

File No.: 3128.00

July 18, 2025

James O'Meara Senior Director of Operations Bausch Health Companies Inc. 100 LifeSciences Parkway Steinbach MB R5G 1Z7 james.omeara@bauschhealth.com

Dear James O'Meara:

Re: Bausch Health Companies Inc. - Environment Act Licence No. 1364 R9

Thank you for your notice of alteration dated May 23, 2024, and additional information dated May 7, 2025. You wish to replace the existing old thermal oxidizer with two new efficient ones. It is understood there is no change in the production capacity of the facility.

The requested alteration per Section 14(2) of The Environment Act has been approved, and the revised Environment Act Licence No. 1364 R9 is enclosed.

All licence requirements and federal, provincial, and municipal regulations and by-laws must be followed. The licensee must get approval from the director per The Environment Act to alter the development.

Anyone affected by this decision may appeal, in writing, to the Minister of Environment and Climate Change at <u>minecc@manitoba.ca</u> by August 17, 2025. The licence is available on the public registry at <u>https://www.gov.mb.ca/sd/eal/registries/index.html</u>.

If you have any questions regarding this approval, please contact Allan Cyrenne, Regional Supervisor, Environmental Compliance and Enforcement Branch at <u>EnvCEEastern@gov.mb.ca</u> or 204-485-6410.

Sincerely,

Original Signed By Agnes Wittmann Director The Environment Act

Enclosure

c. Charlene Robert - Bausch Health Allan Cyrenne - Environmental Compliance and Enforcement Eshetu Beshada – Environmental Approvals

THE ENVIRONMENT ACT LOI SUR L'ENVIRONNEMENT

LICENCE

File No.: 3128.00

Licence No. / Licence n°: <u>1364 R9</u> Issue Date / Date de délivrance : <u>May 9, 1990</u> Revised : <u>July 18, 2025</u>

Manitoba San

In accordance with The Environment Act (C.C.S.M. c. E125)/ Conformément à la Loi sur l'environnement (C.P.L.M. c. E125)

Under Section 11(1) and 14(2) / Conformément au Paragraphe 11(1) et 14(2)

THIS LICENCE IS ISSUED TO: / CETTE LICENCE EST DONNÉE À:

Bausch Health Companies Inc.; "the licensee"

for the continued operation and maintenance of the development being a a pharmaceutical manufacturing facility, including all related activities, located at the junction of Hespeler Street North and Provincial Trunk Highway No. 52 East in Steinbach, Manitoba, in accordance with a proposal received on April 27, 1999, the Notices of Alteration dated April 8, 2002, May 27, 2015, August 1, 2018 and May 13, 2024, with additional information dated May 7, 2025, and subject to the following specifications, limits, terms, and conditions:

DEFINITIONS

In this licence,

"accredited laboratory" means an analytical facility accredited by the Standards Council of Canada (SCC), or accredited by another accrediting agency recognized by Manitoba Environment and Climate Change to be equivalent to the SCC, or be able to demonstrate, upon request, that it has the quality assurance/quality control (QA/QC) procedures in place equivalent to accreditation based on the international standard ISO/IEC 17025, or otherwise approved by the director;

"affected area" means a geographical area, excluding the property of the development;

*Revised: July 12, 1993 *Revised: October 30, 1995 *Revised: June 5, 1998 *Revised: March 9, 2000 *Revised: June 19, 2003 *Revised: March 21, 2016 *Revised: September 5, 2018 *Revised: May 28, 2020 Bausch Health Companies Inc. - Pharmaceutical Facility Licence No. 1364 R9 Page 2 of 12

"approvals branch" means the Environmental Approvals Branch of Manitoba Environment and Climate Change, or any future branch responsible for issuing licences under The Environment Act;

"approved" means approved by the director or assigned environment officer in writing;

"approved facility" means a facility operating in accordance with the requirements of The Environment Act and the Regulations thereunder;

"Closure Plan" means a plan indicating the actions to be taken for the closure of the Development;

"dangerous good" means a product, substance or organism as defined in The Dangerous Goods Handling and Transportation Act, or any amendments thereto;

"day" or "daily" means any 24-hour period;

"director" means an employee so designated under The Environment Act;

"environment officer" means an employee so designated under The Environment Act;

"fugitive emissions" means particulate matter escaping from sources within the development property into the atmosphere other than through any of the emission stacks or vents;

"hazardous waste" means a product, substance or organism as defined in The Dangerous Goods Handling and Transportation Act, or any amendments thereto;

"odour nuisance" means a continuous or repeated odour, smell, or aroma, in an affected area, which is offensive, obnoxious, troublesome, annoying, unpleasant, or disagreeable to a person:

- a) residing in an affected area;
- b) working in an affected area; or
- c) present at a location in an affected area which is normally open to members of the public;

if the odour, smell, or aroma is

- d) the subject of at least 5 written complaints, received by the director in a form satisfactory to the director and within a 90-day period, from 5 different persons falling within clauses (a), (b), or (c), who do not live in the same household; or
- e) is the subject of at least one written complaint, received by the director in a form satisfactory to the director, from a person falling within clauses (a), (b), or (c), and the director is of the opinion that if the odour, smell, or aroma had occurred in a more densely populated area, there would have been at least 5 written complaints received within a 90-day period, from 5 different persons who do not live in the same household;

"opacity" means the degree to which emissions reduce the transmission of light and obscure the view of an object in the background;

"operator" means the company or person who is responsible for the day-to-day maintenance and operation of the Development;

"particulate matter" means any finely divided liquid or solid matter other than water droplets;

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"**particulate residue**" means that part or portion of an atmospheric emission which is deposited onto a surface;

"point source" means any point of emission from a Development where pollutants are emitted to the atmosphere by means of a stack;

"pollutant" means a pollutant as defined in The Environment Act;

"Post-Closure Plan" means a plan indicating the actions to be taken for the care, maintenance, and monitoring of the Development after closure, that will prevent, mitigate, or minimize the threat to public health and the environment;

"QA/QC" means quality assurance/quality control;

"record drawings" means engineering drawings complete with all dimensions which indicate all features of the development as it has actually been built;

"solid waste" means solid waste as defined in Manitoba Regulation 37/2016, or any future amendments thereto, respecting waste management facilities, excluding waste rock;

"stack" means a duct, pipe, chimney, vent, opening or other structure through which pollutants are emitted to the atmosphere;

"Standard Methods for the Examination of Water and Wastewater" means the most recent edition of Standard Methods for the Examination of Water and Wastewater published jointly by the American Public Health Association, the American Waterworks Association and the Water Environment Federation;

"volatile organic compound (VOC)" means any organic compound which participates in atmospheric photochemical reactions, excluding methane, carbon monoxide, carbon dioxide, carbonic acid, metallic carbides and carbonates, ammonium carbonate, and other compounds which may be exempt by the director; and

"wastewater" means any liquid containing a pollutant as defined in The Environment Act, associated with or resulting from the Development which is discharged into the environment.

GENERAL TERMS AND CONDITIONS

Retain Copy of Licence

1. The licensee shall at all times maintain a copy of this licence at the development or at the premises from which the development's operations are managed.

Sampling

2. In addition to any of the limits, terms, and conditions specified in this licence, the licensee shall, upon the request of the director:

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- a) sample, monitor, analyze, or investigate specific areas of concern regarding any segment, component or aspect of pollutant storage, containment, handling, treatment, and disposal systems, for such pollutants, ambient quality, aquatic toxicity, seepage characteristics, and discharge rates and for such duration and frequencies as may be specified;
- b) determine the environmental impact associated with the release of any pollutant from the development;
- c) conduct specific investigations in response to the data gathered during environmental monitoring programs; or
- d) provide the director within such time as may be specified, with such reports, drawings, specifications, analytical data, bioassay data, flow rate measurements, and such other information as may from time to time be requested.
- 3. The licensee shall, unless otherwise specified in this licence:
 - carry out all preservations and analyses of liquid samples in accordance with the methods prescribed in the Standard Methods for the Examination of Water and Wastewater or in accordance with equivalent preservation and analytical methodologies approved by the director;
 - b) carry out all sampling of, and preservation and analyses on, soil, compost, and air samples in accordance with methodologies approved by the director;
 - c) have all analytical determinations undertaken by an accredited laboratory; and
 - d) report the results to the director, in writing and in an electronic format acceptable to the director, within 60 days of the samples being taken.

Reporting Format

4. The licensee shall submit all information required to be provided to the director or environment officer under this licence, in writing, in such form (including number of copies), and of such content as may be required by the director or environment officer, and each submission shall be clearly labelled with the licence number and file number associated with this licence.

Noise Nuisances

5. The licensee shall not cause or permit a noise nuisance to be created as a result of the construction, operation, or alteration of the development, and shall take such steps as the director may require to eliminate or mitigate a noise nuisance.

Equipment Breakdown or Process Upset

- 6. The licensee shall, in the case of physical or mechanical equipment breakdown or process upset where such breakdown or process upset results or may result in the release of a pollutant in an amount or concentration, or at a level or rate of release, that causes or may cause a significant adverse effect, immediately report the event by calling the 24-hour environmental accident reporting line at 204-944-4888 (toll-free 1-855-944-4888). The report shall indicate the nature of the event, the time, estimated volume, and estimated duration of the event, and the reason for the event.
- 7. The licensee shall, following the reporting of an event under clause 6,
 - a) identify the repairs required to the mechanical equipment;

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- b) undertake all repairs to minimize unauthorized discharge of a pollutant;
- c) complete the repairs in accordance with any written instructions of the director and/or the environment officer; and
- d) submit a report to the director about the causes of breakdown and measures taken, within one week of the repairs being done.
- 8. The licensee shall, during construction and operation of the development, report spills of fuels or other contaminants to an environment officer in accordance with the requirements of the Environmental Accident Reporting Regulation or any future amendment.

Environmental Coordinator

9. The licensee shall designate an employee, within 14 days of the date of issuance of this licence, as the licensee's environmental coordinator, whose job description will include assisting the licensee in complying with the limits, terms and conditions in this licence and assisting senior management of the licensee to manage environmental issues at the development. The name of the environmental coordinator shall be submitted in writing to the director within 14 days of appointment and any subsequent appointment.

Compliance With Other Acts and Regulations

- 10. The licensee shall comply with the requirements of The Heritage Resources Act, and suspend construction and immediately notify the Historic Resources Branch if heritage resources are encountered during the construction of the development.
- 11. The licensee shall obtain all necessary provincial and federal permits and approvals for construction of relevant components of the development prior to commencement of construction.

SPECIFICATIONS, LIMITS, TERMS, AND CONDITIONS

Construction - General

- 12. The licensee shall notify the assigned environment officer prior to beginning any construction of the development. The notification shall include the intended starting date of construction and the name of the contractor responsible for the construction.
- 13. The licensee shall dispose of non-reusable construction debris from the development at a waste disposal facility operating under the authority of a permit issued under the Waste Management Facilities Regulation, or any future amendments, or a licence issued under The Environment Act.
- 14. The licensee shall, during construction and maintenance of the development, prevent the introduction and spread of foreign aquatic and terrestrial biota by cleaning equipment prior to its delivery to the site of the development and complying with the requirements of the Aquatic Invasive Species Regulation, or any future amendments.

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- 15. The licensee shall locate fuel storage and equipment servicing areas established for the construction and operation of the development a minimum distance of 100 metres from any waterbody and shall comply with the requirements of the Storage and Handling of Petroleum Products and Allied Products Regulation, or any future amendments.
- 16. The licensee shall, during construction and maintenance of the development, operate, maintain and store all materials and equipment in a manner that prevents any deleterious substances (fuel, oil, grease, hydraulic fluids, coolant, paint, uncured concrete, and concrete wash water, etc.) from entering the environment to the satisfaction of the director or environment officer, and have an emergency spill kit for in-water use available on site during construction.

Record Drawings

- 17. The licensee shall:
 - a) prepare "record drawings" for the development and shall label the drawings "Record Drawings"; and
 - b) provide to the director, within four months following the completion of construction, an electronic copy of the "record drawings".

Respecting Air Emissions – Limits

- 18. The licensee shall not emit particulate matter from the development such that:
 - a) particulate matter:
 - exceeds 0.23 grams per dry standard cubic metre calculated at 25 degrees Celsius and 760 millimetres of mercury, and corrected to 12 per cent carbon dioxide for processes involving combustion, from any point source of the development.
 - ii) exhibits a visible plume with an opacity of greater than five per cent at any point beyond the property line of the development; or
 - iii) results in the deposition of visible particulate residue at any time beyond the property line of the development; or
 - b) opacity from any point source of the development equals or exceeds:
 - i) 20 percent as the average of any 24 consecutive opacity observations taken at 15 second intervals;
 - ii) 20 percent for more than 16 individual opacity observations within any 1 hour period; or
 - iii) 40 percent for any individual opacity observation.
- 19. The licensee shall not cause or permit an odour nuisance to be created as a result of the construction, operation, or alteration of the development, and shall take such steps as the director may require to eliminate or mitigate an odour nuisance.
- 20. The licensee shall control, by methods acceptable to the director or environment officer, the emission of dust into the air at the development resulting from the operation of vehicles or the transportation, storage or handling of aggregate or other material.
- 21. The licensee shall operate and maintain any boiler at the development in accordance with the most recent version of the Environment and Climate Change Canada Multi-Sector Air Pollutants Regulation SOR/2016-151.

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Respecting Air Pollution Control Equipment

- 22. The licensee shall direct all air streams that contain a pollutant(s) of concern to the director to a pollution control device which has been designed for and demonstrated to be capable of reducing, altering, eliminating or otherwise treating the pollutant(s).
- 23. The licensee shall prepare, within 90 days prior to commissioning of the facility for operation, and maintain the following manuals which shall be kept at the development and available for review upon request by an environment officer:
 - a standard operating procedural manual and a maintenance schedule for each air pollution control device based on the manufacturer's specifications and recommendations;
 - b) an updated standard operating procedural manual and a maintenance procedure for each air emission pollution control device within 120 days of the addition, elimination or change regarding any air emission control device; and
 - c) a copy of the manufacturer's operational and maintenance manual.
- 24. The licensee shall not operate any process directing an emission to an air pollution control device at the development unless:
 - a) the operating and maintenance measures and status of the device are in full compliance with the procedures and timetables as per clause 23;
 - b) all emissions from the process are directed to the fully operational air pollution control device;
 - c) all discharges of treated emissions from the air pollution control devices are immediately directed to a stack; and
 - d) the emissions do not contain concentrations of pollutants which:
 - i) are in violation of any other applicable legal instrument including an act, regulation or by-law; or
 - ii) otherwise create a significant negative environmental or health impact in the affected area.
- 25. The licensee shall direct the exhaust air from the product dryer into the pollution control device for a minimum of 4 hours during the product drying process.
- 26. The licensee, notwithstanding clauses 24 and 25 of this licence, unless otherwise approved by the director, shall not bypass an air pollution control device, for greater than twelve (12) hours within a single calendar year.
- 27. The licensee shall maintain a daily record of mass balance of VOC emissions from the development, for those compounds listed in clause 44 of this licence, for
 - a) emissions from thermal oxidizer,
 - b) fugitive emissions calculated as 10% of alcohols used for cleaning activities, and
 - c) any accidental releases due to system failures or upsets, and

if this daily mass balance indicates that the cumulative VOC emissions in any calendar year is approaching 4500 kilograms, the licensee shall immediately notify the director in writing.

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- 28. The licensee, where the conditions of clause 26 of this licence are exceeded and excepting development scale equipment, shall:
 - a) cease the process as soon as is possible; and
 - b) discontinue any further processing until the air pollution control device is fully operational and in service.
- 29. The licensee shall maintain a log of the most recent 24 month period to record any downtime of an air pollution control device due to either the breakdown or maintenance of that air pollution control device. The log shall be kept at the development and shall be available upon request for inspection by an environment officer. The log shall record, at minimum, the following information:
 - a) identification of the air pollution control device and the process(es) it serves;
 - b) time/date of log entry;
 - c) nature of event;
 - d) time and duration of event;
 - e) action taken;
 - f) the accumulated downtime of this air pollution control device for the events for each calendar year; and;
 - g) approval by the environmental coordinator.
- 30. The licensee shall handle, store and dispose of all pollutants collected by the air pollution control equipment in a manner suitable to their characterization as a type of waste or dangerous good.

Respecting Air Emission Sampling and Analysis

31. The licensee shall, upon written request from the director, perform stack sampling and analysis in accordance with schedule A of this licence.

Respecting Wastewater

- 32. The licensee shall discharge wastewater generated at the facility in a manner acceptable to the director or environment officer.
- 33. The licensee shall dispose of any liquid waste contaminated with any chemicals and/ or other pharmaceutical products in the plant operation in a manner acceptable to the director or environment officer.

Respecting Solid Waste

- 34. The licensee shall dispose of all solid waste generated at the development, which is not recycled, only to a waste management facility operating under the authority of a permit issued under the Waste Management Facilities Regulation or any future amendments, or a licence issued under The Environment Act.
- 35. The licensee shall dispose of any solid chemicals or other waste pharmaceutical products not in use in the plant operation in a manner acceptable to the director or environment officer.

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36. The licensee shall recycle rejected concrete products in a manner acceptable to the director or environment officer.

Respecting Chemical Storage and Spill Containment

- 37. The licensee shall provide containment for all vessels containing chemicals in each area of the development where the chemicals are stored, loaded, transferred, used or otherwise handled, in compliance with the current Manitoba Fire Code Regulation, or any future amendment.
- 38. The licensee shall prevent pollution of groundwater and surface water from any product leakage or spillage and any contaminated liquid generated on site.
- 39. The licensee shall store and handle all dangerous goods and chemicals in a manner acceptable to the director or environment officer.
- 40. The licensee shall remove and dispose of all spilled dangerous goods and pollutants at a facility approved under The Environment Act or The Dangerous Goods Handling and Transportation Act to handle that type of waste.
- 41. The licensee shall comply with all the applicable requirements of:
 - a) the Storage and Handling of Petroleum Products and Allied Products regulation or any future amendment;
 - b) The Dangerous Goods Handling and Transportation Act, and its regulations; and
 - c) the Office of the Fire Commissioner Province of Manitoba.
- 42. The licensee shall not receive at the development any hazardous waste from any generator off site of the development.
- 43. The licensee shall install and maintain spill recovery equipment at the development.

MONITORING AND REPORTING SPECIFICATIONS

Records Maintenance and Reporting

- 44. The licensee shall maintain a monthly inventory log of the quantities of the following chemicals used at the development:
 - a) methanol;
 - b) isopropanol;
 - c) ethyl alcohol;
 - d) denatured ethanol; and
 - e) Acetone.
- 45. The licensee shall maintain the inventory log required pursuant to clause 44 of this Licence such that the monthly quantities of the latest 24 months of records are made available for inspection by an environment officer and shall supply a copy of any part or portion of the inventory log to the director upon request.

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- 46. The licensee shall:
 - a) notify the director of any chemicals proposed to be used in the operation and not listed in clause 44 of this Licence; and
 - b) receive approval from the director prior to using the new chemical.
- 47. The licensee shall during each year maintain the following records and retain them for a minimum period of five calendar years:
 - a) reports of visual inspections conducted on thermal oxidizer a minimum of once per month;
 - b) original copies of any laboratory analytical results;
 - c) a summary of laboratory analytical results; and
 - d) maintenance and repairs.

Alterations

48. The licensee shall notify the director and receive the approval of the director for any alterations to the development as licensed, prior to proceeding with such alterations.

DECOMMISSIONING

- 49. Within one year prior to imminent closure of the development, the licensee shall submit, for the approval of the director, a formal detailed Closure and Post-Closure plan for the development.
- 50. The licensee shall implement and maintain the approved Closure and Post-Closure plan.

REVIEW AND REVOCATION

- 51. This licence replaces Licence No. 1364 R8, which is hereby rescinded.
- 52. If, in the opinion of the director, the licensee has exceeded or is exceeding, or has failed or is failing to meet the specifications, limits, terms, or conditions set out in this licence, the director may, temporarily or permanently, revoke this licence.
- 53. If, in the opinion of the director, new evidence warrants a change in the specifications, limits, terms, or conditions of this licence, the director may require the filing of a new proposal under Section 11 of The Environment Act or request the filing of a Notice of Alteration.

Original Signed By Agnes Wittmann Director The Environment Act

Schedule A to Environment Act Licence No. 1364 R9

Air Emission Sampling and Analysis Pursuant to clause 31

- 1. The licensee shall provide a stack or stacks including all necessary sampling facilities for the sampling of air emissions at the development. The stack or stacks shall be provided:
 - a) at a location(s) and within a time frame satisfactory to the director; and
 - b) to the specifications and in accordance with the most recent version of Manitoba Environment and Climate Change Guideline, Guideline for Stack Sampling Facilities, unless otherwise approved by the director.
- 2. The licensee shall submit a detailed plan which is acceptable to and approved by the director, for the sampling and analysis of potential air pollutants, released as stationary point and fugitive emissions, including any compounds determined by the director. The plan shall identify the rationale for the sampling, the ways and means by which the sampling program will be implemented including any special measures or methods which would be necessitated by influencing factors such as unfavourable weather conditions, the need for large or additional sample volumes, the need for multiple sampling runs, the methods used for the sampling and the analysis for each compound, the detection level to be attained, a comprehensive QA/QC program, and other items as may be identified by the director.
- 3. The licensee shall perform all stack sampling in accordance with the most recent version of Manitoba Environment and Climate Change Report No. 96-07, Interim Stack Sampling Performance Protocol, unless otherwise approved by the director.
- 4. The licensee shall arrange the scheduling of the sampling program submitted pursuant to clause 2 of this schedule such that a representative of Manitoba Environment and Climate Change is available to monitor and audit the implementation of the sampling program.
- 5. The licensee shall complete the sampling of emissions according to the approved plan submitted pursuant to clause 2 of this schedule, within a timeframe to be determined by the director.
- 6. The licensee shall submit a report, for the approval of the director, of the completed sampling and analysis plan approved pursuant to clause 2 of this schedule, within 60 days of the receipt of the analytical results of that sampling plan. The report shall contain at minimum:
 - a) the raw data collected;
 - b) a discussion of the sampling and analytical portions of the program including any anomalies of sampling and analysis; and
 - c) a discussion of the significance of the data gathered with specific attention to:
 - i) the significance for potential acute and chronic impacts to health or environment from exposure to concentrations of the compounds detected;
 - ii) the need for risk assessment of the impact of emissions;
 - iii) the need for the establishment of ambient air monitoring stations;
 - iv) the need for dispersion modeling of emissions;
 - v) results and conclusions of the QA/QC program; and
 - vi) other issues as may be determined by the director.

7. The licensee, upon the written request of and in a timeframe stipulated by the director, shall comply with any air emission or ambient air quality criteria specified by the director for any pollutant of concern to the director which has been identified pursuant to this schedule.