**Bacterial Reverse Mutation Assay with PROJECT A**

**SUMMARY AND CONCLUSION**

The test article, PROJECT A, was tested to evaluate its mutagenic potential by measuring its ability to induce reverse mutations at selected loci of several strains of *Salmonella typhimurium* and at the tryptophan locus of *Escherichia coli* strain WP2 *uvr*A in the presence and absence of an exogenous metabolic activation system. Dimethyl sulfoxide (DMSO) was used as the vehicle.

In the preliminary toxicity assay, the concentration levels tested were 6.67, 10.0, 33.3, 66.7, 100, 333, 667, 1000, 3333 and 5000 µg per plate. Precipitate was observed beginning at 333 or 667 µg per plate. No definitive background lawn toxicity was observed; however, toxicity as a reduction in revertant count was observed at 5000 µg per plate with a few conditions. Based upon these results, the maximum concentration tested in the mutagenicity assay was 5000 µg per plate.

In the mutagenicity assay, the concentration levels tested were 50.0, 150, 500, 1500 and 5000 µg per plate (see [Deviations](#_bookmark6)). Precipitate was observed beginning at 500 µg per plate with all conditions. No definitive background lawn toxicity was observed; however, toxicity, defined as a reduction in revertant count, was observed at 5000 µg per plate with one condition. No positive mutagenic responses were observed with any of the tester strains in either the presence or absence of S9 activation.

These results indicate PROJECT A did not induce reverse mutations at selected loci of several strains of *Salmonella typhimurium* or at the tryptophan locus of *Escherichia coli* strain WP2 *uvr*A in the presence and absence of an exogenous metabolic activation system.