DEPARTMENT OF HEALTH & HUMAN SERVICES

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
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NIOSH Reference: TN-21163
Mfr. Reference: MAK-1624

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 MAK520+ air purifying filtering facepiece respirator with exhalation valve for protections against particulates at a N95 filter efficiency level. Reference the assembly matrix MAK520+AMaR0.xls, dated 09/30/2016.

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-7773 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,

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-21163 **Reference No.:** CFR 84.180
Test: Exhalation Resistance Test **STP No.:** 3
Manufacturer: Makrite Industries, Inc.

Filter Type: Filter Only

Item Tested: MAK520+

Sample	Maximum Allowable Resistance (MM of H2O) Exhalation	Actual Resistance (MM of H2O) Exhalation	Result
1	25	6.1	PASS
2	25	6.4	PASS
3	25	6.5	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: Nicole L. Petitta **Date:** 11/29/2016

Engineering Technician

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

Task Number: TN-21163 **Reference No.:** CFR 84.182
Test: Exhalation Valve Leakage Test **STP No.:** 4
Manufacturer: Makrite Industries, Inc.
Item Tested: MAK520+

LEAKAGE						
Sample	**Trial #1 (mL/min.)**	**Trial #2 (mL/min.)**	**Trial #3 (mL/min.)**	**Average (mL/min.)**	**Maximum Allowable (mL/min.)**	**Result**
Valve 1	14.11	14.16	14.09	14.12	30.00	PASS
Valve 2	5.57	5.55	5.52	5.55	30.00	PASS
Valve 3	9.29	9.39	9.35	9.34	30.00	PASS
Overall Result: PASS						

Signature: Nicole L. Petitta **Date:** 12/2/2016

Engineering Technician

Task Number: TN-21163 **Reference No.:** CFR 84.182
Test: Exhalation Valve Leakage Test **STP No.:** 4
Manufacturer: Makrite Industries, Inc.
Item Tested: MAK520+

Comments:

Samples were tested on Gilibrator 000041.

Was all equipment verified to be in calibration throughout all testing?	◉ Yes	◯ No

Signature: Nicole L. Petitta **Date:** 12/2/2016

Engineering Technician

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

Task Number: TN-21163
Test: Inhalation Resistance Test
Manufacturer: Makrite Industries, Inc.
Item Tested: MAK520+

Reference No.: CFR 84.180
STP No.: 7

Filter Type: Filter Only

Sample	Maximum Allowable Resistance (MM of H2O) Inhalation	Actual Resistance (MM of H2O) Inhalation	Result
1	35	9.8	PASS
2	35	9.7	PASS
3	35	10.8	PASS

Overall Result: PASS

Signature: Nicole L. Petitta

Date: 11/29/2016

Engineering Technician

Task Number: TN-21163
Test: Inhalation Resistance Test
Manufacturer: Makrite Industries, Inc.
Item Tested: MAK520+

Reference No.: CFR 84.180
STP No.: 7

Comments:
Samples were tested on manometer 000285.

Was all equipment verified to be in calibration throughout all testing?	◉ Yes	○ No

Signature: Nicole L. Petitta

Date: 11/29/2016

Engineering Technician

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

Task Number: TN-21163 **Reference No.:** CFR 84.181
Test: Sodium Chloride (NaCl) - N95 **STP No.:** 59
Manufacturer: Makrite Industries, Inc.
Item Tested: MAK520+

Filter	Flow Rate	Initial Filter Resistance	Maximum Allowable Percent Leakage	Initial Percent Leakage	Maximum Percent Leakage	Result
1	85	10.6	5.00	2.440	2.620	PASS
2	85	10.0	5.00	1.410	1.890	PASS
3	85	10.5	5.00	2.260	2.260	PASS
4	85	10.4	5.00	1.410	1.790	PASS
5	85	10.8	5.00	1.510	2.010	PASS
6	85	10.1	5.00	1.410	1.880	PASS
7	85	11.7	5.00	1.510	1.850	PASS
8	85	10.3	5.00	1.710	1.990	PASS
9	85	10.5	5.00	1.480	1.920	PASS
10	85	11.0	5.00	1.570	1.860	PASS
11	85	10.5	5.00	2.270	2.430	PASS
12	85	10.3	5.00	1.840	2.010	PASS
13	85	9.8	5.00	1.510	2.020	PASS
14	85	10.3	5.00	2.420	3.050	PASS
15	85	10.2	5.00	1.460	1.780	PASS
16	85	10.4	5.00	0.764	1.280	PASS
17	85	10.2	5.00	1.470	1.800	PASS
18	85	10.6	5.00	1.920	2.270	PASS
19	85	10.2	5.00	1.710	2.150	PASS
20	85	10.5	5.00	1.440	1.830	PASS

Overall Result: PASS

Signature: Nicole L. Petitta **Date:** 11/30/2016

Engineering Technician

Task Number: TN-21163 **Reference No.:** CFR 84.181

Test: Sodium Chloride (NaCl) - N95 **STP No.:** 59

Manufacturer: Makrite Industries, Inc.

Item Tested: MAK520+

Comments:

Samples 1-10 were tested on TSI 8130 machine 000332 using timer 000213. Samples 11-12 were tested on TSI 8130 machine 000333. Samples 13-20 were tested on TSI 8130 machine 000334 using timer 000217.

Was all equipment verified to be in calibration throughout all testing?	◉ **Yes**	○ **No**

Signature: Nicole L. Petitta **Date:** 11/30/2016

Engineering Technician

National Institute for Occupational Safety and Health
NIOSH

National Institute for Occupational Safety and Health
National Personal Protective Technology Laboratory
Evaluation and Testing Branch
626 Cochrans Mill Road
Pittsburgh, PA 15236

TEST REPORT

Task Number: TN-21163

Manufacturer: Makrite Industries, Inc.

Prepared by: Nichole Petitta

Date: December 2, 2016

Tests Conducted by: Nichole Petitta

Respirator Tested: MAK520+

Background Information

Respirator tested as per test request.

Tests Assigned

Test Description	STP Number
A. Exhalation Resistance	TEB-APR-STP-0003
B. Exhalation Valve Leakage Test	TEB-APR-STP-0004
C. Inhalation Resistance	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 procedures listed above.