



DATE 29 June, 2021

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To whom it may concern

Lubo Global Innovation, Kortgene, Netherlands has requested Triskelion to verify whether their product is in accordance with the Code of Federal Regulations of the USA. For this purpose, samples as well as detailed information on the composition were provided.

Project and sample details:

Client	:	Lubo Global Innovation, Kortgene, Netherlands
Project number	:	P30002-30084
Preceding projects	:	P10617-113 and 093.20544/01.35
Sample description	:	Lubricant for threads (hereafter referred to as 'Sample')
Date of issue	:	July 2021 (re-evaluation)
Validity period	:	July 2021 – July 2024
Evaluation	:	This evaluation is valid for the validity period given above, or until any change in the product composition, in the production process or in the legal requirements affects the final conclusions, whichever comes first. Prolongation after the validity period has expired will require a new sample evaluation including extraction tests.

Relevant Legislation:

- FDA 21 Code of Federal Regulations of the USA of 1 April 2020, §175.300.

The investigation comprised the following determinations:

- Administrative check of the composition of the 'Sample'.
- FDA extraction tests according to FDA 21 CFR 175.300(c)(4).

Results:

The results were described in detail in the statement of project number P10617-113 (administrative check) and analytical report ARPC/13-664/VEH of project number 093.20544/01.35 (extraction tests). The client has confirmed that the composition and the production process of the 'Sample' have not changed since the 'Sample' and the compositional information were evaluated in the preceding projects. We have re-evaluated the compositional information, as well as the analytical results, in view of the updated 'Relevant Legislation'.

The composition of the 'Sample' and the results of the extraction tests are still in accordance with the requirements of the updated 'Relevant Legislation'.



TRISKELION

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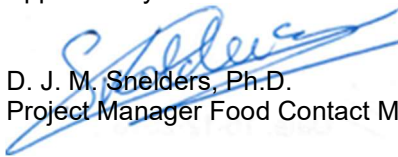
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Conclusion:

Given the composition and the values obtained for the relevant extraction tests, the 'Sample' can be used for contact with all food types, under repeated use conditions and employed other than as a component of a container and under conditions E through G (maximum room temperature with no thermal treatment).

On the basis of the results obtained in the preceding projects P10617-113 and 093.20544/01.35 and provided that the composition and the production process of the 'Sample' have not changed, the statement is prolonged until July 2024. Prolongation after the validity period has expired will require a new sample evaluation including extraction tests.

Approved by


D. J. M. Snelders, Ph.D.
Project Manager Food Contact Materials