

Quality Assurance (QA) for Health Products

QA Notice

IN N° 2021-03 Version - 21/10/2021	Precautionary measures in procuring IRS supplied by Bayer in water soluble bags (Fludora Fusion WP-SB / Ficam WP-SB / K-Othrine WG-SB)
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Addressees

- Any person having products in stock, in transit
- Any procurers, buyers

Purpose

The GF Quality Assurance team is issuing this notice to provide precautionary measures following quality issues observed for two IRS products, Fludora Fusion WP-SB 100g and Ficam VC WP-SB 125 g commercialized by Bayer, on the basis of out of specification results determined by the reference laboratory during pre-shipment sampling. Although no quality issues were observed with Deltamethrin WG-SB to date, the precautionary measures also apply to this product due to the nature of the defects observed for Ficam and Fludora Fusion.

This 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 of Supplier	Bayer
Product Specifications	Clothianidin + deltamethrin Wettable Powder in sealed Water-Soluble Bag (sold as Fludora Fusion WP-SB) and Bendiocarb Wettable Powder in Sealed Water-soluble bag (sold as Ficam VC WP-SB)
Batch(es)	All
Manufacturing Date	All

Note: This notice does not apply to the alternative specifications Clothianidin + Deltamethrin Wettable Powder, Bendiocarb Wettable Powder and Deltamethrin Water Dispersible Granules, which are WHO-PQ Listed.

Background

In October 2020, the Global Fund Supply Operations (SO) team received several product out-of-specifications (OOS) results from our reference laboratory for WP-SB product specifications based on appearance of the soluble bag, before and after storage, and dissolution rate of the water-soluble bag after storage.

The SO alerted the supplier, and a root cause analysis was performed followed by a detailed plan of corrective actions, which were to be implemented during the course of 2021. During the first half of 2021, seven more OOS events were identified for both products across 13 batches on several types of major non-compliance.

Information has been forwarded to WHO Prequalification. At the date of publication of this notice, WHO-PQ has approved an alternative product specification, Clothianidin + Deltamethrin Wettable Powder (WP) without a soluble bag. The alternative product is published in the WHO-PQ List on their website and in the GF list of IRS products. The supplier has initiated registration variation for the alternative product specification in multiple countries.

The precautionary measures included in this notice constitute adequate risk mitigations measures.

Nature of defect(s)

Details of defect or problem.	Defects in dissolution rate, suspensibility and welding of the water-soluble bag (mainly after accelerated storage and, with one batch, pre-storage)
Is there any evidence or suspicion of a risk to public health?	The reduced suspensibility and longer dissolution time of the water-soluble bag may affect distribution of the insecticide in the spray tank and result in uneven deposits on surfaces, leading to less predictable results against mosquitoes.
Extent of the problem (e.g. No of batches).	Unknown
Extent of distribution of the product / batch (es).	The known countries which the products were distributed include Honduras, Malawi, Mozambique, Nicaragua, Zambia and Zimbabwe However, a wider distribution cannot be excluded.
Number of patients potentially impacted	No directly impacted patients known/reported

Recommendations

Based on the information available to date and until further notice, the following actions are required to be undertaken as precautionary measures.

Next orders

1. To halt any new orders or procurements for the WP-SB and WG-SB product specifications in order to give the supplier some time to properly investigate and resolve the issue without the pressure of meeting delivery dates. This concerns Bendiocarb WP-SB (sold as "Ficam"), Deltamethrin WG-SB ("K-Othrine") and Clothianidin + Deltamethrin WP-SB (sold as "Fludora Fusion").

2. Consider alternative procurement of either: -
 - a) Alternative product specifications from the same supplier without soluble bag. In such a case, the supplier should be committed to highlight the revised label directions which apply to the WP or WG product to ensure that spray programs adjust their training and PPE-use accordingly. -
 - b) Similar product specification from a different supplier
3. For ongoing orders where WP-SB or WG-SB procurement is underway, increase the sample size for testing especially for dissolution rate of the products

Already procured products (or procurement underway)

Where pre-shipment sampling identifies no non-compliance then supply should continue. However, where pre-shipment sampling identifies non-compliance, the following is recommended, in line with a risk-based assessment depending on the country context:

- Product batches with issues related to dissolution before storage should be segregated as an inherent risk of poor product stability with time and should not be released except in case of serious disruption of the access / programmatic risk
- Product batches with issues related to dissolution after storage, can be released for use until May 2022 remaining stock not used by the stated time to be quarantined and returned to suppliers as per agreed procedures
- Product batches with issues related to poor welding should be segregated and put in quarantine; return to suppliers as per agreed procedures

Contacts

This notice does require specific written response from Principal Recipients. All sampling reports and certificate of analysis should be forwarded to GF Quality Assurance team.

Please direct the respective answers and any questions about this matter to the technical contact listed below

Organisation	Name / Function	E-mail address
Global Fund	Stephen Kimatu, Specialist-Vector Control Products, Quality Assurance Team	Stephen.Kimatu@theglobalfund.org
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