Health Canada Santé Canada

Section 12 Notice

Additional Information Required to Fulfill a Condition of Registration

Product Name:	**Mosquiron 0.12P-D**
Registration Number:	**31077**
Application Number:	**2011-1682**
PMRA #:	**2967992**
Date of Issuance:	**March 11, 2019**

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 **October 15, 2019**.

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 3 **CHEMISTRY REQUIREMENTS FOR THE REGISTRATION OF MANUFACTURING CONCENTRATES AND END-USE PRODUCTS FORMULATED FROM REGISTERED TECHNICAL GRADE OF ACTIVE INGREDIENTS OR INTEGRATED SYSTEM PRODUCTS**

DACO: 3.5.10/ 3.5.14
Title: Storage stability data/ Corrosion characteristics

Deficiency: A storage stability study, where corrosion characteristics are confirmed, was not submitted

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Required Data: **A storage stability study, where corrosion characteristics are confirmed, must be conducted under at least one of the following regimes:**

at least one year's duration at a constant ambient temperature of 20 or 25°C and, if the package is permeable, at a relative humidity of

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50%, with quantitative analysis for the active ingredient(s) at study commencement and following storage periods of 3, 6 and 12 months; or

at least one year's duration under warehouse conditions that reflect the expected storage conditions of the commercial product (this may include the need for freeze-thaw studies). Where possible, the storage environment should approximate any extremes of temperature or climate expected to occur under actual storage conditions. Quantitative analysis for the active ingredient(s) is required at study commencement and following storage periods of 3, 6 and 12 months; or

of 14 days' duration under accelerated conditions at a constant temperature of 54°C, with quantitative analysis for the active ingredient(s) at study commencement and after 14 days.