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December 12, 2008

Ralph C. Northrop, PhD.
High Production Chemicals Branch
Risk Assessment Division
U.S. Environmental Protection Agency
EPA East, Room 6334T
1200 Pennsylvania Avenue, N.W. (7403M)
Washington, D.C. 20004-2403

Dear Dr. Northrop:

With reference to your inquiry of October 16, 2008, as I mentioned to you recently by telephone, the test substance cited in the Robust Summary concerning our Test Plan was misidentified as the result of a transcription error. We have enclosed a corrected copy of page 35 of that Test Plan identifying the test substance. We have struck through the incorrectly cited substance, and corrected it to be 2-Amino-5-methylbenzenesulfonic (4b Acid).

In submitting this correction CPMA continues to reserve the rights and limitations of CPMA's representation of substances in the HPV program as set forth in our letter of February 3, 2006

We hope this clarifies the error, and regret any confusion it might have caused.

Please let me know if you have any questions.

Sincerely,

J. Lawrence Robinson
President

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F. Toxicity to Reproduction

Test Substance

Test substance: ~~2-Naphthalenecarboxylic acid, 3-hydroxy-4-[(4-methyl-2-sulfophenyl)azo]-, calcium salt~~ 2-Amino-5-methylbenzenesulfonic acid

Remarks: Commercial purity 98%

Method

Method: OECD 421
GLP: Yes
Year: 1999
Species/strain: Rat
Sex: male and female
Route of exposure: gavage
Exposure levels: 0,100,300 or 1000 mg/kg

Exposure period: males 48 days including /females 41-48 days

Duration of test:
Remarks:

Results

Maternal toxicity NOEL: Parental, 1000 mg/kg/day
Parental toxic responses:
Fetal toxic responses dose:
Statistical Methods:
Remarks: No effects were observed in the copulation index, fertility index, gestation length, number of corpora lutea or implantations, implantation index, gestation index, parturition or maternal behavior. There were no significant differences in number of offspring or live offspring, sex ratio, the live birth index, the viability index and the body weight. No abnormal findings related to the test substance were noted for external features, clinical signs, or on necropsy finding for the offspring. No pups with malformation were found in any group. No change in clinical signs and necropsy finding were observed in offspring.

Conclusions

Data Quality

Reliability: Reliable without restriction
Remarks:

References

Ministry of Health & Welfare, Japan (1999): Toxicity Testing Reports of Environmental Chemicals, vol.7 p163-171, "Preliminary Reproduction Toxicity Screening Test of 2-Amino-5-methylbenzenesulfonic acid by Oral Administration in Rats".

Other