TRISKELION

DATE	23 September 2024	OUR REFERENCE	P60002-60055/001
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To LUBO International BV
Att. Mr. De Bruine
Het Rip 9
4493 RL Kamperland

Food contact Compliance EU and FDA evaluation report

Project data

Product	:	**Lubricant for threaded bolts**
Client	:	LUBO International BV, Kamperland, NL
Subject	:	Food contact compliance investigation according to EU legislation, FDA legislation, and Drinking water directive
Project number	:	P60002-60055
Date of issue	:	September 2024
Expiry date	:	September 2026
Validity	:	The conclusions of this investigation are valid until the above expiry date, or until any change in composition, production process or legal requirements affects the regulatory status of the product, whichever comes first. If the validity has expired, a re-evaluation of the regulatory status should be performed.

Summary

EU: The Product meets the compositional requirements specified in the Relevant Legislation in view of the client's intended use. Worst case calculations indicated that all limits were met and as a result overall or specific migration testing of the Product can be omitted.
The products can be considered **in compliance for food contact under the intended use for EU**.

USA: All the components were evaluated against the relevant FDA regulations. All except one component, graphite could be cleared for use. Worst case calculations indicated that the extraction limits for the end tests of the product were met. As such, these end tests can be omitted.
The Product can be considered **not in compliance for food contact under the intended use for USA (FDA).**

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1 Introduction

1.1 Product

Lubo International BV has requested Triskelion to investigate whether their product **Lubricant for threaded bolts** – hereafter referred to as the 'Product' – complies with the relevant EU and FDA food contact regulations and in addition to evaluate the products compliance with the Drinking water directive. The product is lubricant for threaded bolts.

1.2 Intended use

The Product is intended to be used for food processing machines, for contact with all food types, under repeated use conditions at a maximum of room temperature with no thermal treatments. For the FDA use in contact with food types all food types under conditions of use: E-G. The following use conditions were specified by the client:

1) 5% Product /bolt
2) 1.4 bolt / kg food

1.3 Legislative context

The report, the experiments described, and the evaluation of the results are based on the following legislation (hereafter referred to as 'Relevant Legislation'):

- Regulation (EC) No 1935/2004 of 27 October 2004 on materials and articles intended to come into contact with food and its amendments up to and including 27 March 2021
- Commodity Act Packaging and Food Utensils Regulation of The Netherlands of 20 November 1979 and its amendments up to and including 3348384-1027396-VGP of 26 April 2022
- Regulation (EC) No 1333/2008 of 16 December 2008 on food additives, and its amendments up to and including Regulation (EU) No 2023/1329 of 08 May 2024
- Regulation (EC) No 1334/2008 of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods, and its amendments up to and including Regulation (EU) No 2023/441 of 15 January 2024
- FDA Code of Federal Regulations (CFR) of the USA, Parts 170 to 199 of 1 January 2023

An outline of the regulatory context for food contact materials is given below.

1.3.1 European Union (EU)

Framework and harmonized regulations

All food contact materials and articles (FCM) on the EU market are regulated by regulation (EC) No 1935/2004 on materials and articles intended to come into contact with food, often referred to as the 'Framework Regulation'. This regulation stipulates that FCM shall be manufactured in compliance with good manufacturing practice so that they do not transfer their constituents to food in quantities which could (a) endanger human health, or (b) bring about an unacceptable change

in the composition of foodstuffs, or (c) bring about a deterioration in the organoleptic characteristics thereof (Article 3 of regulation (EC) No 1935/2004).

Under the Framework Regulation, the European Commission (EC) has adopted specific measures that regulate certain groups of materials and articles, such as Regulation (EU) No 10/2011 on plastic materials and articles. For most groups of materials and articles, no specific measures have yet been implemented; in these cases, the Framework Regulation refers to national provisions (e.g., legislation) in the EU member states.

Non-harmonised regulations

For so-called 'non-harmonised' FCM, i.e., FCM for which no specific measures have been adopted by the EC, we follow the principles provided the Council of Europe in the appendix to Resolution CM/Res(2020)9 on the safety and quality of materials and articles for contact with food. The Council of Europe has 39 member states, including all EU member states. According to these principles, substances can be used in the manufacture of FCM if:

a) they are approved by the authorities of Council of Europe member states; or
b) they are in compliance with material-specific provisions in EU or national legislation or official recommendations; or
c) absence of their release into food as well as absence of the release of their impurities and their foreseeable reaction or degradation products can be demonstrated with a (detection) limit not higher than 0.01 mg/kg, provided these are not in nano-form, do not have a CMR (carcinogenic, mutagenic, or toxic to reproduction) classification according to sections 3.5, 3.6. and 3.7 of Annex I to Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures ("the CLP regulation"), and are not assessed or predicted to be genotoxic; or
d) when none of the criteria a), b), and c) are met: are risk-assessed in accordance with internationally recognised scientific principles on risk assessment and in compliance with Article 3 of Regulation (EC) No. 1935/2004 or relevant national legislation.

At the beginning of Section 1.3 we have included any material-specific provisions in EU, national legislation and official recommendations that we have used in the regulatory check in this investigation.

Dual-use additives

Some substances used in food contact plastics as regulated by (EU) No 10/2011 are, at the same time, authorized food additives or authorized flavourings respectively by Regulation (EC) No 1333/2008 or Regulation (EC) No 1334/2008. These substances are called *dual-use additives*. To avoid the unauthorized presence of food additives or flavourings in food, specific requirements are set out for the migration of these substances from food contact materials. The substances shall not be released into foods in quantities that have a technological function in the food.
Although the above requirements regarding dual-use additives are set out in Regulation (EU) No 10/2011 on plastic materials, some national provisions (such as the Dutch Warenwet) extend these requirements on dual-use additives to other (non-plastic) FCM.

1.3.2 United States (FDA)

Under the Federal Food, Drug, and Cosmetic Act (FFDCA) of the United States, any substance '*the intended use of which results or may reasonably be expected to result, directly or indirectly, either in their becoming a component of food or otherwise affecting the characteristics of food*' is considered a food additive. If not exempted by the FFDCA, each individual substance in a food contact material that is a food additive shall be covered by one of the following:

- a regulation listed in Title 21 Code of Federal Regulations
- meeting the criteria for a Generally Recognized As Safe (GRAS) status (including but not limited to a GRAS regulation or GRAS notice)
- a prior sanction
- a Threshold of Regulation (TOR) exemption request
- or an effective Food Contact Substance Notification (FCN).

The food contact substance must comply with the specifications and limitations in the applicable authorization, such as limitations on food types and conditions of use (link: Food Types & Conditions of Use for Food Contact Substances | FDA), maximum dosage levels, extraction limits, specifications on molecular mass, density, or viscosity, or use in a particular application.
End tests (compliance tests) may be required to demonstrate compliance.

2 Regulatory check

The client and their suppliers have provided Triskelion with compositional information and additional compliance documents. We consider this information to be complete and true.

2.1 Compositional compliance check for EU

For all raw materials used in the Product, we have received supplier documents on the regulatory status and/or the composition of their raw materials. These raw materials comply with the applicable EU regulation 1935/2004, the Dutch Commodities Act, and other EU food contact regulations for the client's intended use as described Section 1.2.

One component; graphite, could not be confirmed to meet the purity specifications as defined in the relevant regulations. The statement should contain a disclosure stating the client assumes these specifications to be met and once available this disclosure can be removed from the statement.

We have identified the substances that have a restriction (i.e., a specific migration limit (SML), a maximum concentration in the Product, or other limitation) according to an authorization in a material-specific provision in the EU, a national legislation, or an official recommendation.

1) The restriction on the product as defined in the Dutch commodities act:
"The weight of the applied layer, in case of continuous contact between the foodstuff and the packaging material, must be no more than 50 g/m^2…."

Based on information from the client, it is estimated that per kg of bolts 0.5 g of Product is applied on the surface of the bolts. It is known that maximal 5% of the surface of the threaded bolt is in contact with the foodstuff. Therefore the maximal (worst case) surface area of a treated bolt in contact with food is 0.005655 m^2.

This is equivalent to 64 g/m^2 of bolts and of taken into account that 5% of the threaded bolt is in contact with the foodstuff, which equates to 3.18 g/m^2 Product. The maximal weight of the Product in continues contact with the foodstuff therefore meets the limit of 50 g/m^2 as specified in the Dutch commodities act .

2) Specific and overall migration limits
For the substances in the Product, we have performed worst-case migration calculations to determine the theoretically maximum concentration in food in case of 100% migration to the food based on the (packaging) surface to (food) volume ratio of 6 dm^2 per kg of food for films not yet in contact with food. All substances met their specifications.

In addition it is required to determine if the overall migration limit of 10 mg/dm^2 is met. This OML level can be converted to 60 mg/kg food taken into account the surface to (food) volume ratio of 6 dm^2 per kg of food for films not yet in contact with food.

The contact area of the Product with the food is 0.03958 dm^2/kg food. When converted to the correct units and multiplied with the weight of the applied layer of 3.18 g/m^2 the maximal weight of the Product in contact with one kg of food is calculated to be 1.26 mg Product/kg food, which is far below the overall migration limit of 60 mg/kg. As such overall migration testing can be omitted.

2.2 Dual-use additives

The composition of the Product contains the following dual-use additives, i.e., substances authorized as a food additive or flavouring according to EU Regulations (EC) No 1333/2008 and (EC) No 1334/2008, respectively.

Table 1: Dual-use additives in the Product.

Substance name	E or FL number
Calcium carbonate	E 170
Tricalcium phosphate	E 341
Beeswax	E 901
Silicon dioxide	E 551

2.3 Compositional compliance check for FDA

For all raw materials used in the Product, we have received supplier documents on the regulatory status and the composition of their raw materials. The raw materials are FDA authorized to be used as a coating according to 21CFR 175.300 or considered as GRAS or based on authorized based on prior sanction, except one substance: graphite.

Since 28 May 2024 Graphite has been delisted as formerly exempt from certification. As a result, this substance is no longer FDA authorized to be used for food contact materials or articles.
Graphite is authorized for use by FCN 1789, but can only be used when the graphite is obtained from the corresponding notifier/ supplier.

The FDA end tests for the product as defined in the FDA 21CFR 175.300
In the following chapter the maximum extraction level of a coating is defined:
21CFR 175.300 (c) (4) *From coating intended for repeated use, and employed other than as a component of a container, not to exceed 18 milligrams per square inch of coated surface*.

This translates to a maximum extractable content of 279 mg/dm^2 (using the conversion that 1 dm^2 equals 15.5 in^2). Taken into account the maximal weight of the applied layer of 3.18 g/m^2 as calculated in EU section which can be converted to mg results in a maximal weight of 31.8 mg/dm^2 of coated surface. This is below the request limit of 279 mg/dm^2 that equals 18 mg/in^2. As such the FDA extraction test can be omitted.

3 Conclusions

In this investigation we have considered the compliance documentation and the compositional information of the Product that was available to us, as provided by the client and the client's suppliers. We have checked this information against the relevant EU and FDA regulations on food contact materials.

EU

The Product meets the compositional requirements specified in the Relevant Legislation in view of the client's intended use.

The Product contains 4 known dual-use additives as defined by the EU regulations.

Worst case calculations indicated that all limits were met and as a result overall or specific migration testing of the Product can be omitted.

In addition to the above requirements, the manufacturer must ensure that food contact materials and articles are manufactured according to Regulation (EC) No. 2023/2006 of 22 December 2006 on Good Manufacturing Practice for materials and articles intended to come in contact with food. The verification of compliance with (EC) No. 2023/2006 was not part of the investigation described in this report.

In our compliance investigation we have included the Non-Intentionally Added Substances (NIAS) that were communicated to us by you or your suppliers. Our compliance conclusion does not extend to NIAS that have not been disclosed to us. If you want to be assured that your product does not contain NIAS that may jeopardize its suitability for use in food contact applications in view of Framework Regulation (EC) 1935/2004, we recommend a NIAS screening and risk assessment of your product.

In the final application no deterioration in the organoleptic characteristics of the food may occur (according to the requirements of article 3 of the Regulation (EC) No 1935/2004). The test for changes in organoleptic characteristics was not part of the investigation described in this report. A general recommendation is to demonstrate the absence of the deterioration in the real-life food application using industrial filling conditions.

Based on all this information, the products can be considered in compliance for food contact under the intended use for EU.

FDA

All the components were evaluated against the relevant regulations. All except one component, graphite could be cleared for use. Since 28 May 2024 Graphite is no longer FDA authorized as it has been delisted as formerly exempt from certification. Graphite is authorized for use as FCN 1789, but can only be used when the graphite is obtained from this notifier/ supplier.

Worst case calculations indicated that the extraction limits for the end tests of the product were met. As such, these end tests can be omitted.

Based on the above, and taken into account the delisting of graphite it hast be concluded that the Product can be considered **not in compliance for food contact under the intended use for USA (FDA).**
Our strong suggestion for our client is to switch to the graphite supplier following **FCN 1789**.

Food contact materials must comply with the FDA's good manufacturing practices (GMP) regulation, described in Title 21 of the Code of Federal Regulations (CFR) Section 174.5. The verification of compliance with 21 CFR 174.5 was not part of the investigation described in this report and is the responsibility of the manufacturer.

Supporting documents will be filed for a period of seven years and can be accessed by enforcement authorities upon agreement of the client.

On behalf of Triskelion,

Zaskia Eksteen and Inge van Schöll
Project Manager Food Contact Materials