eFax

FROM: Gulnara Gabidullina

EMAIL: gabidullina.g@pg.com

TO:

COMPANY:

FAX NUMBER: 16139540941

DATE: 2020-12-02 11:30:05 EST

RE: GCR13310284 - MD Tampax Tampons Malfunction Report- Final

HIGHLY CONFIDENTIAL- Section 20 Access To Information Act Relied Upon

Please find attached the Preliminary Problem Report for Tampax Tampons. The manufacturer awareness date for this MDR report is December 01, 2020.

Tampons fell apart. The MDR is being filed for the following malfunction cause; coming apart/ or Product is coming apart/or in pieces/ or shredding. These malfunctions have been determined to have the possibility of increasing the severity of Toxic Shock Syndrome (TSS).

If there are any questions, please feel free to contact the undersigned.

Thanks,

Richard Yekka / yekka.rl@pg.com / phone: 416-730-4121
Manager, Regulatory & Technical Relations / Procter & Gamble, Inc., / 4711 Yongs Street / North York, On M2N 6K8 / Canada

For Business Use Unless Otherwise Classified

Global Product Stewardship

Safety • Sustainability • Regulatory • Technical Relations

Health Canada / Santé Canada

Mandatory Medical Device Problem Reporting Form for Industry

CANADA VIGILANCE - MEDICAL DEVICE PROBLEM REPORTING PROGRAM

If more space is required, please attach additional sheets
Fields required to be completed for updates/final reports are indicated by an *

A. REPORTER INFORMATION

1. i. Reporter Type
○ Manufacturer ◉ Importer

In the case where the reporter is the importer:

ii. Did the importer report the incident to the manufacturer?
◉ Yes ○ No

iii. Is the importer also submitting the report on behalf of the manufacturer?
◉ Yes ○ No

2. Reporter Contact Information *

Richard Yekka,
P&G Inc., Manager, Regulatory & Technical Relations
Phone: 4160730-4121,
Email: yekka.rl@pg.com

3. Reporter File No. *
GCR13310284

4. Health Canada File No. (if applicable) *

5. Type of Report *
○ Preliminary ○ Update ◉ Final ○ Preliminary & Final

If "preliminary" only, anticipated date for the final report:
(YYYY-MM-DD)

If "update/final", date the previous report was submitted to Health Canada:
2020-09-07 (YYYY-MM-DD)

6. Date Submitted *
2020-12-02 (YYYY-MM-DD)

	Manufacturer	Importer
7. Name and Address	TAMBRANDS INC. UNITED STATES AUBURN, MAINE 2879 HOTEL ROAD 04210-8823	Procter & Gamble Inc., 4711 Yonge Street, 2nd Floor, Po Box 355 Station A, Toronto, Ontario, Canada, M5W 1C5
8. Health Canada assigned company identification number (if known):	127628	127628
9. Establishment License Number (if applicable):	N/A	523

B. INCIDENT INFORMATION

1. Classification of Incident *
i. ○ 10-Day ◉ 30-Day
ii. ◉ Canadian ○ Foreign
iii. ○ Investigational testing ○ Special Access Program
○ Radiation emitting device (if applicable)

2. Date of Incident
2020-06-20 (YYYY-MM-DD)

3. Reporter's Awareness Date
2020-12-01 (YYYY-MM-DD)

4. Patient Consequences

The consumer "freaked out" thinking the cotton is stuck inside of her.

5. Details of Incident

When bought Tampax Tampons and noticed a chunk of cotton came right out. I checked multiple Tampons from the pack, they all did it. I believe this is a health hazard and i am freaked out thinking there may be stuff still inside of me.

C. MEDICAL DEVICE INFORMATION

1. Trade/Brand Name *
Tampax Tampons

2. Control/Lot/Serial No.

3. Expiration Date
(YYYY-MM-DD)

4. i. Device Classification
○ I ◉ II ○ III ○ IV
ii. Device License No.
32077
iii. Device Identification No
N/A
iv. Manufacturer's Medical Device Identifier (catalogue/model no.)
N/A

5. Software Version
N/A

6. Age of Device

7. How long was the device in use?

8. Was the device labelled as sterile?
○ Yes ◉ No

9. Availability of device for evaluation
○ Destroyed ○ Returned to Manufacturer/Importer
◉ Neither (with explanation)
The consumer provided photos about the carton of the product and about a tampon in a wrapper with the lot code information.

D. COMPLAINANT INFORMATION

1. Complainant is a:
◉ Consumer ○ Health professional ○ Other

2. Name of Complainant
PII - Withheld

3. Name of Health Care Facility (if applicable)

4. Address
PII - Withheld

5. Telephone No. and/or E-mail Address
PII - Withheld

E. INVESTIGATION INFORMATION

1. Investigative Actions and Timeline

Production code 7068208000V20903171747. The Tampax Pearl Active Fresh Regular Scented product was produced on 9th of March 2017 on Pearl V2 line.

The production documentation was checked related to the complaint and sampling and documentation was checked and no Quality defect was found that could be connected to the complaint. All equipment were checked and there were no deviations in the midrange report. There was no entry in the shift log book what may be directly in connection with the issue.

Quality Alerts/Incidents, consumer complaints and retain samples were checked in the local system with ± 15 days opening date range from the production date and no alerts initiated in the system that can be directly connected to the issue reported by the consumer.

This section only applies for preliminary & final, and final reports

2. Root Cause of Problem
Based on the available information there is no sign in the system about any manufacturing failure, and there was no product testing result that show any deviation; the product was produced as intended.
In case the consumer returns the samples further investigation can be executed based on relevant test method results.

3. Corrective Actions taken as a result of the investigation
N/A

There is no sign in the system about any manufacturing failure, and there was no product testing result what would show any deviation; the product was produced as intended.
In case the consumer returns the samples further investigation can be executed based on relevant test method results.

Tremblay, Jo-Anne C (HC/SC)

From: Tweedie, Brianne (HC/SC) on behalf of HPFB MHPSEIB EFAX / BIIEPSC DGPSA (HC/SC)
Sent: 2020-12-02 11:36 AM
To: mdpr / dimm (HC/SC)
Subject: FW: From " 15137600785"(Fax Message NO.0922)
Attachments: 20201202113202165.pdf

Brianne Tweedie
Senior Support Officer
MHPSEIB | BIIEPSC
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200 Eglantine Drive, Tunney's Pasture, A.L. 1908C Ottawa, Ontario K1A 0K9
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-----Original Message-----
From: 0808-1468-01-RICOHMP3555MFP@hc-sc.gc.ca <0808-1468-01-RICOHMP3555MFP@hc-sc.gc.ca>
Sent: 2020-12-02 11:32 AM
To: HPFB MHPSEIB EFAX / BIIEPSC DGPSA (HC/SC) <hc.hpfb.mhpseib.efax-biiepsc.dgpsa.sc@canada.ca>
Subject: From " 15137600785"(Fax Message NO.0922)

This E-mail was sent from "0808-1468-01-RICOHMP3555MFP" (MP 3555).

Queries to: 0808-1468-01-RICOHMP3555MFP@hc-sc.gc.ca