

## PUBLIC NOTICE

Notice is hereby given that the Massachusetts Department of Environmental Protection (MassDEP), under authority granted by the Massachusetts Clean Waters Act, M.G.L. c. 21, §§ 26 – 53, is proposing to: (1) issue a federal Clean Water Act (CWA) section 401 certification for the U.S. Environmental Protection Agency's (EPA) proposed 2020 Draft NPDES Permit (Federal Permit) (MA Permit No. MA0040321) to Shire Human Genetic Therapies, Inc. for their Cambridge facility's pollutant discharges to the Alewife Brook (MA 93-45); and (2) issue the 2020 Draft Massachusetts Permit to Discharge Pollutants to Surface Waters (State Permit) for the same discharge pursuant to the Massachusetts Clean Waters Act. The Shire Human Genetic Therapies, Inc. is located at 205 Alewife Brook Parkway in Cambridge, Massachusetts. The proposed section 401 certification, proposed State Permit, and proposed Federal Permit are all available at <https://www.mass.gov/service-details/massdep-public-hearings-comment-opportunities>. Alternatively a copy of the documents can be obtained by contacting Xiaodan Ruan, MassDEP Surface Water Discharge Program, at 617-654-6517 or [xiaodan.ruan@mass.gov](mailto:xiaodan.ruan@mass.gov). Written comments on both the proposed section 401 certification and the proposed State Permit will be accepted until 5:00 p.m. on Thursday, August 13, 2020. During the state of emergency, MassDEP strongly encourages written comments to be submitted by email to [npdes@mass.gov](mailto:npdes@mass.gov); subject line: Shire Human Genetic Therapies. If not possible, please send by mail to Xiaodan Ruan, MassDEP Surface Water Discharge Program, Bureau of Water Resources, 1 Winter Street – 5<sup>th</sup> Floor, Boston 02108.

Following the close of the comment period, MassDEP will issue a final CWA section 401 certification and final State Permit and forward copies to the applicant and each person who has submitted written comments or requested notice.

For special accommodations, please call the MassDEP Diversity Office at 617-292-5751. TTY# MassRelay Service 1-800-439-2370. This information is available in alternate format upon request.

By Order of the Department

Martin Suuberg, Commissioner

**MASSACHUSETTS PERMIT TO DISCHARGE POLLUTANTS TO SURFACE WATERS**

In compliance with the provisions of the Massachusetts Clean Waters Act, as amended (M.G.L. Chap. 21, §§ 26 - 53) and the implementing regulations at 314 CMR 3.00 and 4.00,

Shire Human Genetic Therapies, Inc.

is authorized to discharge from the facility located at

Shire Human Genetic Therapies, Inc.  
205 Alewife Brook Parkway  
Cambridge, MA 02138

to receiving water named

Alewife Brook  
Mystic River Watershed

in accordance with the following effluent limitations, monitoring requirements and additional conditions:

1. This permit shall become effective on [DATE].<sup>1</sup>
2. This permit shall expire five years after the effective date.
3. This permit supersedes the permit issued on March 13, 2015.
4. This permit incorporates by reference Part IA., Effluent Limitations and Monitoring Requirements, Part IB., Unauthorized Discharges, Part IC., Special Conditions, Part ID. Reporting Requirements, and Part IIE., Standard Conditions, as set forth in the 2020 draft NPDES Permit No. MA0040321, issued by the United States Environmental Protection Agency (EPA), Region 1, issued to Shire Human Genetic Therapies, Inc. on July 1, 2020 (the 2020 Draft NPDES Permit) and attached hereto as Appendix A; provided, however:
  - a. that the notification required by Part IA.8. shall also be provided to MassDEP;
  - b. that the reporting required by Part IB.1 shall be in accordance with 314 CMR 3.19(20)(e) (24 hour reporting);
  - c. that discharges of a new chemical or additive authorized under Part IC.1. are only authorized under this permit 30 days following written notification to MassDEP, unless otherwise notified in writing by MassDEP;
  - d. that a copy of the requests, reports, and information required by Part ID.3. to be submitted to EPA shall also be submitted to MassDEP electronically to [npdes@mass.gov](mailto:npdes@mass.gov);
  - e. that, if there is a conflict between the definitions in 314 CMR 3.02 and/or 314 CMR 4.00 and the definitions in Part IIE, the definitions in 314 CMR 3.02 and/or 314 CMR 4.00 shall control, as applicable;
  - f. that the notifications required by 4.a. and 4.c. above shall be provided as follows:

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<sup>1</sup> If no comments objecting to the issuance or terms of the permit were received by the Department during the public comment period, then this permit shall be effective upon issuance. If comments objecting to the issuance or the terms of the permit are received by the Department during the public comment period, then this permit shall become effective 30 days after issuance.

Susannah King, NPDES Section Chief  
 Division of Watershed Management  
 Department of Environmental Protection  
 1 Winter Street – 5<sup>th</sup> Floor  
 Boston, MA 02108

5. This permit incorporates by reference the Standard Permit Conditions set forth in 314 CMR 3.19.
6. This permit includes the following additional conditions:
  - a. Within six (6) months of the effective date of the permit, the permittee shall submit to MassDEP an evaluation of whether the facility uses any products containing any per- and polyfluoroalkyl substances (PFAS) and whether use of those products can be reduced or eliminated. The analysis shall be submitted electronically to [npdes@mass.gov](mailto:npdes@mass.gov).
  - b. Within six (6) months after EPA's multi-lab validated method for wastewater is made available to the public on EPA's Clean Water Act methods program website<sup>2</sup>, or two (2) years from the effective date of the NPDES permit, whichever is earlier, the permittee shall conduct monitoring of the effluent for PFAS compounds as detailed in the table below. If EPA has not issued a validated test method by twenty (20) months after the effective date of the NPDES permit, the permittee shall contact MassDEP ([npdes@mass.gov](mailto:npdes@mass.gov)) for guidance on an appropriate analytical method.

#### Effluent (Outfall 002)

Parameter	Units	Measurement Frequency	Sample Type
Perfluorohexanesulfonic acid (PFHxS)	ng/L	Quarterly <sup>3</sup>	24-hour Composite
Perfluoroheptanoic acid (PFHpA)	ng/L	Quarterly	24-hour Composite
Perfluorononanoic acid (PFNA)	ng/L	Quarterly	24-hour Composite
Perfluorooctanesulfonic acid (PFOS)	ng/L	Quarterly	24-hour Composite
Perfluorooctanoic acid (PFOA)	ng/L	Quarterly	24-hour Composite
Perfluorodecanoic acid (PFDA)	ng/L	Quarterly	24-hour Composite

Notwithstanding any other provision of the 2020 Federal NPDES permit to the contrary, monitoring results shall be reported to MassDEP electronically ([npdes@mass.gov](mailto:npdes@mass.gov)) within 30 days after they are received. Those results do not need to be reported to EPA through NetDMR unless EPA establishes a requirement through a future permitting action.

- c. After completing one year of monitoring, if four (4) consecutive samples are reported as non-detect for all six PFAS compounds, then the permittee may submit a request to discontinue PFAS monitoring. Any such request shall be made in writing and sent to: [npdes@mass.gov](mailto:npdes@mass.gov). The permittee shall continue such monitoring pending written approval from MassDEP to discontinue it.

<sup>2</sup> See <https://www.epa.gov/cwa-methods/other-clean-water-act-test-methods-chemical> and <https://www.epa.gov/cwa-methods>.

<sup>3</sup> Quarters are defined as January to March, April to June, July to September, and October to December. Samples shall be taken during the same month each quarter and shall be taken 3 months apart (e.g., an example sampling schedule could be February, May, August, and November).

MA Permit No. MA0040321

July 14, 2020

2020 DRAFT PERMIT

Signed this \_\_\_\_ day of \_\_\_\_\_, 20\_\_

Lealdon Langley, Director  
Division of Watershed Management  
Department of Environmental Protection

**MASSACHUSETTS DEPARTMENT OF ENVIRONMENTAL PROTECTION**

**FACT SHEET SUPPLEMENT**

**MASSACHUSETTS PERMIT TO DISCHARGE POLLUTANTS TO SURFACE WATERS**

**MA PERMIT NUMBER:** MA0040321

**NAME AND MAILING ADDRESS OF APPLICANT:**

Shire Human Genetic Therapies, Inc., 205 Alewife Brook Parkway, Cambridge, MA 02138

**NAME AND ADDRESS OF FACILITY WHERE DISCHARGE OCCURS:**

Shire Human Genetic Therapies, Inc., 205 Alewife Brook Parkway, Cambridge, MA 02138

**RECEIVING WATER AND CLASSIFICATION:**

Alewife Brook (MA71-04), Mystic River Watershed, Class B (CSO)

**SIC CODE:**

2834 (Pharmaceutical Preparation)

PER – AND POLYFLUROALKYL SUBSTANCES

MassDEP is implementing a number of actions to address the potential health effects of exposure to per- and polyfluoroalkyl substances (PFAS).<sup>1</sup> According to the United States Environmental Protection Agency (EPA),<sup>2</sup> PFAS are a group of man-made chemicals that includes perfluorooctanoic acid (PFOA), perfluorooctane sulfonic acid (PFOS), GenX, and many other chemicals. PFAS have been manufactured and used in a variety of industries around the globe, including in the United States since the 1940s. PFOA and PFOS have been the most extensively produced and studied of these chemicals. Both chemicals are very persistent in the environment and in the human body – meaning they do not break down and they can accumulate over time. There is evidence that exposure to PFAS can lead to adverse human health effects.

PFAS can be found in:

- **Food** packaged in PFAS-containing materials, processed with equipment that used PFAS, or grown in PFAS-contaminated soil or water.
- **Commercial household products**, including stain- and water-repellent fabrics, nonstick products, polishes, waxes, paints, cleaning products, and fire-fighting foams (a major source of groundwater contamination at airports and military bases where firefighting training occurs).
- **Workplace**, including production facilities or industries (e.g., chrome plating, electronics manufacturing or oil recovery) that use PFAS.

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<sup>1</sup> To learn more about Per- and polyfluoroalkyl substances (PFAS) in the environment and what Massachusetts is doing to address them, go to: <https://www.mass.gov/info-details/per-and-polyfluoroalkyl-substances-pfas>.

<sup>2</sup> For basic information on PFAS provided by EPA, go to: <https://www.epa.gov/pfas/basic-information-pfas>

- **Drinking water**, typically localized and associated with a specific facility (e.g., manufacturer, landfill, wastewater treatment plant, firefighter training facility).
- **Living organisms**, including fish, animals and humans, where PFAS have the ability to build up and persist over time.

Certain PFAS chemicals are no longer manufactured in the United States as a result of phase-outs including the PFOA Stewardship Program, in which eight major chemical manufacturers agreed to eliminate the use of PFOA and PFOA-related chemicals in their products and as emissions from their facilities. Although PFOA and PFOS are no longer manufactured in the United States, they are still produced internationally and can be imported into the United States in consumer goods such as carpet, leather and apparel, textiles, paper and packaging, coatings, rubber and plastics.

Scientific information and regulatory actions on PFAS are rapidly evolving. Currently, there are no enforceable federal standards for these substances in public drinking water. However, in May 2016, EPA issued a lifetime drinking water Health Advisory (HA) of 70 nanograms per liter (70 ng/L, which equals 70 parts per trillion or ppt) for any combination of PFOA and PFOS. In June 2018, MassDEP extended this advisory to include three additional related PFAS chemicals - perfluorononanoic acid (PFNA), perfluorohexanesulfonic acid (PFHxS) and perfluoroheptanoic acid (PFHpA). This Massachusetts value, called a MassDEP Office of Research and Standards Guideline (ORSG), is a maximum recommended level for drinking water. It is set to be protective against adverse health effects for all people consuming the water for a lifetime and also applies to shorter-term exposures of weeks to months during pregnancy and breast-feeding.

In December 2019, MassDEP promulgated final regulations at 310 CMR 40.0000 establishing groundwater and soil limits at waste cleanup sites for 6 PFAS compounds - PFOS, PFOA, PFHxS, PFNA, PFHpA, and perfluorodecanoic acid (PFDA). At the same time, MassDEP proposed revisions to the Massachusetts drinking water regulations that would establish a regulatory drinking water standard or Massachusetts Maximum Contaminant Level (MMCL) for PFAS. These revisions would establish a MMCL of 20 ng/L (or parts per trillion) for the sum of the concentrations of the same six PFAS included in the waste site clean up regulations. The proposed standard is supported by recent scientific developments in understanding the health effects of PFAS and is aligned with PFAS cleanup standards promulgated by the Waste Site Cleanup Program. For information on the proposed MMCL see: <https://www.mass.gov/regulations/310-CMR-22-the-massachusetts-drinking-water-regulations>. The ORSG and the technical support document explain the basis of both the MassDEP revised cleanup standards and the proposed MMCL for drinking water.

In January 2020, MassDEP updated the ORSG, which is now 20 ng/L for the sum of 6 PFAS compounds. The updated ORSG replaces the June 2018 guideline for PFAS in drinking water. See the updated ORSG and technical support document here: <https://www.mass.gov/info-details/per-and-polyfluoroalkyl-substances-pfas#health-advisories-and-downloadable-fact-sheets>

Based on the current ORSG, MassDEP recommends that:

- 1) consumers in sensitive subgroups (pregnant women, nursing mothers, and

infants) not consume water when the level of the six PFAS substances, individually or in combination, is above 20 ppt; and,  
2) public water suppliers take steps expeditiously to lower levels of the six PFAS, individually or in combination, to below 20 ppt for all consumers.

Given that PFAS are persistent in the environment and may lead to adverse human health and environmental effects, MassDEP has identified a comprehensive approach for addressing PFAS in wastewater discharges. Additionally, based on review of data collected by other states for residuals produced from wastewater treatment and other processes, MassDEP has concerns regarding the levels of PFAS in residuals land applied in Massachusetts. All residuals products sold, distributed, and applied in Massachusetts are subject to an Approval of Suitability (AOS), which classifies residuals for different uses based on the chemical quality and treatment to reduce pathogens. Therefore, MassDEP began including a requirement for PFAS testing in all new or renewed AOSs in January 2019, and as of July 2020, MassDEP will be requiring all AOS holders to test their products for PFAS.

MassDEP is also concerned about the potential impacts PFAS wastewater discharges may have on downstream drinking water, recreational, and aquatic life uses. The Massachusetts Surface Water Quality Standards do not include numeric criteria for PFAS. However, the narrative criterion for toxic pollutants at 314 CMR 4.05(5)(e) states:

*All surface waters shall be free from pollutants in concentrations or combinations that are toxic to humans, aquatic life or wildlife.*

In addition, this narrative criterion is further elaborated on at 314 CMR 4.05(5)(e)2 which states:

*Human Health Risk Levels. Where EPA has not set human health risk levels for a toxic pollutant, the human health-based regulation of the toxic pollutant shall be in accordance with guidance issued by the Department of Environmental Protection's Office of Research and Standards. The Department's goal is to prevent all adverse health effects which may result from the ingestion, inhalation or dermal absorption of toxins attributable to waters during their reasonable use as designated in 314 CMR 4.00.*

To assess whether PFAS discharges from the Shire Human Genetic Therapies, Inc. facility are occurring and whether they may be contributing to a violation of the narrative toxics criteria, MassDEP is including conditions in the Massachusetts Surface Water Discharge Permit for the facility to require the permittee to monitor its discharges for PFAS and to conduct an evaluation of its use of PFAS-containing products.

DRAFT

Clean Water Act Section 401 Certification  
For the Proposed 2020 Federal NPDES Permit  
For the Shire Human Genetic Therapies, Inc.  
MA Permit No. MA0040321

The Massachusetts Department of Environmental Protection (MassDEP), having examined Shire Human Genetic Therapies, Inc.'s National Pollutant Discharge Elimination System (NPDES) permit application for the Shire Human Genetic Therapies, Inc., reviewed the United States Environmental Protection Agency (EPA) – Region 1's draft 2020 Federal NPDES permit (MA Permit No. MA0040321) for the Shire Human Genetic Therapies, Inc. issued July 1, 2020, and considered the public comments received on MassDEP's proposed Clean Water Section 401 Certification for the draft 2020 Federal NPDES Permit for the Shire Human Genetic Therapies, Inc., and in consideration of the relevant water quality considerations, hereby certifies:

1. that the following conditions, together with the terms and conditions contained in the proposed 2020 Federal NPDES permit for the Shire Human Genetic Therapies, Inc., are necessary to assure compliance with the applicable provisions of the Federal Clean Water Act Sections 208(e), 301, 302, 303, 306, and 307 and with appropriate requirements of State law, including, without limitation, the Massachusetts Clean Waters Act, M.G.L. c. 21, §§ 26-53 and the Massachusetts Water Quality Standards published at 314 CMR 4.00:
  - a. Pursuant to 314 CMR 3.11 (2)(a)6., and in accordance with MassDEP's obligation under 314 CMR 4.05(5)(e) to maintain surface waters free from pollutants in concentrations or combinations that are toxic to humans, aquatic life, or wildlife, within six (6) months of the effective date of the 2020 Federal NPDES permit, the permittee shall submit to MassDEP an evaluation of whether the facility uses any products containing any per- and polyfluoroalkyl substances (PFAS) and whether use of those products can be reduced or eliminated. The analysis shall be submitted electronically to [npdes@mass.gov](mailto:npdes@mass.gov).
  - b. Pursuant to 314 CMR 3.11 (2)(a)6., and in accordance with MassDEP's obligation under 314 CMR 4.05(5)(e) to maintain surface waters free from pollutants in concentrations or combinations that are toxic to humans, aquatic life, or wildlife, within six (6) months after EPA's multi-lab validated method for wastewater is made available to the public on EPA's Clean Water Act methods program website<sup>1</sup>, or two (2) years from the effective date of the 2020 Federal NPDES permit, whichever is earlier, the permittee shall conduct monitoring of the effluent for PFAS compounds as detailed in the table below. If EPA has not issued a validated test method by twenty (20) months after the effective date of the 2020 Federal NPDES permit, the permittee shall contact MassDEP ([npdes@mass.gov](mailto:npdes@mass.gov)) for guidance on an appropriate analytical method.

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<sup>1</sup> See <https://www.epa.gov/cwa-methods/other-clean-water-act-test-methods-chemical> and <https://www.epa.gov/cwa-methods>.

This information is available in alternate format. Contact Michelle Waters-Ekanem, Director of Diversity/Civil Rights at 617-292-5751.

TTY# MassRelay Service 1-800-439-2370

MassDEP Website: [www.mass.gov/dep](http://www.mass.gov/dep)



**Effluent (Outfall 002)**

Parameter	Units	Measurement Frequency	Sample Type
Perfluorohexanesulfonic acid (PFHxS)	ng/L	Quarterly <sup>2</sup>	24-hour Composite
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Perfluorononanoic acid (PFNA)	ng/L	Quarterly	24-hour Composite
Perfluorooctanesulfonic acid (PFOS)	ng/L	Quarterly	24-hour Composite
Perfluorooctanoic acid (PFOA)	ng/L	Quarterly	24-hour Composite
Perfluorodecanoic acid (PFDA)	ng/L	Quarterly	24-hour Composite

Notwithstanding any other provision of the 2020 Federal NPDES permit to the contrary, monitoring results shall be reported to MassDEP electronically ([npdes@mass.gov](mailto:npdes@mass.gov)) within 30 days after they are received. Those results do not need to be reported to EPA through NetDMR, unless EPA establishes a requirement through a future permitting action.

- c. Pursuant to 314 CMR 3.11 (2)(a)6., and in accordance with MassDEP's obligation under 314 CMR 4.05(5)(e) to maintain surface waters free from pollutants in concentrations or combinations that are toxic to humans, aquatic life, or wildlife, after completing one year of monitoring, if four (4) consecutive samples are reported as non-detect for all six (6) PFAS compounds, then the permittee may submit a request to MassDEP to discontinue PFAS monitoring. Any such request shall be made in writing and sent to [npdes@mass.gov](mailto:npdes@mass.gov). The permittee shall continue such monitoring pending written approval from MassDEP to discontinue it.
2. that there is a reasonable assurance that the activity will be conducted in a manner which will not violate applicable state water quality standards.

To meet the requirements of Massachusetts laws, each of the conditions cited in the draft permit and this certification shall not be made less stringent unless new data or other information is presented and MassDEP determines modification of this certification is appropriate in consideration of the relevant water quality considerations.

If any condition in the draft 2020 Federal NPDES permit for the Shire Human Genetic Therapies, Inc. is changed during EPA's review in any manner inconsistent with this certification, the Department reserves the right to modify this certification in consideration of the relevant water quality considerations. In addition, the Department reserves the right to modify this certification if there is a change in Massachusetts law or regulation upon which this certification is based, or if a court of competent jurisdiction or MassDEP Office of Appeals and Dispute Resolution stays, vacates or remands this certification, as provided by 40 C.F.R. § 124.55.

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<sup>2</sup> Quarters are defined as January to March, April to June, July to September, and October to December. Samples shall be taken during the same month each quarter and shall be taken 3 months apart (e.g., an example sampling schedule could be February, May, August, and November).

Signed this \_\_\_\_ day of \_\_\_\_\_, 2020.

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Lealdon Langley, Director  
Massachusetts Department of Environmental Protection  
Bureau of Water Resources  
Division of Watershed Management