

Aptar Requests U.S. FDA Emergency Use Authorization for N95 Filtering Facepiece Respirator Decontamination with ActivShield™

Statement

Aptar is seeking U.S. FDA Emergency Use Authorization (EUA) for a solution that allows easy disinfection of N95 filtering facepiece respirators (N95 masks). The N95 masks are desperately needed by healthcare personnel due to the shortage of disposable masks during the COVID-19 pandemic.

In this simple disinfection process, the N95 mask and a small strip of Aptar's ActivShield™ are placed inside any commonly available one-gallon plastic bag. The strip releases a controlled amount of chlorine dioxide inside the sealed bag to decontaminate the N95 mask. The process takes only two hours until the mask is ready to wear again. It can be performed on site at the local hospital where the mask is being used.

Aptar is leveraging over 20 years of material science experience that has been reformulated to deliver ActivShield™ and we are committed to using our advanced technologies to support healthcare workers around the world working on the front line in the fight against COVID-19.

Frequently Asked Questions

Technology and Process

Why this method of disinfecting and decontaminating masks as opposed to other methods being used today?

This unique method of applying chlorine dioxide gas for the decontamination, disinfection and subsequent reuse of N95 masks is effective and easy to use during this current pandemic crisis. In addition to efficiency and efficacy, it is quick to roll out, is amenable to various methods of workflow, and can be deployed in almost any work environment.

Does this process degrade the mask material?

Third-party data confirms that the ActivShield™ solution did not degrade the mask material and has no impact on its performance for up to ten cycles (10 reuses).

How many times can each strip be used?

Each strip can only be used once. One strip = one treatment = one use.

How does ActivShield™ work?

In this simple disinfection process, a small strip of Aptar's ActivShield™ is wet and sealed inside any commonly available one-gallon plastic bag along with the N95 mask. The strip releases a controlled amount of chlorine dioxide inside the bag to decontaminate the mask. The process takes only two hours. Local hospitals can perform this on site where the mask is used.

I work a day shift and will return the next day. Is it safe to leave the ActivShield™ strips in overnight and take them out in the morning before my next shift?

Once the two hours of treatment are completed, the mask is ready for use. If the mask is not needed after the two hours of treatment, we recommend storing the mask in a fresh paper bag. The mask can stay in the paper bag until use to help airing of the mask.

Do the strips have an expiration date?

We recommend using the strips within 12 months of receipt.

Is this FDA approved ?

Aptar has requested U.S. FDA Emergency Use Authorization for use with N95 Mask decontamination. Aptar filed for EUA on April 3, 2020. We are also evaluating effectiveness on other PPE and we will file a supplemental when the data is completed.

Testing and Safety

Is chlorine dioxide safe for placing into masks and then placing the mask on your face?

Chlorine dioxide has been widely used as a disinfectant in different industries, including the paper industry, drinking water treatment, food processing, and medical equipment. Aptar's delivery mechanism uses the disinfecting properties of chlorine dioxide in a controlled sustained release within the headspace of the bag.

How do you know that this is an effective decontamination method?

Third-party testing has shown the treatment is sufficient to achieve greater than 99.999% reduction in viruses, far exceeding the requirement for disinfection levels. Given the unavailability of the novel Covid-19 strain to test, we have conducted and obtained strong results on comparable, and more difficult to inactivate, viruses. Chlorine dioxide has been widely used for disinfection for decades and there is significant data available. The benefit of our solution is the ease of handling and relatively precise dosing, without the need for the mask to change hands as health care providers can disinfect their own mask.

Supply

Are you supplying the mask along with the strips?

We are not supplying the masks. We are supplying the vial with the ActivShield™ strips and instructions. The instructions can be found at the end of the FAQs.

How much do the strips cost and how many are in each vial?

We are in the process of gathering the cost information as there is a considerable amount of testing involved and final pricing is being developed. There are 150 strips in each vial. We are also looking to donate some initial quantities; that plan is also being developed but is not final.

How many strips are you able to produce today?

We are working to provide approximately four million ActivShield™ strips per week and working to expand our production capacity with the intent to deliver ten million per week by the end of April.

The strips are produced in Auburn, Alabama, and we are focusing on capacity expansion serving the US market and we believe that we can make this available to other countries in the very near future.

Will you license this to others?

We do not plan to license this technology at this time. We are open to strategic partnerships to serve the global health care community fighting the Covid-19 pandemic.

Where can I buy the strips?

All sales will be coordinated through our commercial teams with relationships with existing governments, hospital groups and hospital distributors. As of now, the strips will not be available for consumers to purchase.

Are you evaluating the possibility of donating certain quantities to high COVID-19 incident states to help relieve PPE shortage?

We are focused on producing as many ActivShield™ strips as possible at this time and we will be distributing them to different areas of need. Some of those distributions will be donations in the communities where our employees live and work.

What other products can Aptar provide during the pandemic?

Aptar is considered an essential business supply chain partner to the food, healthcare and consumer products industries. We are providing dispensing and packaging solutions for hand sanitizers, antibacterial soaps and lotions, actuators for air and surface disinfecting, infant nutrition closures, valves for metered dose inhalers, nasal spray pumps for allergy treatments and life-saving medications, stoppers for medications and vaccines, active packaging for glucose monitoring tests, influenza diagnostics, and other important medications, and many more critical solutions during this time. Aptar is committed to taking all necessary measures to maintain the continuity of business, supplying our customers, consumers and patients with the critical solutions needed during this time, while prioritizing the health and well-being of our people.

Step-by-Step Instructions for Decontamination

ActivShield™ N95 Respirator Decontamination System

Items Needed



Used, formed N95 Respirator



Gloves



Permanent Marker



Tweezers



ActivShield™ 10x10mm film



Cup Filled with Tap Water



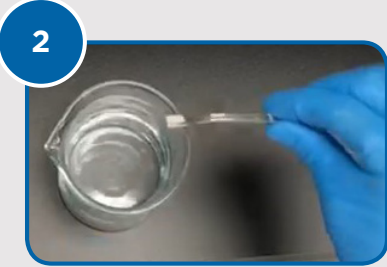
1 gallon sealable plastic bag



Paper Bag



1 Label plastic bag with the respirator owner's name, date, and start time. Put on gloves, open vial, remove 1 full strip, and close vial immediately. Keep vial closed when not in use.



2 Immediately after removing strip, use tweezers to fully submerge it in tap water for 2 seconds. Complete this step within 5 minutes of removing strip from vial.



3 Using tweezers, place wet strip into bag immediately after submerging in water.



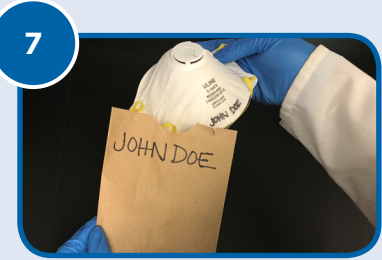
4 Verify respirator is not structurally compromised. Then place respirator in bag. Do not allow the respirator to cover any part of the strip as it will reduce decontamination efficiency.



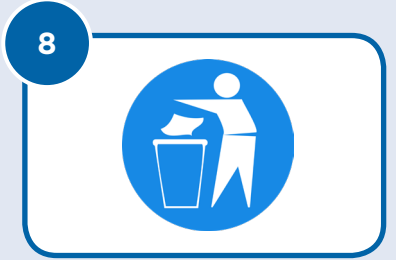
5 Seal bag completely. Within 5 minutes, check for improper seal or leak. (If found, return to step 1.) Confirm start time is recorded. Wait at least 2 hours. During this time the strip is releasing ClO₂ gas to decontaminate the respirator.



6 Remove respirator from bag and mark the respirator filter with a permanent marker. A new mark must be added after each treatment.



7 Transfer respirator to fresh paper bag labeled with owner's name. Respirator is now ready for use.



8 Be sure to discard the plastic treatment bag with used strip inside, as the outside of the bag has not been decontaminated. The strip cannot be reused.

Important Notes

To ensure best results, the respirator should be formed. It should not be smashed, crushed, or deformed in any way. Do not stack the respirators or sealed bags. Discontinue using respirator after 10 treatments or if contaminated with soils (blood, mucus, etc.).

Visit www.aptaractivshield.com to view a list of compatible respirators and answers to frequently asked questions.

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