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STUDY OUTLINE

BACTERIAL REVERSE MUTATION ASSAY
(using Salmonella typhimurium and *Escherichia coli* strains*)*

OECD 471 (adopted 21st July, 1997);

Objective:	To establish the potential of the test item to induce gene mutations in bacteria (*Salmonella typhimurium* and *Escherichia coli)* by means of reversions from auxotrophic strains to prototroph.
Tester strains:	*Salmonella typhimurium* TA98, TA1537 (for frameshift mutations); TA100, TA1535 (for base-pair substitution) and *Escherichia coli* WP2 *uvrA*/ or TA102 (for base-pair substitution).
Metabolic activation:	The experiments are performed in the presence and absence of a post mitochondrial supernatant (S9) prepared from livers of phenobarbital/β-naphthoflavone-induced rats.
Dose levels:	Maximum dose level: 5 mg/plate or 5 μL/plate, depending on the solubility and the results of the preliminary toxicity experiment. In the main test at least five dose levels are tested with approximately half log or smaller intervals.
Procedure:	In the preliminary toxicity test applies the plate incorporation method. Untreated, vehicle, positive reference controls and seven dose levels are investigated in absence and presence of S9 with *Salmonella typhimurium* TA98 and TA100 tester strains. Three parallel plates are prepared at each dose level and at each control. The first main experiment (Initial Mutation Test) applies the plate incorporation method. Untreated, vehicle, positive reference controls and at least five dose levels are investigated in absence and presence of S9 with all strains. Three parallel plates are prepared at each dose level and at each control. When the results of the Initial Mutation Test are negative or inconclusive, a Confirmatory Mutation Test will be performed using pre-incubation method. In the Confirmatory Mutation Test untreated, vehicle, positive reference controls and at least five dose levels are investigated in absence and presence of S9 with all strains. Three parallel plates are prepared at each dose level and at each control. When the results of the Initial Mutation Test are clearly positive no further experiments are considered as necessary.
Amount of test item required:	At least 1 g
Draft Report:	Approximately 6 weeks from the arrival of the test item