Health Canada Santé Canada

Section 12 Notice

Additional Information Required to Fulfill a Condition of Registration

Product Name: **Maxim Technical Strychnine**
Registration Number: **31756**
Application Number: **2020-4354**
PMRA #: **3159048**
Date of Issuance: **October 22, 2020**

The information specified below is required to be submitted to the Pest Management Regulatory Agency in accordance with section 12 of the *Pest Control Products Act* by **February 26, 2021**.

PART 0	**INDEX**
DACO:	0
Title:	Index
Required Data:	**Please submit an electronic index of the data package submitted in response to this letter. Please refer to Regulatory Directive 2006-05, *Requirements for Submitting Data Index, Documents and Forms*, for additional information.**

PART 2	**CHEMISTRY REQUIREMENTS FOR THE REGISTRATION OF A TECHNICAL GRADE OF ACTIVE INGREDIENT (TGAI) OR AN INTEGRATED SYSTEM PRODUCT**
DACO:	2.13.1
Title:	Methodology/Validation
DATA Required:	**As per Dir98-04 – *Chemistry Requirements for the Registration of a Technical Grade Active Ingredient or an integrated System Product*, methodology for specifically identifying and quantifying the product is required. Because all methodology must be validated to show that it is suitable for the analysis of the product, a description of the analytical method used with the appropriate validation data needs to be provided. All studies must be GLP compliant. The standard used for quantitation of the active ingredient has to be well characterized or of commercial grade. Please note that internationally recognized**

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specific standard methods can be used, but must be clearly identified along with a description of the method.

DACO: 2.13.3
Title: Batch data

DATA Required: **The composition of a minimum of five batches of the product manufactured at the site being proposed for registration is required to support the specifications, determined using the methods described under DACO 2.13.1. Date of and site of production for each batch must be included. Corresponding raw data to be submitted include representative quantitative chromatograms of: (1) standards; (2) blanks, and (3) the five batches of the TGAI that were used to support the active ingredient and impurities specifications. Chromatograms must be clearly labelled to identify all analytical parameters and peaks. The study presenting batch data must be GLP compliant. Please note that the study doesn't have to be conducted by the manufacturing plant itself. It can be done by a laboratory which has a GLP certificate from a national monitoring authority in any country.**