3M Occupational Health and
Environmental Safety Division

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3M

March 1, 1996

Ms. Diane Manning
Robert A. Taft Laboratories (C-34)
4676 Columbia Parkway
Cincinnati, OH 45226

Dear Ms. Manning:

Several individuals at 3M, Craig Colton, Larry Janssen, and Robert Weber were asked for comments regarding the draft Users Notice regarding small particles and respirator selection. These comments represent their response and the position of 3M as a respirator manufacturer.

3M's position, as set forth below, lends itself to division into two major areas of concern that are not addressed in the draft Users Notice; technical points and practical points.

Technical Points

Data

NIOSH does not supply any data to indicate that workplace exposures to particulates having particle size distributions with mass median aerodynamic diameters (MMAD) <2 μm constitutes a hazard that truly exists. Theoretically, the potential exists, but it may not be a real hazard. If NIOSH has information that identifies potential workplaces without fume exposures that fall into these parameters, it should identify those workplaces or operations. Otherwise, the notice is most likely to do nothing but generate fear for past and present respirator users.

Industrial experience indicates there are very few real workplaces with these type particle exposures. For example, Hinds and Bellin collected particle size information from 33 different types of operations[1]. These data indicate only 3 operations produced non-fume aerosol distributions in this range. Two of these operations probably did not use respirators. 3M's particle size work, done in conjunction with 17

[1] Hinds, W.C. and P. Bellin: Effect of Facial-seal Leaks on Protection Provided by Half-mask Respirators. *Appl. Ind. Hyg.* 3(5):158-164.

workplace protection factor tests in a wide variety of industries, has never shown a particle size distribution with particle size distributions smaller than the 2 μm limit when fumes are excluded. Even in operations where fume was produced, the MMAD was quite large, probably due to agglomeration and the dust particles being so much more significant with regards to exposure. We have enclosed particle distribution data from a number of 3M workplace studies. It should be noted that the very small particles make up a relatively small percentage of the mass of the total aerosol. Even more important to note is that while HEPA filters were used in five of the studies due to OSHA regulatory constraints, a properly selected DM or DFM filter, as required, provided actual, measured workplace protection factors in excess of the Assigned Protection Factors (APF) (See enclosure sheets 1, 3, &5). Based on this data, the leakage NIOSH appears to be concerned about does not manifest itself in actual respirator performance.

ANSI

The recommendation made by the American National Standards Institute (ANSI) Z88.2-1992 was not based on any evidence of increased risk to workers where the particle size distribution MMAD was <2 μm. In a conversation with the chair of the Z88.2-1992 committee, it was indicated the recommendation came about as being a more pertinent criterion for selecting filters as compared to using the PEL ($\geq$0.05 mg/m^3 or <0.05 mg/m^3).[2] The 2 μm number was arbitrarily chosen. Earlier drafts of the standard had chosen an MMAD of < 1 μm as the cut off point. In addition, ANSI makes an exception to the particle size guideline for fume. ANSI states that if the contaminant is a fume, use a filter approved for fumes (e.g. dust/fume/mist respirators).[3] This recommendation comes about because even though the MMAD may be less than 2 μm, fumes are filtered with greater efficiency than this diameter would predict.[4]

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[2] Nelson, T. J.: "ANSI's Reasons for Using Particle Size Criteria for Filter Selection." February 20, 1996. [Private Conversation] NIHS,, Inc.; 2401 East Mall; Ardentown, DE 19810.

[3] American National Standards Institute: *American National Standard for Respiratory Protection (ANSI Z88.2)*. New York: American National Standard Institute, Inc.

[4] Japuntich, D. A.: Respiratory Particulate Filtration. *J. Intl. Soc. Respir. Protec.* 2(1):137-169. (1984).

Mass

Thirdly, very small particles have very little mass. Mass dose from small particles penetrating filters would be insignificant, especially when compared to faceseal leaks. Very large particles (>5 μm), however, have been shown in actual workplace studies to penetrate faceseal leaks[5]. Thus, the contribution of large particles to particle mass inside the respirator is great. As a consequence, even if particles less than 2 μm did penetrate certain filters to a higher degree than larger particles, the health effect of these small particles would not be of concern due to their extremely low mass, producing an almost immeasurable dose to the wearer.

Practical Points

Performance

The Users Notice should point out that not all 30 CFR 11 DM and DFM filters are grossly inefficient in filtering small particles. While the old approval test may have allowed for filter inefficiency for small particles (based on MMAD measurements), several articles have been published showing significant differences in filter performance within these respirator classes. Hence, the notice should indicate that this low filter efficiency does not occur with all DM and DFM respirators. Users should be advised to contact their respirator manufacturer for any data they could provide.

Transition Period

The draft Users Notice states that because NIOSH believes most employers do not know particle size distributions in their workplace and assumes they will not measure them, that DM and DFM respirators should not be used. This position represents a de facto elimination of the three year transition phase from 30 CFR 11 filters to 42 CFR 84 filters. The effect is that NIOSH is changing the 42 CFR 84 rule without proper notice and comment period required for rulemaking.

The impact on users is to push them to 42 CFR 84 filters. This push, however, will only direct users to a cupboard that is relatively bare. At present, NIOSH testing and

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[5] Myers, W.R., Z. Zhuang, T. Nelson, S. Sides, et al.: Field Performance Measurements of Half Facepiece Respirators-Study Protocol. *Am. Ind. Hyg. Assoc. J.* 56:765-775 (1995).

certification has such a large back log of respirators to test that it will be many months before there are adequate choices and supplies of 42 CFR 84 products available. For example, according to NIOSH personnel at Morgantown, a submission by 3M sent in early February (2/2/96) has 170 submissions ahead of it for testing. An additional 150 submissions have been tested and are awaiting the required paperwork review. The levels of submissions for approvals to NIOSH have not dropped off since July '95 as they expected and a huge delay has occurred. In addition, respirator manufacturers expect several hundred more approval submissions to be made to NIOSH in the near future.

Finally, there is the matter of fairness. This Users Notice unequivocally provides an unfair competitive advantage to those manufacturers, who by luck of the initial lottery, have approvals over those who do not. Meanwhile, the rest wait helplessly in an ever growing line at Morgantown.

HEPA Color

In the draft notice, NIOSH states all 30 CFR 11 high efficiency filters are magenta in color. NIOSH has granted approvals to high efficiency filters, however, that do not carry the approval for radionuclides and thus are not colored magenta. For example, NIOSH approval TC -21C-336 falls into this category.

Particle Size

The draft notice also states that particle size measurements are not necessary when either HEPA respirators or with the new Part 84 particulate respirators are used. This suggestion simply does not constitute good industrial hygiene advice. There are many industrial hygiene reasons for doing particle size distribution measurements in addition to filter selection. This "carte blanche" recommendation is ill advised.

Breathing Resistance

The "across-the-board" recommendation to use HEPA filters is also ill advised for another reason. That is, the increased breathing resistance, or pressure drop, of a HEPA filter may well lead to increased face seal leakage as air follows the path of least resistance. Both Klaus Willeke from the University of Cincinnati and Don Campbell of NIOSH have found this in laboratory testing. The result is, in many cases, going from a DM filter to a HEPA filter may actually <u>increase</u> wearer exposures to the contaminant through an increase in face seal leakage.

Conclusion

In summary, it is 3M's opinion that this draft Users Notice in its present form will create unnecessary fear among workers and employers, since there is no published evidence showing that workers properly using DM and DFM respirators have been overexposed to and harmed by particles <2 µm MMAD. While a health issue may theoretically exist, all of the data indicate the scope of this concern is very small. If NIOSH has data showing that certain work environments pose a health risk to workers from particles <2 µm MMAD, then this specific data should be presented.

In addition, 3M encourages NIOSH to issue a technical correction amendment to 42 CFR 84 to correct some editorial or typographical errors in the standard. For example, the tests specified in paragraph 84.181 specify tests are for each filter rather than for each respirator. Additionally, paragraph 84.193 references ANSI standard K13.1 - 1973. This standard is out-of-date and is no longer available. Likewise, paragraphs 84.79 and 84.141 reference the Compressed Gas Association Commodity Specification for Air, G-7.1 - 1966. This standard was revised in 1973 and again in 1989. The 1966 edition is out-of-date and no longer available.

If NIOSH has questions on these comments or seeks additional information concerning 3M's position on the draft Users Notice, please contact us.

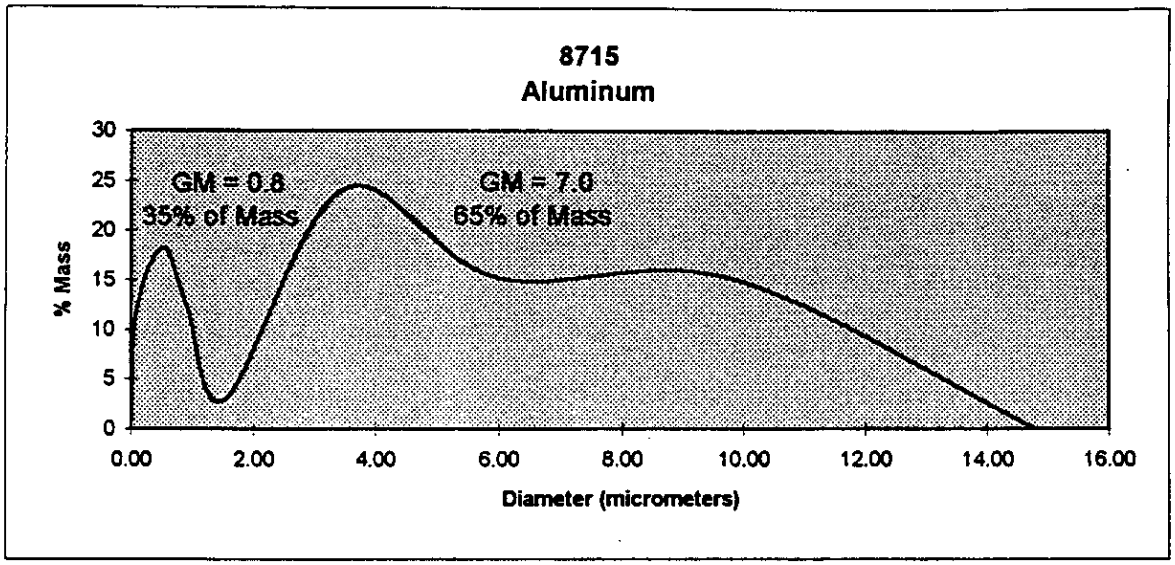
Sincerely,

Katherine E. Reed/REK

Katherine E. Reed, Ph.D.
Technical Director

KER:REK:llj/163
Attachments

SHEET #1



Particle Size	0.1	0.52	0.93	1.6	3.5	6	9.8
% Mass	12.1	18.2	12.1	3	24.2	15.2	15.2

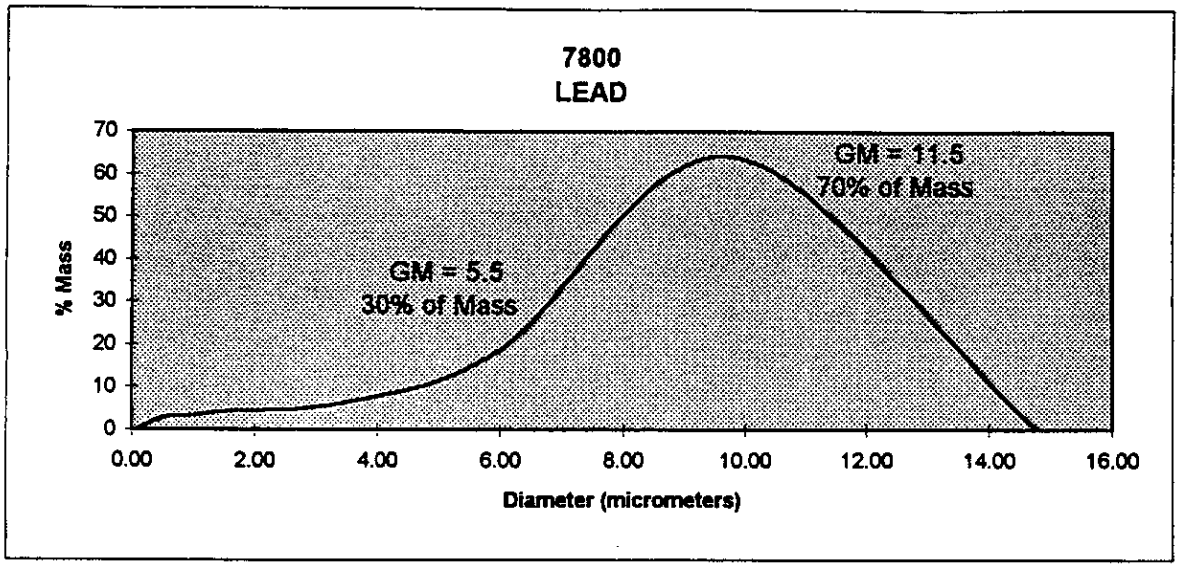
Product	8715, maintenance-free
Respirator Type	Half mask
Filter type	Electret - Dust/Mist
Application	Grind and polish
Industry Type	Aircraft parts
Study Date	October, 1986
Elements	Al, Si, Ti
Geometric Mean WPF	145, 172, 59
5th% WPF	32, 24, 24

Comments

This was a buffing and polishing operation. The major contaminant is aluminum. The particle size distribution is definitely bimodal. The fines (<1.0um) were generated by the buffing and make up a large part of the distribution due to the settling rate of the larger particles.

The respirator tested is an electret-filtered, disposable half-mask approved by NIOSH as a Dust/Mist per 30 CFR 11. Even though 35% of the mass had a particle size below 1.0um, the protection factors measured were well above the Assigned Protection Factor of 10 for a half-mask.

SHEET #2



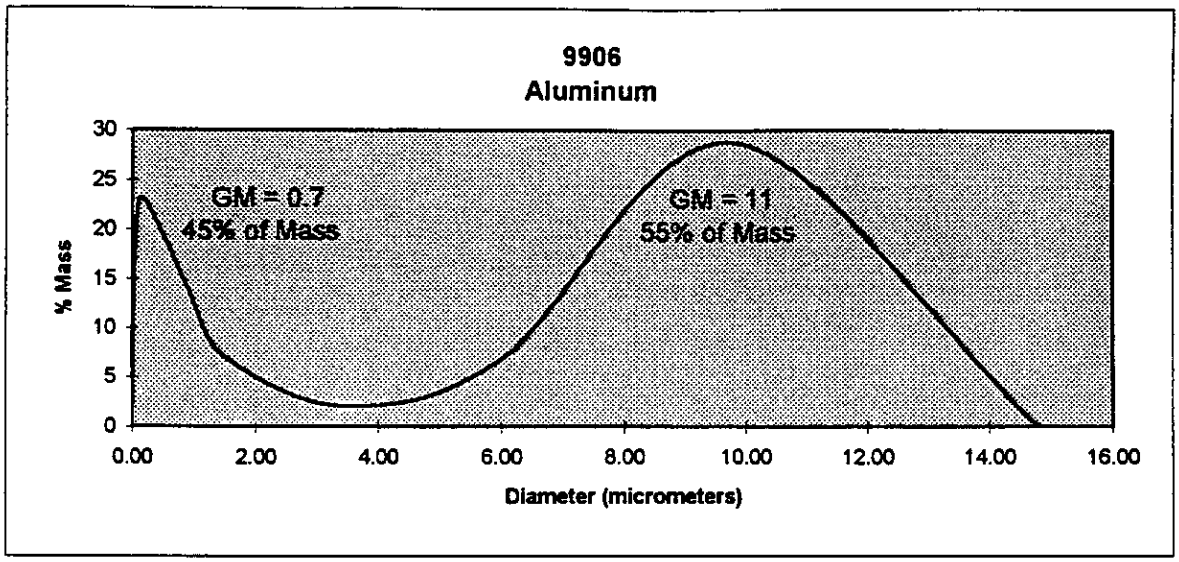
Particle Size	0.1	0.52	0.93	1.6	3.5	6	9.8
% Mass	0.2	2.8	3.3	4.4	6.4	18.8	64.1

Product	7800 Series with 7255 high efficiency filters
Respirator Type	Full face mask
Filter type	Fiberglass, HEPA
Application	Blast furnaces and casting
Industry Type	Lead smelter
Study Date	September, 1989
Elements	Pb
Geometric Mean WPF	4226
5th% WPF	728

Comments

As indicated, this is a smelting operation. Small size metal fume particles would normally be expected. However, the measured size shows the majority to be around 11.5um. We suspect this is due to high ventilation carrying away fines and the tendency for lead fume to agglomerate into larger particles. The measured protection factor was very high.

SHEET #3



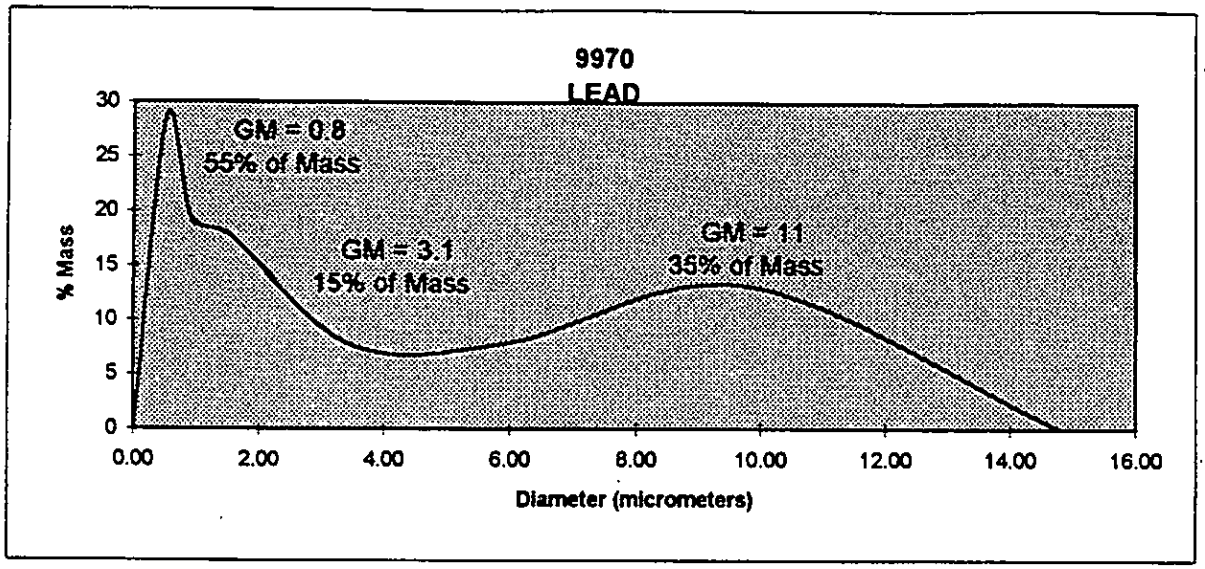
Particle Size	0.1	0.52	0.93	1.6	3.5	6	9.8
% Mass	22.6	19.2	13.7	6.9	2.1	6.9	28.8

Product	9906, maintenance-free
Respirator Type	Half mask
Filter type	Electret, Dust/Mist
Application	Potroom
Industry Type	Aluminum smelter
Study Date	November, 1988
Elements	Al
Geometric Mean WPF	27
5th% WPF	13

Comments

This is a typical aluminum smelting operation with a high percentage of small metal fume size aerosols. Even with the high percentage of submicron particles, the electret, Dust/Mist filter provided protection factors well above 10.

SHEET #4



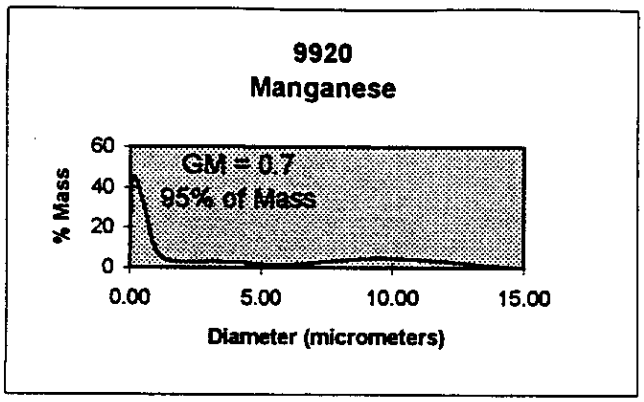
Particle Size	0.1	0.52	0.93	1.6	3.5	6	9.8
% Mass	5.39	28.8	19.3	17.7	7.6	7.9	13.2

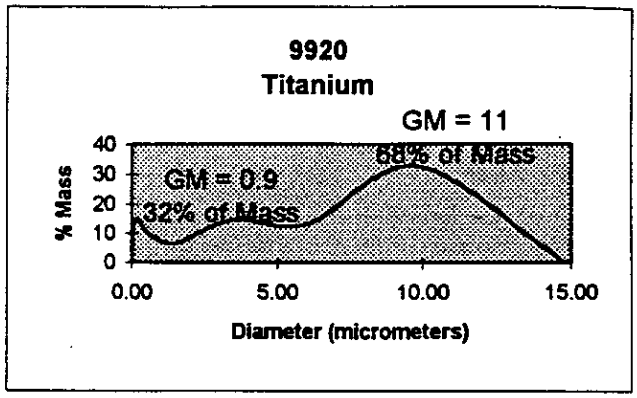
Product	9970 maintenance-free, high efficiency
Respirator Type	Half mask
Filter type	Electret, HEPA
Application	Mold-making and pouring
Industry Type	Brass foundry
Study Date	April, 1989
Elements	Pb, Zn
Geometric Mean WPF	310, 681
5th% WPF	28, 40

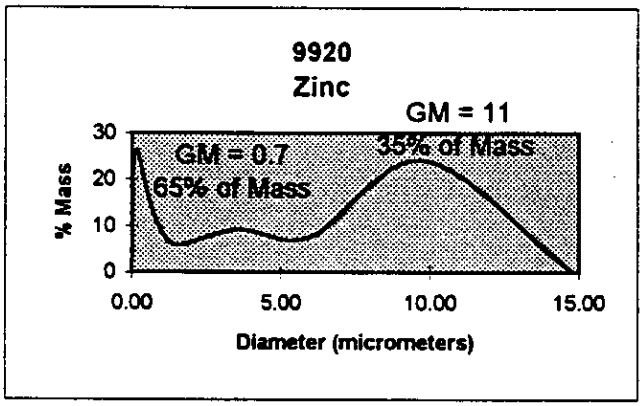
Comments

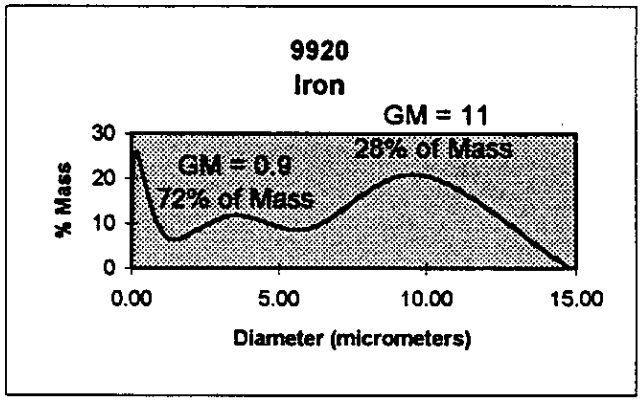
This test also shows a bimodal particle distribution as might be expected in a pouring operation. 55% of the mass is less than 1um. The electret, HEPA-filtered, half-mask provided protection factors well above 10.

SHEET #5









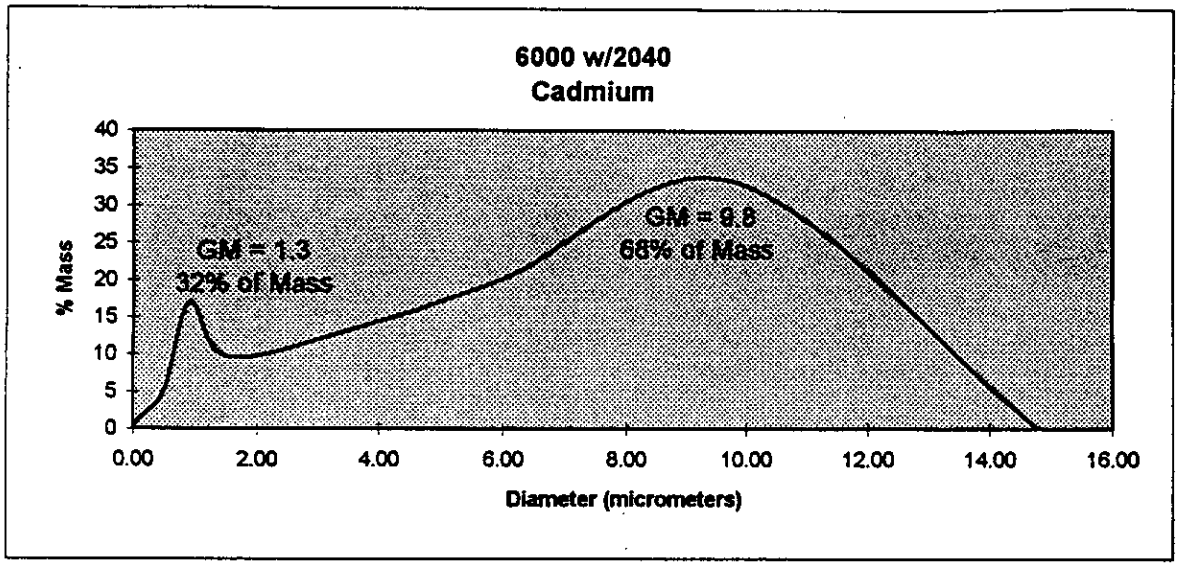
Particle Size	0.1	0.52	0.93	1.6	3.5	6	9.8
% Mass Manganese	44.2	32.2	10.5	3.4	3.2	1.7	4.9
% Mass Titanium	14.4	10.6	7.6	6.8	14.8	13.1	32.7
% Mass Zinc	25.8	17.1	9.7	6	9.3	7.8	24.2
% Mass Iron	25.3	17.3	9.4	6.5	11.8	8.9	20.8

Product	9920, maintenance-free
Respirator Type	Half mask
Filter type	Electret, Dust/Fume/Mist
Application	Welding
Industry Type	Shipbuilding
Study Date	July, 1990
Elements	Fe, Zn, Ti, Mn
Geometric Mean WPF	139, 146, 324, 104
5th% WPF	22, 33, 43, 16

Comments

A variety of elements measured exhibited bimodal distribution in this welding operation. The electret-filtered, D/F/M, half-mask, disposable respirator provided excellent protection despite the small particles in the atmosphere.

SHEET #6

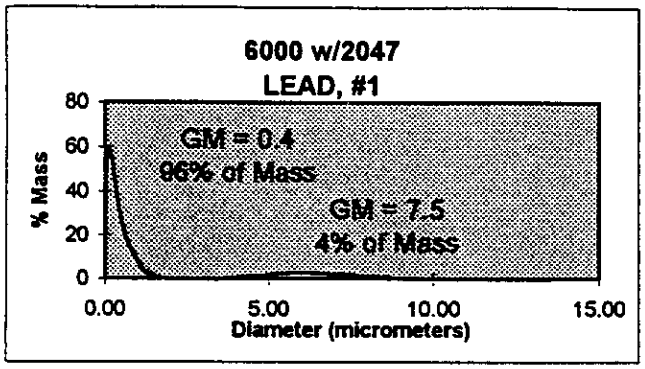


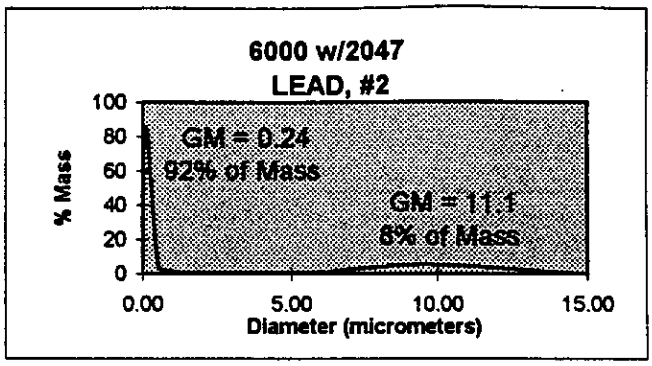
Particle Size	0.1	0.52	0.93	1.6	3.5	6	9.8
% Mass	1.4	5.2	17	9.7	13.2	20.1	33.3

Product	6000 Series with 2040 high efficiency filters
Respirator Type	Half mask
Filter type	Electret, HEPA
Application	Mixing and extruding
Industry Type	Plastic colorants
Study Date	March, 1993
Elements	Cd
Geometric Mean WPF	353
5th% WPF	34

Comments — As indicated, the majority of the mass of the contaminant was in the 10um range. The performance of the electret HEPA filter was excellent.

Sheet #7





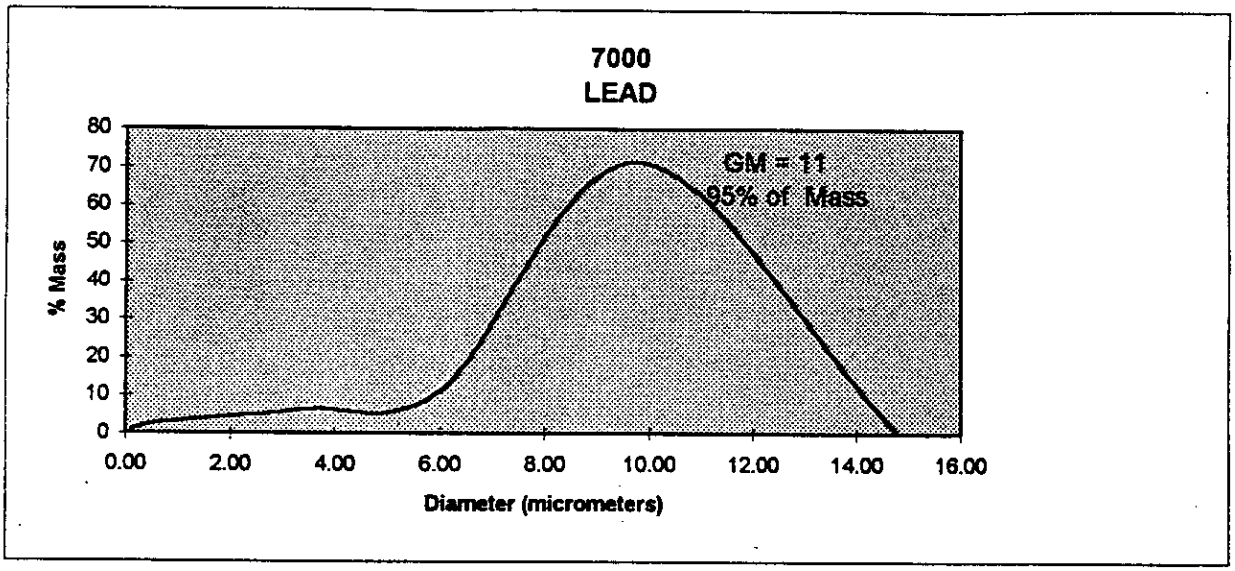
Particle Size		0.1	0.52	0.93	1.6	3.5	6	9.8
% Mass	#1	59.7	25.9	10.4	1.3	0	2.6	0
% Mass	#2	85.5	4.7	1.8	0.65	0.84	0.94	5.6

Product	6000 Series with 2047 high efficiency filters
Respirator Type	Half mask
Filter type	Electret, HEPA
Application	Acetylene torch-cutting
Industry Type	Ship-breaking
Study Date	April, 1993
Elements	Pb
Geometric Mean WPF	135
5th% WPF	15

Comments

The two graphs shown represent the different areas of a ship-breaking or salvaging operation. The particle size distributions are not significantly different; both being mainly in the submicron range. The lead in this operation comes from torch-cutting steel that has years of built-up, lead-based paint. The ship being cut up was a Navy aircraft carrier. The electret HEPA filter provided excellent results and WPF's well above 10 despite the small particle size.

SHEET #8



Particle Size	0.1	0.52	0.93	1.6	3.5	6	9.8
% Mass	1.1	2.7	3.2	4	6.4	11.1	71.5

Product	7000 Series with 7255 and 2040 high efficiency filters
Respirator Type	Half mask
Filter type	Fiberglass (7255), electret (2040) - both HEPA
Application	Pasting and assembly
Industry Type	Battery manufacturing
Study Date	April, 1994
Elements	Pb
Geometric Mean WPF	515, 433
5th% WPF	117, 99

Comments

In this operation the majority of the particles are large as would be predicted in mechanical manipulation of lead material. This distribution is typical of most non-fume operations. It should be noted that 7% of the mass of the particles are below 1um. Even so, the performance of the electret HEPA filter and the typical fiberglass HEPA filter are not statistically different.