

9. Efficacy and Animal/Target Crop Safety

9.1	Is efficacy 'deemed' or must it be 'assessed'?	Assessed	
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Information assessed

9.2	☐ Data ☒ Scientific argument in lieu of data ☐ Nominated reference product/s ☐ Overseas data and associated approval report ☐ No change to existing assessment ☐ Other:	
9.3	Was further efficacy or animal/target crop safety information required (s159 notice)?	No

Section 14 Legislative Criteria

9.4	For the purpose of being satisfied of the chemical product meeting the safety and efficacy criteria, the APVMA had regard to the following:	☒ toxicity of the constituents and its residues, including metabolites and degradation products, in relation to relevant organisms ☐ whether any trials or laboratory experiments have been carried out to determine the efficacy of the product and, if so, the results of those trials or experiments
Risk identification and assessment:		
9.5	The proposed product is similar to the currently registered products. 81351 - Eezi Pool All-In-One Monthly Pool Care 89246 - Eezi Pool All-in-One Stabilized Monthly Pool Care The proposed product has a two-part formulation, same as the nominated reference products. One formulation is for the part A (booster dose used once a	

month) and one formulation is for the maintenance parts (Parts 1-4 - used weekly).

CCI Withheld

The maintenance component is sodium dichloroisocyanurate whereas the reference product 81351 has calcium hypochlorite and reference product 89246 has trichloroisocyanuric acid as the maintenance component.

Proposed product's formulation

CCI Withheld

Efficacy and Safety

Efficacy

The applicant provided a scientific argument in support of the efficacy of the proposed product. The use pattern and instructions for the maintenance parts 1-4 are same as the reference product (noting that this product will not be used in indoor or commercial pools).

CCI Withheld

Applicant has provided an argument to justify the similarity between the second part of the formulation (part 1 - 4) with the reference products'. The dosing rates of the maintenance parts 1-4 of proposed product is (250 g) are different to the reference products (200 g/kg) and the amount of available chlorine when using sodium dichloroisocyanurate will be 560 g/kg while for trichloroisocyanuric acid and calcium hypochlorite, the available chlorine is 900 g/kg and 650 g/kg respectively.

Based on the reference products containing 4 x 200 g calcium hypochlorite (650 g/kg free chlorine), 4 x 200 g trichloroisocyanuric acid (900 g/kg free chlorine) as the 4-part maintenance component and the proposed product containing 4 x 250 g sodium dichloroisocyanurate (560 g/kg free chlorine); the amount of free chlorine dosed into the pool is 140 g/kg, which is less than trichloroisocyanuric acid and more than calcium hypochlorite, as shown in the table below:

Product Name	Active Constituent	Weekly Dose (g)	Available Chlorine (g)
Eezi Pool All-In-One Monthly Pool Care	650 g/kg available chlorine present as calcium hypochlorite	200	130
Eezi Pool All-in-One Stabilized Monthly Pool Care	900 g/kg available chlorine present as trichloroisocyanuric acid	200	180
Blu52 + 4 Week Pool Sanitiser	560 g/kg available chlorine present as sodium dichloroisocyanurate	250	140

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	The calculated amount of chlorine derived from sodium dichloroisocyanurate in the proposed new product (140 g per 250 g weekly dose) falls between that derived from calcium hypochlorite contained in Eezi Pool All-In-One Monthly Pool Care (130 g per 200 g weekly dose) and that derived from trichloroisocyanuric acid (180 g per 200 g weekly dose) in Eezi Pool All-in-One Stabilized Monthly Pool Care. This demonstrate that the sodium dichloroisocyanurate active constituent contained in the proposed new product is similar to the existing registered products and will be as efficacious as the reference products. In addition, the label carries directions for users to shock treat the pool in the even of extreme weather or high bather load. Safety The amount of free chlorine dosed into the pool is 140 g/kg, which is less than trichloroisocyanuric acid and more than calcium hypochlorite, as shown in the table above. Therefore, based on the amount of free chlorine being below than the nominated reference product - 89246 - EEZI POOL ALL-IN-ONE STABILIZED MONTHLY POOL CARE, this product is expected to be safe for users when used as per the label directions.	
9.6	☐ Link to agency/reviewer report:	N/A

Risk mitigation measures

9.7	Are label statements required to mitigate the identified risks?	No	
9.8	Are non-standard conditions required to mitigate the identified risks?	No	
9.9	Are other measures required to mitigate the identified risks?	No	
9.10	Relied on information:	Yes, 255019	
9.11	Link to data list:	See information list	

Summary for Statement of Reasons for s 14 Legislative Criteria

	<i>Information to be included in an s8S notice or other publications:</i>
9.12	Based on the provided argument, the APVMA can be satisfied of 5A safety and 5B efficacy criteria.

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