TRISKELION
RESEARCH FOR BETTER LIVING

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OUR REFERENCE	Lubo EU evaluation	PAGE	1 of 2

To whom it may concern

Lubo Global Innovations, Kortgene, the Netherlands has requested Triskelion to verify whether their product, a lubricant for threaded bolts, is suitable for use in food processing machines, in view of EU Regulations. For this purpose, detailed information on the chemical composition of the lubricant was provided. Project details are as follows:

Project number	:	P10617-114
Client	:	**Lubo Global Innovations, Kortgene, the Netherlands**
Product description client	:	**Lubricant for threaded bolts**
Date of issue	:	July 2018
Validity period	:	July 2018 –July 2024
Evaluation	:	This evaluation is valid for a period of three years, or until any change in production process or legal requirements affect the final conclusions, whichever comes first. After this three year period, a re-evaluation of the final conclusions should be executed.

Tests and Regulations
The evaluation was executed in line with the requirements of Regulation (EU) No 10/2011 up to and including amendment (EU) No 2018/831 of 5 June 2018 and Regulation (EC) No 1935/2004 of 27 October 2004, (hereinafter called 'Relevant Legislation').

The investigation comprised the following
- Administrative check of the composition of the sample and theoretical calculations on worst case migration.

Coating materials have to comply with Article 3 of the Framework Regulation 1935/2004, wherein it is stated that food contact materials may not endanger human health nor bring about an unacceptable change in the composition of the food, nor bring about a deterioration in the organoleptic characteristics of food.
As the product concerns a coating and not a plastic, the composition of the product as such is not subject to the positive list of the abovementioned Plastics Regulation. However, since all the components in the product are listed in the Plastics Regulation (10/2011), the safety evaluation of the chemical composition of the product was based on the limits as mentioned in the Plastics Regulation.

Results
The chemical composition of the lubricant has been confidentially disclosed to Triskelion by Lubo Global Innovations. All components were found to be listed in the 'Relevant Legislation' as listed above. One compound in the composition of the product is listed in the Plastics Regulation with a Specific Migration Limit (SML) of 0.05 mg/kg of food. A worst case calculation for migration of this compound was performed, taking said limit into account.

As the product will be used on different types of threaded bolts, the calculation was performed for bolts ranging in size from M3-M24. For the calculation, it was assumed that a minimum amount of 2000kg of food would be processed by the machine wherein the treated bolts are placed. Also, it was assumed for the calculation that a maximum of 5% of the threaded part of the bolt would come into contact with the foodstuff.

The calculations based on the above worst case situation revealed that the composition of the lubricant is in accordance with the 'Relevant Legislation', and no limit can be exceeded, provided that the below listed maximum amounts of food come into contact with a single bolt of a certain size.

Bolt type	Calculated maximum allowed amount of food/bolt when 5% of bolt comes into contact with food.	Calculated migration (mg/kg food)
M3	300 g/bolt	<0.05 mg/kg
M4	1 kg/bolt	<0.05 mg/kg
M5	2 kg/bolt	<0.05 mg/kg
M6	3 kg/bolt	<0.05 mg/kg
M8	7 kg/bolt	<0.05 mg/kg
M10	14 kg/bolt	<0.05 mg/kg
M12	21 kg/bolt	<0.05 mg/kg
M14	30 kg/bolt	<0.05 mg/kg
M16	40 kg/bolt	<0.05 mg/kg
M20	100 kg/bolt	<0.05 mg/kg
M24	133 kg/bolt	<0.05 mg/kg

Conclusion:
The composition of the lubricant product, as provided by the client, is considered to be complete and correct. The composition provided is in compliance with the requirements specified in the 'Relevant Legislation'. Based on the information that was supplied about the composition, the application of the lubricant product and 'Relevant Legislation', calculations were performed (as described in detail in the Results sections).

In conclusion, the lubricant for threaded bolts can be considered suitable for use in food processing machines based on the requirements of the 'Relevant Legislation', provided that for the different bolt sizes, the abovementioned maximum amounts of food can come into contact per bolt. The calculation was based on a minimum of 2000kg of foodstuff processed by the machine.

Approved by:

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