CALIFORNIA ENVIRONMENTAL PROTECTION AGENCY
DEPARTMENT OF PESTICIDE REGULATION
MEDICAL TOXICOLOGY BRANCH

SUMMARY OF TOXICOLOGY DATA

Ammonia

Chemical Code #: 22, **Tolerance #:** 53173
SB 950 # NA

Date: 5/8/12

I. DATA GAP STATUS

Chronic toxicity, rat:	Not required at this time*
Chronic toxicity, dog:	Not required at this time*
Oncogenicity, rat:	Not required at this time*
Oncogenicity, mouse:	Not required at this time*
Reproduction, rat:	Not required at this time*
Teratology, rat:	Not required at this time*
Teratology, rabbit:	Not required at this time*
Gene mutation:	Not required at this time*
Chromosome effects:	Not required at this time*
DNA damage:	Not required at this time*
Neurotoxicity:	Not required at this time*

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*Ammonia has been submitted and classified as an "antimicrobial" for purpose of toxicological data requirements by USEPA. No further studies are required at this time for study types marked with (*). Please see U. S. EPA Data Call-in Notice for Antimicrobial Pesticide Active Ingredients (January, 1987).

File name: T120508
Revised by R. Pan, 5/8/12

II. TOXICOLOGY CONCLUSIONS

Repeated dosing of ammonium sulfate for 13 weeks via diets to rats (Malish, S. L., 2011) resulted in NOEL at 886/1975 (for males/females) mg/kg/day. The only toxic sign observed was diarrhea in male animals dosed with 1792 mg/kg/day. Ammonium sulfate readily dissociates in biological system into ammonium and sulfate ions, which are body constituents. Therefore the negative results of fertility and developmental toxicity studies (Malish, S. L., 2011)) conducted with ammonium salts were used for assessment of its fertility and developmental toxicity. In a similar manner, the *in vitro* genotoxicity study (Malish, S. L., 2011)) conducted with ammonium sulfate and the *in vivo* genotoxicity study (Malish, S. L., 2011)) on ammonium chloride indicates that mutagenicity activity of ammonium sulfate is unlikely.

Based on its natural occurrence, being a body constituent, history of safe use as a direct food additive, and its absence of adverse effects in test animals at high doses, the hazard associated with human exposure to ammonium sulfate is deemed to be minimal. Therefore additional toxicity data are not considered to be needed in order to adequately assess the potential hazards associated with its use as an antimicrobial pesticide.

Reference: Malish, S. L., 4/19/2011, U.S.EPA, Office of Prevention, Pesticide and Toxic Substances. Hazard Assessment of Ammonium Sulfate (Part 1) and Monochloramine (Part 2).