

Considerations for healthcare, first responders, and occupational health professionals on the disinfection and reuse of Tyvek® garments during the COVID-19 pandemic

DuPont offers a range of Tyvek® garments intended to address the limited supply of personal protective equipment (PPE) relating to the Proclamation Declaring a U.S. National Emergency Concerning the Novel Coronavirus Disease (COVID-19) Outbreak¹ and the World Health Organization (WHO) declaration of the virus outbreak as a Public Health Emergency of International Concern (PHEIC)².

Tyvek* is a unique DuPont fabric and should not be confused with other nonwoven materials (MPF, SMS, etc.).

Information below is only reflective of DuPont™ Tyvek® garments.

Tyvek® coveralls are composed of flash spun, high-density polyethylene which creates a unique, nonwoven material available only from DuPont, providing limited protection against infective agents.

Tyvek* industrial protective garments are single-use products and not intended for reuse. DuPont does not recommend washing or disinfecting Tyvek* garments for reuse.

Tyvek* protective coveralls are for single use only and are to be discarded after each use. We recommend proper doffing and disposal of contaminated garments. The wearer should follow best practices of good hand hygiene after PPE removal to prevent the spread of infection.

Although extended use and reuse of PPE may have the potential benefit of conserving limited supplies of disposable PPE, concerns about these practices have been raised during previous pandemic outbreaks where adequate PPE supplies could not be obtained.³ The CDC provides Strategies to Optimize the

Supply of PPE for the emerging pathogen COVID-19.4 The current recommendation from the CDC for clothing and soft porous surfaces is washing.5

To date there is no available method for decontamination and reuse of a disposable Tyvek® garment that meets the criteria below:

- · Is harmless to the user
- Ensures original performance properties
- · Removes the viral threat
- Does not compromise the integrity of both the garment fabric and trim components (thread, tape, elastic, zippers, adhesive storm flap, etc.).

While DuPont does not recommend conditioning and reuse of Tyvek® garments, we are providing some information on the expected impact of typical conditioning treatments to garments based on our current state of knowledge. We have no information on the efficacy of any of these treatments against the coronaviruses, including COVID-19, or other infective agents.

The test results mentioned in this document are limited, usually not repeated tests and reflect only testing on unused garments. As the Tyvek® protective coveralls are for single use only, the CE marking of our different products is invalidated by any additional processing that the garment undergoes (i.e., heating, washing, disinfecting).

Inspection of garments after treatment

The garment should be considered as a system and comprises not just the Tyvek® barrier, but also the seams (taped, sewn or welded), closures, elastics, etc. The integrity of the system is critical to the level of protection provided. If the user chooses to treat the garment for reuse in any way, then the garment should be inspected for visual evidence that the system is defective. Although the inspection is no guarantee of the barrier properties, this inspection looks for gross defects in the barrier system.

Garment inspection steps:

- 1. Lay the garment on a clean, smooth surface.
- 2. The inspection should include all areas of the suit.
- 3. Use a flashlight inside the suit to examine for holes, cuts, or tears. Confirm that any suspected visual imperfection is actually a void by using a small amount of water to confirm penetration. NOTE: For taped seam garments, visible stitch holes which are covered by seam sealing tape do not constitute a defect.
- 4. Examine garment seams. For taped seam garments, look for areas where seam tape has lifted away from the suit or where seam tape does not fully cover stitch holes. For bound seam garments, look for areas where the binding (top) fabric piece is missing or not fully attached. For serged seam garments, look for areas where the sewing thread is missing or not fully attached.
- **5.** Examine the entire garment for signs of damage. A breach, rupture, or hole of any component of the suit is cause for rejection. Note that for taped seam garments, the fabric and seam areas may have visual blemishes that do not affect barrier performance. Such blemishes can include areas adjacent to the seam tape that appear to be dull, white, or frosted.
- **6.** Examine the garment zipper and zipper cover flap to make sure they are in good working order. Operate the zipper. The adhesive on the zipper cover flap likely will no longer function upon treatment and reuse.

DuPont shall not accept any responsibility whatsoever for the improper use or additional conditioning of Tyvek* garments and gowns.

Common methods of disinfection include:

Ultraviolet (UV) irradiation

Tyvek* fabric is not considered UV resistant. Ultraviolet germicidal irradiation (UVGI) is a disinfection method that uses short-wavelength ultraviolet (UV-C) light to kill or inactivate microorganisms. UVGI systems are less effective against microorganisms on surfaces that are not in a direct line of sight of the radiation source and the amount of UV irradiation delivered to different surface locations can vary.

Gamma and electron beam irradiation

Healthcare facilities are not set up to perform gamma and e-beam sterilization. Extensive knowledge of product bioburden is required to determine the proper radiation dose. Many materials are not compatible with irradiation methods due to crosslinking or chain-scission reactions. These methods would not be recommended as a means of "emergency" disinfection.

DuPont sells Tyvek® sterilized coveralls to SAL of 10-6 following ISO 11137-1 as part of their offering. Tyvek® garments can be gamma irradiated up to 55 kGy cumulative dose. However, irradiation causes a drop in mechanical and potentially to the barrier properties of the Tyvek® fabric. For additional information regarding large-scale gamma irradiation, please contact DuPont.

Ethylene oxide (EO)

Ethylene oxide will readily penetrate Tyvek* fabric and is a very effective sterilant with unknown effects on mechanical and barrier properties. EO is considered one of the most compatible forms of sterilization on materials. Most thermoplastics, thermosets, elastomers, adhesives, and silicones are EO sterilized with limited effects. It is a gaseous process and must have breathable packaging due to the multiple pressure and vacuum changes. Common parameters include temperatures of 37°C to 63°C with the most common healthcare cycles performed at either 37°C or 55°C, RH ranges of 40% to 80%, and gas concentration ranges from 450 mg/L to 800 mg/L.7

It is important that patient and health provider safety be addressed by minimizing exposure to EO and its byproducts following sterilization. ISO 10993-7 specifies limits for EO and ethylene chlorohydrin (ECH). Products must be aerated appropriately to meet these limits. The time and aeration conditions can vary widely.

Hydrogen peroxide/hydrogen peroxide gas plasma sterilization (VH2O2)

Hydrogen peroxide vapor is used in many applications to sterilize medical items. Tyvek* used for medical packaging has been extensively used and has been shown to be compatible with all common cycles. Sterilization cycles operate at low temperature and are suitable for processing medical devices sensitive to heat and moisture. Sterilant chamber concentrations can range from 59% to 94% (wt/wt) or 8 to 26 mg/L H₂O₂ in subatmospheric pressure cycles. Temperature ranges of 45°C to 60°C are typical. Any humidity or water present in the chamber is removed before introduction of the sterilant. For gas plasma cycles only, plasma will affect some materials by surface modification. In some instances, the effect is temporary. Devices to be processed should be evaluated for surface modifications and effects on functionality such as resistance to liquid penetration.⁷

DuPont does not have data on the impact of VH2O2 exposure related to the mechanical and barrier properties of garments made with Tyvek* nor does it have data on the impacts to the trims (tapes, elastics, closures, etc.)

Steam (autoclaving)

The soft bonded grade of Tyvek* fabric used in PPE is autoclavable using steam sterilization under well-controlled conditions (250°F to 260°F [121°C to 127°C] at 30 psi [207 kPa] for 30 minutes) using commercial equipment and following consensus-based industry standard practices.8 Tyvek* fabric is 100% high-density polyethylene and it begins to shrink at 250°F (121°C), and melts at 275°F (135°C), so shrinkage can be expected. Garment shrinkage can impact mechanical and barrier properties of the Tyvek* fabric and the ability of the garment components to work as a barrier system.

Dry heat treatment: 65°C

Unused Tyvek* 500 Xpert and Tyvek* 600 Plus coveralls have been tested after exposure at 65°C for 200 days in simulated aging tests. Fabric mechanical properties, penetration and repellency by liquids met the performance classification according to EN 14325 shown in the Instruction For Use (IFU) with the exception of surface resistivity. The fabric resistance to penetration of infective agents complied with EN 14126 requirements as shown in the IFU.

Surface resistivity no longer met the minimum requirements defined in EN 1149-1 & EN 1149-5.

The whole suit performance test performed with Tyvek* 500 Xpert and Tyvek* 600 Plus passed the minimum requirements of Type 6 (Low level spray test) and Type 5 (Inward leakage of airborne solid particulates).

Tyvek® 600 Plus passed the minimum requirements of Type 4 (High level spray test). Seam strength classification remained unchanged.

Dry heat treatment: 70°C

An unused Tyvek* 500 Xpert has been tested after holding at 70°C for 30 min and 80°C for 30 min. There was no significant difference in tensile strength, tear resistance, seam strength, and barrier properties, as measured by hydrostatic head and by particle filtration efficiency.

These tests were repeated at 70°C for 30 min for 3 cycles and 5 cycles, showing no significant difference in tensile strength, tear resistance, seam strength, hydrostatic head and particle filtration efficiency. Biobarrier properties were not evaluated in this study.

Washing

Although Tyvek® coveralls are dedicated to single use, some tests have demonstrated that unused Tyvek® garments can be washed one time at low temperature. The following changes to the garment may occur:

- Tyvek® coveralls may shrink up to one size
- · Mechanical properties remain within specifications range
- · The antistatic treatment is removed on both sides
- · Fabric becomes thicker, allowing a more open structure
- Barrier properties may decrease by up to 30%, including chemical resistance
- Bacterial filtration efficiency still show values higher than 98% (3 um challenge size).

If laundering of garments is attempted, conditions should be chosen to minimize shrinkage and damage to the Tyvek® fabric.

The following steps should be taken into consideration during laundering and drying of garments:

- Load washer to minimize exposure to contaminated garments
- Wash only Tyvek® garments together in a load; do not mix with other clothing or linens
- · Use low (cold) water temperature setting
- · Low agitation, e.g., delicate cycle
- Minimal amount of mild household detergent (preferably without bleach or enzymes) to remove soil from garments
- · Rinse thoroughly to remove residual detergent
- · Hang garments to air dry or use "cool" machine dry setting
- · Do not iron

DuPont has experience using industrial equipment for single laundering and drying cycle as part of their Tyvek® IsoClean® cleanroom garments offering. Many considerations listed above are applied during processing of cleanroom garments in industrial washers and dryers.

Surface treatments (sprays, spot cleaning, etc.)

Tyvek* is a nonwoven material and is porous. Spot cleaning or surface treatment with chemical sprays or wipes to disinfect the surface may not be effective at getting to virus particles trapped within the structure. The structure may also trap the chemicals, which could then irritate the wearer's skin.

References

- ¹ https://www.cdc.gov/coronavirus/2019-nCoV/index.html, https://www.coronavirus.gov/ and https://www.fema.gov/ coronavirus/disaster-declarations
- ² https://www.who.int/emergencies/diseases/novelcoronavirus-2019
- ³ Casanova, L., W.A. Rutala, D.J. Weber, and M.D. Sobsey: Coronavirus survival on healthcare personal protective equipment. *Infection Control and Hospital Epidemiology* 31(5): 560-561 (2010).
- ⁴ CDC Strategies to Optimize the Supply of PPE and Equipment https://www.cdc.gov/coronavirus/2019-ncov/hcp/ppe-strategy/index.html
- ⁵CDC Guidance on Cleaning and Disinfection for Community Facilities: https://www.cdc.gov/coronavirus/2019-ncov/community/organizations/cleaning-disinfection.html
- ⁶William G. Lindsley, Tia L. McClelland, Dylan T. Neu, Stephen B. Martin Jr., Kenneth R. Mead, Robert E. Thewlis & John D. Noti. Allergy and Ambulance Disinfection using Ultraviolet Germicidal Irradiation (UVGI): Effects of Fixture Location and Surface Reflectivity. *J Occup Environ Hyg.* 2018 Jan; 15(1): 1–12. doi: 10.1080/15459624.2017.1376067
- ⁷Association for the Advancement of Medical Instrumentation. AAMI TIR 17:2017. Compatibility of materials subject to sterilization. AAMI. Arlington, VA, 2017.
- ⁸ ANSI/AAMI ST79 (2017); Comprehensive guide to steam sterilization and sterility assurance in health care facilities.



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