NPPTL COVID-19 Response: Beyond Shelf Life/Stockpiled Respirator Assessment

Manufacturer: Handan Hengyong Protective and Clean Products Co., Ltd.
Model Tested: HY8510 (LOT # SW091208)
Date Tested: May 6, 2020
Report Prepared: May 6, 2020

These findings pertain to the Handan Hengyong Protective and Clean Products Co., Ltd., model HY8510 submitted for testing, and may not be applicable to other stockpile facilities and/or under different environmental storage conditions. All samples from the Handan Hengyong Protective and Clean Products Co., Ltd., model HY8510 (LOT # SW091208) failed the NIOSH filtration efficiency test. The maximum and minimum filter efficiency was 94.00% and 69.20%, respectively. All twenty respirators measured less than 95% efficiency. No shelf life was designated for this model by the previously held NIOSH approval holder.

NIOSH regulation sets the minimum quality and performance requirements for the approval of respirators (42 CFR 84). NIOSH does not have requirements for shelf life or storage conditions for particulate-only APRs. The approval holder (i.e. the entity that is granted the approval from NIOSH) is responsible for understanding how their products’ design or performance may be affected by various use or storage conditions and must provide instruction for establishing the proper use, storage, and maintenance procedures for their approved products, which may include designating a shelf life. FFR or particulate filter packaging (such as the box) often includes NIOSH-approved user instructions, label information, and recommendations on shelf life. Additionally, some approval holders also disseminate recommendations related to storage and shelf life through resources such as user and web notices. The respirators tested in this study were generally not designed for long-term storage.

Based on research conducted by NIOSH and this limited testing, NIOSH does not have enough information to definitively know the level of protection that may be provided by respirators that 1) are stored for prolonged periods of times; 2) are stored under various storage conditions; or 3) have exceeded the approval holder’s designated shelf life. Users of respirators that have exceeded the designated shelf life should be forewarned to avoid a false sense of confidence; these devices may not provide the same level of protection as those that have not exceeded the designated shelf life. We recommend contacting the approval holder(s) of the respirators in the stockpile with specific questions regarding the use of product beyond the manufacturer-designated shelf life.

The results provided in this letter are specific to the subset of NIOSH-approved N95s, past their designated shelf life, that were provided to NPPTL for evaluation.

These results will be added to the CDC guidance for Stockpiled N95 Filtering Facepiece Respirators Beyond the Manufacturer-Designated Shelf Life.
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Evaluation of Stockpiled and Beyond Manufacturer-Designated Shelf Life N95s

Test: TEB-APR-STP-0059

Manufacturer: Handan Hengyong Protective and Clean Products Co., Ltd.

Item Tested: HY8510 (LOT # SW091208)

Expiration Date: None Provided

Manufacture Date: None Provided

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<th>Flow Rate (LPM)</th>
<th>Initial Filter Resistance (mmH₂O)</th>
<th>Initial Percent Leakage (%)</th>
<th>Maximum Percent Leakage (%)</th>
<th>Filter Efficiency (%)</th>
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Minimum Filter Efficiency: 69.20

Maximum Filter Efficiency: 94.00
FITTING INSTRUCTIONS:

1. Hold respirator horizontally with nosepiece on top and pull open (as shown).
2. Place chin and face in mask with nosepiece on the bridge of your nose.
3. Place the top band high on the back of your head and the bottom band below your ears.
4. Using both hands, mold metal nosepiece to shape of nose for tight fit.

Test fit by cupping both hands on respirator and exhale vigorously. If air leaks around the edges, adjust nosepiece and strap for better fit.

INSTRUCCIONES DE COLOCACIÓN:

1. Sujete el respirador horizontalmente y sujetando la parte de la nariz y la parte superior halle para abrir (como se indica).
2. Coloque mentón y la cara encima de la máscara del puente de su nariz.
3. Coloque la banda superior en la parte trasera de su cabeza y la parte inferior doblando hacia sus orejas.
4. Utilizando ambas manos moldée el metal dándole forma a su nariz para un ajuste perfecto.

Prueba de ajuste por ventosas colocar ambas manos en respirador exhale vigorosamente, si aire se filtra por los bordes, tire la correa para mejor ajuste.
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**WARNING:**

1. This product does not eliminate the risk of contracting any disease or infection.
2. Failure to follow all instructions and limitations on the use of this product could reduce the effectiveness of respirator and result in toxicants or dust.
3. Only use a properly selected respirator is essential to protect your health. Before using this respirator consult an Industrial Hygienist or Occupational Safety Professional to determine the suitability for your intended use.
4. This product does not supply oxygen. Use only in adequately ventilated areas containing sufficient oxygen to support life. Do not use this respirator when oxygen concentration is less than 19.5%.
5. Do not use when concentrations of contaminants are immediately dangerous to health or life.
6. Leave work area immediately and return to fresh air if the breathing becomes difficult or chest distress occurs.
7. Facial hairs or beards and certain facial characteristics may reduce the effectiveness of this respirator.
8. Never alter or modify this respirator in any way.
9. Only for single use. No maintenance necessary. Discard the used respirator after single use.
10. Keep respirators in the display box away from direct sunlight until use.

**ADVERTENCIAS:**

1. Este producto no elimina el riesgo de contraer una enfermedad o infección.
2. Si no se siguen cuidadosamente todas las indicaciones y advertencias de uso del respirador, la eficacia del mismo puede disminuir y podría resultar en enfermedad o muerte.
3. La elección de un respirador adecuado es esencial para proteger su salud. Antes de usar este respirador, consulte a un especialista en Higiene Industrial o Profesional de Seguridad Ocupacional para determinar la adecuación de su uso previsto y adecuado.
4. Este respirador no aporta oxígeno. Sólo use en áreas adecuadamente ventiladas con oxígeno suficiente para soportar la vida. No use este respirador cuando la concentración de oxígeno es inferior al 19.5%.
5. No use si las concentraciones de contaminantes exceden los límites de salubridad.
6. Abandone el área de trabajo inmediatamente y vuelva al área con aire fresco.
7. Si el respirador se hace difícil de respirar (disfagia, tos, y dificultad para respirar), deben tomar medidas.
8. Barbas y barbas cortas que pueden reducir la eficacia de este respirador.
9. No modifique o altere el respirador.
10. Sólo para uso único, no requiere mantenimiento. Después de su utilización, mantenga los respiradores en su casa lejos de la luz del sol antes de usar.
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