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

OFFICE OF PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

January 10, 2005

MEMORANDUM

SUBJECT:

Human Exposure Considerations:
Residential Exposure and Risk Assessments for
Pool Frog Mineral Reservoir,
Containing Silver Chloride

TO:

Marshall Swindell, Product Manager Team 33
Regulatory Management Branch I
Antimicrobials Division (7510C)

FROM:

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THRU:

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DP Barcode:

D307255

Pesticide Chemical No.: 072506

EPA File Symbol: 53735-RR

Action Requested: Residential exposure and risk assessments in support of a proposed new active ingredient registration for silver chloride (0.37%) used in King Technology Inc.'s Pool Frog Mineral Reservoir.

Summary of Findings: Based on the proposed swimming pool use pattern for the King Technology Inc.'s Pool Frog Mineral Reservoir containing 0.37% silver chloride, RASSB anticipates negligible residential exposure potential via the dermal and inhalation routes for handlers involved in the application of the product. Furthermore, RASSB concludes from the results of this exposure and risk assessment that the calculated Margins of Exposure (MOEs)

for short- and long-term postapplication 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.

Background:

The Antimicrobials Division (AD), Regulatory Management Branch I, received an application for new active ingredient registration of silver chloride in a Pool Frog Mineral Reservoir. The Pool Frog product is to be marketed to the pool industry as a pool sanitizer to control bacteria when used in conjunction with a chlorine source and to reduce standard chlorine use up to 50% - 80%. The proposed product contains 0.37% silver chloride as the active ingredient which is coated on calcium carbonate beads and packaged in a self contained "mineral reservoir".

Human Exposure Considerations:

The Risk Assessment and Science Support Branch (RASSB) assessed potential handler and postapplication exposures associated with the proposed pool use patterns. Based on a review of the submitted labeling and administrative materials, RASSB conducted non-dietary handler and postapplication exposure and risk assessments for the proposed Pool Frog Mineral Reservoir product.

Product Use Profile:

The draft label states that the Frog Mineral Reservoir should be replaced after six months. It also specifies directions for two types of treatment applications. One set is for use with chlorine Bac Pac EPA Reg. No. 53735-2 (for Cartridge System) and the second set is for use with an alternate source of chlorine using an EPA registered source of chlorine. An overview of the actual use directions is provided below:

Directions for use with chlorine BacPac:

"Before inserting the Frog Mineral Reservoir, balance the pH to between 7.2 and 7.8 and total alkalinity between 60 and 120 ppm and shock the pool with a chlorine shock per the manufacturer's directions. Then follow the directions below:

- 1. Turn circulation pump off, turn control dial to Pac Removal setting, unscrew knob on side of Cyclor to drain water and remove cap from Cyclor.*
- 2. Line up slot on the side of the Frog Mineral reservoir with the fin inside the Cyclor and lower into the Cyclor.*

3. If using the chlorine Bac Pac, insert into the center of this product according to the directions on its label then replace the cap and knob on the Cyclor and turn pump back on. Set the control dial on the Cyclor per the size of the pump run time of your pool according to the chart in the manual."

Directions for use with alternative source of chlorine:

"If using an alternative EPA registered source of chlorine, follow steps 1 and 2 above then replace the Cyclor cap and knob, set the control dial to "maximum" and turn pump back on. Maintain recommended chlorine levels of at least 0.25 ppm in the pool."

Residential Handler Exposure Scenarios:

Based on the use patterns and conditions specified on the Frog Mineral Reservoir product label, RASSB anticipates that the dermal and inhalation exposures to handlers will be negligible. The dermal exposures are considered to be negligible due to the fact the silver chloride is coated on to calcium carbonate beads which are packaged in a self contained "reservoir" and therefore, the handler will not actually touch the silver chloride. Furthermore, the inhalation exposures are considered to be negligible due to the extremely low vapor pressure of silver chloride. Furthermore, the product has a low use frequency (i.e., typically one treatment every six months) and short application exposure time (i.e., placing the product in the pool is performed in only a few minutes). Therefore, a quantitative assessment for the handlers was not conducted.

Residential Postapplication Exposure Scenarios:

RASSB assumed that once the Frog Mineral Reservoir was added into the pool water that the silver chloride dissociates therefore, postapplication swimmers would be exposed to silver ions. Based on the use patterns of the Frog Mineral Reservoir product and physical properties of inorganic ions, RASSB anticipates that there is only potential for incidental ingestion exposure for swimmers using the pool after application of the product. RASSB anticipates that the dermal exposure is not necessary to assess because silver ions tend to bind to the skin and **not** penetrate causing systemic effects.¹

Selection of Toxicological Endpoints for the Exposure Assessment:

The silver endpoints were chosen based on the ^{12/8/04} ~~November 11, 2004~~ evaluation of the toxicology database by RASSB¹ and were used to determine the incidental oral risks associated with short- and long-term postapplication exposures to the silver ion active ingredient in the Frog Mineral Pool Reservoir formulation. Based on the Agency's current database for silver, the relevant toxicological effects were taken into account.

¹ Refer to "Memorandum Interim Position for Toxicological End-points for Silver" written by Jonathan Chen and Steve Malish, dated ~~11/02/04~~ ^{12/8/04}

The toxicological endpoint for silver ion (used for silver salts) selected for the residential incidental oral exposure assessment was based on the Office of Water's drinking water Secondary Maximum Contaminant Level (SMCL) of 0.1 mg/L which, was converted to a corresponding dose of 0.003 mg/kg/day assuming a human body weight of 70 kg and water consumption of 2 L/day.² Furthermore, since the SMCL was based on human data but RASSB determined that it is necessary to apply an extra 3-fold uncertainty factor due to ..., the Target MOE for silver ion oral exposure is 3.²

Postapplication Residential Exposure and Risk Assessments:

For the postapplication residential scenario previously identified, AD/RASSB conducted an exposure assessment using EPA's Swimmer Exposure Assessment Model (SWIMODEL) and residue data provided by the registrant. Based on the intended use patterns of the product, the potential incidental oral exposures were characterized for competitive and non-competitive adult and child swimmers as short-term (i.e., 1 - 30 days/year) and long-term duration exposures.

SWIMODEL Exposures:

The SWIMODEL was developed by EPA as a screening tool to conduct exposure assessments of pesticides found in swimming pools and spas. The SWIMODEL uses well-accepted screening exposure assessment equations to calculate the total worst-case exposure for swimmers expressed as a mass-based intake value (mg/event). The model focuses on potential chemical intakes only and does not take into account metabolism or excretion of the chemical of concern. Detailed information and the downloadable executable file are available at <http://www.epa.gov/oppad001/swimodel.htm>.

Although, the actual model was not used in this assessment, the same equations and default parameters as provided in the SWIMODEL User's Manual (version 3.0)³ were used in a spreadsheet format to estimate postapplication incidental oral exposure and risk to silver ions.

The short-term potential daily dose for incidental oral exposure was calculated using the following equation:

$$PDR = \frac{C_w \times I_g \times ET}{BW}$$

² Refer to "Memorandum Interim Position for Toxicological End-points for Silver" written by Jonathan Chen and Steve Malish, dated 11/02/04.

³ Refer to *User's Manual Swimmer Exposure Assessment Model (SWIMODEL) Version 3.0*. Prepared for US EPA Antimicrobials Division. Prepared by Versar, Inc. November 2003.

where,

PDR (mg/kg/day)	=	Potential dose rate
Cw (mg/L)	=	Concentration of ai in pool water
I _g (L/hr)	=	Ingestion rate of pool water
ET (hr/day)	=	Exposure time
BW (kg)	=	Body weight

The concentration of silver ion in the pool water was the maximum level detected in data provided by the registrant (MRID 46124001).^{4,5} Table 1 presents the input parameters and resulting short-term oral exposures for competitive and noncompetitive swimmers after application of the Frog Mineral Reservoir pool product.

The long-term potential daily dose for incidental oral exposure was calculated using the following equation:

$$ADD = \frac{Cw \times I_g \times ET \times EF \times ED}{BW \times AT \times 365 \text{ (day/yr)}}$$

where,

ADD (mg/kg/day)	=	Average Daily Dose
Cw (mg/L)	=	Concentration of ai in pool water
I _g (L/hr)	=	Ingestion rate of pool water
ET (hr/event)	=	Exposure time
EF (events/yr)	=	Exposure frequency
ED (yr)	=	Exposure duration
BW (kg)	=	Body weight
AT (yr)	=	Averaging time

The concentration of silver ion in the pool water was the maximum level detected in data provided by the registrant (MRID 46124001). Table 2 presents the input parameters and resulting long-term oral exposures for competitive and noncompetitive swimmers after application of the Frog Mineral Reservoir pool product.

Non Cancer Risks:

The calculations of the daily oral doses received by swimmers in pools treated with the Frog Mineral Reservoir pool product are used to estimate the oral risks. Short- and long-term MOEs were calculated for both competitive and noncompetitive incidental oral exposure routes. The target MOE is 3 for both short- and long-term risks.

⁴ Hill, H; Brookman, D; Weulander, N. 2003. Frog Mineral Reservoir – 2002 Field In-Use Test. Unpublished study prepared by Microbac Laboratories, Inc. MRID 46124001.

⁵ Refer to Memorandum “Review of the King Technology Inc. Registration for the New Chemical, Silver Chloride, for its Use in Swimming Pools” prepared by Bob Quick (RASSB), dated January 6, 2005.

The following equation was used to calculate the MOEs:

$$\text{Oral MOE} = \text{Oral NOAEL (mg/kg/day)} / \text{Daily Oral Dose (mg/kg/day)}$$

Tables 1 and 2 present the calculated short- and long-term MOEs for swimmers after treatment with the Frog Mineral Reservoir pool sanitizer product, respectively.

Table 1. Short-term Exposures and MOEs for Competitive and Noncompetitive Swimmers after a Frog Mineral Reservoir Pool Sanitizer Treatment Containing 0.37% Silver Chloride

$PDR = Cw \times IgR \times ET/BW$		Competitive	Noncomp	Source
Concentration of ai in pool water (mg/L)	<i>CW</i>	0.028	0.028	King Tech Data
Ingestion Rate of pool water (L/hr)	<i>IgR</i>			
adult				
child		0.0125	0.025	SWIMMODEL 2003
Exposure Time (hr/day)	<i>ET</i>	0.05	0.05	SWIMMODEL 2003
adult				
child		3	5	SWIMMODEL 2003
Body weight (kg)	<i>BW</i>	1	5	SWIMMODEL 2003
All adults				SWIMMODEL 2003
Female adults		70	70	EFH
Children (7-10 yrs of age)		60	60	EFH
		30	30	EFH
Adult dose (mg/kg/day)	<i>PDR</i>	0.00002	0.000050	
Female adult dose (mg/kg/day)	<i>PDR</i>	0.00002	0.000058	
Child dose (mg/kg/day)	<i>PDR</i>	0.00005	0.00023	
NOAEL mg/kg/day	0.003			
Adult MOE		200	60	
Female adult MOE		170	51	
Child MOE		64	13	

Note: EFH = EPA's Exposure Factors Handbook

Table 2. Long-term Exposures and MOEs for Competitive and Noncompetitive Swimmers after a Frog Mineral Reservoir Pool Sanitizer Treatment Containing 0.37% Silver Chloride

$ADD = CW \times IgR \times ET \times EF \times ED / BW \times AT \times 365 \text{ d/yr}$		Competitive	Noncomp	Source
Concentration of ai in pool water (mg/L)	<i>CW</i>	0.028	0.028	King Tech Data
Ingestion Rate of pool water (L/hr)	<i>IgR</i>	0.0125	0.025	SWIMMODEL 2003
adult				SWIMMODEL 2003
child				
Exposure Time (hr/event)	<i>ET</i>	0.05	0.05	SWIMMODEL 2003
adult				SWIMMODEL 2003
child				
Exposure Frequency	<i>EF</i>	1.83	1.3	SWIMMODEL 2003
adult (event/yr)		1	2.3	SWIMMODEL 2003
child (events/yr)				
Exposure Duration	<i>ED</i>	238	120	SWIMMODEL 2003
adult (yr)		65	120	SWIMMODEL 2003
child (yr)				
Averaging Time	<i>AT</i>	22	30	SWIMMODEL 2003
adult (yr)		4	4	SWIMMODEL 2003
child (yr)				
Body weight (kg)	<i>BW</i>	22	30	SWIMMODEL 2003
All adults		4	4	SWIMMODEL 2003
Female adults				
Children (7-10yrs of age)		70	70	EFH
		60	60	EFH
		30	30	EFH
Adult dose (mg/kg/day)	<i>ADD</i>	0.0000060	0.00000427	
Female adult dose (mg/kg/day)	<i>ADD</i>	0.0000070	0.00000499	
Child dose (mg/kg/day)	<i>ADD</i>	0.0000083	0.0000353	
NOAEL mg/kg/day	0.003			
Adult MOE		500	700	
Female adult MOE		430	600	
Child MOE		360	85	

Discussion of Exposure Assessment Findings and Risk Determination:

Although, a quantitative assessment for the handlers was not conducted, there appears to be reasonable certainty of no harm for short-term dermal and inhalation exposures to handlers of the Frog Mineral Reservoir pool product while placing the reservoir in the pool. RASSB anticipates that the dermal and inhalation exposures to handlers will be negligible. The dermal exposures are considered to be negligible due to the fact the silver chloride coated beads are packaged in a self contained "reservoir" and the handler will not actually touch the silver chloride. Furthermore, the inhalation exposures are considered to be negligible due to the extremely low vapor pressure of silver chloride.

Based on the results of this exposure and risk assessment, there appears to be reasonable certainty of no harm for short- and long-term incidental oral exposures to competitive and noncompetitive swimmers after a pool treatment of the Frog Mineral Reservoir product. The oral MOEs were well above the Agency's target MOE of 3. The short-term competitive and noncompetitive adult oral MOEs for swimming in a pool treated with the Frog Mineral Reservoir product were 200 and 60, respectively; while the short-term oral MOEs for the competitive and noncompetitive adult (7-10 yrs) swimmer were 64 and 13, respectively. The long-term competitive and noncompetitive adult oral MOEs for swimming in a pool treated with the Frog Mineral Reservoir product were 500 and 360, respectively; while the long-term oral MOEs for the competitive and noncompetitive child (7-10 yrs) swimmer were 700 and 85, respectively. These MOEs were well above 3 and therefore exceeded the Agency's target MOE. All of the results from this assessment support the proposed new active ingredient when used in the Pool Frog Reservoir product.

CONCLUSIONS:

AD/RASSB concludes based on the findings of this residential handler and postapplication exposure and risk assessment that the calculated MOEs for short- and long-term incidental oral exposures do not exceed the Agency's level of concern for the intended use patterns and conditions.

There is reasonable certainty of no harm to handlers while placing the Frog Mineral Reservoir in the pool as proposed. The factors which contribute to the virtually negligible potential for adverse dermal and inhalation exposures include: low use frequency (i.e., typically one treatment every six weeks), short application exposure time (i.e., the mixing/loading/application tasks are performed in only a few minutes), the use of a self contained reservoir which eliminates dermal exposure potential to the product, and the low volatility of silver chloride. Furthermore, there is reasonable certainty of no harm for competitive and noncompetitive adult and child swimmers using a pool that has been treated with the Frog Mineral Reservoir pool product.