

NPPTL COVID-19 Response: International Respirator Assessment

Manufacturer: Dongguan Sure-On Plastic & Fiber Products Co., Ltd., (Makrite Industries, Inc.)

Model Tested: 9500-N95; Lot# 071720

Date Tested: October 7, 2020

These findings pertain to the Dongguan Sure-On Plastic & Fiber Products Co., Ltd., (Makrite Industries, Inc.), model 9500-N95; Lot# 071720. 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 99.97% and 99.41%, 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 \(during known shortages\)](#).

Evaluation of International Respirators

Test: Modified TEB-APR-STP-0059

Date Tested: October 7, 2020

Report Prepared: October 8, 2020

Manufacturer: Dongguan Sure-On Plastic & Fiber Products Co., Ltd., (Makrite Industries, Inc.)

Item Tested: 9500-N95; Lot#071720

Country of Certification: China (GB2626), USA (claimed, 42 CFR 84)

Pictures have been added to the end of this report.

Filter	Flow Rate (LPM)	Initial Filter Resistance (mmH ₂ O)	Initial Percent Leakage (%)	Maximum Percent Leakage (%)	Filter Efficiency (%)
1	85	13.1	0.14	0.14	99.86
2	85	16.4	0.04	0.04	99.96
3	85	15.5	0.15	0.15	99.85
4	85	15.2	0.11	0.11	99.89
5	85	16.3	0.05	0.05	99.95
6	85	14.4	0.17	0.17	99.83
7	85	14.8	0.26	0.26	99.74
8	85	15.2	0.59	0.59	99.41
9	85	14.2	0.10	0.10	99.90
10	85	15.5	0.03	0.03	99.97
Minimum Filter Efficiency: 99.41%			Maximum Filter Efficiency: 99.97%		

- 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.



**N95
Particulate
Respirators**

**20
Particulate
Respirators**



Makrite
Life Holds Unlimited Possibilities

9500-N95

MTF-2020-394.25



**NIOSH
Approved
Product**

**N95
Particulate
Respirators**

**20
Particulate
Respirators**

**LIMITED WARRANTY
IMPORTANT NOTICE TO
PURCHASER:**

This limited warranty is made in lieu of the warranties of merchantability, fitness for particular purposes and all other warranties, expressed or implied. There are no other warranties which extend beyond the description on the face hereof. The physical standards and specifications of Makrite will be met by products sold.

Exclusive Remedies: damages for the breach of this limited warranty are limited to the replacement of such quantity of Makrite, products proved to be defectively manufactured. Except as provided above, Makrite shall not be liable or responsible for any loss, damage, or liability, direct, indirect, incidental, special, or consequential, arising out of sale, use, or misuse, or the inability to use products by the user.

WARNINGS:

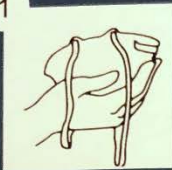
1. Wearer must read fitting instructions and use limitations before use.
2. This respirator is not guaranteed to protect against the risk of contracting a disease or infection.
3. Before occupational use of this respirator, a written respiratory protection program must be implemented meeting all the local government requirements. In the United States employers must comply with OSHA 29 CFR 1910.134 which includes medical evaluation, training, and fit testing.

Made in China



RESPIRATOR FITTING INSTRUCTION

1



STEP 1

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

2



STEP 2

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

3



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.

4



STEP 4

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

5

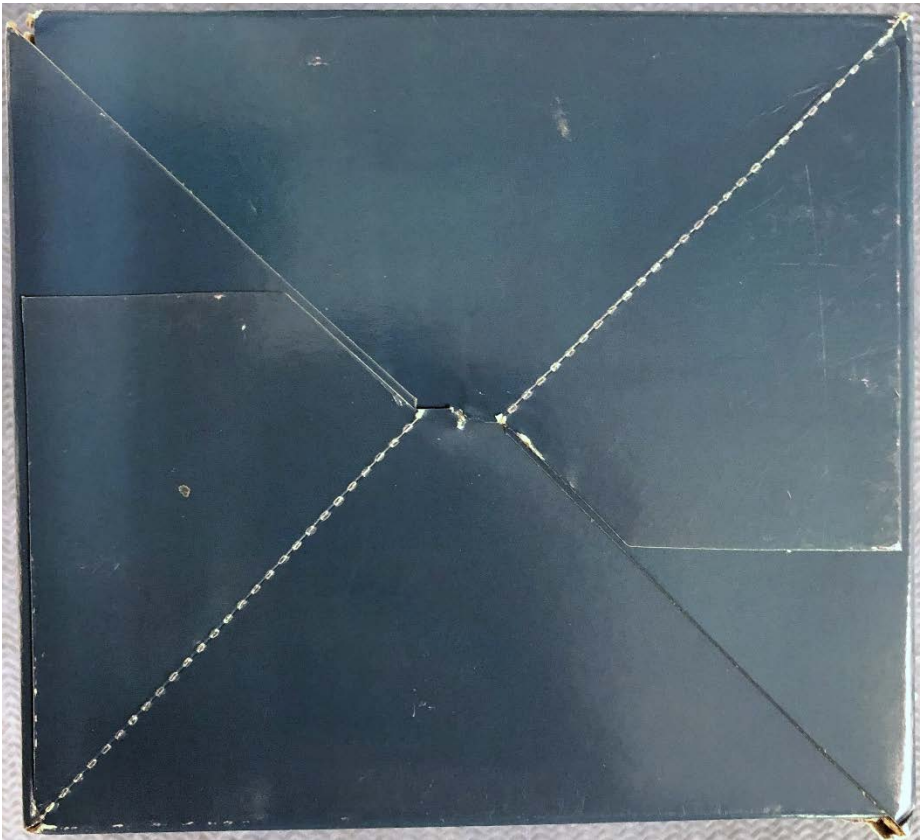


STEP 5

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.

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This respirator is approved only in the following configuration:

TC-	Protection ¹	Respirator	Cautions and Limitations ²
		9500-N95	
84A-5411	N95	x	ABCJMNOP

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
- 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.
- 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.

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 time of this respirator is five (5) consecutive calendar days (including days of non-use), beginning from the first day of use.

LOT NO./MFG Date:

071720

Expiration Date:

071623

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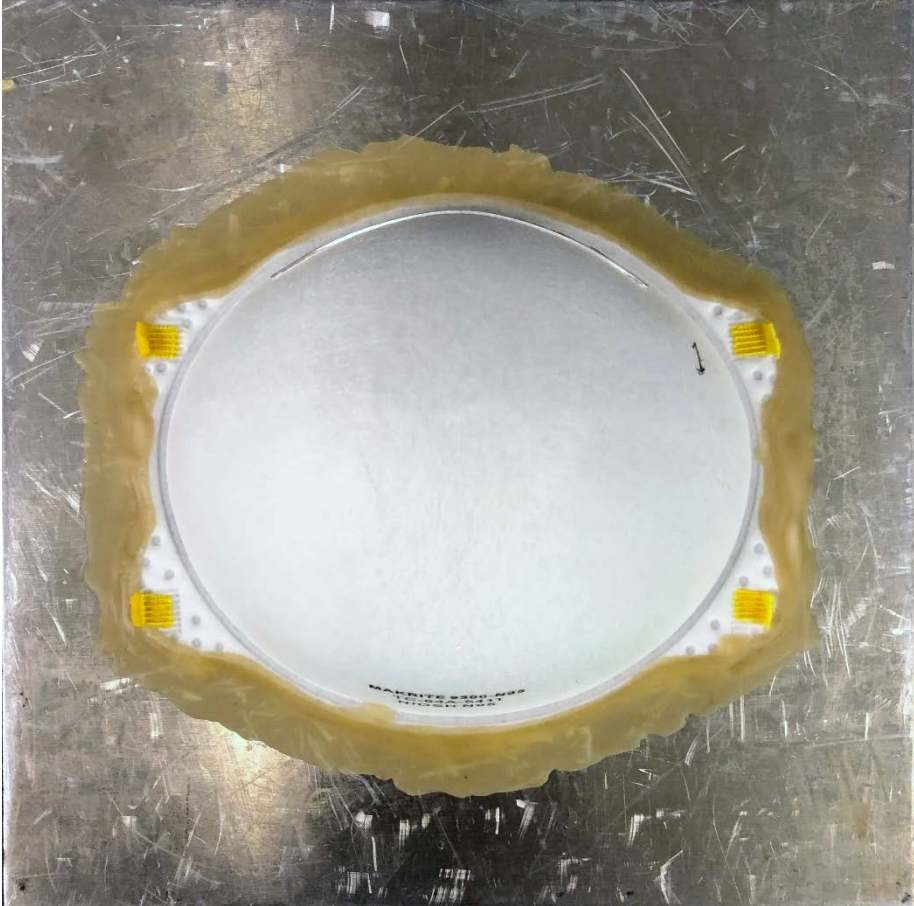
Non-medical use



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