

SUMMARY REPORT Aug 14, 2008

Bacterial Reverse Mutation Assay of PRISM IC42/46 BCMY Pigment Ink

Study Number: 08-VG-302

SPONSOR

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1. Synopsis

Objective: To evaluate the mutagenic potential of PRISM IC42/46 BCMY Pigment Ink (lot No.: PPL80624) in the bacterial reverse mutation assay system.

GLP compliance and Guideline: Conducted in accordance with the Good Laboratory Practice Standards and Test Guidelines of Notification No. 2007-29 (Dec 28, 2007) issued by Korea National Institute of Environmental Research (NIER)

Experimental period: Jul 29, 2008 - Aug 01, 2008

2. Materials and Methods

Tester strains: *Salmonella typhimurium* TA100, TA1535, TA98, TA1537 and *E. coli* WP2 *uvrA*.

Method: Direct plate incorporation, Maron and Ames (1983).

Vehicle: Sterile distilled water

Concentration range: 62, 185, 556, 1,667, 5,000 µg/plate, positive/negative controls.

Number of plates/concentration: 3

Exogenous metabolic activation system: Aroclor-1254-induced rat liver S-9 and cofactor

Criteria: It was considered as positive if there is a reproducible increase in the number of revertant colonies/plate at one or more dose levels in at least one strain with or without metabolic activation system.

3. Results

1. The number of viable cell counts of overnight cultures, estimated by optical density at 600 nm, were $1.15-1.63 \times 10^9$ CFU/ml.
2. There was neither increase in the number of colonies/plate nor antibacterial effect in all of the 5 tester strains. There were no microbial colonies due to contamination in plates for sterility check.
3. There were apparent increases in the number of colonies/plate in the positive control plates.

4. Conclusion

It was concluded that the test item, PRISM IC42/46 BCMY Pigment Ink, is not able to induce reverse mutation in the tester strains used under the present experimental conditions.

Annex 1. Result of bacterial reverse mutation assay with PRISM IC42/46 BCMY Pigment Ink

APPROVALS

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Management

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