

URGENT PRODUCT DEFECT CORRECTION

23 September 2020

Attention: Wholesaler/Distributor/Retailer

TGA Reference:	RC-2020-RN-00819-1
ARTG:	277597
Product Name:	AEROWIPE Cleansing Wipes supplied in various first aid kits
Product Description:	Non-sterile device consisting of an absorbent fabric pre-soaked in a liquid solution intended for cleaning a localized body surface before a procedure or device application, and/or to maintain skin hygiene. It is commonly known as a wet wipe and is normally available [non-prescription] over-the-counter (OTC) for use in the home or healthcare facility. This is a single-use device.
Product Code:	AW8000
Affected Product:	Cleansing wipes of two batches, contained in first aid kits, supplied between 7 May 2020 and 25 August 2020 . Affected kits are listed in Appendix A .

Due to the visual presence of black spots resembling mould growth and following consultation with the Therapeutic Goods Administration, Aero Healthcare AU Pty Ltd is electing to recall two specific batches of AW8000 AEROWIPE Cleansing Wipes supplied in some first aid kits as detailed below:

Batch 1	Batch 2
LOT: 24473	LOT: 24706
MFG: 02/2020	MFG: 04/2020
EXP: 02/2025	EXP: 04/2025

No other batches of AEROWIPE Cleansing Wipes are affected by this recall. A full lab investigation of this anomaly is in process.

Please quarantine **ALL** stock that you have received from Aero Healthcare between **7 May 2020 and 25 August 2020** from the list of affected first aid kits identified in **Appendix A**, that are within your control.

You are being notified of the potentially affected AEROWIPE Cleansing Wipes included in Aero Healthcare's first aid kit range as our records indicate that you have received affected first aid kits between **May 2020 and August 2020**. If any stock from the information in **Appendix A** is in your possession, please quarantine. If the stock has been further distributed to your customers, please forward this notice to them.

Aero Healthcare will supply replacement AEROWIPE Cleansing Wipes to its distributors for any affected first aid kits or arrange with distributors to return the complete first aid kit for rework. For details of your requirements in this recall process, please see required actions below:

Required Actions

1. Please inform all users of this product defect correction and forward this notice to all who need to be aware of the affected product within your organisation.
2. Inspect all first aid kits in your possession which were delivered to you between **7 May 2020 and 25 August 2020**, to determine if the batches (identified in **Appendix A**) of the AEROWIPE Cleansing Wipes can be found in the kit.
3. Remove and retain the affected AEROWIPE Cleansing Wipes and record the quantity of first aid kits affected in the **Response Card** enclosed and contact Aero Healthcare to confirm the replacements required for the first aid kits or if you would prefer to return the first aid kits to Aero Healthcare for rework instead.
4. Aero Healthcare will then arrange for replacement AEROWIPE Cleansing Wipes to be sent to you along with rework instructions.
5. Included in the parcel sent from Aero Healthcare will be a return satchel of a size depending on the quantity of affected wipes found. All affected AEROWIPE Cleansing Wipes are to be returned to Aero Healthcare as soon as possible, once the parcel is received.

Please complete the attached **Response Card** at your next best convenience and return it to us. Kindly complete the form even if you have no stock which is subject to recall, as we require this information to reconcile this process.

Finally, please retain this letter in a prominent position for one month in the case that stock is in transit.

We apologise for any inconvenience this recall may cause and if you have further questions, please do not hesitate to contact Aero Healthcare.

Kind Regards,



Murray Scott
Regulatory Officer

Appendix A – Affected First Aid Kits (between May 2020 to August 2020)

#	Product Code	Product Description
1	AFAK3M	DEFENDER Tough Metal First Aid Kit Metal 23 x 16.5 x 70cm
2	AFAK3P	DEFENDER Plastic Neat First Aid Kit Orange Plastic 25.5 x 23.5 x 9cm
3	AFAK3S	DEFENDER Softpack Versatile First Aid Kit Softpack 19.5 x 13 x 9cm
4	AFAK3W	DEFENDER First Aid Kit W/Proof Plastic Plastic 17.6 x 24.8 x 7.6cm
5	AFAK4C	RESPONDER Plastic Rugged First Aid Kit Orange/White 23.3 x 26.6 x 9.8cm
6	AFAK4M	RESPONDER Tough Metal First Aid Kit Small Metal 38 x 24 x 12cm
7	AFAK4P	RESPONDER Plastic Neat First Aid Kit Small Plastic 27 x 28 x 9.5cm
8	AFAK4R	RESPONDER Refill
9	AFAK4S	RESPONDER Softpack Versatile F/A Kit Small Softpack 24.5 x 15.5 x 10cm
10	AFAK4SF	RESPONDER F&B Softpack Versatile F/A Kit Small Softpack 24.5 x 15.5 x 10cm
11	AFAK4T	RESPONDER Plastic Tacklebox Kit White/Clear 42 x 21 x 22
12	AFAK4W	RESPONDER First Aid Kit W/Proof Plastic Plastic 24.3 x 24.3 x 8cm
13	AFAK5C	OPERATOR Plastic Rugged First Aid Kit Orange/White 26.3 x 34.7 x 11cm
14	AFAK5M	OPERATOR Tough Metal First Aid Kit Medium Metal 42 x 28.5 x 13cm
15	AFAK5P	OPERATOR Plastic Neat First Aid Kit Medium Plastic 28 x 34 x 10cm
16	AFAK5R	OPERATOR 5 Series Refill Refill
17	AFAK5RF	OPERATOR 5 Series F&B Refill Refill
18	AFAK5S	OPERATOR Softpack Versatile F/A Kit Medium Softpack 27 x 36 x 10cm
19	AFAK5SF	OPERATOR F&B Softpack Versatile F/A Kit Medium Softpack 27 x 36 x 10cm
20	AFAK5T	OPERATOR Plastic Tacklebox Kit White/Clear 42 x 21 x 22
21	AFAK6M	COMMANDER Tough Metal First Aid Kit Large Metal 57.5 x 41 x 13cm
22	AFAK6MF	COMMANDER Tough F&B Metal First Aid Kit Large Metal 57.5 x 41 x 13cm
23	AFAK6S	COMMANDER Softpack Versatile F/A Kit Large Softpack 34 x 36 x 23cm
24	AFAKHFA45S	Highlands First Aid Workplace Softpack, Green 36 x 27 x 10cm
25	AFAKRA34C-I	Remote Area LOW RISK F/A Kit Rugged Orange/White 27 x 23 x 9cm
26	AFAKRA45C-I	Remote Area Plastic Rugged F/A Kit Rugged Orange/White 23.3 x 26.6 x 9.8cm
27	AFAKRA4R-I	Remote Area_ 4 Series REFILL
28	AFAKRA5C-I	Remote Area Plastic Rugged F/A Kit Rugged Orange/White 26.3 x 34.7 x 11cm
29	AFAKRA5R-I	Remote Area_ 5 Series REFILL

30	AFAKRA6C-I	Remote Area HIGH RISK Plastic F/A Kit Rugged Orange 42.8x30.4x14.6cm
31	AFAKTQ4S-I	Tacmed Responder Vehicle F/A Kit Small Softpack 24.5 x 15.5 x 10cm
32	C.AFAK3CS	CUSTOM_ Plastic Rugged Sports Kit Orange/White 23.3 x 26.6 x 9.8cm
33	C.AFAK3M	CUSTOM_ Metal First Aid Kit Metal 23 x 16.5 x 70cm
34	C.AFAK3P	CUSTOM_ Plastic First Aid Kit Orange Plastic 25.5 x 23.5 x 9cm
35	C.AFAK3R	CUSTOM_ Series 3 Refill Pack
36	C.AFAK3S	CUSTOM_ Softpack Versatile First Aid Kit Softpack 19.5 x 13 x 9cm
37	C.AFAK3W	CUSTOM_ Plastic W/P First Aid Kit Plastic 17.6 x 24.8 x 7.6cm
38	C.AFAK4C	CUSTOM_ Plastic First Aid Kit Orange/White 23.3 x 26.6 x 9.8cm
39	C.AFAK4M	CUSTOM_ Metal First Aid Kit Small Metal 38 x 24 x 12cm
40	C.AFAK4MF	CUSTOM_ Metal F&B First Aid Kit Small Metal 38 x 24 x 12cm
41	C.AFAK4P	CUSTOM_ Plastic First Aid Kit Small Plastic 27 x 28 x 9.5cm
42	C.AFAK4R	CUSTOM_ 4 Series Refill Pack Refill
43	C.AFAK4RF	CUSTOM_ 4 Series F&B Refill Pack Refill
44	C.AFAK4S	CUSTOM_ Softpack Versatile First Aid Kit Small Softpack 24.5 x 15.5 x 10cm
45	C.AFAK4T	CUSTOM Plastic Tacklebox Kit White/Clear 42 x 21 x 22
46	C.AFAK4W	CUSTOM_ Plastic W/P F/A Kit Plastic 24.3 x 24.3 x 8cm
47	C.AFAK5C	CUSTOM_ Plastic First Aid Kit Orange/White 26.3 x 34.7 x 11cm
48	C.AFAK5M	CUSTOM_ Metal First Aid Kit Medium Metal 42 x 28.5 x 13cm
49	C.AFAK5MF	CUSTOM_ Metal F&B First Aid Kit Medium Metal 42 x 28.5 x 13cm
50	C.AFAK5P	CUSTOM Plastic Neat First Aid Kit Medium Plastic 28 x 34 x 10cm
51	C.AFAK5R	CUSTOM_ 5 Series Refill
52	C.AFAK5S	CUSTOM_ Softpack Versatile First Aid Kit Medium Softpack 27 x 36 x 10cm
53	C.AFAK5T	CUSTOM Plastic Tacklebox Kit White/Clear 42 x 21 x 22
54	C.AFAK6C	CUSTOM_ Plastic First Aid Kit Orange/White 30.5 x 43 x 14.5cm
55	C.AFAK6CF	CUSTOM F&B Rugged First Aid Kit Orange/White 30.5 x 43 x 14.5cm
56	C.AFAK6M	CUSTOM_ Metal First Aid Kit Large Metal 57.5 x 41 x 13cm
57	C.AFAK6R	CUSTOM_ 6 Series Refill Refill
58	C.AFAK6S	CUSTOM Softpack Versatile F/A Kit Large Softpack 34 x 36 x 23cm
59	C.COSAFAK3TS	COS_ 3 Series Sports Tacklebox_ FIRST082 White/Clear 42 x 21 x 22
60	C.COSAFAK45S	COS_ 4 Series in 5S softpack_ FIRST072 Medium Softpack 27 x 36 x 10cm
61	C.COSAFAK4C	COS_ 4 Series Rugged F/A Kit_ FIRST077 Orange/White 23.3 x 26.6 x 9.8cm
62	C.COSAFAK4M	COS 4 Series Tough F/A Kit FIRST074 Small Metal 38 x 24 x 12cm
63	C.COSAFAK4R	COS 4 Series Refill FIRST9913 Plastic 13 x 21 x 7.5cm
64	C.COSAFAK5S	COS_ 5 Series Softpack Kit_ FIRST4203 Medium Softpack 27 x 36 x 10cm