



DATE 27 June 2018  
OUR REFERENCE FDA evaluation lubricant

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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 FDA legislations. For this purpose, samples as well as detailed information on the composition were provided for the initial investigation. The composition information provided was considered to be complete and true. The sample was identified as follows (hereinafter called 'Sample'):

Project number, this investigation : P10617-113  
Project number, initial investigation : 093.20544/01.35  
Valid till : June 2019  
Client : **Lubo Global Innovation, Kortgene, Netherlands**  
Sample description client : Lubricant for threads  
Date of issue : June 2018  
Validity period : June 2018 – June 2024  
Evaluation : This investigation must be re-evaluated if the relevant regulation is changed, or the composition or the production process of the product is changed, or at June 2021 the latest.

### *Tests and Regulations:*

The tests performed in the initial investigation were in line with the FDA 21 CFR parts 170-199 of the USA of April 1<sup>st</sup>, 2018 (hereinafter called 'Regulations').

### *The investigation comprised the following determinations:*

- Administrative check of the composition of the sample.
- Relevant extraction tests

### *Results:*

The results were described in detail in analytical report ARPC/13-664/VEH. In summary it is stated that the composition of the 'Sample' is in accordance with the 'Regulations' and that the extraction tests meet the limits of the 'Regulations'.

The values obtained for these extraction tests from the 'Sample' using heptane for 30 minutes at 21°C, using water for 24 hours at 40°C and using 8% ethanol for 24 hour at 49°C, meet the limits as specified above in the 'Relevant Legislation'.



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**Conclusion:**

Given the composition and the values obtained for the extraction tests, the 'Sample' can be used for repeated use for contact with all food types, and employed other than as a component of a container and under conditions E through H (maximum room temperature with no thermal treatment) regarding the composition and relevant extraction tests according FDA 21 CFR 175.300(c)(4) of 1 April 2018.

Approved by:

Dr. S.M. Kuiper  
Project Manager Food Contact Materials