

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

October 28, 2015

MEMORANDUM

Subject: Efficacy Review for FABGUARD; EPA File Symbol 90270-R; DB Barcode:

D428149.

From: Ibrahim Laniyan, Ph.D.

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Antimicrobials Division (7510P)

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Regulatory Management Branch II Antimicrobials Division (7510P)

Applicant: Fabco Industries, Inc.

66 Central Ave.

Farmingdale, NY 11735

Formulation from the Label:

Active Ingredient(s)	<u>% by wt.</u>
3-(trihydroxysilyl) Propyldimethyloctadecyl ammonium	
chloride	0.157 %
Other Ingredients:	<u>99.843 %</u>
Total	100.000 %

I. BACKGROUND

The product, FABGUARD (EPA File Symbol 90270-R), is a new product. The applicant requested to register the product as a filtration medium in storm water, industrial wastewater, and municipal wastewater (excluding potable and drinking water) to reduce the amount of coliform bacteria. The registrant submitted two non-GLP studies conducted by Fabco Industries, Inc in support of these claims.

This data package, identified as D428149, contained a letter from the applicant representative to EPA (dated June 24, 2015), EPA Form 8570-1 (Application for Pesticide), EPA Form 8570-27 (Formulator's Exemption Statement), EPA Form 8570-4 (Confidential Statement of Formula), EPA Form 8570-34 (Certification with Respect to Citation of Data), EPA Form 8570-35 (Data Matrix), two studies (MRID Nos. 496259-06 and 496259-07), Statements of No Data Confidentiality Claims for both studies, and the proposed label.

II. USE DIRECTIONS

Do not use for treatment of potable and/or drinking water.

For stormwater, industrial wastewater, and municipal wastewater treatment only. FABGUARD is installed as an independent filtration media for the following applications:

- Underground, single pass, storm water filtration systems including catch basin inserts, filtration beds, filtration units, cartridges, filtration layers and helix segments
- Industrial wastewater filtration systems: including cartridges, vessels for batch or continuous operations, and filtration panels for treatment of industrial discharges, and process water, excluding drinking and potable water.
- Municipal wastewater filtration: systems for treatment of secondary or tertiary municipal sewage treated effluent, excluding drinking and potable water. FABGUARD must not be used as a stand-alone treatment for raw sewage.

The sizing and installation directions for FABGUARD will vary according to the Fabco product used.

Fabco stormwater filtration products can be applied in either decentralized or centralized treatment approach. Our products are uniquely designed to function effectively in a variety of climates and drainage system designs.

Using decentralized treatment methods, specific pollutants like bacteria are targeted at the catchbasin level with adjustable filter inserts installed directly into the opening of an existing drainage structure, e.g., catchbasin drain inlets. Examples of Fabco products designed for a decentralized treatment approach include: StormBasin and StormPod.

Centralized treatment methods are sub-surface vaults installed at the outfall of a stormwater pipe system. Fabco vault systems are purposely designed to handle the large volumes of stormwater at this end of pipe location prior to discharge into surface waters or infiltration to ground water. Examples of Fabco products designed for a centralized treatment approach include: StormSafe and Helix filter vaults.

III. BRIEF DESCRIPTION OF THE DATA

1. MRID 496259-06 "Product Test Procedure for E. Coli Reduction, Microorganism: Escherichia coli," for "Helix Filter" by John Peters. Study conducted at Fabco. Study completion date – September 3, 2014.

Test Conditions

Air Temp.: 78 Deg F Water Temp.: 80 Deg F Water pH: 7.6 N/A Chlorine: 0 PPM

Target Influent Concentration	50-GPM	10-GPM	40-GPM	100-GPM
E. Coli @	Influent			
350,000 MPN/100mL	Sample (Raw)	Test 1	Test 2	Test 3

Dosage Statistics

E. coli OD: 0.293 4 x Dilution

Target Conc.: 350000 MPN/100mL

Calc. Broth Vol.: 238.3 mL Act. Broth Vol.: 250 mL

2. MRID 496259-07 "Product Test Procedure for Enterococci Reduction, Microorganism: Enterococci," for "Helix Filter" by John Peters and Scott Gorneau. Study conducted at Fabco. Study completion date – September 3, 2014.

Test Conditions

Air Temp.: 78 Deg F Water Temp.: 80 Deg F Water pH: 7.6 N/A Chlorine: 0 PPM

Target Influent Concentration	50-GPM	10-GPM	40-GPM	100-GPM
Enterococci @ 50,000 MPN/100mL	Influent Sample (Raw)	Test 1	Test 2	Test 3

Dosage Statistics

Enterococci OD: 0.323 4 x Dilution Target Conc.: 500 MPN/100mL Calc. Broth Vol.: 301.9 mL

Act. Broth Vol.: 100 mL

IV. RESULTS

1. MRID 496259-07 (E. coli)

Raw Test: 50 GPM (Untreated)			
	Flow Rate:	50	GPM
Volume In Tank:		4000	GAL
Sample Number	Client ID	Result [MPN/100mL]	Outlier Check [MPN/100mL]
1	SIEU 1	250,000	250,000
2	SIEU 2	450,000	450,000
3	SIEU 3	450,000	450,000
4	SIEU 4	250,000	250,000
5	SIEU 5	120,000	120,000
	Mean:	304,000	304,000
	Median:	250,000	
	MAD:	130,000	

Performance Test: 10 GPM (Treated)			
Flo	w Rate	10	GPM
Stat	ic Head	6.5	IN
Sample Number	Client ID	Result [MPN/100mL]	Outlier Check [MPN/100mL]
6	SIET L1	40,000	40,000
7	SIET L2	17,000	17,000
8	SIET L3	120,000	OUTLIER
9	SIET L4	25,000	25,000
10	SIET L5	15,000	15,000
	Mean:	43,400	24,250
	Median:	25,000	
	MAD:	10,000	
Percent (Change [%]:	-92.	02%

Performance Test: 40 GPM (Treated)			
Flov	v Rate	40	GPM
Statio	c Head	10.5	IN
Sample Number	Client ID	Result [MPN/100mL]	Outlier Check [MPN/100mL]
11	SIET M1	40,000	40,000
12	SIET M2	65,000	OUTLIER
13	SIET M3	40,000	40,000
14	SIET M4	40,000	40,000
15	SIET M5	65,000	OUTLIER
	Mean:	50,000	40,000
	Median:	40,000	
	MAD:): O	
Percent	Change:	-86.84%	

Performance Test: 100 GPM (Treated)			
Flow	Rate	100	GPM
Statio	Head	28.5	IN
Sample Number	Client ID	Result [MPN/100mL]	Outlier Check [MPN/100mL]
16	SIET H1	15,000	15,000
17	SIET H2	55,000	55,000
18	SIET H3	140,000	140,000
19	SIET H4	140,000	140,000
20	SIET H5	65,000	65,000
	Mean:	83,000	83,000
	Median:	65,000	
	MAD: 50,000		
Percent	Change:	-72.70%	

2. MRID 496259-07 (Enterococci)

Raw Test: 50 GPM (Untreated)			
Flow Rate:		50	GPM
Volume In Tank:		4000	GAL
Sample Number	Client ID	Result [MPN/100mL]	Outlier Check [MPN/100mL]
1	SIEU 1	92,100	92,100
2	SIEU 2	51,700	51,700
3	SIEU 3	61,300	61,300
4	SIEU 4	68,700	68,700
5	SIEU 5	86,600	86,600
	Mean:	72,080	72,080
	Median:	68,700	
	MAD:	17,000	

Performance Test: 10 GPM (Treated)			
Flov	w Rate	10	GPM
Stati	c Head	6.5	IN
Sample Number	Client ID	Result [MPN/100mL]	Outlier Check [MPN/100mL]
6	SIET L1	100	100
7	SIET L2	100	100
8	SIET L3	100	100
9	SIET L4	100	100
10	SIET L5	100	100
	Mean:	100	100
	Median:	100	
	MAD:	0	
Percent Change [%]: -99.86%		86%	

Performance Test: 40 GPM (Treated)			
Flov	v Rate	40	GPM
Statio	c Head	10.5	IN
Sample Number	Client ID	Result [MPN/100mL]	Outlier Check [MPN/100mL]
11	SIET M1	100	100
12	SIET M2	100	100
13	SIET M3	100	100
14	SIET M4	100	100
15	SIET M5	100	100
	Mean:	100	100
	Median:	100	
	MAD:	0	
Percent	Change:	-99.86%	

Performance Test: 100 GPM (Treated)			
Flow	Rate	100	GPM
Statio	Head	28.5	IN
Sample Number	Client ID	Result [MPN/100mL]	Outlier Check [MPN/100mL]
16	SIET H1	100	100
17	SIET H2	100	100
18	SIET H3	100	100
19	SIET H4	100	100
20	SIET H5	100	100
	Mean:	100	100
	Median:	100	
	MAD:		
Percent	Change:	-99.86%	

V. LABEL

1. The proposed label claims that the product, FABGUARD, is a filtration media that reduces the amount of coliform bacteria that may be present in non-drinking and non-potable storm water, industrial waste water, municipal waste water, agricultural systems, and water destined for routine potable water purification; **are acceptable**.

- 2. Registrant must indicate on the label how long the filter media system is expected to stay efficacious. Conditions or parameters indicating a non-effectiveness of the media system can be added to the label. This will allow consumer to know when it is time to change filter.
- 3. The applicant must make the following changes to the proposed label, as appropriate:
 - On page one, remove "only" in "FABGUARD is the [only] open cell foam product...."
 - On page 2 under Direction of Use", replace "wasterwater" with "wastewater"