NPPTL COVID-19 Response: International Respirator Assessment

Model Tested: 9500-N95; Lot# 060220
Date Tested: October 6, 2020

These findings pertain to the Dongguan Sure-On Plastic & Fiber Products Co., Ltd., (Makrite Industries, Inc.), model 9500-N95; Lot# 060220. The packaging and labeling indicate that it is a NIOSH-approved product, under approval number TC-84A-5411. The packaging also indicates that it meets GB2626-2006 (the Chinese standard for Respiratory Protective Equipment – Non-Powered Air-Purifying Particle Respirator).

Ten respirators were submitted for evaluation. 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 99.69% and 99.11%, 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 respirators 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).
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Evaluation of International Respirators

Test: Modified TEB-APR-STP-0059

Date Tested: October 6, 2020

Report Prepared: October 6, 2020


Item Tested: 9500-N95; Lot#060220

Country of Certification: China (GB2626), USA (claimed, 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>
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</thead>
<tbody>
<tr>
<td>1</td>
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<td>12.8</td>
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<td>11.9</td>
<td>0.56</td>
<td>0.56</td>
<td>99.44</td>
</tr>
</tbody>
</table>

Minimum Filter Efficiency: 99.11%
Maximum Filter Efficiency: 99.69%

- 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.
RESPIRATOR FITTING INSTRUCTION

STEP 1
Hold the respirator in hand with the nosepiece at your fingertips, allowing the headbands to hang freely below your hand.

STEP 2
Press the respirator firmly against your face with the nosepiece on the bridge of your nose.

STEP 3
Stretch and position the top band high on the back of the head. Stretch the bottom band over the head and position below your ears.

STEP 4
Using both hands, mold nosepiece to the shape of your nose.

STEP 5
To test fit: a) Cup both hands over the respirator being careful not to disturb position, and b) inhale vigorously. If air leaks around the edges, reposition the straps or adjust strap tension for better fit. Please carefully follow these fitting instructions during each use to achieve proper fit.

MAKRITE INDUSTRIES INC.
11F-5, No. 79, Sec 1, Xintai 5th Rd., Xizhi Dist, New Taipei City 221, Taiwan
Tel: 886 2 2698 2419
Manufactured by Dongguan Sure_On Plastic & Fiber Products Co., Ltd.
Zhuhai Ling Industrial Area, Tangxia Town, Dongguan City, Guangdong, China
Tel: 86 769 8772 3170

www.makrite.com
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Makrite Industries Inc.
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New Taipei City 221, Taiwan
Tel: +886-2-2698-2419

This respirator is approved only in the following configuration:

<table>
<thead>
<tr>
<th>TC</th>
<th>Protection</th>
<th>Respirator</th>
<th>Cautions and Limitations</th>
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<tbody>
<tr>
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<tr>
<td>84A-5411</td>
<td>N95</td>
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</table>

1. Protection

- N95-Particulate Filter (95% filter efficiency level) for effective protection against particulate aerosols.
- Free of oil/water 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.
- J - 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, OSHA, 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.
- G - 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.

Service Time Limitation

1. Do not use the same respirator for more than 8 hours, continuous or intermittent, in dirty workplaces that could result in high filter loading.

2. Leave contaminated area and remove respirator if breathing becomes difficult or proper fit cannot be obtained or the respirator is damaged, soiled, or distorted. Do not use the same respirator again once it has been used in contaminated area.

3. The maximum service life of this respirator is five (5) consecutive calendar days (including days of non-use), beginning from the first day of use.

Made in China
Non-medical use
Makrite

Qualification

Product Type: Disposable Respirator
Product Model: N95
Product Colour: White
Product Size: 144mm*117mm*53mm (±10%)
Major Ingredients: 87.6%PE/12.4%melt-blown fabric

Production Date: 060220
Lot number: 060220

Period Of Validity: 3 years
Inspector: Q003

Manufacturer: Dongguan Sure_On Plastic & Fiber Products Co., Ltd.
Address: ZhuFo Ling Industrial Area, TangXia Town, DongGuan City, GuangDong, China
Telephone: 86 769 8772 3170

Executive Standard: American NIOSH N95/GB 2626-2006
The factory has passed ISO 9001:2015 international quality management system
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