Farmasia Sdn Bhd

August, 28th, 2023

URGENT: MEDICAL DEVICE RECALL
BIO-AQUACEL EYE SAFE
MDA NO. : GB9985320-46507

(See enclosed Product Label)

TEGA KUANTUM SDN. BHD. (1078563-M)
Block A-F-TG2 & A-F-TG3, FRIM-MTDC Technology Centre II,
Jalan Kapur, Forest Research Institution Malaysia,
52109, Kepong,
Selangor.

28th August 2023

(Attn: Mr Lee Kian Leong)

Dear Device Distributor,

The purpose of this letter is to advise you that Farmasia Sdn. Bhd. is voluntarily recalling the Product Bio-AQUACEL Eye Safe. Product detail as follows:

Product Name : BIO-AQUACEL EYE SAFE

MDA NO. : GB9985320-46507

Intended Use : Intended for used as lubricant that gently soothes and moisturise eyes. This product is sterile and indicated for temporary relief of burning, irritation and discomfort due to dryness of eyes. Indication is to instil 1-2 drops into the affected eyes as needed, discard contents 4 weeks after opening.

Farmasia Sdn. Bhd. first started manufacture Bio-AQUACEL Eye Safe on August 2019.

This recall is classified under *Class II – Medium Risk*. The reason for the voluntary recall is under the reason of **Contamination Problem – Code A18**. This problem associates with the presence of any unexpected foreign substance found in the device, which may affect performance or intended use of the device. On 24th August 2023, Medical Device Authority (MDA) sent a notification to Farmasia Sdn. Bhd. and stated that Bio-AQUACEL Eye Safe have been confirmed to have chemical contamination of Germanium, which is an undeclared ingredient as per registered and approved by the authority. This raise concerns and safety issues as our finished product quality has been compromised without our knowledge.

The effects of the undeclared ingredient in Bio-AQUACEL Eye Safe however has not yet been studied and could possibly cause temporary or reversible health consequences; or there is remote probability that the device will cause serious consequences. Nevertheless, to current date, Bio-AQUACEL Eye Safe has not received any complaints and has no reported adverse event associated to this issue.

Consequently, we would like you to **immediately** execute product recall for the mentioned device manufactured and distributed from Year 2019 to current date, August 2023 which are the following batch ;

Batch Number	Name	Batch Size	Quantity	Mfg Date
2019				
19KL0012	Bio-Aquacel Eye Safe 10 mL	30 kg	2437	19/08/2019
19KL0015	Bio-Aquacel Eye Safe 10 mL	25 kg	2306	26/08/2019
19KL0016	Bio-Aquacel Eye Safe 10 mL	30 kg	2721	27/08/2019

2020				
20EL0050	Bio-Aquacel Eye Safe 10 mL	40 kg	3818	15/05/2020
20EL0058	Bio-Aquacel Eye Safe 10 mL		3813	30/05/2020
20EL0060	Bio-Aquacel Eye Safe 10 mL		3809	02/06/2020
20FL0064A	Bio-Aquacel Eye Safe 10 mL	128 kg	2841	17/06/2020
20FL0064B	Bio-Aquacel Eye Safe 10 mL		2867	19/06/2020
20FL0064C	Bio-Aquacel Eye Safe 10 mL		2927	19/06/2020
20FL0064D	Bio-Aquacel Eye Safe 10 mL		3087	19/06/2020
20JL0066A	Bio-Aquacel Eye Safe 10 mL	30 kg	2916	14/07/2020
20JL0066B	Bio-Aquacel Eye Safe 10 mL		2916	15/07/2020
20KL0077A	Bio-Aquacel Eye Safe 10 mL	30 kg	2830	14/08/2020
20KL0077B	Bio-Aquacel Eye Safe 10 mL		2900	18/08/2020
20NL0093A	Bio-Aquacel Eye Safe 10 mL	40 kg	4093	14/10/2020
20NL0093B	Bio-Aquacel Eye Safe 10 mL	40 kg	3971	14/10/2020
20NL0093C	Bio-Aquacel Eye Safe 10 mL	40 kg	3993	14/10/2020
20QL0102A1	Bio-Aquacel Eye Safe 10 mL	40 kg	1802	14/12/2020
20QL0102A2	Bio-Aquacel Eye Safe 10 mL		2000	15/12/2020
20QL0102B	Bio-Aquacel Eye Safe 10 mL	40 kg	3847	16/12/2020
2021				
21AL0003A	Bio-Aquacel Eye Safe 10 mL	120 kg	2064	14/01/2021
21AL0003B	Bio-Aquacel Eye Safe 10 mL		3038	15/01/2021
21AL0003C	Bio-Aquacel Eye Safe 10 mL		2681	26/01/2021
21AL0003D	Bio-Aquacel Eye Safe 10 mL		2319	27/01/2021
21DL0035A	Bio-Aquacel Eye Safe 10 mL	120 kg	2800	05/04/2021
21DL0035B	Bio-Aquacel Eye Safe 10 mL		2811	06/04/2021
21DL0035C	Bio-Aquacel Eye Safe 10 mL		2864	06/04/2021
21DL0035D	Bio-Aquacel Eye Safe 10 mL		3024	07/04/2021
21JL0062A	Bio-Aquacel Eye Safe 10 mL	120 kg	2978	12/07/2021
21JL0062B	Bio-Aquacel Eye Safe 10 mL		1950	12/07/2021
21JL0062C	Bio-Aquacel Eye Safe 10 mL		1935	12/07/2021
21JL0062D	Bio-Aquacel Eye Safe 10 mL		1939	12/07/2021
21JL0062E	Bio-Aquacel Eye Safe 10 mL		2723	12/07/2021
21ML0082A	Bio-Aquacel Eye Safe 10 mL	80 kg	2786	13/09/2021
21ML0082B	Bio-Aquacel Eye Safe 10 mL		2331	13/09/2021
21ML0082C	Bio-Aquacel Eye Safe 10 mL		2537	13/09/2021
21QL0105A	Bio-Aquacel Eye Safe 10 mL	79 kg	2695	08/12/2021
21QL0105B	Bio-Aquacel Eye Safe 10 mL		2280	09/12/2021
21QL0105C	Bio-Aquacel Eye Safe 10 mL		2538	10/12/2021
2022				
22CL0022A	Bio-Aquacel Eye Safe 10 mL	82.69 kg	3357	10/03/2022
22CL0022B	Bio-Aquacel Eye Safe 10 mL		2326	11/03/2022
22CL0022C	Bio-Aquacel Eye Safe 10 mL		2323	14/03/2022

22FL0040	Bio-Aquacel Eye Safe 10 mL	20 kg	1926	21/06/2022
22FL0041	Bio-Aquacel Eye Safe 10 mL		2007	27/06/2022
22KL0051A	Bio-Aquacel Eye Safe 10 mL	160 kg	4215	09/08/2022
22KL0051B	Bio-Aquacel Eye Safe 10 mL		4415	11/08/2022
22KL0051C	Bio-Aquacel Eye Safe 10 mL		3596	12/08/2022
22KL0051D	Bio-Aquacel Eye Safe 10 mL		3342	15/08/2022
22NL0071A	Bio-Aquacel Eye Safe 10 mL	12 kg	4638	18/10/2022
22NL0071B	Bio-Aquacel Eye Safe 10 mL		3069	18/10/2022
22NL0071C	Bio-Aquacel Eye Safe 10 mL		4012	18/10/2022
2023				
23FL0034A	Bio-Aquacel Eye Safe 10 mL	80 kg	3899	20/06/2023
23FL0034B	Bio-Aquacel Eye Safe 10 mL		4025	21/06/2023

This recall should be carried out to the retail level and recalled product shall be returned to Farmasia Sdn. Bhd. For end-user level, kindly discontinue use or discard product.

Kindly complete and return the enclosed return response form as soon as possible (*See Attachment*). Your cooperation is highly appreciated and necessary to prevent any further consequences from the authority. Should you have any questions, kindly contact us through contact details below:

Name : Nurul Asikin Mohammad Rapi
Contact No. : 03-89251888
Email : asikin@farmasia.com.my
Address : Farmasia Sdn. Bhd.
B2-2, Blok Ribosom, UKM-MTDC Technology Centre
43650, Bandar Baru Bangi,
Selangor Darul Ehsan.

Note : This recall is being made with the knowledge of the Medical Device Authority (MDA).

Authorised by:

FARMASIA SDN BHD 772557-D

Name : Wan Rizzal Bin Wan Zaki
Title : General Manager
Contact No. : 03-89251888
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