

Environment Act Licence Loi sur l'environnement Licence

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Licence No./Licence n° 1554 S2
Issue Date/Date de délivrance December 6, 1995

In accordance with the Manitoba Environment Act (C.C.S.M. c. E125)

THIS LICENCE IS ISSUED TO:

APOTEX FERMENTATION INC.: "the Licencee"

STAGE 2 LICENCE

for the construction and operation of the Development being a pharmaceutical facility which manufactures, handles or processes natural products of fermentation, including all related activities, located on Lots 1 and 4 and parts of Lots 2 and 3, Block 7, Plan 13723 as shown on Misc. Plan Number SBSV3572/7, in the St. Boniface Industrial Park in the City of Winnipeg and subject to the following specifications, limits, terms and conditions:

DEFINITIONS

In this Licence,

"**A-weighted sound level**" means the sound level measured in dBA units with a sound level meter set on the A-weighting network, being a filter designed to approximate the relative sensitivity of the normal human ear to different frequencies of sound;

"**appreciable impulsive or impact character**" means sound which has a significant amount of impulsive or impact nature, such as hammering, explosions and clanking or banging. Impulsive or impact sounds are sounds of short duration, usually less than one second, characterized by an abrupt onset followed by a rapid decay;

"**dB**" (decibel) means a dimensionless measure of sound level or sound pressure level, where,

$$\text{sound level} = 20 \log_{10} \frac{\text{sound pressure (actual)}}{\text{sound pressure (reference)}};$$

"**4 minute period(s) in the aggregate**" means any 16 readings, not necessarily contiguous, taken at 15 second intervals within a 1 hour sampling period;

"**Leq (energy equivalent level)**" means the A-weighted sound level (as decibels {dBA}) of a constant or steady sound, for a stated period, which has an amount of acoustic energy equivalent to that contained in the sound being measured;

"**Leq(1)**" means the Leq for a one hour period;

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

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

"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 ducted into the atmosphere;

"predominant discrete tone" means sound (for example a whine or hum) having a one-third octave band sound level which, when measured in a one-third octave band, exceeds the arithmetic average of the sound levels of the two adjacent one-third octave bands on either side of such one-third octave band by:

- i) 5 dB for such one-third octave band with a center frequency from 500 Hertz to 20,000 Hertz, inclusive, provided such one-third octave band sound level exceeds the sound level of each adjacent one-third octave band; or
- ii) 8 dB for such one-third octave band with a center frequency from 160 Hertz to 400 Hertz, inclusive, provided such one-third octave band sound level exceeds the sound level of each adjacent one-third octave band; or
- iii) 15 dB for such one-third octave band with a center frequency from 25 Hertz to 125 Hertz, inclusive, provided such one-third octave band sound level exceeds the sound level of each adjacent one-third octave band;

"VOC" (Volatile Organic Compound) means any chemical compound containing the element carbon, excluding methane, carbon monoxide, carbon dioxide, carbonic acid, metallic carbides and carbonates, ammonium carbonate, and other compounds which may be exempt by the Director.

GENERAL SPECIFICATIONS

1. The Licencee shall ensure that a high standard of equipment maintenance and good housekeeping and operational practices are carried out with respect to the Development, at all times.
2. The Licencee shall reduce and prevent the production and dissemination of wastes by initiating and maintaining waste reduction and waste recycling programs.

LIMITS, TERMS AND CONDITIONS

3. The Licencee shall not emit particulate matter from the Development such that:
 - i) particulate matter:
 - a) exceeds 0.23 grams per dry standard cubic metre calculated at 25 degrees Celsius and 760 millimetres of mercury, corrected to 12 percent carbon dioxide for processes involving combustion from any point source of the Development;
 - b) exhibits a visible plume with an opacity of greater than 5 percent at any point beyond the property line of the Development; or
 - c) results in the deposition of visible particulate residue at any time beyond the property line of the Development.

- ii) opacity from any point source of the Development equals or exceeds:
 - a) 20 percent for a 4 minute period(s) in the aggregate in any one hour; or
 - b) 40 percent at any time.

- 4. The Licencee shall not emit odour from any part or process of the Development such that any emission is detectable when measured at a point of reception:
 - i) within an area which is zoned or used as residential or commercial when one volume of odorous air is diluted with one equal volume of odour-free air; or

 - ii) within an area which is zoned or used as industrial when one volume of odorous air is diluted with six equal volumes of odour-free air.

- 5. The Licencee shall not emit sound from any part or process of the Development, such that any emission when measured at a point of reception within an area which is zoned or used as residential, exceeds the following $\{L_{eq}(1)\}$ limits:
 - i) subject to sub-Clause 5 (ii):
 - a) 60 dBA during the daytime hours of 7:00 a.m. to 10:00 p.m., local time; or
 - b) 50 dBA during the nighttime hours of 10:00 p.m. to 7:00 a.m., local time.

 - ii) when the sound has an appreciable impulsive or impact character or a predominant discrete tone:
 - a) 55 dBA during the daytime hours of 7:00 a.m. to 10:00 p.m., local time; or
 - b) 45 dBA during the nighttime hours of 10:00 p.m. to 7:00 a.m., local time.

- 6. The Licencee shall not emit sound from any part or process of the Development, such that any emission when measured at a point of reception within an area which is zoned or used as commercial, exceeds the following $\{L_{eq}(1)\}$ limits:
 - i) 70 dBA during the daytime hours of 7:00 a.m. to 10:00 p.m., local time; or

 - ii) 60 dBA during the nighttime hours of 10:00 p.m. to 7:00 a.m., local time.

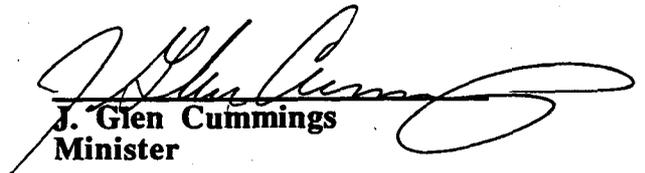
- 7. The Licencee shall not emit sound from any part or process of the Development, such that any emission when measured at a point of reception within an area which is zoned or used as industrial, exceeds 70 dBA at any time.

- 8. The Licencee shall provide sampling station(s) at designated point source stacks. Stations shall provide proper access, personnel safety features, power supply and other features that may be specified by the Director. All stations must be pre-approved as to location and design by the Director.

9. The Licencee shall, when requested by the Director, conduct a sampling program and analyze air emissions at the Development for all or any of the following:
- i) total VOC's;
 - ii) toluene;
 - iii) methanol;
 - iv) ethyl acetate;
 - v) compounds derived from 9ii), iii) or iv).

Samples are to be collected using methods approved by the Director, and analysis is to be performed in a manner approved by the Director.

10. The Licencee shall notify the Director of an intended use of any material(s) in the operation of the Development, in addition to toluene, methanol, or ethyl acetate, prior to such usage.
11. The Licencee shall notify the Director of an intended alteration of process, which may effect in any manner a waste discharge or emission, prior to implementing such alteration.
12. The Licencee shall submit a copy of the sampling report complete with analytical results as specified pursuant to Clause 9, to the Director within 60 days of the completion of the sampling program.
13. The Licencee shall submit, on a quarterly basis (calendar year), a written report to the Director containing the following information for each solvent used at the Development:
- i) identification of solvent;
 - ii) amount (litres) acquired in the report period;
 - iii) total amount (litres) acquired in the calendar year;
 - iv) total amount in 13 iii) sewerred;
 - v) total amount in 13 iii) incorporated in solid waste; and
 - vi) disposition of solvent reclaimed.
14. The Licencee shall not direct any spillage or accidental release of solvent to a sanitary sewage or storm sewer system.
15. The Licencee shall submit, prior to the storage and/or handling of any solvent at this Development, an emergency response plan to be approved by the Director. This plan must include, but is not limited to, items which will address: measures implemented for spill prevention and containment; security; personnel training and response arrangements.
16. This Licence replaces Licence No. 1575 which is hereby rescinded.


J. Glen Cummings
Minister