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 *

Baxter Corporation 7125 Mississauga Road Mississauga Ontario L5N0C2 Phone - 1(800) 387 8399 Fax - 1(855) 767 4572/Email: Randeep Cheema, randeep_cheema@baxter.com

3. Reporter File No. *

PR-1626761-1634780

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

NOT AVAILABLE

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:

2019-06-05 (YYYY-MM-DD)

6. Date Submitted *

2020-07-16 (YYYY-MM-DD)

	Manufacturer	Importer
7. Name and Address	BAXTER HEALTHCARE SA Po Box 8010 Zurich, CH, 8010	BAXTER CORPORATION, 7125 MISSISSAUGA ROAD, MISSISSAUGA, ON, L5N 0C2
8. Health Canada assigned company identification number (if known):	129789	101173
9. Establishment License Number (if applicable):	N/A	191

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

2019-02-12 (YYYY-MM-DD)

3. Reporter's Awareness Date

2019-03-11 (YYYY-MM-DD)

4. Patient Consequences

There was no patient involvement.

5. Details of Incident

On 11 Mar 2019, a healthcare professional reported Baxter that three (3) EXACTAMIX EVA TPN BAG 2000ML (product code 740, lo# 60131932) had leaked at the port. The bags were used to pump parenteral nutrition and leak was noted prior to administration to patient. Date of occurrence was on the 12th of February 2019. There was no patient involvement or medical injury involved.

C. MEDICAL DEVICE INFORMATION

1. Trade/Brand Name *
EXACTA-MIX EVA CONTAINER

2. Control/Lot/Serial No.
60131932

3. Expiration Date
(YYYY-MM-DD)

4. i. Device Classification
○ I ● II ○ III ○ IV

ii. Device License No.
5557

iii. Device Identification No
740

iv. Manufacturer's Medical Device Identifier (catalogue/model no.)
H938740

5. Software Version
Not Applicable

6. Age of Device
Not Available

7. How long was the device in use?
UNKNOWN

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

9. Availability of device for evaluation
○ Destroyed ● Returned to Manufacturer/Importer
○ Neither (with explanation)

Two samples were returned for evaluation.

D. COMPLAINANT INFORMATION

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

2. Name of Complainant
Kim Cook

3. Name of Health Care Facility (if applicable)
University of Alberta Hospital

4. Address
8440-112 Street Edmonton AB T6G 2B7 CANADA

5. Telephone No. and/or E-mail Address
780-407-8360/ Kim.Cook2@albertahealthservices.ca

Privacy Notice Statement: For the purposes of the Canada Vigilance - Medical Device Problem Reporting Program, information related to the identity of the complainant and/or reporter will be protected as personal information under the *Privacy Act*, and under the *Access to Information Act* in the case of an access to information request. For details with regard to personal information collected under this program, visit the Personal Information Bank; Health Canada; Health Products and Food Branch; Branch Incident Reporting System; HC PPU 088 at: http://infosource.gc.ca/inst/1476/1476-fedemp00-eng.asp

E. INVESTIGATION INFORMATION

1. Investigative Actions and Timeline
This is being submitted as an update to the final mandatory report submitted on 2019-06-05.

Two (2) samples were received at Baxter for evaluation. Functional testing was performed and revealed a leak between the spike port tubing and spike port connector. The reported issue was confirmed.

A batch review was performed for the reported Lot#, which indicated that this batch was released in accordance with manufacturing specifications. No related defects or exceptions were noted during the manufacturing, testing, and inspection of this lot.

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

2. Root Cause of Problem
The cause was not determined, however the most likely cause of the reported condition was due to inadequate or lack of cyclohexanone being applied to the cap when it was inserted to the spike port tubing during the manufacturing process.

3. Corrective Actions taken as a result of the investigation

Baxter will continue to monitor this issue and any identified trend will be addressed by Corrective and Preventative Actions (CAPA) as necessary.

Matson, Sarah (HC/SC)

From: Canada SHS PS Quality <Canada_ProductSurveillance_Quality@baxter.com>
Sent: 2020-07-16 4:31 PM
To: mdpr / dimm (HC/SC)
Subject: Four Final MDPRs updates PR-1626761-1664136 & PR-1626761-1634758 & PR-1626761-1634746 & PR-1626761-1634780
Attachments: PR-1626761-1664136_Update to Final MDPR.pdf; PR-1626761-1634758_Update to Final MDPR.pdf; PR-1626761-1634746_Update to Final MDPR.pdf; PR-1626761-1634780 _Update to Final MDPR.pdf

Dear Sir/Madam,

Please find enclosed four (4) follow-up MDPRs to four their respective Final Medical Device Problem Report submissions.

Please confirm receipt of this document. Thank you.

Christine He
Sr Quality Specialist, Product Surveillance
Baxter International Inc
7125 Mississauga Road
Mississauga, ON
L5N 0C2, Canada
Toll free 1-800-387-8399 x 6845
T: 905-369-6845
F: 1-855-767-4572