

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

JAN 18 2005



Office of Pesticide Programs

MEMORANDUM

SUBJECT: Summary Comments RE: Risk Assessment and Science Support Branch's (RASSB's) Reviews of Product 53735-RR, "Pool Frog Mineral Reservoir", Containing Silver Chloride (072506)

FROM: Norm Cook, Chief *N. Cook 1/18/05*
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DP

BARCODE: None

**PESTICIDE
CHEMICAL**

NO.: 072506

Introduction

Product Manager (PM) Team-33 submitted the product, 53735-RR, "Pool Frog Mineral Reservoir", containing silver chloride (072506) for RASSB review. Silver chloride has been identified by PM Team-33 as a new active ingredient and RASSB has completed its reviews with this in mind. The reviews RASSB has completed, and attached to this memo, are:

Chemistry (D307225),
Human exposure and risk (D307255), and
The 12/8/04 interim memo re: silver toxicology end-points (no barcode).

However, this memo also discusses two other areas: the silver ADTC memo of October, 2004, (copy attached) and those environmental data required for product labeling purposes (as outlined in the Silver RED document).

RASSB Summary Comments

Chemistry (D307225)

RASSB's review of chemistry issues for this product (D307225) concluded that chemistry considerations for this registration submission were not adequately addressed. Three major issues were identified in this review:

1. An MSDS from the registrant, King Technology, Inc., for their product listed the chemical family of the product as "Calcium Carbonate with Silver and Zinc compound". RASSB is unclear as to what this statement means and how it relates to the product under review. The registrant needs to provide clarification concerning this;
2. The label does not indicate the size of pool that can be treated with the product. However, the "Frog Mineral Reservoir Patented Mineral Pool Sanitizer Instruction Manual" states the product purifies up to 30,000 gallons. The registrant needs to supply us with information explaining how the level of silver in pool water in various sized pools is controlled and how the desired level of silver in pool water is maintained. Presumably, the solubility of silver and silver chloride which are expected to form in the swimming pool is the controlling factor; and
3. It is unclear to us what the active ingredient in the pool water will be from use of this product. It would seem that any silver ion that goes into solution in the pool water would immediately become silver chloride. The registrant needs to explain what the mechanism of action is for the efficacy of the "Frog Mineral Reservoir" containing silver chloride as the active ingredient. Is (are) the active ingredient(s) silver and silver chloride?

For a full discussion of chemistry issues please see the attached RASSB review for this proposed use pattern.

Human Exposure and Risk (D307255)

In RASSB's review of human exposure and risk (D307255), we concluded that:

1. The proposed swimming pool use pattern for the "Pool Frog Mineral Reservoir", containing 0.37% silver chloride, provides for negligible residential exposure potential via the dermal and inhalation routes for handlers involved in the application of the product; and, furthermore,
2. The calculated Margins of Exposure (MOEs) for short- and long-term post-application incidental oral route do not exceed the Agency's level of concern for the intended use patterns and conditions. (It should be noted that the intermediate-term duration of exposure was not necessary to assess since all of the endpoints were based on the same

toxicological database and the short- and long-term exposures provide an upper and lower bounding estimate where the intermediate-term exposure would fall somewhere within this range.)

For a full discussion of exposure and risk estimates please see the attached RASSB review for this proposed use pattern.

Toxicology

In completing its review of human exposure and risk RASSB relied on two toxicology documents:

The 12/8/04 interim memo re: silver toxicology end-points (no barcode); and
The 10/20/04 silver ADTC memo.

The 12/8/04 memo, "Interim Position for Toxicological End-points for Silver", is the memo that RASSB utilizes for assessing human risks from silver uses once exposure estimates are developed. As indicated, this is an interim memo which provides conservative end-points that RASSB can utilize to complete its reviews. However, AD toxicologists have concluded that useful toxicology data for establishing end-points and performing risk assessments for silver salts and/or silver compounds other than silver salts (e.g., silver zeolites) are lacking. A full toxicology data set for silver salts, including silver chloride, is required in order for RASSB to complete assessments for high exposure uses such as swimming pools. These data, which can be performed with silver chloride, or silver nitrate, as Technical Grade Active Ingredient (TGAI), are:

- Acute toxicity [six pack];
- Ninety (90) day subchronic toxicity in rodents with neurotoxicity endpoint evaluation;
- Ninety (90) day subchronic toxicity in non-rodents with neurotoxicity endpoint evaluation;
- Developmental toxicity study in rats;
- Developmental toxicity study in rabbits;
- Two (2) generation reproduction toxicity study in rats;
- Chronic toxicity in non-rodent species;
- Chronic toxicity (two species, rat and mouse preferred);
- Carcinogenicity (two species, rat and mouse preferred); and
- Mutagenicity testing battery.

The registrant for silver chloride should be notified of the above data requirements (which would be requirements conditional to the registration since RASSB has concluded that minimal risks are likely).

For a full discussion of the toxicology issues and data requirements related to silver products please see the attached toxicology memos discussed above.

Environmental Data/Labeling

Environmental Fate

The silver RED waived most environmental fate data for silver because there is a large database for silver. However, the RED stated that registrants needed to clarify "...the nature of the concentrate used in swimming pools, due to concern about the potential formation of water soluble or colloidal species that swimmers may ingest." We note that this comment is similar to our issue 3 shown above under Chemistry.

Other than the issue raised in the paragraph above no further environmental fate data are required at this time.

Ecological Effects

The silver RED indicated that avian toxicity data are lacking. These data are outlined as a data gap in the RED and are required in order to adequately label silver products. Considering this, the following data are required for silver chloride, as TGAI:¹

850.2100: Avian oral LD50 (preferably mallard or bobwhite)

In closing, the above represents RASSB's summary comments for the various reviews completed for silver chloride as proposed for use in swimming pools. Again, for a full discussion of each science area the original reviews should be consulted. However, if you have questions on this review, please contact Norm Cook of RASSB.

¹ These data may be made a condition to the registration.