

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 April 1, 2021.
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 2021 NPDES Permit No. MA0040321, issued by the United States Environmental Protection Agency (EPA), Region 1, issued to Shire Human Genetic Therapies, Inc. on January 27, 2021 (the 2021 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 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 massdep.npdes@mass.gov;
 - d. 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;
 - e. that the notifications required by 4.a. and 4.c. above shall be provided as follows:

Susannah King, NPDES Section Chief
Division of Watershed Management
Department of Environmental Protection
1 Winter Street – 5th 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 massdep.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 website¹, 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 (massdep.npdes@mass.gov) for guidance on an appropriate analytical method.

Effluent (Outfall 001)

Parameter	Units	Measurement Frequency	Sample Type
Perfluorohexanesulfonic acid (PFHxS)	ng/L	Quarterly ²	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 2021 Federal NPDES permit to the contrary, monitoring results shall be reported to MassDEP electronically at massdep.npdes@mass.gov, or as otherwise specified, 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: massdep.npdes@mass.gov. The permittee shall continue such monitoring pending written approval from MassDEP to discontinue it.

Signed this 2nd day of March, 2021



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

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

² 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).

RESPONSE TO COMMENTS

MA Permit No. MA0040321
Shire Human Genetic Therapies, Inc.
205 Alewife Brook Parkway Cambridge, Massachusetts

The Massachusetts Department of Environmental Protection (MassDEP or the “Department”) is issuing a Surface Water Discharge (SWD) Permit to Shire Human Genetic Therapies, Inc. (the Permittee) for the facility (the Facility) located in Cambridge, Massachusetts. The permit is being issued under 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.

In accordance with the provisions of 314 CMR 2.09, MassDEP is obligated to prepare a response to comments received on the draft SWD Permit No. MA0040321 (the “Draft Permit”). The Response to Comments explains and supports MassDEP’s determinations that form the basis of the final permit (the “Final Permit”). From July 14, 2020 through August 13, 2020, MassDEP solicited public comments on the Draft Permit for the reissuance of a permit to discharge reverse osmosis (RO) reject water from Outfall Serial Number 001 to the Alewife Brook and the associated Draft WQC.

During the public comment period for the draft NPDES permit (July 1, 2020 through July 30, 2020), EPA received comments from:

1. Jonathan Tomer, Sr. Environmental Specialist, Shire Human Genetic Therapies, Inc., dated July 28, 2020

EPA’s Response to Comments is included as part of the final NPDES permit issuance.

During the public comment period for the draft SWD Permit, MassDEP received comments from:

1. Jonathan Tomer, Sr. Environmental Specialist, Shire Human Genetic Therapies, Inc., dated July 29, 2020
2. Andreae Downs, Executive Director, Wastewater Advisory Committee to the MWRA, dated August 4, 2020.

MassDEP’s knowledge of the facility has benefited from the various comments and additional information submitted during the public comment period but the information and arguments presented did not raise any substantial new questions concerning the Permit that warranted MassDEP exercising the discretion to reopen the public comment period. MassDEP does, however, make certain clarifications in response to comments. Any improvements and changes are explained in this document and reflected in the Final Permit. Below, MassDEP provides a summary of the changes made in the Final Permit. The analyses underlying these changes are contained in the responses to individual comments that follow.

A copy of the Final Permit and this Response to Comments document will be posted on the MassDEP website.

A copy of the Final Permit may be also obtained by writing or calling Xiaodan Ruan, MassDEP, Surface Water Discharge Permitting Program, Bureau of Water Resources, 1 Winter Street – 5th Floor, Boston 02108; telephone: 617-654-6517; email: xiaodan.ruan@mass.gov. During this current COVID-19 emergency, MassDEP is working remotely. As such, interested parties are strongly encouraged to email MassDEP Xiaodan Ruan if they wish to obtain a copy of the Final Permit.

I. Summary of Changes to the Final Permit

1. Paragraph 4.c. in the Draft Permit, “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;” has been removed in the Final Permit to be consistent with EPA NPDES Permit.
2. Paragraph 6.b., the table title has been revised from “Outfall 002” to “Outfall 001” due to a typographical error.
3. Paragraph 6.b. has been revised to clarify that results shall be reported through email, or otherwise specified, if MassDEP directs permittees to report through another mechanism.

II. Responses to Comments

Comments are reproduced below as received; they have not been edited, corrected or otherwise modified.

A. Comment from Jonathan Tomer, Sr. Environmental Specialist, Shire Human Genetic Therapies, Inc., dated July 29, 2020**Comment 1**

I think there is a minor error on the draft permit (Shire Draft MA Permit 7-14-20.pdf). In Section 6. B. the Table lists “Effluent (Outfall 002)” for site. On our site and initial application our only outfall is related to surface water discharge is Outfall 001.

Response 1

The Permittee was correct that there was a typographical error on the Outfall Serial Number in the table title in paragraph 6.b. of the Draft Permit. The Final Permit has been revised to change the table title from “Outfall 002” to “Outfall 001.”

B. Comment from Andreae Downs, Executive Director, Wastewater Advisory Committee to the MWRA, dated August 4, 2020.**Comment 2**

The Wastewater Advisory Committee (WAC) supports the DEP’s draft requirements for industries with NPDES permits (including Shire Human Genetic Therapies’ Cambridge facility and Genzyme Corporation) to monitor effluent for six PFAS.

Collecting such data can help both publicly owned treatment works (POTWs)s and DEP in future limit decisions. This is helpful since more information about PFAS is still needed, including who is discharging them in what concentrations, and their fate in the environment.

WAC also supports requiring these industries and those that discharge to POTWs to evaluate whether their facilities use any products containing any PFAS and whether such use can be reduced or

eliminated, with the caveat that “any PFAS” not be exclusively the six compounds DEP is asking the facilities to monitor.

Recycling residuals from POTWs is continually threatened by contaminants of emerging concern. With several New England states establishing guidance limiting PFAS to 20ppt or lower for drinking water, the levels of PFAS in residuals which may be land-applied is even more important.

WAC asks DEP to consider the following:

- Ease of detection and testing (and a limit high enough to be easily detectable)
- Ease of reporting
- Cost of the above

Response 2:

MassDEP acknowledges Wastewater Advisory Committee (WAC)’s comments on detection, testing and reporting of PFAS. As stated in the State Permit, the Permittee shall follow the Permit Condition 6.b. for the testing method and reporting of the monitoring results. MassDEP is available to provide guidance should the Permittee have questions or difficulties. MassDEP acknowledges WAC’s comment to DEP to consider the cost of PFAS monitoring. MassDEP has considered the cost of PFAS testing, which is one of the reasons the permit includes Condition 6.c., which allows for the Permittee to request to discontinue PFAS monitoring if four (4) consecutive samples are non-detect for all compounds.

**NOTICE OF APPEAL RIGHTS for
STATE SURFACE WATER DISCHARGE PERMIT**

Within 30 days of the issuance of MassDEP's decision to grant or deny a Surface Water Discharge Permit pursuant to M.G.L. c. 21, § 43, and 314 CMR 3.00, any person aggrieved may request an adjudicatory hearing.

How should the request for an adjudicatory hearing be made?

A request for an adjudicatory hearing for the state Surface Water Discharge Permit must be made during the 30-day period following issuance of the state permit, in accordance with 314 CMR 2.08 and 310 CMR 1.01. 310 CMR 1.01(6)(b) establishes the required form and content of the request. Failure to meet the requirements of 310 CMR 1.01 may result in dismissal of the request or the requirement to file a more definite statement.

A person filing a request for an adjudicatory hearing must complete and mail a MassDEP Fee Transmittal Form and send it with a valid check to the Commonwealth Master Lockbox, as instructed below, if a fee is required by 310 CMR 4.06. The MassDEP Fee Transmittal Form can be downloaded from:

<http://www.mass.gov/eea/agencies/massdep/service/approvals/transmittal-form-for-payment.html>.

The written notice requesting an adjudicatory hearing shall be delivered to MassDEP's Case Administrator together with (i) a photocopy of the decision being appealed, (ii) a photocopy of the completed MassDEP Fee Transmittal Form, if required, and (iii) a photocopy of the check used to pay any adjudicatory hearing filing fee due for the appeal under 310 CMR 4.06. The notice of claim must be made in writing and sent by email to Caseadmin.OADR@state.ma.us.

Please do not send the original of the completed MassDEP Fee Transmittal Form and check to the Case Administrator. Instead, please follow the instructions below for delivery of the original of the completed Fee Transmittal Form and check to the Commonwealth Master Lockbox.

A \$100 adjudicatory hearing filing fee must be paid, unless (i) a simplified hearing is requested for a reduced fee of \$25, (ii) the person requesting an adjudicatory hearing is a town, a municipal agency, a county or a municipal housing authority, in which case there is no fee, or (iii) the person requesting the hearing is seeking to have MassDEP waive the adjudicatory hearing filing fee because paying the fee will create an undue financial hardship.

A person who believes that payment of the fee would be an undue financial hardship shall file with the request for adjudicatory hearing a request for waiver of the fee together with an affidavit setting forth the facts the appellant believes constitute the undue financial hardship. For more information on the adjudicatory hearing filing fee and the grounds on which the Department may waive the fee, please see 310 CMR 4.06.

If a fee is required, the completed MassDEP Fee Transmittal Form and a valid check made payable to the Commonwealth of Massachusetts for the amount of the fee due must be mailed to:

Mass. Department of Environmental Protection
Commonwealth Master Lockbox

P.O. Box 4062
Boston, Massachusetts 02211

Failure to pay the adjudicatory hearing filing fee, if required, may be grounds for dismissal of the appeal.

In accordance with 314 CMR 2.08(5), any person, other than the permit applicant or permittee, who files a request for an adjudicatory hearing with the Department pursuant to 314 CMR 2.08(2) on an individual permit or general permit coverage, also shall simultaneously send a copy of the request by certified mail, return receipt requested, to the applicant or permittee. Any person who files a request for an adjudicatory hearing with the Department pursuant to 314 CMR 2.08(2) on a general permit also shall simultaneously send a copy of the request by certified mail, return receipt requested, to each permittee covered by the general permit.



Massachusetts Department of Environmental Protection
One Winter Street, Boston MA 02108 • Phone: 617-292-5751

Communication for Non-English Speaking Parties - 310 CMR 1.03(5)(a)



1 English:

This document is important and should be translated immediately. If you need this document translated, please contact MassDEP's Diversity Director at the telephone numbers listed below.



2 Español (Spanish):

Este documento es importante y debe ser traducido inmediatamente. Si necesita este documento traducido, comuníquese con el Director de Diversidad de MassDEP a los números de teléfono que aparecen más abajo.



3 Português (Portuguese):

Este documento é importante e deve ser traduzido imediatamente. Se você precisa deste documento traduzido, entre em contato com Diretor de Diversidade da MassDEP para os números de telefone listados abaixo.



4(a) 中國（傳統）(Chinese (Traditional)):

本文件非常重要，應立即翻譯。如果您需要翻譯這份文件，請用下面列出的電話號碼與 MassDEP 的多元化總監聯繫。



4(b) 中国（简体中文）(Chinese (Simplified)):

本文件非常重要，应立即翻译。如果您需要翻译这份文件，请用下面列出的电话号码与 MassDEP 的多元化总监联系。



5 Ayisyen (franse kreyòl) (Haitian) (French Creole):

Dokiman sa-a se yon bagay enpòtan epi yo ta dwe tradui imedyatman. Si ou bezwen dokiman sa a tradui, tanpri kontakte Divèsite Direktè MassDEP a nan nimewo telefòn ki nan lis pi ba a.



6 Việt (Vietnamese):

Tài liệu này rất quan trọng và cần được dịch ngay lập tức. Nếu bạn cần dịch tài liệu này, xin vui lòng liên hệ với Giám đốc Đa dạng của MassDEP theo các số điện thoại được liệt kê dưới đây.



7 ប្រទេសកម្ពុជា (Kmer (Cambodian)):

ឯកសារនេះគឺមានសារៈសំខាន់និងត្រូវបានបកប្រែភាសា ប្រសិនបើអ្នកត្រូវបានបកប្រែ ឯកសារនេះសូមទំនាក់ទំនងឆ្នោតជានាយក MassDEP នៅលេខទូរស័ព្ទដែលបានរាយខាងក្រោម។



8 Kriolu Kabuverdianu (Cape Verdean):

Es documento é importante e deve ser traduzido imidiatamente. Se bo precisa des documento traduzido, por favor contacta Director de Diversidade na MassDEP's pa es numero indicode li d'boche.



9 Русский язык (Russian):

Это важный документ и он должен быть безотлагательно переведен. Если вам нужен перевод данного документа, пожалуйста, свяжитесь с директором по разнообразию компании MassDEP по телефону указанному ниже

**10 العربية (Arabic):**

هذه الوثيقة مهمة ويجب ترجمتها على الفور. إذا كنت بحاجة إلى هذه الوثيقة المترجمة، يرجى الاتصال بمدير التنوع في MassDEP على أرقام الهواتف المدرجة أدناه.

**11 한국어 (Korean):**

이 문서는 중요하고 즉시 번역해야 합니다. 이 문서의 번역이 필요하시다면, 아래의 전화 번호로 MassDEP의 다양성 감독에 문의하시기 바랍니다.

**12 հայերեն (Armenian):**

Այս փաստաթուղթը շատ կարևոր է և պետք է թարգմանել անմիջապես. Եթե Ձեզ անհրաժեշտ է այս փաստաթուղթը թարգմանվել դիմել MassDEP բազմազանությունը տնօրեն է հեռախոսահամարների թվարկված են ստորև.

**13 فارسی (Farsi [Persian]):**

این سند مهم است و باید فوراً ترجمه شده است. اگر شما نیاز به این سند ترجمه شده، لطفاً با ما تماس تنوع مدیر MassDEP در شماره تلفن های ذکر شده در زیر.

**14 Français (French):**

Ce document est important et devrait être traduit immédiatement. Si vous avez besoin de ce document traduit, s'il vous plaît communiquer avec le directeur de la diversité MassDEP aux numéros de téléphone indiqués ci-dessous.

**15 Deutsch (German):**

Dieses Dokument ist wichtig und sollte sofort übersetzt werden. Sofern Sie die Übersetzung von diesem Dokument benötigen, wenden Sie sich bitte an den Diversity Director MassDEP unter der unten aufgeführten Telefonnummer.

**16 Ελληνική (Greek):**

Το παρόν έγγραφο είναι σημαντικό και θα πρέπει να μεταφραστεί αμέσως. Αν χρειάζεστε μετάφραση του παρόντος εγγράφου, παρακαλούμε επικοινωνήστε με τον Διευθυντή Διαφορετικότητας του MassDEP στους αριθμούς τηλεφώνου που αναγράφονται παρακάτω.

**17 Italiano (Italian):**

Questo documento è importante e dovrebbe essere tradotto immediatamente. Se avete bisogno di questo documento tradotto, si prega di contattare il Direttore di Diversità di MassDEP ai numeri di telefono elencati di seguito.

**18 Język Polski (Polish):**

Dokument ten jest ważny i powinien zostać natychmiast przetłumaczony. Jeśli potrzebujesz przetłumaczonej wersji dokumentu, prosimy o kontakt z dyrektorem ds. różnorodności MassDEP pod jednym z numerów telefonu wymienionych poniżej.

**19 हिन्दी (Hindi):**

यह दस्तावेज़ महत्वपूर्ण है और तुरंत अनुवाद किया जाना चाहिए. यदि आपको इस दस्तावेज़ का अनुवाद करने की आवश्यकता है, तो कृपया नीचे सूचीबद्ध टेलीफोन नंबरों पर मासडेप्स डाइवर्सिटी के निदेशक से संपर्क करें।