



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

NIOSH Reference: TN-15022
Mfr. Reference: MAK-0701

Centers for Disease Control
and Prevention (CDC)
National Institute for Occupational
Safety and Health (NIOSH)
National Personal Protective
Technology Laboratory (NPPTL)
P.O. Box 18070
Pittsburgh, PA 15236-0070
Phone: 412-386-4000
Fax: 412-386-4051
July 11, 2007

Mr. Alexander Freedman
Makrite Industries Inc.
236 Upland Ave.
Newton Highlands, MA 02461-2003

Dear Mr. Freedman:

The National Institute for Occupational Safety and Health (NIOSH) has reviewed your request dated March 6, 2007. This request was for extensions of approval to TC-84A-3323, TC-84A-4107, TC-84A-3904, TC-84A-4241, TC-84A-4242 and TC-84A-4081 to add private label versions of these N95 and N99 filtering facepiece models with and with out exhalation valves for Westingarea Corporation of Shanghai, China as follows:

<u>Makerite No.</u>	<u>Westingarea Corp. No.</u>	<u>Protection</u>	<u>Approval No.</u>
910-N95	A8107	N95	TC-84A-3323
910-N95OV	A8107O	N95	TC-84A-3323
910-N95S	A8107S	N95	TC-84A-4107
N95-910V	A8107V	N95	TC-84A-3904
TS01-N95	A8108L	N95	TC-84A-4241
N95-TS01V	A8108VL	N95	TC-84A-4242
N99-810V	A9109V	N99	TC-84A-4081

These respirators are also described on assembly matrix MAK0701AM1.xls.

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.

The CD enclosed with this letter contains the final respirator approval labels. The abbreviated labels have been accepted as submitted. The cautions and limitations which apply to these approvals are on the approval labels. 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 assemblies consist of the parts as listed on the approval labels 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).

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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 "Heinz W. Ahlers". The signature is stylized with a large, looped "H" and a trailing flourish.

Heinz W. Ahlers
Chief, Technology Evaluation Branch
National Personal Protective Technology Laboratory

Enclosures



TEST REPORT

Task Number: TN-15022

Manufacturer: Makrite Industries, Inc.

Prepared by: Jeremy J. Brannen

Tests Conducted by: Jeremy J. Brannen/Courtney Neiderhiser

Date: May 16, 2007

Respirator Tested: N95-TS01V/N99-810V/910-N95S

Background Information

In an application dated March 6, 2007 Makerite Industries requested extensions of approval to TC-84A-3323, TC-84A-4107, TC-84A-3904, TC-84A-4241, TC-84A-4242 and TC-84A-4081 to add private label versions of these N95 and N99 filtering facepiece models with and with out exhalation valves for Westingarea Corporation of Shanghai China as follows:

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N95-910V	A8107V	N95	TC-84A-3904
TS01-N95	A8108L	N95	TC-84A-4241
N95-TS01V	A8108VL	N95	TC-84A-4242
N99-810V	A9109V	N99	TC-84A-4081

These respirators are also described on assembly matrix MAK0701AM1.xls.

Tests Assigned

<u>Test Description</u>	<u>STP Number</u>	<u>Reference</u>
A. Exhalation Resistance Test	RCT-APR-STP-0003	84.180
B. Exhalation Valve Leakage Test	RCT-APR-STP-0004	84.182
C. Inhalation Resistance Test	RCT-APR-STP-0007	84.180
D. Sodium Chloride (NACL) N99 Test	RCT-APR-STP-0058	84.181
E. Sodium Chloride (NACL) N95 Test	RCT-APR-STP-0059	84.181

Overall Results

The items tested passed laboratory testing.

Individual Test Results

See attached data sheets.

Minimum Allowable Resistance - Actual Resistance		Ratio	
(ASTM A 1501)		(ASTM A 1501)	
Item	Ratio	Ratio	Result
1	24	10.9	PASS
2	24	10.9	PASS
3	24	10.9	PASS
4	24	10.9	PASS
5	24	10.9	PASS
6	24	10.9	PASS
7	24	10.9	PASS
8	24	10.9	PASS
9	24	10.9	PASS
Overall Results		PASS	