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PWS CG\_Travis\_CO\_20240909\_challenge study

## TEXAS COMMISSION ON ENVIRONMENTAL QUALITY

*Protecting Texas by Reducing and Preventing Pollution*

September 9, 2024

Mr. Yosei Fujita  
Toray Industries, Inc.  
1-1-2, Nihonbashi-Muromachi  
Chuo-ku, Tokyo  
103-8666  
Japan

Re: Toray HFUG-B2315AN Hollow Fiber Ultrafiltration Membrane  
Review and Approval of Challenge Testing  
Removal of Microbial Contaminants

Dear Mr. Fujita:

Membrane filtration systems installed on, or replaced after, April 1, 2012 for the removal of *Cryptosporidium* and *Giardia* must undergo challenge testing to evaluate the membrane's removal efficiency and for the Texas Commission on Environmental Quality (TCEQ) to establish a challenge test log removal value ( $LRV_{C-Test}$ ) as required by Title 30 of the Texas Administrative Code (30 TAC) §290.42(g)(3). In addition, these TCEQ regulations require a membrane manufacturer to provide the non-destructive performance test (NDPT) and associated quality control release value (QCRV) that will be used to verify that all manufactured membrane modules that were not subject to challenge testing will achieve at least the same log removal as those that were challenge tested.

On June 28, 2023, the TCEQ received a copy of the August 15, 2019 report of the challenge study conducted on the Toray Industries, Inc., (Toray) HFUG-B2315AN hollow-fiber (HF) ultrafiltration (UF) membrane modules.

The NSF International (NSF) challenge study was conducted in accordance with NSF/American National Standards Institute (ANSI) Standard 419-2018: Public Drinking Water Equipment Performance - Filtration. According to the Test Report, the NSF/ANSI Standard 419 is based on the Environmental Technology Verification (ETV) *Generic Protocol for the Product Specific Challenge Testing of Microfiltration or Ultrafiltration Modules* (May 2011) and the product-specific challenge testing requirements in the United States Environmental Protection Agency (USEPA) Long Term 2 Enhanced Surface Water Treatment Rule (LT2ESWTR). The NSF certification of performance is based only on reduction of *Cryptosporidium* as it is linked to the QCRV.

### **CHALLENGE STUDY DATA FOR TORAY HFUG-B2315AN HF UF MEMBRANE MODULES**

We reviewed the submitted challenge study data for compliance with the *Cryptosporidium* treatment requirements in the LT2ESWTR. The criteria for compliance is found in Title 40 of the Code of Federal Regulations (40 CFR) §141.719(b)(2). Additional guidance for compliance with these requirements can be found in the USEPA Membrane Filtration Guidance Manual (EPA 815-R-06-009). Based on our review of the challenge study data for the Toray HFUG-B2315AN HF UF membrane modules, we have determined that the challenge study is compliant with LT2ESWTR requirements. Please review the conditions in the following pages regarding the approved log

removal value demonstrated during challenge testing ( $LRV_{C-Test}$ ) and the approved NDPT for production membrane modules that did not undergo challenge testing.

TCEQ-APPROVED  $LRV_{C-Test}$

For the Toray HFU-B2315AN HF UF membrane modules, the TCEQ is approving a  $LRV_{C-Test}$  of 5.21 for the removal of *Cryptosporidium* for systems operated in deposition mode. The  $LRV_{C-Test}$  approval by the TCEQ does not apply to systems operated in a crossflow mode as this hydraulic configuration was not demonstrated in this challenge test study. The following are the parameters of the approved challenge study:

Full-scale module tested	Toray HFUG-B2315AN HF UF Membrane Modules
Number of Independent Modules Tested	5
Criterion of Selected Modules	None*
Serial Numbers of Tested Modules	F148117130, F417107S08, F148117131, F417107S06, and F417107S04
Nondestructive Performance Testing (NDPT) Process	Pressure-Decay Test
Quality Control Release Value (QCRV)	0.074 pounds per square-inch per minute (psi/min) (max)
Challenge Particulate	<i>Bacillus atrophaeus</i> American Type Culture Collection (ATCC) number 9372 (as a surrogate for <i>Cryptosporidium</i> ) with an average diameter of 0.8 microns ( $\mu\text{m}$ ) and an average length of 1.8 $\mu\text{m}$
Detection Limit	1 colony forming unit (CFU) per 100 milliliters (mL)
Feed Concentration Range	$2.30 \times 10^6$ CFU/100 mL to $3.15 \times 10^6$ CFU/100 mL**
Test Flux Rate (temperature corrected to 20° C)	110.03 - 124.6 gallons per square-foot per day (gfd) @ 20° C
Mode of Operation	Deposition mode

\* In regard to the selection of modules for testing, there was no consideration of manufacturing variability. However, the challenge study established a QCRV of 0.074 psi/min based on the highest observed average pressure decay results for the five modules (including a test on a module with a poked hole) that were tested to establish the  $LRV_{C-Test}$  as required by 40 CFR 141.719(b)(2)(vii) (and as discussed on pages 36 and 37 of the NSF International Test Report). The average pressure decay results ranged from 0.000 psi/min to a maximum of 0.074 psi/min. Any membrane module that does not meet the QCRV established in the challenge study is not eligible for the approved  $LRV_{C-Test}$  of 5.21-log.

\*\* As allowed by 40 CFR 141.719(b)(2)(iii), the maximum allowable feed concentration is  $3.16 \times 10^6 \times \text{Filtrate Detection Limit}$ . The goal for the *Bacillus atrophaeus* challenges was to be able to measure the highest feasible log reductions. Therefore, NSF International selected a target of 6.26 log ( $1.8 \times 10^6$  CFU/100 mL) in order to account for less than 100% recovery of the spiked challenge organism concentration and variability associated with counting of microorganisms. The actual feed concentration ranges (excluding the damaged fiber tests) are shown in the table above. Note that the TCEQ did not include or consider any feed concentrations greater than  $3.16 \times 10^6 \times \text{Filtrate Detection Limit}$ .

LIMITS OF TCEQ-APPROVED  $LRV_{C-TEST}$

The TCEQ-approved  $LRV_{C-TEST}$  is valid for only the Toray HFUG-B2315AN HF UF membrane modules operated under the parameters used for the challenge testing and only for modules that have passed the NDPT. Per our review of the challenge study, an acceptable Toray HFUG-B2315AN HF UF membrane module must comply with the following specifications to receive the TCEQ-approved  $LRV_{C-TEST}$ :

- Specifications of the approved Toray HFUG-B2315AN HF UF membrane modules:
  - a) Constructed of polyvinylidene fluoride (PVDF) hollow-fiber membranes
  - b) Number of fibers per element is 10,600
  - c) A molecular cut-off rating of 150,000 Daltons
  - d) A fiber inside diameter of 0.7 millimeters (mm)
  - e) A fiber wall thickness of 0.2 mm
  - f) Fiber active length of 81.34 inches (2,066 mm)
  - g) Active membrane area per module of 807-ft<sup>2</sup>
  - h) An outside-to-inside flow path
  - i) Operational mode: Deposition
  - j) A temperature tolerance range of 0 °C to 40°C (104°F)
  - k) Maximum trans-membrane pressure (TMP) of 43.5 pounds per square-inch (psi)
  - l) A pH tolerance range of 1 to 10
  - m) Allowable pH range for cleaning of 0 to 12
  - n) Maximum oxidant tolerance during cleaning of 3,000 mg/L (Cl<sub>2</sub>)
  
- For use by public water systems (PWSs) in Texas for microbial contaminant removal credit, only Toray HFUG-B2315AN HF UF modules that have been certified for performance by NSF are allowed. As defined in the NSF challenge study report (pages 4, 36, and 37), this means only modules that have passed a NDPT with a QCRV of 0.074 psi/min (from a starting pressure of 18.85 psi).
  
- The manufacturer, Toray Industries, Inc., must record the results of each HFUG-B2315AN HF UF membrane module's NDPT with the module's assigned unique serial number. The NDPT result for each HFUG-B2315AN HF UF membrane module delivered to a Texas PWS must be provided upon delivery of the HFUG-B2315AN HF UF membrane modules to a PWS.
  
- The manufacturer, Toray Industries, Inc., must notify the TCEQ in writing if the Toray HFUG-B2315AN HF UF membrane modules are modified or if the NDPT method is modified in any manner. After receiving written notification, the TCEQ shall determine if the modified Toray HFUG-B2315AN HF UF membrane module shall be required to undergo challenge testing or if the modified NDPT method is acceptable.
  
- The TCEQ shall grant log removal credits to Texas PWSs using membrane filtration for *Giardia* and *Cryptosporidium*. The log removal credits shall not exceed the lower of:
  - a) The TCEQ-approved  $LRV_{C-TEST}$ ; or,
  - b) The maximum removal efficiency that can be verified through a membrane unit's site-specific direct integrity test ( $LRV_{DIR}$ ).
  
- Each Toray HFUG-B2315AN HF UF membrane module must conform to ANSI/NSF Standard 61 and must be certified by a testing organization accredited by ANSI.
  
- Please note that the approved  $LRV_{C-TEST}$  is for the current Federal and Texas statutes, and the USEPA and TCEQ rules. If any of these statutes or rules are revised, the TCEQ-approved  $LRV_{C-TEST}$  in this letter may also be revised.

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Please provide a copy of this letter to each of your Texas PWS customers. This letter is **not** to be construed as:

- A granted TCEQ exception for any Texas PWS to use the Toray HFUG-B2315AN HF UF membrane modules. Each Texas PWS must request and receive site-specific approval to use membrane filtration in accordance with 30 TAC §290.42(g) and §290.39(l);
- TCEQ approval for a Texas PWS to install a Toray HFUG-B2315AN HF UF membrane module; or
- TCEQ approval for a Texas PWS's required concentration time (CT) study.

If you have any questions concerning this letter, or if we can be of additional assistance, please contact Mr. David Williams, P.E., at the letterhead address, by email at david.williams@tceq.texas.gov or by telephone at (512) 239-4674.

Sincerely,



David Williams, P.E.  
Technical Review and Oversight Team  
Plan & Technical Review Section  
Texas Commission on Environmental Quality



Joel Klumpp, Manager  
Plan and Technical Review Section  
Water Supply Division  
Texas Commission on Environmental Quality

JPK/daw

cc: Mr. Ben Freeman, Product Manager, Toray Membrane USA, Inc., 13435 Danielson Street,  
Poway, CA 92064