

## Quality Assurance (QA) for Health Products

### QA Information Notice

<b>IN N° 2019-08</b> <b>Version - 18/12/2019</b>	<b>Precautionary measures with Interceptor G2 Nets commercialized by BASF</b>
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#### Addressees

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

#### Purpose

The GF QA is issuing this information notice (IN) to provide information on precautionary measures identified for Interceptor G2 commercialized by BASF on the basis of information collected with the support of the supplier.

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	<b>BASF</b>
Commercial Name(s)	<b>Interceptor G2</b>
Packaging & Pack size & Type	<b>All (Size, Color)</b>
Batch(es)	<b>All</b>
Manufacturing Date	<b>All</b>

#### Background

GF Supply Operations (SO) received the information from its Procurement Service Agent of an out-of-specification for flammability test when performed as per EN 1102 standards.

Subsequently, the SO alerted the supplier. The nets were retested by second party laboratory selected by the manufacturer and then subsequently re-tested at an independent laboratory under GF supervision. Finally, **four months ageing nets were found compliant** for the flammability test.

Information have been forwarded to WHO Prequalification for further investigation and advice. At the date of publication of this notice, no specific guidance has been received from WHO PQ and Interceptor G 2 remains on the current list of prequalified vector control products.

While waiting for the final outcome of the investigations GF QA decided to provide advice on the precautionary measures included in this notice which constituted adequate risk mitigations measures.

## Nature of defect(s)

Details of defect or problem.	<p><b>Initially, 4 consignments of the same batch (produced in January 2019) were found to have an out of specification (OOS) for flammability test.</b></p> <p><b>Following root cause analysis and manufacturer's investigations, compliance to flammability testing could be assured by additional drying time (under adequate storage conditions).</b></p>
Is there any evidence or suspicion of a risk to public health?	<p><b>Testing with EN 1102 showed that some nets continue to combust after removal of the flame, resulting in extreme hole enlargement and, in some cases, dripping of flaming polymer melt. In a household, flaming melt could cause serious personal injury and ignite other combustible items, allowing the fire to spread further.</b></p>
Extent of the problem (eg. nb batches).	<b>Unknown</b>
Extent of distribution of the product / batch (es).	<p><b>Limited distribution to countries procuring under the New Net Project (NNP) pilots for evaluation work such as Burkina Faso, Mozambique, Rwanda are identified</b></p>
Number of patients potentially impacted	<b>No directly impacted patients known/reported</b>

## Recommendations

Based on the information available to date and until further notice, the following actions are recommended by GF QA as precautionary measures.

- To perform sampling taking into consideration the testing requirements hereunder.
- To perform testing as per the **whole set of approved specifications**.
- To ensure that the test for Flammability is included in the current test implemented **using EN 1102 Method imperatively**.
- To ensure that all lots/consignments are tested in case multiple lot are procured
- To test an increased number of samples compared to the usual recommendations such as **6 nets per lots/consignments**.
- To ensure with the quality control laboratory that the washing procedure before the flammability is implemented as per simulated **hand washing conditions**.

NOTE: Because the specifications are not publicly available at the time of the publication of this notice, please liaise with GF QA or manufacturer to receive the interim specifications.

## Contacts

This IN does require specific written response from PR. **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

<b>Organisation</b>	<b>Name / Function</b>	<b>E-mail address</b>
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