**A Bacterial Reverse Mutation Test of PROJECT C**

**SUMMARY AND CONCLUSION**

The objective of this study was to assess the potential of PROJECT C for inducibility of gene mutation.

A bacterial reverse mutation test was performed with 5 test strains of bacteria [Salmonella typhimurium (TA100, TA1535, TA98, and TA1537) and Escherichia coli (WP2uvrA)], using the pre-incubation method with and without metabolic activation. Based on the results of the dose-finding test at 4.1, 12.3, 41, 123, 410, 1230, and 4100 μg/plate, the main test was

performed at 4.69, 9.38, 18.8, 37.5, 75, and 150 μg/plate.

Test article precipitation was not observed at up to 150 μg/plate upon addition of the test article formulation with or without metabolic activation, but test article precipitation was observed at 75 μg/plate and greater and at 150 μg/plate on the plates after incubation for 48 hours without and with metabolic activation, respectively.

Growth inhibition was not observed at up to 150 μg/plate in any test strain with or without metabolic activation.

In comparison with the negative control, no 2-fold or greater increase in the number of revertant colonies was observed in any test strain with or without metabolic activation.

It was concluded that PROJECT C has no potential to induce gene mutation in bacteria under the conditions of this study.