Emergent Protective Products USA, Inc.

Rev 2: February 2023
FSN Ref: RSDL2022

FSCA Ref: RSDL2022

Date: 2023-02-06

Field Safety Notice
Reactive Skin Decontamination Lotion (RSDL®)

For Attention of*: Identify either by name or role who needs to be aware of the hazard and/or take action. If this is multiple recipients then include full list.

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Field Safety Notice (FSN)
Reactive Skin Decontamination Lotion (RSDL®)
In a situation whereby an individual is exposed to CWA and needs immediate decontamination with RSDL, there exist the possibility of lack of efficacy of the device which may make the person vulnerable to health hazards from the Chemical Warfare Agents or T-2 toxin.

1. Information on Affected Devices*	
1.	1. Device Type(s)*
	The RSDL® (Reactive Skin Decontamination Lotion) Kit is an FDA-cleared device consisting of a lotion impregnated sponge in an easy-to-open packet. The RSDL Kit is intended to remove and/or neutralize chemical warfare agents and T-2 Toxin from the skin.
1.	2. Commercial name(s)*
	Reactive Skin Decontamination Lotion (RSDL®)
1.	3. Unique Device Identifier(s) (UDI-DI)
	N/A
	4. Primary clinical purpose of device(s)*
	To remove and/or neutralize chemical warfare agents and T-2 Toxin from the skin.
1.	5. Device Model/Catalogue/part number(s)*
	F5410ENG
1.	6. Software version
	N/A
1.	7. Affected serial or lot number range
	23005061
1.	8. Associated devices
	N/A

2. Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem*
	Emergent received 3 complaints from customers between 18 OCT 2022 - 15 NOV 2022 related to leaking packets. Note – Only one complaint was from Switzerland, the other 2 were from consignees in Canada and the United States.
2.	2. Hazard giving rise to the FSCA*
	Product in leaking packets may not perform as effectively as intended
2.	3. Probability of problem arising
	Low. The issue identified with the affected material was limited to the lots involved in the recall. Material manufactured prior to or after these lots would not be affected by the same root cause.
2.	4. Predicted risk to patient/users
	The leak could make the composition of the packet dry out or less RSDL available and that may affect the efficacy of the device. In a situation whereby an individual is exposed to CWA and needs immediate decontamination with RSDL, there exist the possibility of lack of efficacy of the device which may make the person vulnerable to health hazards from the Chemical Warfare Agents or T-2 toxin. Additionally, it was noted that the non-

	opened packets had come in contact with lotion from the leaked packets. This could result in unintentional prolonged skin, eyes, and mucous membrane exposure.
2.	5. Further information to help characterise the problem
	No recalled packets were distributed by the Swiss ICRC.
2.	6. Background on Issue
	Emergent received 3 complaints from customers between 18 OCT 2022 - 15 NOV 2022 related to leaking packets. Investigation identified that a change in the dimensions of a packet seal component led to inadequate heat sealing of the device which caused some packets to leak. The manufacturing process has been revised to address this issue.
2.	7. Other information relevant to FSCA
	N/A

3. Type of Action to mitigate the risk*		
3.	**1. Action To Be Taken by the User***	
	☐ Identify Device ☐ Quarantine Device ☐ Return Device ☒ Destroy Device ☐ On-site device modification / inspection ☐ Follow patient management recommendations ☐ Take note of amendment / reinforcement of Instructions For Use (IFU) ☐ Other ☒ None No recalled packets were distributed by the Swiss ICRC to end users.	
3.	2. By when should the action be completed?	February 2023
3.	3. Particular considerations for: (N/A) Choose an item. Is follow-up of patients or review of patients' previous results recommended? No N/A	
3.	4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	Yes
3.	**5. Action Being Taken by the Manufacturer***	
	☒ Product Removal ☐ On-site device modification/inspection ☐ Software upgrade ☐ IFU or labelling change ☒ Other ☐ None Replacement product provided to the distributor.	
3.	6. By when should the action be completed?	Q1 2023
3.	7. Is the FSN required to be communicated to the patient /lay user?	No

3.	8. If yes, has manufacturer provided additional information suitable for the patient/lay user in a patient/lay or non-professional user information letter/sheet?	
	No	Not appended to this FSN

4. General Information*		
4.	1. FSN Type*	New
4.	2. For updated FSN, reference number and date of previous FSN	N/A
4.	3. For Updated FSN, key new information as follows:	
	N/A	
4.	4. Further advice or information already expected in follow-up FSN? *	No
4.	5. If follow-up FSN expected, what is the further advice expected to relate to:	
	N/A	
4.	6. Anticipated timescale for follow-up FSN	N/A
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	Emergent Protective Products USA Inc.
	b. Address	46 Shelby Thames Drive, Hattiesburg MS 39402
	c. Website address	https://www.emergentbiosolutions.com/
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. * Yes – U.S. FDA was notified 07-12-2022	
4.	9. List of attachments/appendices:	N/A
4.	10. Name/Signature	Brent Sadler (Recall Lead) Sr. Director, Quality bsadler@ebsi.com204-275-4013

	Transmission of this Field Safety Notice
	This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (As appropriate) Please transfer this notice to other organisations on which this action has an impact. (As appropriate) Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback.*

Note: Fields indicated by * are considered necessary for all FSNs. Others are optional.