



**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460**

**OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION**

October 5, 2021

Tom Jonaitis  
Regulatory Consultant  
Decernis LLC  
2101 Gaither Road, Suite 150  
Rockville, MD 20850

**Subject: M009 FIFRA Regulated Determination: Pesticide Determination**  
Product Name: Cougar Creek's On-Site, On-Demand, Portable, Medium-Size HOCl Generator  
Manufacturer: Cougar Creek Electrolysed Water, LLC  
EPA File Symbol: 99897PA1  
Application Date: April 19, 2021  
Action Case Code: 00298925

Dear Tom Jonaitis:

This letter is in response to your request, submitted on April 19, 2021, for an Agency determination on whether the product "Cougar Creek's On-Site, On-Demand, Portable, Medium-Size HOCl Generator," manufactured and marketed by Cougar Creek Electrolysed Water, LLC (Cougar Creek), is regulated as a device under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). The Agency has reviewed your request and determined that the product is a device.

You submitted the following supporting information:

- Cover Letter including User Manual and draft label (4/19/21; and revised 7/9/21)
- 8570-1 Application Form (7/9/21)
- Small Business Fee Waiver
- Payment Receipt
- Agent Authorization Letter
- Utility Patent Application Transmittal Document
- USPTO Notice of Allowance
- Our Ref. CCLL-1-002.0 Allowed Claims

**Description of Apparatus and Mode of Action**

Cougar Creek describes this product as a hypochlorous acid (HOCl) generator:

The proposed device produces on-demand hypochlorous acid solutions (60 to 200 ppm) for on-site broad-spectrum disinfection for hard, non-porous surfaces. The produced solution contains 0.006% to 0.02% hypochlorous acid (as free available

chlorine), depending on device settings. The remainder of solution is 99.9% water and other inert ingredients. Users of the device are instructed to use clean tap water and clean refined (>99%) granular sodium chloride to produce the hypochlorous acid solution for use on site.<sup>1</sup>

The tap water and granular sodium chloride components are not sold with the product. According to the Cougar Creek,

The device produces HOCl with low leftover salt concentrations in the final solution which provides advantages in various applications. It also allows for the use of regular tap water (vs. some products that require specific types of water to be purchased) and creates a buffered HOCl solution, which increases the stability of the HOCl during temporary storage. A small amount of vinegar solution is also used to clean the device for scale/buildup. Generated solutions are to be used on site and used within 7 days.<sup>2</sup>

Cougar Creek states that the generated solution is not for sale.<sup>3</sup>

### **Pesticidal Claims**

Cougar Creek makes the following pesticidal claims associated with Cougar Creek's On-Site, On-Demand, Portable, Medium-Size HOCl Generator:<sup>4</sup>

- "Hypochlorous acid solutions have an established history of being safe and effective in disinfecting hard surfaces against bacteria, viruses, and fungi. The exact mechanism of action has not been fully elucidated, although several may be working simultaneously. Generally, it is currently believed that HOCl penetrates cell walls/membranes, which causes direct microbial membrane/DNA damage, inhibition of necessary microbial enzyme processes, or possibly membrane transport interference."
- "This device produces on-demand hypochlorous acid solutions (60 to 200 ppm) for on-site broad-spectrum disinfection for hard, non-porous surfaces."

### **Determination**

EPA has reviewed your request and determined that the product, as the supporting material describes it, is a device. FIFRA defines a device as "any instrument or contrivance . . . intended for trapping, destroying, repelling, or mitigating any pest or any other form of plant or animal life (other than man and other than bacteria, virus, or other microorganism on or in living man or other

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<sup>1</sup> Cover Letter

<sup>2</sup> Cover Letter

<sup>3</sup> Cover Letter

<sup>4</sup> Cover Letter

living animals).”<sup>5</sup> EPA believes that Cougar Creek’s On-Site, On-Demand, Portable, Medium-Size HOCl Generator is a device because (1) it is not sold or distributed with a substance (salt)<sup>6</sup> and uses electrochemical activation to generate an output substance (hypochlorous acid) on site, and (2) is intended for a pesticidal purpose.

EPA determines whether a device is intended for a pesticidal purpose by evaluating whether the product is “intended to trap, destroy, mitigate, or repel any pest.”<sup>7</sup> EPA finds that Cougar Creek’s On-Site, On-Demand, Portable, Medium-Size HOCl Generator is intended for pesticidal purpose. This product “produces on-demand hypochlorous acid solutions (60 to 200 ppm) for on-site broad-spectrum disinfection for hard, non-porous surfaces.”<sup>8</sup> This claim demonstrates that Cougar Creek intends this product to be used for a pesticidal purpose. *See* “Pesticidal Claims,” above, for complete list of claims. Further, the product is described as a “generator” that creates solutions that can be easily made from over-the-counter household materials:

For the table salt and vinegar solutions, a concentrated precursor solution must be made for each before diluting them with water. Once prepared, pour these solutions into their respective compartments. To make the solutions the user will need table salt, 45 wt% or diluted vinegar, and soda ash or baking (sodium carbonate or sodium bicarbonate).”<sup>9</sup>

Based on this statement, and other made by Cougar Creek, EPA believes that seller or distributor of this product should be aware that consumers will use it for pesticidal purposes. On balance, these factors suggest that Cougar Creek’s On-Site, On-Demand, Portable, Medium-Size HOCl Generator is intended for pesticidal purposes.

## Conclusion

Based on the information provided, EPA has determined that this product is a device. In addition, EPA has provided some preliminary compliance assistance. *See* “Appendix A” below. If you have any questions, please contact Heather A. Garvie by phone at 703-308-0034 or by email at [garvie.heather@epa.gov](mailto:garvie.heather@epa.gov).

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<sup>5</sup> FIFRA § 2(h), 7 U.S.C. § 136(h); *see also* EPA, Notice, Pest Control Devices and Device Producers, 41 Fed. Reg. 51,065 (Nov. 19, 1976).

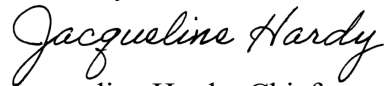
<sup>6</sup> Cover Letter.

<sup>7</sup> FIFRA § 2(h), 7 U.S.C. § 136(h). EPA assessment of pesticidal intent for devices is generally analogous to the assessment of pesticidal intent for pesticides articulated in 40 C.F.R. § 152.15.

<sup>8</sup> Cover Letter not dated; emailed on 7/9/21

<sup>9</sup> Cover Letter not dated; emailed on 7/9/21

Sincerely,

A handwritten signature in black ink that reads "Jacqueline Hardy". The script is fluid and cursive, with the first letters of each word being capitalized and prominent.

Jacqueline Hardy, Chief  
Regulatory Management Branch  
Antimicrobials Division  
Office of Pesticide Programs

## **Appendix A: Additional Resources**

FIFRA-regulated devices are subject to a variety of regulatory requirements.<sup>10</sup> Among other things, devices are subject to FIFRA Section 7 and 40 C.F.R. Part 167 (must be produced in a registered device-producing establishment), FIFRA Section 2(q)(1) and 40 C.F.R. Part 156 (labeling requirements), FIFRA Section 12, 13 and 14 (violations, enforcement actions and penalties), and FIFRA Section 17 (import and export requirements).

### **False or Misleading Claims**

M009 determinations are solely intended to decide whether a product is subject to FIFRA. Therefore, EPA has not evaluated either the potential risks or the possible effectiveness of this product or done the type of complete premarket review afforded to pesticides when registered under FIFRA Section 3. Nevertheless, reviewing a M009 application affords EPA an opportunity to provide some preliminary compliance assistance on materials EPA has reviewed in the course of making the M009 determination.

It unlawful to distribute, sell, or offer to sell pesticide devices that are misbranded.<sup>11</sup> A device may be misbranded under variety circumstances, including when its labeling<sup>12</sup> is false or misleading in any particular.<sup>13</sup> EPA recommends that you have sufficient efficacy data available to substantiate your claims about your product and that you refrain from making any claims that may mislead consumers about your product's purposes or capabilities, including claims that may mislead consumers to believe that the device is "registered" or otherwise evaluated or approved by EPA.

EPA believes that the following claims and issues could result in misbranding violations:<sup>14</sup>

- The claim for "broad-spectrum disinfection" would need to be qualified with the target pests. Cougar Creek must list the target pests on the product's label. Further, as noted above, efficacy testing must be conducted for each microorganism. The company should keep all disinfection efficacy data on file and be able to substantiate any disinfectant claims.
- The labeling must include adequate directions for use to allow users to effectively use the product.<sup>15</sup> As part of these directions for use, Cougar Creek should include contact times needed to kill the target pests listed on the device's label. User directions should be included for each of the HOCl ppm levels that may be generated. Directions for use should also include hard surface disinfectant contact times. EPA believes that contact times greater than 10 minutes may be false and misleading unless the material to be disinfected

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<sup>10</sup> See 40 C.F.R. § 152.500.

<sup>11</sup> See FIFRA § 12(a)(1)(F), 7 U.S.C. § 136j(a)(1)(F).

<sup>12</sup> See FIFRA § 2(p)(2), 7 U.S.C. § 136(p)(2) (device labeling includes everything referenced on the label, such as a website, and any other written materials accompanying the device).

<sup>13</sup> See FIFRA § 2(q)(1)(A), 7 U.S.C. § 136(q)(1)(A); 40 C.F.R. §§ 152.500(b)(1), 156.10(a)(5).

<sup>14</sup> EPA identified any claims presented below solely for compliance assistance and has not completed a comprehensive review of this product's labeling. EPA suggests deleting or revising those claims wherever they appear in product labeling (e.g., the product's label and any written, printed, or graphic materials accompanying the product or referenced on the label) to reduce the chances of a FIFRA violation. EPA only evaluated claims submitted as of 7/9/21. Subsequent changes to the claims may alter EPA's compliance assistance advice.

<sup>15</sup> FIFRA § 2(q)(1)(F), 7 U.S.C. § 136(q)(1)(F); 40 C.F.R. §§ 156.10(a)(1)(viii), 156.10(i).

is to be immersed in the disinfectant product solution as part of the disinfection process. Disinfectants that are applied to surfaces that are not immersed in the disinfectant product solution will dry out and therefore contact with the disinfectant product solution will generally not last longer than 10 minutes.

- The product's manual should include precautionary language and safety language for the product's use.<sup>16</sup>
- Remove any claims that the product is "safe and effective."<sup>17</sup>

### **Additional Compliance Concerns**

The solution generated by this device is an unregistered pesticide. The solution should be used on site and may not be sold or distributed. Sale or distribution of the generated solution could be subject to enforcement action by EPA.<sup>18</sup>

### **State, Territorial, and Tribal Information**

Some States, Territories, and Tribes impose additional requirements on pesticides and devices. Please check with the State, Territorial, or Tribal jurisdiction where you plan to sell your pesticide or device to ascertain their requirements, including requirements for registration and efficacy data.<sup>19</sup>

### **Importing Pesticides or Devices**

Importers of all FIFRA-regulated pesticides and devices must comply with FIFRA Section 17(c)(1) and U.S. Customs and Border Protection (CBP) regulations.<sup>20</sup> No imported pesticide or device may be adulterated, misbranded, or otherwise violative of FIFRA. Importing pesticides and devices is prohibited without a completed EPA Notice of Arrival of Pesticides and Devices (EPA NOA). The EPA NOA information may be submitted on paper using EPA Form 3540-1 or electronically via any CBP-authorized electronic data interchange system.<sup>21</sup>

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<sup>16</sup> FIFRA § 2(q)(1)(G), 7 U.S.C. § 136(q)(1)(F); 40 C.F.R. §§ 156.10(a)(1)(vii)

<sup>17</sup> FIFRA § 2(q)(1)(A), 7 U.S.C. § 136(q)(1)(A); *see also* 40 C.F.R. § 156.10(a)(5)(ix).

<sup>18</sup> FIFRA § 12(a)(1)(A), 7 U.S.C. § 136j(a)(1)(A).

<sup>19</sup> For more information, see EPA's website on State and Territorial Pesticide Agencies, <https://www.epa.gov/pesticide-advisory-committees-and-regulatory-partners/state-and-territorial-pesticide-agencies>.

<sup>20</sup> 19 C.F.R. §§ 12.110-12.117.

<sup>21</sup> For more information, see EPA's website on importing and exporting pesticides and devices, <https://www.epa.gov/compliance/importing-and-exporting-pesticides-and-devices>.