**A Bacterial Reverse Mutation Test of Project 5**

**SUMMARY AND CONCLUSION**

In order to assess the potential of Project 5 to induce gene mutation, a bacterial reverse mutation test was performed with 5 strains of bacteria [*Salmonella typhimurium* (TA98, TA100, TA1535, and TA1537) and *Escherichia coli* (WP2*uvrA*)], using the pre-incubation method with and without metabolic activation.

The dose-finding test and the main test were performed at the following dose levels: Dose-finding test: (all strains)

With and without metabolic activation

5, 15, 50, 150, 500, 1500, and 5000 µg/plate as PROJECT 5

Main test: (all strains)

With and without metabolic activation

156, 313, 625, 1250, 2500, and 5000 µg/plate as PROJECT 5

1. In comparison with the negative control, a 2-fold or greater increase in the number of revertant colonies was not observed in any test strain in the dose-finding test or the main test, with or without metabolic activation.
2. Growth inhibition was not observed up to 5000 µg/plate in any test strain, with or without metabolic activation.
3. Test article precipitation was not observed up to 5000 µg/plate upon addition of the test article preparation with or without metabolic activation. On the plates after incubation for 48 hours, test article precipitation was observed at 1500 µg/plate and greater, with and without metabolic activation.
4. The number of revertant colonies in both the negative and positive controls was within the range (mean3S.D.) of the background data of SNBL DSR. Accordingly, it was judged that this study was performed satisfactorily.

It was concluded that Project 5 did not induce gene mutation in bacteria when tested under the conditions of this study.