Summary of Health Data for
DOW CORNING™ QP1-50 Silicone Elastomer

SUMMARY

The test article (platinum and peroxide cured) was tested to meet USP Class VI requirements including Class V and 7-day implantation studies. Extracts of the test article did not produce effects different from controls when injected into mice and rabbits. The test article passed the USP seven day implant test.

TOXICOLOGY DATA

Biocompatibility

Intracutaneous Reactivity. The potential of the test article (platinum cured) to cause irritation following intradermal injection in rabbits was evaluated based on the USP, General Chapter <88>, Biological Reactivity Tests, *In Vivo*. The test article was extracted in 0.9% sodium chloride USP solution (SC), sesame oil, NF (SO), alcohol in saline (AS), and polyethylene glycol (PEG). Extractions conditions were 3 cm^2 of test article/mL of vehicle at 121 °C for 1 hour. A 0.2 mL dose of the appropriate test article extract was injected by the intracutaneous route into five separate sites on the right side of the back of each of two animals. Similarly, the corresponding control was injected on the left side of the back of each animal. Observations for erythema and edema were conducted at 24, 48 and 72 hours after intracutaneous injection. There was no evidence of significant irritation from the test article extracts injected intracutaneously into rabbits. Each test article extract met the USP requirements. The cumulative average scores for the SC, AS, and PEG test and control sites were 0.0. The cumulative average score was 1.1 for the SO test sites and 1.4 for the SO control sites. These results are not considered remarkable, because the difference between test article extract and corresponding control average scores did not exceed 1.0 at any observation interval. Under the conditions of this test, the acceptance criteria stated in the USP34/NF29 for a passed test were met (1).

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The potential of the test article (platinum cured) produced in Kendallville to cause irritation following intradermal injection in rabbits was evaluated based on the USP, General Chapter <88>, Biological Reactivity Tests, *In Vivo*. The test article was extracted in 0.9% sodium chloride USP solution (SC), sesame oil, NF (SO), alcohol in saline (AS) and polyethylene glycol (PEG). Extractions conditions were 3 cm^2 of test article/mL of vehicle at 121 °C for 1 hour. A 0.2 mL dose of the appropriate test article extract was injected by the intracutaneous route into five separate sites on the right side of the back of each of two animals. Similarly, the corresponding control was injected on the left side of the back of each animal. Observations for erythema and edema were conducted at 24, 48, and 72 hours after intracutaneous injection. There was no evidence of significant irritation from the extracts injected intracutaneously into rabbits. Each test article extract met the USP requirements. The cumulative average scores for the SC, AS, and PEG test and control sites were 0.0. The cumulative average score was 0.8 for the SO test sites and 0.5 for the SO control sites. These results are not considered remarkable, because the difference between test article extract and corresponding control average scores did not exceed 1.0 at any observation interval. Under the conditions of this test, the acceptance criteria stated in the USP35/NF30 for a passed test were met (3).

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Systemic Toxicity. The test article (Platinum cured) was evaluated for systemic toxicity in mice is based on the USP, General Chapter <88>, Biological Reactivity Tests, *In Vivo*. The test article was extracted in 0.9% sodium chloride (SC), sesame oil (SO), alcohol in saline solution (AS), and polyethylene glycol 400 (PEG). Extractions conditions were 3 cm^2 of test article/mL of vehicle at 121 °C for 1 hour. A single dose of the appropriate test article extract was injected into a group of five animals. Similarly, a separate group of five animals were dosed with each corresponding extraction vehicle alone (control). The animals were observed for signs of systemic toxicity immediately after injection and at 4, 24, 48 and 72 hours after injection. Body weights were recorded prior to dosing and on Day 3. There was no mortality or remarkable systemic toxicity attributable to the extracts. None of the animals treated with the test extract showed a significantly greater reaction than the control animals. Under the conditions of this test, the acceptance criteria for a passed test were met (5).

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sodium chloride (SC), sesame oil (SO), alcohol in saline solution (AS), and polyethylene glycol 400 (PEG). Extractions conditions were 3 cm^2 of test article/mL of vehicle at 121 °C for 1 hour. A single dose of the appropriate test article extract was injected into a group of five animals. Similarly, a separate group of five animals were dosed with each corresponding extraction vehicle alone (control). The animals were observed for signs of systemic toxicity immediately after injection and at 4, 24, 48 and 72 hours after injection. Body weights were recorded prior to dosing and on Day 3. There was no mortality or remarkable systemic toxicity attributable to the extracts. None of the animals treated with the test extract showed a significantly greater reaction than the control animals. Under the conditions of this test, the acceptance criteria for a passed test were met (6).

The test article (platinum cured) produced in Kendallville was evaluated for systemic toxicity in mice in accordance with the USP, General Chapter <88>, Biological Reactivity Tests, *In Vivo*. The test article was extracted in 0.9% sodium chloride (SC), sesame oil (SO), alcohol in saline solution (AS), and polyethylene glycol 400 (PEG). Extractions conditions were 3 cm^2 of test article/mL of vehicle at 121 °C for 1 hour. A single dose of the appropriate test article extract was injected into a group of five animals. Similarly, a separate group of five animals were dosed with each corresponding extraction vehicle alone (control). The animals were observed for signs of systemic toxicity immediately after injection and at 4, 24, 48 and 72 hours after injection. Body weights were recorded prior to dosing and on Day 3. There was no mortality or evidence of systemic toxicity attributable to the extracts. None of the animals treated with any test extract showed a significantly greater reaction than the associated control animals. Under the conditions of this test, the acceptance criteria for a passed test were met (7).

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Implant. The test article (platinum cured), was implanted to evaluate the local tissue response in accordance with the USP, General Chapter <88>, Biological Reactivity Tests, In Vivo. Implant test articles and negative control articles (USP high density polyethylene reference standard) were sterilized by steam. The test article and negative control article were intramuscularly implanted and animals were euthanized 7 days later. Muscle tissues were excised and the implant sites were examined macroscopically. Under the conditions of this test, the difference between the average score of the test sites and the average score of the control sites did not exceed 1.0, and no significant differences were noted during the macroscopic examination. Therefore, the test article met the USP criteria for acceptance (9).

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control articles (USP high density polyethylene reference standard) were sterilized by steam. The test article and negative control article were intramuscularly implanted and animals were euthanized 7 days later. Muscle tissues were excised and the implant sites were examined macroscopically. Under the conditions of this test, the difference between the average score of the test sites and the average score of the control sites did not exceed 1.0, and no significant differences were noted during the macroscopic examination. Therefore, the test article met the USP criteria for acceptance (10).

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