

## **Fast Facts:**

- The FDA is alerting tattoo artists and consumers that they should not use tattoo inks marketed and distributed by A Thousand Virgins, in grey wash shades labeled G1, G2, and G3 (Lot #129 exp 1/16).
- Through testing, the agency has found bacterial contamination, including *Mycobacterium chelonae*, in unopened bottles of these tattoo inks. The FDA tested the inks to assist the Florida Department of Health in its investigation of an outbreak of mycobacterial infections in people who recently got tattoos.
- On August 4, 2015, A Thousand Virgins recalled certain tattoo inks sold separately and in sets, but the FDA is concerned that artists and consumers are continuing to use these contaminated inks from their current stock. Also, tattoo products with the same lot number manufactured by A Thousand Virgins may still be available online and may be marketed by other distributors. The inks were sold in single units and in sets.
- Artists who purchase tattoo inks and consumers who purchase tattoo inks or who seek tattooing should check the ink bottles to see if they are included in the recall. If you find inks subject to recall, place the closed bottles of ink into a plastic bag, sealing or tying off the bag to prevent leakage. Put this first bag into a second bag and tie off this bag separately. Check with your local waste management authorities for any disposal requirements in effect in your area.

## **What is the Problem?**

FDA has identified microbiological contamination in unopened tattoo inks made by A Thousand Virgins, Inc. The tattoo inks are labeled G1, G2, and G3, indicating the shade.

FDA has tested unopened bottles of these inks and found contamination with a human pathogen, *Mycobacterium chelonae*, as well as *Microbacterium* organisms, and the molds *Cryptococcus albidus* and members of the *Penicillium* genus.

FDA is warning tattoo ink manufacturers, tattoo artists and consumers not to use these tattoo inks that are contaminated or have been recalled.

## **What are the Symptoms of Illness/Injury?**

When tattoo ink contaminated with *mycobacteria* is injected into the skin, the bacteria can cause an infection that remains at the site or that may spread throughout the body. Such infection might result in redness; swelling; itching; raised pink, red, or purple blemishes in the tattoo; or pain in the tattoo that does not go away. If you have these symptoms, you should seek medical treatment. You may also notice swollen and tender lymph nodes, at sites local and distant to the infected tattoo.

These infections can be severe and may require extensive treatment with antibiotics, hospitalization, or surgery. Sepsis, a potentially life-threatening body-wide infection of the blood, has been reported in cases of injection of contaminated tattoo inks. Once the infection has healed, the area may remain permanently scarred.

## **Who is at Risk?**

Because tattooing involves injecting ink under the skin, the use of contaminated inks may lead to an infection. People with pre-existing medical conditions, including heart or circulatory disease, diabetes, or patients with compromised immune systems, are particularly vulnerable.

## **What Do Consumers and Tattoo Artists Need To Do?**

Consumers and tattoo artists should know where their materials come from and should be able to identify and remove the contaminated inks described above. If you have used these inks and adverse events occur, contact the manufacturer and the FDA. Tattoo artists should not dilute inks with tap water, distilled water, filtered water, reverse osmosis water, or other non-sterile water that has the potential to be contaminated. In addition, consumers and tattoo artists should purchase inks from reputable manufacturers who source their ink ingredients appropriately and can attest to using good manufacturing practices. If you are a tattoo artist and are applying body art, advise your clients to monitor the application site closely and seek medical care if they notice redness, swelling, itching, bumps, or blemishes, or have pain in the tattoo site that does not go away. Please also inform your clients that they should be alert for rashes and inflamed tattooed areas beyond the normal healing period, as well as any tender lymph nodes, even those that are not near the tattoo. Please ask your clients to contact you, the artist, if they experience any of these symptoms, so you may remove the potentially contaminated ink from use. They should also seek medical care for their symptoms.

People with infected tattoos and tattoo artists whose clients notify them of potentially infected tattoos can report adverse events or side effects through the MedWatch Safety Information and Adverse Event Reporting Program.

### **What Do the Contaminated Products Look Like?**

The front panel of the label bears a circular logo with the name of the manufacturer, “A Thousand Virgins.” Centered within the circle are G1, G2, or G3, indicating the particular shade of grey wash ink. Bottles are marked as Lot #129 with an expiration date of 1/16. The contaminated inks are sold singly and in sets of three or four bottles.

### **Where are they Distributed?**

The tattoo inks and tattoo kits are sold online by A Thousand Virgins, at tattoo conventions and through other websites.

### **What is FDA doing about the Problem?**

The FDA is working with A Thousand Virgins to recall the contaminated inks and is investigating to determine how they became contaminated. The FDA and the Florida Department of Health will provide more information as it becomes available.

### **How can I Report a Problem?**

Adverse events (bad reactions) related to the use of FDA-regulated products can be reported through the MedWatch Safety Information and Adverse Event Reporting Program by:


- completing and submitting the adverse report online at [www.fda.gov/MedWatch/report.htm](http://www.fda.gov/MedWatch/report.htm); or
- downloading the pre-addressed, postage-paid FDA Form 3500 (or calling 1-800-332-1088 to request the form) and:
  - completing it and faxing it to 1-800-FDA-0178; or
  - mailing the completed form to MedWatch, 5600 Fishers Lane, Rockville, MD 20857.


### **For More Information:**


- Inks Used in Certain Tattoo Kits Cause Infections
- FDA Consumer Advice on Certain Tattoo Inks and Tattoo Kits Sold Online
- A Thousand Virgins, Inc. recall information

# Tattoo Inks Pose Health Risks

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## On This Page:

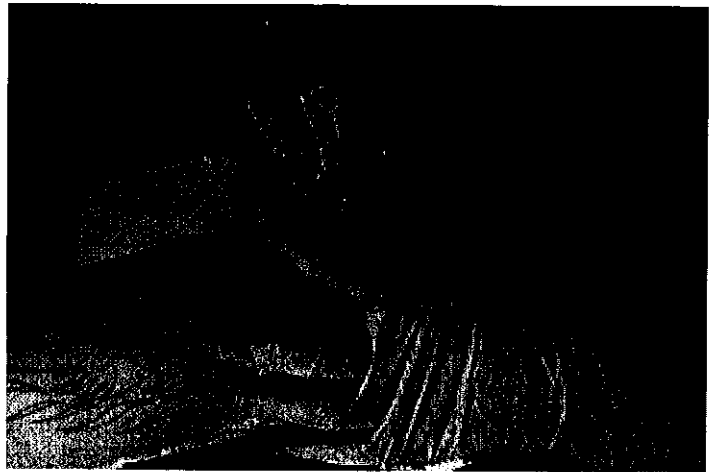
- [A Challenging Investigation](#)
- [Strategies for Controlling Risks of Infection](#)
- [Why Tattoo Inks Go Bad](#)

Tempted to get a tattoo? Today, people from all walks of life have tattoos, which might lead you to believe that tattoos are completely safe.

But there are health risks that can result in the need for medical care. The Food and Drug Administration (FDA) is particularly concerned about a family of bacteria called nontuberculous *Mycobacteria* (NTM) that has been found in a recent outbreak of illnesses linked to contaminated tattoo inks.

*M. chelonae*, one of several disease-causing NTM species, can cause lung disease, joint infection, eye problems and other organ infections. These infections can be difficult to diagnose and can require treatment lasting six months or more.

Some of these contaminated inks have caused serious infections in at least four states in late 2011 and early 2012. FDA is reaching out to tattoo artists, ink and pigment manufacturers, public health officials, health care professionals, and consumers to warn them of the potential for infection.



The bottom photo shows a tattoo infected with a nontuberculous *Mycobacteria* (NTM) bacteria. It is provided courtesy of Matthew J. Mahilberg, M.D., Dermatology Associates of Colorado, Englewood, Colo., and was obtained by Sarah Jackson, MPH, Colorado Department of Public Health and Environment.

FDA also warns that tattoo inks, and the pigments used to color them, can become contaminated by other bacteria, mold and fungi. To raise awareness and make diagnoses more accurate, FDA strongly encourages reporting of tattoo-associated complications to its MedWatch<sup>4</sup> program, says Linda Katz, M.D., M.P.H., director of FDA's Office of Cosmetics and Colors.

Getting the word out to tattoo artists is particularly critical. Even when they diligently follow hygienic practices, they may not know that an ink itself may be contaminated. Contamination is not always visible in the inks, Katz says.

FDA's goal is to encourage these artists to take certain precautions in their practice and to urge potentially infected clients to seek medical care. "Reporting an infection to FDA and the artist is important. Once the problem is reported, FDA can investigate, and the artist can take steps to prevent others from being infected," says epidemiologist Katherine Hollinger, D.V.M., M.P.H., from the Office of Cosmetics and Colors.

[back to top](#)

## **A Challenging Investigation**

Tattoo inks are subject to FDA regulation. FDA investigates and intervenes when a serious safety issue arises. And that's what happened here.

FDA's CORE (Coordinated Outbreak Response and Evaluation) Network initiated and coordinated the investigation with state and local health departments and laboratories, the Centers for Disease Control and Prevention (CDC), and FDA investigators working in numerous district offices.

The investigation began in January 2012 when FDA, through its MedWatch reporting program, learned about seven people in Monroe County, New York who had NTM infections. They'd all gotten tattoos from the same artist, who used the same brand of ink on all of them. The infections occurred on the newly acquired tattoos, with red bumps appearing soon after the tattoo had healed.

FDA later learned of 12 more people with an NTM infection who were also clients of this same tattoo artist. The same brand of ink was also used on them. Of these 19 people, 14 were confirmed to have the same type of NTM infection. An NTM sample from a sealed container of the same type of ink used to tattoo the affected individuals was a perfect match to the NTM linked to these infections.

Meanwhile, FDA learned of outbreaks of NTM infections in other states, including but not limited to Washington, Iowa, and Colorado. The cases in these states involved different NTM species or different ink manufacturers than those in New York. While the infections in Washington, Iowa, and Colorado were not linked to the New York infections, there was a link identified between the *M. chelonae* infections in Washington and Iowa.

For the New York outbreak alone, FDA investigators visited the tattoo ink supplier and manufacturer. These were located as far away as California. These investigations resulted in a recall of the implicated ink.

[back to top](#)

## **Strategies for Controlling Risks of Infection**

Tattoo artists can minimize the risk of infection by using inks that have been formulated or processed to ensure they are free from disease-causing bacteria, and avoiding the use of non-sterile water to dilute the inks or wash the skin. Non-sterile water includes tap, bottled, filtered or distilled water.

Consumers should know that the ointments often provided by tattoo parlors are not effective against these infections. NTM infections may look similar to allergic reactions, which means they might be easily misdiagnosed and treated ineffectively.

Once an infection is diagnosed, health care providers will prescribe appropriate antibiotic treatment according to Katz. Such treatment might have uncomfortable side effects, such as nausea or gastrointestinal problems. However, without prompt and proper treatment an infection could spread beyond the tattoo or become complicated by a secondary infection.

If you suspect you may have a tattoo-related infection, FDA recommends the following:

- Contact your health care professional if you see a red rash with swelling, possibly accompanied by itching or pain in the tattooed area, usually appearing 2-3 weeks after tattooing.
- Report the problem to the tattoo artist.
- Report the problem to MedWatch, on the Web or at 1-800-332-1088; or contact FDA's [consumer complaint coordinator](#)<sup>5</sup> in your area.

[back to top](#)

## Why Tattoo Inks Go Bad

Inks and pigments can be contaminated through:

- use of contaminated ingredients to make inks,
- use of manufacturing processes that introduce contaminants or allow contaminants to survive,
- use of unhygienic practices that contaminate ink bottles or mixing with contaminated colors,
- use of non-sterile water to dilute the inks, and
- using tattoo inks past their expiration date.

This article appears on [FDA's Consumer Updates page](#)<sup>6</sup>, which features the latest on all FDA-regulated products.

*August 22, 2012*

## For More Information

- [New England Journal of Medicine Article \(August 23, 2012\)](#)<sup>7,8</sup>
- [Tattoo-Associated Nontuberculous Mycobacterial Skin Infections — Multiple States, 2011–2012 \(CDC's Morbidity and Mortality Weekly Report\)](#)<sup>9</sup>
- [The Hidden Dangers of Getting Inked](#)<sup>10</sup>
- [Tattoos & Permanent Makeup](#)<sup>11</sup>
- [Outbreaks: Investigation, Response & Evaluation](#)<sup>12</sup>

## Related Consumer Updates

- [Bad Reaction to Cosmetics? Tell FDA](#)<sup>13</sup>
- [Think Before You Ink: Are Tattoos Safe?](#)<sup>14</sup>

Page Last Updated: 08/23/2012

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## **Risk of Infection from Contaminated Tattoo Inks**

August 23, 2012

The Food and Drug Administration (FDA) is alerting tattoo artists, ink and pigment manufacturers, public health officials, health care professionals, and consumers that some tattoo inks, and the pigments used to color them, can become contaminated by bacteria, mold, and fungus. Contaminated inks are known to have caused serious infections in people in at least five states over the past year.

Anyone who receives a tattoo with a contaminated ink is at risk for infection.

Tattoo inks can become contaminated with a variety of bacteria, but the family of bacteria called nontuberculous *Mycobacteria* (NTM), which has been linked to a 2011-2012 outbreak of infections, is of particular concern.

*M. chelonae*, one of several disease-causing NTM species, can cause a rash or raised red bumps in a tattooed area within a couple of weeks of receiving a tattoo. The infection can be difficult to diagnose and may be mistaken for an "allergic" reaction. *M. chelonae* can also cause lung disease, joint infection, eye problems, and other organ infections, and can require treatment lasting six months or more.

Tattoo artists can help to minimize the risk of infection by only using inks that have been processed to be free from harmful microorganisms. When purchasing inks, artists should ask the ink distributors what steps were taken to ensure that the product is free from harmful microorganisms.

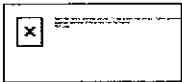
Use of sterile water to dilute inks helps to ensure that bacteria are not introduced during the dilution process. (Unboiled tap, bottled, distilled, and filtered water are not sterile and should not be used to dilute inks.)

Companies and individuals who manufacture or market cosmetics, including tattoo inks, have a legal responsibility to ensure the safety of their products. Steps to help ensure tattoo inks are free of harmful contaminants may include: carefully choosing the inks ingredients, using hygienic processing techniques, using preservatives to prevent the growth of microorganisms, validating post-manufacture processing and testing to ensure safety, or a combination of these and/or other approaches.

At present there is no specific FDA regulatory requirement that tattoo inks be sterile; however, consumers can reduce the likelihood of experiencing infections by asking tattoo artists if the inks have been formulated or processed to ensure they are free from harmful pathogens. In addition consumers should ask that the artist only use sterilized water to dilute the inks.

For more information:

- [Tattoo Inks Pose Health Risks](#)
- [New England Journal of Medicine: Tattoo Ink–Related Infections — Awareness, Diagnosis, Reporting, and Prevention](#)
- [Centers for Disease Control Morbidity and Mortality Weekly Report: Tattoo-Associated Nontuberculous Mycobacterial Skin Infections — Multiple States, 2011–2012](#)



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