
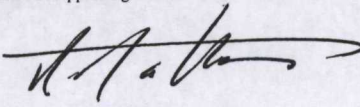


84059-5

7/29/2011

1/11

 U.S. ENVIRONMENTAL PROTECTION AGENCY Office of Pesticide Programs Biopesticides and Pollution Prevention Division (7511P) 1200 Pennsylvania Avenue NW Washington, D.C. 20460	EPA Registration Number: 84059-5	Date of Issuance: JUL 29 2011
	Term of Issuance:	Unconditional, Time Limited
	Name of Pesticide Product: MOI-401 EP	
NOTICE OF PESTICIDE: <input checked="" type="checkbox"/> Registration <input type="checkbox"/> Reregistration (under FIFRA, as amended)		
Name and Address of Registrant (include ZIP Code): Marrone Bio Innovations 2121 Second Street, Suite B-107 Davis, CA 95618		
Note: Changes in labeling, differing in substance from that accepted in connection with this registration, must be submitted to and accepted by the Biopesticides and Pollution Prevention Division prior to use of the label in commerce. In any correspondence on this product, always refer to the above EPA Registration Number.		
<p>On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA or the Act). Registration is in no way to be construed as an endorsement or recommendation of this product by the Environmental Protection Agency (EPA or the Agency). In order to protect health and the environment, the Administrator, on his or her motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.</p> <p>This registration does not eliminate the need for continual reassessment of the pesticide. If EPA determines at any time that additional data are required to maintain in effect an existing registration, the Agency will require submission of such data under section 3(c)(2)(B) of FIFRA.</p> <p>This product is unconditionally registered in accordance with FIFRA section 3(c)(5) and is subject to the following terms and conditions:</p> <ol style="list-style-type: none">1. Revise the EPA Registration Number to read as follows: "EPA Reg. No. 84059-5."2. The subject registration will automatically expire on July 29, 2012. For EPA to consider extending the expiration date of the registration, on or before April 30, 2012, you must submit a written request to EPA that both asks for an extension and details how you have complied with each of the terms set forth in this registration notice.		
-Continued on Page 2-		
Signature of Approving Official:  Keith A. Matthews, Director Biopesticides and Pollution Prevention Division	Date: 29 Jul 2011	

Marrone Bio Innovations
EPA Reg. No. 84059-5

3. Address the requirements for certain aspects of the manufacturing process described in Confidential Attachment #1.
4. Submit/cite all data required to support the manufacturing-use product, MOI-401 TGAI, which is used to create this product, by the due dates required in the terms and conditions of EPA Registration Number 84059-4:

Study Type	Required Data/Information	Due Date
Storage Stability (OPPTS Guideline 830.6317)	Provide the results of the ongoing one-year (minimum) storage stability study.	January 29, 2012

5. Submit the following data and/or information, determined by EPA to be acceptable, by the due dates specified below:

Study Type	Required Data/Information	Due Date
Storage Stability (Guideline Number 830.6317)	The storage stability study for this end-use product has been cited as ongoing. When the study has been completed and the results have been compiled, submit these data to EPA.	January 29, 2012
Corrosion Characteristics (Guideline Number 830.6320)	The corrosion characteristics study for this end-use product has been cited as ongoing. When the study has been completed and the results have been compiled, submit these data to EPA.	January 29, 2012

6. If you intend to request an extension to the registration expiration date (see term #2) to allow for longer term use of MOI-401 EP, on or before September 27, 2011, you must meet with EPA to discuss the need for additional data to support such use. Based on currently available information, EPA asserts that you must address the nontarget organism study irradiation and test substance equivalency issue, ensure maximum hazard dose testing, and provide test substance enumeration for the following toxicity or toxicity/pathogenicity studies:

- i) Avian Oral Toxicity (Guideline Number 885.4050)
- ii) Freshwater Fish Toxicity/Pathogenicity (Guideline Number 885.4200)
- iii) Freshwater Invertebrate Toxicity/Pathogenicity (Guideline Number 885.4240)
- iv) Estuarine and Marine Animal Testing (Guideline Number 885.4280)
- v) Nontarget Plant Testing (Guideline Number 885.4300)
- vi) Nontarget Insect Testing (Guideline Number 885.4340)

Marrone Bio Innovations
EPA Reg. No. 84059-5

- vii) Aquatic Invertebrate Range Testing (Guideline Number 885.4650)
- viii) Fish Life Cycle Studies (Guideline Number 885.4700)
- ix) Bivalve Acute Toxicity Test (Embryo – Larval) (Guideline Number 850.1055)
- x) Oyster Acute Toxicity Test (Shell Deposition) (Guideline Number 850.1025)

7. Adhere to the following expected environmental concentration (EEC) calculations, mitigation factors, and reporting requirements:

The pre-release calculated concentration of MOI-401 EP must be at or below 100 parts per million (ppm) in receiving waters (Refer to SOP #MBI 20.16.0, July 26, 2011) and treatment monitoring must ensure that the measured concentration is at or below 1 ppm at a pre-determined location 200 meters from discharge into flowing or static water (Refer to SOP #MBI-G-20.15.1, July 26, 2011 and SOP #MBI-G-20.17.1, July 26, 2011).

You must provide the pre-treatment notification information (see i – xv directly below) to EPA 30 days prior to treatment. If calculations show that the 100 ppm concentration is expected to be exceeded per the model results or that the facility may be within 5 miles of the critical habitat of federal endangered or threatened species, you must consult EPA for further guidance and obtain EPA concurrence on application to the site prior to treatment.

- i) Type of facility
- ii) Facility address and contact person details
- iii) Sampling locations for application monitoring
- iv) Water intake location (and water body)
- v) Treated system flow rate (e.g., gallon/day, m³/hr) or volume (L)
- vi) Application concentration (mg a.i./L)
- vii) Application time (min)
- viii) Calculated total kg/site/day
- ix) Water body and location of discharge
- x) River flow rate from nearest United States Geological Survey (USGS) gauging station. In locations with no USGS gauging station, flow rate will be attained from an independent and scientifically validated source (e.g., state and federal agencies and local non-profits such as Streamkeepers).
- xi) Calculations and calculated expected environmental discharge concentration per treatment application rate, treated water flow rate, and receiving water body dilution information
- xii) Model assumptions and model summary
- xiii) Model input data
- xiv) Model output data to include a minimum of the expected environmental concentration within 200 yards of the discharge zone
- xv) Endangered and Threatened Species Site Review – you must review the Endangered Species List

4/11

Marrone Bio Innovations
EPA Reg. No. 84059-5

(<http://www.fws.gov/endangered/>) for any endangered or threatened terrestrial or aquatic organisms and their critical habitats, if any, and submit the results of the review. The dates of the search must also be included, since the database is periodically updated. In addition, the notification must confirm that critical habitats of endangered or threatened species are outside of a 5 mile radius of the treatment site.

Treatment monitoring via measurements described in SOPs #MBI-G-20.15.1, July 26, 2011 and #MBI-G-20.17.1, July 26, 2011 are required to ensure that the EEC is measured at or below 1 ppm at a pre-determined location 200 meters from discharge into flowing or static water. In treatment monitoring, if the downstream turbidity concentration exceeds expected environmental concentration of 1 mg a.i./L based on correlation between turbidity and dry cell weight per SOP #MBI-G-20.15.1, you or the applicator will take corrective action. You or the applicator will perform additional downstream turbidity monitoring after every thirty minutes of any corrective action. If measurements continue to show an exceedance of the expected environmental concentration of 1 mg a.i./L after 1.5 hours, you or the applicator will turn off treatment metering pump. Any exceedance of the expected environmental concentration will be reported by you to Dr. Sheryl Reilly, Microbial Pesticides Branch Chief (EPA – BPPD), within 24 hours by phone (703-308-8269) and e-mail (reilly.sheryl@epa.gov).

On a quarterly basis, you will submit a report to EPA that includes the recorded measurement data. The report will be organized by facility and present a data summary per facility. The discharge monitoring data will present the turbidity and *Pseudomonas fluorescens* concentrations during and after treatment. The turbidity correlation and application monitoring will present data demonstrating the in-facility treatment concentration.

Per SOP #MBI-G-20.16.1, Site Selection Criteria and Calculation of Expected Environmental Concentration for MOI-401 EP, pre-release calculations will be conducted as follows:

Calculated total kg/site/day released $\rightarrow B = (X)(O)(T) (4 \text{ kg/gal})(10^{-6} \text{ mg/L})$

B = Release of material via blowdown water to surface water (kg/site/day)

X = Application concentration of material in water (mg a.i./L)

T = Application time (minutes)

O = Treated system flow rate (e.g. gallon/day, m³/hr) or volume (L)

Below are the three scenarios under which data will be presented in the pre-notification documentation:

- i) For facilities with National Pollutant Discharge Elimination System (NPDES) permits discharging to flowing waters that are included in the EFAST V 2.0 Probabilistic Dilution Model

Marrone Bio Innovations
EPA Reg. No. 84059-5

(PDM), you will run the PDM model and provide a printout of the PDM site specific results page. PDM is a screening-level exposure assessment tool developed by EPA to model chemical releases from point sources to flowing surface waters. For this analysis, the PDM component within EPA's Exposure and Fate Assessment Screening Tool Version 2.0 (E-FAST2) were used.¹

PDM uses detailed USGS stream flow data and facility specific data from NPDES permits to model chemical releases from actual facilities. For a modeling period of a given number of days, PDM calculates probability distribution of the chemical concentration in the receiving stream, and then estimates the number of days during which the in-stream chemical concentration is expected to exceed a concentration of concern (COC). PDM counts a day as having an exceedance of a COC if the COC is exceeded for any part of a 24-hour day. As a screening-level model, PDM outputs do not include the duration, location, or aerial extent of exceedances.

Inputs to PDM include facility NPDES number, pre-treatment release (i.e., loading rate), post-treatment release, number of release days, and COCs. Input values and assumptions used for this analysis are discussed below.

- ii) For facilities discharging to flowing waters that currently do not hold an NPDES permit or for facilities in which the discharge water body does not have a USGS gauging station and therefore is not included in the EFAST V 2.0 PDM, you will conduct and document mass balance calculations to determine the expected environmental concentration as follows:

$$C_c F_c + C_R F_R = C_T F_T$$

C_c = Applied concentration of product in cooling water. The maximum label amount is 0.026 oz. a.i./gallon (200 mg a.i./L).

F_c = Treated volumetric flow rate (Liters/hour, gallons/minute).

C_R = Concentration of MOI-401 EP in the river prior to point discharge. This value should be zero as there should not be product already existing in the water.

F_R = River volumetric flow rate prior to point discharge from cooling water systems (Liters/hour, gallons/minute).

C_T = Concentration after dilution with river water. This should be less than

¹ The E-FAST2 model is available from EPA at <http://www.epa.gov/opptintr/exposure/pubs/efastdl.htm> and documentation is available at <http://www.epa.gov/opptintr/exposure/pubs/efast2man.pdf>.

6/11
Marrone Bio Innovations
EPA Reg. No. 84059-5

0.00013 oz. a.i./gallon (1 mg a.i./L) per MOI-401 EP label requirements.

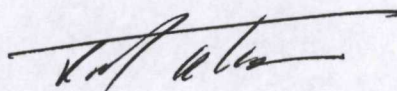
F_T = Total river volumetric flow rate and volume of discharge water.

These calculations and assumptions will be presented in the pre-notification documentation. Documented information will include the following: water body and location of discharge, river flow rate from nearest USGS gauging station (In locations with no USGS gauging station, flow rate will be attained from an independent and scientifically validated source (e.g., state and federal agencies and local non-profits such as Streamkeepers)), calculations and calculated expected environmental discharge concentration per treatment application rate, treated water flow rate, and receiving water body dilution information.

- iii) For facilities discharging to still waters (harbors, lakes, forebays), you will request diffusion and dilution models developed specifically for the facility and that have been certified to be representative of actual discharge dilution. You will use the models that facilities currently discharging under NPDES permits have previously developed and validated to determine the expected environmental concentration within 200 yards of the discharge point.
8. Submit two (2) copies of the final printed labeling before you release the product for shipment. Refer to the A-79 enclosure for further description of final printed labeling.

A stamped copy of the label is enclosed for your records.

Sincerely,



Keith A. Matthews, Director
Biopesticides and Pollution
Prevention Division (7511P)

Enclosures (3):
- MOI-401 EP Accepted Label
- A-79 Enclosure
- Confidential Attachment #1

7/11

MOI-401 EP

Biological Quagga and Zebra Mussel Control

ACTIVE INGREDIENT:

Pseudomonas fluorescens strain CL145A cells* 14.6%

OTHER INGREDIENTS: 85.4%

TOTAL: 100.0%

*Contains no more than 1.0×10^5 CFU/mL of *Pseudomonas fluorescens* strain CL145A cells.

One gallon of MOI-401 EP contains 20.47 ounces of active ingredient (or one liter contains 153 grams of active ingredient)

KEEP OUT OF REACH OF CHILDREN CAUTION

FIRST AID	
If inhaled	<ul style="list-style-type: none"> • Move person to fresh air. • If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. • Call poison control center or doctor for treatment advice.
HOT LINE NUMBER	
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1-800-222-1222 for emergency medical treatment information.	

EPA Reg. No.: (84059-~~A~~)

EPA Est. No.: 84059-CA-001

(Batch)(Lot) No: XXXX

Net Contents: 264 gallons (1000 liters)

Use by: (6 months after date of manufacture)

Manufactured by: Marrone Bio Innovations, Inc.
2121 Second St., Suite B-107
Davis, CA 95618 USA

Patent No. 6,194,194; Canada Patent No. 2,225,436

MOI-401 EP is a registered trademark of Marrone Bio Innovations, Inc. © 2008

ACCEPTED

JUL 29 2011

Under the Federal Insecticide, Fungicide,
and Rodenticide Act, as amended, for
the pesticide registered under
EPA Reg. No.

84059-5

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS – CAUTION: Harmful if inhaled. Avoid breathing vapor or spray mist. Remove and wash contaminated clothing before reuse.

Mixer/loaders and applicators must wear a dust/mist filtering respirator meeting NIOSH standards of at least N-95, R-95, or P-95. Repeated exposure to high concentrations of microbial proteins can cause allergic sensitization. Follow the manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables are available, use detergent and hot water. Keep and wash PPE separately from other laundry.

ENVIRONMENTAL HAZARDS: Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit (if required) and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this

product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA

DIRECTIONS FOR USE

It is a violation of federal law to use this product in a manner inconsistent with its labeling. Applications of MOI-401 EP must be under the supervision of Marrone Bio Innovations (MBI).

This label must be in the possession of the user at the time of pesticide application.

Mode of Action: Zebra and quagga mussels filter the product out of water and process the active ingredient as a food source. When the zebra and quagga mussels digest the product, the active ingredient disrupts the epithelial cells lining their digestive system causing mussel mortality. Since the MOI-401 EP efficacy is dependent on zebra and quagga mussel feeding activity and metabolism, which is affected by such factors as water temperature and mussel breeding activity, site assessments must be conducted to ensure appropriate timing of product application.

Treatment sites for MOI-401 EP: Treatments of MOI-401 EP are limited to enclosed and other confined static or flowing water infrastructures infested with zebra and/or quagga mussels. Treatment area must be a completely enclosed pipe or water conveyance system or concrete chamber with a defined inlet or outlet. Application of MOI-401 EP assumes the full flow and volume of water through the treated pipe or water conveyance system or concrete chamber with a defined inlet or outlet. Enclosed and other confined static or flowing water infrastructures include water storage chambers and tanks, pipes, general plumbing and equipment, and other water conveyance structures associated with civil infrastructure such as the cooling water systems and contained water storage chambers of power plants, pump stations, irrigation systems, industrial and manufacturing facilities (e.g. automobile and steel), and dams. **Treatment of open water, such as infested ponds, lakes, reservoirs, rivers and streams, or other unconfined aquatic systems, with MOI-401 EP is prohibited.**

Method of Application: Apply MOI-401 EP by injecting the product from a tote using chemical metering pumps directly into the enclosed system. This is similar equipment commonly used for chemical injection in water and wastewater treatment. Application is based on volumetric flow rates. For enclosed and confined systems (e.g. cooling and service water lines and fire

suppression systems), treated water flow rates and chemical injection rates are measured by using equipment such as flow meters and calibration columns. Use turbidity measurements before, during and after application as a surrogate to measure actual applied product.

Maximum Rate of Application of MOI-401 EP: Up to 0.026 oz/gallon (200 mg/L) active ingredient for up to 24 hours total per month.

Limitations on Discharge of Treated Water: Prior to treatment, site assessments must be conducted to ensure that the concentration of treated water from mussel infested infrastructure does not exceed an EEC (expected environmental concentration) of 0.00013 oz/gallon (1 mg/L) active ingredient no more than a 200 yard radius of the discharge or dilution zone of the treated infrastructure.

Monitoring Discharge of Treated Water: Water samples pre-, during, and post-treatment will be collected below the discharge location and above the treatment location to be analyzed for *Pseudomonas* concentrations and for turbidity. Number of samples and sampling frequency will be determined by Marrone Bio Innovations prior to treatment and described in the pre-notification.

Treatment Scenarios: Apply MOI-401 EP by one or both treatment scenarios, depending on the system, level of infestation, stage within mussel lifecycle, time of year and sensitivity of the system to abrasion/occlusion from invasive mussels:

1) Rehabilitation Level Treatment.

Rehabilitation treatments are conducted at high concentrations to remove adult mussel infestations. A rehabilitation treatment can be followed by a settlement maintenance treatment to protect facilities sensitive to any shell debris. (The settlement maintenance treatment scenario is described in the next section below entitled, "Settlement Maintenance Treatment"). The purpose of the rehabilitation treatment is to kill and/or remove attached adult mussels from infested systems. These treatments would be at concentrations near or at the maximum rate of 0.026 oz/gallon (200 mg/L) active ingredient for no more than 12 hours in a continuous 24 hour period. Cold water environments, such as the Great Lakes region, typically have only 2-3 zebra and/or quagga mussel lifecycles per year and require one rehabilitation treatment per year. Warm water environments, such as the Lower Colorado River, have up to 7 zebra and/or quagga mussel lifecycles per year. Rehabilitation level treatments are typically done once per year, but cannot occur more than twice per year.

2) Settlement Maintenance Level Treatments

Settlement maintenance is an on-going, lower dose treatment during the mussel spawning season and prevents juvenile mussels from settling and growing to the adult stage within the system and is similar, in function, to chlorine treatments. It is performed to protect pipes and orifices that are more susceptible to damage by mussel settlement, and prevents shell debris from clogging equipment or abrasion damage to equipment. Settlement maintenance treatments cannot exceed 0.0067 oz/gallon (50 mg/L) active ingredient for up to 12 hours per treatment and can be done no more than two times per month per treatment site.

Calculation of Application Rates:

For all applications, prior to product application, dilute MOI-401 EP into double contained plastic injection tank, tote, or similar container appropriate for use for chemical application into water. For every 0.26 gallon (1 liter) of MOI-401 EP added to plastic container add between 0.13 to 0.92 gallons (0.5 to 3.5 liters) of non-chlorinated water to achieve a concentration of 10.2 to 5.8 oz/gallon (76.5 to 43.7 g/L). Mix well. Once MOI-401 EP is diluted, follow application instructions as described below.

Enclosed, and other confined static and flowing water infrastructure

Rehabilitation Level Treatment: For adult zebra and quagga mussels control in enclosed and confined static and flowing water in infested infrastructures, e.g. water storage chambers or tanks and pipes and any water conveyance structures, associated with civil infrastructure such as, power plants, pumping stations, irrigation systems, industrial and manufacturing facilities (e.g. automobile and steel) and dams, inject diluted MOI-401 EP contained in the appropriate chemical injection tank (container) into flowing water at a point with heavy mixing with standard chemical injection metering pump to reach a completely mixed and homogeneous suspension of up to 0.026 oz/gallon (200 mg/liter) concentration of active ingredient.. Maintain continuous injection with the chemical metering pump production for 6 to 12 hours or until up to 0.026 oz/gallon (200 mg/L) active ingredient is reached in a static environment. For non-flowing, static, application conditions, product should be held in the contained treatment system for the total treatment time of 12 to 18 hours. To maintain a completely mixed and dispersed concentration, use a submersible pump or other mixing unit. To achieve the maximum desired concentration, calculate the injection rate (volumetric dose) based on the total volumetric water flow rate (or volume) and diluted product concentration.

Settlement Maintenance Level Treatment: For settlement prevention control of juvenile and planktonic zebra and quagga mussel life stages (veliger life stage) in enclosed and confined static and flowing water in infested infrastructures, e.g. water storage chambers and tanks and pipes and any water conveyance structures associated with civil infrastructure such as, power plants, pumping stations, irrigation systems, industrial and manufacturing facilities (e.g. automobile and steel) and dams, inject diluted MOI-401 EP contained in the appropriate chemical injection tank (container) at a location with heavy mixing with standard chemical injection metering pump to reach a completely mixed and homogeneous suspension of up to 0.0067 oz/gallon (50 mg/L) concentration of active ingredient. Maintain continuous injection with the chemical metering pump production for 1 to 6 hours until up to 0.0067_oz/gallon (50 mg/L) active ingredient is reached in a static environment. For non-flowing, static, application conditions, product should be held in the contained treatment system for the total treatment time of 6 hours. To achieve the necessary concentration, calculate the injection rate (volumetric dose) based on the total volumetric water flow rate (or volume) and diluted product concentration. Repeat injection up to two times a month, dependent on viable veliger density, continuously through mussel spawning season.

Product measurement in treated system

Perform turbidity measurements to determine when the desired completely mixed homogenous concentration of MOI-401 EP active ingredient is achieved and to the required MOI-401 EP active ingredient concentration. In order to correlate target turbidity to desired active ingredient concentration, add the necessary volume of diluted MOI-401-EP to achieve the target concentration into a known volume of water contained in a plastic or glass container and mix. Read turbidity of this mixture – this is the target turbidity for desired completely mixed homogenous concentration. If turbidity concentrations exceed label or pre-notification intended

11/11

use, applicator will adjust chemical metering pump or shut down application system entirely to prevent exceeding the expected environmental concentration upon discharge.

Prior to any treatment, site assessments must be conducted to ensure that the concentration of treated water from mussel infested infrastructure does not exceed an EEC (expected environmental concentration) of 0.00013 oz/gallon (1 mg/L) active ingredient no more than a 200 yard radius from the discharge or dilution zone of the treated infrastructure.

Water samples pre-, during, and post-treatment will be collected below the treated discharge location and above the treatment location to be analyzed for *Pseudomonas* and for turbidity). Number of samples and sampling frequency will be determined by Marrone Bio Innovations prior to treatment and included in the pre-notification.

After application, allow 2 to 4 weeks, respectively, at warm (ca. > 68°F (20°C)) to cold (ca. < 50 F (10°C)) water temperatures before determining the final mortality achieved, via biobox monitoring or similar industry practice, from each treatment.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

Pesticide Storage: Store in original container at less than -4°F (-20°C) for up to 6 months after date of manufacture.

Pesticide Disposal: To avoid wastes, use all material in this container by application according to label directions. If wastes cannot be avoided, offer remaining product to a waste disposal facility or pesticide disposal program (often such programs are run by state or local governments or by industry).

Container Disposal: Triple rinse container promptly after emptying. Triple rinse as follows: Empty remaining contents into application equipment or a mix tank. Fill the container ¼ full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container on its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times.

WARRANTY

To the extent consistent with applicable law, the seller makes no warranty, expressed or implied, of merchantability, fitness or otherwise concerning use of this product. To the extent consistent with applicable law, the user assumes all risks of use, storage or handling that are not in strict accordance with the accompanying directions.