



DEPARTMENT OF HEALTH & HUMAN SERVICES

NIOSH Reference: TN-21162
Mfr. Reference: MAK-1623

Centers for Disease Control
and Prevention (CDC)

National Institute for Occupational
Safety and Health (NIOSH)
National Personal Protective
Technology Laboratory (NPPTL)
626 Cochran Mill Road
Pittsburgh, PA 15236-0070
Phone: 412-386-4000
Fax: 412-386-4051
January 19, 2017

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

Dear Mr. Freedman:

The National Institute for Occupational Safety and Health (NIOSH) has reviewed your request accepted October 14, 2016. This request was for approval of the MAK368+ air purifying filtering facepiece respirator for protections against particulates at a N95 filter efficiency level. Reference the assembly matrix MAK368+AMaR0.xls, dated 09/28/2016.

This request is granted. Approvals are granted only for documentation written in the English language. It is the manufacturer's responsibility to correctly translate materials desired in languages other than English. Approval number TC-84A-7774 has been assigned. This respirator is approved for protection against particulates at a 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 cursive script, appearing to read "David Chirdon".

David Chirdon
Chief, Conformity Verification and
Standards Development Branch
National Personal Protective Technology Laboratory

Enclosures

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



Task Number: TN-21162

Reference No.: CFR 84.180

Test: Exhalation Resistance Test

STP No.: 3

Manufacturer: Makrite Industries, Inc.

Filter Type: Filter Only

Item Tested: MAK368+

Sample	Maximum Allowable Resistance (MM of H ₂ O)	Actual Resistance (MM of H ₂ O)	Result
	Exhalation	Exhalation	
1	25	8.4	PASS
2	25	8.6	PASS
3	25	8.1	PASS

Overall Result: PASS

Comments:

Samples were tested on manometer 000283.

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

Yes No

Signature:

Nichole L. Petitta

Date: 11/28/2016

Engineering Technician

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



Task Number: TN-21162

Reference No.: CFR 84.180

Test: Inhalation Resistance Test

STP No.: 7

Manufacturer: Makrite Industries, Inc.

Item Tested: MAK368+

Filter Type: Filter Only

Sample	Maximum Allowable Resistance (MM of H ₂ O)	Actual Resistance (MM of H ₂ O)	Result
	Inhalation	Inhalation	
1	35	8.8	PASS
2	35	9.9	PASS
3	35	8.8	PASS

Overall Result: PASS

Signature:

Nichole L. Petitta

Date: 11/28/2016

Engineering Technician

Task Number: TN-21162

Reference No.: CFR 84.180

Test: Inhalation Resistance Test

STP No.: 7

Manufacturer: Makrite Industries, Inc.

Item Tested: MAK368+

Comments:

Samples were tested on manometer 000285.

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



Yes



No

Signature:

Nickole L. Petitta

Date: 11/28/2016

Engineering Technician

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



Task Number: TN-21162

Reference No.: CFR 84.181

Test: Sodium Chloride (NaCl) - N95

STP No.: 59

Manufacturer: Makrite Industries, Inc.

Item Tested: MAK368+

Filter	Flow Rate	Initial Filter Resistance	Maximum Allowable Percent Leakage	Initial Percent Leakage	Maximum Percent Leakage	Result
1.42	2.22	8.7	5.00	1.180	1.780	PASS
2	2.22	9.9	5.00	1.290	1.550	PASS
3	2.22	9.0	5.00	1.180	1.730	PASS
4	2.22	9.8	5.00	1.220	1.570	PASS
5	2.22	9.9	5.00	1.760	1.880	PASS
6	2.22	10.4	5.00	1.300	1.470	PASS
7	2.22	9.3	5.00	1.270	1.540	PASS
8	2.22	9.8	5.00	1.480	1.750	PASS
9	2.22	10.2	5.00	1.560	1.800	PASS
10	2.22	9.2	5.00	1.420	2.220	PASS
11	2.22	10.5	5.00	1.490	1.790	PASS
12	2.22	9.2	5.00	1.060	1.650	PASS
13	2.22	9.3	5.00	1.490	2.050	PASS
14	2.22	10.2	5.00	1.650	2.020	PASS
15	2.22	9.3	5.00	1.190	1.660	PASS
16	2.22	9.0	5.00	1.590	2.140	PASS
17	2.22	9.4	5.00	1.190	1.730	PASS
18	2.22	9.9	5.00	1.400	1.660	PASS
19	2.22	10.8	5.00	1.280	1.620	PASS
20	2.22	9.7	5.00	1.170	1.460	PASS

Overall Result: PASS

Signature: *Sichela L. Petitta*

Date: 12/8/2016

Engineering Technician

Task Number: TN-21162

Reference No.: CFR 84.181

Test: Sodium Chloride (NaCl) - N95

STP No.: 59

Manufacturer: Makrite Industries, Inc.

Item Tested: MAK368+

Comments:

Samples 1-6 were tested on TSI 8130 machine 000332. Samples 7-14 were tested on TSI 8130 machine 000333 using timer 000214. Samples 15-20 were tested on TSI 8130 machine 000334.

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



Yes



No

Signature:

Nichole L. Petitta

Date: 12/8/2016

Engineering Technician



Form date 8/15

Date: 1/18/2017

NPPTL-APR (Air Purifying Respirator) Fee Invoice

Manufacturer		Makrite Industries (MAK)		
Task Number:		TN-21162		
Test Number ¹	Tests Required	No. Tests Performed	Fee/Test	Total
0003 Exhalation Resistance	1	1	\$150.00	\$150.00
0007 Inhalation Resistance	1	1	\$150.00	\$150.00
0059 NaCl (Salt) Particulate Testing N95	1	1	\$1,200.00	\$1,200.00
Total Testing and Associated Fees				\$1,500.00
		Number of Approvals	Cost / Approval	Approval Fee
NIOSH/NPPTL Admin Fee New Approval		1	\$100.00	\$100.00
Total Administration Fees				\$100.00
TOTAL ALL FEES				\$1,600.00

Remarks:

Examiner Cathy Calvert

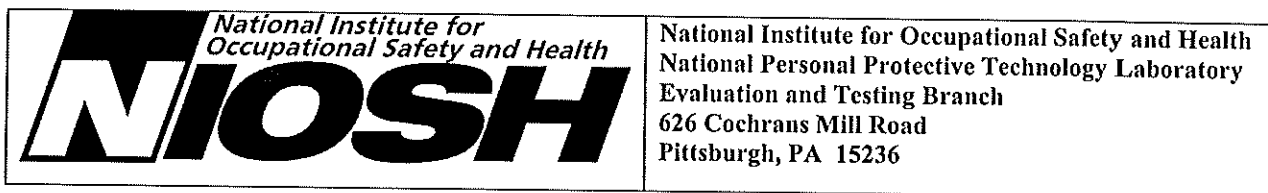
Date: 1/18/2017

Team Leader Tom Pouchot

Date: 1/19/2017

Branch Chief *David Oliver*

Date: 1-19-17



TEST REPORT

Task Number: TN-21162

Manufacturer: Makrite Industries, Inc.

Prepared by: Nichole Petitta

Date: December 8, 2016

Tests Conducted by: Nichole Petitta

Respirator Tested: MAK368+

Background Information

Respirator tested as per test request.

Tests Assigned

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

Overall Results

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