UNITED STATES ENVIRONMENTAL PROTECTION AGENCY



WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

Memorandum

SUBJECT: Prometon Use Closure Memorandum Case No. 2545

PC Code 080804

FROM: Rosanna Louie, Chemical Review Manager

Reregistration Branch 3

Special Review and Reregistration Division

TO: Prometon Reregistration Eligibility Decision Team Members

DATE: January 22, 2007

The purpose of this memorandum is to provide use information that will be incorporated into the preliminary risk assessments and other supporting documents for prometon. This memorandum is based on information presented at the January 9, 2007, SMART Meeting, subsequent discussions with the sole registrant Makhteshim-Agan of North America, Inc. (MANA), and the Agency's review of product labels. This memorandum and the attachment serve as a guide as the Agency prepares for the reregistration of this chemical.

Prometon is a nonselective "bare-ground" herbicide labeled for pre- and postemergence applications to manage annual and perennial grasses and broadleaf weeds. Prometon is a photosynthesis inhibitor and acts by disrupting CO₂ fixation and production of intermediary energy components - ATP and NADPH₂. The most efficacious method of controlling weeds is by direct soil applications, which, with sufficient water from rainfall or irrigation, allows prometon to readily move to the root systems.

According to OPPIN, there are currently a total of 64 registered products as of the date of this memorandum, of which three are technical or manufacturing concentrate formulations. Please consider the following information when conducting the risk assessment:

- Typical use rate range from 0.175 to 0.23 pound of active ingredient per 500 ft² (lb ai/500 ft²), regardless of regional variabilities.
- The registrant is supporting a maximum single application rate of 0.23 lb ai/500 ft² applied once a year. However, there are some active labels that permits higher single maximum application rates than that which the registrant wishes to support (i.e. EPA Reg. #228-213 permits a maximum single application rate of 0.6885 lb ai/500 ft²). SRRD is looking into whether another registrant may wish to support the higher rate. If so, I will amend this memorandum accordingly.

- There is no restriction on any label stating a seasonal or annual maximum rate.
- Less than one million pounds of prometon are produced annually.
- The registrant states that the use of prometon in residential areas is discouraged. However, prometon is registered for use in residential areas or recreational areas for persistent, total vegetative control (e.g. driveways, fencelines, and playgrounds).

The registrant states that depending on rainfall and soil conditions, a single application is efficacious for at least one year, but noted that customers have reported efficacy ranging from 8 to 18 months. Prometon is registered for weed control around buildings, storage areas, fences, pumps, machinery, fuel tanks, recreational areas, roadways, guard rails, airports, military installations, highway medians, pipelines, railroads, lumberyards, rights-of-way, and industrial sites (such as cross connects, pedestals, transformers, vaults, buried cable closures, telephone booths, fire plugs).

MANA is supporting all uses on current labels. There are currently no pending petitions or registered food uses of prometon. Prometon is formulated as an emulsifiable concentrate, Ready-to-Use, water-based flowable concentrate, and pelleted granule. Liquid applications may be made by handheld sprayer or a sprinkling can. Granular prometon may be applied using a whirly-bird spreader, or other similar handheld spreaders. There is no aerial application for products containing prometon. The registrant reports that the greatest usage of prometon is in the Midwest, South, and Southeast US, with lower usage of prometon in the Northwest, Northeast, and California. State restrictions apply in Colorado, Washington, and Texas. Attached is MANA's slideshow presentation on prometon uses from the January 9th SMART Meeting.

Should you become aware of any new use information become available during the development of the preliminary risk assessments, please inform me as the Chemical Review Manager so that I can coordinate the new information with the entire team. If you have any questions or concerns regarding this memorandum, please contact me at (703) 308-0037.

Attachment: Makhteshim-Agan's Slideshow Notes



Prometon SMART Meeting

Agan Chemical Manufacturers Ltd. Makhteshim Agan of North America, Inc.

Control Solutions, Inc.

Tuesday, January 9th, 2007 10:00 AM – 12:00 PM EPA OPP One Potomac Yard Conference Room S-9100

Who's Who

Agan Chemical Manufacturers, Ltd.

- Parent company, based in Israel
- Holds technical registration

Makhteshim Agan of North America, Inc. (MANA)

- Wholly owned subsidiary and daughter company of Agan; sister company to CSI
- Manages technical registration for Agan
- Holds end use product registrations in U. S.

Control Solutions, Inc. (CSI)

- Partially owned subsidiary of Agan; sister company to MANA
- Markets end use product registrations in U. S.

What is Prometon?

Prometon is a methoxytriazine herbicide used for non-selective total control of pest weeds and grasses around buildings, storage areas, fences, pumps, machinery, fuel tanks, recreational areas, roadways, guard rails, airports, military installations, highway medians, pipelines, railroads, lumberyards, industrial sites, rights-of-way, and similar areas. (cont.)

What is Prometon? (cont.)

Prometon is a photosynthetic inhibitor. While it can injure old growth by contact, it can only move upward through the plant system. Moisture is required to move the active ingredient into the root zone of the where it is taken up throughout the entire plant.

What is Prometon? (cont.)

History of the Molecule

- Agan acquired the technical registration, and MANA acquired their end use registrations from Syngenta in 1998. The product was first registered in the U. S. in 1974.

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EPA SMART Meeting Topic

- Describe all registered formulations (both technical and end-use labels):
 - Types of formulations (granular, soluble concentrate, emulsifiable concentrate, etc.)
 - Any feeding / grazing restrictions on product labels
 - Any label changes planned or will be submitted in the near future
 - Any special local needs (SLN) registrations

Manufacturing Formulations

- Technical
 - Prometon Technical (97%) (11603-30)
- Manufacturing Concentrates
 - Pramitol MG 25E (25%)(66222-24)
 - Emulsifiable Concentrate
 - Pramitol 4 MUP (45.3%) (66222-43)
 - Water-Based Flowable

Prometon EUP Formulations - MANA

- Pramitol 25E (25%) (66222-22)
 - Emulsifiable Concentrate
- Pramitol 5PS (5%*)(66222-23)
 - Pelleted Granule, Ready-to-Use
- Pramitol 1.5% (66222-25)
 - Ready-to-Use
- Pramitol 2.5% (66222-26)
 - Emulsifiable Concentrate
- Pramitol 3.75% (66222-27)
 - Emulsifiable Concentrate

(* Also contains 40% sodium metaborate, 39.8% sodium chlorate and 0.76% simazine)

Prometon EUP Formulations – MANA (cont'd.)

- Pramitol 4SC (45.3%) (66222-38)
 - Water-Based Flowable Concentrate
- Pramitol 1.8L (1.8%) (66222-44)
 - Water-Based Flowable Concentrate
- Pramitol 2.2L (2.2%) (66222-45)
 - Water-Based Flowable Concentrate
- Pramitol 1.8RTU (1.8%)(66222-52)
 - Water-based Flowable, Ready-to-Use
- Pramitol 2L / Diuron 2L (21.62% ea.)(66222-55)
 - Water-Based Flowable Concentrate

Prometon EUP Formulations – CSI

- Prometon 5PS (5%*) (53883-97)
 - Pelleted Granule, Ready-to-Use
- Prometon 25E (25%) (53883-98)
 - Emulsifiable Concentrate
- Prometon 4SC (45.3%) (53883-99)
 - Water-Based flowable concentrate

(* Also contains 40% sodium metaborate, 39.8% sodium chlorate and 0.76% simazine)

NOTE – CSI markets MANA products and does not market any of these registrations

 There are other end use product registrants with active prometon registrations. The large majority (if not all) of these products are 'me-too's' based on MANA registrations. All of these registrants are MANA / CSI customers.

Grazing/Feeding Restrictions

Grazing/feeding of treated areas not addressed by current labeling, therefore not allowed.

Prometon is a non-selective, "bare-ground" herbicide, therefore it will not be used in grazing/feeding sites.

Planned Label Changes

There are no planned label changes for Prometon registration at this time. [Exception – Combo products going through RED's for other a.i.'s: Pramitol 5PS, Pramitol 2L / Diuron 2L]

SLN(s)

There are no SLN registrations for any Prometon registration.

EPA SMART Meeting Topic

- Describe the supported and unsupported uses:
 - Will supported uses be at the current maximum label rates, number of applications, and the application intervals as currently stated on the labels?
 - Any federal or state imposed buffer zones for aerial or ground application
 - Any other existing restrictions
 - Any uses that are currently registered but not marketed
 - Any uses that you are not supporting for reregistration, are you aware of anyone who will be supporting these uses?

Supported and Unsupported Uses

- All supported uses will be at current labeled rates and number of applications.
 - Prometon is used once per year for total vegetation control, therefore multiple applications are not addressed in the product's labeling.
- There are no Federal or State imposed buffer zones for aerial applications
 - Prometon formulations are not applied by air.
- Pramitol 5PS is currently in review under Sodium Chlorate re-registration, and as a result, the use rates and some use sites may be altered on proposed labeling.
- Pramitol 2L / Diuron 2L currently in review under Diuron reregistration. As a result, use rates have not changed, but General Precautions and Restrictions are more explicitly defined on proposed labeling.

Other Restrictions

- TEXAS restricts the sale of some herbicides, including Prometon, to licensed applicators if sold in containers greater than 1 quart (liquid), or greater than 2 lbs. (granular).
- COLORADO Restricts the sale of Prometon and certain other herbicides
- WASHINGTON Restricts the sale of Prometon and certain other herbicides

Non-Marketed Uses

None

Unsupported Uses

 None - Agan, MANA and CSI are planning on supporting all labeled uses through reregistration

EPA SMART Meeting Topic

Use Practices

- Frequency and timing of application (typical and maximum)
- How often is the pesticide applied
- The typical and minimum interval between application(s)
- Describe seasonal variations in use
- Provide information on typical and maximum areas of application

Use Practices

- Frequency and Timing of Applications
 - Prometon products are applied once per year, usually at the beginning of the growing season, for total vegetative control.
- Typical Areas of Application
 - Along fencelines, around structures, under driveways, in pump stations, industrial plants along runways, around tank batteries, etc. where persistent total vegetative control is desired.
- Variations in Use
 - Product is typically applied at the beginning of the growing season, however some users might choose to use the product mid or even late growing season

EPA SMART Meeting Topic

Actual Use

- In the past three years, how many lbs a.i. were used nationally for each use site? Please provide regional information as well.
- What are the typical application rates for each use site? Please provide regional information as well.
- By use site, how many total acres are treated per day and per season (or year) for each method of application?
- What information do you have on the distribution of rates, particularly for products that are often used in combination with other pesticides?

Actual Use

- Typical Application Rates
 - Pramitol 25E 14 oz. concentrate per 500 sq. ft. in sufficient water.
 - Pramitol 5PS 0.70 to 0.92 lbs per 100 sq.
 ft.

Above rates are typical, regardless of region.

Pounds Used Per Site

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Tank-Mixes

Prometon products are rarely tank-mixed with other herbicides due to the difference in mode of action.

EPA SMART Meeting Topic

- Occupational Exposure Information
 - Describe the typical personal protective Equipment (PPE) used for mixing, loading and applying
 - What is the market niche? What are the key pests or other conditions that drive the use? Please discuss on both a regional and national basis.
 - Describe all methods of application (air, ground, chemigation, soil injection, etc.) By site, how much a.i. is applied by each method of application? Explain why.
 - Do you know of any emerging equipment or cultural practices that could reduce exposure to your product in food, to workers, or in the environment?

Personal Protective Equipment

- This is not an agricultural label, and does not have a typical 'Personal Protective Equipment' heading and section, which is required on agricultural product labeling (Worker Protection Standard).
- Some of the products (liquid labeling) require goggles and/or face shield for mixing and use.

Market

The primary market is rural America in the Midwest, South and Southeast. The Northwest, Northeast, and California all have lower demand.

Market Niche

Non-selective total control of pest weeds and grasses around buildings, storage areas, fences, pumps, machinery, fuel tanks, recreational areas, roadways, guard rails, airports, military installations, highway medians, pipelines, railroads, lumberyards, industrial sites, rights-of-way, and similar areas. The market is driven by the need to make one application last the entire growing season.

Methods of Application

- Liquids are applied by ground sprays, usually handheld, or by sprinkling can, to bare ground or to pest weed sites followed by irrigation or rainfall to move the material to the root zone.
- Granular is applied to bare ground or to pest weed sites followed by irrigation or rainfall to activate the dissolvable pellet and to move the material to the root zone.

Emerging Equipment / Cultural Practices

None Known

EPA SMART Meeting Topic

Incidents

- Are there any reported incidents of drinking water contamination? Please provide specific details
- Are there any reported spray drift or volatilization incidents? Please provide specific details
- What are the ecological incidents (nontarget plant damage and avian, fish, reptilian, amphibian and mammalian mortalities) that have been reported while the current use practices have been in place?
- Are there any air or water monitoring data available from public sources, such as CARB, USGS, and states?

Water Monitoring Data

- The following water monitoring data sources were examined for prometon:
 - USGS National Water Quality Assessment (NAWQA) database
 - EPA STORET database
 - USDA PDP database
 - Relevant available state water monitoring databases

USGS NAWQA

- NAWQA groundwater and surface water databases for Cycle II (2002 to present) were examined for detects of prometon
- Prometon was detected in approximately 10% of the 2817 groundwater samples. The maximum detection level was 1.05 μg/L
- In surface water, prometon was detected in approximately 55% of the 5343 samples. The maximum detection level was 0.82 μg/L
- In groundwater and surface water the urban land use type showed the highest frequency of detects

EPA STORET Database

- The EPA STORET database contains 5,284 groundwater and surface water samples analyzed for prometon from 2002 to the present
- There were 86 detects for a frequency of detection of 1.63%
- The maximum detection level was 0.8
 μg/L and the minimum detection level was
 0.02 μg/L
- Samples were taken from the following states: Arizona, California, Florida, Iowa, Kansas, Kentucky, Oklahoma, and Utah

USDA PDP Monitoring

- USDA Pesticide Data Program (PDP) currently tests bottled water and drinking water
- 2005 sampling from 12 states
 - Approximately 53% detects in 374 finished water samples
 - Approximately 56% detects in 376 untreated water samples
 - Highest detect in finished water was 83 ppt (0.083 μ g/L) and 65 ppt (0.065 μ g/L) in untreated water

State Water Monitoring

- States vary regarding publicly available water monitoring data
- States in which detects were found in the NAWQA database were contacted to inquire about monitoring data for pesticides
- Majority of states indicated that monitoring databases were not available or prometon was not a constituent in their monitoring program
- Water monitoring information were gathered from
 - California groundwater and surface water
 - Texas groundwater
 - Nebraska groundwater and surface water
 - Nevada groundwater

State Water Monitoring (cont'd)

Texas groundwater monitoring data

 Majority of the 174 prometon samples reported as <0.018 μg/L

Nebraska

- Prometon is not monitored in surface water
- Of 1,096 groundwater monitoring samples for prometon, only three were reported as detects with a maximum of 0.09 $\mu g/L$
- Reporting limit for majority of groundwater samples was 0.3 μg/L

Nevada

 Groundwater monitoring found prometon detects in 2 to 3 wells at low levels.

State Water Monitoring (cont'd)

- California Groundwater monitoring
 - 25 Pesticide Management Zones have been established for pesticide monitoring
 - 4,796 wells were sampled for prometon between 1985 and 2004
 - 20 wells had unverified detections
 - 33 wells had verified detections
 - Detects ranged from 0.05 to 80 μ g/L (1985 to 2004)
 - In 2004/2005 detects ranged from 0.08 $\mu g/L$ to 0.093 $\mu g/L$

State Water Monitoring (cont'd)

- California Surface Water monitoring
 - Prometon was sampled in surface water monitoring from 1992 to the present
 - Of the 2,671 samples, there were 2,530 nondetects
 - Detects ranged from 0.009 μg/L to 0.7 μg/L

TMDL Data

- EPA TMDL database does not list prometon (or alternate names pramitol or ontracic) as a cause for impairment, nor is there established numeric criteria
- States in which detects were found in the NAWQA database were contacted to inquire about a TMDL for prometon
- The states that were contacted indicated that no TMDL had been set or was under consideration for prometon
- However, prometon is noted in a variety of assessment reports regarding water quality

EPA Office of Water

2006 Drinking Water Standards and Health Advisory

10 Kg Child					
One-day (µg/L)	Ten-day (μg/L)	RfD (µg/kg/day)	DWEL (µg/L)	Life-time (µg/L)	Mg/L at 10E4 Cancer Risk
200	200	1.5	500	100	-

Range of Reported Detects (µg/L)								
NAWQA	STORET	PDP	Texas	Neb.	Calif.	Calif.		
					Ground	Surface		
1.05	0.8	0.083	0.018	0.09	80	0.009		
					(1985)			
0.82	0.02	0.065		0.3	0.08	0.7		

Air Monitoring

- The California Air Resources Board (CARB) did not include any air monitoring data for prometon
- EPA's STORET database also did not include any air monitoring data for prometon
- Based on the low vapor pressure of 2.3 x 10⁻⁶ mmHg at 20° C (pure compound), prometon is not expected to be detected in the air

[NOTE – because of the vapor pressure and because of the nature of the application of the product, Spray Drift and Volatilization are not issues with Prometon]

Ecological Incident Data

- EPA's Ecological Incident Information System (EIIS) reported two incidents
 - Plant damage due to runoff following application of prometon on a roadway
 - A fish kill following an accidental spill
- A literature search for ecological incidents related to prometon did not return any incident data.

EPA SMART Meeting Topic

Benefits

- What is unique about product(s) containing this active ingredient?
- What alternatives are available
- Are there any constraints to the use of alternatives such as cost or efficacy?
- Is there any geographic area where there are no alternatives
- What is the largest droplet size that is efficacious?

Use Benefit

 Prometon keeps working where competitive products require multiple applications during the growing season. Multiple applications are not as cost/labor effective.

Alternative Products

- Glyphosate (e.g., RoundUp[®]) non-selective, non-persistent. Requires several applications per year.
- Diuron (e.g., Diuron, Krovar®)

 Non-selective, persistent. Not available in small quantities or in liquids. Dispersible granules and Wettables not user friendly.
- Imazapyr (e.g. Arsenal[®]) very cost prohibitive at the point of sale.

Geographic Areas with No Alternative?

None Known

Largest Efficacious Droplet Size?

Not Applicable

EPA SMART Meeting Topic

Additional Data / Information

- Are you aware of any sub-populations who may have higher exposure than the general population?
- Are there any additional new tox, chemical-specific exposure, biomonitoring or epidemiological data available? Are there any plant toxicity data using typical eup's?
- Are you aware of metabolites, degradates or contaminants in the end-use or technical grade products? What information do you have regarding the metabolism / toxicology of these metabolites, degradates or contaminants?
- What additional data do you plan to submit in the next two years, if any?

Additional Data / Information

 Farmstead populations are the greatest users of prometon, and therefore may have higher exposure risk than the general population.

 Currently, Agan, MANA and CSI have no plans to submit additional data for this product.

Metabolism and Degradation

- Microbial degradation is the primary mechanism by which prometon is lost from soil and water.
- Degradation occurs fastest under aerobic conditions and comparatively high temperatures.
- Not affected by hydrolysis and photolysis
- Degradates and metabolites are less toxic than parent prometon.

Process-Related Impurities

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Process-Related Impurities

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New Data

- We neither have nor know of any new data for prometon.
- Literature searches were conducted for biomonitoring, epidemiology, toxicology (human health) or ecotoxicology incident data
 - No relevant articles were found for ecotoxicology incidents or human health incidents
 - Majority of articles were related to water quality assessments

Prometon SMART Meeting

QUESTIONS AND ANSWERS

TIMELINE

CONCLUSIONS