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TEST RESULT CERTIFICATE

Sponsor	KWO® Dichtungstechnik-GmbH	**Technical Initiation**	11/15/2021
Address	Am Eschengrund 3 Schechen, 83135 Germany	**Technical Completion**	2/10/2022
Contact	Julian Häuser	**Test Result Certificate Date**	6/21/2022
P.O. Number	93002145	**Final GLP Report**	21-03879-G1

Test Article	KWO® MultiTex® Sheet	**Ratio**	60 cm^2 / 20 mL
Study	Class VI Test - USP	**Vehicles**	USP 0.9% Sodium Chloride for Injection (NaCl), Cottonseed Oil (CSO), 1 in 20 Ethanol in NaCl (EtOH), and Polyethylene Glycol 400 (PEG)
Storage Condition	Room Temperature	**Extraction Conditions**	70 ± 2 °C for 24 ± 2 hours

REFERENCES:

The study was based upon the following:

USP-NF 2021. <88> Biological Reactivity Tests, *In Vivo*.

ISO/IEC 17025, 2017, General Requirements for the Competence of Testing and Calibration Laboratories.

GENERAL PROCEDURE:

The test article was cut into pieces for testing. A total of 5 units (4 units in the original test and 1 unit in the repeat NaCl group Systemic test) of test article was used for extraction. The extraction conditions were performed as stated above. The test article extracts and corresponding blanks were injected systemically and intracutaneously in mice and rabbits, respectively. The injections were in the amounts and routes set forth by USP, including the further dilution of the extracts prepared with PEG. The animals were observed for signs of toxicity and skin reactivity for up to 72 hours post treatment. In addition, the test article was implanted into the paravertebral muscles of rabbits for 7 days and observed macroscopically for signs of hemorrhage, necrosis, discoloration, encapsulation, and infection.

RESULTS AND CONCLUSION:

In the original test, one test animal and one control animal lost an insignificant amount of weight (less than 5%). Due to clinical signs of toxicity, NaCl test animal #4 was euthanized immediately after dosing in the original test. All the remaining animals in the original test increased in weight. In the repeat test, all the NaCl test and NaCl control animals either maintained or increased in weight. In the original test, NaCl test animal #4 was observed with prostration, dyspnea, abdominal breathing and was observed death immediately after dosing. Due to moribund condition, per Veterinarian suggestion, animal #4 was euthanized and a gross necropsy was performed with no abnormal findings. In the original test, NaCl test animal #2 was observed with hunched body posture immediately after dosing. The animal recovered and was observed to be normal at 4, 24, 48, and 72 hour time points. None of the remaining test or control animals in the original study exhibited overt signs of toxicity at any of the observation points. None of the NaCl test and NaCl control animals in the repeat test exhibited overt signs of toxicity at any of the observation points.

The test is considered negative because none of the animals injected with CSO, EtOH, and PEG extracts of the test article in the original test and none of the NaCl test and NaCl control animals in the repeat test showed a significantly greater biological reaction than the animals treated with the control articles.

In addition, none of the rabbits injected intracutaneously with NaCl, EtOH and PEG, test article extracts exhibited any signs of erythema, or edema in both test and control sites and no signs of clinical toxicity. One of the rabbits injected intracutaneously with CSO extracts exhibited mild signs of erythema and edema at 48 and 72 hour time points at both test and control sites with no signs of clinical toxicity. CSO sensitivity is commonly seen in laboratory rabbits. As scores were observed at the test and control sites it is unlikely this is related to the test article. Also, the implant sites exhibited no significant signs of hemorrhage, necrosis, discoloration, encapsulation, or infection compared with the control sites.

The test article meets the requirements of the guidelines for the Biological Test for Plastics, Class VI - 70°C.

AUTHORIZED PERSONNEL:

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Quality Assurance

D. Radhika

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Study Director

Konformitätserklärung / Declaration of compliance

Diese Konformitätserklärung gilt für folgendes Produkt / This declaration of conformity applies to the following product:

KWO® MultiTex® Sheet 2.0

Hersteller / Manufacturer

KWO Dichtungstechnik GmbH
Am Eschengrund 3
83135 Schechen
Germany

Wir erklären hiermit, dass das Herstellungsverfahren der Dichtungsplatte „KWO MultiTex Sheet 2.0“ der gleichen Technologie entspricht wie bei der Dichtungsplatte „KWO MultiTex Sheet“. Wir haben im Zuge unserer Optimierung lediglich die technischen Parameter der Dichtungsplatte „KWO MultiTex Platte 2.0“ verbessert um die Zuverlässigkeit des Produktes zu erhöhen.
Somit sind die vorhandenen Zertifikate für die „KWO MultiTex Sheet“ auch für das optimierte Produkt „KWO MultiTex Sheet 2.0“ anwendbar.

We hereby declare that the manufacturing process of the sealing sheet "KWO MultiTex Sheet 2.0" complies with the same technology as for the sealing sheet "KWO MultiTex Sheet". In the course of our optimization, we have only improved the technical parameters of the sealing sheet "KWO MultiTex Sheet 2.0" in order to increase the reliability of the product.
This means that the existing certificates for the “KWO MultiTex Sheet“ can also be used for the optimized product "KWO MultiTex Sheet 2.0".

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