

## Recall Procedure Jungbunzlauer Inc.

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In the event of product or products necessitating a recall or market withdrawal, the following Jungbunzlauer Inc. contacts are to be notified:

<b>Recall Committee</b>	
Dan Rainville, President Carlos Torres, Sales Director Kendall Tyler, Head of Order Processing	Tze-Mai Wong, Technical Service Manager Anne Wimette, Financial Controller

If none of the above are available, contact Head Finance and Administration.  
In case of personal injury, contact Corporate Council.

### **Definitions (US Food and Drug Administration)**

Recalls are actions taken by a firm to remove a product from the market. Recalls may be conducted on a firm's own initiative, by FDA request, or by FDA order under statutory authority.

#### ***Class I***

A Class I recall is a situation in which there is a reasonable probability that the use of or exposure to a violative product will cause serious adverse health consequences or death.

#### ***Class II***

A Class II recall is a situation in which use of or exposure to a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.

#### ***Class III***

A Class III recall is a situation in which use of or exposure to a violative product is not likely to cause adverse health consequences.

#### ***Market withdrawal***

A market withdrawal occurs when a product has a minor violation that would not be subject to FDA legal action. The firm removes the product from the market or corrects the violation. For example, a product removed from the market due to tampering, without evidence of manufacturing or distribution problems, would be a market withdrawal.

### **Information Gathering**

The nature of the problem or cause for recall, the product, lot numbers in question must be identified and recorded. All other relevant information such as the person reporting the emergency, their phone numbers, location and affiliation should also be taken.

### **Management Notification**

The Recall Committee shall be immediately notified.

### **Determination of Recall Class**

If possible, the class of recall is I, II, III or market withdrawal as defined is determined.

**Determination of the location and distribution of the product(s)**

Using our business system and any other available information, all customers and warehouses to whom the lot was sent will be immediately identified.

**Notification, Quarantine and Containment**

Using fax and phone, each customer and warehouse will be personally contacted and shall be requested to immediately determine the status of the inventory of the material and quarantine any of the product in question.

**Third Party Notification**

If the product has been subject to further distribution, the customer will be asked to contact subsequent customers to do likewise.

**Advisory of Containment and Quarantine**

Warehouses and customers will notify Jungbunzlauer of their success and/or failure to locate and quarantine the recall material. If the product has been incorporated into another product, this should also be noted. Based on the situation, subsequent products may need to be recalled.

**Reporting**

Jungbunzlauer personnel will report to the recall committee the status of the quarantined materials and or subsequent usage thereof.

**Resolution and/or Retrieval**

As necessary, arrangements will be made to retrieve the quarantined product and handle appropriately.

**Investigation and Corrective Actions**

Investigation into the cause of the problem will be made and corrective actions taken. Preventative actions will be taken to minimize the possibilities of future occurrences.

**Customer Notifications**

Customers involved will be notified of the results of the investigation and the corrective actions to be taken. If there are liability issues and or financial considerations, information releases should be approved by corporate council.

**Conclusion**

A follow-up meeting of the Recall Committee will be held to de the efficiency of the Recall, review the results, and if necessary institute any changes needed in recall procedures.

Questions, comment, suggestions, etc. regarding this recall procedure should be directed to the Technical Service Manager.

Any liability issues will be referred to Corporate Council.

## Emergency Contact List

<b>National Chemical Emergency Centre</b> 24 Hour Emergency Phone Number <b>NCEC 1 202 464 2554</b>	<b>President</b> <b>(24/7 Emergency Contact)</b> Dan Rainville Phone: 781 532 8607    Mobile: 508 400 7575 <a href="mailto:dan.rainville@jungbunzlauer.com">dan.rainville@jungbunzlauer.com</a>
<b>Sales Director</b> Carlos Torres Phone: 781 532 8605    Mobile: 774 278 3758 <a href="mailto:carlos.torres@jungbunzlauer.com">carlos.torres@jungbunzlauer.com</a>	<b>Head of Order Processing</b> <b>(24/7 Emergency Contact)</b> Kendall Tyler Phone: 781 532 8615    Mobile: 617 417 3763 <a href="mailto:kendall.tyler@jungbunzlauer.com">kendall.tyler@jungbunzlauer.com</a>
<b>Financial Controller</b> Anne Wimette Phone: 781 532 8604    Mobile: 774 573 9549 <a href="mailto:anne.wimette@jungbunzlauer.com">anne.wimette@jungbunzlauer.com</a>	<b>Technical Contact</b> Tze-Mai Wong Phone: 781 532 8624 <a href="mailto:tze-mai.wong@jungbunzlauer.com">tze-mai.wong@jungbunzlauer.com</a>

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