# Safety of machinery - Lubricants with incidental product contact - Hygiene requirements

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#### **EESTI STANDARDI EESSÕNA**

#### **NATIONAL FOREWORD**

Käesolev Eesti standard EVS-EN ISO 21469:2006 sisaldab Euroopa standardi EN ISO 21469:2006 ingliskeelset teksti. This Estonian standard EVS-EN ISO 21469:2006 consists of the English text of the European standard EN ISO 21469:2006.

Käesolev dokument on jõustatud 30.03.2006 ja selle kohta on avaldatud teade Eesti standardiorganisatsiooni ametlikus väljaandes.

This document is endorsed on 30.03.2006 with the notification being published in the official publication of the Estonian national standardisation organisation.

Standard on kättesaadav Eesti standardiorganisatsioonist.

The standard is available from Estonian standardisation organisation.

#### Käsitlusala:

# This International Standard specifies hygiene requirements for the formulation, manufacture, use and handling of lubricants which, during manufacture and processing, can come into incidental contact (e.g. through heat transfer, load transmission, lubrication or the corrosion protection of machinery) with products and packaging used in the food, food-processing, cosmetics, pharmaceutical, tobacco or animal-feeding-stuffs industries.

#### Scope:

This International Standard specifies hygiene requirements for the formulation, manufacture, use and handling of lubricants which, during manufacture and processing, can come into incidental contact (e.g. through heat transfer, load transmission, lubrication or the corrosion protection of machinery) with products and packaging used in the food, food-processing, cosmetics, pharmaceutical, tobacco or animal-feeding-stuffs industries.

**ICS** 13.110, 67.020

Võtmesõnad:

# EUROPEAN STANDARD NORME EUROPÉENNE

**EUROPÄISCHE NORM** 

#### **EN ISO 21469**

February 2006

ICS 67.020: 13.110

#### **English Version**

#### Safety of machinery - Lubricants with incidental product contact - Hygiene requirements (ISO 21469:2006)

Sécurité des machines - Lubrifiants en contact occasionnel avec des produits - Exigences relatives à l'hygiène (ISO 21469:2006)

Sicherheit von Maschinen - Schmierstoffe mit nicht vorhersehbarem Produktkontakt - Hygieneanforderungen (ISO 21469:2006)

This European Standard was approved by CEN on 6 February 2006.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the Central Secretariat has the same status as the official versions

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EUROPEAN COMMITTEE FOR STANDARDIZATION COMITÉ EUROPÉEN DE NORMALISATION EUROPÄISCHES KOMITEE FÜR NORMUNG

Management Centre: rue de Stassart, 36 B-1050 Brussels

#### **Foreword**

This document (EN ISO 21469:2006) has been prepared by Technical Committee ISO/TC 199 "Safety of machinery" in collaboration with Technical Committee CEN/TC 114 "Safety of machinery", the secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by August 2006, and conflicting national standards shall be withdrawn at the latest by August 2006.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

## Endorsement notice

Approv. The text of ISO 21469:2006 has been approved by CEN as EN ISO 21469:2006 without any modifications.

# **INTERNATIONAL STANDARD**

ISO 21469

> First edition 2006-02-15

### Safety of machinery — Lubricants with incidental product contact — Hygiene requirements

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October 1900 and 1900 Sécurité des machines — Lubrifiants en contact occasionnel avec des produits — Exigences relatives à l'hygiène



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#### **Foreword**

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The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 21469 was prepared by Technical Committee ISO/TC 199, Safety of machinery.

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#### Introduction

During the production of foodstuffs, cosmetics, pharmaceutical, tobacco and animal feeding products — including packaging in direct contact with the product — it is essential to avoid contamination with lubricants from machine elements such as gears, bearings, hydraulics, pneumatics, compressors, slideways and chains. In all cases where product and lubricant contact cannot be fully prevented, lubricants have to be used which are acceptable for use should cross-contamination occur.

Up until 1998, the United States Department of Agriculture (USDA) issued the USDA H1 authorization for lubricants, which met these requirements. Use of such lubricants gave users confidence that they were complying with best practice in relation to their duty of care to the consumer. Following the end of the USDA scheme, the need was recognized for an International Standard to be developed in this area.

The structure of safety standards in the field of machinery is as follows.

- a) Type-A standards (basis standards) give basic concepts, principle for design, and general aspects that can be applied to machinery.
- b) Type-B standards (generic safety standards) deal with one or more safety aspect(s) or one or more type(s) of safeguards that can be used across a wide range of machinery:
  - type-B1 standards on particular safety aspects (e.g. safety distances, surface temperature, noise);
  - type-B2 standards on safeguards (e.g. two-hands controls, interlocking devices, pressure-sensitive devices, guards).
- c) Type-C standards (machinery safety standards) deal with detailed safety requirements for a particular machine or group of machines.

This International Standard is a type-B standard as stated in ISO 12100-1.

When provisions of a type-C standard are different from those which are stated in type-A or type-B standards, the provisions of the type-C standard take precedence over the provisions of the other standards for machines that have been designed and built according to the provisions of the type-C standard.

# Safety of machinery — Lubricants with incidental product contact — Hygiene requirements

#### 1 Scope

This International Standard specifies hygiene requirements for the formulation, manufacture, use and handling of lubricants which, during manufacture and processing, can come into incidental contact (e.g. through heat transfer, load transmission, lubrication or the corrosion protection of machinery) with products and packaging used in the food, food-processing, cosmetics, pharmaceutical, tobacco or animal-feeding-stuffs industries. Included in this document are registration criteria that can be used to assess conformance with this International standard for lubricants with incidental product contact (see Annex B). It is not applicable to substances used as product additives or to those in direct product contact (see Annex A), but confines itself to hygiene without addressing occupational health and safety matters. Nevertheless, it is considered essential that where occupational health and safety is associated with the processes concerned it be considered along with hygiene so that measures satisfying the needs of both can be taken.

#### 2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 6743-99:2002, Lubricants, industrial oils and related products (class L) — Classification — Part 99: General

ISO 6743 (all other parts), Lubricants, industrial oils and related products (class L) — Classification

ISO 12100-1:2003, Safety of machinery — Basic concepts, general principles for design — Part 1: Basic terminology, methodology

#### 3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

#### 3.1

#### **lubricant**

substance capable of reducing friction, adhesion, heat and wear when introduced as a film between solid surfaces

#### 3.2

#### product

any substance intended to be applied or taken into humans or domestic animals, e.g. by ingestion, injection, topical application, insertion

#### 3.3

#### manufacture

obtainment, production, preparation and processing of lubricants and of products