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Laboratoire de Toxicologie & Maîtrise du Risque Chimique

FIELD SAFETY NOTICE TEMPLATE

URGENT FIELD SAFETY NOTICE

DIPHOTERINE® - MINI-DAP & MICRO-DAP
Ref. PREVOR NC 18589-2

Type of action : Information to user, updated instructions for use

Date: 18/03/2019

Subject: Protection of MINI-DAP & MICRO-DAP of DIPHOTERINE® solution

Details of affected medical devices:

MINI-DAP (200 mL) & MICRO-DAP (100 mL) of DIPHOTERINE® solution is an emergency washing solution in case of chemical splash onto the skin. DIPHOTERINE® solution contained in the MINI-DAP or MICRO-DAP removes the chemical from the skin surface, stops its penetration and with a sufficient prolonged washing, is able to remove the chemical from tissues.

MINI-DAP and MICRO-DAP are not designed to undergo strong shocks during their shelf life. If damage is caused to MINI-DAP or MICRO-DAP canisters during the shelf life of the product, the devices may not operate anymore. Consequently, when needed for decontamination, MINI-DAP or MICRO-DAP may not deliver the DIPHOTERINE® solution.



Examples of damaged MINI-DAP & MICRO-DAP:





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Problem description:



When MINI-DAP or MICRO-DAP of DIPHOTERINE® solution faces a shock (fall, crushing, friction), the energy transmitted by this shock is diffused into the canister. This shock could lead to the following consequences:

- 1- A breakage of the seal between the internal pouch containing the solution and the external valve of the canister,
- 2- A tearing of the pouch in the canister.

In both cases, the pouch containing the DIPHOTERINE® solution is no longer sealed. If the device is triggered, gas (N₂) contained in the canister is directly released by the diffuser instead of pressing the pouch and releasing the solution. Consequently, in such cases, DIPHOTERINE® solution is no longer available for decontamination. MINI-DAP & MICRO-DAP are not operational anymore.

The probability of this issue arising is very low and happens in very specific circumstances. The occurrence of reported similar events in the last year is about 0.009% over MINI-DAP and MICRO-DAP on the market.

The only consequence of this situation is a non-operational device. Users are not endangered by a potential defective product even though the device is triggered.

Recommendation about the actions to be taken by the user:

In order to get the optimal efficiency of DIPHOTERINE® solution contained in the MINI-DAP & MICRO-DAP, PREVOR recommend to all customers to:

- Store the MINI-DAP of DIPHOTERINE® solution in a protected place in a manner that minimises the risk of damage to the product,
- Protect MICRO-DAP of DIPHOTERINE solution in a strengthened holster if handling conditions can generate shocks, crushings or friction.
- Avoid using MINI-DAP and MICRO-DAP if canisters have been exposed to shocks or have visible signs of damage.

Customers instructions for use have been updated in order to include such information.

Forwarding the safety notice: (if applicable)

This information must be given to all customers of MINI-DAP & MICRO-DAP of DIPHOTERINE® solution and shared as necessary within the organizations of the customers.

This notice must be communicated to anyone who must be aware of it within your organization and to any organization to which the affected medical device has been transferred. (if applicable)

Please also communicate this notice to other organizations affected by this action. (if applicable)

Keep awareness of this notice and the resulting measures long enough to ensure the effectiveness of the corrective action. (if applicable)



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The signature below confirms that the appropriate authority for medical devices has been notified of this notification.

Signature: