



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

March 20, 2020

Nicole Perkinson
Authorized Agent for Medentech Ltd.
Medentech Ltd.
Whitemill Industrial Estate
Clonard Road, Wexford, Ireland

Subject: Label Amendment – Addition of use directions and minor label changes
Product Name: FLOGENIC
EPA Registration Number: 71847-5
Application Date: July 5, 2019
Decision Number: 554358

Dear Ms. Perkinson:

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.

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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, please contact Melanie Bolden by phone at (703) 347-0165, or via email at Bolden.Melanie@epa.gov.

Sincerely,

A handwritten signature in blue ink that reads "Wanda G. Fuller, for". The signature is written in a cursive style.

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

Enclosure

{All text in brackets [xxx] is optional and may or may not be intended on a final label.}
 {All text in braces {xxx} is administrative and will not appear on a final label.}
 {Note to Reviewer: In accordance with 40 CFR 156.68(d), all first aid statements, as prescribed, will appear on the front panel of the product label.}

Flogenic

{Alternate product names:}

[Aquatabs Flo]

[Aquasept Flo]

[Aquasept InLine]

[Aquatabs InLine]

{Optional marketing statements that may be used with drinking water uses. One or more statements may be combined.}

[Stabilized]

[Chlorinating Tablets]

[1" Tablets]

[Concentrated]

[Concentrate]

[Long Lasting]

[Sanitizer]

[Sanitizes, Clarifies, and protects against Algae]

[Suppresses algae]

[Controls Algae, and Clarifies]

[For Routine Sanitation and Clarification]

[Keeps Water Clear]

[Slow Dissolving]

[Completely soluble]

[For Routine Use]

[Chlorinating tablets for water disinfection]

[No mineral scale build-up]

[24-hr chlorine residual for round-the-clock activity]

[Contains No Heavy Metals]

[Easy To Use]

[Easy to install]

[Treats up to 360,000 Liters of Water]

[Treats up to 145,000 Liters of Water]

[For [Animal] [And] [Human] Drinking Water]

[Water Purification System]

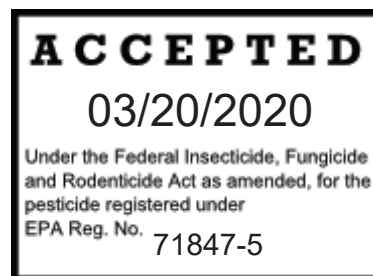
[Tablets Dissolve in Flowing Water]

[No Power Required]

[Simple]

[Maintenance Free]

[Cost Effective]



KEEP OUT OF REACH OF CHILDREN

DANGER

Active Ingredient:

Trichloro-s-triazinetrione:99%

Other Ingredients:1%

Total:100%

Available Chlorine:90%

FIRST AID	
If in eyes	<ul style="list-style-type: none"> • 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 on skin or clothing	<ul style="list-style-type: none"> • 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 inhaled	<ul style="list-style-type: none"> • Move person to fresh air.

	<ul style="list-style-type: none"> If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible. Call a poison control center or doctor for further treatment advice.
If swallowed	<ul style="list-style-type: none"> 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 by mouth to an unconscious person.
<p>IN THE EVENT OF A MEDICAL EMERGENCY CALL YOUR POISON CONTROL CENTER AT 1-800-222-1222 Have the product container or label with you when calling a poison control center or doctor, or going for treatment</p>	
<p>NOTE TO PHYSICIAN Probable mucosal damage may contraindicate the use of gastric lavage.</p>	

See [back] [side] [inside] [panel[s]][insert][booklet][pamphlet] [outer carton label][product label], [product container label] [and][or] [leaflet] for additional [precautionary statements] [and] [full] [directions for use] [storage and disposal]

PRECAUTIONARY STATEMENTS
HAZARDOUS TO HUMANS AND DOMESTIC ANIMALS
DANGER

CORROSIVE.

Causes irreversible eye damage and skin burns. May be fatal if inhaled or absorbed through skin.

Harmful if swallowed.

Do not breathe dust or spray mist. Irritating to nose and throat. Do not get in eyes, on skin, or on clothing. Wear protective eyewear (goggles or face shield), protective clothing, and chemical-resistant gloves when handling this product. 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.

{for end-use products packaged in containers sizes of less than 50 pounds}

[ENVIRONMENTAL HAZARDS

This pesticide is toxic to fish and aquatic organisms.]

{for end-use products packaged in container sizes greater than or equal to 50 pounds}

[ENVIRONMENTAL HAZARDS

This pesticide is toxic to fish and aquatic organisms. Do not contaminate water by cleaning of equipment or disposal of waste. Do not discharge effluent containing this product into lakes, ponds, streams, estuaries, oceans, or public 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 Board or Regional Office of the EPA.]

PHYSICAL OR CHEMICAL HAZARDS

STRONG OXIDIZING AGENT. Do not mix with other chemicals. Mix with water only. Use only clean dry utensils. Contamination with moisture, dirt, organic matter or other chemicals (including pool chemicals) or any other foreign matter may start a chemical reaction with generation of heat, liberation of hazardous gasses and possible generation of fire and explosion. Avoid any contact with flaming or burning material such as a lighted cigarette. Do not use this product in any chlorinating device which has been used with any inorganic or unstabilized chlorinating compounds (e.g. calcium hypochlorite). Such use may cause fire or explosion.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Read entire label and use strictly in accordance with precautionary statements and directions.

[NON PRESSURIZED SYSTEM]

[Public Systems: A free available chlorine residual of at least 0.2 ppm is attained at the furthest point in the distribution system, as measured by a suitable test kit. Check water frequently as prescribed by the National Primary and Secondary Drinking Water Regulations. Contact your local Health Department for further details.]

[*Drawing-see master

(1) (2) (3)

Figure 1. Flogenic (1), 1/2" pipe connector (2), and Flogenic float valve (3)]

[Flogenic {or marketed product name}. First Installation

Flogenic {or marketed product name} (1) is for connection at the point at which the water discharges to a storage tank or container. The product container is connected to the water supply by way of a ½" pipe fitting (2) or with the Flogenic {or marketed product name} float valve (3) depending on what the individual system requires. The standard fitting or float valve is installed first.

To install using the standard fitting.

Turn off the water flow at the supply. The outlet of the water supply must be a valve or other connector with a ½" pipe fitting. If the water pipe does not end in a ½" female pipe thread, a suitable adaptor is required. Connect the Flogenic {or marketed product name} ½" connector to the water outlet using PTFE pipe tape to get a leak free connection. Turn the device using a 22 mm wrench until the two connecting points are horizontal.]

[*Drawing-see master

Figure 2. Connect ½" pipe connector (2) to a valve using 22 mm wrench. Seal with PTFE pipe tape. Turn until clips are horizontal.]

[To install the Flogenic {or marketed product name} float valve

Turn off the water flow at the supply. Replace the current ballcock float valve with the Flogenic float valve.]

[*Drawing-see master

Figure 3. Flogenic {or marketed product name} float valve connector.]

[Fitting the Flogenic {or marketed product name} Cartridge

Remove the Flogenic {or marketed product name} container from its packaging. Look at the outlet at the bottom of the unit. The bottom of the internal screw must be in line with the wall or use a flat head screw driver to adjust until it is. The screw should now be set. For less chlorination, under 2 ppm, leave the screw as it is.]

[*Drawing-see master

Figure 4. Adjust screw with screwdriver as shown until 0 threads (a) or 5 threads show (b).]

[Place the Flogenic {or marketed product name} container on the connector (figure 5) and turn 1/8th of a turn clockwise to lock in place. The unit should be horizontal or tilted slightly downward in the direction of flow. Turn on the water flow and allow it to flow for 1 minute. Sample the water and test with the chlorine strips provided. If the amount of chlorine as indicated on the guide is within the required range, >0.2 ppm, the device is ready until it is rechecked 24 hours later. If the amount of chlorine is too low, turn the adjustment screw clockwise ensuring not to over-tighten the screw as this will shear the threads. If the amount of chlorine is too high, turn counterclockwise. Let the water flow for another minute and retest. If the amount of chlorine is within the desired range, leave for 24 hours.]

[*Drawing-see master

Figure 5. Place Flogenic {or marketed product name} container on connector and turn 1/8th of a turn until it clicks in place.]

[Retest the chlorine in the storage tank and at the end of the line after 24 hours. The chlorine level in the storage tank must be in the range of at least 0.2 ppm. There must be a residual chlorine level of at least 0.2 ppm at the furthest point on the line. If the amount of chlorine is too low or too high, adjust the screw as shown above and test again after 24 hours until the system is in the correct range. Make a note of the final setting and use it to set the device when it is replaced.]

[Replacing the Flogenic {or marketed product name} cartridge

When the tablets can no longer be seen in the unit, it should be replaced. Alternatively, the chlorine test strips provided can be used to determine if the unit requires replacement.

To replace the cartridge, first turn off the water at the source. Remove the spent cartridge. Note the screw setting in the spent device by counting the number of threads visible when looking into the device through the outlet. Use a flat head screw driver to set the screw on the new cartridge by turning the screw one full turn clockwise for each visible thread. Follow steps as above for fitting Flogenic {or marketed product name} Cartridge.]

[PRESSURIZED SYSTEM]

{Mandatory text}

[ADDITIONAL INFORMATION]

Minimum water pressure: 1 bar

Maximum water pressure: 5 bar

DO NOT remove the safety relief valve from the housing under any circumstances

Do not use if safety relief valve is not in place.

Do not tamper with safety relief valve

Use only Polypropylene connections

Ensure instructions for flushing the device are followed correctly at all times]

[INSTALLATION OF [FLOGENIC {or marketed product name}] HOUSING

The [Flogenic {or marketed product name}] housing unit [reference figure 6] fits easily onto a bypass system for cold water. Turn off the main water supply. Cut away required length of pipe. Using a 1 ½" piping adapter if needed, place stop valves suitable for a 1 ½" pipe at each end of the cut on the mains pipe. Attach a 1 ½" female thread securely to each end of the [Flogenic {or marketed product name}] housing (Figure 6) using [plumbing] [PTFE] tape. Do not use sealant. Ensure the water inlet arrow is pointing in the direction of the water flow. Keeping the housing in an upright position connect to the stop valves attached the mains pipe.]

[HOW TO ATTACH THE [TABLET] CARTRIDGE [SOLD SEPERATLY]

Wear safety goggles mask and gloves. Unscrew the retaining ring from the housing unit. Remove the cap from the cartridge [reference Figure 7]. Guide the cartridge into the [Flogenic {or marketed product name}] housing [reference figure 8] aligning the circular grid opening [(x)] with the water inlet situated on the underside of the housing [(y)]. Apply gentle upward pressure to secure. To ensure the cartridge is fitted correctly, when gently twisted, limited movement should be observed. Until the retaining ring is secured ensure the tablet cartridge is held in place by the user. Replace the retaining ring and tighten in a counter-clockwise direction.]

[OPERATION OF FLOGENIC {or marketed product name}] FOR PRESSURIZED SYSTEMS

Turn on the water supply and **flush the system continuously for a least 5 minutes to ensure all components are fitted correctly. If the water supply has been closed off or diverted for any length of time, flush the system for at least 5 minutes.** During the flushing stage, all water that has passed through the system should be disposed of as per label storage and disposal instructions.

As the tablet cartridge may become discolored over time, ensure a free available chlorine residual of at least 0.2 ppm is attained at the furthest point in the distribution system, as measured by a suitable test kit. [Check water frequently as prescribed by the National Primary and Secondary Drinking Water Regulations. Contact your local Health Department for further details]. If the available chlorine content in treated water is less than 0.2 ppm, the cartridge needs to be changed.]

[CHANGING THE [TABLET] CARTRIDGE

Flush the system for at least 5 minutes. Ensure that safety goggles, mask and gloves are being worn when replacing the cartridge. Unscrew the retaining ring and gently pull the cartridge from the housing. Dispose of as per label storage and disposal instructions. Remove the cap from the new cartridge. Guide the cartridge into the [Flogenic {or marketed product name}] housing [figure 8] aligning the circular grid opening [(x)] with the water inlet situated on the underside of the housing [(y)], apply gentle pressure to secure. To ensure the cartridge is fitted correctly, when gently twisted, limited movement should be observed. Until the retaining ring is secured ensure the tablet cartridge is held in place by the user. Replace the retaining ring and tighten in a counter-clockwise direction]

STORAGE AND DISPOSAL

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

PESTICIDE STORAGE

Store in a dry, cool and well-ventilated area. Avoid moisture getting into container. Keep off wet floors. In case of spillage, wash with large amounts of water. After each use, keep container tightly closed. OXIDIZING MATERIAL. Keep away from flames, sparks, and all sources of heat. Avoid contact with organic material.

PESTICIDE DISPOSAL

Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, 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.

{Nonrefillable container – household/residential use; size: 50 pounds or less.}

[CONTAINER HANDLING

Nonrefillable container. Do not reuse or refill this container. Rinse empty container thoroughly with water to dissolve all material prior to disposal. Offer for recycling, if available.]

{Nonrefillable container – single-use, non-resealable package; size: 50 pounds or more, less than 50 pounds.}

[CONTAINER HANDLING

Nonrefillable container. Do not reuse or refill this container. Rinse and discard empty container thoroughly with water to dissolve all material prior to disposal. Offer for recycling, if available.]

{Nonrefillable container – Dry Granulated Product – single-use, non-resealable package; size: 50 pounds or more, less than 50 pounds.}

[CONTAINER HANDLING

Nonrefillable container. Do not reuse or refill this container. Completely empty bag into application equipment by shaking and tapping sides and bottom to loosen clinging particles. If not emptied in this manner, the bag may be considered an acute hazardous waste and must be disposed of in accordance to local, state, and federal regulations. When completely empty, offer for recycling, if available.]

{Nonrefillable container – Fiber Drums with Liners; size: 50 pounds or more.}

[CONTAINER HANDLING

Nonrefillable container. Do not reuse or refill this container. Completely empty liner into application equipment by shaking and tapping sides and bottom to loosen clinging particles. If not emptied in this manner, the bag may be considered an acute hazardous waste and must be disposed of in accordance to local, state and federal regulations. When completely empty, offer for recycling, if available.]

{Nonrefillable container- non-household/residential use; size: 50 pounds or less, 50 pounds or more.}

[CONTAINER HANDLING

Nonrefillable container. Do not reuse or refill this container. Rinse empty container thoroughly with water to dissolve all material prior to disposal. Offer for recycling, if available.]

EMERGENCY HANDLING

In case of contamination or decomposition do not reseal container. If possible, isolate container in open well-ventilated area. Flood with large volumes of water. Dispose of contaminated material in an approved landfill area.

SPILLS

When handling or dealing with spills, use goggles with side-shields, or face shield; protective clothing; including chemical-resistant gloves and boots; use a dust respirator if dusting occurs. Sweep up dry spills and dispose of as described for pesticide disposal. If contents are contaminated or decomposing, do not reseal container; isolate unsealed container in the open or in a well-ventilated area; flood with large volumes of water if necessary.

[WARRANTY

Seller warrants that this product conforms to its chemical description and is reasonably fit for the purposes stated on the label when used in accordance with label directions under normal conditions of use, but to the extent consistent with applicable law, neither this warranty nor any other warranty of MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, expressed or implied, extends to the use of this product contrary to label instructions, or under abnormal conditions, or under conditions not reasonably foreseeable to Seller, and Buyer assumes the risk of any such use.]

Manufactured by:

Medentech Ltd.
Whitemill Industrial Estate, Clonard Road
Wexford, Ireland

EPA Reg. No. 71847-5

EPA Est. No. _____

[Material][Label] No. _____

NET CONTENTS: _____ [lbs.][kg.]

[Batch][Lot] No. _____

Master Drawings

Figure 1

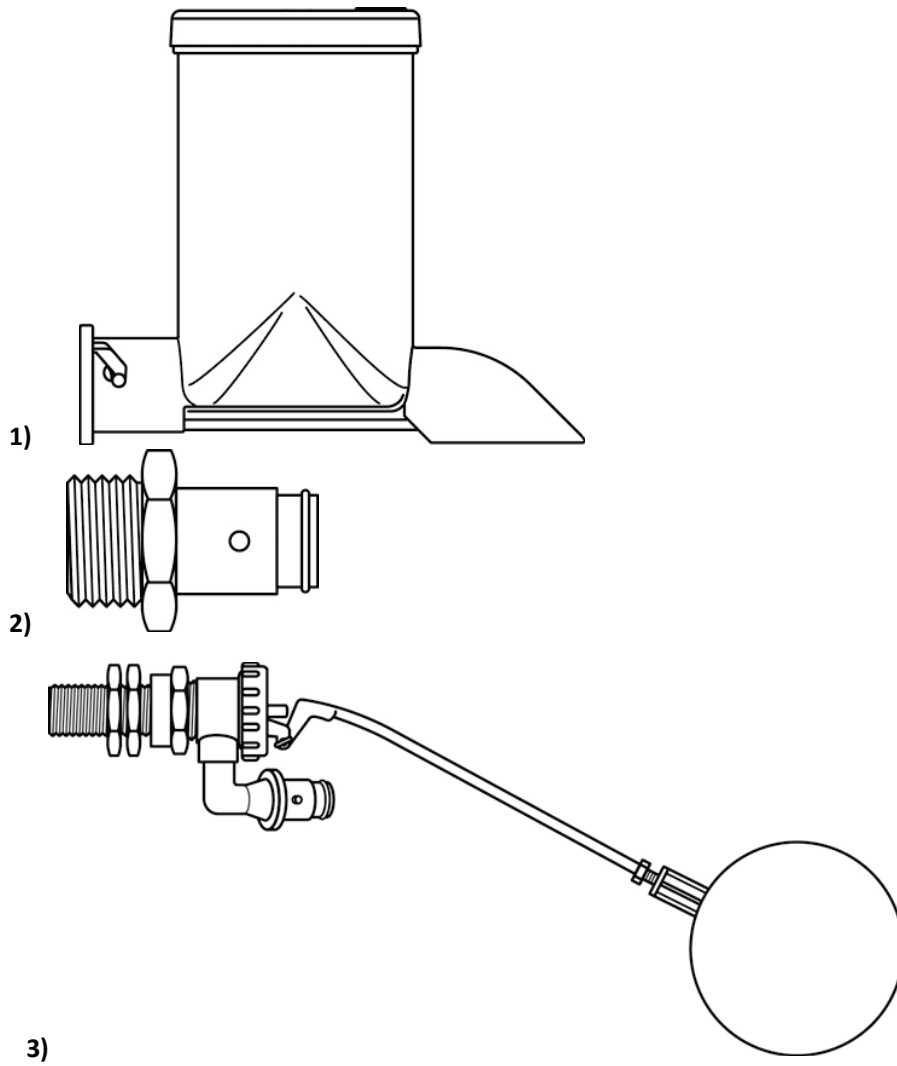


Figure 2

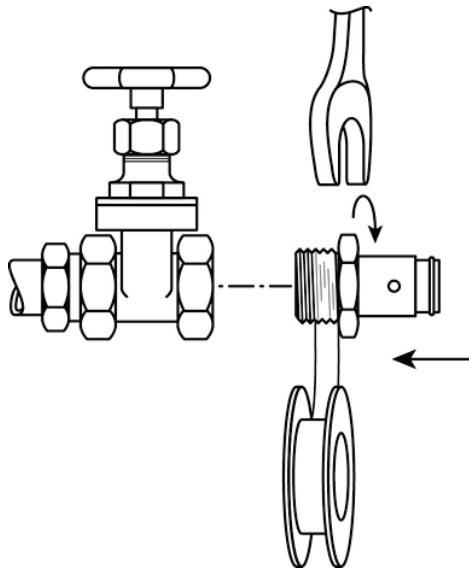


Figure 3

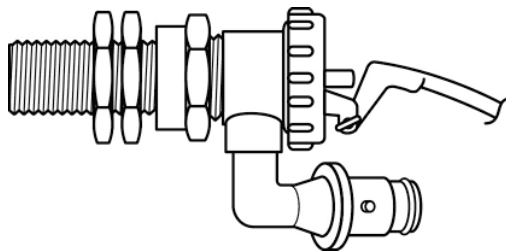


Figure 4

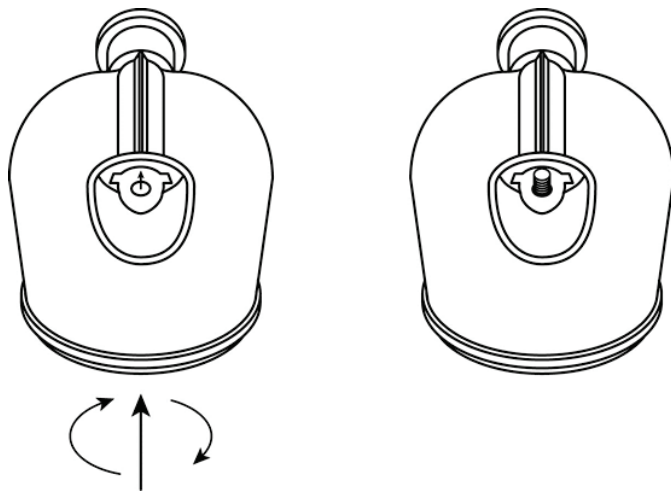


Figure 5

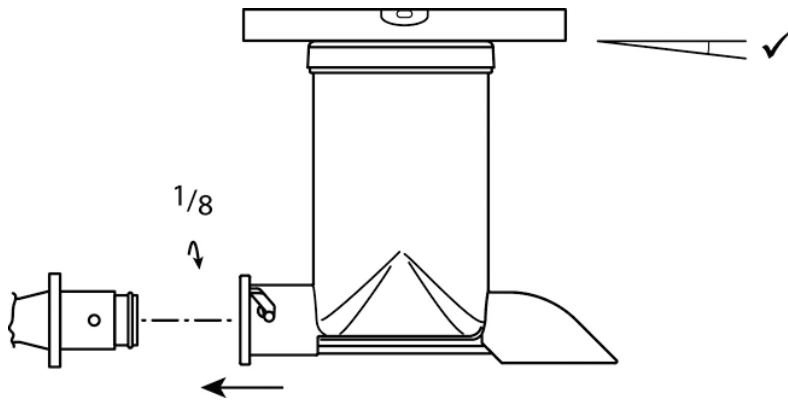


Figure 6 – Inline housing unit



Figure 7- Cartridge

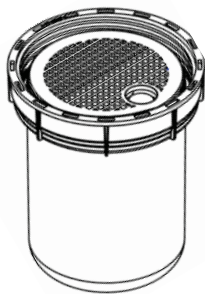


Figure 7 – fitting cartridge to unit

