19-03-2021

# URGENT PRODUCT DEFECT CORRECTION

**TGA Reference Number: RC-2021-RN-00924-1**

**DIPHOTERINE® DAPD / HEXAFLUORINE® DAPF**

| | |
|---|---|
| ARTG identifier : | 124480 |
| Manufacturer : | PREVOR |
| Product : | DIPHOTERINE® solution, HEXAFLUORINE® solution |
| Product model : | DAPD, DAPF |

AMARE SAFETY Pty Ltd, after consultation with the Therapeutic Goods Administration (TGA), is conducting a correction of the above products (DAPD, DAPF). We are contacting you as the potentially concerned product may be present in your organisation.

DAPD (5 L) of DIPHOTERINE® solution & DAPF (5 L) of HEXAFLUORINE® solution are emergency washing solutions in case of chemical splash onto the skin. The solutions aim to rapidly eliminate the residual chemical product present on the tissues in order to prevent or limit the penetration of the product into the tissues. As a result, the extent and severity of the chemical injury are limited and the necessary secondary cares can be implemented.


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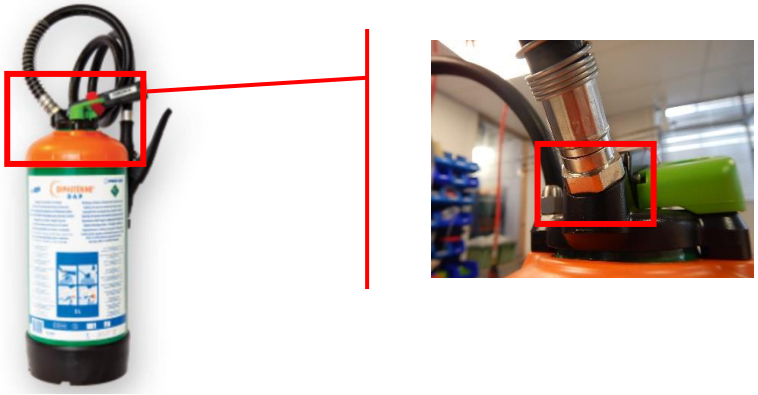
**Description of the problem**

DAP devices are made up of 4 main elements: the shower body (green cylinder), the shower head (black element to start operating the device), the hose (diffusion pipe) and the internal system containing the solution.
The defect is located at the level of the hose's attachment (following photo) at the head of the DAP.



Two similar incidents were reported to us indicating that **the hose had come off** at the nut holding it in connection with the DAP head.
These two incidents took place under similar circumstances which we were able to reproduce according to the following protocol:

- Activation of the shower (= pressurisation by means of the black handle)
- Diffusion of the solution while applying a stress to the hose (rotation at the nut and/or shaking of the device)

**Affected batch**: the hoses potentially affected by this defect are numbered **1907**.

Please note that not all devices incorporating this set of hoses are likely to have the defect. However, should this happen, we are aware that this defect coupled with the chemical accident situation can be confusing for the user.

**Conduct and potential risk for the user in the event of the hose coming off**

The frequency of occurrence of the defect on the hose batch N° **1907** is 0.2%.
If the hose should come off during the dispensing of the solution, it does not create an immediate danger to the user or people nearby.

The DAP remains functional and solution will continue to flow through the DAP port. However, the application of the solution will not be as easy. We recommend lifting the device to keep the solution flowing over the person affected by a chemical splash, as shown in the photo below. The solution stream can be directed using a finger to direct the flow.

Thus, the person can continue the decontamination process thanks to all the effects of the Diphoterine® or Hexafluorine® solutions, which will have the effect of carrying out the essential surface rinsing.

The surprise caused to the user in the event of the hose unhooking can lead to a momentary stop or delay in the application of the solution. In this case, the rinsing may not be optimal or even not complete.

Also, after this DAP has been fully used, we recommend a secondary rinsing by applying a second DAP to the victim.

Finally, as with all cases of chemical splashes on a person, we recommend that you follow your procedure for the care and control of the victim with the appropriate medical service.

**What measures has Prevor taken to resolve this defect?**

The defect having been identified, we were able to develop a safety collar that fits over the nut. Thanks to a simple and resistant fixing system, this collar will prevent any risk of the hose coming off.

**What is the procedure to follow?**

1. Check if the batch number of the hoses connected to your DAP devices is 1907

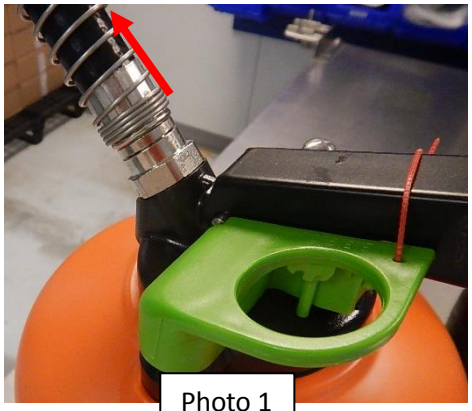


Photo 1

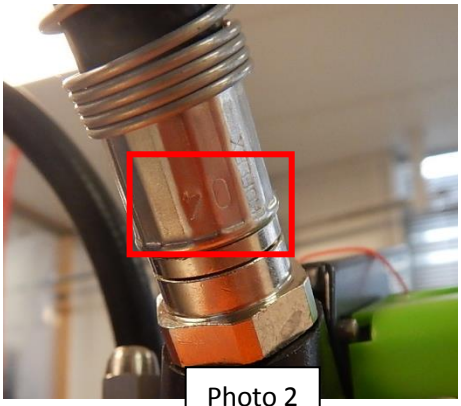
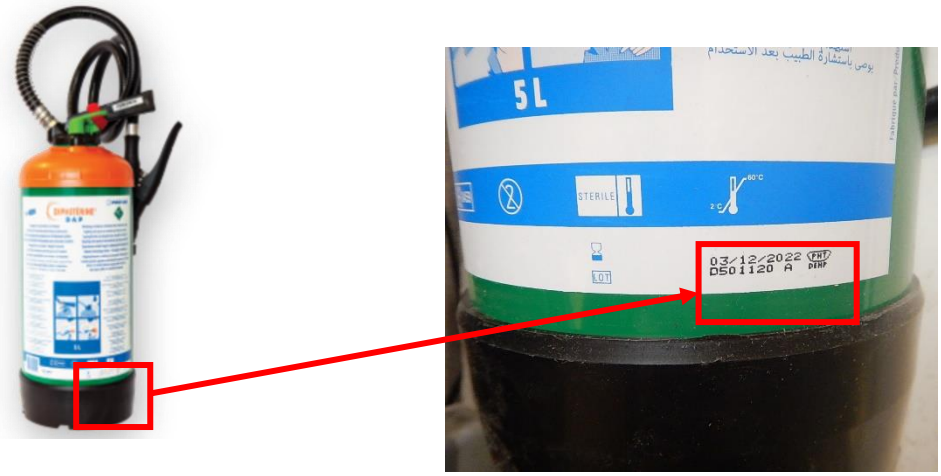


Photo 2

To read the batch number of the hose: lift the spring (photo 1) and read the 4 digits engraved on the metal part (photo 2).

2. Fill in the form available in appendix 2 and send it back to us by email as soon as possible and at the latest within 10 days following receipt of this letter, whether or not you have identified this hose number (natalie.stephens@amare.com.au).

**2.a** Indicate on the form the batch number of the complete identifiable device as shown below:




**2.b** Take photos of the hose batch numbers on the devices affected and attach them to the form.

3. **If you have identified devices on your site with hose number 1907**:
   **3.a**
   Inform your employees and potential users of the defect and of the measures to be taken in case of need of use according to the paragraph "Conduct and potential risk".
   **3.b**
   We will send you the special securing piece (safety collar) with its assembly plan as soon as you confirm.

**Forwarding the safety notice:** (if applicable)
This information must be given to all customers of DIPHOTERINE® solution DAPD & HEXAFLUORINE® solution DAPF and shared as necessary within the organisations of the customers.

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

Please also communicate this notification to other organisations affected by this action. (if applicable)

Keep awareness of this notification and the resulting measures long enough to ensure the effectiveness of this action.

Place this letter in a prominent position for at least one month.

If you require any further information regarding this issue, please contact AMARE SAFETY on 03 8542 0400 or email Prevor@amare.com.au.

AMARE SAFETY Pty Ltd sincerely regrets any inconvenience caused to your organization.

Natalie Stephens
Product Specialist

AMARE SAFETY PTY LTD

## Customer acknowledgement form

Please complete this form *even if you do not have any affected stock.*

## 1.1.1 URGENT PRODUCT DEFECT CORRECTION

*TGA Ref No. RC-2021-RN-00924-1*

**Prevor ref No. NC 23850 (DAPF & DAPD)**

**Aust 124480**

**DIPHOTERINE® DAPD / HEXAFLUORINE® DAPF**

Batches effected are numbered **1907**.

On behalf of this organisation, I acknowledge receipt of the Product Defect Correction notification notice date Monday 19th of April 2021 relating to the above product.

FROM:

| | |
|---|---|
| **Organisation** | |
| **Position** | |
| **Name** | |
| **Email or fax no.** | |
| **Telephone no.** | |
| **Date** | |
| **Signature** | |

If you have **no affected** stock, tick this box: ☐

If you have affected stock, please complete the stock details table below.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| Product | Batch | Quantity of stock effected | Batch numbers of effected |
|---|---|---|---|
| | | | |
| | | | |
| **Total affected product** | | | |
| | | | |

## Other organisations

Has your organisation supplied potentially affected product to any other organisation?

☐ No

☐ Yes I/we will forward all the recall information to the suppliers/distributors/customers

## Return completed forms by fax or email to:

| | |
|---|---|
| **Name** | Natalie Stephens |
| **Position** | Product Specialist |
| **Organisation** | Amare Safety Pty Ltd |
| **Address** | 125 Henderson Rd. Rowville, Vic, 3178 |
| **Email** | Natalie.stephens@amare.com.au |
| **Subject of email** | Urgent Product Defect Correction of DIPHOTERINE® DAPD / HEXAFLUORINE® DAPF Batches effected are numbered 1907 |
| **Fax no.** | 03 9561 1962 |
| **Telephone no.** | 03 8542 0400 |