Change Assessment

Case: PQC-VCP-2022-0011
Product: ICON 10 CS - IRS (PQ Ref# 012-003)
Applicant: Syngenta Crop Protection AG

Description of the submission

Syngenta Crop Protection AG submitted a PPQC application to WHO PQT/VCP proposing a revised clause for **2.4 Release of lambda-cyhalothrin** to be included in the supporting WHO Lambda-cyhalothrin CS specification.

Syngenta Crop Protection AG proposed that the clause be changed from:

2.4 Release of lambda-cyhalothrin (MT 190, CIPAC Handbook L, p.140, 2005)

The release of lambda-cyhalothrin from the capsules shall be:

- *at 15 min, 30 to 75% of that released at 180 min;*
- *and at 30 min, 50 to 90% of that released at 180 min;*
- *and at 180 min, a minimum of 80% of the total lambda-cyhalothrin content, determined according to clause 2.2.*

to:

2.4 Release of lambda-cyhalothrin (MT 190.1, pre-published)

The release of lambda-cyhalothrin from the capsules shall be:

- *at 15 min, 15 to 60% of the total lambda-cyhalothrin content found under clause 2.2.1.*

Assessment

No change in the formulation nor manufacturing process of the product was declared by the applicant.

The supporting studies were assessed by the JMPS and the PQT/VCP ASVCP. The studies showed that the product complied with the revised specification clause.

It was concluded that based on the revision of the CIPAC method (MT190.1) and the supporting data that the proposed change should be accepted.

The applicant included two bioassay studies in the submission. The WHO efficacy assessment (conducted by WHOPES) and conversion decision for the prequalified product did not include data substantiating the efficacy of the product on cockroaches. Therefore, the study on German cockroaches (Blattella germanica) was not reviewed by WHO as part of this change submission.

A second bioassay study was submitted using *Aedes aegypti* mosquitoes. In the study, three-day old non-blood fed female *Ae. aegypti* were exposed to treated ceramic tiles at 1, 2, 4, 8 and 12 weeks after treatment. The mosquitoes were exposed to the treated surface for one hour within a 9 cm Petri dish. The non-standard method used in the study differs significantly from the standardized cone method

bioassay for assessing indoor residual sprays. As such, these data were not considered in the assessment.

Conclusion

The submitted quality data and the adoption of the MT 190.1 method by CIPAC support the acceptance of the proposed change to the WHO specification for lambda-cyhalothrin CS. As no change has been made to the formulation nor manufacturing process, there is no indication that this change in method an criteria for quality testing would impact the established efficacy of the product.

Therefore, the amended WHO specification for lambda-cyhalothrin CS (slow release) is acceptable and will be reflected in the next update of the published WHO specification.

Additional changes reviewed by JMPS

In addition, based on the Syngenta Crop Protection AG submission reviewed by JMPS, CIPAC MT methods for persistent foam, suspensibility and accelerated storage (MT 47.3, MT 184.1 and MT 46.4, respectively) will be updated and the freeze-and-thaw cold temperature stability test the clause for the free active ingredient (4 % "free" *lambda*-cyhalothrin after the freeze-and-thaw cycles) will be added.

These changes will be reflected in the next update of the published WHO specification.