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

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



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Foreword

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International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

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*.

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