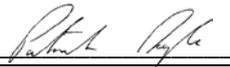


This Report has been cleared for submission to the Director by Marie O'Connor,
Programme Manager

Signed: 

Date: 22/07/2018



**OFFICE OF
ENVIRONMENTAL
SUSTAINABILITY**

**ENVIRONMENTAL LICENSING PROGRAMME
MEMORANDUM**

To: EIMEAR COTTER, DIRECTOR

From: JENNIFER COPE, INSPECTOR

Date: 22/07/2019

Re: AbbVie Ireland NL B.V. P1087-01 – Submission of
Confidential Information

AbbVie Ireland NL B.V., Old Bundoran Road, Ballytivnan, Sligo submitted a licence application for an IE licence P1087-01 on 05 September 2018. This application is for a biopharmaceutical manufacturing installation which falls under class 5.16 of the First Schedule of the EPA Act 1992, as amended.

Class 5.16: The production of pharmaceutical products including intermediates.

Request

As part of the IE licence application, the licensee submitted with a cover letter a document marked as 'Confidential Information' on 11 September 2018. The document in question is the table of process related raw materials, intermediates and products (Section 4.6.2 of the application form), and the licensee highlighted two out of 80 specific materials/substances in use at the installation, indicating that it wished the names and CAS numbers of these two materials/substances to be deemed confidential. The material/substance names are labelled Ingredient 1 and Ingredient 2 and the CAS numbers are blank in Section 4.6.2 of the application form on the public file. Section 4.6.2 of the application form has been submitted in a non-confidential format in the application which is available on the public file.

In the cover letter the applicant deemed the information confidential and cited the grounds of commercial confidentiality and intellectual property rights including know-how and trade secrets.

Assessment

I have assessed the content of the documents which comprises the confidential aspect of the Section 4.6.2 Process related raw materials, intermediates and products. I consider that the confidential aspect of Section 4.6.2, the names and CAS numbers of the two materials, is commercially sensitive and therefore confidential. Information on the substances which relates to environmental concerns, such as Hazard statements, nature of use, and quantities stored, have been fully disclosed in the application.

Recommendation

Following assessment of this information, I consider this information is necessary for the processing of the application. I consider that the names and CAS numbers of the two raw materials are commercially sensitive and therefore confidential.

I recommend that the information be deemed confidential (the material/substance names and CAS number). I recommend that, following a decision on the application, the 'Confidential Information' be returned to the licensee, and the licensee informed that this information should be held at its premises and made available to EPA inspectors upon request.

Signed: Jennifer Cope
Jennifer Cope, Inspector

Date: 22 July 2019