

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

April 27, 2017

Jeff Jones Agent, Clarion Water, LLC c/o Delta Analytical Corp. 12510 Prosperity Drive, Suite 160 Silver Spring, MD 20904

Subject: Label Amendment – Adding use sites and alternate brand names Product Name: loMax Recharge EPA Registration Number: 91282-2 Application Date: December 9, 2016 Decision Number: 524815

Dear Mr. Jones:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

The following alternate brand names have been added to the product record:

• loMax

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• loMax Aqueous Iodine

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6. If you have any questions, you may contact Donna Kamarei at (703)347-0443 or via email at Kamarei.donna@epa.gov.

Sincerely,

Wark A Sh, you

Demson Fuller, Product Manager 32 Regulatory Management Branch II Antimicrobials Division (7510P) Office of Pesticide Programs

Enclosure

Precautionary Statements

Hazards to Humans and Domestic Animals

DANGER. CORROSIVE. Crystal iodine causes irreversible eye damage and skin burns. May be fatal if swallowed or inhaled. Harmful if absorbed through the skin. Do not get in eyes, or on skin or on clothing. Do not breathe dust. When handling crystal iodine, wear protective eyewear (goggles, face shield or safety glasses) and protective clothing (coveralls worn over long-sleeved shirt and long pants, socks, chemical-resistant footwear, and gloves). Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

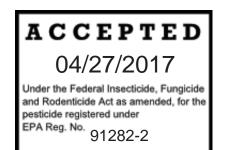
Environmental Hazards

lodine In crystal form is toxic to fish. 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 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 treatment Board or Regional Office of the EPA.

Physical and Chemical Hazards

Do not store or ship in the presence of ammonia. This product will form explosive nitrogen iodides when contacted with liquid ammonia, aqueous ammonia solutions such as household ammonia or alkaline solution of ammonium salts.

EPA Reg. No. 91282-EPA Est. No. xxxxx-xx-xxx



IoMax[™] Recharge

[Alternate Brand Names to be added: IoMax[™] and IoMax[™] Aqueous Iodine]

FOR INDUSTRIAL, COMMERCIAL AND AGRICULTURAL USE ONLY

Net Contents:

ACTIVE INGREDIENT:

lodine:	. 99.9%
OTHER INGREDIENTS:	0.1%
TOTAL:	100.0%

Keep Out of Reach of Children

DANGER

See Side Panel for Additional Precautionary Statements

FIRST AID

If on Skin: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

If in Eyes: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

If Inhaled: 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 a poison control center or doctor for further treatment advice.

If Swallowed: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything to an unconscious person.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may contact poison control center at 1-800-222-1222 for emergency medical treatment information.

Note to Physician: Probable mucosal damage may contraindicate the use of gastric lavage.

Manufactured by: Clarion Water Inc. 3530 W. Garry Ave. Santa Ana, CA 92704 714 352-2300

Storage and Disposal

Do not contaminate water, food or feed by storage or disposal Storage: Keep IoMax[™] Recharge canister tightly closed. Store In a dry place. Do not store in the presence of ammonia.

Pesticide Disposal: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your state pesticide or environmental control agency, or the hazardous waste representative at the nearest EPA Regional Office for guidance.

Canister Handling: Refillable container. This container to be refilled with iodine only. Do not reuse this container for any other purpose. Clarion is responsible for cleaning the container before refilling and final disposal. <u>Do not throw expended IoMax[™] Recharge canisters in the trash</u>. Contact your Clarion rep for collection and disposal.

Directions for Use

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

For Direct Injection Systems: Deliver metered IoMaxTM via Clarion direct injection dosing appliance, installed and calibrated by Clarion authorized personnel, utilizing pre-configured concentrations and application frequency.

For Batch Systems: Produce IoMax[™] via Clarion batch dosing appliance, installed and calibrated by Clarion authorized personnel and discharge into Clarion-approved secondary container. Keep full storage containers sealed when not in use.

General Guidelines: Install IoMax[™] Recharge canister into Clarion Aqueous Iodine Dosing System unit as explained in the Clarion Aqueous Iodine Dosing System Operating Instructions. Adjustments can be made manually in the touch screen interface to achieve iodine concentrations specified per application. Clarion Aqueous Iodine Dosing Systems can achieve dosing concentrations between 2 and 220 ppm. $IoMax^{TM}$ canisters may only be changed by certified Clarion technicians.

APPLICATION INFORMATION

FOR SANITIZING POULTRY DRINKING WATER:

Use Clarion Aqueous lodine Dosing System to achieve a concentration of 6 to 16 ppm within drinking water system. Do not use this product together with other water treatments.

FOR SANITIZING LIVESTOCK DRINKING WATER & NON-POTABLE FARM WATER SYSTEMS: Use

Clarion Aqueous lodine Dosing System to achieve a concentration of 6 to 16 ppm within drinking water system. Do not use this product together with other water treatments

LIVESTOCK BARNS & TRANSPORTATION

VEHICLES: Utilize a solution containing 25 ppm titratable iodine.

1. Remove all livestock from premises, trucks, coops and crates.

2. Remove all litter and droppings from floors, walls and surfaces of facilities occupied or traversed by livestock.

3. Empty all troughs, racks, and other feeding and watering appliances.

4. Thoroughly clean all surfaces with soap or detergent and rinse with water.

5. Saturate surfaces with the recommended disinfecting solution for a period of 10 minutes.6. Ventilate buildings, coops and other closed spaces.Do not house livestock or employ equipment until treatment has been absorbed, set or dried.

7. Thoroughly scrub treated feed racks, troughs, automatic feeders, fountains and waterers with soap or detergent, and rinse with potable water before reuse.

FOR SANITIZING MILKING EQUIPMENT, CLAW SYSTEMS, TEAT CUPS AND DAIRY UTENSILS:

Immediately after milking, flush milking equipment and utensils with lukewarm (100°F, 38°C) water to wash out all milk. Take apart milking machines and immerse air hoses, inflations, metal parts (except pulsator) and utensils in a solution containing 25 ppm titratable iodine. Brush all parts thoroughly. Drain completely, rinse with water and allow to air dry. After emptying bulk tanks, flush tanks thoroughly with 100°F (38° C) water to wash out all milk. Allow wash solution to drain, rinse with water and allow rinse water to adequately drain.

SANITIZING FOOD-GRADE EGG SHELLS: Coarse spray previously cleaned food-grade eggshells with a solution containing 25 ppm titratable iodine. Solution temperature should be warmer than the eggs, but not to exceed 130°F (53°C). Wet eggs thoroughly for 1 minute and allow to drain. Eggs should be reasonably dry before casing or breaking. Do not reuse solution to sanitize eggs.

RETORT COOLING WATER: Utilize an IoMax[™] solution containing 12.5 – 25 ppm to control slime, and odor causing bacteria. Add prior to starting up operation and as needed thereafter to maintain a titratable iodine reading of 12.5 - 25 ppm in the cooling water.

HVAC UNITS: Use an IoMax[™] solution containing 12.5 - 25 ppm to clean and sanitize cooling coils, heating coils, and drain pans. This sanitization claim does not include use in air ducts. If heavy deposits are present, remove before applying. Allow 10 minutes contact time. Rinse with water.

DEODORIZING: IoMaxTM destroys many odors as it sanitizes and disinfects. For general deodorant applications (garbage pails, refuse containers, landfills, recycling centers, etc.), swab surface to be treated with an IoMaxTM solution containing 200 ppm titratable iodine. Allow treated surface to adequately drain.

GENERAL FARM PREMISES: For general cleaning of farm premises use an $IoMax^{TM}$ solution containing 12.5 ppm titratable iodine. Thoroughly rinse down all surfaces.

CONDITIONS OF SALE AND LIMITATION OF WARRANTY AND LIABILITY

NOTICE: Read the entire Directions for Use and Conditions of Sale and Limitation of Warranty and Liability before buying or using this product. If the terms are not acceptable, return the product at once, unopened, and the purchase price will be refunded.

Manufacturer and Seller warrant that this product conforms to the chemical description on the label and is reasonably fit for the purposes stated in the Directions for Use, subject to the inherent risks referred to above, when used in accordance with directions under normal use conditions. This warranty does not extend to the use of this product contrary to label instructions, or under abnormal conditions or under conditions not reasonably foreseeable to or beyond the control of Seller or Manufacturer, and Buyer and User assume the risk of any such use. MANUFACTURER AND SELLER MAKE NO WARRANTIES OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE NOR ANY OTHER EXPRESS OR IMPLIED WARRANTY EXCEPT AS STATED ABOVE.

In no event shall Manufacturer or Seller be liable for any incidental, consequential or special damages resulting from the use or handling of this product. THE EXCLUSIVE

REMEDY OF THE USER OR BUYER. AND THE EXCLUSIVE LIABILITY OF MANUFACTURER AND SELLER FOR ANY AND ALL CLAIMS, LOSSES, INJURIES OR DAMAGES (INCLUDING CLAIMS BASED ON BREACH OF WARRANTY, CONTRACT, NEGLIGENCE, TORT, STRICT LIABILITY OR OTHERWISE) RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, SHALL BE THE RETURN OF THE PURCHASE PRICE OF THE PRODUCT OR. AT THE ELECTION OF MANUFACTURER OR SELLER, THE **REPLACEMENT OF THE PRODUCT. Manufacturer** and Seller offer this product, and Buyer and User accept it, subject to the foregoing conditions of sale and limitations of warranty and of liability, which may not be modified except by written agreement signed by a duly authorized representative of Manufacturer.

IoMaxTM Clarion Aqueous Iodine Dosing System



Operating Instructions

Direct Injection System



3500 W. Garry Ave. Santa Ana CA 92704 Web: www.clarionwater.com For Service please call: (1) 714.352.2300

Release Level

Date	Issue	Application	Author	Approval	Description of Revision
30/09/05	2.0	Microsoft Word	B.T.	C.W.	New Manual layout
15/03/16	3.0	Microsoft Word	S.D.	T.B	New System Schema
25/04/17	4.0	Microsoft Word	S.D.	T.B.	New Naming Convention

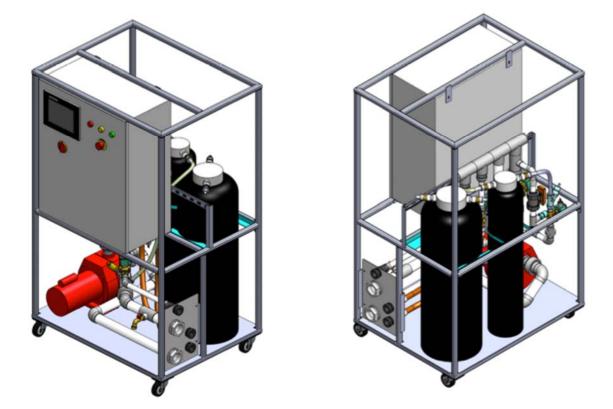


Date:	25/04/17
Issue:	4.0

INTRODUCTION

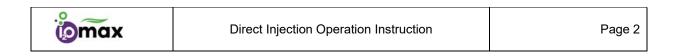
Thank you for choosing the Clarion Aqueous lodine Dosing System. We know that you will be pleased with your purchase and have many years of reliable service from the system. To achieve the best from the system it is important that customers have a good understanding of all the features that the system offers. The standard features of the system are described in this document and if operators have any questions about the correct method of operation they must consult their authorized representative as required.

Features as Standard



Touch Screen HMI

The Clarion Aqueous lodine Dosing System instrumentation features the next generation of microprocessors which ensures a user-friendly approach to functions, which enables the operator to confidently go about their business without undue concerns about the day to day running of their system.





It is recommended that the electrodes are wiped at least twice weekly and preferably daily for optimum performance. (Refer Customer Maintenance Manual).

In the case where a filter is fitted it should be cleaned at the end of each day for best results.

Iodine Measuring and Dosing

Two **Ion Selective Electrodes (ISE)** are incorporated in the system and their function is to measure millivolts in the water line generated by the presence of iodine in the water. The instrument converts the millivolt reading into a ppm digital reading. The instrument is programmed to automatically compare the actual ppm in the water line against the set point entered by the operator and adjust as required.

As the water flow in the line increases or decreases and the iodine in the water line becomes high or is depleted due to iodine coming in contact with dirt and organic matter the electrodes record a drop or rise in millivolts and the instrumentation responds accordingly by adjusting the valve to dose iodine (or reduce dosing) into the line until the desired level has been reached to coincide with the set point.

lodine does not react with organic matter in the same way as other biocides and as such the reading at the instrument is usually similar to the reading further down the line.

Display Set Points ppm vs Actual ppm

A feature of the Clarion Aqueous lodine Dosing System is that it has a very user friendly, simple operating system. The digital display on the control panel displays a set point (required iodine level) and actual level. The operator simply presses an "**up or down**" button located on the instrument panel (after entering password – see relevant section) to set the desired iodine ppm level.

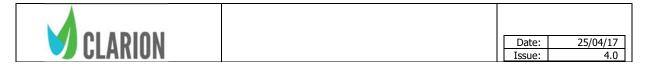
Iodine Canister Level Controls

The Clarion Aqueous lodine Dosing System actively measures iodine supply. When the cartridge has only 5% remaining, the instrument displays "Canister Empty" message. It is recommended that when canister level reaches 30% Clarion will contact you to schedule cartridge replacement by an Authorized Clarion Service Technician.

Fail Safe Mechanisms

The iodine system uses the highest quality components with fail safe mechanisms incorporated in the design.





- High iodine alarm warns operator of high iodine overdosing situation.
- Low iodine alarm warns operator of a low iodine situation.
- The Clarion Aqueous lodine Dosing System has the ability to interface with other equipment for complete automation of facility.
- Standard inbuilt modem for customer assistance or unit service as required.

All alarms feature digital display, audio signal and the ability to operate a self powered alarm flashing strobe light if required.

OPTIONS

PC System Interface.

This PC system interface is optional on all Clarion Aqueous lodine Dosing Systems and provides the highest level of operational sophistication available in a disinfection system. This feature enables an operator to fully interact, and operate the iodine dosing system in the same manner as if present at the instrument itself.

The system also has the ability to further interface with any Windows based PLC controller to further customize or automate the dosing process.

The PC interface also enables operator to data log their dosing and if necessary prepare a Q/A certificate for their customers. It also enables additional tasks to be undertaken as follows:

- Open full mimic instrument panel remotely (e.g. at the office).
- Investigate current remote operation.
- Alter all settings as required.
- Check iodine canister levels.
- Check iodine levels in the main line.
- Check past performance through integral data logger software.
- Conduct system audit via data logger information.
- Check correct valve/pump/pressure operation.
- A comprehensive diagnostics program is incorporated within the Clarion Water software for use by Clarion Water staff.

Modem - Dial in Option.

This standard feature enables an operator or Clarion Water staff to interact fully with the Clarion Aqueous lodine Dosing System anywhere in the country. The system dosing requirements can still be managed from remote locations.





All the normal above software is featured and operator can fully manage the system remotely as with the standard hard wiring.

Q/A Certificate.

The easy to follow Clarion Aqueous lodine Dosing System software enables an operator to print out a Q/A certificate with actual dosing levels data attachment, showing all the disinfection ppm levels for a given period. Graph print out is also available.

This certificate may accompany the goods to final destination.

Custom Designed Interface.

In larger facilities the Clarion Aqueous Iodine Dosing System can interface with other computer controlled equipment and interface with PLC controllers automatically. The dosing system will shut down solenoid valves or pumps when iodine levels are too high or too low and may take evasive action automatically as required as it has temperature and pressure sensors built into as standard.

IoMax[™] IODINE CRYSTALS

The IoMax[™] Recharge (patented) 99.9% pure iodine crystals have been specifically manufactured by Clarion Water. Limited to operate in the Clarion Aqueous Iodine Dosing System.

lodine crystals from other sources have vastly different characteristics and are not suitable for use in the system.

If iodine crystals from another source are used the Clarion Aqueous Iodine Dosing System will fail to operate correctly.

The use of other forms of iodine crystals also constitutes a breach of license agreement, warranty and service agreement as they could seriously damage the Clarion Aqueous lodine Dosing System and electrodes.

lodine crystals from other sources may not be registered with the Statutory Authorities and consequently illegal to use with this system.



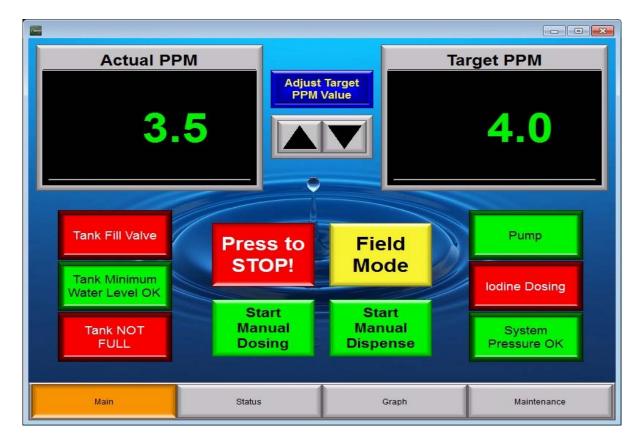


The Material Safety Data Sheet contained in this document must be observed at all time by operators when running the Clarion Aqueous lodine Dosing System or when your authorized agent handles loMax[™] iodine crystals cartridges or open iodine canisters.

The Clarion Aqueous lodine Dosing System is a precision piece of equipment, which must be regularly serviced in accordance with the Clarion Water. Limited. authorized service manual.

Only Clarion Authorized Service Technicians are permitted to install and service the Clarion Aqueous Iodine Dosing System. A service cycle time is negotiated with your authorized representative at the time of purchase. The servicing of the dosing system must be carried out with due care and diligence as certain aspects to the procedure can be hazardous and cause serious injury.

Your authorized service representative staff must to always wear the relevant personal protective equipment as outlined in the MSDS. It is recommended that the dosing system area be kept well ventilated at all times.



INSTRUMENT OPERATIONS AND COMMANDS

ADJUST TARGET PPM



Target PPM can be adjusted by pressing up or down on the arrows. A Clarion Authorized Service Technician will provide the recommended PPM based upon water quality samples and trials performed at time of system commissioning.

FIELD MODE

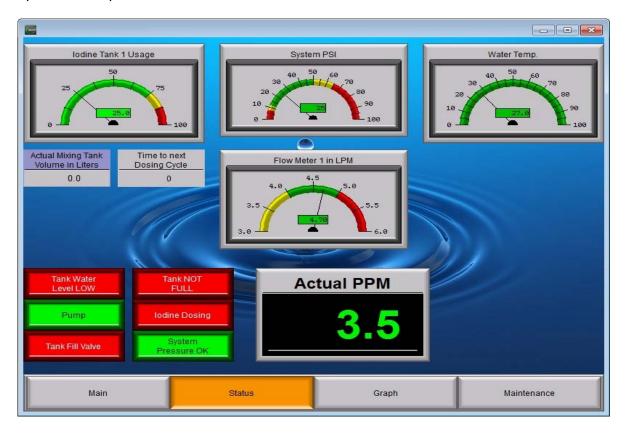
Field Mode allows for "set and forget" operation. It must be configured by a Clarion Authorized Service Technician

STOP

"Press to STOP" button ceases all dosing and dispensing immediately.

START MANUAL DOSING & DISPENSING

Manual Dosing allows the user to fill to and dispense fro a tank rather than directly injecting into a water piping. A Clarion Authorized Service Technician will configure these options as required.



DIAGNOSTICS





The Clarion Aqueous lodine Dosing System controls system monitors the status of all critical system components and will report the status as Green or Red for the following:

- Tank Fill Valve Green means tank fill valve is open.
- Tank Water Level Minimum Green means tank is filled to above minimum level for dosing.
- Tank Full Green means tank is full.
- Pump Green means pump is operational.
- Iodine Dosing Green means the system is currently dosing Iodine.
- System Pressure Green means system pressure is within upper and lower limits.

The Clarion Aqueous lodine Dosing System controls system also provides real time monitoring on lodine supply, pressure, water temperature and flow, which can be viewed on the status screen, shown above.

CANISTER REPLACEMENT

For instructions on how to replace canisters, please see Direct Injection System Canister Replacement Manual or call (1) 714.352.2300 to setup a service appointment for an Authorized Clarion Technical Representative.

