

Section 12 Notice

Additional Information Required to Fulfill a Condition of Registration

Product Name: Atlantic Copper Antifouling Paint
Registration Number: 23511
Application Number: 2013-2772
PMRA #: 2980066
Date of Issuance: April 2, 2019

The information specified below is required to be submitted to the PMRA in accordance with section 12 of the *Pest Control Products Act (PCPA)* by October 15, 2019.

PART 0	INDEX
DACO: Title:	0 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: Title:	3.5.10 Storage stability data
Deficiency:	The applicant stated that the product is stable for a maximum of two years since copper oxide is protected by a pigment. This is based on test result of ASTM D1849-95 (Standard Test Method for package stability of paint). However, this method does not analyze for the content of the active ingredient. In addition, the applicant provided data for 3 samples stored at warehouse conditions for 19 months. The upper and lower limits for the active is acceptable for one sample and they are outside the acceptable limits for 2 samples; however, it is difficult to determine

storage stability without the initial content of active ingredient.

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 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.