TRISKELION
RESEARCH FOR BETTER LIVING

DATE	27 June 2018	PROJECT NUMBER	P10617-113
OUR REFERENCE	FDA evaluation lubricant	PAGE	1 of 2

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 1st, 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'.

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