

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

Manufacturer: Makrite Industries Inc. for Cardinal Health

Model Tested: N95-ML (TC-84A-3323)

Date Tested: September 8, 2020

Report Prepared: September 8, 2020

These findings pertain to the Makrite Industries Inc. for Cardinal Health, model N95-ML (TC-84A-3323) submitted for testing; and may not be applicable to other stockpile facilities and/or under different environmental storage conditions. The maximum and minimum filter efficiency was 99.76% and 99.52%, respectively. All twenty respirators measured more than 95% filter efficiency. There was no designated expiration date.

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](#).

## Evaluation of Stockpiled and Beyond Manufacturer-Designated Shelf Life N95s



**Test:** TEB-APR-STP-0059

**Manufacturer:** Makrite Industries Inc. for Cardinal Health

**Item Tested:** N95-ML (TC-84A-3323)

**Expiration Date:** None Provided

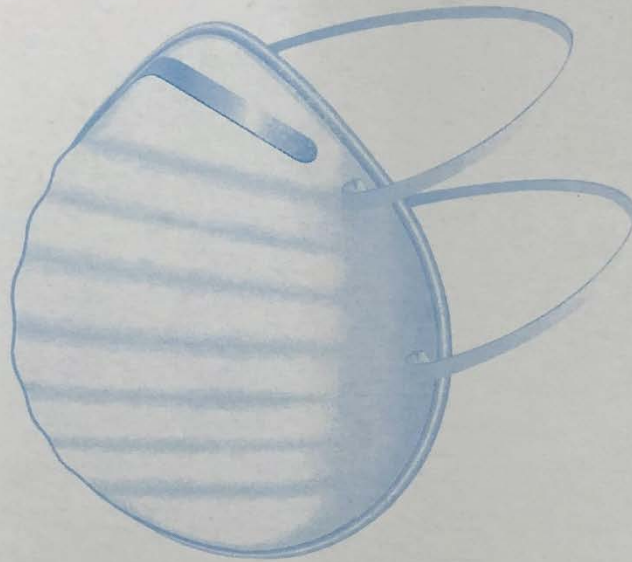
**Manufacture Date:** None Provided

Filter	Flow Rate (LPM)	Initial Filter Resistance (mmH <sub>2</sub> O)	Initial Percent Leakage (%)	Maximum Percent Leakage (%)	Filter Efficiency (%)
1	85	11.1	0.30	0.30	99.70
2	85	10.7	0.38	0.38	99.62
3	85	10.5	0.29	0.29	99.71
4	85	12.2	0.28	0.28	99.72
5	85	10.9	0.38	0.38	99.62
6	85	11.5	0.24	0.24	99.76
7	85	10.6	0.33	0.33	99.67
8	85	12.9	0.30	0.30	99.70
9	85	10.6	0.28	0.28	99.72
10	85	13.1	0.26	0.26	99.74
11	85	12.4	0.30	0.30	99.70
12	85	10.7	0.44	0.44	99.56
13	85	11.7	0.32	0.32	99.68
14	85	11.5	0.47	0.48	99.52
15	85	10.8	0.33	0.33	99.67
16	85	11.4	0.38	0.39	99.61
17	85	11.8	0.28	0.28	99.72
18	85	10.6	0.32	0.32	99.68
19	85	11.1	0.30	0.30	99.70
20	85	10.0	0.37	0.37	99.70
<b>Minimum Filter Efficiency: 99.52%</b>			<b>Maximum Filter Efficiency: 99.76%</b>		

Cat. N95-ML

MTT-2020-347 Qty. 20

## Secure-Gard® N95 Healthcare Particulate Respirator



- Fluid Resistant
- Meets CDC Guidelines For TB Exposure Control
- Healthcare Particulate Respirator and Surgical Mask
- NIOSH Approved
- Medium/Large Size

Distributed by:  
**Cardinal Health**  
Waukegan, IL 60085 USA

Made in China  
DN95ML-61



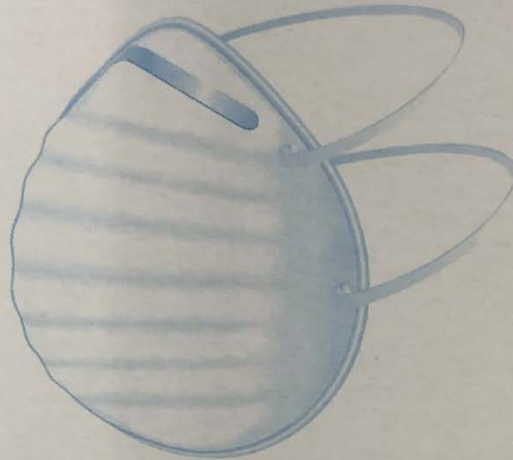
**Latex Free**



Cat. N95-ML

Qty. 20

## Secure-Gard® N95 Healthcare Particulate Respirator



### Warnings

#### Read and Understand Before Use.

1. A properly selected respirator is essential to protect your health. Before using this product, consult a safety professional to determine its suitability for your intended application.
2. As with any respiratory device, the wearer MUST be adequately trained prior to use.
3. This product does not protect the wearer against gases, vapors or mist whose liquids produce harmful vapors or gases.
4. Do not use in sandblasting operations.
5. This product does not supply oxygen. Use this respirator only in well ventilated areas containing sufficient oxygen (at least 19.5%) to support life.
6. Do not use when contaminant and the concentration are unknown or immediately dangerous to life and health.
7. Leave work area immediately if: a) breathing becomes difficult, b) dizziness or other distress occurs, c) the respirator becomes damaged: d) an emergency occurs.
8. If user has any illness or discomfort, consult a licensed medical doctor to determine suitability of use.
9. Facial hair and certain facial characteristics will prohibit effective use of this product.
10. Replace a respirator when the breathing resistance becomes excessive due to dust or mist loading or after a maximum of 8-hour usage. "Only for single use."
11. Failure to observe all warnings and instructions on the use of this respirator may result in serious illness or permanent injury.
12. Store respirator in a sealed container away from contaminated areas when not in use.
13. Before use, the wearer must be trained in the proper use, including fit testing, in accordance with applicable safety and health standards for the containment and exposure level in the work area as per the OSHA guidelines, 29 CFR 1910.134



(01)20885380017244

Cat. N95-ML

Qty. 20

## Secure-Gard® N95 Healthcare Particulate Respirator



### Respirator Fitting Instructions

1. Hold the respirator in hand with the nosepiece at your fingertips, allowing the headbands to hang freely below your hand.
2. Press the respirator firmly against your face with the nosepiece on the bridge of your nose.
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. Using both hands, mold the metal nosepiece to the shape of your nose.
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.
6. Please carefully follow these fitting instructions during each use to achieve proper fit.



Cat. **N95-ML**

Qty. **20**



Cardinal Health  
Waukegan, IL 60085  
1-800-327-7503



This respirator is only approved in the following configuration:

TC	Protection <sup>1</sup>	Respirator	Cautions and Limitations <sup>2</sup>
		N95-ML	
84A-3323	N95	X	ABCJMNOPS

**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 as surgical masks.
- S - Special or critical User's Instructions and/or specific use limitations apply. Refer to User's Instructions before donning.

**S - Special or Critical User's Instructions:** The model N95-ML filtering face piece respirator has been manufactured by Approval Holder Makrite Industries Inc. for Cardinal Health under TC-84A-3323.

**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, express or implied. There are no other warranties which extend beyond the description on the face hereof. The physical standards and specifications of Cardinal Health will be met by products sold.

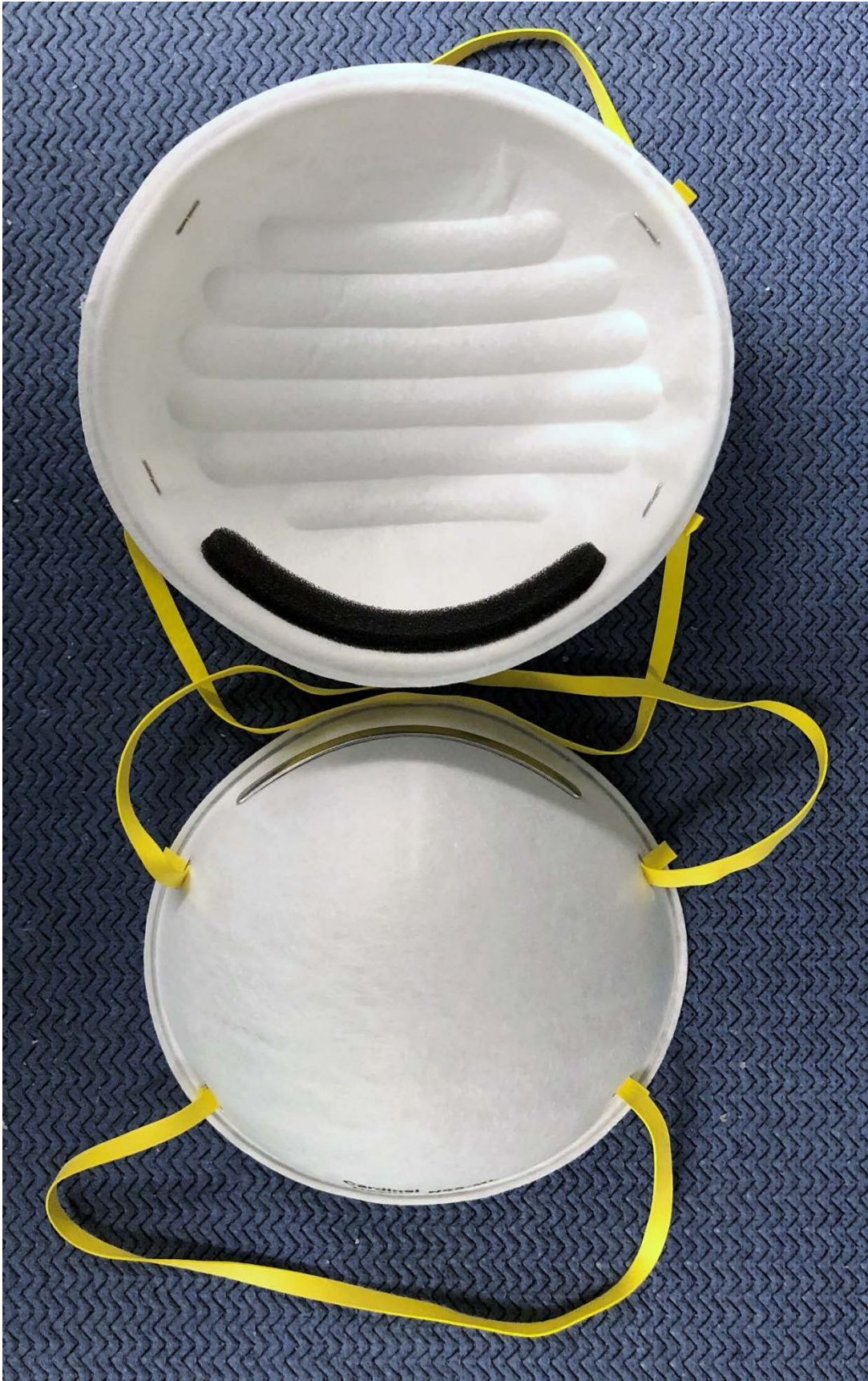
**Exclusive Remedies:** Damages for the breach of this limited warranty are limited to the replacement of such quantity of Cardinal Health products proved to be defectively manufactured. Except as provided above, Cardinal Health shall not be liable or responsible for any loss, damage, or liability, direct,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

**INDICATIONS FOR USE**

The Cardinal Health model N95-ML Healthcare Particulate Respirator and Surgical Mask is a fiberglass-free, fluid-resistant single use mask that helps protect both the patient and healthcare worker from transfer of microorganisms, body fluids and particulate material.



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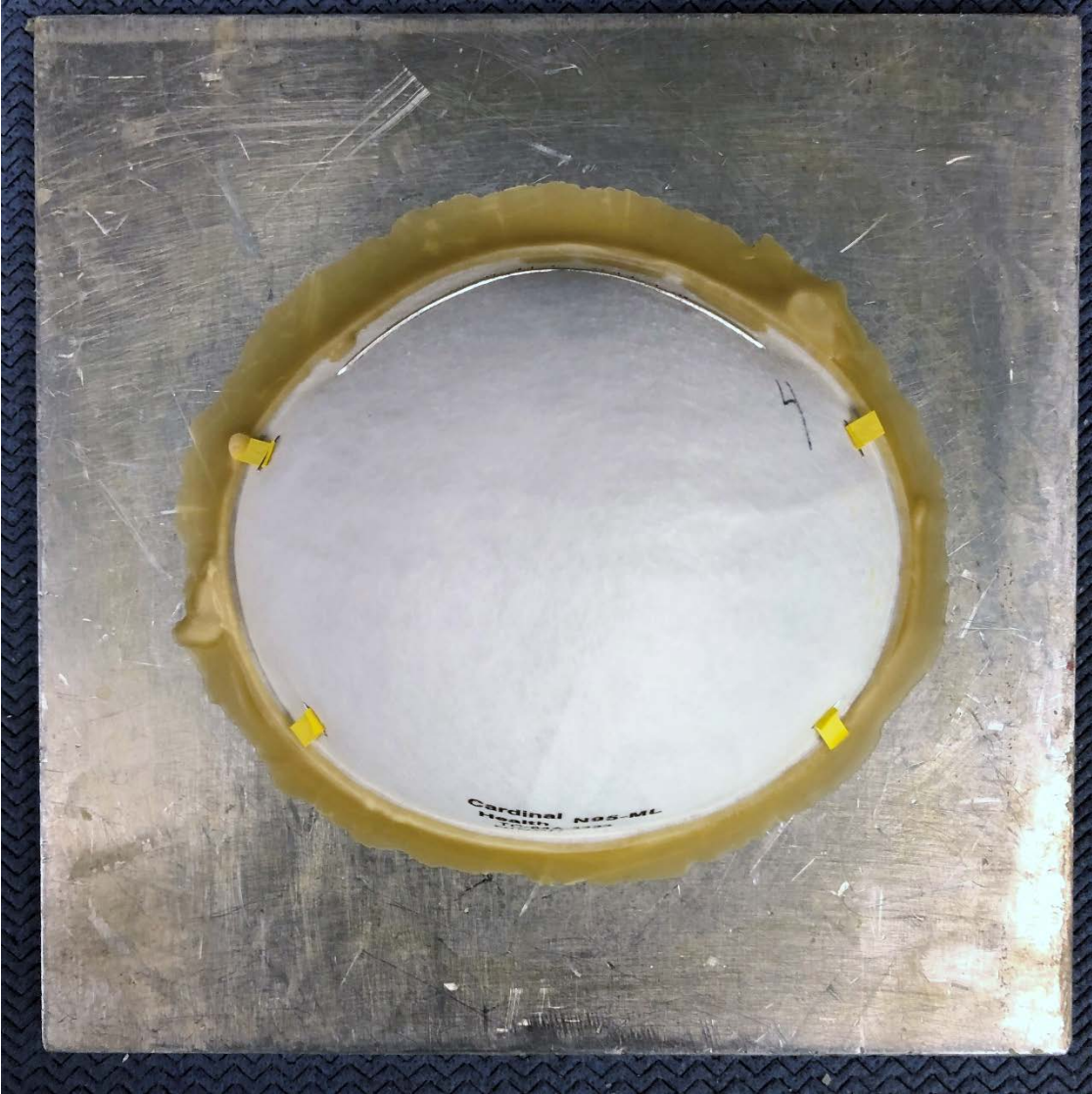


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