



PREVOR

PRÉVOIR ET SAUVER

Laboratoire de Toxicologie & Maîtrise du Risque Chimique

FIELD SAFETY NOTICE DISTRIBUTOR/IMPORTER REPLY FORM

DISTRIBUTOR/IMPORTER REPLY FORM

1. Field Safety Notice (FSN) information	
FSN Reference number*	NC 18589-2
FSN Date*	30/01/2019
Product/ Device name*	DIPHOTERINE® - PREVIN®
Product Code(s)	MINI-DAP MICRO-DAP MINI-TAD MIKRO-TAD
Batch/Serial Number (s)	N/A

2. Distributor/Importer Details	
Company Name*	
Account Number	
Address	
Shipping address if different to above	
Contact Name*	
Title or Function	
Telephone number*	
Email*	

3. Return acknowledgement to Sender	
Email	affairesreglementaires@prevor.com
Distributor/Importer Helpline	+33(0)1 30 34 76 76
Postal Address	PREVOR Moulin de Verville 95760 Valmondois FRANCE
Web Portal	www.prevor.com
Deadline for returning the Distributor/Importer reply form*	18/04/2019

4. Distributors/Importers (Tick all that apply)		
<input checked="" type="checkbox"/>	*I confirm the receipt, the reading and understanding of the Field Safety Notice.	<i>To complete</i>
<input type="checkbox"/>	I have checked my stock and quarantined inventory	N/A
<input checked="" type="checkbox"/>	I have identified customers that received or may have received this device	<i>To complete</i>
<input type="checkbox"/>	I have attached customer list	N/A



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<input checked="" type="checkbox"/>	I have informed the identified customers of this FSN	<i>To complete with date (or period) of communication</i>
<input type="checkbox"/>	I have received confirmation of reply from all identified customers	N/A
<input type="checkbox"/>	I have returned affected devices - enter number of devices returned and date complete.	N/A
<input type="checkbox"/>	have destroyed affected devices – enter number destroyed and date complete.	N/A
<input type="checkbox"/>	Neither I nor any of my customers has any affected devices in inventory	N/A
Print Name*		<i>To complete</i>
Signature*		
Date *		

Mandatory fields are marked with *

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN.

Your organisation's reply is the evidence we need to monitor the progress of the corrective actions.



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FIELD SAFETY NOTICE TEMPLATE

EMERGENCY SAFETY NOTICE

PREVIN® - MINI-TAD & MIKRO-TAD
Ref. PREVOR NC 18589-2

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

Date: 30/01/2019

Subject: Protection of MINI-TAD & MIKRO-TAD of PREVIN® solution

Details of affected medical devices:

MINI-TAD (200 mL) & MIKRO-TAD (100 mL) of PREVIN® solution is an emergency washing solution in case of chemical splash onto the skin. PREVIN® solution contained in the MINI-TAD or MIKRO-TAD 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-TAD and MIKRO-TAD are not designed to undergo strong shocks during their shelf life. In case of damages inflicted to MINI-TAD or MIKRO-TAD during the shelf life of the product, the devices could not operate anymore. Consequently, when needed for decontamination, MINI-TAD or MIKRO-TAD could not deliver the PREVIN® solution. .

Examples of damaged MINI-TAD:





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Problem description:



When MINI-TAD or MIKRO-TAD of PREVIN[®] solution faces a shock (fall, crushing, important rubbings), the energy transmitted by this shock is diffused into the canister. This shock could lead to the following consequences :

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

In both cases, the pouch containing the PREVIN[®] solution is no more sealed. If the device is triggered, gas (N₂) contained into the canister is directly blown by the diffuser instead of pressing the pouch unreleasing the solution. Consequently, in such cases, PREVIN[®] solution can not be available for decontamination. MINI-TAD & MIKRO-TAD are not operating anymore.

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

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

Recommendation about the action to be introduced by the user:

In order to get the optimal efficiency of PREVIN[®] solution contained in the MINI-TAD & MIKRO-TAD, PREVOR recommend to all customers to:

- Store the MINI-TAD of PREVIN[®] solution in a protected place in a manner that no shock or fall alter the working conditions of the product,
- Protect MIKRO-TAD of PREVIN[®] solution in a strengthened holster if handling conditions can generate shocks, crushings or important rubbings phenomena.
- Avoid using MINI-TAD and MIKRO-TAD if these latter have underwent shocks or have visible signs of shocks.

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

Forwarding a security notice: (if applicable)

This information must be given to all customers of MINI-TAD & MIKRO-TAD of PREVIN[®] solution and share 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 measure long enough to ensure the effectiveness of the corrective action. (if applicable)



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Contact person:

For Germany:

Gaëlle Rehme

PREVOR GmbH
Gereonshof 2A
50670 Köln
0221-337722-0

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

Signature: