NPPTL COVID-19 Response: International Respirator Assessment

Manufacturer: San Huei United Co., Ltd.
Model Tested: SH 9550
Date Tested: May 28, 2020

These findings pertain to the San Huei United Co., Ltd., model SH 9550. The packaging and labeling for this product indicates that it is a NIOSH-approved product, under approval number TC-84A-3713.

Forty respirators were submitted for evaluation. However, since these are NIOSH-approved respirators, only ten samples were tested. Samples 1-5 were from the container labeled 1B37 and samples 6-10 were from the container labeled 1B39. The samples were tested using a modified version of NIOSH Standard Test Procedure (STP) TEB-APR-STP-0059. This modified assessment plan can be found here.

The maximum and minimum filter efficiency was 99.32% and 98.70%, respectively. All ten respirators measured more than 95%.

This product has head bands/straps. While filter efficiency shows how well the filter media performs, users must ensure a proper fit is achieved.

This assessment is not a part of the NIOSH respirator approval process and will in no way lead to or preclude NIOSH approval through the official approval process. This assessment was developed as an assessment of the filter efficiency for those respirator’s represented as certified by an international certification authority, other than NIOSH, to support the availability of respiratory protection to US healthcare workers due to the respirator shortage associated with COVID-19. Only particulate filter efficiency was assessed.

The results provided in this letter are specific to the subset of samples that were provided to NPPTL for evaluation.

These results will be used to update the CDC guidance for Crisis Capacity Strategies (during known shortages).
Evaluation of International Respirators

Test: Modified TEB-APR-STP-0059
Date Tested: May 28, 2020
Report Prepared: May 29, 2020
Manufacturer: San Huei United Co., Ltd.
Item Tested: SH 9550
Country of Certification: USA (42 CFR 84)

<table>
<thead>
<tr>
<th>Filter</th>
<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>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>85</td>
<td>9.5</td>
<td>0.68</td>
<td>0.68</td>
<td>99.32</td>
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<td>1.05</td>
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<tr>
<td>3</td>
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<td>9.3</td>
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<td>6</td>
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<tr>
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<td>9.0</td>
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<tr>
<td>9</td>
<td>85</td>
<td>9.3</td>
<td>1.26</td>
<td>1.27</td>
<td>98.73</td>
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<tr>
<td>10</td>
<td>85</td>
<td>9.1</td>
<td>1.23</td>
<td>1.30</td>
<td>98.70</td>
</tr>
</tbody>
</table>

Minimum Filter Efficiency: 98.70  Maximum Filter Efficiency: 99.32

- The test method utilized in this assessment is not the NIOSH standard test procedure that is used for certification of respirators. Respirators assessed to this modified test plan do not meet the requirements of STP-0059, and therefore cannot be considered equivalent to N95 respirators that were tested to STP-0059.
- Respirators tested may not be representative of all respirators with the same certification mark. NIOSH has no control over suppliers and distributors of respirators certified by other national or international parties.
- This assessment is not a confirmation that it conforms with any or all of its specifications in accordance with its certification mark.
- This assessment was not a part of the NIOSH approval program. These results do not imply nor preclude a future approval through the NIOSH respirator approval program.
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 sickness or death.
3. 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 lab breathing becomes difficult, or lab dizziness or other 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 Se Ciminal el Peligro de Contractar Una enfermedad O Infection.
2. Si no se siguen cuidadosamente todas las instrucciones y advertencias al utilizar el respirador, la efectividad del mismo disminuirá y podrá resultar en enfermedad o muerte.
3. Una adecuada selección de respirador es esencial para proteger la salud. Antes de usar este respirador, consulte a un experto en Higiene Industrial o Profesional de Seguridad Ocupacional para determinar si su uso previsto es adecuado.
4. Este respirador no aporta oxígeno. Use sólo 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 cuando las concentraciones de contaminantes sean inmediatamente peligrosas a salud o vida.
6. Abandonare el area de trabajo inmediatamente y vuelvar a área con aire fresco si lab la respiración se hace dificultosa, o lab siente vértigo, mareos y otro malestar.
7. Barbas y certas caracteristicas faciales pueden reducir la efectividad de este respirador.
8. Nunca modifique o altere el respirador.
10. Mantenga los respiradores nuevos en su caja lejos de la luz del sol antes del uso.
### NPPTL COVID-19 Response: International Respirator Assessment

#### 1. Protection

**N95-Particulate Filter** (95% filter efficiency level) effective against particulate aerosols free of oil; time use restrictions may apply.

#### 2. Cautions and Limitations

- **A**: Not for use in atmospheres containing less than 19.5% oxygen.
- **B**: Not for use in atmospheres immediately dangerous to life or health.
- **C**: Do not exceed maximum use concentrations established by regulatory standards.
- **D**: Failure to properly use and maintain this product could result in injury or death.
- **M**: All approved respirators shall be selected, fitted, used, and maintained in accordance with MSHA and other applicable regulations.
- **N**: Never substitute, modify, add, or omit parts. Use only exact replacement parts in the configuration as specified by the manufacturer.
- **O**: Refer to users instructions, and/or maintenance manuals for information on use and maintenance of these respirators.
- **P**: NIOSH does not evaluate respirators for use as surgical masks.

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**WARNING**

NIOSH APPROVED: N95

NIOSH APPROVED: N95

35% efficient against particulate aerosols free of oil.

This respirator helps protect against certain particulate contaminants but does not eliminate exposure to or the risk of contracting disease or infection. Mice exposure is sickness or death.

**ADVERTENCIA**

APPROBADO POR NIOSH: N95

Ofrece 95% de eficiencia contra aerosol de partículas libre de aceite.

Este respirador ayuda a proteger contra ciertos polvos y nublones pero no elimina la exposición al riesgo de contraer infecciones o enfermedades. El uso incorrecto de este producto puede ser causa de enfermedad o muerte.
FITTING INSTRUCTIONS:
1. Hold the respirator in hand with the nosepiece at your fingertips. Allow headbands to hang freely below hand.
2. Cup the respirator firmly against your face with the nosepiece on the bridge of your nose.
3. Stretch and pull the lower headband over the head and position below your ears. Stretch and pull the top headband on the back of your head above your ears.
4. Press soft metal nosepiece to conform snugly around the nose.
5. To test fit, cup both hands over the respirator and exhale sharply. If air flows around your nose, tighten the nosepiece. If air leaks around the edges, reposition the headband for better fit.
6. Change respirator immediately if breathing becomes difficult or respirator becomes damaged or distorted, or a proper face fit can not be maintained. Careful observance of these instructions is an important step in safe respirator use.

INSTRUCCIONES DE COLOCACIÓN:
1. Coloque el respirador en la palma de la mano, con la pieza metálica hacia los dedos. Deje que las bandas cuelguen libremente.
2. Coloque la parte inferior del respirador por debajo de la barbilla con la pieza metálica sobre la nariz.
3. Pase la banda superior alrededor de la cabeza y colóquela por encima de las orejas. Pase la banda inferior por la cabeza hasta colocarla en la nuca, por debajo de los orejas.
4. Molée la zona de la nariz, apretando la pieza metálica por ambos lados a la vez.
5. Para comprobar el ajuste facial, cubra completamente el respirador con ambas manos y exhale con fuerza. Si nota alguna fuga de aire en la zona de la nariz, ajuste nuevamente la pieza metálica. Si hay alguna fuga de aire por los bordes, vuelva a ajustar las bandas elásticas.
6. Cambie inmediatamente el respirador si hay dificultades de respiración o daños en el respirador, o imposibilidad en mantener un ajuste facial adecuado. La práctica cuidadosa de estas instrucciones es un paso importante en el empleo seguro del respirador.
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