

STUDY OUTLINE

MOUSE MICRONUCLEUS TEST (BONE MARROW)

OECD No. 474

<i>Test system:</i>	CRL: NMRI BR mice
<i>Test item required</i>	5 g
<i>Delivery of draft report</i>	4 weeks after test item and CA arrives in laboratory

Preliminary Toxicity Test

<i>Number of animals</i>	2 animals/sex/group (~ 12-20 animals)
<i>Number of groups</i>	at least 3 dose levels of test item In the absence of differences in toxicity between the sexes, only the male animals will be used in the main experiment.

Main Experiment

<i>Number of animals</i>	35+2 males (two male additional mice will be dosed in highest group)
<i>Number of groups</i>	5 groups
<i>Routes of administration</i>	oral, iv, intraperitoneal depending on the proposed used
<i>Dose levels</i>	Non toxic item: 500, 1000 and 2000 mg/kg bw Toxic item: 25, 50 and 100% of MTD
<i>Formulation analysis</i>	depending on Sponsor's request
<i>Treatment/Sampling times</i>	once/24 (negative, positive control and 3 dose of test item) and 48 hour (negative control and high dose of test item twice/24 hours after the final treatment
<i>Number of analysed cells</i>	4000 PCE/animal immature among total (immature + mature) at least 500 erythrocytes.