TRISKELION

DATE	23 September 2024	OUR REFERENCE	P60002-60055/002
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To LUBO International BV
Att. Mr. De Bruine
Het Rip 9
4493 RL Kamperland

Drinking Water Compliance EU evaluation report

Project data

Product	:	**Lubricant for threaded bolts**
Client	:	LUBO International BV, Kamperland, NL
Subject	:	Drinking Water compliance investigation according to EU legislation
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 for drinking water in view of the client's intended use. Worst case calculations indicated that all limits were met for the PL substances and as a result migration testing of the Product for PL substances can be omitted.
Based on the composition, the substances used in the product can be considered in compliance for materials with the intention to be in contact with drinking water for EU.

Note: No PFAS were used during the manufacturing process of the Product. In addition, based on the information provided by the suppliers, no PFAS were used as started substances for the raw materials. That said, it is not likely that PFAS are present in the Product.

For the final application, the product has to meet the limits for additional testing as required according to the DWD.

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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 Drinking Water regulations. The product is lubricant for threaded bolts.

1.2 Intended use

The Product is intended to be used for drinking water equipment, under repeated use conditions at a maximum of room temperature with no thermal treatments under the following conditions:

1) 5% Product /bolt
2) 1.4 bolt / L water

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'):

- Drinking Water Directive (EU) 2020/2184 by the European Parliament and the Council
- Commission implementing decision (EU) 2024/367, 23 January 2024
- 4 MS initiative positive lists
- Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food, and its amendments up to and including (EU) No 2023/1627 of 10 August 2023

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

1.3.1 European Union (EU)

Drinking water directive (EU) 2020/2184

On January 12, 2021, a new version of the Drinking Water Directive (DWD) was adopted as Directive (EU) 2020/2184 by the European Parliament and the Council. This updated the original DWD from 1998. The main goal is to protect the environment and human health from the harmful effects of contaminated drinking water and to make sure that the rules are applied consistently across all of Europe. Member states had to make this DWD part of their national laws and follow its rules by January 12, 2023.

Article 11 of the DWD includes minimum hygiene requirements for materials that come into contact with water intended for human consumption. Member States shall ensure that materials used in new or repaired water systems (such as for collecting, treating, storing, or distributing drinking water) do not:

- Harm people's health.
- Change the water's colour, smell, or taste.
- Promote the growth of harmful microbes.
- Release more contaminants into the water than needed.

Testing Criteria:

- Test Parameters : Check for substances that effect the water, such as flavor, odor, color, as well as the total organic carbon, any unexpected substances and the potential for microbial growth.
- Testing Methods: The testing methods will consider relevant European (CEN) standards.
- Pass/Fail Criteria: The criteria for passing these tests are based on how substances in the material might migrate into the water and at what levels they might appear at the tap.

Commission implementing decision (EU) 2024/367

Laying down rules for the application of Directive (EU) 2020/2184 of the European Parliament and of the Council by establishing the European positive lists of starting substances, compositions and constituents authorised for use in the manufacture of materials or products that come into contact with water intended for human consumption.

The Drinking Water Directive requires that starting substances, compositions or constituents used in manufacturing materials that come into contact with drinking water, from the water source to the tap, must be listed in one of four European positive lists. Once the water flows from the tap, materials that come into contact with it are managed under food safety regulations.

The European Commission has adopted positive lists for four different types of materials that come into contact with drinking water:

1. organic;
2. metallic;
3. cementitious; and
4. enamel, ceramic or other inorganic materials.

The adopted positive lists are based on the national positive lists that the EU Member States notified to ECHA in July 2021. The organic materials positive list incorporates the plastic food contact materials list found in Annex I of the Commission's Regulation on plastic materials and articles intended to come into contact with food ((EU) No 10/2011).

ECHA will publish the first European positive lists, that will apply starting 31 December 2026. Until then, national positive lists and other national provisions will apply, provided that the starting substances, compositions and constituents comply with the parametric value of 5 µg/l Pb (lead) at the tap as set out in Part B of Annex I to Directive (EU) 2020/2184.

Concentration limits may be set for a substance in the water that comes out of the tap. These are known as Maximum Tolerable Concentrations at the tap (MTCtap) and may apply to the listed substance itself or to another relevant chemical species which migrates into the water. Such relevant chemical species could include a chemical substance which is present as an impurity or is a reaction product of the listed entry.

4 MS initiative

The four Member States (MS): Germany, France, the Netherlands and 'the United Kingdom of Great Britain and Northern Ireland' have agreed on collaboration in the harmonization of tests for the hygienic suitability of products in contact with drinking-water, in 2011. These 4MS-collaboration efforts have evolved successfully and now are termed "4MS-Initiative" (4MSI) in view of extension perspectives. In 2018 Denmark joined the 4 MSI as full member.
The 4MSI published documents on a common approach for organic materials, including Part B: Positive List of starting substances for Organic Materials and Part C: (DRAFT) Procedures and Methods for Testing and Accepting Products Made of organic materials.

Certification of products in contact with drinking water

Compliance with the requirements can be demonstrated through the issue of a certificate from a certifying authority accredited for the drinking water field.

Dual-use additives

Some substances used in products in contact with drinking water and or 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. The substances shall not be released into foods in quantities that have a technological function in the food.

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 DWD

For all raw materials used in the Product, we have received supplier documents on the regulatory status and the composition of their raw materials. These raw materials comply with the applicable EU DWD 2021/2184, the Commission implementing decision (EU) 2024/367 and the 4MSI positive list, and taken into account the monomers and other starting substances and additives according to plastic regulation EU 10/2011, for the client's intended use as described Section 1.2.

We have identified the substances that have a restriction (i.e., Maximum Tolerable Concentration (MTC) or 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.

Note: No PFAS were used during the manufacturing process of the Product. In addition, based on the information provided by the suppliers, no PFAS were used as started substances for the raw materials. That said, it is not likely that PFAS are present in the Product.

2.2 Migration testing for organic materials according to the DWD

Organic materials shall be tested in accordance with Table 1 (See Annex 1) in line with methods for testing specified in relevant European standards or, in the absence thereof, an internationally or nationally recognised method and shall satisfy the requirements stipulated therein. For this purpose, the test results in terms of substance migration shall be converted into estimated levels at the tap.

For assembled products: minor components, parts and materials shall be described in detail and testing shall be reduced accordingly. For this purpose, 'minor' refers to a level of influence on the quality of water intended for human consumption that does not require full testing.

Leaching of total organic carbon (TOC):

Products or components may not release more than 0.5 mg/l Total Organic Carbon (TOC) into the water expressed as Ctap. In addition, it is required to show that there is no increasing trend (in time / migration periods). However, if the TOC in the last migration period is below 0.1 mg/l expressed as Ctap, no trend-analysis is required.

The contact area of the Product with water is calculated as 0.03958 dm^2/kg water. The maximal weight of the Product in contact with one L water is calculated to be 1.26 mg Product/L water. Therefore the TOC level is maximal 1.26 mg/L water in case of 100% migration of the Product to the water. This is above the TOC level of 0.5 mg/L and TOC testing cannot be omitted.

MTC_{tap} of PL substances:

For the PL substances in the Product, we have performed worst-case calculations to determine the theoretically MTC_{tap} in water in case of 100% migration to the water, based on the (packaging) surface to (water) volume ratio of 6 dm^2 per kg and taken into account 1/20 SML levels as described below. All substances met their specifications and testing of the MTC tap levels of the PL substances can be omitted.

If for the relevant substance a specific migration limit (SML) is mentioned in 10/2011/EC the MTCtap was derived according to the formula :

$$MTC_{tap}\ (mg/l) = \frac{SML\ (mg/kg\ of\ food) \times 1\ (kg)}{2\ (L) \times 10}$$

2.3 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	E901
Silicon dioxide	E 551

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 DWD and related legislation.

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.

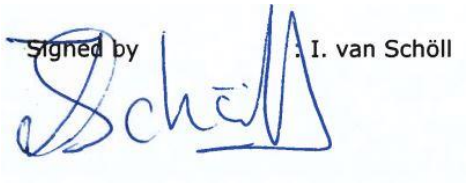
Worst case calculations for the PL substances indicated that all MTC_{tap} limits were met and as a result the specific migration testing for the PL substances of the Product can be omitted.

In the final application additional tests are required, such as organoleptic tests (Odour and Flavour, Colour and Turbidity), general hygiene assessments (leaching of TOC), migration testing of unexpected substances (GC-MS) and Enhancement of Microbial Growth. The required additional testing might be reduced as the Product is used as lubricant for assembled products.

Based on the above, the substances used in the product can be considered in compliance for materials with the intention to be in contact with drinking water for EU.

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,



Inge van Schöll and Zaskia Eksteen
Project Manager Food Contact Materials

Annex 1

DWD (EU) 2020/2184 Annex V Table 1

Table 1. Testing related to material types

Criteria	Organic (See Note 1)	Metallic (See Note 2)	Cementitious	Enamels and ceramic materials
European positive lists				
European positive list of starting substances for organic materials	X	N.N.	X	N.N.
European positive list of accepted metallic compositions	N.N.	X	N.N.	N.N.
European positive list of constituents for cementitious materials	N.N.	N.N.	X	N.N.
European positive list of compositions for enamels and ceramic materials	N.N.	N.N.	N.N.	X
Organoleptic tests				
Odour and flavour	X	N.N.	X	N.N.
Colour and Turbidity	X	N.N.	X	N.N.
General hygiene assessments				
Leaching of total organic carbon	X	N.N.	X	N.N.
Surface residues (metals)	N.N.	X	N.N.	N.N.
Migration testing				
Relevant parameters of this Directive	X	X	X	X
MTC_{tap} of PL substances	X	N.N.	X (See Note 3)	N.N.
Unexpected substances (GCMS)	X	N.N.	X (See Note 3)	N.N.
Compliance with compositions lists	N.N.	X	N.N.	X
Enhancement of microbial growth	X	N.N.	X (See Note 3)	N.N.

N.N.:	Not necessary
MTCtap:	Maximum tolerable concentration at the tap (either derived from the opinion of ECHA for the purposes of inclusion of the substance in the European positive list, or based on a specific migration limit set in Commission Regulation (EU) No 10/2011 (1) and considering a 10 % allocation factor and water consumption of 2 litres per day)
GCMS:	Gas Chromatography – Mass Spectrometry (screening method)
Note 1:	Specific exceptions to be determined in line with point 5 of this Annex.
Note 2:	Metals shall not be subject to organoleptic testing because it is generally accepted that if the parametric values set out in Annex I are met, organoleptic problems are unlikely to arise.
Note 3:	Depending on the existence of organic substances in the composition.