

SUMMARY OF THE STUDY OF ISO 10993 BIOLOGICAL EVALUATION OF MEDICAL DEVICE

TEST ARTICLE:

Polypropylene Random Copolymer 5090R

TEST ARTICLE NO:

UB/2019/90096

SPONSOR

Name: Formosa Plastics Corporation

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Testing was conducted in accordance with International Standard ISO 10993. Under the conditions of the test, there was no evidence of toxic or irritant reactivity

ISO 10993-5 *In vitro* cytotoxicity Test-Agar Diffusion Test, Report Number: UB/2019/90096

In vitro cytotoxicity test by agar diffusion was performed in this study to evaluate the biological compatibility of test article “Polypropylene Random Copolymer 5090R”. Preparation of test article and treatment of mouse lung fibroblast cells (L929 cells) with test article were performed as request as client and according to ISO10993-5, ISO10993-12 and ASTM F895-11. Examined the cells microscopically using neutral red and assessed changes in cell morphology and monolayer confluency. These results showed that the test article induced none reactivity in L929 cells. Base on ISO 10993-5 guidelines, the test article was considered no cytotoxic effect.

ISO 10993-4 Hemolysis Test, Report Number: UB/2019/90096A-01

The study was performed according to the guideline ISO 10993-4 and ASTM F756. Base on the hemolytic index, the “Polypropylene Random Copolymer 5090R” was non-hemolytic in both extract test and direct contact test. (ISO 10993-4:2017)

ISO 10993-11 White Rabbit Pyrogen Test, Leon Biotech Report No.: R-PY-KL20191008

The study was performed by following USP 151, ISO 10993-11. The study results showed the response of pyrogen study was negative. Therefore, “Polypropylene Random Copolymer 5090R“ extract meet the requirements for the absence of pyrogen. (USP 151, ISO 10993-12:2017)

ISO 10993-10 White Rabbit Skin Irritation Test, Leon Biotech Report No.: R-SR-KL20191008

The study was performed by following ISO 10993-10. The results showed that there was no obvious erythema and edema finding in either the test or control of polar and non-polar group, and there was no mortality in this study. Furthermore, the primary irritation index (PII) values of polar and non-polar groups were 0 and 0 respectively. Therefore, a single topical application of polar and non-polar extract of “Polypropylene Random Copolymer 5090R” did not cause skin irritation. (OECE#404, ISO 10993-10:2010)

ISO 10993-11 Acute Systemic Toxicity Study, Leon Biotech Report No.: R-AST-KL20191008

The study was performed according to the guideline ISO10993-11 and ISO10993-12. The results showed that a single application of “Polypropylene Random Copolymer 5090R” polar and non-polar extracts induced neither observable clinical signs nor significant weight loss in mice at each observation time point. Therefore, the “Polypropylene Random Copolymer 5090R” polar and non-polar extracts did not cause systemic toxicity reaction or death after tail vein and intraperitoneal injection in mice. (OECD #423(2001), ISO 10993-11:2017)

ISO 10993-10 Skin Sensitization Study (Maximization Test), Leon Biotech Report No.: R-GPMT-KL20191008

The experiment was performed by following ISO 10993-10. The score mean of the test and control group in the polar and non-polar group at the observation period, approximately in 24±2 and 48±2 hours after challenge phase, were all less than 1.0. Neither the control nor the test group showed significant skin response on the treated area. Thus, the results indicated that the polar and non-polar extracts of “Polypropylene Random Copolymer 5090R” did not produce skin sensitization in guinea pigs.

Study Director:


Benson Liu / SGS Taiwan Ltd. 2020.01.16
Date Completed

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Date Completed