

**SANTE SERVICES**  
**9 rue Edward Steichen L-2540**  
**LUXEMBOURG**

Martillac, 18 September 2020

**Assessment of sensitising properties on albino Guinea Pigs with the item:**  
**25-40-25 ICS**  
**Batch N°: 202007**

**Study: SMKiso-PH-20/0599**

Study carried out between 14 August 2020 and 17 September 2020.

The study was performed to assess the contact sensitization potential of a test item in the albino Guinea Pig after a polar and non-polar extraction, carried out between 70 hours and 72 hours and 30 minutes between 34.5°C and 38.5°C, with an extraction ratio of 3 cm<sup>2</sup>/mL.

The induction phase (intradermic injection at 100% and topical application at 100%) was conducted with the polar or non-polar extract of the test item **25-40-25 ICS** in the treated group 2 or 4 of 10 Guinea Pigs, respectively, and a 14-day rest phase. The challenge phase, under occlusive dressing for 24 hours, consisted to a single topical application of the test extracts at 100% and of the vehicle. The experimental protocol was established according to the *Magnusson and Kligman method (J. Invest. Dermatol. 1969. 52, 268-276)* and to the *International Standard ISO 10993-10 (August 2010) concerning biological evaluation of medical devices: Tests for irritation and skin sensitization*.

No macroscopic cutaneous reactions attributable to allergy was recorded during the examination following the removal of the occlusive dressing (challenge phase) from the animals of the group 2 treated with the polar test extract.

No cutaneous intolerance reaction was recorded in animals from the control group 1.

No macroscopic cutaneous reactions attributable to allergy was recorded during the examination following the removal of the occlusive dressing (challenge phase) from the animals of the group 4 treated with the non-polar test extract.

No cutaneous intolerance reaction was recorded in animals from the control group 3.

In conclusion, in view of these results, under these experimental conditions, the polar and non-polar extracts of the test item **25-40-25 ICS** do not have to be classified as a skin sensitizer, in accordance with International standard ISO 10993-10.

Mrs. Amandine Laupénie  
Study Director

*Results not submitted to the control of the Assurance Quality Unit.*