**Bacterial Reverse Mutation Test of Project U**

**SUMMARY AND CONCLUSION**

The mutagenicity of the test article, Project U, was investigated by a bacterial reverse mutation test, and a negative result was obtained.

Tests were performed by the preincubation method with and without a metabolic activation system (S9 mix) using *Salmonella typhimurium*, TA100, TA1535, TA98 and TA1537, and *Escherichia coli* WP2 *uvrA* as tester strains.

A dose-finding test was carried out with the highest dose of 5000 μg/plate and using 7 doses (i.e., 5.00, 15.0, 50.0, 150, 500, 1500 and 5000 μg/plate) in all strains. As a result, growth inhibition of tester strains was not observed in any strain used with or without S9 mix. The precipitate derived from the test article was not observed on the surface of agar plates at any dose with or without S9 mix just before and just after the incubation for 48 hours.

Based on these results, the two mutagenicity tests were carried out with the highest dose of 5000 μg/plate, using 5 doses (i.e., 313, 625, 1250, 2500 and 5000 μg/plate) with a common ratio of 2 in all strains. As a result of the both mutagenicity tests, growth inhibition of tester strains was not observed in any strain used with or without S9 mix. The precipitate derived from the test article was not observed on the surface of agar plates at any dose with or without S9 mix just before and just after the incubation for 48 hours. The mean number of revertant colonies was not increased twice or more than that in the negative control in any strain used with or without S9 mix in the both mutagenicity tests.

In conclusion, the test article, Project U, has no mutagenic activity (negative) in this test system.