



DEPARTMENT OF HEALTH & HUMAN SERVICES

NIOSH Reference: TN-21734
Mfr. Reference: MAK-1725

Centers for Disease Control
and Prevention (CDC)

National Institute for Occupational
Safety and Health (NIOSH)
National Personal Protective
Technology Laboratory (NPPTL)
626 Cochrans Mill Road
Pittsburgh, PA 15236-0070
Phone: 412-386-4000
Fax: 412-386-4051
November 2, 2017

Mr. Alexander Freedman
Makrite Industries, Inc.
105 Palmer River Road
Swansea, MA 02777-N95

Dear Mr. Freedman:

The National Institute for Occupational Safety and Health (NIOSH) has reviewed your request accepted August 16, 2017. This request was for approval of the model 9600-N95VOV air purifying filtering facepiece respirator with exhalation valve for protection against particulates at N95 filter efficiency level. Reference the assembly matrix 9600-N95VOVAMaR0.xls dated 08/11/2017.

This request is granted. Approval is granted only for documentation written in the English language. It is the manufacturer's responsibility to correctly translate materials desired to be produced in languages other than English. Approval number TC-84A-7883 has been assigned. This respirator is approved for protection against particulates at N95 filter efficiency level.

The final respirator approval label is included as an attachment to this letter. The abbreviated label has been accepted as submitted. The cautions and limitations which apply to this approval are on the approval label. Only those assemblies affected by this request, or where new approval numbers are assigned, apply to this approval action. Production approval labels cannot include information on unapproved configurations.

The approved assembly consists of the parts as listed on the approval label and the assembly matrix. Parts are to be marked with the numbers indicated on the approval label in a legible and permanent manner (marking cannot be removed without evidence of its previous presence).

This certificate of approval is not an endorsement of the respirator by NIOSH, and such endorsement shall not be stated or implied in advertisements or other publicity. However, you may publicize the fact that this respirator has met the requirements of Title 42, *Code of Federal Regulations*, Part 84 (42 CFR 84).

No changes may be made to any respirators and accompanying documentation without prior written approval of NIOSH. Requests for changes must be submitted to NIOSH and a modification of this approval must be granted before changes are made.

Sincerely,

A handwritten signature in blue ink, appearing to read 'Jeffrey Peterson', with a long horizontal stroke extending to the right.

Jeffrey Peterson
Acting Chief, Conformity Verification and
Standards Development Branch

Enclosures



National Institute for Occupational Safety and Health
National Personal Protective Technology Laboratory
Evaluation and Testing Branch

TEST REPORT

Task Number: TN-21734

Manufacturer: Makrite Industries, Inc.

Prepared by: Nichole Petitta

Date: October 17, 2017

Tests Conducted by: Nichole Petitta / Emily Merkle

Respirator Tested: 9600-N95VOV

Background Information

Respirator tested as per test request.

Tests Assigned

<u>Test Description</u>	<u>STP Number</u>
A. Exhalation Resistance Test	TEB-APR-STP-0003
B. Exhalation Valve Leakage Test	TEB-APR-STP-0004
C. Inhalation Resistance Test	TEB-APR-STP-0007
D. Sodium Chloride (NaCl) N95 Test	TEB-APR-STP-0059

Overall Results

The respirator system tested did meet the requirements of all the above procedures.

**National Institute for Occupational Safety and Health
Respirator Branch
Test Data Sheet**



Task Number: TN-21734

Reference No.: CFR 84.180

Test: Exhalation Resistance Test

STP No.: 3

Manufacturer: Makrite Industries, Inc.

Filter Type: Filter Only

Item Tested: 9600-N95VOV

Sample	Maximum Allowable Resistance (MM of H2O)	Actual Resistance (MM of H2O)	Result
	Exhalation	Exhalation	
1	25	5.8	PASS
2	25	5.2	PASS
3	25	5.5	PASS

Overall Result: PASS

Comments:

Samples were tested on manometer 000282.

Was all equipment verified to be in calibration throughout all testing?



Yes



No

Signature:

Nichole L. Petitta

Date: 9/13/2017

Engineering Technician

National Institute for Occupational Safety and Health
Respirator Branch
Test Data Sheet



Task Number: TN-21734

Reference No.: CFR 84.182

Test: Exhalation Valve Leakage Test

STP No.: 4

Manufacturer: Makrite Industries, Inc.

Item Tested: Valve Assembly

LEAKAGE						
Sample	Trial #1 (mL/min.)	Trial #2 (mL/min.)	Trial #3 (mL/min.)	Average (mL/min.)	Maximum Allowable (mL/min.)	Result
Valve 1	7.90	7.89	7.89	7.89	30.00	PASS
Valve 2	10.60	10.70	10.70	10.67	30.00	PASS
Valve 3	8.50	8.53	8.49	8.51	30.00	PASS
Overall Result: PASS						

Signature:

A handwritten signature in black ink that reads "Emily M. Merkle".

Engineering Technician

Date: 9/8/2017

Task Number: TN-21734

Reference No.: CFR 84.182

Test: Exhalation Valve Leakage Test

STP No.: 4

Manufacturer: Makrite Industries, Inc.

Item Tested: Valve Assembly

Comments:

Samples 1-3 test data was generated by Manometer 000297 and Gilibrator 000041.

Was all equipment verified to be in calibration throughout all testing?



Yes



No

Signature:



Engineering Technician

Date: 9/8/2017

**National Institute for Occupational Safety and Health
Respirator Branch
Test Data Sheet**



Task Number: TN-21734

Reference No.: CFR 84.180

Test: Inhalation Resistance Test

STP No.: 7

Manufacturer: Makrite Industries, Inc.

Item Tested: 9600-N95VOV

Filter Type: Filter Only

Sample	Maximum Allowable Resistance (MM of H2O)	Actual Resistance (MM of H2O)	Result
	Inhalation	Inhalation	
1	35	11.5	PASS
2	35	9.4	PASS
3	35	10.3	PASS
Overall Result: PASS			

Signature:

Nicholas L. Petitta

Date: 9/13/2017

Engineering Technician

Task Number: TN-21734

Reference No.: CFR 84.180

Test: Inhalation Resistance Test

STP No.: 7

Manufacturer: Makrite Industries, Inc.

Item Tested: 9600-N95VOV

Comments:

Samples were tested on manometer 000286.

Was all equipment verified to be in calibration throughout all testing?



Yes



No

Signature:

Nicholas L. Petitta

Date: 9/13/2017

Engineering Technician

National Institute for Occupational Safety and Health
Respirator Branch
Test Data Sheet



Task Number: TN-21734

Reference No.: CFR 84.181

Test: Sodium Chloride (NaCl) - N95

STP No.: 59

Manufacturer: Makrite Industries, Inc.

Item Tested: 9600-N95VOV

Filter	Flow Rate	Initial Filter Resistance	Maximum Allowable Percent Leakage	Initial Percent Leakage	Maximum Percent Leakage	Result
1	85	12.0	5.00	0.327	0.412	PASS
2	85	11.2	5.00	0.502	0.618	PASS
3	85	12.7	5.00	0.328	0.409	PASS
4	85	11.3	5.00	0.398	0.486	PASS
5	85	11.0	5.00	0.399	0.486	PASS
6	85	11.2	5.00	0.391	0.484	PASS
7	85	11.5	5.00	0.410	0.498	PASS
8	85	10.7	5.00	0.374	0.488	PASS
9	85	11.5	5.00	0.460	0.563	PASS
10	85	11.8	5.00	0.475	0.556	PASS
11	85	11.4	5.00	0.389	0.480	PASS
12	85	11.2	5.00	0.425	0.526	PASS
13	85	11.9	5.00	0.465	0.538	PASS
14	85	11.3	5.00	0.691	0.908	PASS
15	85	11.2	5.00	0.317	0.479	PASS
16	85	11.6	5.00	0.321	0.418	PASS
17	85	11.5	5.00	0.770	0.939	PASS
18	85	12.1	5.00	0.532	0.679	PASS
19	85	11.4	5.00	0.385	0.485	PASS
20	85	12.0	5.00	0.490	0.600	PASS

Overall Result: PASS

Signature:

Nicholas L. Petitta

Date: 10/17/2017

Engineering Technician

Task Number: TN-21734

Reference No.: CFR 84.181

Test: Sodium Chloride (NaCl) - N95

STP No.: 59

Manufacturer: Makrite Industries, Inc.

Item Tested: 9600-N95VOV

Comments:

Samples 1-5 were tested on TSI 8130 machine 000332. Samples 6-13 were tested on TSI 8130 machine 000333 using timer 000214. Samples 14-20 were tested on TSI 8130 machine 000334 using timer 000215.

Was all equipment verified to be in calibration throughout all testing?



Yes



No

Signature:

Nicholas L. Petitta

Date: 10/17/2017

Engineering Technician