

Environment Act Licence Loi sur l'environnement Licence

Manitoba
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Manitoba



Licence No./Licence n° 1402 RR

Issue Date/Date de délivrance August 30, 1990

Revised: **April 3, 1997**
September 25, 1997

IN ACCORDANCE WITH THE MANITOBA ENVIRONMENT ACT (C.C.S.M. c. E125)
THIS LICENCE IS ISSUED PURSUANT TO SECTION 10(1) TO:

APOTEX FERMENTATION INC.: "the Licencee"

for the construction and operation of the Development being a pharmaceutical facility, classified in accordance with the NIH guidelines as a Biosafety Level 1 and 2 facility, which manufactures, handles or processes products of naturally occurring microbes, recombinant DNA technology and other genetic engineering techniques, including all related activities, located at 40 Scurfield Boulevard in the City of Winnipeg, in accordance with the correspondence dated February 8, 1996, September 6, 1996, December 9, 1996, and August 18, 1997, and subject to the following specifications, limits, terms and conditions:

DEFINITIONS

In this Licence,

"affected area" means a geographical area, beyond the boundary of the property on which the Development is located;

"biological solid waste material" includes materials which may be contaminated during operational procedures through contact with biota e.g.: HEPA filters, etc.;

"Director" means an employee so designated pursuant to The Environment Act;

"NIH" means National Institutes of Health;

"noise nuisance" means an unwanted sound, in an affected area, which is annoying, troublesome, 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 the members of the public;

if the unwanted sound

- d) is 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;

"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 the members of the public;

if the odour, smell or aroma

- d) is 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;

"solvent" means any non-aqueous substance, either organic or inorganic, that is used in any process for purposes of cleaning, concentrating, purifying, dissolving, dispersing, suspending or otherwise altering the physical properties of any material used or produced at the Development;

"waste(s)" means waste products of any kind whatsoever or the run-off from such waste products and includes both liquid and solid materials; and

"wastewater" means the spent or used water of the Development which contains dissolved and suspended matter.

GENERAL TERMS AND CONDITIONS

This Section of the Licence contains requirements intended to provide guidance to the Licencee in implementing practices to ensure that the environment is maintained in such a manner as to sustain a high quality of life, including social and economic development, recreation and leisure for present and future Manitobans.

1. The Licencee shall implement a high standard of equipment maintenance and good housekeeping and operational practices with respect to the Development, at all times.
2. The Licencee shall reduce the production and dissemination of wastes by initiating and maintaining waste reduction and waste recycling programs.
3. The Licencee shall, upon the request of the Director and notwithstanding any of the limits, terms or conditions specified in this Licence:
 - a) sample, monitor, analyze and/or investigate specific areas of concern regarding any segment, component or aspect of pollutant storage, containment, treatment, handling, disposal or emission systems, for such pollutants or ambient quality, aquatic toxicity, leachate characteristics and discharge or emission rates, for such duration and at such frequencies as may be specified;
 - b) determine the environmental impact associated with the release of any pollutants from the said Development; or

- c) provide the Director, within such time as may be specified, with such reports, drawings, specifications, analytical data, descriptions of sampling and analytical procedures being used, bioassay data, flow rate measurements and such other information as may from time to time be requested.
4. The Licencee shall, unless otherwise specified in this Licence:
 - a) carry out all preservations and analyses on liquid samples in accordance with the methods prescribed in the most current 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 Pollution Control Federation, or in accordance with an equivalent analytical methodology approved by the Director;
 - b) carry out all sampling of, and preservation and analyses on, air samples in accordance with methodologies approved by the Director;
 - c) ensure that all analytical determinations are undertaken by an accredited laboratory or a laboratory approved by the Director; and
 - d) report the results to the Director within 60 days of the samples being taken.
5. The Licencee shall provide to the Director, upon request, all information required under this Licence, in writing and in such form and content (including number of copies), as may be specified by the Director.
6. The Licencee shall carry out, as deemed necessary by the Director, any remedial measures or modifications in respect to matters authorized under this Licence.

LIMITS, TERMS AND CONDITIONS

7. The Licencee shall not cause or permit a noise nuisance to be created as a result of the operation of the Development, and shall take such steps as the Director may require to eliminate or mitigate a noise nuisance.
8. The Licencee shall not cause or permit an odour nuisance to be created as a result of the operation of the Development, and shall take such steps as the Director may require to eliminate or mitigate an odour nuisance.
9. The Licencee shall submit, within 30 days of the issuance of this Licence, for the Director's review and approval, a list of solvents whose primary classification is other than that of Class 3 as specified in Manitoba Regulation 282/87 being Classification Criteria for Products, Substances and Organisms Regulation.
10. The Licencee shall not use any solvent as specified in Clause 9 of this Licence without the Director's written approval.
11. The Licencee shall operate and maintain solvent recovery systems at all times.

12. The Licencee shall submit, in writing, the following information regarding the solvents referred to in Clause 9 and 10 of this Licence:
 - a) Common Name;
 - b) CAS Number;
 - c) Classification of solvent under Manitoba Regulation 282/87 being Classification Criteria for Products, Substances and Organisms Regulation;
 - d) Carcinogenic hazards level where applicable;
 - e) Projected quantities to be used per day/week/month/year; and
 - f) Method of waste solvent recovery (addressing air, liquid, and solid waste streams).
13. The Licencee shall submit, in writing, the following information regarding all solvents excluded by Clauses 9 and 10 of this Licence:
 - a) Projected quantities to be used per day/week/month/year; and
 - b) Method of waste solvent recovery (addressing air, liquid, and solid waste streams).
14. The Licencee shall submit a mass balance for total solvent use on an annual basis by March 31, of each year. The Director may also request, from time to time, a mass balance for specific solvents. The mass balance shall include:
 - a) Total quantity used;
 - b) Quantities recovered by waste stream;
 - c) Quantities recycled; and
 - d) Methods of disposal and quantities disposed.
15. The Licencee shall notify the Director of an intended alteration of process, which may result in a significant change to a waste discharge or emission, prior to implementing such alteration.
16. The Licencee shall not direct any spillage or accidental release of solvent or other chemical compound to a sanitary sewage or storm sewer system.
17. The Licencee shall comply with all current Medical Research of Canada Laboratory Biosafety Guidelines, during the research and development, pilot scale and production stages of the Development. Compliance is to be based on classification of organism as per the NIH guideline and scale of operation.
18. The Licencee shall comply with all current Health and Welfare Canada, Drugs Directorate guidelines, during both the research and development and the pilot scale production stages of the Development. Compliance is to be based on classification of organism as per the NIH guidelines and the scale of operation.
19. The Licencee shall dispose of biological solid waste material as per current Medical Research of Canada Laboratory Biosafety Guidelines.

20. The Licencee shall submit, prior to the storage and/or handling of any solvent, radioisotope or other chemical at this Development, an emergency response plan to be approved by the Director. This plan must include, but is not limited to, items that will address: measures implemented for spill prevention and containment; security; personnel training and response arrangements.

REVIEW AND REVOCATION

- A. This Licence replaces Licence No. 1402 R that is hereby rescinded.
- B. If, in the opinion of the Director, the Licencee has exceeded or is exceeding or has 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.
- C. 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 pursuant to Section 10 of The Environment Act.



Larry Strachan, P. Eng.
Director
Environment Act

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