

QA Information Notice for Health Products

IN N° 2025-02 Version 1- 2025-02-07	Precautionary measures in procuring Indoor Residual Spraying (IRS) product, 2Gard Wettable Powder (WP) supplied by Tagros Chemicals India Pvt. Ltd
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Addressees

- Through Health Product Management (HPM) Specialists, all Principal Recipients (PR) reporting procurement of the impacted product financed by the Global Fund.
- All procurers, buyers reporting procurement of the impacted product financed by the Global Fund.

Purpose

The Global Fund Quality Assurance and Compliance Team is issuing this QA Information Notice to provide precautionary measures following out-of-specifications observed on IRS product, 2Gard Wettable Powder (WP), commercialized by Tagros Chemicals India Pvt. Ltd.

This QA Information Notice is for internal and external dissemination and country teams are expected to communicate this information to their relevant stakeholders.

Identification of the product(s) and manufacturer

Name & Address of the Manufacturer	Tagros Chemicals India Pvt. Ltd A-4/1 & A-4/2, SIPCOT Industrial Complex, Pachayankuppam, Cuddalore-607 005 Tamil Nadu, India
Commercial / Brand Name(s)	2Gard WP (clothianidin 500g/kg+ deltamethrin 62.5g/kg)
Formulation	Wettable powder
Batch(es)	All
Manufacturing Date	All

Background

In December 2024, the Global Fund Supply Operations (SO) received quality analysis reports from a contracted ISO 17025 accredited Quality Control Laboratory for 2 batches of 2Gard WP manufactured by Tagros Chemical India Pvt Ltd which showed out of specification results for both batches. The supplier has been informed of the OOS, and a root cause analysis is being performed to identify any potential necessary corrective and preventive actions to be implemented.

Nature of defect(s)

Details of the defect or problem	<ul style="list-style-type: none"> Higher level of active ingredients (clothianidin and deltamethrin) content before storage Persistent high volume of foam after 1 min (Maximum 50mL) before and after 14 days storage at $54^{\circ}\text{C} \pm 2^{\circ}\text{C}$. Poor wettability before and after 14 days storage at $54^{\circ}\text{C} \pm 2^{\circ}\text{C}$ of the product, taking longer time (Maximum 1 min) to have water spread over or penetrate the powder to make the final solution.
Is there any evidence or suspicion of a risk to users/others	<ul style="list-style-type: none"> Excessive levels of active ingredients can pose safety risks to both the residents of sprayed houses and the spraying personnel. The persistent foam may cause adverse effects to the spraying personnel. The poor wettability leads to slower dissolution, causes clumping and uneven distribution, leading to inconsistent product quality with potential effectiveness concerns related to the indoor residual spraying.
Extent of the problem (e.g. No. of batches)	Only two batches ACDP24J004 and ACDP24J005 procured for Comoros were tested and identified as defective, but other batches could be impacted.
Extent of distribution of the product / batch(es)	No known countries where the product has been distributed. However, procurement and distribution of impacted products directly through Principal Recipients cannot be excluded
Number of users/others potentially impacted	No directly impacted users known or reported

Recommendations

Based on the information available to date and until further notice, the following actions are recommended by the Global Fund Quality Assurance & Compliance team as precautionary measures.

• New orders

1. Halt any new orders or procurements of the 2Gard WP product.
2. Consider alternative procurement of:
 - a) Interchangeable/Substitutable product from a different supplier of the non-soluble bag formulation.
 - b) Different IRS product as per the National Malaria program guidelines

- **Already procured products (or procurement underway)**

Where pre-shipment Quality Control testing did not identify any non-compliance, supply of the procured batch(es) should continue.

However, it is requested to segregate from other products, put under quarantine and dispose of, as per agreed procedures with the supplier, any product batches with issues related to persistent foam above the expected time and those with reduced wettability, taking a longer time of the chemical formulation to form the final solution.

Any of these product deficiencies should be reported to the Global Fund through the respective Country Team/HPM Specialist.

Exceptions to accommodate programmatic risks are to be submitted to the respective Country Team/HPM Specialist on case-by-case basis to be forwarded to the Quality Assurance and Compliance team for assessment and guidance

Users/Others

Users who have experienced any adverse reactions or quality problems with the use of the impacted products may report this to the relevant Regulatory Authorities, manufacturer and the Global Fund Country Team/HPM Specialist.

Transmission of QA Information Notice

This QA Information Notice needs to be passed on to all those who need to be aware within your organization and/or to any organization where the potentially impacted products have been transferred.

Please maintain awareness of this QA Information Notice and resulting action for an appropriate period to ensure effectiveness of the action.

Contacts

This QA Information Notice does not require specific written response from PR and procurers to the Global Fund.

PRs and procurers should copy the Global Fund's Country Team/HPM Specialist on correspondences regarding the matter for follow-up.

Please direct any questions about this matter to the technical contact listed below.

Organisation	Name / Function	E-mail address
Global Fund	Respective Country Team/HPM Specialist for the portfolio	
Global Fund	Anne-Sophie Briand, Senior Specialist, Vector Control Products, Direct Sourcing	Anne-Sophie.Briand@theglobalfund.org
Global Fund	Stephen Kimatu, Specialist-Vector Control Quality Assurance, Quality Assurance & Compliance	Stephen.Kimatu@theglobalfund.org