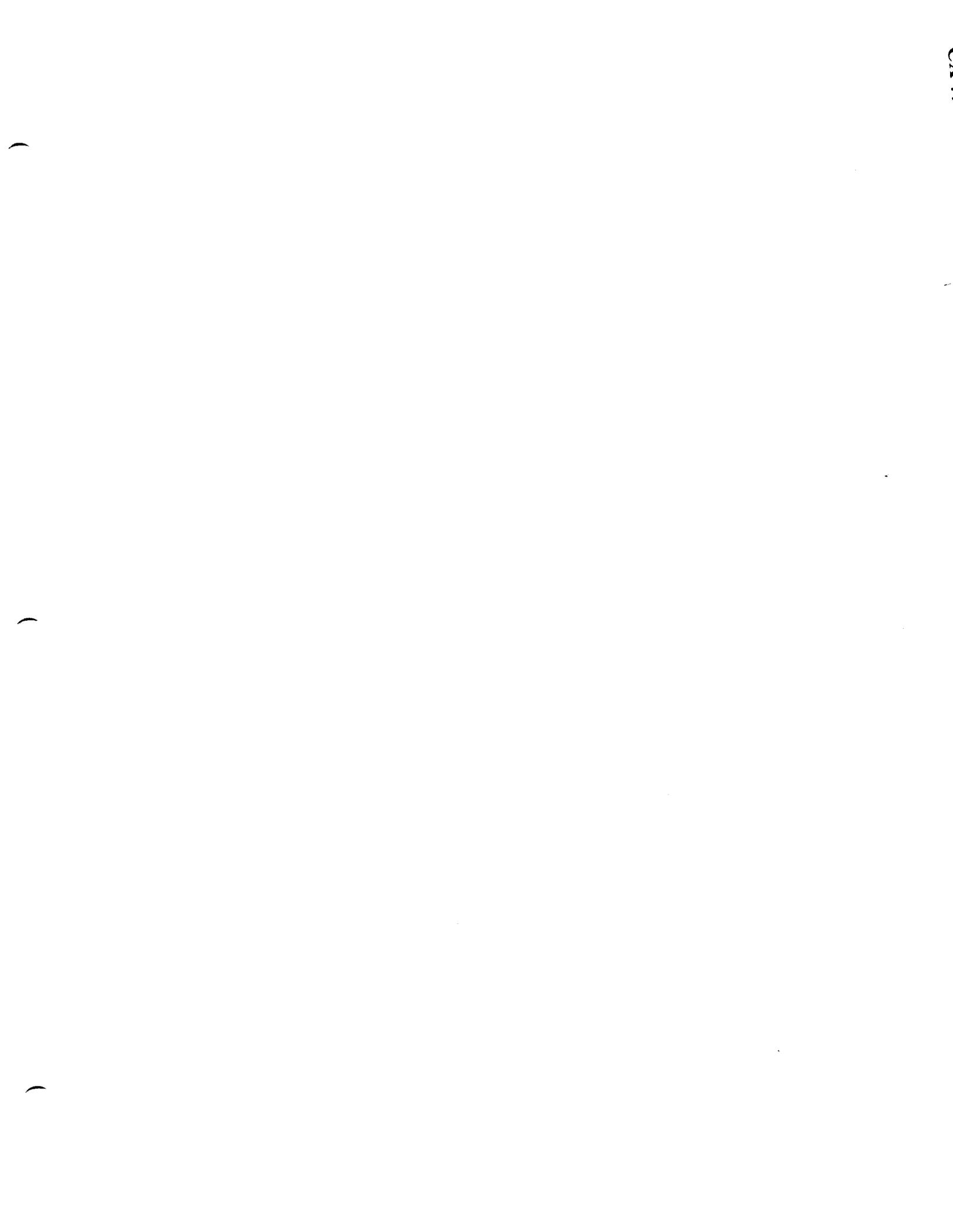
I hereby certify that the original and one true, accurate and complete copy of Complainant's Rebuttal Prehearing Exchange, together with true, accurate and complete copies of Complainant's Exhibits 44 through 46, were filed with the Regional Hearing Clerk, U.S. EPA, Region 5, on the date indicated below, and that true, accurate and complete copies of Complainant's Rebuttal Prehearing Exchange and Complainant's Exhibits 44 through 46, were served on the Honorable Barbara Gunning, Administrative Law Judge (service by Pouch Mail), and Mr. Bruce McIlroy, Esq., Counsel for Respondent Behnke Lubricants, Inc. (service by Federal Express), on the date indicated below:

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Dated in Chicago, Illinois, this 15 day of November, 2007.



Patricia Jeffries-Barwell
Legal Technician
Office of Regional Counsel
U.S. EPA, Region 5



**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 5**

In the Matter of:)
)
BEHNKE LUBRICANTS INC.)
MENOMONEE FALLS, WISCONSIN) Docket No. FIFRA-05-2007-0025
)
Respondent.)
_____)

DECLARATION of MARK HEPP

State of Maryland
County of Prince George

I, Mark Hepp, declare and state as follows:

1. I am a Consumer Safety Officer in the Division of Food Contact Notifications in the Center for Food Safety and Applied Nutrition ("CFSAN") of the United States Food and Drug Administration ("FDA"), located in College Park, Maryland. I have held this position since January, 1996.
2. In my position, I am responsible for managing the safety review of proposed new uses of food additives. I am also responsible for responding to inquiries from the public regarding the federal regulation of food additives.
3. The statements made in this declaration are based upon my personal knowledge.
4. Food additives can include substances like lubricants used on machinery in food processing environments. These lubricants may become components of food when the food comes into incidental contact with the machinery.
5. On April 4, 2007, the Division of Food Contact Notifications received a letter dated March 26, 2007, from Bruce McIlroy, an attorney for Behnke Lubricants, Inc. ("Behnke").
6. The letter stated that the United States Environmental Protection Agency ("EPA") had contacted Behnke to alert the firm that it had sold unregistered pesticides in violation of the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA") and threatened an enforcement action.
7. The letter also requested FDA's opinion as to whether a lubricant containing a pesticide registered under FIFRA could also be in compliance with 21 C.F.R. § 178.3570,

a food additive regulation that specifies the conditions of safe use for lubricants that may come into contact with food.

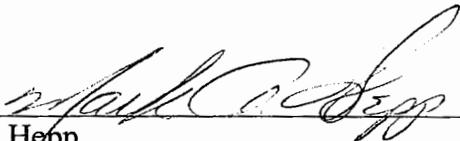
8. On May 11, 2007, I spoke by telephone with Mr. McIlroy regarding his clients' request for FDA's opinion.

9. During this telephone call, I explained to Mr. McIlroy that I was only able to answer questions regarding FDA's regulatory authority and could not answer any questions relating to the applicability of FIFRA.

10. I also explained that it is not unusual for certain substances that are regulated as food additives under the Federal Food Drug and Cosmetic Act to also be registered by EPA as pesticides under FIFRA.

11. I suggested that Behnke contact the EPA if he had any questions regarding the applicability of FIFRA to any product.

Pursuant to 28 U.S.C. § 1746, I declare under penalties of perjury that the foregoing is true and correct.



Mark Hepp
Consumer Safety Officer
United States Food & Drug Administration



U.S. Food and Drug Administration



CENTER FOR FOOD SAFETY AND APPLIED NUTRITION

FDA Home Page | CFSAN Home | Search/Subject Index | Q & A | Help

September 2007

Guidance for Industry

Microbiological Considerations for Antimicrobial Food Additive Submissions

DRAFT GUIDANCE

This guidance is being distributed for comment purposes only.

Comments and suggestions regarding this draft document should be submitted within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document contact the Center for Food Safety and Applied Nutrition (CFSAN) at 301-436-1226.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Food Safety and Applied Nutrition
September 2007

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Guidance for Industry^[1]

Microbiological Considerations for Antimicrobial Food Additive Submissions

This draft guidance, when finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate telephone number listed on the title page of this guidance.

I. INTRODUCTION

The Food and Drug Administration (FDA) is responsible for prescribing the conditions of safe use of food additives under section 409 of the Federal Food, Drug, and Cosmetic Act (the Act). To evaluate the safety of food additives and determine their conditions of safe use, the agency

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uses the food additive petition (FAP) process and the food contact notification (FCN) process. In addition, FDA may, upon request, exempt from regulation as a food additive those substances used in food-contact articles (also known as food contact substances) that migrate into food at levels that are below the threshold of regulation (TOR). This guidance is directed at questions regarding microbiological data requirements for FAPs, FCNs, and TOR requests that are unique to the use of antimicrobial food additives and food contact substances. This guidance will assist petitioners and notifiers in designing studies to determine whether an antimicrobial food additive achieves its intended technical effect. Also, this guidance discusses microbiological data that may be necessary to demonstrate that an antimicrobial agent will be safe for the intended use.

This guidance applies to all FAPs, FCNs and TOR requests where the food additive is intended to control microbes in or on food. This includes sources of radiation for treating food. However, it is important to note that the U.S. Department of Agriculture (USDA) Food Safety and Inspection Service (FSIS) is responsible for determining the suitability of food additives in meat and poultry products; according to FSIS, "*suitability* relates to the effectiveness of the substance in performing the intended technical purpose of use, at the lowest level necessary, and the assurance that the conditions of use will not result in an adulterated product or one that misleads consumers."^[2] FSIS derives its authority to regulate the suitability of food additives in meat and poultry from the Federal Meat Inspection Act (FMIA) and the Poultry Products Inspection Act (PPIA), respectively. FDA and FSIS currently have a Memorandum of Understanding (MOU) regarding each agency's responsibilities in the evaluation and approval of food ingredients and sources of radiation used in the production of meat and poultry products. In accordance with this MOU, FDA will collaborate with FSIS on any antimicrobial food additive submission to FDA involving meat or poultry.

Given the complexity and variety of antimicrobial products and the diverse conditions of use, no single document can anticipate and address all microbiological issues. Therefore, this guidance is intended to answer common questions associated with microbiological data requirements for FAPs, FCNs, or TOR requests for antimicrobial food additives so that meaningful and sufficient data are provided with each submission. It is intended to assist developers of antimicrobial agents for use in or on food in providing evidence to support their intended uses. FDA recommends that petitioners and notifiers discuss with the agency any proposed studies prior to their initiation to ensure that these studies will address FDA's safety concerns. In addition, FDA recommends that submitters meet with the agency prior to the submission of a petition or notification to prevent an expenditure of resources on activities that may not provide adequate data.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

II. QUESTIONS AND ANSWERS

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A. What is and is not a food additive?

The term "food additive" is defined in section 201(s) of the Act. The first part of that section states that a food additive is any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food including any substance intended for use in packing, packaging, producing, manufacturing, processing, preparing, treating; transporting, or holding food; and including any source of radiation intended for any such use. Section 201(s) goes on to expressly exempt from the definition of food additive certain categories of substances, including substances that are "generally recognized as safe" or "GRAS" for the intended use. A partial list of substances recognized by FDA as GRAS may be found in 21 CFR Part 182, and a list of substances affirmed by FDA as GRAS appears in 21 CFR Part 184. These lists may include substances which are GRAS for use as antimicrobial agents.

"Pesticide chemicals," as defined at section 201(q) of the Act, are exempt from the definition of a food additive. Pesticide chemicals and pesticide chemical residues in or on food must conform to a tolerance, or an exemption from tolerance, established by the Environmental Protection Agency (EPA) under section 408 of the Act.

For the complete definition of a food additive and the exemptions, see section 201(s) of the Act.

B. What is an antimicrobial food additive?

The term "antimicrobial food additive," as used in this guidance, refers to a substance or a source of radiation that meets the food additive definition and is used to control microorganisms such as bacteria, viruses, fungi, protozoa, or other microorganisms in or on food or food contact articles.

C. What is FDA's regulatory authority with respect to antimicrobial food additives?

FDA is the primary Federal agency responsible for ensuring the safety of food additives. Under section 409 of the Act, all food additives are subject to review and approval by FDA before they can be marketed in the United States. This guidance applies to FAP, FCN, and TOR submissions. Food additives that are intended to have a technical effect in food are authorized through the petition process prescribed in section 409 of the Act. The standard that FDA applies to determine whether the intended use of a food additive is safe is reasonable certainty of no harm (see 21 CFR 170.3(i)). For food additives demonstrated to FDA to be safe under the intended conditions of use, FDA will issue a regulation that specifies the conditions of safe use. The food additive regulations are codified in 21 CFR parts 172-180 and may be obtained from the Internet by searching the current edition of the CFR. Part 172 lists food additives for direct addition to food, part 173 lists food additives used during food processing, and parts 174-178 list food additives used in food packaging and other food contact articles. Approved sources of radiation for inspecting and treating food are listed in 21 CFR part 179. Food additives permitted in food or in contact with food on an interim basis pending additional study are listed in 21 CFR part 180.

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Food additives that are intended for use as a component of materials used in manufacturing, packing, packaging, transporting, or holding food, if such uses are not intended to have any technical effect in food, are considered food contact substances (see section 409(h)(6) of the Act). As a result of the FDA Modernization Act of 1997, the primary method for authorizing new uses of food contact substances is the FCN process (see section 409(h) of the Act). In the case of a food contact substance, FDA will allow a notification for the subject food contact substance to become effective prescribing the conditions under which a food additive may be safely used. The standard used to establish the safety of a food contact substance is the same as that for any other food additive (i.e., reasonable certainty of no harm). More information on this process is available from the Food Contact Substance Program website. A current Inventory of Effective Food Contact Substance Notifications is found on the CFSAN Internet.

In addition, under 21 CFR 170.39, FDA may, upon request, exempt from regulation as a food additive food contact substances that become a component of food at levels below the threshold of regulation. Such a request is commonly referred to as a threshold of regulation (TOR) submission. More information on the TOR submission process is available in Guidance for Industry: Submitting Requests Under 21 CFR 170.39 Threshold of Regulation For Substances Used in Food-Contact Articles. A current inventory of Threshold of Regulation Exemptions issued by FDA is available on the CFSAN Internet. The data requirements for a TOR submission are the same as those for a FAP or FCN and the safety standard that FDA applies is the same.

For a detailed discussion of FDA's regulatory authority over antimicrobial food additives, see FDA's Guidance to Industry entitled, Antimicrobial Food Additives – Guidance. It is important to note that, depending on the proposed use, an antimicrobial food additive may also be a pesticide under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). As such, it may be subject to registration as a pesticide by the EPA as well as regulation as a food additive.

D. What is FDA's regulatory authority with respect to requesting microbiological data?

Microbiological data may need to address certain issues raised by the findings that FDA makes under section 409 of the Act. Several are described below.

- Under section 409(c)(3)(B) of the Act, a food additive regulation will not be established if an evaluation of the data "shows that the proposed use of the food additive would promote deception of the consumer in violation of [the] Act or would otherwise result in adulteration or in misbranding of food within the meaning of the Act." Here, the microbiological data may be used to demonstrate that an antimicrobial agent does not promote consumer deception, such as making a food product appear to be fresher or of greater value than it actually is.
- Under section 409(c)(4) of the Act, if "a tolerance limitation is required in order to assure that the proposed use of an additive will be safe, the Secretary shall not fix such a tolerance limitation at a level higher than he finds reasonably required to accomplish the physical or other technical effect for which such additive is intended; and, shall not establish a regulation for such proposed use if he finds upon a fair evaluation of the data before him that such data do not establish that such use would accomplish the intended physical or other technical effect." When a tolerance limitation is required, the

microbiological data may be used to demonstrate that an antimicrobial agent achieves its intended technical effect and that the maximum permitted use level is not higher than what is reasonably required to achieve this effect.

- Microbiological data may be needed to supplement the safety assessment of the antimicrobial food additive under section 409(c)(3)(A) of the Act, which states that "... [n]o such regulation shall issue if a fair evaluation of the data before the Secretary fails to establish that the proposed use of the food additive, under the conditions of use to be specified in the regulation, will be safe..." Cases where microbiological data may be used to supplement the safety assessment are described in Items I, L, and M below.

E. How do I get my antimicrobial food additive approved?

Antimicrobial food additives are regulated through the FAP process, the FCN process, or the TOR exemption process. Section 409(b) of the Act sets forth the statutory requirements for data in an FAP to establish the safety of a food additive; section 409(h) sets forth the requirements for notification of a food contact substance; and 21 CFR 170.39 sets forth the requirements for a TOR submission. A more detailed description of the information to be submitted in an FAP and the proper format are specified in 21 CFR 171.1; information requirements for a food contact notification are found in 21 CFR 170.101. Guidance documents from the FDA detailing the procedures for preparing and submitting an FAP, FCN, or TOR submission can be found on the CFSAN Internet.

It is important to note that there are some antimicrobial additives for which the proposed use makes them both a food additive and drug (e.g., a no-rinse hand sanitizer used by food handlers). In this case, the product will have to comply with the requirements of the Act applicable to both food additives and drug products.

F. Why does FDA require that data on the intended effect of an antimicrobial food additive be included as part of the submission seeking approval of the additive?

Section 409(b)(2)(C) of the Act requires that a petition for a food additive contain all relevant data bearing on the physical or other technical effect such additive is intended to produce, and the quantity of such additive required to produce such effect. Therefore, data on the intended effect are required in a petition for an antimicrobial food additive. Furthermore, if FDA determines that a tolerance is needed to ensure that the petitioned use of an antimicrobial food additive will be safe, intended effect data will be used to ensure that the tolerance is set at a level no higher than what is reasonably required to achieve the intended physical or other technical effect. In addition, if a tolerance is necessary and data do not establish that the petitioned use will accomplish the intended physical or other technical effect, FDA is not authorized to establish a regulation for that use (section 409(c)(4) of the Act).

For antimicrobial food additives used on meat or poultry, FDA and FSIS have separate regulatory responsibilities which must be satisfied before the additive may be legally marketed. For these cases, intended effect data will be needed to satisfy the requirements of both FDA and FSIS. Under the Federal Meat Inspection Act (FMIA) and the Poultry Products Inspection Act (PPIA), FSIS has authority over suitability of food ingredients and sources of radiation used in meat and poultry processing plants.

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In accordance with the procedures described in the MOU between FDA and FSIS, requests for approval to use food ingredients and sources of radiation in the production of meat and poultry products are evaluated simultaneously for safety by FDA and for suitability by FSIS. Prior to submission, petitioners and notifiers may wish to consult with FSIS independently; however, FDA believes joint consultations with FDA and FSIS facilitate the petition and notification processes.

G. What types of data and other information should be included to demonstrate that the use of an antimicrobial food additive achieves its intended physical or other technical effect?

To demonstrate that an antimicrobial agent achieves its intended technical effect and that the proposed use level is the minimum level necessary to accomplish the intended technical effect, the following information is recommended at a minimum:

- The chemical identity or biological identity of the antimicrobial agent, which ever is appropriate;
- A detailed description of intended antimicrobial effect and identification of any individual or groups of targeted microbes, if appropriate;
- A description of the conditions of use and any limitations on conditions of use, e.g.:
 - types of foods;
 - proposed use level or range;
 - temperature range of use;
 - method of application, such as spraying, dipping or fumigating, when applicable;
 - post-processing steps (e.g., potable water rinse, cooking by the consumer);
- Antimicrobial effect data, including full reports of the efficacy studies;
- Directions, recommendations, and suggestions regarding the proposed use, as well as a sample of the label proposed for the food additive and any labeling that will be required on the finished food as a result of the use of the food additive; and
- For a petition, proposed wording for establishing or amending a food additive regulation is recommended. This draft regulation helps FDA understand the petitioner's intent and may help the petitioner understand the issues that need to be addressed.

H. How should a study be designed to demonstrate the antimicrobial food additive's effect?

FDA recommends that any study carried out to support the intended technical effect of an antimicrobial food additive should be designed to generate data that directly supports any particular effect(s) specified. For example, if the intended technical effect is extending shelf life, the study should generate data which measure shelf life; or if the intended technical effect is the control of specific organisms, the study should generate data which directly enumerate those organisms. FDA recommends that any of the subject studies reflect the following characteristics, to the extent practical:

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- The study is conducted in a manner that simulates, to the extent feasible, the intended conditions of use of the antimicrobial food additive;
- The study is conducted using samples of the relevant medium (e.g., food, process water, food packaging) treated under the proposed conditions of use, and the study includes appropriate controls;
- The study focuses on pertinent organisms that the antimicrobial food additive is intended to target, especially those associated with a given medium (e.g., Salmonellas and *Campylobacter jejuni* for poultry, *E. coli* for beef, *Vibrio* spp. for seafood, Salmonellas for juices, etc.);
- Where appropriate, a study uses a direct method for enumeration of microorganisms such as plate counting or visual microscopic counts, as opposed to measuring biomass, and evaluates the reduction (or suppression) of microorganisms affected by the treatment;
- Enumeration methods capture damaged or stressed microbial cells that survive the antimicrobial treatment;
- The study includes collection and analysis of replicate samples for each data point with a description of the variability of the data; and
- When appropriate, the study includes an analysis of the data such as a comparison of the treatment and control.

A petition or notification will not be treated differently simply because an alternative approach was chosen. FDA invites submitters to consult with the agency in designing experimental protocols and recommends that submitters provide their experimental protocol to the agency for comment prior to the initiation of any study. It is the agency's experience that these consultations lead to consensus between the agency and the submitter prior to experimentation being conducted. FDA believes these consultations result in studies that are more likely to address the agency's concerns which leads to a more efficient regulatory process and a faster time to market for the proposed food additive.

I. Are there unique circumstances that should be taken into consideration when designing a study to show that an antimicrobial food additive achieves its intended effect?

There are a number of unique circumstances that might be considered when designing a study to show an antimicrobial food additive's effect. Several are described below.

- A study should consider the typical organisms expected to be observed under the conditions under which they would be present. For example, the commonly consumed portions of beef, lamb, pork, and poultry are generally considered uncontaminated with pathogens prior to slaughter. Contamination with enteric pathogens may occur as a result of improper slaughtering techniques and subsequent processing. Therefore, we believe that enteric pathogens are the likely organisms of concern for meat and poultry, and they should be the subject of any intended effect studies. (NOTE: We recommend that FSIS be consulted regarding the design of any study where the intended use includes the treatment of meat and poultry.)
- Seafood, fruits and vegetables may have indigenous pathogens present at harvest, or

(different) pathogens may be introduced during harvest or processing. We recommend that petitioners/notifiers consider whether their additive is equally effective against indigenous and introduced microorganisms.

- Experimental design should consider and address whether the use of the antimicrobial agent may result in unintended consequences. For example, an antimicrobial agent may change the microbiological profile of food such that it suppresses one group of pathogenic microorganisms while allowing others to proliferate, thereby creating a potential health problem.
- Organoleptic changes affected by spoilage organisms are indicators that consumers may use to gauge the freshness of meat and poultry, seafood, and produce, and indirectly, their safety. As such, an antimicrobial agent that preferentially eliminates spoilage organisms over pathogens might allow the pathogens to proliferate while suppressing spoilage organisms and their effects. Under such conditions, a consumer's senses may not reliably discern spoiled and contaminated products, and the use of an antimicrobial agent under those conditions might not be safe. We recommend submitters provide data on the effects of their agent on specific pathogens as well as general (spoilage) populations for comparison; typically, aerobic plate counts are sufficient to characterize general populations.

J. Does FDA recommend any specific experimental methods?

FDA recognizes it is impractical to design a standard experimental protocol that addresses all relevant safety issues for every antimicrobial agent. However, there are a number of resources specific to microbiological methods that the agency recommends. FDA publishes an online version of its Bacteriological Analytical Manual which presents useful laboratory procedures for microbiological analyses of foods and cosmetics. Furthermore, FDA maintains a website with numerous links to related resources on Microbiological Methods. Also, FSIS maintains a Microbiology Laboratory Guidebook of current protocols for analytical tests required by FSIS in its regulatory activities on meat, poultry and egg products; these test procedures may be useful in the experimental design of technical effect studies. However, a petition or notification will not be treated differently simply because an alternative study design was chosen.

K. What is FDA's performance standard for a new antimicrobial food additive?

A performance standard defines the minimal level of reduction of microorganisms from the use of the antimicrobial food additive (e.g., a 5-log reduction in the number of microbe(s) targeted).

Given the variability in the intended technical effect of antimicrobial food additives and types of food treated, FDA does not have a single performance standard for antimicrobial food additives. However, to prove that an additive achieves its intended technical effect as an antimicrobial agent, data from an efficacy study should demonstrate that, at a minimum, there is a measurable difference between the treated samples and a negative control (e.g., the treatment absent the active agent). Such a demonstration may be achieved through statistical analysis, graphical comparison, or another equivalent method. In those particular cases where the intended technical effect specifies the use of the additive as part of a process where a performance standard has been established by regulation (e.g., Juice HACCP (21 CFR 120.24)) or regulatory guidance (e.g., FSIS guidance on control of *Listeria monocytogenes*), FDA may consider that performance standard when regulating the additive.

EPA 0872

L. What information may be helpful to provide to FDA to demonstrate the intended technical effect of a source of radiation as an antimicrobial treatment for food?

A source of radiation used to treat food is included in the food additive definition (section 201 (s) of the Act). Furthermore, section 402(a)(7) of the Act states that a food is adulterated if it has been subjected to radiation, unless the use of the radiation was in conformity with a regulation or exemption under section 409 of the Act. Because a source of radiation used to treat food does not meet the definition of a food contact substance in that it has a technical effect in the food, it is regulated through the FAP process under section 409 rather than the FCN process or the TOR exemption process. In addition to information typically submitted in an FAP, a petition for the use of a source of radiation as an antimicrobial treatment for food should include information related to technical effect, such as:

1. Information describing the microbiological profile of targeted foods (occurrence and levels of pathogenic and non-pathogenic microorganisms); and
2. Information describing the effects of the proposed irradiation on microorganisms in or on the targeted food, including growth patterns of surviving microorganisms compared with food that has not been irradiated. For example, *Clostridium botulinum* is of particular concern as a potential microorganism surviving irradiation. Therefore, it may be necessary to consider whether *C. botulinum* is able to proliferate to a greater extent in food treated by irradiation than in untreated food because of a reduced number of competing spoilage organisms.

M. What additional safety information may be helpful to provide to FDA if my antimicrobial food additive is derived from a microorganism?

If an antimicrobial food additive is derived from a microorganism, FDA recommends that the following additional information be provided, at a minimum:

1. The biological identity of the specific isolate of microorganism to be used for production. If the strain has been genetically manipulated, a description of how the strain was derived, including information about any strain contributing genetic material to the production strain should be included with the submission;
2. A description of the procedures used to maintain the cultural purity and genetic stability of the production microorganism. Details of procedures employed to assure strain purity and integrity should be included with the submission;
3. A description of the quality control procedures used during production, the procedures for assurance of cultural purity, and the procedures to be followed if contamination is observed in the starter (pure) cultures or during production;
4. A description of the methods used to verify the absence of clinically relevant antibiotics. Antibiotics approved by FDA for pharmaceutical uses should not be produced during the manufacture of the antimicrobial agent;
5. Information that demonstrates that the production strain is not infectious or toxicogenic, and that no toxin is present at toxicologically significant levels in the preparation for use in food, if it is necessary to employ a toxicogenic strain; and

EPA 0873

6.A description of the methods employed and relevant quality control procedures followed to ensure that no viable cells of the production strain are found in the product when those cells represent a safety concern.

FDA understands that there may be newly developed antimicrobial products for which some of these recommendations may not be valid. A petition or notification will not be treated differently simply because safety information other than that recommended here was provided.

We will consider the sufficiency of the safety information provided with antimicrobial product petitions on a case-by-case basis.

[1] This guidance has been prepared by the Office of Food Additive Safety in the Center for Food Safety and Applied Nutrition at the U.S. Food and Drug Administration.

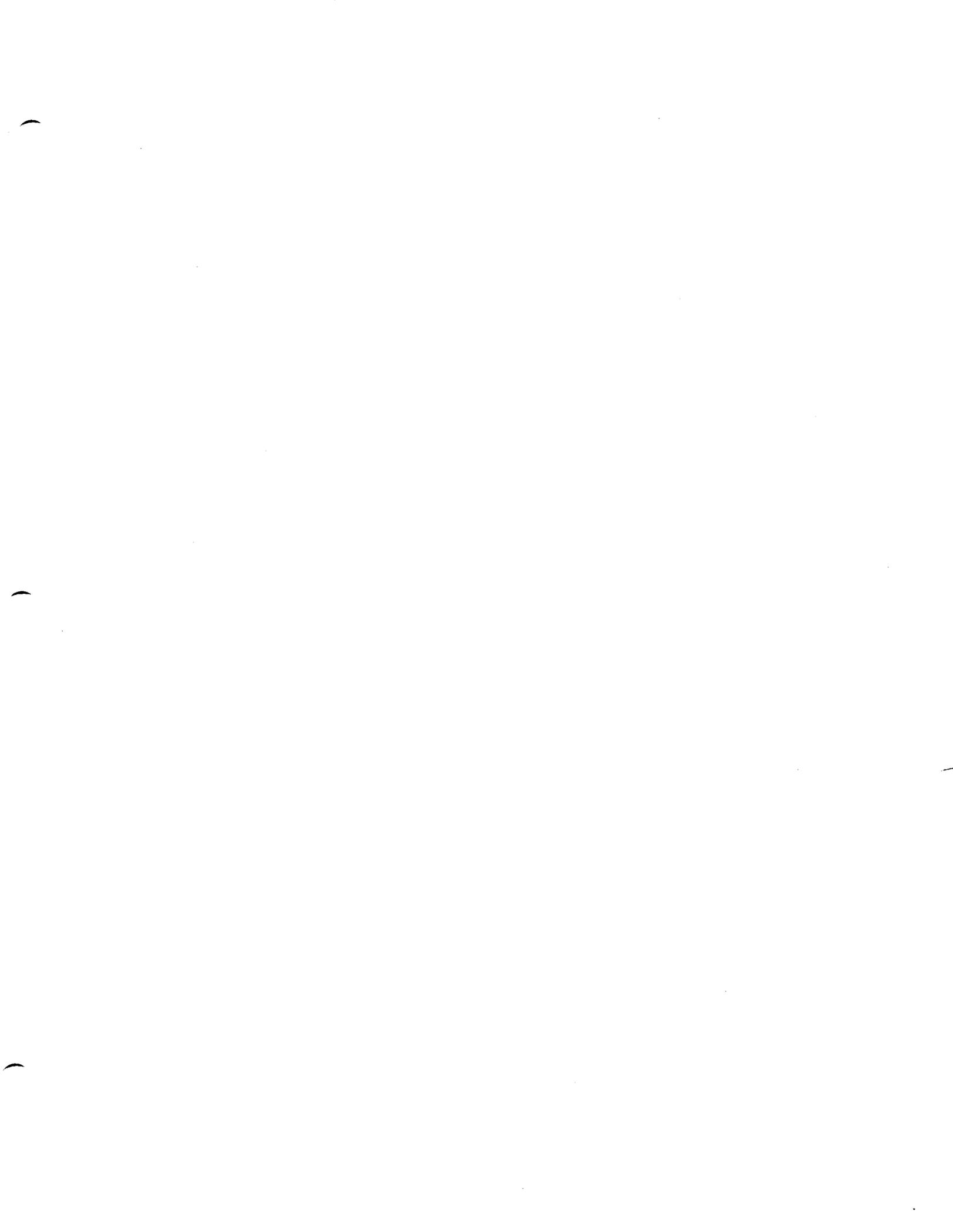
[2] *Guidance on the Procedures for Joint Food Safety and Inspection Service (FSIS) and Food and Drug Administration (FDA), Approval of Ingredients and Sources of Radiation Used in the Production of Meat and Poultry Products*, U.S. Department of Agriculture, Docket No. 00-022N, *E. coli* O157:H7 Contamination of Beef Products.

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FDA/Center for Food Safety & Applied Nutrition
Hypertext updated by emw/dms September 24, 2007

EPA 0874



EXTEND EQUIPMENT LIFE.
REDUCE MACHINERY DOWNTIME.
IMPROVE PLANT PROFITABILITY.



Food-Grade

X-FACTOR

DISCOVER THE X-FACTOR.



Worldwide food and beverage processing is a dynamic and constantly evolving mix of new processes, new equipment and new regulations. JAX has been at the forefront of food and beverage plant lubrication since the inception of true USDA food-grade lubricants nearly 50 years ago. JAX was first with a registered food-grade grease at the birth of commercial food-grade lubricants in our industry and we continue to be first today with new products offerings for evermore demanding applications.

JAX is a manufacturer and global supplier of the highest quality industrial, synthetic and food-grade lubricants for machinery and processes. As you will discover in this booklet, we have been the driving, innovative force in lubrication for food processors for the last half century.

JAX is a wholly-owned American company that has become a global player in food-grade lubrication with international distribution and the most technical expertise and experience in the industry. We are not a major oil company, a satellite division of a multi-national owner, or a piece of a venture capital portfolio. As an independent company, we have the freedom and autonomy to compound lubricants without compromising superior performance for price. From formulating new lubricants for unique new processes to rushing emergency testing through our independent RPM laboratory, it's the hundreds of little and not-so-little things that separate JAX from other lubricant companies. Obviously, to enable us to do this, we seek to employ only dedicated people who provide real, hands-on assistance to our customers' businesses, management and machinery on a daily basis.

Why is this important to you? It means we are never distracted from our primary goal of bringing the newest technology to your equipment and production lines, and we are dedicated to providing only America's finest in terms of lubrication, support service and technical innovation.

Listed below are some recent highlights of state-of-the-art developments in food and beverage plant lubrication from JAX:

- JAX Halo Guard® FO Series are EP, food machinery greases that usher in a new era of longevity, protection and remarkable extreme pressure and antiwear capabilities in a plant-wide, food-grade grease.

- JAX Halo Guard® FC Series greases provide the ultimate in food machinery lubrication where high temperatures coupled with high bearing speeds and loads have caused premature wear to lubricated parts.

- JAX Halo Guard® Fluids are 100% synthetic, food-grade lubricants developed specifically for extended drain intervals in high-speed beverage can seamers, including those manufactured by Angelus Specialty Can Machinery Company.

- JAX Halo Guard® Technology is a groundbreaking advance in food-grade technology designed to improve performance in preserving and protecting food-grade lubricants from microbial contamination in meat and poultry plants worldwide.

If your company is looking for an experienced, hands-on partner to help get control of your lubrication practices, programs and production, talk to us. Nobody knows your equipment, your industry and your applications better than JAX. Nobody.



With a fully
dedicated staff
of nearly 100,000
employees serving
a diverse group of
food and beverage
processors including:

- Bakeries
- Canned Foods
- Confectioneries
- Dairy Products
- Distilleries
- Food Processing Plants
- Freezing Plants
- Fruits
- Meat and Poultry
- Non-Ferrous Metals
- Paper Mills
- Pharmaceutical
- Textiles



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Products are listed separately as Food-Grade (USDA/NSF H1) and Industrial-Grade (USDA/NSF H2) and further divided into Greases and Fluids. Common application and usage charts are shown in each section.

There are also brief "Technical Highlights" sections, which list some of the most useful charts and answers to some of the most commonly asked questions in the lubricant business.

EXPERIENCE COUNTS

When we say that JAX was first in the inception of food-grade lubricants, it does not mean some other firm was not already producing such products. In fact, there were.

Recent entries into the food-grade plant lubrication market were made, but JAX's long development experience of over 30 years in the U.S. and on the international scene is significant. This extensive experience cannot be overcome by competitors' flashy advertising, limited experience and untested product quality.

Until the early 1960s, lubrication of machinery in most food and beverage plant operations was not any different from non-food processing plants. FDA approval while still was available for process use, but the limited lubrication options and added expense of these base oils made them unfeasible for all but the simplest machinery lubrication.

At that time, the USDA developed a program which utilized approved products from the developing FDA regulations regarding standards for lubricants with incidental exposure to processed products. Although the USDA's jurisdiction of food safety and control was primarily over meat, poultry and egg plants, the fact that these products would, over the next three decades, become the U.S. and in many instances, the worldwide standard for non-food compounds used in processing plants.

The first classification of lubricants were AA for use in possible incidental contact situations and BB for non-food contact areas. There was also a "knock-out" list of chemicals that could not appear in any food-grade compounds. The presence of these components would immediately disqualify a product for use in any inspected facility.

The very first branded approval of a USDA food-grade grease, JAX Magna-Plate 6, was developed by us for the prosperous and growing U.S. meatpacking industry.

Although total sanitation of these lubricants was mandated in USDA-inspected plants of the day, other processing industries outside of the authority of the USDA, were not required to adopt these new standards. These industries were food grades. The individual and additive technologies were developed and refined for the food processing industry. The USDA's jurisdiction in typical food processing plants was limited to the final inspection of the product. Some improvements would have been made in the areas of wear protection, corrosion resistance and stability.

During the early 1960s, the standards were changed from AA, BB and BB to BB, BB and BB. The BB classification was the highest and most stringent. It was the only classification for grease.

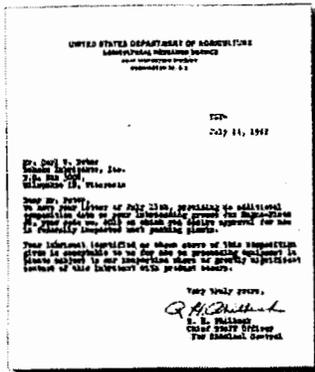
JAX's reputation for quality and reliability was well known. The industry was looking for a lubricant that would meet the new standards. JAX's Magna-Plate 6 was the first to be approved. It was the only one to be approved. It was the only one to be approved.

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Since then, several government non-governmental agencies have offered certification procedures similar to those approved by USDA or JAX internal process. None has become a readily accessible source of product review and approval and new ISO standards (referring to ISO) to incorporate the review process, well, JAX is consistently staying in front of the regulatory changes that may affect the future of our industry.

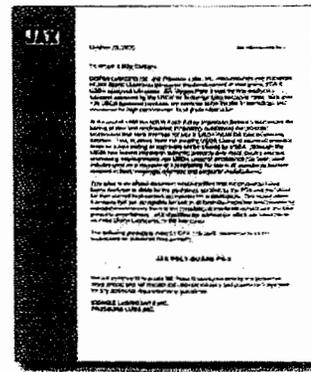
LETTERS OF APPROVAL



JAX received the first USDA approval in 1962 for Magna-Plate 8



JAX now has nearly 200 NSF-registered products



JAX provides official certification of food-grade products as FG/H1

FOOD & BEVERAGE SOLUTIONS

JAX offers a myriad of solutions including turnkey whole-plant services, laboratory proactive maintenance testing, new product research, lube school seminars, innovative packaging solutions and the highest quality, technically proficient distributor network in the lubricants industry. We maintain strong OEM contacts in the processing industry, enabling JAX to understand the technical requirements of this diverse machinery.

Virtually every member of Food Processing's Top 100 is taking advantage of JAX products or services. Many have streamlined and optimized their lubrication programs by converting entire plant operations.

If your company is looking for an experienced, hands-on partner to help get control of your lubrication practices, programs and downtime, talk to us. Nobody knows your equipment, your industry and your applications better than JAX.

- Technical Consulting
- Worldwide Distribution Network
- HACCP Analysis
- USDA, CFIA, NSF, Kosher, Halal Approvals
- JAX FG Cert/FDA and ISO Compliant
- In-Plant Engineering Services
- Complete New Plant Start-Up Programs
- Lube-It Lubrication Software
- RPM Laboratory - Rapid Response
- Xact Fluid - Automated Lubrication Systems
- High Volume Production Capabilities
- Custom Product Application R&D

OEM RELATIONSHIPS & APPROVALS

JAX has engineered custom lubrication solutions recommended for or approved by today's finest OEMs.

- | | | | | |
|-------------------|-------------------|-----------------|-------------|---------------|
| • Angelus | • FrigoScandia | • Bosch-Rexroth | • Krones | • Marlen |
| • APV | • Stewart Systems | • Racine Pump | • AROL | • Multivac |
| • FMC | • Odenberg | • Busch | • Frick | • Poly-Clip |
| • Tetra-Pak | • Stork | • CPM | • Vilter | • Reiser |
| • Ferrum | • Best & Donovan | • Buhler | • Mycom | • Urschel |
| • H & K | • Jarvis | • Simonazzi | • IJ White | • Alfa-Laval |
| • Barry-Wehmiller | • Beach-Russ | • Formax | • Weiler | • Bonfiglioli |
| • Cryovac | • Stock | • Continental | • Key | • Hub City |
| • Atlas Pacific | • CCM | • Magnuson | • Lyco | • Eurodrive |
| • Waukesha | • Bettcher | • Leybold | • Kinney | • Sumitomo |
| • Elmar | • Andritz | • Matador | • BMA | • Dodge |
| • Meyn | • AEW-Thurne | • Dupps | • Westfalia | • Falk |
| • Baloor | • Boston | | | |

FOOD-GRADE GREASES

NSF H-1

NSF H-1

NSF H-1

NSF H-1, 100% Synthetic

NSF H-1

NSF H-1

Oven Ice FG-2

NSF H1, 100% Synthetic

A 100% synthetic PAO-based grease with an inorganic thickener system for extreme high-temp and moderate low-temp conditions. Oven Ice is crystal clear and meets the requirements of NSF H1 and FDA 21 CFR 178.3570.

Gear-Guard FG

NSF H1, 100% Synthetic

Food Plant Open Gears

This is a 100% synthetic, E.P., NSF H1 food-grade open gear grease which provides the adhesion, water resistance and load-carrying properties of the best non-food-grade open gear lubes. Gear-Guard FG provides incredible "stay-put" performance in all food plant open gear applications.

FOOD-GRADE GREASES USAGE CHART

	General Greasing	Closers & Fillers	Conveyor Bearings	High Temp > 300°F	Low Temp < 40°F	Freezers to -60°F	Automated Lube	Meat Saws & Knives	Wet Environments	Corrosive Environments	Open Gears
Poly-Guard FG Series	●	●	●	●	⊗		LT	⊗	⊗	⊗	
Halo-Guard FG Series	●	●	●	●	⊗		LT 00	●	●	●	⊗
Magna-Plate 8					●			●			
Magna-Plate 22					●	●				●	
Magna-Plate 44 Series	●	●	●	●	⊗		44-1 44-0	●	●	⊗	
Clear-Guard FG	⊗	⊗	⊗	●				⊗	⊗		
Oven Ice FG-2				●							
Gear-Guard FG				●					●	⊗	●

● Primary Recommendations ⊗ Secondary Recommendations

Closing Machines/Seamers

- Lower gun pressures will help to remove more contamination since new grease will force out contaminated grease without flowing around it as easily.
- Cover feed cam life can be increased with a small drip feed or spray system using Magna-Plate 78.
- Generally speaking, the higher the bearing speeds or the lower the temperature, the lighter the grease has to be in order to provide proper oil flow for good lubrication.

FOOD-GRADE FLUIDS



Magna-Plate® 60, 62, 64, 66 ISO 32, 46, 68, 100

NSF H1

America's Finest Food-Grade Hydraulic Fluids can be used in a variety of applications where an NSF H1 fluid is required. They are food-grade, Group II white mineral based oils containing rust and oxidation additives and excellent antiwear protection. They are fully tested and OEM-approved for hydraulic systems, and are recommended for compressors and gear systems requiring food-grade oils.

Magna-Plate® 72, 74

NSF H1

Food Plant Air Line Lubrication

Magna-Plate 72 and 74 are low viscosity air line oils with rust inhibitors for use in all air-operated equipment. Magna-Plate 74 contains an effective antiwear additive, additional rust inhibitors, and a high percentage of emulsifiers to pick up and exhaust tramp moisture in the air lines. Contains Micronox®.

Magna-Plate® 78, 78E Fluids

NSF H1

These fluids are heavy, tackified, E.P. food-grade oils for superb wear protection on overhead chains and conveyors, drip systems, can lid cams, or anywhere a positive antiwear NSF H1 approved lubricant film is needed. Magna-Plate 76 is recommended for automatic oiling systems. Magna-Plate 78 and 78E (Emulsified) provide excellent antiwear performance in Angelus Can Seamers.

Magna-Plate® 80, 86, 88 Extreme Low Temperature

NSF H1, 100% Synthetic

These synthetic fluids are formulated with antiwear, rust inhibitor and "non-drip" additives for freezer chain and conveyor lubrication. The base fluids are food-grade synthetic oils with pour points as low as -90°F. These fluids have excellent penetration properties.

Angel-Guard® Fluids

NSF H1, 100% Synthetic

State-of-the-art, 100% synthetic, food-grade antiwear fluids compounded to provide the ultimate in wear and corrosion protection. JAX Angel-Guard fluids provide long drain performance in recirculating systems and include JAX complimentary, ongoing RPM Oil Analysis services. Formulated specially for high-speed beverage can seamers including those manufactured by Angelus Sanitary Can Machine Company.

Flow-Guard Synthetic Fluids ISO 22 through 680

NSF H1, 100% PAO Synthetic

These are state-of-the-art 100% synthetic food-grade lubricating oils for use in a myriad of food and beverage plant applications. JAX Flow-Guard Fluids usage range includes industrial hydraulics, gear drives, compressors, chains and other lubricated machinery. This series of antiwear fluids is compounded to provide superior long drain performance, minimize component wear and eliminate system "downtime."

Magna-Plate 1500 (1500) NSF H1
ISO 220FC (220PS)

This gear oil is formulated with a base oil based with three stable VI modifiers. A special additive package provides excellent protection against oxidation, wear, and corrosion. It is formulated to provide excellent protection against oxidation, wear, and corrosion. It is formulated to provide excellent protection against oxidation, wear, and corrosion.

Magna-Plate 1700 (1700) 100% Synthetic NSF H1
ISO 220FC (220PS)

This gear oil is formulated with a base oil based with three stable VI modifiers. A special additive package provides excellent protection against oxidation, wear, and corrosion. It is formulated to provide excellent protection against oxidation, wear, and corrosion.

RGH-AW 500 (500) NSF H1
ISO 32 (46) (68) (100)

This compound oil is formulated with a base oil based with three stable VI modifiers. A special additive package provides excellent protection against oxidation, wear, and corrosion. It is formulated to provide excellent protection against oxidation, wear, and corrosion.

RGH-AW 68 (68) NSF H1
ISO 68

This compound oil is formulated with a base oil based with three stable VI modifiers. A special additive package provides excellent protection against oxidation, wear, and corrosion. It is formulated to provide excellent protection against oxidation, wear, and corrosion.

Syn-Sym 210 (210) NSF H1, 100% Synthetic
ISO 220FC (220PS)

This gear oil is formulated with a base oil based with three stable VI modifiers. A special additive package provides excellent protection against oxidation, wear, and corrosion. It is formulated to provide excellent protection against oxidation, wear, and corrosion.

Magna-Shell 68 (68) NSF H1, Semi-Synthetic
ISO 68

This gear oil is formulated with a base oil based with three stable VI modifiers. A special additive package provides excellent protection against oxidation, wear, and corrosion. It is formulated to provide excellent protection against oxidation, wear, and corrosion.

FOOD-GRADE FLUIDS

Uniqon 150

Uniqon 150 is a NSF H1 food grade hydraulic fluid. Uniqon 150 is a high performance hydraulic fluid for use in food processing equipment. It is formulated with a wide range of properties to meet the requirements of NSF H1. It provides excellent performance characteristics for high pressure, high speed, high temperature applications. It is formulated for excellent performance and filterability in a wide range of hydraulic applications.

NSF H1

Conveyor Glide Series Lx, Med, Hvy

NSF H1 Conveyor Glide Series lubricants form a family of products designed for use in food processing equipment. They are formulated with a wide range of properties to meet the requirements of NSF H1. They provide excellent performance characteristics for high pressure, high speed, high temperature applications. They are formulated for excellent performance and filterability in a wide range of hydraulic applications. These products are NSF H1 compliant and are suitable for use in food processing equipment.

NSF H1

Magnum-Kate[®] 46/EG

This metal forming lubricant has exceptional metal wetting characteristics and provides improved finish, minimizes burning and prevents loading of forming components. Developed specifically for use in cold heading and air bending machines, it meets the demanding lubrication requirements of all types of can manufacturing equipment. Approved for NSF H1 use in food processing equipment.

NSF H1

Magnum-Kate[®] 68/EG

This metal forming lubricant has exceptional metal wetting characteristics and provides improved finish, minimizes burning and prevents loading of forming components. Developed specifically for use in cold heading and air bending machines, it meets the demanding lubrication requirements of all types of can manufacturing equipment. Approved for NSF H1 use in food processing equipment.

NSF H1

Magnum-Kate[®] 100/EG

This metal forming lubricant has exceptional metal wetting characteristics and provides improved finish, minimizes burning and prevents loading of forming components. Developed specifically for use in cold heading and air bending machines, it meets the demanding lubrication requirements of all types of can manufacturing equipment. Approved for NSF H1 use in food processing equipment.

NSF H1, NSF 3H

Magnum-Kate[®] 150/EG

This metal forming lubricant has exceptional metal wetting characteristics and provides improved finish, minimizes burning and prevents loading of forming components. Developed specifically for use in cold heading and air bending machines, it meets the demanding lubrication requirements of all types of can manufacturing equipment. Approved for NSF H1 use in food processing equipment.

NSF H1

Magnum-Kate[®] 220/EG

This metal forming lubricant has exceptional metal wetting characteristics and provides improved finish, minimizes burning and prevents loading of forming components. Developed specifically for use in cold heading and air bending machines, it meets the demanding lubrication requirements of all types of can manufacturing equipment. Approved for NSF H1 use in food processing equipment.

NSF H1

Factor Oil 20

Factor Oil 20 is an advanced food plant spray down oil. It contains a wide spectrum of microbicides and provides knockdown of a wide spectrum of microbes in the lubricant. Factor Oil 20 may provide an extra measure of protection sought by corporate HACCP programs in sanitation procedures.

NSF H1

FOOD-GRADE FLUIDS USAGE CHART

	General Oiling	Hydraulic Systems	Compressors	Gear Boxes	Drip Feed Oilers	Air Lines	Chains < 200°F	Chains up to 600°F	Freezers to -70°F	Vacuum Pumps	Angelus Seamers	Trolley Systems	Spray-Down Oil	Rotary Cookers & Peelers	Metal Forming	Box Slides
MP 60, 62, 64, 66	●	●	⊗	⊗	●	⊗	⊗			⊗						
MP 72, 74	⊗				⊗	●							⊗			
MP 78, 78E	●			⊗	●		●									
MP 80, 86, 88				⊗	●		●		●							
Angel-Guard Fluids			⊗	⊗						⊗	●					
Flow-Guard Fluids	●	●	●	⊗	●	⊗	⊗		⊗	⊗						
MP-FG ISO Gear Oils				●	⊗		⊗									
MP FG PAG Gear Oils				●	⊗		●	⊗								
FGH-AW Series Hyd.	●	●	⊗		●	⊗	⊗									
FGG-AW Series Gear				●												
Syncomp-FG Fluids			●							●						
Cylinder Oil-FG				●												
Unitran FG		●		⊗												
Conveyor Glide Series												●				
Magna-Kote 467 FG																
Aqua-Guard FG															●	
White Mineral Oils					●	●							⊗			
Dry-Glide Silicone Bulk	⊗															⊗
Magna-Plate 2000FG														●	●	
Packer Oil 22	⊗				⊗	⊗							●			
Pyro-Kote FG								●								

● Primary Recommendations ⊗ Secondary Recommendations

Hydraulic Systems

- KEEP IT CLEAN, KEEP IT DRY, AND KEEP IT COOL

Gearboxes

- Typically the most ignored lube point in a plant. Usually they aren't noticed until they fail. Because gearboxes are fairly trouble-free, they should rarely fail if properly maintained.
- Use the proper fluid for the loads, temperatures and gear type, and change the gear oil on a regular interval. Monitor critical boxes using a routine oil analysis program.

INDUSTRIAL-GRADE GREASES



Poly-Plate EP

This is a high-temperature, "sealed-for-life" grease made with a nonmetallie. It offers excellent compatibility with most elastomers and other greases. Poly-Plate EP exhibits low oil bleed, high EP properties and excellent shear and oxidation stability. Also highly recommended for electric motor bearing applications.

Magna-Plate® 300 (with moly)

NSF H2

This high-temperature grease features enhanced oxidation and antiwear properties. It will outperform all conventional petroleum greases that are exposed to high temperatures for extended periods. This dramatically reduces caking and carbonized deposits. The high percentage of suspension-grade moly and graphite in Poly-Plate 300 produces a high degree of solid particle orientation on the lubricated surface in order to provide a low initial friction, providing real and long-term lubrication.

Magna-Plate® 500-0, 500-1, 500-2

NSF H2

By applying advances in the technology of water resistance, IAX has formulated one of the world's most water-resistant greases. It is an excellent general plant grease for wear protection, rust and water problems, and multipurpose applications. Magna-Plate 500 is known throughout the industry for outstanding performance. Now available in NLGI #0 grade for fully automated centralized greasing systems, you take advantage of the remarkable technology.

Magna-Plate® 1000-1, 1000-2

NSF H2

These greases are formulated for plant equipment and are suitable for use on most types of equipment. Formulated from the finest raw materials, these greases exhibit superior properties. They will withstand temperatures up to 600°F and are formulated for lubricating far longer than greases.

Magna-Plate® 2000

USDA H2

This grease is formulated for heavy-duty work on high salt and process chemical environments. It has excellent oxidation and anti-rust formation characteristics. It is also chemically compatible. Superior water resistance, high EP properties, and excellent compatibility with other greases and elastomers make this grease an ideal grease for general plant-wide applications.

Magna-Plate® 2000

100% Synthetic

This grease is formulated for temperatures up to and exceeding 600°F. This thermally stable grease is formulated with a fully synthetic ester and a proprietary base. It offers excellent oxidation stability and lubrication properties for extended periods and at extremely high temperatures.

Millennium Grease

100% Synthetic

This is a synthetic, low-lead, synthetic bearing lubricant. Its high dropping point, low mechanical stability and high load bearing resistance make it the best for long-term industrial applications. Millennium Grease is formulated from the finest raw synthetic base oils and additives and will withstand temperatures above the dropping point without caking or oxidizing for far longer than greases of any other base type. It is MIL-G-108240 qualified and thus designed to operate from -70°F to 350°F under the harsh environment experienced by military ground and air equipment, including salt water corrosion.

Pyro-Plate EPN-2

100% Synthetic

This high-temperature, synthetic grease combines 100% high viscosity synthetic base oils with a proven high-temp thickener for outstanding performance in severe applications that may encounter heavy loads and infrequent relubrication. Numerous difficult industrial and automotive applications can be solved with JAX Pyro-Plate EPN-2 grease.

Hydro-Guard RCG

A specially formulated water-resistant grease solubilized in a non-flammable high-evaporation rate solvent. It is formulated for applications where conventional lubricating greases are difficult to apply, and light viscosity liquid is required for proper penetration, such as retort cart wheel bearings.

Hydro-Chain Grease

NSF H2

JAX Hydro-Chain Grease is a specially formulated water-resistant grease made to withstand the steam, water and high loads found in hydrostatic cooker chain applications.

Gear-Guard Synthetic

NSF H2, 100% Synthetic

This 100% Synthetic open gear lubricant provides unsurpassed performance in severe applications. Excellent water resistance, extreme-pressure capabilities, film adhesion and wear protection. Ultimate "stay-put" performance.

INDUSTRIAL-GRADE GREASES USAGE CHART

	General Greasing	Closers & Fillers	Conveyor Bearings	High Temp > 300°F	Low Temp < 0°F	Extreme High Temp > 450°F	Automated Lube	Open Gears	Wet Environments	Corrosive Environments	Electric Motor Bearings	Retort Cart Bearings
Poly-Plate EP-0, EP-2	●		⊙				-0				●	
MP 300	●	●	●	●					●	⊙		
MP 500-0, 500-1, 500-2	●	●	●				-1		●	⊙		
MP 1000-1, 1000-2	●	●	●	●		⊙	-1		●	⊙	⊙	
MP 1100	●	●	●	●		⊙			●	●	⊙	
MP 1200				●		●						
Millennium Grease				●	●							
Pyro-Plate EPN-2						⊙			●	●		
Hydro-Guard RCG												●
Hydro-Chain Grease			⊙						●	●		
Gear-Guard Synthetic								●	●			

● Primary Recommendations ⊙ Secondary Recommendations

General Greasing

- Always try to do your greasing immediately after washdown. This will force the water and caustic soaps out of the bearing before they get a chance to pit and corrode during shutdown.
- Not all greases are compatible. There may be a temporary phenomenon when switching from one grease to another called incompatibility. The problem can range from a mild softening, to greases literally running out of the bearings. As the old grease is flushed out, the problem will correct itself. Refer to the Compatibility Chart in this book, or contact your JAX representative if in doubt about grease compatibility.

INDUSTRIAL-GRADE FLUIDS



GEAR OILS:

Gearboxes come in a wide variety of styles, speeds, and duty levels. We have an industrial gear oil to match any application:

- Multipurpose Gear Oils (NSF H2) SAE 85W90, 85W140
- H-P Industrial Gear Oils (NSF H2) ISO Grades 68 through 680
- Magna-Plate® Gear Oils (NSF H2) 90, 140, 90MV, 140MV
- Synax EP Gear Oils (NSF H2, 100% Synthetic)
ISO 150, 220, 320, 460, 680
- Syngear Industrial Gear Oils (NSF H2, 100% Synthetic)
ISO Grades 22 through 680
- Perma-Gear Fluids EP-PAG (100% Synthetic)
- Syngear-GL Gear Oils (100% Synthetic) SAE 75W90, 80W140

HYDRAULIC FLUIDS:

Our hydraulic oils are compounded for years of trouble-free hydraulic system performance. We have a fluid type and viscosity to match any environment or OEM requirement.

- Premium Hydraulic Oils (NSF H2) ISO 22, 32, 46, 68, 100, 150
- Premium Hydraulic Oil Type Z (NSF H2) HVI-Multi-Grade
- Hydra-Plate® Fluids (NSF H2) ISO Grades 22 through 460
- Hydra-Plate® Fluid-MV (NSF H2) HVI-Multi-Grade

COMPRESSOR FLUIDS:

100% synthetic air compressor fluids for severe operating environments. Syncomp fluids meet the most demanding OEM requirements for extended drain intervals in all industrial compressor applications. Cryoguard Plus is JAX premium, high-performance refrigeration compressor oil.

- Syncomp-P Fluids (100% Synthetic PAO) ISO 22, 32, 46, 68, 100
- Syncomp-FG Fluids (NSF H1, 100% Synthetic PAO) ISO 32 through 150
- Syncomp-D Fluids (NSF H2, 100% Synthetic Diester) ISO 32 through 100
- Cryoguard Plus Fluids (NSF H2 Ammonia Refrigeration) ISO 32, 68
- Syntec Ammonia Compressor Oil (NSF H2, 100% Synthetic) ISO 68
- Premium Rotary Pump Oil HT (NSF H2)
- Syn-Air PGE Fluid (100% Synthetic PAG/Ester) ISO 32, 46

CHAIN & CONVEYOR LUBES

- Magna-Blair[®] 200 ISO 22, 46, 100
- Magna-Blair[®] 200NM ISO 22, 46, 100
- Conveyor Grease
- Magna-Blair[®] 200, 400, 412, 412 Plus, 420, 440 (NSF H2)
- Super-Glide Chain Oil with EPF (NSF H2)
- Pyro-Kate[®] Series Grease (NSF H2, 100% Synthetic) ISO 22, 46, 100

SPECIALTY LUBES:

Premium AEP Grease Oil NSF H1
This specialty grease is formulated for use in applications where high temperature, high speed, and high load conditions are encountered. It is formulated with a synthetic base oil and contains extreme pressure additives for protection against wear and tear. It is suitable for use in a wide range of applications, including industrial machinery, automotive engines, and marine engines.

Premium AEP Grease Oil USDA H2
This specialty grease is formulated for use in applications where high temperature, high speed, and high load conditions are encountered. It is formulated with a synthetic base oil and contains extreme pressure additives for protection against wear and tear. It is suitable for use in a wide range of applications, including industrial machinery, automotive engines, and marine engines.

Unifilm[®] Grease Oil USDA H2
This specialty grease is formulated for use in applications where high temperature, high speed, and high load conditions are encountered. It is formulated with a synthetic base oil and contains extreme pressure additives for protection against wear and tear. It is suitable for use in a wide range of applications, including industrial machinery, automotive engines, and marine engines.

Unifilm[®] Grease Oil NSF H2

Unifilm[®] Grease Oil NSF H2

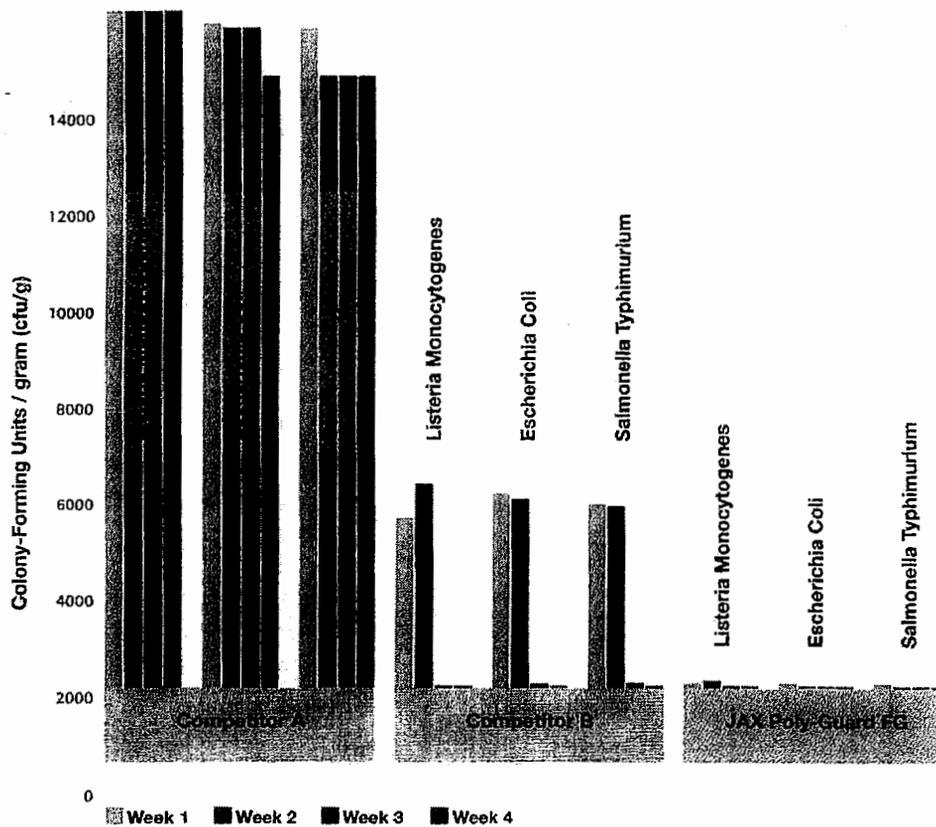
Unifilm[®] Grease Oil NSF H2
This specialty grease is formulated for use in applications where high temperature, high speed, and high load conditions are encountered. It is formulated with a synthetic base oil and contains extreme pressure additives for protection against wear and tear. It is suitable for use in a wide range of applications, including industrial machinery, automotive engines, and marine engines.

JAX MICRONOX® TECHNOLOGY

Independently engineered and field tested by JAX, the Micronox® additive system is a groundbreaking advance that was developed with the intention of preserving and protecting food-grade lubricants from bacterial contamination in meat, poultry and fresh food processing plants worldwide.

In independent laboratory results, the use of lubricants containing Micronox® was shown to reduce the yeast and mold counts and prevent the formation of Listeria, E. coli and Salmonella.

INDEPENDENT LAB RESULTS



Industry and OEM recognition does not come without JAX having done the groundbreaking development work on advances in food machinery lubrication. Listed below are a few of the firsts and innovations that JAX has brought to the industry:

JAX FOOD INDUSTRY FIRSTS

- The first Extreme-Pressure antiwear food-grade lubricants for chains and conveyors in meat packing and other food plants.
- The first 100% synthetic food-grade grease for use in freezing tunnel bearings and other incidental non-contact areas where extreme cold temperatures are experienced.
- The first high-performance antiwear food-grade greases for general plant maintenance.
- The first food-grade antiwear hydraulic oils meeting pump manufacturers' specifications for use in hydraulic systems where the fluid may be exposed to the processed product.
- A fully synthetic food-grade gearbox lubricant providing extended drain intervals and excellent antiwear and extreme-pressure characteristics.
- The first fully synthetic food-grade lubricant for cold temperature conveyor lubrication in freezing plant applications.
- The first food-grade grease for the high-speed closing machines found in the brewing and beverage industry compatible with the centralized lubrication equipment found on these machines.
- The first food-grade EP antiwear fluid for use in high-speed Angelus can sealers.
- The first food-grade universal hydraulic/transmission fluid for use in hydraulic equipment where the fluid may be exposed to the lubricant.
- The first food-grade hydraulic fluid for high performance low viscosity applications where the fluid may be exposed to the processed product.
- The first food-grade high performance synthetic oven chain lubricant for use in continuous sterilization processes.
- A synthetic food-grade spindle oil for use in food plant applications.
- The first food-grade wheel oil for use in food plants with a non-zinc formulation.
- The first food-grade steel can seaming lubricant providing low wax content and high metal finish quality for can and end manufacturers.
- The first food-grade non-zinc antiwear steam boiler and continuous cooker/sterilizer lubricating oils.
- The first high-temperature, vegetable food-grade synthetic oven chain lubricant.
- Microtox™ the first effective food-grade antimicrobial additive for protecting lubricants with knock-down capabilities, effectively partitioning lubricants into plant HACCP programs.

Top left:
First food-grade
and non-zinc
cooker oils

Bottom left:
First food-grade,
antiwear oil for
high speed fillers
and seamers

Bottom right:
Industry leading
synthetic oven
chain oils

AEROSOL LUBRICANTS, SEALANTS & COATINGS



Listed below are JAX premium quality aerosol products for food plant, industrial and fleet maintenance. We put our time and effort into developing the best available for each application. JAX aerosols are not just a sideline to a paint or parts line, and we don't believe in a "one product does all" philosophy.

This line has been developed and improved over decades of use in the field. Our experience has taught us about the compromises a professional encounters when using inexpensive multipurpose sprays.

Our market is not the mass-merchandise discount house. We have tailored our line exclusively for professional engineers, mechanics and maintenance managers. These people demand products that will work. JAX aerosol products are working, day in and day out.

NSF H1 PRODUCTS

Dry-Glide® Silicone with Micronox® Aerosol, Trigger Spray

A silicone lubricant authorized for use in all sanitary food plant applications where there is a need to eliminate friction between unlike surfaces.

Dry-Glide® WB Silicone Aerosol

A non-flammable, water-based version of our high-percent food-grade silicone spray.

Food-Grade Penetrating Oil Aerosol, Trigger Spray

A food-grade oil with the same penetrating and wetting abilities as our "America's Finest" formula. Also makes an excellent spray-down oil.

Magna-Plate® 86 with Micronox® Aerosol, Trigger Spray

A 100% synthetic lubricant for food-plant extreme-temperature use. Operating range is -70°F to 460°F.

Halo-Guard® FG with Micronox® Aerosol

Cures to a thick coating of white grease to protect against metal-to-metal contact and washout. Very water- and chemical-resistant.

Magna-Plate® 74 with Micronox® Drip-Top Bottles

Compounded to provide the best air line lubricant performance in all areas requiring NSF H1 food-contact authorization. With a high percentage of emulsifiers and rust inhibitors, it provides trouble-free operation of all air-operated equipment.

Magna-Plate® 78 with Micronox® Aerosol, Trigger Spray

An E.P. antiwear food-grade lubricant for the chains and conveyors on equipment in a food-processing environment.

BDF Cling-Lube with Micronox® Aerosol

Formulated with high performance food-grade oil and food-grade grease designed to eliminate dripping from overhead conveyors.

Brush Bottles, Pails

NSF H2 PRODUCTS

Aerosol

Aerosol, Trigger Spray

Aerosol, Trigger Spray

Aerosol, Trigger Spray

Aerosol

Aerosol, Trigger Spray

Aerosol

Aerosol

NSF 3H PRODUCTS

Trigger Spray, Bulk

AEROSOL PRODUCTS

NSF 3H PRODUCTS

Aerosol, Trigger Spray

Aerosol, Grease Tube, Squeeze Tube

Aerosol

NSF K1 PRODUCTS

Aerosol, Trigger Spray

NSF K2 PRODUCTS

Aerosol

Aerosol

Aerosol, Bulk

NSF A7 PRODUCTS

Aerosol, Trigger Spray

NSF A1 PRODUCTS

Aerosol

XACT Fluid Solutions is a new division of XACT that provides lubricant application and dispensing systems. These systems exactly control the application of the lubricants and extend the life of industrial and food plant machinery.

DISPENSING AND APPLICATIONS SOLUTIONS

The XACT product line includes:

- Single-point lubricators
- Precision chain lubrication
- Multi-point grease lubrication
- Intermediate bulk containment systems
- Clean and safe oil transfer
- Desiccant breathers & vent plugs

XACT Fluid Solutions is also the authorized reseller for many major brands. For more information about XACT Fluid products and services, visit our website at www.xactfluid.com



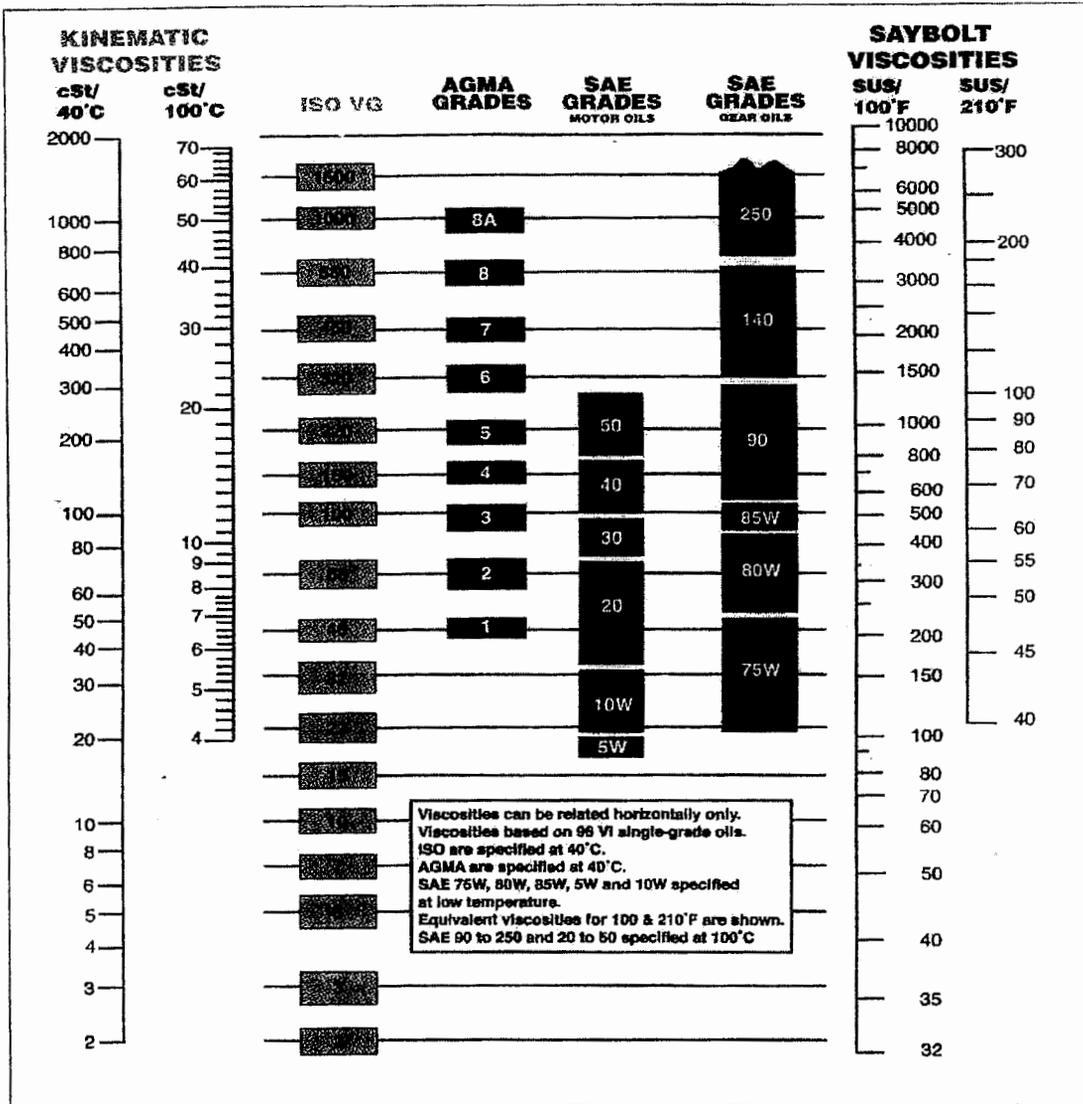
Top left:
Precision positive displacement pumps

Bottom left:
Precision chain lubrication

Center:
Remote single-point lubrication

Bottom right:
Nema 4X washdown safe

VISCOSITY REFERENCE CHART



NLGI GREASE COMPATIBILITY CHART

	Aluminum Complex	Barium	Calcium	Calcium 12-hydroxy	Calcium Complex	Clay	Lithium	Lithium 12-hydroxy	Lithium Complex	Polyurea
Aluminum Complex	●	●	●	●	●	●	●	●	●	●
Barium	●	●	●	●	●	●	●	●	●	●
Calcium	●	●	●	●	●	●	●	⊗	●	●
Calcium 12-hydroxy	●	●	●	●	⊗	●	●	●	●	●
Calcium Complex	●	●	●	⊗	●	●	●	●	●	●
Clay	●	●	●	●	●	●	●	●	●	●
Lithium	●	●	●	●	●	●	●	●	●	●
Lithium 12-hydroxy	●	●	⊗	●	●	●	●	●	●	●
Lithium Complex	●	●	●	●	●	●	●	●	●	●
Polyurea	●	●	●	●	●	●	●	●	●	●

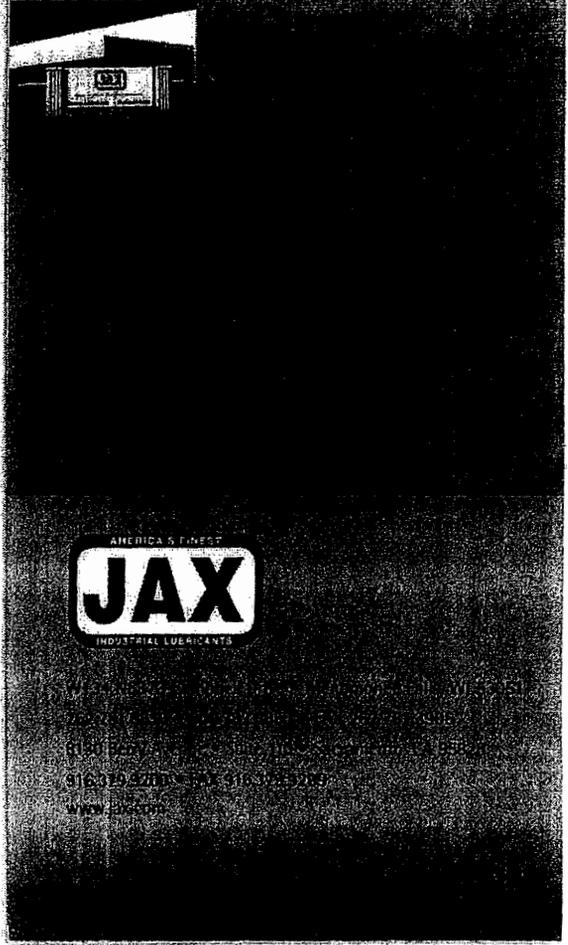
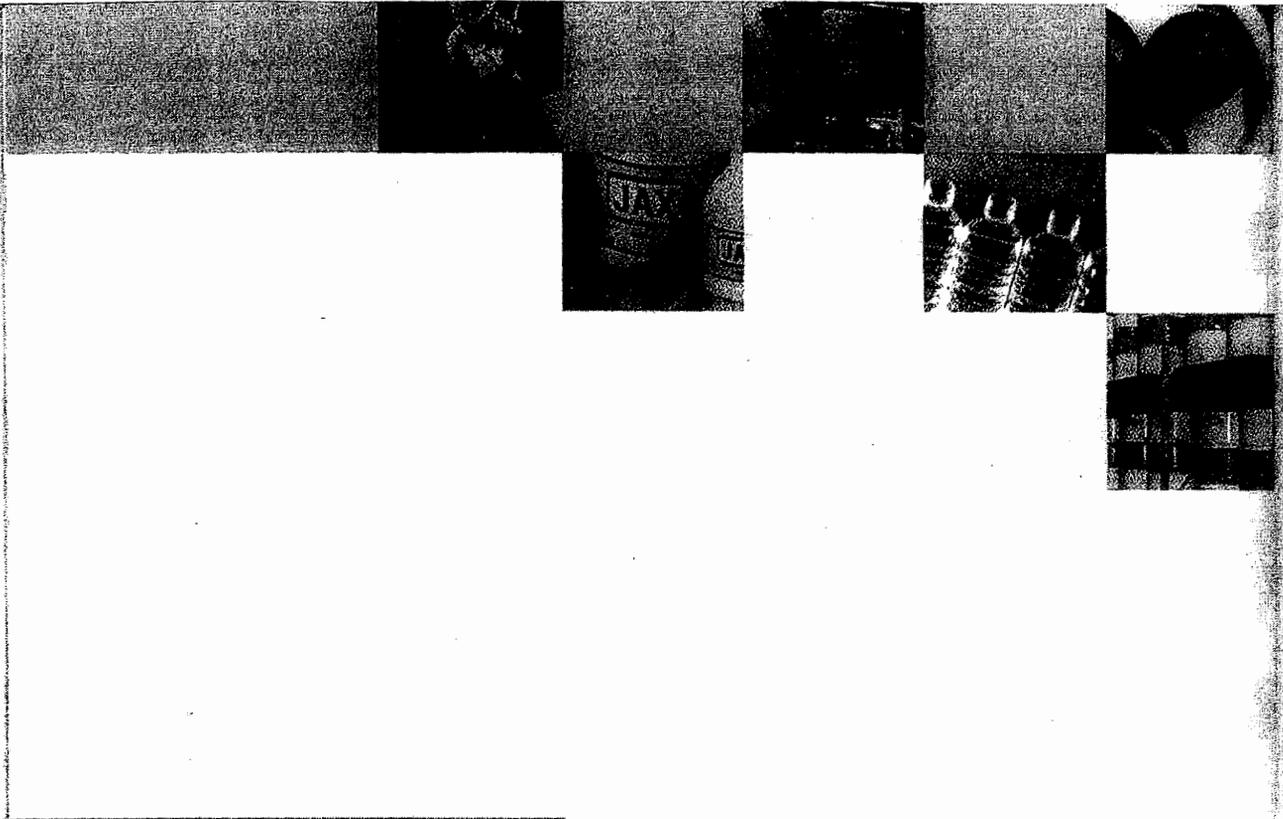
● Compatible ⊗ Borderline Compatibility ● Incompatible

NLGI NUMBERS FOR GREASE

A scale for the classification of consistency of a grease, based on penetration numbers determined by ASTM Method D 217. The scale was originally designed by the National Lubricating Grease Institute (NLGI).

NLGI Consistency Number	ASTM Worked (60 strokes) Penetration at 25°C (77°F), tenths of a millimeter
000	445 to 475
00	400 to 430
0	355 to 385
1	310 to 340
2	265 to 295
3	220 to 250
4	175 to 205
5	130 to 160
6	85 to 115

Although there are no official "half" numbers (e.g. 2 1/2), it has become a tradition to give such "half" numbers to intermediate grades (e.g. a grease with a penetration range of 230-260 is called a 2 1/2 NLGI).



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