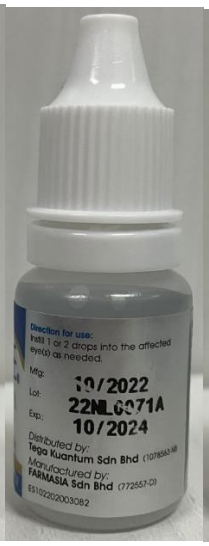
PIHAK BERKUASA PERANTI PERUBATAN
***MEDICAL DEVICE AUTHORITY* (*MDA*)**
Aras 6, Prima 9, Prima Avenue II
Blok 3547, Persiaran APEC
63000 CYBERJAYA
SELANGOR DARUL EHSAN

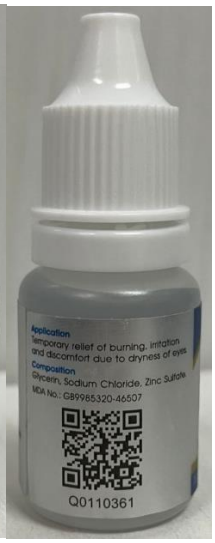
Tel. : 03-8230 0300
E-mel : mdb@mda.gov.my
Portal : portal.mda.gov.my

MEDICAL DEVICE RECALL NOTICE

MDA REFERENCE NUMBER	**MDA/Recall/P0205-45964073-2023**
MEDICAL DEVICE NAME	**Bio-Aquacel Eye Safe**
INTENDED USE	**Bio-aquacel eye safe is intended for used as lubricant that gently soothes and moisturise eyes. This product is 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.**
BATCH NO./LOT NO.	**Refer APPENDIX I**
RECALLING ESTABLISHMENT	**FARMASIA SDN BHD**
REASON OF RECALL	**Contaminated with an undeclared Germanium that is not registered and approved.**
RECALL CLASS	**CLASS II**
ACTION & RECOMMENDATION	**Consumers and other parties that have the recalled product should stop using the product and discard it. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this product.** **Field Safety Notice APPENDIX II**
CONTACT INFORMATION	**For further information, please contact:** **Authorized representative:** **FARMASIA SDN BHD** **B2-2, BLOCK RIBOSOM, UKM-MTDC TECHNOLOGY CENTRE, 43650, SELANGOR.** **Tel:+60389251888 Email: enquiries@farmasia.com.my**

DEVICE PHOTOS





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APPENDIX I

BATCH NO./LOT NO.

19KL0012 19KL0015 19KL0016 20EL0050 20EL0058 20EL0060 20FL0064A 20FL0064B 20FL0064C 20FL0064D 20JL0066A 20JL0066B 20KL0077A 20KL0077B 20NL0093A 20NL0093B 20NL0093C 20QL0102A1 20QL0102A2 20QL0102B 21AL0003A 21AL0003B 21AL0003C 21AL0003D 21DL0035A 21DL0035B 21DL0035C 21DL0035D 21JL0062A 21JL0062B 21JL0062C 21JL0062D 21JL0062E 21ML0082A 21ML0082B 21ML0082C 21QL0105A 21QL0105B 21QL0105C 22CL0022A 22CL0022B 22CL0022C 22FL0040 22FL0041 22KL0051A 22KL0051B 22KL0051C 22KL0051D 22NL0071A 22NL0071B 22NL0071C 23FL0034A 23FL0034B

APPENDIX II

FARMASIA

10th October 2023

URGENT - Field Safety Notice

To all users of the BIO-AQUACEL EYE SAFE

Re: Bio-Aquacel Eye Safe with Contamination Problem

Dear customer,

This letter is to inform you of a potential malfunction and hence hazard to patients when using Bio-Aquacel Eye Safe manufactured and distributed from Year 2019 to current date, August 2023 which are the following batch ;

Product Number/ Catalogue Number	Lot/Serial Number	Manufacturing/ Distribution Date	Expiration Date
FFP032.010	19KL0012	08/2019	08/2021
FFP032.010	19KL0015	08/2019	08/2021
FFP032.010	19KL0016	08/2019	08/2021
FFP032.010	20EL0050	05/2020	05/2022
FFP032.010	20EL0058	05/2020	05/2022
FFP032.010	20EL0060	06/2020	06/2022
FFP032.010	20FL0064A	06/2020	06/2022
FFP032.010	20FL0064B	06/2020	06/2022
FFP032.010	20FL0064C	06/2020	06/2022
FFP032.010	20FL0064D	06/2020	06/2022
FFP032.010	20JL0066A	07/2020	07/2022
FFP032.010	20JL0066B	07/2020	07/2022
FFP032.010	20KL0077A	08/2020	08/2022
FFP032.010	20KL0077B	08/2020	08/2022
FFP032.010	20NL0093A	10/2020	10/2022
FFP032.010	20NL0093B	10/2020	10/2022
FFP032.010	20NL0093C	10/2020	10/2022
FFP032.010	20QL0102A1	12/2020	12/2022
FFP032.010	20QL0102A2	12/2020	12/2022
FFP032.010	20QL0102B	12/2020	12/2022
FFP032.010	21AL0003A	01/2021	01/2023
FFP032.010	21AL0003B	01/2021	01/2023
FFP032.010	21AL0003C	01/2021	01/2023
FFP032.010	21AL0003D	01/2021	01/2023
FFP032.010	21DL0035A	04/2021	04/2023
FFP032.010	21DL0035B	04/2021	04/2023
FFP032.010	21DL0035C	04/2021	04/2023
FFP032.010	21DL0035D	04/2021	04/2023
FFP032.010	21JL0062A	07/2021	07/2023
FFP032.010	21JL0062B	07/2021	07/2023
FFP032.010	21JL0062C	07/2021	07/2023
FFP032.010	21JL0062D	07/2021	07/2023
FFP032.010	21JL0062E	07/2021	07/2023

FARMASIA Sdn. Bhd.772557-D B2-2 Block Ribosom, UKM-MTDC Technology Centre, 43650 Bandar Baru Bangi, Selangor, Malaysia
tel : +60 3 8925 1888 fax : +60 3 8925 2888 email : enquiries@farmasia.com.my

FFP032.010	21ML0082A	09/2021	09/2023
FFP032.010	21ML0082B	09/2021	09/2023
FFP032.010	21ML0082C	09/2021	09/2023
FFP032.010	21QL0105A	12/2021	12/2023
FFP032.010	21QL0105B	12/2021	12/2023
FFP032.010	21QL0105C	12/2021	12/2023
FFP032.010	22CL0022A	03/2022	03/2024
FFP032.010	22CL0022B	03/2022	03/2024
FFP032.010	22CL0022C	03/2022	03/2024
FFP032.010	22FL0040	06/2022	06/2024
FFP032.010	22FL0041	06/2022	06/2024
FFP032.010	22KL0051A	08/2022	08/2024
FFP032.010	22KL0051B	08/2022	08/2024
FFP032.010	22KL0051C	08/2022	08/2024
FFP032.010	22KL0051D	08/2022	08/2024
FFP032.010	22NL0071A	10/2022	10/2024
FFP032.010	22NL0071B	10/2022	10/2024
FFP032.010	22NL0071C	10/2022	10/2024
FFP032.010	23FL0034A	06/2023	06/2025
FFP032.010	23FL0034B	06/2023	06/2025

When does this malfunction occur and what are the potential risks ?

Malfunction of the medical device is due to **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 contamination from 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.

What steps can the user take to avoid the potential risk of this issue?

- Immediate stop and discontinuance of the Bio-Aquacel Eye Safe usage.
- Return the remaining stock of Bio-Aquacel Eye Safe to the Manufacturer.
- Seek medical attention if any adverse reaction is observed.

How will the issue finally be resolved?

Farmasia Sdn. Bhd. have de-registered the medical device Bio-Aquacel Eye Safe from the Medical Device Authority effective 30th August 2023. This is to ensure the product is no longer in the market and accessible to the public at large.