



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

MEMORANDUM

JUL 13 1983

TO: Richard Mountfort, PM#23  
Registration Division (TS-767)

OFFICE OF  
PESTICIDES AND TOXIC SUBSTANCES

THRU: David Ritter, Acting Section Head  
Review Section #1  
Toxicology Branch/HED (TS-769)

*DLR 7-7-83*

SUBJECT: Thidiazuron (DROPP) 2139-122: Review and Evaluation of the revised Protocol for the Chromosome Aberrations in Human Lymphocytes with and without in-vitro Metabolic Activation (Litton Bionetics Protocol No. 449.1 - Edition 6). CASWELL#659A

Comments on Litton Bionetics responses to the deficiencies noted in the previous TB review of 4/21/83 for the protocol of human lymphocytes cytogenetics:

1. The preliminary test procedure for mitotic suppression and cell cycle delay submitted for the dose determination in this test system is acceptable. The include details with respect to the maximum dose determination are reasonable. Registrant has provided the information asked for.

2. Registrant's statement for the selection of one-hour exposure time under the in-vitro metabolic activation (S9 mix) is justified and acceptable.

3. The modification of procedures with respect to the hypotonic treatment, cell fixation, and chromosome slide preparation is adequate. Registrant's response relieves the deficiencies with respect to the lymphocyte fixation.

Recommendation:

Toxicology Branch considers the revised protocol for the in-vitro human lymphocytes cytogenetics is acceptable.

*John H.S. Chen*  
John H.S. Chen, D.V.M.  
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