Section 12 Notice

Additional Information Required to Fulfill a Condition of Registration

Product Name:

Sodium Hypochlorite 10.8%

Registration Number:

23344

Application Number:

2016-3779

PMRA #:

3064441

Date of Issuance:

December 10, 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 January 31, 2020.

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 2	CHEMISTRY REQUIREMENTS FOR THE REGISTRATION OF A TECHNICAL GRADE OF ACTIVE INGREDIENT (TGAI) OR AN INTEGRATED SYSTEM PRODUCT
DACO:	2.12
Title:	Specifications – Statement of Product Specification Form (SPSF)
Deficiencies:	There is no approved SPSF on file at PMRA for Sodium Hypochlorite 10.8% and the latest SPSF submitted (dated 2011-09-26) is for two sources. For a TGAI/ISP each source is required to have a separate SPSF with specifications that are consistent with batch data from that site; the following deficiencies were identified for the latest SPSF submitted (dated 2011-09-26) based on batch data which seems to be from the Winnipeg site. 1. Page 1, row 1: 2) Royer 9, 11, 12, and 13: The % weight and nominal concentration
	a) Boxes 9, 11, 12, and 13: The % weight and nominal concentration
	are

not consistent with the batch data on file.

- b) Boxes 14B, 14D, 14E: The guarantee value is not consistent with the batch data on file.
- 2. Page 1, row 2, box 13: The upper certified limit is lower than the maximum level found in batch samples.
- 3. This SPSF can only be for one site/source.

Required Data:

Submit a revised SPSF for the Winnipeg site with the following changes:

- 1. Page 1, row 1:
- a) Boxes 9, 11, 12, and 13: Based on batch data, % weight (box 9) and nominal concentration (box 12) should be around "11.5" with limits of "10.9" (box 11) and "12.1" (box 13) (based on standard limits of $\pm 5\%$).
- b) Boxes 14B, 14D, 14E: Based on batch data, the guarantee value (box 14B) should be around "10.9" with limits of "10.4" (box 14D) and "11.4" (box 14E).
- 2. Page 1, row 2 box 13: Based on batch data, an appropriate upper limit would be "1.0".
- 3. The multiple formulation sites box must be unchecked and the additional formulation site (Langley, BC) must be removed from the final page.

If Langley, BC is to be used as a second source, the applicant must submit a separate SPSF (F2V1) for this source. The applicant must include supporting batch data for five batches of Sodium Hypochlorite 10.8% recently manufactured at the Langley site. The specifications on the SPSF (F2V1) must be consistent with the batch data from that site. Please note that the guarantee (box 14) must be identical on both SPSFs (F1V1 and F2V1).