

## Quality Assurance (QA) for Health Products

### QA Information Notice

<b>IN N° 2024-02</b> <b>Version 1- 2024-09-18</b>	<b>Precautionary measures in procuring water soluble bags Indoor Residual Spraying (IRS) product 2Gard WP-SB supplied by Tagros Chemicals India Pvt. Ltd</b>
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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 WP-SB, 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-SB (clothianidin 500g/kg+ deltamethrin 62.5g/kg)
Formulation	Wettable powder in sealed water-soluble bag
Batch(es)	All
Manufacturing Date	All

### Background

In August 2024, the Global Fund Supply Operations (SO) was reported several product out-of-specification results from its reference laboratory for the 2Gard WP-SB product. SO has informed the supplier, 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"> <li>• Appearance of the soluble bag before and after storage (badly closed soluble bags with signs of leakage or rupture)</li> <li>• Change of appearance of the wettable powder after storage from fine powder free from visible extraneous matter and hard lumps to uneven yellow to beige colored powder with hard lumps</li> <li>• Suspensibility of clothianidin and deltamethrin after storage</li> <li>• Poor dissolution rate of water-soluble bag after storage leading to blocking of the filter</li> <li>• Presence of iron filings</li> </ul>
Is there any evidence or suspicion of a risk to users/others	<p>The badly closed soluble bags with signs of leakage and/or rupture may directly expose users to the chemical formulation, resulting potentially in safety concern.</p> <p>The reduced suspensibility and longer dissolution time of the water-soluble bag may affect dispersion of the chemical formulation in the final solution, resulting potentially in effectiveness concerns related to the indoor residual spraying.</p>
Extent of the problem (e.g. No. of batches)	Only two batches (ACDP24J002 & ACDP24J003) procured for Comoros were tested and identified as defective, but other batches could be affected
Extent of distribution of the product / batch(es)	No known countries where the products have been distributed. However, procurement and distribution of affected products directly through Principal Recipients cannot be excluded
Number of users/others potentially impacted	No directly impacted users/others known/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-SB product.

2. Consider alternative procurement:

- a) Alternative product from the same supplier without soluble bag. In such a case, the supplier should highlight the revised label directions which apply to the wettable powder (WP) product to ensure that spray programs adjust their training and personal protective equipment use accordingly, OR

b) Alternative product from a different supplier of the non-soluble bag formulation.

- **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 badly closed soluble bags with signs of leakage and/or rupture, and/or for product batches with issues related to change of appearance (colour) of the wettable powder, poor suspensibility of clothianidin and deltamethrin after storage and/or poor dissolution rate of water-soluble bag after storage.

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 assessed with the respective Country Team/HPM Specialist on case-by-case basis with due consideration for risk-benefit analysis.

## **Users/Others**

Users who have experienced any adverse reactions or quality problems with the use of the impacted product 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 affected 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.

<b>Organisation</b>	<b>Name / Function</b>	<b>E-mail address</b>
Global Fund	Respective Country Team/HPM Specialist for the portfolio	
Global Fund	Anne-Sophie Briand, Senior Specialist, Vector Control Products, Direct Sourcing	<a href="mailto:Anne-Sophie.Briand@theglobalfund.org">Anne-Sophie.Briand@theglobalfund.org</a>
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