Subject: Recall of Probiotic Dietary Supplement for Infants and Children due to contamination with Rhizopus oryzae-reg.

An alert has been received from INFOSAN with regard to the recall of a probiotic health supplement, known as ABC Dophilus Powder, for infants and children due to contamination with Rhizopus oryzae. The fungus Rhizopus oryzae may cause Mucormycosis.

2. Mucormycosis is a rare infection that may cause health problems to consumers, particularly pre-mature infants/infants, children, and those with weakened immune systems. It may also occur (rarely) in people who are otherwise healthy. Risk factors for developing Mucormycosis include: uncontrolled diabetes; cancer; organ transplant; neutropenia (low white blood cell count); skin trauma (cuts, scrapes, punctures, or burns).

3. The distribution of the product has been suspended while US FDA and the company continue to investigate the source of the problem. However, the product has been distributed in India through pharmacies, retail stores, wholesale outlets, internet etc.

4. The Recalled Product Details are as follows:

   (i) Description: Solgar ABC Dophilus® Powder NET Wt. 1.75 oz (50 g)
   (ii) UPC Code: 0 33984 00010 0
   (iii) Label: Solgar
(iv) Lot#: 074024-01R1, 074024-01, 074024-02
(v) Expiration Date: 7/31/15

Since the implicated product has been sold to India, it is important to report the cases of infection, if any and suspend the consumption of the supplement for infants and Children.

This information is being brought to the notice of all stakeholders and public at large.

(Kotwal)
(Vinod Kotwal)
Director (Codex)

Enclosed: INFOSAN Documents

To:

1. Director, National Centre of Control Disease (NCDC)
2. All Authorized Officers, FSSAI
3. Custom Authorities
4. All Food Safety Commissioner of State/UTs
5. Shri Sanjay Gupta, Assistant Director, Enforcement, FSSAI
6. FSSAI Website
Recall of Probiotic Dietary Supplement for Infants and Children due to contamination with Rhizopus oryzae

Alert details

On 19 November 2014 in the United States of America, the US FDA announced that Solgar, INC. issued a recall of ABC Dophilus Powder because the product was found to contain Rhizopus oryzae, a fungus which may cause Mucormycosis. Testing conducted by a local medical facility revealed the presence of mold in unopened 1.75oz (50g) containers of Solgar ABC Dophilus Powder. This mold was later confirmed by the US CDC as Rhizopus oryzae. US CDC provided this information to the US FDA on November 12, 2014.

Mucormycosis is a rare infection that may cause health problems to consumers, particularly pre-mature infants/infants, children, and those with weakened immune systems. It may also occur (rarely) in people who are otherwise healthy. Risk factors for developing Mucormycosis include: uncontrolled diabetes; cancer; organ transplant; neutropenia (low white blood cell count); skin trauma (cuts, scrapes, punctures, or burns).

ABC Dophilus® Powder, sold by Solgar Inc. of Leonia, New Jersey, was used as part of the in-hospital course of treatment for a preterm infant who died on 11 October 2014 in the USA. Gastrointestinal tissue from the infant underwent laboratory testing at US CDC which revealed invasive mucormycosis due to the mold Rhizopus oryzae.

This product was distributed across the USA and also to the United Kingdom and Israel. In addition, the product was available for purchase via the internet. Further details regarding which countries may have received the recalled product via the internet are pending.

The distribution of the product has been suspended while US FDA and the company continue to investigate the source of the problem.

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Recall -- Firm Press Release

Consumers who have purchased the recalled product should not consume it or give it to infants, and should consult with their physician or health care provider if they have.

To date, the INFOSAN Secretariat has not been informed of additional cases of illness linked to this product outside of the USA.

If cases of Mucormycosis are found to be linked to the implicated product (which has a
long shelf-life), please liaise with your National IHR Focal Point and also ensure this information is reported to the INFOSAN Secretariat so that we can accurately summarize the international aspects of this event.

Please note that information about this event will also be shared with National IHR Focal Points through their Event Information Site (EIS).

Hazard:

- Yeast/Fungi → Rhizopus oryzae

**Food category:** Products for special nutritional use
**Food involved:** Probiotic Dietary Supplement (Solgar ABC Dophilus® Powder)
- **WHO regions:** European Region
- Region of the Americas

**Countries:** United States of America
United Kingdom
Israel

**Source URL:** [https://extranet.who.int/infosan/en/content/recall-probiotic-dietary-supplement-infants-and-children-due-contamination-rhizopus-oryzae](https://extranet.who.int/infosan/en/content/recall-probiotic-dietary-supplement-infants-and-children-due-contamination-rhizopus-oryzae)
Recall -- Firm Press Release

FDA posts press releases and other notices of recalls and market withdrawals from the firms involved as a service to consumers, the media, and other interested parties. FDA does not endorse either the product or the company.

Solgar, INC. Issues Voluntary Class I Recall Of ABC Dophilus® Powder

Contact:
Consumer:
1-800-332-1088

FOR IMMEDIATE RELEASE — November 17, 2014 — Solgar, Inc., of Leonia, NJ, is voluntarily recalling ABC Dophilus® Powder. The recall was initiated, out of an abundance of caution, because the product was found to contain Rhizopus oryzae, which may cause Mucormycosis. This is a rare infection that may cause health problems to consumers, particularly pre-mature infants/infants, children, and those with weakened immune systems. Although, it may also occur (rarely) in people who are otherwise healthy. ABC Dophilus was used as part of the in-hospital course of treatment for a very preterm infant (<32 week gestation) who suffered from multiple complications, including intestinal mucormycosis, and died on October 11, 2014. Susceptible consumers should consult with their physician or health care provider if they have used this product.

Solgar is notifying consumers and customers not to consume this product

This product was distributed to: AL, AR, AZ, CA, CT, CO, FL, IA, IL, IN, MI, ME, MO, MA, NC, NE, NY, NJ, NV, OH, OK, PA, PR, UT, TN, TX, VT, KY, WI, WA, UK and Israel through pharmacy, retail stores, wholesale, internet, etc.

Description: Solgar ABC Dophilus® Powder NET Wt. 1.75 oz (50 g)
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Date 7/31/15

http://www.fda.gov/Safety/Recalls/ucm423219.htm
Testing conducted by the Centers for Disease Control revealed the presence of Rhizopus oryzae in 1.75 oz (50 g) containers of Solgar ABC Dophilus Powder.

The distribution of the product has been suspended while FDA and the company continue to investigate the source of the problem.

Risk factors for developing Mucormycosis include: uncontrolled diabetes; cancer; organ transplant; neutropenia (low white blood cells); skin trauma (cuts, scrapes, punctures, or burns). Susceptible consumers should consult with their physician or health care provider.

Consumers who have purchased Solgar ABC Dophilus® Powder are urged not to consume the product and should return it to the place of purchase for a full refund. Consumers with questions may contact the company at 888-534-6370, Monday-Friday, 9AM-7PM ET.

Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

Complete and submit the report Online: [www.fda.gov/MedWatch/report.htm](https://www.accessdata.fda.gov/scripts/medwatch/medwatch-online.htm)

Download form [http://www.fda.gov/Safety/MedWatch/HowToReport/DownloadForms/default.htm#](http://www.fda.gov/Safety/MedWatch/HowToReport/DownloadForms/default.htm#) or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178.

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RSS Feed for FDA Recalls Information
([AboutFDA/ContactFDA/StayInformed/RSSFeeds/Recalls/rss.xml](http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/Recalls/rss.xml))

Photo: [Product Labels (/Safety/Recalls/ucm423220.htm)](http://www.fda.gov/Safety/Recalls/ucm423220.htm)

Recalled Product Photos Are Also Available on FDA's [Flickr Photostream](http://www.flickr.com/photos/fdaphotos/set/72157639317944704/).