

**DUREX REAL FEEL CONDOM - 3 BATCHES RECALL****30 July 2018**

Description	SKU	Batch no.	Expiration Date	Registration No.
Durex Real Feel Condom 3s pack	8104034	1000422259	31 Jan 2021	DE0009146
Durex Real Feel Condom 10s pack	8103522	1000433144	31 Jan 2021	
		1000438055	31 Jan 2021	

***The above product identifiers are specific to Singapore. There are other identifiers and/lots affected globally, please verify with the distributor from the country of your purchase.**

Distributed by:

Reckitt Benckiser (Singapore) Pte Ltd

Manufacturing Facility Information:

SSL MANUFACTURING LTD.

Wellgrow Industrial Estate, 100 Moo 5, Bangna-Trad KM 36

Bangsamak, Bangpakong, Chachoengsao, 24180, Thailand

TO WHOM IT MAY CONCERN

Durex Real Feel Condoms are lubricated polyisoprene (PI) non-latex condoms engineered to provide natural skin on skin feeling for latex-sensitive users. We are writing to inform you of a decision to conduct a consumer level recall of 3 batches of Durex Real Feel Condom in Singapore.

Reason for Recall

Following observation of variable burst pressure performance of PI condoms manufactured during 2018, RB conducted an internal investigation and identified that batches 1000433144, 1000438055 & 1000422259 marketed in Singapore have failed our stringent quality standards (1.0kPa) on retesting.

We have undertaken stress testing and determined that at the end of the shelf-life, batches 1000433144, 1000438055 & 1000422259 may not meet the minimum requirements (0.8kPa) of the relevant international standard ISO23409:2011 standard for Male condoms – requirements and test methods for condoms made from synthetic materials. The batches in question passed burst pressure testing at the time of release.

An investigation is ongoing to clearly identify the root cause of the variable performance. All batches of PI condoms manufactured in 2018 have been retested and all other batches marketed previously in this market have passed our stringent quality specification limit.

Health Assessment

This product is intended to provide a method of contraception and prevent the transmission of sexually transmitted infections (STIs) through the physical barrier properties of the polyisoprene (PI) non-latex condom. PI condoms are manufactured from synthetic rubber cis-polyisoprene that has a

similar chemical structure to natural rubber. They have very similar properties to natural latex condoms but do not contain the naturally occurring proteins that can cause Type I allergies so are considered to offer a benefit to consumers sensitive to latex.

The risk to the general population with regards to this incident is this could result in an increase in the number of condoms that break during application or use. A certain level of breakage is anticipated and is contemplated as part of the acceptance quality limit (AQL) of 1.5 for non-conforming condoms in the ISO 23409:2011 standard for Male condoms – Requirements and test methods for condoms made from synthetic materials. The product is labelled as follows to ensure consumers are informed: "Seek medical advice as soon as possible, at least within 72 hours should a condom leak or burst during use."

There are two relevant ISO standards for assessing the quality of male condoms ISO 23409:2011 (Male condoms – Requirements and test methods for condoms made from synthetic materials) and ISO 4074:2015 (Natural rubber latex condoms - Requirements and test methods).

When Reckitt Benckiser Healthcare (UK) LTD registered and marketed condoms from Synthetic Polyisoprene (PI), the only standard available was ISO 4074:2002 (Natural rubber latex condoms - Requirements and test methods) which has now been updated to ISO 4074:2015. To ensure a consistent global quality standard was applied to male condoms, the limits for the airburst properties were set at the time to comply with the ISO 4074:2002 requirements. The minimum 1.0kPa burst pressure was therefore established as a specification limit for the PI condoms because there was no other applicable standard available at the time.

The synthetic condom standard, ISO 23409:2011 (Male condoms – Requirements and test methods for condoms made from synthetic materials), was officially published in 2012.

This standard does not contain specific values for airburst properties but defines that manufacturers shall establish appropriate minimum pressure and volume limits for the specific condom based on the airburst properties of the lot or lots used for the clinical trial and determine the airburst properties using a sample size of at least 2000 condoms.

The ISO 23409 standard permitted manufacturers who had product marketed prior to the publication of the International Standard, to use existing specifications as established by their regulatory bodies for bursting properties, subject to those specifications being consistent with the requirements based on a representative sample of the product tested at the time of the clinical trial (ISO 23409:2011).

An assessment of the degree of compliance of the latex-free PI condoms against the requirement of the new standard was performed and verified based on 2000 condoms representative of the product sample tested at the time of the clinical trial. This established a minimum burst pressure of 0.8kPa.

RB opted not to change the registered specification of 1.0kPa to 0.8kPa burst pressure at that time as it met the ISO standard for synthetic condoms. The investigation is in progress and updates of relevant information will be provided.

Recall Strategy

As the batches in question do not meet the requirements of the ISO standard of 0.8KPa nor the more stringent internal burst pressure specification of 1.0KPa, RB will conduct a consumer level recall.

From 01 Aug 2018, consumers with unused Durex Real Feel Condoms of the affected batches may refer to Durex product website (www.durex.com.sg) for further information on recall procedure.

For Trade Partner:


Please check your remaining stock of Durex Real Feel condoms and return those of the affect batches via normal stock return process to our official distributor.

For Consumer:

- 1) Mail in affected Durex Real Feel Condom to 1 Sophie Road #04-14 Peace Centre, Singapore 228149.
- 2) Include Full Name, Phone number, Bank and Bank Account Number with the product.
- 3) Receive cash bank in within 14 days.

Please direct any questions or concerns with this recall to Durex Consumer CARELINE: 1800 875 0770

Sincerely,


Eric Yuen
Country Manager
Reckitt Benckiser (Singapore) Pte Ltd

Cc: Chairman Medical Board and relevant Head of Departments.



**DUREX REAL FEEL CONDOM - 3 BATCHES RECALL
NOTIFICATION - BUSINESS ACKNOWLEDGEMENT FORM**

30 July 2018

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		1000438055	31 Jan 2021	

We have received the voluntary medical device recall notification from Reckitt Benckiser (Singapore) Pte Ltd dated 30 July 2018 regarding batches of Durex Real Feel Condom as per above.

Company Representative
(Signature)

Date

Company Representative
(Name)

Name of Company

Please complete this form within 5 business days of receiving this notification and return it via email to lili.chua@rb.com.

**DUREX REAL FEEL CONDOM - 3 BATCHES RECALL
CONFIRMATION OF COMPLETION FROM BUSINESS****30 July 2018**

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		1000438055	31 Jan 2021	

We confirmed that all stocks included in the voluntary medical device recall by Reckitt Benckiser (Singapore) Pte Ltd dated 30 July 2018 have been returned to Reckitt Benckiser (Singapore) Pte Ltd.

Company Representative
(Signature)

Date

Company Representative
(Name)

Name of Company

Please complete this form within 5 business days after the completion of your return to RB and return it via email to lili.chua@rb.com.