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In reply please
refer to: V2-447-3/ML/DS/1

Your reference: 014-018, PQC-VCP-2022-0023

Tagros Chemicals India Ltd
Mr Rajesh Mathew
Tagros House, No. 4, Club House Road, Anna
Salai
Tamilnadu 600002
Inde

24 November 2022

Dear Mr. Mathew,

**WHO Prequalification Team – Vector Control Product Assessment (PQT-VCP)
Post-Prequalification Change (PPQC)
PQ Reference Number: 004-018
Application number: PQC-VCP-2022-0023**

Thank you for submitting your company's Post-Prequalification Change (PPQC) application on 14 March 2022 for the following product:

2GARD – 004-018

The following proposed changes have been found acceptable:

1. Inclusion of the new proposed packaging of the product 2GARD as a Wettable Powder (WP) in tri-laminated pouches.

The updated Declaration of Labelling, dated 11 November 2022, submitted in conjunction with this proposed change is acceptable and will be included on the prequalification website product page for this product.

Yours sincerely,

Marion Law
Team Lead, Vector Control Product Assessment
Prequalification Team
Regulation and Prequalification Department

Change Assessment

Case: PQC-VCP-2022-0023

Product: 2GARD

Applicant: Tagros Chemicals India Ltd

Description of the submission

Tagros Chemicals India Ltd submitted a PPQC application to WHO PQT/VCP for the inclusion of the alternative packaging inclusion of water-soluble bags for the prequalified product 2GARD (PQ Ref# 004-018).

Assessment:

Title	Study Number	Test method ID	Result
Clothianidin content (test item stored at room temperature)	G24294	Clothianidin 738/WP/M/3, CIPAC Handbook P, p.52, 2021	506.1 g/kg Results of ten additional batches were provided, mean value: 500.7 g/kg
Clothianidin content (test item stored for 2 weeks at 54 °C)	G24294	Clothianidin 738/WP/M/3, CIPAC Handbook P, p.52, 2021	507.6 g/kg Results of ten additional batches were provided, mean value: 500.7 g/kg No significant differences between clothianidin concentration values before and after storage stability test
Deltamethrin content (test item stored at room temperature)	G24294	Deltamethrin: 333/WP/M/3, CIPAC Handbook L, p.50, 2005	62.56 g/kg Results of ten additional batches were provided, mean value: 62.8 g/kg
Deltamethrin content (test item stored for 2 weeks at 54 °C)	G24294	Deltamethrin: 333/WP/M/3, CIPAC Handbook L, p.50, 2005	62.0 g/kg Results of ten additional batches were provided, mean value: 62.3 g/kg No significant differences between deltamethrin concentration values before and after storage stability test
pH (1% m/v aqueous dilution) (test item stored at room temperature)	G24294	MT 75.3, CIPAC Handbook J, p. 131, 2000	Measured pH=4.47 pH range should be: 3 to 6 Results of ten additional batches were provided, mean value: 4.90
pH (1% m/v aqueous dilution) (test item stored for 2 weeks at 54 °C)	G24294	MT 75.3, CIPAC Handbook J, p. 131, 2000	Measured pH=4.60 pH range should be: 3 to 6 Results of ten additional batches were provided, mean value: 4.94
Wettability (test item stored at room temperature)	G24294	MT 53.3.1, CIPAC Handbook F, p.165, 1995	Wettability: 2.3 sec Results of ten additional batches were provided, mean value: 17 sec The formulation should be completely wetted in 1 min without swirling.
Wettability (test item stored for 2 weeks at 54 °C)	G24294	MT 53.3.1, CIPAC Handbook F, p.165, 1995	Wettability: 2.3 sec Results of ten additional batches were provided, mean value: 19.5 sec The formulation should be completely wetted in 1 min without swirling.

Title	Study Number	Test method ID	Result
Wet sieve test (test item stored at room temperature)	G24294	MT 185, CIPAC Handbook K, p.149, 2003	Residue: 0.07% Results of ten additional batches were provided, mean value: 0.33 % Maximum: 1% retained on a 75 µm test sieve.
Wet sieve test (test item stored for 2 weeks at 54 °C)	G24294	MT 185, CIPAC Handbook K, p.149, 2003	Residue: 0.073 % Results of ten additional batches were provided, mean value: 0.39 % Maximum: 1% retained on a 75 µm test sieve.
Suspensibility for clothianidin (test item stored at room temperature)	G24294	MT 184.1, CIPAC Handbook P, p.245, 2021	Suspensibility: 77.99% Results of ten additional batches were provided, mean value: 82.47 % A minimum of 70% should be in suspension after 30 minutes in CIPAC Standard Water D at 25 ± 5°C.
Suspensibility for clothianidin (test item stored for 2 weeks at 54 °C)	G24294	MT 184.1, CIPAC Handbook P, p.245, 2021	Suspensibility: 78.15% Results of ten additional batches were provided, mean value: 82.36 % A minimum of 70% should be in suspension after 30 minutes in CIPAC Standard Water D at 25 ± 5°C.
Suspensibility for deltamethrin (test item stored at room temperature)	G24294	MT 184.1, CIPAC Handbook P, p.245, 2021	Suspensibility: 81.42% Results of ten additional batches were provided, mean value: 87.38 % A minimum of 70% should be in suspension after 30 minutes in CIPAC Standard Water D at 25 ± 5°C.
Suspensibility for deltamethrin (test item stored for 2 weeks at 54 °C)	G24294	MT 184.1, CIPAC Handbook P, p.245, 2021	Suspensibility: 81.94% Results of ten additional batches were provided, mean value: 87.27 % A minimum of 70% should be in suspension after 30 minutes in CIPAC Standard Water D at 25 ± 5°C.
Persistent foam (test item stored at room temperature)	G24294	MT 47.3, CIPAC Handbook O, p.177, 2017	Persistent foam: 10.7 ml Results of ten additional batches were provided, mean value: 24.5 ml Maximum: 50 ml after 1 min.
Persistent foam (test item stored for 2 weeks at 54 °C)	G24294	MT 47.3, CIPAC Handbook O, p.177, 2017	Persistent foam: 11.3 ml Results of ten additional batches were provided, mean value: 28.0 ml Maximum: 50 ml after 1 min.

The G24294 GLP study detailed the physical-chemical properties of the 2GARD product. All physical-chemical parameters were in accordance with the specifications limits.

Quality Control data for the product at ambient temperature and after accelerated storage were submitted for a further 10 batches produced between 17/11/2021 and 20/02/2022. All results complied with the specification limits.

No significant differences were recorded between the properties of the product kept at ambient temperature and after accelerated storage stability conditions.

Conclusions

The assessment supports the proposed change for inclusion of the water-soluble bag as an alternative packaging for the product 2GARD.