



## **R-Water's TK60 Disinfectant**

### *Efficacy Summary and Review of Regulatory Classification*

#### **Introduction**

R-Water, LLC is a San Marcos, Texas manufacturer of a small device that generates a cleaner (FC+) as well as a one-step cleaner-disinfectant (TK60) for use in healthcare. The company's mission is to reduce preventable infectious diseases and reduce hazardous waste. The disinfectants produced by R-Water's devices are less hazardous than many common disinfectants and are made from just pure salt and water using electricity.

From late 2014 through 2016, Microchem Laboratory conducted several tests to characterize the efficacy of TK60. The laboratory, founded in 1988, specializes in the testing of environmental surface disinfectants, high-level disinfectants, sanitizers, medical devices, antimicrobial surfaces, personal care products, and antimicrobial devices. Microchem Laboratory is compliant with Good Laboratory Practice (GLP) regulations and stays current with regard to best practices for testing.

R-Water's TK60 demonstrates germicidal efficacy that is similar to, or better than, most traditional disinfectants. However, since it is produced via a physical mechanism from generic ingredients at the hospital or other institution and then used on-site, it falls into a different regulatory category than traditional disinfectants. Traditional disinfectants are regulated as antimicrobial pesticides by EPA. EPA also regulates R-Water's TK60, but as an antimicrobial *pesticide device* rather than as an antimicrobial pesticide.

#### **EPA Efficacy Testing Requirements for Traditional Disinfectants**

EPA describes the test methods recommended for testing traditional disinfectants in a document titled "OCSPP 810.2200: Disinfectants for Use on Hard Surfaces—Efficacy Data Recommendations." This document cohesively defines the different levels of disinfectant efficacy, test methods used for each type and classification of germicide, the test organisms required, and success criteria for testing.

OCSPP 810.2200 requires disinfectants that are intended to be applied as a spray *and* intended for use in hospital or healthcare environments to be tested following the AOAC Official Method 961.02, also known as the Germicidal Spray Products as Disinfectants Test Method. To achieve a claim of disinfection, the product must be tested against two microorganisms: *Staphylococcus aureus* ATCC 6538 and *Pseudomonas aeruginosa* ATCC 15442. Three individual lots/batches of product must be tested using 60 carriers (contaminated test surfaces), each with a contact time not to exceed 10 minutes. To pass a Germicidal Spray Products Test, 59 out of 60 carriers must be negative for growth of the target microorganisms for all lots/batches tested. An organic soil load, such as Fetal Bovine Serum (typically a concentration not to exceed 5%), can be added to the bacterial inoculum in the event the disinfectant is intended to be bactericidal in the presence of organic soil (one-step disinfectant). Furthermore, OCSPP 810.2200 states that Good Laboratory



Practice Standards (GLP), as defined in 40 CFR Part 160, must be employed during conduct of tests used to support disinfection claims.

**Table 1. Summary of EPA-Required Efficacy Testing for Traditional Spray Disinfectants**

Level of Efficacy	Test Method		Test Microorganism(s)	Batches	Passing Criteria
Hospital or Healthcare Disinfectant/ hard non-porous Surfaces	Water soluble Powders/ Liquids	AOAC Use-Dilution Method or AOAC Hard Surface Carrier Test (Distilled Water only)	Staphylococcus aureus (ATCC 6538) and Pseudomonas aeruginosa (ATCC 15442)	Three batches, one at least 60 days old. 60 carriers against each organism (360 carriers).	59/60 carriers are negative for each batch tested for all methods except AOAC Hard Surface Carrier Test, which is 58/60 carriers are negative against <i>Staphylococcus aureus</i> for each batch, And 57/60 carriers are negative against <i>Pseudomonas aeruginosa</i> .
	Spray Products	AOAC Germicidal Spray Products Test			
	Towelettes	Modified Germicidal Spray Test			

**EPA Efficacy Testing Requirements for Disinfectants Generated On-site (Pesticide Devices)**

EPA's current policy is clear: If a device generates a liquid disinfectant that is used on-site, and that disinfectant is made from generic raw materials by a physical process (e.g., plain salt, water and electricity), then the product is regulated as a pesticide device, not as a pesticide.

Registration of pesticide devices is not currently required by the EPA. However, other requirements for pesticide devices are defined in 40 CFR 152.500.

**Comparability of R-Water's Laboratory Tests to Tests for Traditional Disinfectants**

R-Water passed testing using the AOAC Official Method 961.02 Germicidal Spray Products Test under GLP conditions, using three separate lots/batches of TK60 against *S. aureus* ATCC 6538 and *P. aeruginosa* ATCC 15442 in the presence of 5% calf serum, at an aggressive 60 second contact time. TK60 exceeded the testing requirements by showing zero positive carriers in all lots at the 60 second contact time.

These results directly substantiate a one-step disinfectant claim per the EPA requirements for disinfectants defined previously. It should be noted, similar products typically require much longer contact times and testing often does not include an organic soil load.



**R-Water for Routine Surface Disinfection**

TK-60 complies with EPA pesticide device regulations just as traditional disinfectants comply with EPA pesticide regulations.

TK-60 has demonstrated efficacy in independent testing conducted by Microchem as a one-step hospital-use disinfectant with an aggressive contact time of 60 seconds. It has demonstrated efficacy against *S. aureus* and *P. aeruginosa*. In addition, efficacy has been demonstrated for several other organisms, as shown in the table below.

**Table 2: Summary of Efficacy Data for R-Water's TK60 Disinfectant**

Claim	Microorganism(s)	Lab Results	Percent Kill in 60 Seconds
Hospital/Healthcare Disinfectant/ hard Non-porous Surfaces	<i>P. aeruginosa</i> ATCC 15442	Positive Carriers: 0/180	100% kill
	<i>S. aureus</i> ATCC 6538	Positive Carriers: 0/180	100% kill
Tuberculocidal disinfectant/ hard Non-porous Surfaces	<i>Mycobacterium bovis</i> BCG	Positive Carriers: 0/10	100% kill
Efficacy against <i>C. difficile</i> spores	<i>C. difficile</i> spores	99.9997% log reduction	99.9997% kill
Efficacy against Black Mold	<i>A. brasiliensis</i>	Positive Carriers: 0/10	100% kill

The kill times observed for TK60 are impressive when compared to similar disinfectants that have kill times ranging from 3-5 minutes, and in some cases, as long as 10 minutes.

Additionally, R-Water understands their customer's safety is of the utmost importance. The active concentration of TK60 is approximately 200 PPM free available chlorine (FAC). This concentration is relatively non-toxic to end users.

**Unique Advantages of TK 60**

TK60 offers cost benefits when compared to traditional disinfectants. Unlike similar products that must be ordered and shipped, TK60 is generated on site and removes the hassle of shipping and handling while providing convenience to produce the disinfectant at any time.

TK60 is also a ready to use disinfectant. Other disinfectants are not ready to use and must be diluted from hazardous, concentrated solutions prior to use. Requirements to produce TK60 are simply water, salt, and electricity.



Being environmentally conscious, R-water also provides their customers with the opportunity to cut down on their carbon footprint by keeping plastic containers out of landfills, reduce VOCs and potentially earn points toward LEED certification.

### **References**

1. <http://www.r-water.com/>
2. <http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2015-0276-0004>
3. <https://www.epa.gov/pesticide-registration/pesticide-registration-manual-chapter-13-devices>
4. [http://www.ecfr.gov/cgi-bin/text-idx?SID=6549d45d41e826fe520ad9eb277f2add&mc=true&node=se40.24.152\\_1500&rpn=div8](http://www.ecfr.gov/cgi-bin/text-idx?SID=6549d45d41e826fe520ad9eb277f2add&mc=true&node=se40.24.152_1500&rpn=div8)

### **Authorship Information**

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