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OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

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Memorandum

SUBJECT: Metam Sodium: Occupational and Residential Exposure Assessment of Antimicrobial Uses for the Reregistration Eligibility Decision Document. PC Code 039003 (Metam Sodium) and 068103 (MITC).

FROM: Tim Leighton, Environmental Scientist
Antimicrobials Division

Through: Tim McMahon, Senior Toxicologist
Winston Dang, Senior Scientist
Antimicrobials Division

TO: Carol Christensen, Risk Assessor
Health Effects Division

Veronique LaCapra, Chemical Review Manager
Special Review & Reregistration Division

Attached is a review of the non dietary antimicrobial uses of metam sodium (excluding metam potassium). The four antimicrobial uses of metam sodium include (1) a remedial treatment of wooden poles/timbers, (2) a treatment to brine-cured hides and skins (leather) during processing, (3) a treatment during the production of sugar (raw cane and beet sugars), and (4) a treatment for sewage sludge.

EXECUTIVE SUMMARY

The Antimicrobials Division (AD) assessed the occupational antimicrobial uses of metam sodium using the toxicological data from the Health Effects Division (HED). For a complete review of the metam sodium risk assessment and discussion on the degradates, the reader is referred to the HED risk assessment chapter (D284260). The results of the occupational assessment of the antimicrobial uses (i.e., poles, leather, sugar, sewage sludge) indicate that the metam sodium non-cancer dermal and inhalation risks to the handlers are not of concern (i.e., all MOEs greater than 100). The cancer risks

for the handlers are in the range of 1.1E-4 to 6.8E-6. Because of the short loading and/or application durations (i.e., minutes), handlers are not expected to be exposed to the degradate, methylisothiocyanate (MITC). Occupational postapplication and potential bystander (i.e., residents) exposure to MITC after the pole treatment is considered negligible. The postapplication exposure for the pole treatment is considered negligible because after the treatment of metam sodium into predrilled holes, the holes are capped immediately. Any migration of MITC through the wooden cap into the ambient conditions is negligible. However, AD has concerns for the potential postapplication inhalation exposure to MITC after metam sodium applications in the leather and/or sugar processing industries and also to workers in the vicinity of sewage sludge treatments. However, no data are available to estimate the air concentrations at these types of processing facilities. AD recommends that air concentrations of MITC be monitored in leather processing facilities, sugar cane/beet processing facilities, and in the vicinity of sewage sludge treatments.

1. Introduction

The Health Effects Division (HED) has prepared the risk assessment for the Agricultural uses of metam sodium and its degradate, methylisothiocyanate (MITC). The reader is referred to the HED risk assessment for an in depth analysis of the toxicological and residue chemistry of metam sodium and its degradates. This memorandum includes a risk assessment of the occupational exposures and risks for the antimicrobial uses of metam sodium (metam potassium to be assessed at a later date). The antimicrobial uses assessed in this memorandum include: (1) a remedial treatment of wooden poles/timbers, (2) a treatment used during leather processing (i.e., brine-cured hides and skins), (3) a treatment used during the production of sugar (raw cane and beet sugars), and (4) a treatment of sewage sludge. Metam sodium is used to treat internal decay in wooden distribution and transmission poles (as well as other timbers). In leather processing, metam sodium is used to prevent bacterial decomposition of brine-cured hides and skins. Metam sodium is also used as a broad-spectrum microbicide to control bacteria and fungi during the manufacture of raw cane and beet sugar. Finally, metam sodium is applied to sewage sludge to reduce the number of pathogens (e.g., fecal coliform and Salmonella species) and odor in both indoor and outdoor processing systems.

No data have been submitted in support of the metam sodium antimicrobial uses. Therefore, a screening-level assessment has been provided using surrogate data from the Pesticide Handlers Exposure Database (PHED) and data from the Chemical Manufacturers Association (CMA). Use information was provided in telephone calls from the registrants. No data are available to address the potential postapplication inhalation exposure to MITC. However, the only potential exposure scenario for bystanders (i.e., residents) results from the pole treatment. The bystander exposure during pole treatments is considered negligible because of the application technique, minimal application rate, and ambient conditions.

2.0 Toxicological Endpoints of Concern

For a complete review of the toxicological endpoints selected for metam sodium and MITC see the HED *Hazard Identification Assessment Review Committee* (HIARC) report, dated April 2, 2004 (TXR 0052467). Tables 1 and 2 below are identical to those presented in the HIARC report.

Table 1: Summary of Toxicology Endpoint Selection for *Metam Sodium (PC Code 39003)* and *Metam Potassium (PC Code 39002)*

Exposure Scenario	Dose Used in Risk Assessment	Uncertainty Factors and Level of Concern for Risk Assessment	Study and Toxicologial Effects
Acute Dietary general population including infants and children	Acute dietary endpoints were not selected since the use-pattern does not indicate potential for dietary exposure.		
Chronic Dietary all populations	Chronic dietary endpoints were not selected since the use-pattern does not indicate potential for dietary exposure.		
Incidental Oral Short- and Intermediate-Term (1 - 30 Days; 1-6 Months) Residential Only	Short- and intermediate term incidental oral endpoints were not selected since the use-pattern does not indicate potential for this exposure scenario.		
Dermal Short-Term (1 - 30 days) Residential and Occupational	Maternal NOAEL[a,d]= 4.22 mg/kg/day Dermal absorption factor = 2.5%	**Residential** LOC for MOE[b] = N/A[e] **Occupational** = LOC[c] for MOE = 100	**Developmental toxicity in rat (MRID 41577101)** LOAEL[f] = 16.88 mg/kg/day based on reduced body weight gain and decreased food efficiency in maternal rats
Dermal Intermediate-Term (1 - 6 Months) Residential and Occupational	Oral NOAEL[a]= 0.1 mg/kg/day Dermal absorption factor = 2.5%	**Residential** LOC for MOE = N/A **Occupational** = LOC for MOE = 100	**Chronic toxicity in dog (MRID 43275801)** LOAEL = 1 mg/kg/day based on increased ALT and microscopic changes in the liver in females.

Exposure Scenario	Dose Used in Risk Assessment	Uncertainty Factors and Level of Concern for Risk Assessment	Study and Toxicologial Effects
Dermal Long-Term (> 6 Months) Residential and Occupational	Oral NOAEL[a]= 0.1 mg/kg/day Dermal absorption factor = 2.5%	**Residential** LOC for MOE = N/A **Occupational** = LOC for MOE = 100	**Chronic toxicity in dog (MRID 43275801)** LOAEL = 1 mg/kg/day based on based on increased ALT and microscopic changes in the liver in females.
Inhalation Short-, Intermediate, and Long-Term (1 - 30 days, 1-6 Months, and > 6 Months) Residential and Occupational	Inhalation NOAEL= 6.5 mg/m^3 (1.11 mg/kg/day)	**Residential** LOC for MOE = N/A **Occupational** = LOC for MOE = 100	**90-day inhalation study (MRID 00162041)** LOAEL =45 mg/m^3 (7.71 mg/kg/day) in females based on histopathological changes in the naval passages (ie, mucigenic hyperplasia) and changes in clinical chemistry.
Cancer	**Classification:** Probable human carcinogen (B2) **Q1* =** 1.98x10^{-1} in human equivalents converted from animals		

a Since an oral NOAEL was selected, a dermal absorption factor of 2.5% should be used in route-to-route extrapolation.; b Margin of Exposure (MOE) = 100 [10x for interspecies extrapolation and 10x for intraspecies variations.]; c LOC = level of concern; d NOAEL = no observed adverse effect level; e NA = Not Applicable; f LOAEL = lowest observed adverse effect level.

Table 2 Summary of Toxicology Endpoint Selection for Methyl isothiocyanate MITC (PC Code 068103)

Exposure Scenario	Dose Used in Risk Assessment	Uncertainty Factors and Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute Dietary General population including infants and children	Dietary exposure is not expected for MITC at present time.		
Chronic Dietary (All populations)	Dietary exposure is not expected for MITC at present time.		
Incidental Oral Short-Term (1 - 30 Days)	Incidental oral exposure is not expected for MITC		

Exposure Scenario	Dose Used in Risk Assessment	Uncertainty Factors and Level of Concern for Risk Assessment	Study and Toxicological Effects
Incidental Oral Intermediate-Term (1 - 6 Months)	Incidental oral exposure is not expected for MITC		
Dermal Short-Term (1 - 30 days), Intermediate-Term (1 - 6 Months) Long-Term (> 6 Months)	No dermal hazard via typical dermal contact with MITC is expected. Unprotected skin could exposed to MITC vapor; however this exposure can not, at this time, be quantified.		
Inhalation Short-Term (1 - 30 days) Intermediate-Term (1 - 6 Months) Long-Term (>6 Months)	Inhalation NOAEL[c]= 5.4 mg/kg/day	**Residential** LOC for MOE = 100[a] **Occupational** LOC[b] for MOE = 100[a]	**Subchronic inhalation toxicity- rat with *MITC* (MRID 45314802)** LOAEL[d] = 27 mg/kg/day based on persistent clinical signs, body weight changes, and gross and histopathological lesions
Cancer	**Classification:** Based on lack of appropriate data, assumed to be probable human carcinogen (B2) from metam sodium Q1* =3.54 x10^{-1} in human equivalents converted from animals		

a Margin of Exposure (MOE) or Uncertainty Factors (UF) = 100 [10x for interspecies extrapolation, 10x for intraspecies variations.]; b LOC = level of concern; c NOAEL = no observed adverse effect level; d LOAEL = lowest observed adverse effect level.

3.0 Handler Assessment

All of the metam sodium antimicrobial uses are for occupational applications. There are no residential use patterns for metam sodium. Metam sodium is used to (1) treat wooden timbers/poles, (2) treat skins and hides during leather processing, (3) treat sugar cane and beet juice during sugar production, and (4) treat sewage sludge.

3.1 Pole Treatment

Metam sodium is used to control "*...internal decay present in poles, piling and similar large timber members"* (EPA Reg. No. 3008-33). The product, Woodfume, is packaged in 5 gallon containers and contains 3.18 lbs ai per gallon (32.7% sodium methyldithiocarbamate). Specific label directions indicate that Woodfume is applied to poles based on the size of the pole. The label specifies an application rate of 1 pint of product per pole with a circumference of 22 to 39 inches (distribution pole) and 2 pints of product per pole with a circumference of 40 to 65 inches (transmission pole).

Metam sodium is injected into predrilled holes 45 degrees downward. The holes are drilled approximately 6 to 8 inches apart at 90 degrees. After application, each hole is capped with a treated wooden plug. The only personal protective equipment (PPE) listed on the label is to wear safety goggles when capping the hole to avoid splashing. However, Bob Butera (Osmose) indicated that chemical resistant gloves (and other PPE) are worn by the workers/inspectors.

The potential for occupational exposure is based on the loading and application of the product using a hand-held pressurized pump/injector. Chemical-specific exposure data were not submitted to support the pole use. Therefore, the Antimicrobials Division has developed a screening-level assessment using surrogate data to determine the potential risks associated with pole treatment. In addition, the number of poles treated per day with metam sodium were determined by contacting Bob Butera of Osmose. Bob Butera indicated the following use information for metam sodium treatments:

- Distribution Poles - the smaller diameter wooden distribution poles (~140 million distribution poles in service) are treated at a high end rate of ~10 per day. Typical daily treatments ranges from 0 to 10 poles (5 per day is used in the cancer assessment as a typical estimate). Workers treat these types of poles as their main work function, treating 5 days per week, on a yearly basis (i.e., 250 days/year).

- Transmission Poles - the larger wooden transmission lines are treated by an individual inspector for approximately 3 months of the year before that individual moves to other maintenance operations. Approximately 20 poles are treated per day at the high end and approximately 10 poles are typically treated per day over the 3 month period (i.e., 60 days/year).

Although EPA does not have a specific surrogate exposure scenario for injection of pesticides into wooden poles, similar exposure data for hand-held application equipment are available. The exposure data for hand-held applications that are available to EPA include data from the Pesticide Handlers Exposure Database (PHED) and the Outdoor Residential Exposure Task Force (ORETF). The data available from these sources are for garden hose-end sprayers, low pressure hand-wands, backpack sprayers, high pressure handwands, and rod shank termiticide applications. The most representative data available for an injection-type hand-held devise is the rod shank termiticide application from PHED. Other equipment types are not believed to be as representative because each one involves a spray and the injection into the pole will minimize spray.

The rod shank termiticide injection data in PHED are used to develop a screening-level assessment for the pole use. The dermal unit exposure (UE) for combined liquid pour and termiticide injection is based on 17 replicates with the test subjects wearing a single layer of clothing and chemical resistant gloves with AB grades (i.e., guideline recommendations for analytical quality). The dermal UE is 0.36 mg/lb ai. The inhalation UE is based on the same 17 replicates and the grades are also AB. The inhalation UE is 0.0022 mg/lb ai. Although the label does not specify the use of chemical resistant gloves, the “gloved” clothing scenario is the only one available to assess risks.

Table 3 presents the potential non-cancer dermal and inhalation risks for the pole treatment use of metam sodium. Exposure to MITC during injection of metam sodium into drilled holes is not expected (i.e., insufficient time to convert to MITC). The amount of metam sodium applied to each pole varies and is based on the size of the pole. The two application rates listed on the label are presented in Table 3. The maximum number of poles treated on a daily basis is used for the short-term durations. The typical number of poles treated daily are presented for the intermediate- and long-term (IT/LT) durations. Workers treating the distribution poles are believed to represent a long-term exposure duration (i.e., greater than 6 months). The treatment of transmission poles is believed to be captured by the intermediate-term duration (i.e. 1 to 6 months).

Table 3. Potential Metam Sodium Non-cancer Risks During Treatment of Poles.

Unit Exposures (mg/lb ai) [a]		Application Rate [b] (lb ai/pole)	Number of Poles Treated [c]	Daily Dose (mg/kg/day)		MOEs [f]		
Dermal	Inhalation			Absorbed Dermal [d]	Potential Inhalation [e]	Dermal		Inhalation
						ST	IT/LT	
0.36	0.0022	0.4 (Distribution Poles)	10 max	0.0006	0.00015	7,000	170	7,600
			5 typical	0.0003	7.3E-5	14,000	330	15,000
		0.8 (Transmission Poles)	20 max	0.0024	0.00059	1,800	NA	1,900
			10 typical	0.0012	0.00029	3,500	NA	3,800

a Unit Exposures (UE) are from PHED for termiticide combined mixer/loader/applicator, liquid pour, rod shank injection, test subjects wearing single layer clothing and chemical resistant gloves.

b Application rate from EPA Reg. No. 3008-33.

c No. poles treated estimated by Bob Butera, Osmose.

d Abs. Dermal Dose (mkd) = Dermal UE (mg/lb ai) x rate (lb ai/pole) x #poles x 2.5% abs x 1/60kg BW.

e Inhalation Dose (mkd) = Inhalation UE (mg/lb ai) x rate (lb ai/pole) x #poles x 1/60kg BW.

f MOE = NOAEL / Dose. Where ST dermal NOAEL is 4.22 mkd, IT & LT NOAEL is 0.1 mkd, and inhalation NOAEL (all durations) is 1.11 mkd (6.5 mg/m^3). Target MOE is 100.

Table 4 presents the potential cancer risks for the pole treatment use of metam sodium. Workers treating distribution poles are expected to treat ~5 poles/day on average (i.e., typical), 5 days per week, 50 weeks per year, for 35 years over a 70 year lifetime. Workers treating transmission poles are expected to treat ~10 poles/day on average (i.e., typical), 5 days per week, 60 days per year, for 35 years over a 70 year lifetime. Exposure to MITC during injection of metam sodium into drilled holes is not expected (i.e., insufficient exposure time to release MITC). The amount of metam sodium applied to each pole varies and is based on the size of the pole.

Table 4. Potential Metam Sodium Cancer Risks During Treatment of Poles.

Unit Exposures [a] (mg/lb ai)		Application Rate [b] (lb ai/pole)	Number of Poles Treated [c]	Days per year treating poles [d]	Daily Dose (mg/kg/day)			LADD [g] (mg/kg/day)	Risk [h]
Dermal	Inhalation				Absorbed Dermal [d]	Potential Inhalation [e]	Total Dose [f]		
0.36	0.0022	0.4 (Distribution Poles)	5 typical	250	0.00026	6.3E-5	0.00032	0.00011	2.2E-5
		0.8 (Transmission Poles)	10 typical	60	0.0010	0.00025	0.0013	0.00011	2.1E-5

a Unit Exposures (UE) are from PHED for termiticide combined mixer/loader/applicator, liquid pour, rod shank injection, test subjects wearing single layer clothing and chemical resistant gloves.

b Application rate from EPA Reg. No. 3008-33.

c No. poles treated estimated by Bob Butera, Osmose.

d Abs. Dermal Dose (mkd) = Dermal UE (mg/lb ai) x rate (lb ai/pole) x #poles x 2.5% abs x 1/70kg BW.

e Inhalation Dose (mkd) = Inhalation UE (mg/lb ai) x rate (lb ai/pole) x #poles x 1/70kg BW.

f Total Dose (mkd) = Abs. Dermal dose (mkd) + inhalation dose (mkd).

g LADD (mkd) = Total dose (mkd) x (#work days per yr / 365 days per year) x (35 working yrs/70 yr lifetime)

h Risk = LADD (mkd) x CSF 1.98E-1 $(mkd)^{-1}$

3.2 Leather Processing

Metam sodium is used to "*...prevent bacterial decomposition of brine-cured hides and skins*" (EPA Reg. No. 1448-371). The product, Busan 1020L, contains 33% sodium N-methyldithiocarbamate. The product density is 9.6 lbs per gallon (3.168 lbs ai/gallon). The label does specify PPE (e.g., respirator, specific clothing, chemical resistant gloves and boots). Specific label directions on application rates for brine-cured hides and skins are presented for raceways, mixers, and in tanning drums for soaking leather. These rates include 4,000 to 10,000 ppm (0.4 to 1.0%) for temporary preservation (based on weight of green fleshed hides/skins); 100 to 250 ppm (0.01 to 0.025%) in raceways; and 250 to 750 ppm (0.025 to 0.075%) in mixers for salt cured hides. These rates are based on total weight of hides or skins plus the weight of the saturated brine solution. Busan 1020L is also used to treat leather "*to prevent the bacterial decomposition of brine cured, wet salted, air-dried or green fleshed hides/skins in the soaking process*." The treatment rate for leather in the tanning drums used for soaking is 125 to 1,500 ppm (0.0125 to 0.15%) based on the total weight of the hides/skins and an equal amount of brine solution (i.e., 100% float).

The potential for occupational exposure is based on the loading of the product by open pouring or connecting/disconnecting the metering pump. Chemical-specific exposure data were not submitted to support leather processing. Therefore, the Antimicrobials Division has developed a screening-level assessment using surrogate data to determine the potential risks associated with leather processing.

Currently the leather processing market for metam sodium is small (i.e., less than 1,000 pounds ai per year). However, the assessment for this use assumes a larger market in the future (i.e., lifetime

assumptions used in the cancer screening-level assessment). The following use information was provided by Dean Didato of Buckman Laboratories:

- Raceways - High end treatment in raceways is ~1,000 hides per day, 300 hides treated per day is typical (each hide weighs ~65 lbs). The brine capacity of a raceways is ~42,000 gallons (density of brine treatment solution is 10.2 lbs/gallon). Therefore, the high end label concentration of 250 ppm requires 41 lbs ai derived from (42,000 gallons x 10.2 lbs/gallon) + (1,000 hides x 65 lbs/hide) x 0.00025 (i.e., 250 ppm or 0.025%) x 0.33 (i.e., 33% ai in product). The typical amount of ai handled for treating 300 hides per day (assuming high rate of 250 ppm) is 37 lbs ai per day. Assume workers are treating 250 days per year.

- Mixers - Approximately 200 hides are treated in a mixer per day (each hide weighs ~65 lbs). The 200 hides treated per day is assumed to represent the high end as well as typical treatment over the 250 days worked per year. The mixer uses salt in the treatment without water, ~500 lbs of salt is used. Therefore, the high end label concentration of 750 ppm requires 3.3 lbs ai derived from (500 lbs salt) + (200 hides x 65 lbs/hide) x 0.00075 (i.e., 750 ppm or 0.075%) x 0.33 (i.e., 33% ai in product). Assume workers are treating 250 days per year.

- Tanning Drum - During leather processing, 400 hides are soaked in a tanning drum (each hide weighs ~65 lbs). The 400 hides treated per day is assumed to represent the high end as well as typical treatment over the 250 days worked per year. The tanning drum uses an equal amount of brine solution (in lbs) to weight of hides. Therefore, the high end label concentration of 1,500 ppm requires 26 lbs ai derived from (26,000 lbs salt) + (400 hides x 65 lbs/hide) x 0.0015 (i.e., 1,500 ppm or 0.15%) x 0.33 (i.e., 33% ai in product). Assume workers are treating 250 days per year.

- Metered Pump versus Open Pour - Metam sodium is applied by open pouring the product from the container or via a metering pump. Dean Didato (Buckman Laboratories) indicated that up to 5 gallons of the product is the upper limit for the open pouring (i.e., 15.8 lbs ai).

Although EPA does not have a specific surrogate exposure scenario for pouring or metering antimicrobials into raceways, mixers, or tanning drums, similar exposure data for loading products are available. The most representative data available for open pouring for industrial uses is the monitoring data from the Chemical Manufacturers Association Antimicrobial Exposure Assessment Study (CMA). The liquid open pour and liquid pump data from the preservative loading are used to develop the screening-level assessment. The dermal unit exposures (UE) for liquid open pour and liquid pump are both based on only 2 replicates with the test subjects wearing single layer of clothing and chemical resistant gloves (UE are not available for the "no glove" scenarios). The dermal UE is 0.135 mg/lb ai for open pour and 0.00629 mg/lb ai for liquid pump. The inhalation unit exposures are based on the same 2 replicates. The inhalation UE for open pour is 0.00346 mg/lb ai and the UE for liquid pump is 0.000403 mg/lb ai. Although these exposure scenarios are based on minimal replicates, the exposure

values are similar to those found in PHED for similar scenarios.

Table 5 presents the potential non-cancer dermal and inhalation risks for the leather processing use of metam sodium. Exposure to MITC during loading of metam sodium into raceways, mixers, tanning drums is not expected (i.e., insufficient time to convert to MITC – see MITC postapplication assessment below). Leather processors are believed to be exposed for a long-term duration (i.e., greater than 6 months per year, 250 days per year for the cancer assessment). None of the dermal and inhalation handler MOEs are of concern. Table 6 presents the cancer risk assessment for the leather processing. The cancer risks range from 1.1E-4 to 1.4E-5.

3.3 Sugar Production (Cane and Beets)

Metam sodium is used as a *"...broad-spectrum microbicide that is effective in the control of the bacteria and fungi that cause sucrose losses, slime, and odors during the manufacture of raw cane and beet sugar"* (EPA Reg. No. 1448-93). The product, Busan 1016, contains 18% sodium N-methyldithiocarbamate. The product density is 10.3 lbs per gallon (1.85 lbs ai/gallon). Specific label directions indicate a maximum application rate of 3.9 gallons of product per 1000 tons of cane ground or beets sliced per 24 hours. Busan 1016 is fed continuously, and therefore, is considered to be applied via a metering pump. Chemical-specific use information for metam sodium on the number of tons of cane and/or beets processed on a daily basis is not available. The best information available at this time to estimate the number of tons treated daily is from USEPA (1975). USEPA (1975) indicates approximately 3,000 tons of cane are processed at a facility on a daily basis. This assessment can be refined if a more accurate count of the amount of cane/beets processed daily is submitted. Based on this estimate, 21.6 lbs ai are metered into the processing facility on a daily basis (i.e., 1.85 lb ai/gallon product x 3.9 gallons of product per 1,000 tons cane x 3,000 tons of cane processed per day).

Although EPA does not have a specific surrogate exposure scenario for metering antimicrobials into sugar processing facilities, similar exposure data for loading are available. The most representative data available for a metered continuous fed liquid for industrial uses is the monitoring data from the Chemical Manufacturers Association Antimicrobial Exposure Assessment Study (CMA). The liquid pump data from the preservative loading are used to develop the screening-level assessment. The dermal unit exposure (UE) for liquid pump is based on only 2 replicates with the test subjects wearing single layer of clothing and chemical resistant gloves (a UE is not available for a "no glove" scenario). The dermal UE is 0.00629 mg/lb ai for liquid pump. The inhalation unit exposure is based on the same 2 replicates. The inhalation UE for liquid pump is 0.000403 mg/lb ai. Although these exposure scenarios are based on minimal replicates, the exposure values are similar to those found in PHED for similar scenarios.

Table 5 presents the potential non-cancer dermal and inhalation risks for the sugar cane and sugar beet processing use of metam sodium. Exposure to MITC during loading (i.e., metering) of

metam sodium into the cane juice at points where the juice is in contact with equipment (e.g., screens, pipes, etc.) is not expected (i.e., insufficient time to convert to MITC – see MITC postapplication assessment below). Workers at sugar processing facilities are believed to be exposed for a long-term duration (i.e., greater than 6 months per year, 250 days/year for the cancer assessment). None of the dermal and/or inhalation handler MOEs are of concern. Table 6 presents the cancer risk assessment for the sugar processing. The cancer risk is 1.2E-5.

3.4 Sewage Sludge

Metam sodium is *"...effective in reducing the number of viable sludge pathogens in sewage sludge (biosolids) and animal waste ... and also effective in the reduction or elimination of odors in sewage sludge (biosolids) and animal waste"* (EPA Reg. No. 5481-477). The product, RID-A-VEC, contains 42% sodium N-methyldithiocarbamate. The product density is not presented on the label but is assumed to be ~10 lbs per gallon (4.2 lbs ai/gallon). Although the label does not specifically require PPE, it does state to wash the outside of gloves before removing. Specific label directions indicate a maximum application rate of 3 gallons of product per 1 ton of sewage sludge (biosolids). The treated sludge is then stored for 14 to 21 days. The product is *"metered through an injection system into the processing vessel*." Chemical-specific use information for metam sodium on the amount of sludge treated per day is not available. EPA presents the risk for treating 1 ton of biosolids per day. This assessment can be refined if a more accurate determination of the amount of biosolids treated on a daily basis is submitted. Based on this estimate, 12.6 lbs ai are metered into the processing vessel on a daily basis (i.e., 4.2 lb ai/gallon product x 3 gallons of product per 1 ton biosolids processed per day).

Although EPA does not have a specific surrogate exposure scenario for metering antimicrobials into a sludge processing vessel, similar exposure data for closed loading are available. The most representative data available for a metered continuous fed liquid for industrial uses is the monitoring data from the Chemical Manufacturers Association Antimicrobial Exposure Assessment Study (CMA). The liquid pump data from the preservative loading are used to develop the screening-level assessment. The dermal unit exposure (UE) for liquid pump is based on only 2 replicates with the test subjects wearing single layer of clothing and chemical resistant gloves (a UE is not available for a "no glove" scenario). The dermal UE is 0.00629 mg/lb ai for liquid pump. The inhalation unit exposure is based on the same 2 replicates. The inhalation UE for liquid pump is 0.000403 mg/lb ai. Although these exposure scenarios are based on minimal replicates, the exposure values are similar to those found in PHED for similar scenarios.

Table 5 presents the potential non cancer dermal and inhalation risks for the sludge processing use of metam sodium. Exposure to MITC during loading (i.e., metering) of metam sodium into the sludge vessel is not expected (i.e., insufficient time to convert to MITC – see MITC postapplication assessment below). Workers at sludge processing facilities are believed to be exposed for a long-term duration (i.e., greater than 6 months per year, 250 days/year for the cancer assessment). None of the

dermal and/or inhalation handler MOEs are of concern. Table 6 presents the cancer risk assessment for the sewage sludge application. The cancer risk is 6.8E-6.

Table 5. Potential Antimicrobial Metam Sodium Non-cancer Risks.

Equipment	Exposure Scenario	Unit Exposures (mg/lb ai) [a]		Lbs of Active Ingredient (ai) [b,c]	Daily Dose (mg/kg/day)		MOEs [f]		
		Dermal	Inhalation		Absorbed Dermal [d]	Potential Inhalation [e]	Dermal		Inhalation
							ST	IT/LT	
Leather Processing									
Raceway	Open Pour	0.135	0.00346	15.8	0.00089	0.00091	4,700	110	1,200
	Metering Pump	0.00629	0.000403	41	0.00011	0.00028	39,000	360	4,000
Mixer	Open Pour	0.135	0.00346	3.3	0.00019	0.00019	23,000	530	5,800
	Metering Pump	0.00629	0.000403	3.3	8.6E-6	2.2E-5	49,000	4,500	50,000
Tanning Drum	Open Pour	0.135	0.00346	15.8	0.00089	0.00091	4,700	110	1,200
	Metering Pump	0.00629	0.000403	26	6.8E-5	0.00018	62,000	570	6,400
Sugar Cane and Sugar Beet Processing									
Cane/Beets	Metering Pump	0.00629	0.000403	21.6	5.7E-5	0.000145	75,000	690	7,700
Sewage Sludge									
Indoor/Outdoor	Metering Pump	0.00629	0.000403	12.6	3.3E-5	8.5E-5	130,000	1,200	13,000

a Unit Exposures (UE) are from CMA, test subjects wearing single layer clothing and chemical resistant gloves.

b Application rate for leather is from EPA Reg. No. 1448-371, for sugar from EPA Reg. No. 1448-93, and for sewage sludge EPA Reg No. 5481-477.

c Lbs of ai handled based on estimates by Dean Didato, Buckman for leather, USEPA 1975 for sugar processing, and on a 1 ton basis for sewage.

d Abs. Dermal Dose (mkd) = Dermal UE (mg/lb ai) x amount handled (lb ai) x 2.5% abs x 1/60kg BW.

e Inhalation Dose (mkd) = Inhalation UE (mg/lb ai) x amount handled (lb ai) x 1/60kg BW.

f MOE = NOAEL / Dose. Where ST dermal NOAEL is 4.22 mkd, IT & LT NOAEL is 0.1 mkd, and inhalation NOAEL (all durations) is 1.11 mg/kg/day (or 6.5 mg/m^3). Target MOE is 100.

Table 6. Potential Antimicrobial Metam Sodium Cancer Risks.

Equipment	Exposure Scenario	Unit Exposures (mg/lb ai)[a]		Lbs of Active Ingredient (ai)[b,c]	Daily Dose (mg/kg/day)			LADD[g] (mg/kg/day)	Risk[h]
		Dermal	Inhalation		Absorbed Dermal[d]	Potential Inhalation[e]	Total Dose[f]		
Leather Processing									
Raceway	Open Pour	0.135	0.00346	15.8	0.00076	0.00078	0.0015	0.00053	1.1E-4
	Metering Pump	0.00629	0.000403	37	8.3E-5	0.00021	0.0003	0.00010	2.0E-5
Mixer	Open Pour	0.135	0.00346	3.3	0.00016	0.00016	0.0003	0.00011	2.2E-5
	Metering Pump	0.00629	0.000403	3.3	7.4E-6	1.9E-5	2.6E-5	9.1E-6	1.8E-6
Tanning Drum	Open Pour	0.135	0.00346	15.8	0.00076	0.00078	0.0015	0.00053	1.1E-4
	Metering Pump	0.00629	0.000403	26	5.8E-5	0.00015	0.00021	7.1E-5	1.4E-5
Sugar Cane and Sugar Beet Processing									
Cane/Beets	Metering Pump	0.00629	0.000403	21.6	4.8E-5	0.00012	0.00017	5.9E-5	1.2E-5
Sewage Sludge									
Indoor/ Outdoor	Metering Pump	0.00629	0.000403	12.6	2.8E-5	7.3E-5	0.00010	3.5E-5	6.8E-6

a Unit Exposures (UE) are from CMA, test subjects wearing single layer clothing and chemical resistant gloves.

b Application rate for leather is from EPA Reg. No. 1448-371, for sugar from EPA Reg. No. 1448-93, and for sewage sludge EPA Reg No. 5481-477.

c Lbs of ai handled estimates by Dean Didato, Buckman Laboratories for leather, USEPA 1975 for sugar processing, and on a 1 ton basis for sewage.

d Abs. Dermal Dose (mkd) = Dermal UE (mg/lb ai) x amount handled (lb ai) x 2.5% abs x 1/70kg BW.

e Inhalation Dose (mkd) = Inhalation UE (mg/lb ai) x amount handled (lb ai) x 1/70kg BW.

f Total Dose (mkd) = Abs. Dermal dose (mkd) + inhalation dose (mkd).

g LADD (mkd) = Total dose (mkd) x (#work days per yr / 365 days per year) x (35 working yrs/70 yr lifetime)

h Risk = LADD (mkd) x CSF 1.98E-1 $(mkd)^{-1}$

4.0 Postapplication Assessment

4.1 Pole Treatment

4.1.1 Occupational

The potential for dermal and/or inhalation exposure subsequent to pole treatments is expected to be negligible. The process of treating poles requires that the pole be drilled and the metam sodium be injected as a liquid into the holes. After the injection, the holes in wooden poles are capped immediately. Exposure to metam sodium or MITC to the workers after the application is complete is expected to be negligible due to the enclosure of the treatment and the ambient conditions.

4.1.2 Residential/Bystander

The potential for dermal and/or inhalation exposure to adults and/or children in the vicinity of utility poles treated with metam sodium is expected to be negligible. The process of treating poles is to predrill holes after which liquid metam sodium is injected into the holes. After the injection, the holes in wooden poles are capped immediately. Exposure to metam sodium or MITC to adults/children after the application is complete is expected to be negligible due to the enclosure of the treatment and the ambient conditions in which it is applied.

4.2 Leather Processing

AD has no data to assess postapplication occupational exposure to MITC following applications of metam sodium into raceways, mixers, and tanning drums. AD has concerns for potential inhalation exposure to workers regarding the off-gassing of MITC from these types of applications.

4.2 Sugar Production (Cane & Beets)

AD has no data to assess postapplication occupational exposure to MITC following applications of metam sodium into sugar production facilities. AD has concerns for potential inhalation exposure to workers regarding the off-gassing of MITC from these types of applications.

4.3 Sewage Sludge

AD has no data to assess postapplication occupational exposure to MITC following applications of metam sodium into sewage sludge. AD has concerns for potential inhalation exposure to workers regarding the off gassing of MITC from these types of applications.

5.0 Risk Characterization of the Occupational Exposures

Chemical-specific exposure data were not available to assess the antimicrobial uses of metam sodium. Therefore, surrogate data from both PHED and CMA were used to generate screening-level risk estimates. Where possible, chemical-specific use information was solicited from the registrants to determine the amount of product handled on a daily basis. The surrogate data available to assess the handlers is believed to be representative of the use. However, there is no air monitoring data to estimate the potential postapplication MITC exposures (or to determine if MIC will be present). The sections below summarize the uncertainties in the assessment and characterize the potential risks from the antimicrobial uses of metam sodium.

5.1 Summary of Uncertainties

As discussed above, AD has used the best available surrogate exposure data from PHED and CMA to develop a screening-level assessment for the handlers of metam sodium. The following uncertainties should be considered by the regulatory risk managers during the decision making process:

- Unit exposures are not available for the scenarios that are prescribed for metam sodium (i.e., pole injection, open loading and metering into leather processing equipment, and metering into sugar cane/beet juice processing equipment along with sewage sludge vessels). Nonetheless, the data from PHED for combined mixing/loading/injecting a liquid termiticide is a reasonable surrogate for the pole treatment. The termiticide scenario is considered to be of "high confidence" (i.e., 17 replicates of Grade AB data – indicating the analytical portion of the study meets EPA exposure test guidelines). The CMA data used for the leather, sugar processing, and sewage sludge are based on closed loading (and open pour for leather processing) of a material preservative. Although these data are only represented by 2 replicates each, the exposure values are similar to open and closed loading of pesticides in PHED. Data are only available for workers wearing chemical resistant gloves.

- Metam sodium is used to treat both poles and timbers. The assessment for the remedial wood treatments is based on applications to distribution and transmission poles as representative of all the remedial treatments. Although it is unknown how many timbers in a bridge or other structure are treated, the pole use is believed to be representative of the high end use.

- The toxicological endpoints from HED have been used in this assessment. Any changes to the HED endpoints in the future will need to be incorporated into this review.

- The use information for the pole and leather treatments is based on personal communication with the registrants. The individuals contacted have experience in these operations and their estimates are believed to be the best available without undertaking a statistical survey of the uses. However, more information on the temporary preservation use rate of 10,000 ppm for green fleshed hides and skins is needed to assess that rate. The amount of sugar cane treated was derived from an older reference (i.e., USEPA 1975) and the information in that reference

was not from a survey of facilities, but rather a discussion of sugar cane processing. It is assumed a similar number of sugar beets are also processed on a daily basis. The amount of biosolids treated per day for the sewage sludge use is unknown. The assessment presents the risks assuming 1 ton of biosolids are treated on a daily basis for a long-term duration (i.e., 250 days per year). The MOEs and cancer risks for the sewage sludge use are of such magnitude that even if 10 tons of biosolids are treated on a daily basis the MOEs and cancer risks would not be of concern. However, information pertaining to the amount of sewage treated with metam sodium at large facilities should be provided by the registrant.

- The cancer estimates are based on a working lifetime of exposure. For the leather processing, less than 1,000 lbs ai are used per year. It is doubtful at the current production that an individual worker would be exposed for 35 years.

- The potential for the formation of measurable air concentrations of MITC (and potentially MIC) after applications of metam sodium in the leather processing, sugar processing, and sewage sludge treatment is unknown. AD's concerns for the postapplication exposure are based on the fact that metam sodium degrades rapidly to MITC. Additionally, agricultural field studies with metam sodium result in measurable MITC residues in air. Consequently, AD believes that the registrants should conduct air monitoring for these industries.

5.2 Non-cancer Risks

The non-cancer handler assessment of metam sodium indicates no risks of concerns for any of the uses (i.e., dermal and inhalation MOEs are greater than the target MOE of 100). The time required for the loading and application of metam sodium for the antimicrobial uses is very short (i.e., minutes), and therefore, MITC exposures during application are expected to be negligible.

The potential for postapplication exposures from metam sodium and/or MITC are expected to be negligible for the remedial pole injection use. However, AD believes that there is a potential for postapplication inhalation exposure to MITC for workers/bystanders at leather and sugar cane/beet processing facilities and for those working in the vicinity of sewage sludge treatments. No data for MITC are available to estimate the postapplication non-cancer risks.

5.3 Cancer Risks

The handler cancer assessment indicates risks of concerns for all of the occupational uses of metam sodium. The risks for the pole treatments are ~2E-5 and the risks range from 1.1E-4 to 1.8E-6 for the leather processing use. The cancer risks for the handlers applying metam sodium during sugar processing and sewage sludge treatments are 1.2E-5 and 6.8E-6, respectively. The following guidance for occupational cancer risks of concern is provided in the HED metam sodium occupational and residential exposure assessment (D284269):

"HED has defined a range of acceptable cancer risks based on a policy memorandum issued in 1996 by then Office of Pesticide Programs director, Mr. Dan Barolo. This memo refers to a predetermined quantified "level of concern" for occupational carcinogenic risk. In summary, this policy memo indicates occupational carcinogenic risks that are 1 x 10^{-6} or lower require no risk management action. For those chemicals subject to reregistration, HED is to carefully examine uses with estimated risks in the 10^{-6} to 10^{-4} range to seek ways of cost-effectively reducing risks. If carcinogenic risks are in this range for occupational handlers, increased levels of personal protection would be warranted as is commonly applied with non-cancer risk estimates (e.g., additional PPE or engineering controls). Carcinogenic risks that remain above 1.0 x 10^{-4} at the highest level of mitigation appropriate for that scenario remain a concern."

Based on this guidance, the handler risks that are estimated to be in the E-6 to E-4 range should be examined to determine cost-effective risk mitigation for workers.

The cancer risks for postapplication exposures from the remedial pole injection use are expected to be negligible for both metam sodium and MITC. However, AD believes that there is a potential for postapplication inhalation exposure to MITC for workers at leather and sugar cane/beet processing facilities as well as the sewage sludge treatment facilities. No data for MITC are available to estimate the risks.

6.0 References

Personal communication with Dean Didato, VP of Leather Chemical Sales, Buckman Laboratories (901-272-8408) and Tim Leighton, USEPA/OPP/AD (703-305-7435) on April 1, 2004.

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USEPA. 2004. Metam Sodium/Metam Potassium: The HED Chapter of the Reregistration Eligibility Decision Document (RED), dated April 9, 2004. DP Barcode: D284260.

USEPA. 2004. Metam Sodium *Hazard Identification Assessment Review Committee* (HIARC) report, dated April 2, 2004 (TXR 0052467)

USEPA 1975. Development Document for Interim Final Effluent Limitations Guidelines and Proposed New Source Performance Standards for the Raw Cane Sugar Processing. EPA 440/1-75/044. Group I, Phase II.