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OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

SUR for REJ 12/25/12

MEMORANDUM OCT 27 ISE2

TO:

Jay Ellenberger, PM #12

Insecticide/Rodenticide Branch Registration Division (TS-767)

THRU:

R. B. Jaeger, Section Head

Review Section #1

Toxicology Branch/HED (TS-769)

SUBJECT: Carbaryl Registration Standard

Supplemental data of affects on germinal tissue

Two epidemiological studies on the gonadal affects of carbaryl on production workers were reported by Whorton et. al., 1978 (1) and Wyrobek et. al., 1981 (2). In the first study Whorton et. al., evaluated semen samples from 47 carbaryl production workers, with a mean age of 40.7 years who had spent at least one year on the job. Semen samples of this exposed group were compared to semen samples of an external control population of chemical workers that served as a control population in previous studies by this investigator. In the second study (Wyrobek 1981) the original exposed group was compared to an internal control group comprised of newly hired employees, with a mean age of 26.6 years, that had provided semen samples as part of their pre-employment medical examination at the carbaryl production plant. was noted by Whorton et. al., 1978 (1) that there is no significant association between sperm count and age in the under sixty age population group. The exposed population used in both of these studies consisted of a high exposure and low exposure groups. The high exposure group of baggers and operators were exposed to mean concentration of 4.9 mg/m3 and the low exposure group of supervisors and maintenance personnel were exposed to a mean concentration of 0.4 mg/m3. Blood levels of follicle stimulating hormone, luteinizing hormone and testosterone were determined by radioimmunoassay on the exposed and both control groups. Sperm was subject to microscopic analysis of morphological defects and frequencies of fluorescent bodies for the exposed group and second group of controls, but not for the first control group.

Whorton et. al., 1978 (1) concluded from the first study that the human immumoassays were within a normal range for the exposed group, there was no apparent relationship between sperm count and the degree or duration of exposure, and there was no evidence of inferility among workers exposed to carbaryl.

In the second study when the exposed workers were compared to the newly hired employee control group Wyrobek et. al., 1981 (2) reported a significant higher proportion of sperm abnomalities among both of the high and low exposure groups that were not dose related. Particularly the younger men, those under 40 years of age, showed this tendency. There was no significant differences in sperm count and fluorescent body asseys related to exposure as compared to the second control group. In an independant study Wyrobek et. al., 1981 found no statistically significant correlation between age and percent of abnormal sperm.

Subsequent to these findings of sperm shape abnormalities, unstained duplicate slides of the same semen specimens reported on by Wyrobek et. al., 1981 were processed and reexamined by Dr. John MacLeod (3). In his evaluation a comparison was made to a group of 1000 patients whose semen was examined between March 1976 and July 1977. From his experience in analysis of semen quality in human populations he observed that the semen quality from this control population in terms of sperm count, motility and morphology could be compared to an ideal population in their potential for conception. In such a population, depression of sperm count concentrations are seldom observed without a concomitant and often severe distrubance in the sperm morphology. comparing the original exposed group to the internal control group "there was not an obvious depresson of the sperm count in the exposed group" and "the excellent sperm morphology in the total (exposed and control) groups is consistent with unusually high sperm counts".

His preliminary evaluation of the slides lead to the conclusion "that the pattern of sperm morphology in both the control and exposed population is excellent, both being substantially better in quality than the available control population and there is not an essential difference in the distribution of the sperm types within these patterns".

When these findings were subjected to statitical analyses no significant difference in the morphological characteristics were observed to exists between the internal controls group and the exposed group when compared to the population of unexposed individuals examined by Dr. MacLeod.

Ray Landolt

ph 10/24/82

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- 3. MacLeod, J. Cornell University, Medical College Report to Union Carbide Corp. on sperm morphology analysis. Unpublished personnal communication to Union Carbide Corp., March 29, 1982.

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