RAPID ALERT

DRAP ALERT No: I/S/8-24-29

FALSIFIED PROPYLENE GLYCOL REPORTED IN SUPPLY CHAIN MARKET

Date: 22nd August, 2024

Target Audience:

- Regulatory Field Force of DRAP and Provincial Drug Control Administrations
- Therapeutic Goods Manufacturers

Problem Statement:

Dow Chemical's Singapore and the Incidents and Substandard/Falsified Medical Products (ISF) Regulation and Safety Unit, World Health Organization have informed DRAP that some miscreants are supplying falsified batches of Propylene Glycol with counterfeit Dow Chemical labelling in the supply chain market in Pakistan. The quality and safety of this material cannot be assured, and it should not be used in the manufacture of medical products. Details of identified falsified batches are as under:

Material	Batch/Lot No.	Manufacturer	Mfg. date	Exp. date
		(as per label)		
Propylene Glycol USP/EP	F9600L7PPA4	Dow Europe GmbH	18-10-2023	18-10-2025
Propylene Glycol US/EP	F8900L8PPD6	Dow Europe GmbH	Feb-2023	Feb-2025
USP Propylene	SS8900B3PPD5	The Dow Chemical Company	18/May/2023	-Nil-

Risk Statement:

Di-Ethylene glycol (DEG) and Ethylene Glycol (EG) contaminated Propylene Glycol (PG) when used in oral liquid preparations can lead to serious health risks. When ingested, EG and DEG are converted into toxic metabolites that can affect the central nervous system and heart. Moreover, it can also cause kidney damage which may lead to fatal consequences.

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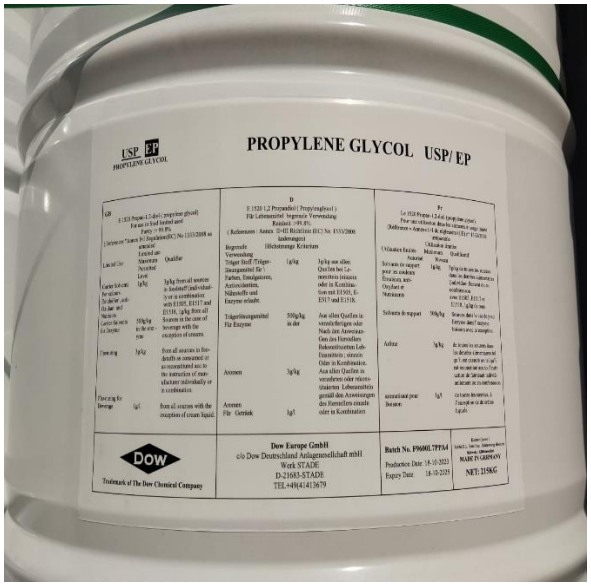
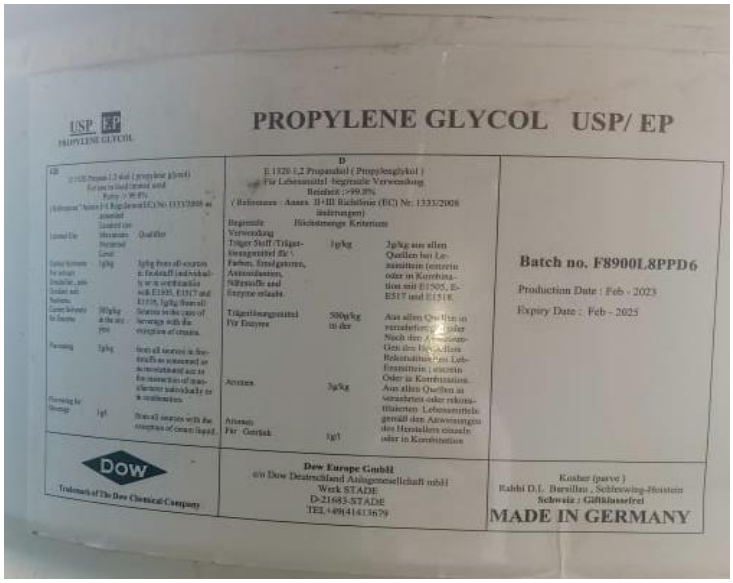
Identification and details of falsified material:

Falsified Propylene Glycol USP/EP
- Lot No. F9600L7PPA4



Falsified Propylene Glycol US/EP –
Lot No. F8900L8PPD6



Falsified USP Propylene –
Lot No. SS8900B3PPD5

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Action Initiated: -

The Regulatory Field Force has been directed to take regulatory actions on the identification of these falsified batches of Propylene Glycol and investigate its supply chain. The therapeutic goods manufacturer has been instructed to not consume any unverified batch of Propylene Glycol and other raw materials, and recall any finished products that were manufactured using the above reported lots of propylene glycol. The Regulatory Field Force has also been instructed to seize all oral preparations that were made using the same lots/batches of propylene glycol if found in the market.

Advice for Therapeutic Goods Manufacturers: -

Manufacturers of therapeutic goods are required to follow these instructions:

1. **Recall Products:** If any batch was manufactured using the same lot of Propylene Glycol that has been identified as contaminated, all finished products from local and export markets should be recalled.
2. **Hold Other Batches:** All finished products manufactured from any other lot of propylene glycol of same vendor/supplier should be kept on hold. These products should be tested for EG/DEG contamination before releasing them into the supply chain.
3. **Screen Raw Materials:** Before using them in the manufacturing of oral liquid preparations, all raw materials should be screened for contamination with EG and DEG.
4. **Compliance:** Ensure compliance with all directives issued by DRAP to safeguard public health from contaminated products and always purchase raw materials from approved/qualified vendors.
5. **Follow Guidelines:** Adhere to the Pharmacopoeial monograph for testing EG/DEG in raw materials and WHO guidelines for finished products.

Advice for Healthcare Professionals: -

DRAP requests healthcare professionals to stay updated with advisories and recalls. Patients should be educated about the risks and symptoms of DEG/EG toxicity. Close monitoring of patients using the affected products is crucial, and any adverse events should be reported to National or Provincial pharmacovigilance centers.

Adverse reactions or quality problems experienced with the use of these products shall be reported to the National Pharmacovigilance Centre(NPC), DRAP using Adverse Event Reporting Form or online through this link. Further information on reporting problems to DRAP is available on this link.

Drug Regulatory Authority of Pakistan
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