



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

June 29, 2023

Georgia Anastasiou
Agent for
A-dec, Inc.
c/o Lewis & Harrison
Electronic Transmittal: georgia@lewisharrison.com

Subject: Label Amendment – Adding state of
California required label language for products viewed as adjuvants
Product Name: ICX Renew
EPA Registration Number: 79662-2
Received Date: February 25, 2021
Action Case Number: 00292600

Dear Georgia Anastasiou:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), 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.

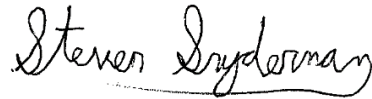
A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. Pursuant to 40 CFR 156.10(a)(6) you must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 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 FIFRA and is subject to review by the Agency. See FIFRA section 2(p)(2). 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) lists 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, FIFRA section 12(a)(1)(B). 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 Assurance.

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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 Zebora Johnson at (202) 566-0730, or via email at johnson.zebora@epa.gov.

Sincerely,

A handwritten signature in black ink that reads "Steven Snyderman". The signature is written in a cursive style with a horizontal line underneath the name.

Steven Snyderman, Product Manager 33
Regulatory Management Branch II
Antimicrobials Division (7510M)
Office of Pesticide Programs

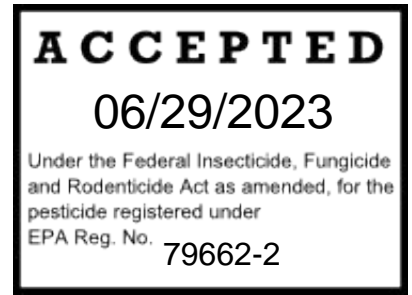
Enclosure: Accepted label

*Italicized text is informational text for the reviewer and not intended to be on the label
Bracketed text denotes alternate or optional language*



ICX Renew®

Outer box label which will contain Solution 1 and Solution 2 and Insert text



ACTIVE INGREDIENT SOLUTION 1:

Hydrogen Peroxide	2.1%
Other Ingredients	97.9%
Total	100.0%

**KEEP OUT OF REACH OF CHILDREN
CAUTION**

[SOLUTION 1:]

EPA Reg. No: 79662-2
EPA Est. No:

Combination package – Solution 1 and 2
[Net Contents] X shock treatments – X fl. oz. (ml) [each Solution 1 and 2]

A-dec [Headquarters]
2601 Crestview Drive
Newberg, Oregon 97132
[United States][USA]

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Continuation of outer box label which will contain Solution 1 and Solution 2 and Insert text

[See side/back panel for First Aid]

FIRST AID:

[SOLUTION 1 AND 2:]

Have product container or label with you when calling a poison control center or doctor, or going for treatment.

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

If on Skin or Clothing: 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.

PRECAUTIONARY STATEMENTS

[SOLUTION 1 AND 2:]

Hazards to Humans and Domestic Animals

CAUTION. Causes moderate eye irritation. Harmful if absorbed through skin. Avoid contact with eyes, skin, or clothing. Wear protective eyewear (goggles, face shield, or safety glasses) and rubber gloves when handling. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

STORAGE AND DISPOSAL

[SOLUTION 1 AND 2:]

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

Product Storage: Keep the product in the closed original container when not in use. Store in a cool, dry area away from potential sources of heat, open flames, sunlight or other chemicals. Store between 5°C (41°F) and 30°C (86°F).

Product Disposal: Wastes resulting from the use of this product must be disposed of on site or at an approved waste disposal facility.

Container Handling: Nonrefillable container. Do not reuse or refill this container. Offer container for recycling if available or puncture and dispose of in a sanitary landfill, or by incineration.

DIRECTIONS FOR USE. It is a violation of federal law to use this product in a manner inconsistent with its labeling. **Always use [ICX Renew] Solution 1 and 2 together**

Applying ICX Renew to a Dental Unit's Waterlines

[This product is to be used in conjunction with regular testing of dental unit water.] [Testing frequency must comply with user's practice protocol.]

1. Turn off the delivery system master toggle; then remove and empty the water bottle.
2. Remove air/water syringe tips, handpieces, detachable motors and couplers, and ultrasonic instruments from their tubing.
3. Add one bottle (4 ounces) of ICX Renew Solution 1 and one bottle (4 ounces) of ICX Renew Solution 2 into the empty water bottle.
4. Cover the opening of the water bottle and carefully swirl the solution, coating all surfaces of the water bottle.
5. Reattach the water bottle to the unit and turn on the master toggle.

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6. Run ICX Renew through the system until the blue solution flows out of the air/water syringe(s), all of the handpiece tubing, and the cuspidor's cupfill waterline. Leave remaining solution in the water bottle.
7. Turn off the master toggle and allow the solution to remain in the unit for 12 to 96 hours.
NOTE Place a cloth or paper towel underneath the handpiece tubing to catch potential drips.
8. After 12 to 96 hours, turn on the master toggle and flush remaining ICX Renew solution through all air/water syringe(s), all handpiece tubing, and the cupfill waterline.
9. Turn off the master toggle, remove the water bottle, discard any remaining solution, and thoroughly rinse the bottle with water.
10. Refill the bottle with water, reattach it to the unit; then turn on the master toggle.
11. Completely flush all air/water syringe(s) and all handpiece tubing into a sink or cuspidor, and run the cupfill until the water is clear and the bottle is empty.
12. Once treatment with ICX Renew is completed, continue with your daily waterline maintenance protocol.

[IMPORTANT. For new equipment apply one treatment before initial use. For existing equipment, apply three treatments when your water quality test results exceed your water quality action level. You may use the dental unit between treatments. For proactive maintenance, you may optionally apply a single treatment according to a schedule, such as monthly or quarterly, established by your practice.]

[Regulatory Information: For required regulatory Information and the A-dec warranty, see the Regulatory Information, Specifications, and Warranty document (p/n 86.0221.00) available in the Resource Center at www.a-dec.com.]

Hangtag labeling that can be hung on delivery system

IMPORTANT! Shock Treatment in Process. Flush water lines before patient treatment.

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SOLUTION 1 Bottle label

ICX Renew® Solution 1

ACTIVE INGREDIENT:

Hydrogen Peroxide	2.1%
Other Ingredients	97.9%
<hr/>	
Total	100.0%

CAUTION

KEEP OUT OF REACH OF CHILDREN

See the package insert prior to use for instructions, precautionary and first aid information.

It is a violation of federal law to use this product in a manner inconsistent with its labeling.
This product is to be used in conjunction with regular testing of dental unit water. Do not add water.

COMBINATION PACKAGE - Solution 1 and Solution 2

This is part one of a two-part product.
Always use with ICX Renew Solution 2

EPA Reg. No.: 79662-2

EPA Est. No:

[Net Contents] X fl. oz. (ml)

A-dec [Headquarters]
2601 Crestview Drive
Newberg, Oregon 97132
[United States][USA]

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SOLUTION 2 Bottle label

ICX Renew® Solution 2

KEEP OUT OF REACH OF CHILDREN

CAUTION

See the package insert prior to use for instructions, precautionary and first aid information.
It is a violation of federal law to use this product in a manner inconsistent with its labeling.
This product is to be used in conjunction with regular testing of dental unit water. Do not add water.

COMBINATION PACKAGE - Solution 1 and Solution 2

This is part two of a two-part product.

Always use with ICX Renew Solution 1

[Net Contents] X fl. oz. (ml)

A-dec [Headquarters]
2601 Crestview Drive
Newberg, Oregon 97132
[United States][USA]

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Optional marketing language that may appear on the outer box label, solution bottle labels or insert

Dental Unit Waterline Shock Treatment

[A-dec ICX Renew Solution 1 and Solution 2 is a specially formulated dental unit waterline shock treatment. It is intended to lower bacterial* contamination in effluent, remove build-up of non-pathogenic microbial contamination from the waterlines and clean the dental unit waterline by removing deposits.]

[A-dec ICX Renew Solution 1 and Solution 2 is a specially formulated dental unit waterline shock treatment. It is intended to lower non-public health bacterial contamination in effluent and remove build-up of non-pathogenic microbial contamination from the waterlines. Easy to use and no diluting required, ICX Renew cleans dental unit waterlines and removes the buildup of odor-causing, foul-tasting bacteria. Always use ICX Renew Solution 1 and 2 together. Do not add water. This product is to be used in conjunction with regular testing of dental unit water.]

[For use in dental unit water lines]

[Lowers] [Reduces] dental unit waterline effluent to ≤ 10 cfu/ml]

[For the [cleaning] [removal] [control] of odor causing or foul tasting microbial contamination in dental unit waterlines.]

[For the [cleaning] [removal] [control] of microbial* contamination in dental unit waterlines.]

[Penetrates and removes [the buildup of] odor causing, foul tasting [bacteria] [microbial contamination in dental unit waterlines]]

[Penetrates and removes [the buildup of] [bacteria*] [microbial* contamination in dental unit waterlines]]

[Removes] [Eliminates] [Purges] odor causing or foul tasting microbial contamination from dental unit waterlines]

[Removes] [Eliminates] [Purges] microbial* contamination from dental unit waterlines]

[Liquid shock solution removes odor-causing, foul-tasting bacteria in dental unit waterlines]

[Liquid shock solution removes bacteria* in dental unit waterlines]

[Clears deposits and removes odor-causing bacteria from dental unit waterlines]

[Clears deposits and removes odor-causing bacteria* from dental unit waterlines]

[Specifically formulated to reduce odor causing or foul tasting bacterial contamination in your dental unit waterlines]

[Specifically formulated to reduce bacterial* contamination in your dental unit waterlines]

[Reduces odor causing or foul tasting bacterial contamination in dental unit waterlines]

[Reduces bacterial* contamination in dental unit waterlines]

[A liquid solution formulated to directly contact dental unit [waterlines] [water bottles] for the cleaning and removal [elimination] [purging] of buildup of odor causing or foul tasting microbial contamination]

[A liquid solution formulated to directly contact dental unit [waterlines] [water bottles] for the cleaning and removal [elimination] [purging] of buildup of microbial* contamination]

*non-public health bacteria

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Continuation of optional marketing language that will appear on the outer box label, solution bottle labels or insert

[Eliminates odor and foul [tasting] [taste] bacteria from the dental unit water]

[Eliminates bacteria* from the dental unit water]

[Reduce] [Control] microbial* contamination]

[For the cleaning and control of microbial* contaminants in dental unit waterlines]

*non-public health bacteria

[Select ICX and ICX Renew for the [total] [complete] care of your dental unit waterlines]

[Select] [Use] ICX and ICX Renew to clean and maintain your dental unit waterlines]

[Proven formula for waterline maintenance]

[ICX Renew will not [corrode] [clog] [leave a residue] in waterlines, water bottles or equipment]

[Does not damage or harm dental unit waterlines or equipment]

[A liquid cleaner for dental unit waterlines]

[Easy to use]

[No measuring required] [No diluting required] [No measuring or diluting required]

[Non-staining solution]

[non-corrosive to dental [unit] waterlines]

[gentle on equipment]

[non-corrosive and gentle on dental [unit] [waterline(s)] [equipment]]

[Will not [corrode or] clog waterlines]

[Odorless]

[Use with A-dec [delivery system] [equipment]

[Blue color improves visibility] [user knows the solution is in the waterlines] [Blue color lets you know the solution is hard at work in the waterlines]

[Shock treatment clears deposits and bacterial contamination from dental unit waterlines]

[Cleaner] [Cleans and protects waterlines] [Cleans dental unit waterlines]

[Simple] [Effective] [Specifically formulated]

[Cost effective way to clean self-contained water systems.]


[Sample]

[NOTE: Do not use with a water maintenance cartridge or straw.]



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Optional packaging information that may appear on the outer box label, solution bottle labels or insert

 [Refer to accompanying documents for additional information.]

[Manufactured for A-dec[:]



A-dec [Headquarters]

2601 Crestview Drive

Newberg, Oregon 97132

[United States][USA]

[Tel: 1.800.547.1883 within USA/CAN]

[Tel: +1.503.538.7478 outside USA/CAN]


[a-dec.com]


EPA [Registration Number][Reg. No.] 79662-x

EPA [Establishment Number][Est. No.] _____

Net Contents _____

[COMBINATION PACKAGE - Solution 1 and Solution 2]




[] [Lot _____]

[] [Expiration Date] _____ [12 months from date of manufacture]

[] [Part Number] [_____ Rev _____]

[Reorder #: _____]

[Barcode]

[CE 1434] [] [For single use] [] [[Keep dry.] [] [$\frac{5^{\circ}\text{C}}{41^{\circ}\text{F}}$ - $\frac{30^{\circ}\text{C}}{86^{\circ}\text{F}}$]

[Made in USA][A-dec, A-dec 360, the A-dec logo, and ICX Renew are trademarks of A-dec Inc. and are registered in the United States and other countries.]

[]

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[Mascot, NSW 2020]

[Australia]

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[A-dec (Hangzhou) Dental Equipment Co., Ltd.]
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(10) 2022-01-01
(17) 202301]

Optional graphics

