

Quality Assurance (QA) for Health Products

QA Notice

IN N° 2023-02 Version 3 - 11/05/2023	Updated Decision: on the procurement of lubricants (sachets and tubes) manufactured by Cupid Limited, India and the request to quarantine Lubricants batches manufactured between January 2022 to date.
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Addressees

- All Principal Recipients (PRs)
- Any person having products in stock, in transit or under custom clearance
- Any procurers, buyers with a pending order

Purpose

The GF QA is issuing this information notice to provide an update regarding the temporary suspension of procurement of lubricants (sachets and tubes) manufactured by Cupid Limited, India as well as the request to quarantine lubricants batches manufactured between January 2022 to date.

Identification of the product(s) and manufacturer

Name of Manufacturer	Cupid Limited, -68, MIDC, MIDC Area, Malegaon, Maharashtra 422113, India
Commercial Name(s)	Cupid lubricant water-based
Packaging & Pack size & Type	4ml; 4.3ml; 5ml; 10ml; 20ml: pack of 10000 sachets 20g and 35g: pack of 25 or 50 tubes
Batch(es)	See attachment (Cupid Ltd. Country and distribution information)
Manufacturing Date	Between January 2022 to date

Background

UNFPA received information that three batches of water-based lubricants packed in sachets manufactured by **Cupid Limited, -68, MIDC, MIDC Area, Malegaon, Maharashtra 422113, India** failed to meet the total aerobic microbial count specification parameter. A review of the test results and further complaints received indicate that the quality of some batches may have been compromised.

February 2023

Consequently, to protect public health while awaiting the results of the ongoing investigation UNFPA had requested to take following precautionary risk mitigation measures:

- To quarantine all batches of personal lubricant (packed in sachets and in tubes) from Cupid Limited manufactured from January 2022 to date.
- To stop the procurement of lubricants (sachets and tubes) from Cupid Limited until further notice.

May 2023: update on the Decision and way forward

After issuing the 'Quarantine notice', independent testing has been performed for lubricants manufactured by Cupid Limited. Review of Corrective and preventive Actions (CAPAs), test results as well as stability studies data have also been undertaken. Outcomes of these reviews have resulted in the below conclusions and way forward (see below table and Next Steps):

Nature of defect(s)

Details of defect or problem.	Out of Specification for the parameter total aerobic microbial count
Is there any evidence or suspicion of a risk to public health?	The failure may increase the risk for the end-user to develop a bacterial infection
Extent of the problem (eg. nb batches). Content updated	Batches manufactured between June 2022 and today. For details on batch numbers, please refer to Attachment 2
Extent of distribution of the product / batch (es). Content updated	For PPM Orders: Belize, Cuba, Comoros, El Salvador, Honduras, Kazakhstan, Kyrgyzstan, Mauritania, Sao tome and Principe, Surinam Worldwide distribution is anticipated
Number of patients potentially impacted	No impacted patients known/reported

Action/Investigations taken

- To align internally to anticipate any procurement decisions.

Next Steps

1. Decision on procured batches manufactured from January 2022 to May 2022.

Quarantined stock of batches produced from January 2022 to May 2022 are to be released and distributed for use.

2. Decision on procured batches manufactured from June 2022 to date.

Quarantined stock of batches produced from June 2022 to date are to be destroyed **IMMEDIATELY** and to be replaced by another Supplier.

Note: All cost associated with the recall and replacement will be borne by Cupid Limited, India. (see attachment 2).

For PPM procurement only:

- Share with nalini@unfpa.org copying serwaa@unfpa.org :
 - the certificate of destruction of the batches listed in *attachment 2*.
 - evidence of induced costs associated with the recall and destruction.

For Non-PPM Procurement:

- To report to the Global Fund QA Team (see below email) the available stock of batches manufactured from June 2022 to date, that were quarantined.
- Share with Amelie.darmon@theglobalfund.org:
 - the certificate of destruction
 - evidence of induced costs associated with the recall and destruction.

3. Decision on new procurement

Based on the reviews performed, the Supplier is still to address some issues relating to overall quality of lubricant packed in sachets and tubes. Any new procurement to be halted until the manufacturer has been reactivated in UNFPA’s catalogue.

Contacts

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	Amélie Darmon, Quality Assurance Specialist	Amelie.darmon@theglobalfund.org
UNFPA	Linda Serwaa, Head, Product Quality Assurance	serwaa@unfpa.org
UNFPA	N Nalini, Product Quality Assurance	nalini@unfpa.org

Attachments:

1. UNFPA Product QA Team letter: Update to Quality alert relating to water-based personal lubricant manufactured by Cupid Limited, India
2. Cost Accountability letter for recall of water-based lubricants from Cupid – 3rd May 2023



United Nations Population Fund, UNFPA
Supply Chain Management Unit (SCMU)
Marmorvej 51, 2100 Copenhagen,
P.O. Box 2530 Denmark
Tel: +45 4533 7277
E-mail: scmu.qa@unfpa.org
Website: www.unfpaprocedurement.org

To: All Stakeholders

Date: May 1st, 2023

Status: **Update to Quality alert relating to water-based personal lubricant manufactured by Cupid Limited, A-68, M.I.D.C. (Malegaon), Sinnar, Nashik – 422113, Maharashtra, India.**

Dear Client,

UNFPA would like to provide an update on the status of the quality alert investigation carried out for lubricant supplied by Cupid Limited. After issuing the 'Quarantine notice', independent testing has been performed for lubricant manufactured by Cupid Limited. Review of Corrective and preventive Actions (CAPAs), test results as well as stability studies data have also been undertaken. Outcomes of these reviews have resulted in the below.

UNFPA has concluded as follows:

1. Quarantined stock of batches produced from *January 2022 to May 2022* are to *be released and distributed for use*.
2. Quarantined stock of batches produced from *June 2022 to date* are to *be destroyed and replaced by another Supplier*.
3. Based on the reviews performed, the Supplier is still to address some issues relating to overall quality of lubricant packed in sachets and tubes. Any new procurement to be halted until the manufacturer has been reactivated in the UNFPA catalogue.

The following actions are to be undertaken to facilitate the process of replacement of recalled batches.

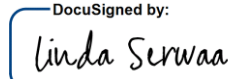
Actions:

- All quarantine batches produced from *June 2022 to date* are to be destroyed **IMMEDIATELY**.
- Share the certificate of destruction with nalini@unfpa.org copying serwaa@unfpa.org.
- Share evidence of induced costs associated with the recall and destruction.
- UNFPA will engage with your office to facilitate the process of product replacement.

All affected batches (produced from *June 2022 to date*) will be replaced by another approved lubricant manufacturer. All cost associated with the recall and replacement would also be borne by Cupid Limited.

Please contact the UNFPA Product Quality Assurance Team at scmu.qa@unfpa.org if you need further clarification.

Thank you.

DocuSigned by:

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Linda Serwaa
Head, Product Quality Assurance



CUPID LIMITED

Manufacturer & Exporter of Male Condoms, Female Condoms,
Water based Lubricants & In Vitro Diagnostics (IVD) Kits

Date: May 03, 2023

United Nations Population Fund (UNFPA)
Supply Chain Management Unit
Marmovej 51, 2100 Copenhagen
Denmark

**Sub: Cost Accountability for Recall of water-based lubricants manufactured
by Cupid from June 2022 - till date**

This serves to confirm that all cost related to the recall of water-based lubricants manufactured from June 2022 to till date listed in our Recall Notice dated 01st Feb 2023 will be on Cupid's account. The following costs to support the recall process for attached **Annexure 1** which would be on our account are as detailed below:

1. Transport / Logistics cost for the replacement's batches from origin to destination warehouses which includes sea / air freight charges.
2. Import custom clearance costs for the replacement batches at destination / in-Country.
3. Destruction of unused lubricant batches in sachets / tubes at destination warehouses and the logistics to move the batches to be destroyed as designated by local authorities in respective countries.
4. Recalled batches of lubricants in sachets / tubes to be destroyed and replaced by an appointed supplier(s) by UNFPA and Cupid to reimburse UNFPA or supplier for the replacements.

Thank you for your kind attention.

Signature

Durgesh Garg

Chief Operating Officer

Cupid Limited



CIN No.: L25193MH1993PLC070846

Factory & Registered Office:

A-68, M.I.D.C. (Malegaon), Sinnar,
Nashik - 422113, Maharashtra, India



+91 2551 230280 / 230772
+91 7722009580



www.cupidlimited.com
info@cupidlimited.com

We Help The World Play Safe



CUPID LIMITED

Manufacturer & Exporter of Male Condoms, Female Condoms,
Water based Lubricants & In Vitro Diagnostics (IVD) Kits

Annexure 1

Sr. No.	PO Number	Country	No. of batches	Batch Numbers	Mfg	Exp	QTY	Volume
1	47438	CUBA	1	LBF2201	2022-06	2025-05	100000	4ml
2	47253	El Salvador	19	LBF2202-LBF2220	2022-06	2025-05	4400000	4ml
3	47612	BELIZE	1	LBF2222	2022-06	2025-05	225000	4ml
4	47432	SURINAME	3	LBF2223-LBF2225	2022-06	2025-05	255000	10ml
5	47556	Cuba	5	LBF2227-LBF2231	2022-06	2025-05	1032000	4ml
6	47695	Kazakhstan	9	LBG2208-LBG2216	2022-07	2025-06	1798000	4.3ml
7	48265	Kyrgyzstan	6	LBI2201-LBI2206	2022-09	2025-08	150000	20ML
8	48817	Honduras	5	LBJ2201-LBJ2205	2022-10	2025-09	389000	10ml
9	48834	Comorus	1	LBJ2206	2022-10	2025-09	150000	5ml
10	49172	Mouritania	7	LBK2208-LBK2214	2022-11	2025-10	1517000	4.3ml
11	49728	Sao Tome	1	LBL22121	2022-12	2025-11	4000	5ml



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