ORIGINAL

TSCA NON-CONFIDENTIAL BUSINESS INFORMATION

DOCUMENT DESCRIPTION	DOCUMENT CONTROL NUMBER	DATE RECEIVED
8EHQ- 07-16750	89110000157	3/11/11

COMMENTS: COMMUN S (DECLASS)

DOES NOT CONTAIN CBI

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333857

CONFIDENTIAL

NALCO

Nalco Company
1601 West Diehl Road
Naperville, IL 60563-1198
phone 630.305.1000
www.nalco.com

Via Federal Express

8EHQ-07-16750

March 5, 2007

Document Processing Center (Mail Code 7407M)
Room 6428
Attention: 8(e) Coordinator
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency, ICC Building
1201 Constitution Ave., NW
Washington, D.C. 20460

8EHQ-0311-16750C

DCN: 89110000157

RECEIVED OPPT CBIC 07 MAR -7 AM 6:04

Company Sanitized

RE: TSCA 8(e) Substantial Risk Notice On:

The chemical identity of the substance is:
CAS Registry Number: 25988-97-0
Aqueous solution of Epichlorohydrin - Dimethylamine Copolymer

Dear 8(e) Coordinator:

This letter is to inform you of the results of a recently conducted acute inhalation study (LC_{50}) with the product referenced above. The draft report received on 16 Feburary 2007 is attached.

Five male and five female rats were exposed whole-body for four hours to aerosols of the test product at concentrations of 0.26, 1.29 and 3.25 mg/l. All 10 animals died after exposure to the 3.25 mg/l concentration. All animals survived both the 0.26 and 1.29 mg/l exposures. The estimated LC_{50} is 2.3 mg/l.

Clinical signs made with all concentrations were sagging eyelids, dyspnea and chromodacryorrhea. Other observed effects included lethargy, piloerection, chromorhinorrhea, gasping for air and edema on the head.

Under these experimental conditions, the findings described above appear to be reportable, based upon the guidance given in the EPA TSCA Section 8(e) Reporting Guide (June 1991). The final report will be sent to EPA upon completion of the project.

RECEIVED OPPT CBIC 07 MAR 1 AM 11:21

Please note that a confidential version of this letter and study are enclosed, treating the product name, chemical name and CAS # as Confidential Business Information.

The information considered confidential is highlighted, inaccordance with the US EPA policy. The non-confidential name is referred to as "Polyquaternary Amine."

A confidentiality substantiation questionnaire for the substance is being submitted.

Regards,

Ricky Stackhouse, Ph.D.
Staff Toxicologist

8807000018875

89110000157

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MB RESEARCH LABORATORIES

1765 Wentz Road
P.O. Box 178
Spinnerstown, PA 18968
phone (215) 536-4110
fax (215) 536-1816

T R A N S M I T T A L F O R M

DATE : **February 8, 2007**

TO : **Ms. Kelly Magurany**

COMPANY : Nalco Company
1601 W. Diehl Road
Naperville, IL 60563-1198

FROM : Barbara Kweder

Transmitted herewith are the following:

- ☒ DRAFT REPORT (s)
- ☐ FINAL REPORT
- ☒ INVOICE (s)
- ☐ RAW DATA
- ☒ PROTOCOL SIGNATURE PAGE (s)
- ☒ SPECIMEN DISPOSITION MEMO
- ☐ OTHER

PROTOCOL	STUDY TITLE	TEST ARTICLE	MB PROJECT #
2300	Inhalation Toxicity in Rats	[illegible]	06-15078.05

PLEASE RESPOND WITH YOUR APPROVAL FOR FINAL REPORT VIA FAX, PHONE OR EMAIL.

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MB Research Laboratories

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VOLUME I

Study Title	:	Acute Inhalation Toxicity/LC_{50} in Rats
Test Article	:	[ ]
Author	:	Albert C. Gilotti, Ph.D., Study Director
Study Completed On	:	
Performing Laboratory	:	MB Research Laboratories 1765 Wentz Road P.O. Box 178 Spinnerstown, PA 18968
MB Research Project #	:	MB 06-15078.05
MB Research Protocol #	:	2300
Sponsor	:	Nalco Company 1601 W. Diehl Road Naperville, IL 60563-1198
Citation	:	Albert C. Gilotti, Ph.D. (2007) Unpublished Report by MB Research Laboratories

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Study Title : Inhalation Toxicity in Rats
Project # : MB 06-15078.05
Test Article : [ ]
Protocol : 2300

GOOD LABORATORY PRACTICES COMPLIANCE STATEMENT

This study meets the Good Laboratory Practice requirements of EPA 40 CFR parts 792 and 160, FDA 21 CFR 58, and as specified in Principles on Good Laboratory Practices, published by the Organization for Economic Cooperation & Development (OECD), 1997, with the following exception:

The Test Article Characterization, supplied by the sponsor prior to study initiation, was not conducted under Good Laboratory Practices.

STUDY DIRECTOR :

Albert C. Gilotti, Ph.D. Date
MB RESEARCH LABORATORIES

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MB Research Laboratories

PROJECT NUMBER : MB 06-15078.05
TEST ARTICLE : [ ]
SPONSOR : NALCO COMPANY
TITLE : Acute Inhalation Toxicity/LC_{50} in Rats
PROTOCOL # : 2300

ABSTRACT

Objective: To provide information on health effects which may arise from short-term exposure by the inhalation route. This study was designed to comply with the standards set forth by OECD GUIDELINES FOR TESTING OF CHEMICALS, NUMBER 403, adopted May 12, 1981.

Method Synopsis: Five healthy male and five healthy female Wistar Albino rats were exposed to an aerosol atmosphere of [ ] at a concentration of 3.25 mg/l for a period of four hours. Based on the results of the first dose, two additional groups of five male and five female rats were exposed in order to determine the LC_{50}. Chamber temperature, relative humidity of air entering the chamber, chamber airflow and negative pressure were monitored and recorded. All rats were monitored during the exposure period, one hour after exposure and once daily thereafter for 14 days for toxicity and pharmacological effects. The rats were observed twice daily for mortality. Body weights were recorded prior to exposure, weekly, at death and at termination in the survivors. All animals were examined for gross pathology. Abnormal tissues were preserved in 10% neutral buffered formalin for possible future histologic examination.

Concentration was estimated prior to exposure. Actual concentrations were determined gravimetrically during exposure. Particle size analyses revealed a mass mean aerodynamic diameter of 1.21 μm with geometric standard deviations of 2.68 μm.

Summary: Mortality response to the four-hour inhalation exposures was:

Actual Concentration in mg/l	# Animals Exposed M/F	# Animals Dead M/F
3.25	5/5	5/5
0.26	5/5	0/0
1.29	5/5	0/0

3.25 mg/l: None of the ten animals survived the 3.25 mg/l inhalation exposure. Four animals died during the four hour exposure. The last survivor died on Day 2. During the exposure, the animals were observed to have sagging eyelids, fur coated with test article and were gasping for air. After exposure, the animals were observed to have lethargy, piloerection, sagging eyelids, wetness and red staining of the nose/mouth area, chromodacryorrhea, dyspnea and few feces. Necropsy revealed fur coated with test article, chromodacryorrhea and abnormalities of the nose/mouth area, anogenital area, thymus, lungs, nasal turbinates, liver, stomach, intestines and cecum.

ABSTRACT (continued)

Summary (continued):

0.26 mg/l: All ten of the animals survived the 0.26 mg/l inhalation exposure. During the exposure, the animals were noted to have fur coated with test article and sagging eyelids. Instances of sagging eyelids, piloerection, fur coated with test article, chromodacryorrhea, edema on head, few feces, dyspnea, chromorhinorrhea and alopecia on the forelimbs were noted during the study. Body weight changes were normal. Necropsy revealed instances of edema and alopecia. Eight animals appeared normal at necropsy.

1.29 mg/l: All ten of the animals survived 1.29 mg/l inhalation exposure. During the exposure, the animals were observed to have eyes closed and fur coated with test article. Instances of sagging eyelids, dyspnea, wetness of the nose/mouth area, few feces, edema on head, emaciated appearance, unkempt appearance, chromodacryorrhea, lethargy, alopecia on the face and chromorhinorrhea were noted during the study. Two males and one female lost weight during the study, but regained by study termination. Necropsy revealed abnormalities of the kidneys and alopecia. Eight animals appeared normal at necropsy.

Conclusion: The LC_{50} of [s greater than 1.29 mg/l but less than 3.25 mg/l.

MB Research Laboratories

Study Title	:	Inhalation Toxicity in Rats
Project #	:	MB 06-15078.05
Test Article	:	[illegible]
Protocol	:	2300

OBJECTIVE

To provide information on health effects which may arise from short-term exposure by the inhalation route. This study was designed to comply with the standards set forth by OECD GUIDELINES FOR TESTING OF CHEMICALS, NUMBER 403, adopted May 12, 1981.

TEST ARTICLE

Identity	:	[illegible]
Test Article Characterization	:	See Appendix 6 for the Test Article Characterization.
Stability	:	The test article is stable according the Test Article Characterization.
Source	:	Nalco Company
Date Received	:	11/06/06
Storage	:	Room temperature and humidity
Description	:	Clear yellow liquid
Sample Preparation	:	Used as received

TEST DATES

Study Initiation	(date protocol signed)	:	11/08/06
Experimental Start Date	(1st exposure to test substance)	:	11/10/06
Experimental Term Date	(last date data collected)	:	12/14/06
Draft Report Signed	(if applicable)	:	02/08/07
Final Report Signed	(study completion)	:	

EXPERIMENTAL DESIGN

Test Animals

Animals were received from Ace Animals, Boyertown, PA on 10/17/06, 10/24/06, 11/08/06, 11/16/06 and 11/21/06. Following an equilibration period of at least five days, fifteen healthy male and fifteen healthy, non-pregnant and nulliparous female Wistar Albino rats were randomly selected for this test from a larger group using standard methods of randomization.

The animals were born the weeks of 08/29/06, 09/12/06, 09/20/06, 09/26/06 and 10/03/06. The pretest body weight range was 243 - 367 grams for males and 209 - 265 grams for females.

Animals were identified by cage notation and indelible tail marks. The animals were housed 1/cage in suspended cages. Bedding was placed beneath the cages and changed at least three times/week. Fresh PMI Rat Chow (Diet #5012) and water were freely available except during the four-hour exposure period. The animal room, reserved exclusively for rats on acute tests, was temperature controlled, had a 12-hour light/dark cycle and was kept clean and vermin free.

EXPERIMENTAL DESIGN (continued)

Dosing

Five male and five female rats were exposed to [ ] at a concentration of 3.25 mg/l in an inhalation chamber for four hours. Based on the results of the first dose, two additional groups of five male and five female rats were exposed at 0.26 mg/l and 1.29 mg/l respectively in order to determine the LC_{50}. Following exposure, the animals were gently washed with warm tap water to remove any residual test substance from the face and body. The animals were then returned to individual housing.

Chamber Conditions (Appendices 1 & 2)

A 100-liter dynamic glass chamber designed to insure uniform spatial distribution of aerosols and which permitted continuous observation during exposure was used. The chamber was partitioned internally with wire screening into a total of ten non-restraining cubicles. One animal was placed in each cubicle. Chamber temperature and humidity of air entering the chamber were recorded. The airflow through the chamber was calculated to yield at least 10 to 15 air changes per hour so that adequate oxygen was supplied to the animals. The chamber was maintained at a negative pressure differential to the immediate environment in order to keep the test atmosphere contained. The temperature, humidity, airflow and negative pressure were recorded at approximately thirty-minute intervals during the exposure period.

Generation

[ ] was added from a Harvard Infusion Pump into an atomizing nozzle (Spraying Systems Model 1/8 JBC). The appropriate flow rate was determined pretest. The spray nozzle was powered by pre-filtered compressed air. Nozzle pressure was monitored using a pressure gauge and was recorded initially. The exhaust air was passed through filters before entering into a rotameter and vacuum pump.

Concentration (Appendices 3 & 4)

The target concentration was determined prior to exposure by determining the best flow rate for generating the desired concentration.

In order to calculate the concentration gravimetrically, the total solid was determined prior to exposure by drying a preweighed sample of the test article for two minutes, reweighing and calculating the total solid:

$$\frac{\text{Final weight}}{\text{Initial weight}}$$

During the exposure, chamber air was drawn through preweighed filters. The filters were removed and reweighed. The actual concentration of the test article was calculated based on the total solid, the amount of test article dispersed and the air flow through the chamber.

Particle Size Measurements (Appendix 5)

Mass mean aerodynamic diameter (MMAD) was calculated pretest and during each exposure period. An 8 stage Andersen cascade impactor was used to determine particle size. Air was drawn through the impactor for 2-5 minutes. The impactor filter paper collection stages were weighed before and after the air sampling to determine the mass collected at each filter paper collection stage. The MMAD was determined graphically using three cycle logarithmic probit paper. The geometric standard deviation was calculated. A pretest MMAD of 4 microns or less was required to ensure that the particles generated during exposure were in the respirable range. Particle size measurements were recorded at least three times during the exposure period. The average particle size was calculated.

EXPERIMENTAL DESIGN (continued)

Type and Frequency of Observations

In Vivo - Animals were observed at hourly intervals during exposure, at one hour post exposure and once daily thereafter for 14 days for signs of toxicity and pharmacological effects. The animals were observed twice daily for mortality. Body weights were recorded pretest, weekly, at death and at termination in the survivors.

Post Mortem: All surviving animals were humanely sacrificed using CO_2 following study termination. All animals were examined for gross pathology. Abnormal tissues were preserved in 10% neutral buffered formalin for possible future histologic examination.

Analysis of Data

An estimate of the LC_{50} was made based on mortality occurring during the study.

Retention of Data

Upon signing the final report, all raw data, supporting documentation and reports are submitted to the Archivist by the Study Director. The raw data is filed at MB Research by project number. The final report is filed at MB Research by sponsor name and MB project number. The preserved tissues are stored at MB Research by sponsor name and MB project number. The sponsor will be contacted for final disposition of the tissues upon submission of the report.

The test article will be discarded following submission of the report.

Amendment to the Protocol

To characterize the aerosolized test article, samples of the filters used to determine concentration will be retained to send to the Sponsor. Each filter (Whatman Catalog Number 1822 047) will be sealed in a labeled Ziploc bag after the end weight determination.

Deviations to the Protocol

1. The second mortality check for animal 30 (F) was inadvertently not recorded on Day 1. This oversight had no impact on the outcome of the study because the animal was observed to be alive on the following day
2. Temperature of the chamber air and humidity of the air entering the chamber was not recorded at exactly 30-minute intervals. This deviation had no impact on the outcome of the study because in all cases the chamber conditions were recorded within ± five minutes of the 30-minute interval.
3. The humidity of the air entering the chamber was slightly below protocol specified levels. This deviation had no impact on the outcome of the study because this condition remained constant throughout each exposure. During these exposures, the mortality was related to the concentration of the test article. Upon verification, the instrument appeared functional.
4. One male (animal #5) at the initiation of the study was outside ± 20% of the mean body weight. This deviation had no effect on the outcome of the study because the toxicity of the test article was apparently independent of body weight.

Deviation to Good Laboratory Practices

The Test Article Characterization, supplied by the sponsor prior to study initiation, was not conducted under Good Laboratory Practices. This is not expected to have any impact on the study.

RESULTS & DISCUSSION

Summary: Mortality, Systemic Observations (Table 1), Body Weights (Table 2) and Necropsy Findings (Table 3):

Mortality response to the four-hour inhalation exposures was:

Actual Concentration in mg/l	# Animals Exposed M/F	# Animals Dead M/F
3.25	5/5	5/5
0.26	5/5	0/0
1.29	5/5	0/0

3.25 mg/l: None of the ten animals survived the 3.25 mg/l inhalation exposure. Four animals died during the four hour exposure. The last survivor died on Day 2. During the exposure, the animals were observed to have sagging eyelids, fur coated with test article and were gasping for air. After exposure, the animals were observed to have lethargy, piloerection, sagging eyelids, wetness and red staining of the nose/mouth area, chromodacryorrhea, dyspnea and few feces. Necropsy revealed fur coated with test article, chromodacryorrhea and abnormalities of the nose/mouth area, anogenital area, thymus, lungs, nasal turbinates, liver, stomach, intestines and cecum.

0.26 mg/l: All ten of the animals survived the 0.26 mg/l inhalation exposure. During the exposure, the animals were noted to have fur coated with test article and sagging eyelids. Instances of sagging eyelids, piloerection, fur coated with test article, chromodacryorrhea, edema on head, few feces, dyspnea, chromorhinorrhea and alopecia on the forelimbs were noted during the study. Body weight changes were normal. Necropsy revealed instances of edema and alopecia. Eight animals appeared normal at necropsy.

1.29 mg/l: All ten of the animals survived 1.29 mg/l inhalation exposure. During the exposure, the animals were observed to have eyes closed and fur coated with test article. Instances of sagging eyelids, dyspnea, wetness of the nose/mouth area, few feces, edema on head, emaciated appearance, unkempt appearance, chromodacryorrhea, lethargy, alopecia on the face and chromorhinorrhea. Two males and one female lost weight during the study, but regained by study termination. Necropsy revealed abnormalities of the kidneys and alopecia. Eight animals were normal at necropsy.

MB Research Laboratories

Study Title : **Inhalation Toxicity in Rats**
Project # : **MB 06-15078.05**
Test Article : [ ]
Protocol : **2300**

CONCLUSION

The LC_{50} of [ ] is greater than 1.29 mg/l but less than 3.25 mg/l.

DRAFT REPORT

Approved by: 2-8-07

Albert C. Gilotti, Ph.D. Date
Study Director

Upon approval of this draft report by the sponsor, a final report with full signatures will be issued.

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Table 1: Systemic Observations

TOXICITY CODE

B	=	Lethargy
F	=	Piloerection
J	=	Chromodacryorrhea
M	=	Dyspnea
Q	=	Sagging eyelids
S	=	Chromorhinorrhea
W	=	Appears emaciated
X	=	Few feces
Z	=	Dead
1	=	Eyes closed
2	=	Nose/mouth area wet
3	=	Nose/mouth area stained red
4	=	Fur coated with test article
7	=	Unkempt appearance
10	=	Gasping for air
12	=	Edema on head
13	=	Alopecia on forelimbs
15	=	Alopecia on face

Study Title : **Inhalation Toxicity in Rats**
Project # : **MB 06-15078.05**
Test Article :
Protocol : **2300**

Table 1 (cont'd): Systemic Observations

Concentration: 3.25 mg/l

TIME PERIODS	ANIMAL # / SEX									
	1/M	2/M	3/M	4/M	5/M	6/F	7/F	8/F	9/F	10/F
Day 0=Exposure	Q,4,10	Q,4	Q,4, 10	Q,4	Q,4	Q,4,10	Q,4	Q,4	Q,4	Q,4
Day 0= 60Minutes	Q,4,10	Q,4	Q,4	Q,4	Q,4	Q,4	Q,4,10	Q,4	Q,4	Q,4
Day 0 = 120 Minutes	Q,4,10	Q,4	Q,4	Q,4	Q,4,10	Q,4	Q,4,10	Q,4	Q,4	Q,4,10
Day 0 = 180 Minutes	Z	Q,4	Q,4,Z	Q,4	Z	Q,4	Z	Q,4	Q,4	Z
Day 0 = 240 Minutes		B,F,Q,2,3		B,F,Q,2,3,J		B,Q,F,2,3,J		B,Q,F,2,3,J	B,Q,F,2,3	
Day 0 = Hour 5		Z (317 g)		Z (284 g)		J,B,Q,2,3,M		Z (216 g)	Z (217 g)	
Day 1						X,Z (201 g)				
Day 2										
Day 3										
Day 4										
Day 5										
Day 6										
Day 7										
Day 8										
Day 9										
Day 10										
Day 11										
Day 12										
Day 13										
Day 14										

Systemic observation code is on page preceding systemic observation tables.

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Study Title : Inhalation Toxicity in Rats
Project # : MB 06-15078.05
Test Article : [redacted]
Protocol : 2300

Table 1 (cont'd): Systemic Observations

Concentration: 0.26 mg/l

TIME PERIODS	ANIMAL # / SEX									
	11/M	12/M	13/M	14/M	15/M	16/F	17/F	18/F	19/F	20/F
Day 0=Exposure	4	4	4	4	4	4	4	4	4	4
Day 0= 60Minutes	4	4	4	4	4	4	4	4	4	4
Day 0 = 119 Minutes	4,Q	4,Q	4,Q	4,Q	4,Q	4,Q	4,Q	4,Q	4,Q	4,Q
Day 0 = 129 Minutes	4,Q	4,Q	4,Q	4,Q	4,Q	4,Q	4,Q	4,Q	4,Q	4,Q
Day 0 = 238 Minutes	Q,F,4	Q	Q			Q,F	Q			Q
Day 0 = Hour 5	4,Q,F,J,12		S			X	X			X
Day 1	J,12,Q,F,4,X		S			X				X
Day 2	X,12,J,4,Q									
Day 3	X,12,J,4,Q									
Day 4	Q,12,M							13	13	13
Day 5	Q,12,M							13	13	13
Day 6	Q,12,M							13	13	13
Day 7	Q,12							13	13	13
Day 8	Q,12									13
Day 9	Q,12									13
Day 10	Q,12									13
Day 11	12									13
Day 12	12									13
Day 13	12									13
Day 14										

No entry indicates animal appeared normal at that observation period. Systemic observation code is on page preceding systemic observation tables.

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Study Title : Inhalation Toxicity in Rats
Project # : MB 06-15078.05
Test Article : [ ]
Protocol : 2300

Table 1 (cont'd): Systemic Observations

Concentration: 1.29 mg/l

TIME PERIODS	ANIMAL # / SEX									
	21/M	22/M	23/M	24/M	25/M	26/F	27/F	28/F	29/F	30/F
Day 0=Exposure	4	4	4	4	4	4	4	4	4	4
Day 0= 60Minutes	4,1	4,1	4,1	4,1	4,1	4,1	4,1	4,1	4,1	4,1
Day 0 = 120 Minutes	4,1	4,1	4,1	4,1	4,1	4,1	4,1	4,1	4,1	4,1
Day 0 = 180 Minutes	4,1	4,1	4,1	4,1	4,1	4,1	4,1	4,1	4,1	4,1
Day 0 = 238 Minutes	Q,2	S		M,2		Q,S	Q,S,J,M	Q,J		Q,J
Day 0 = Hour 5	Q,2,X	S,M	X			X	X	M,J,X	X	M,J,X
Day 1	Q,12,X					X	X,S			X,S
Day 2	Q,12,X									
Day 3	X,W									
Day 4	W,7,J									
Day 5	7,W									W
Day 6	7,W,B	W								7,W
Day 7	7,W	W								
Day 8	7	W								
Day 9	7	W								
Day 10	7,15									
Day 11	J,15									
Day 12	15,M									
Day 13	15,M									
Day 14										

No entry indicates animal appeared normal at that observation period. Systemic observation code is on page preceding systemic observation tables.

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Study Title : Inhalation Toxicity in Rats
Project # : MB 06-15078.05
Test Article : [ ]
Protocol : 2300

Table 2: Body Weights (grams)

Concentration: 3.25 mg/l

An. #	Sex	Day 0	Day 7	Day 14
1	M	344		
2	M	351		
3	M	356		
4	M	316		
5	M	367		
	MEAN	347		
	S.D.	19.1		
	#	5		
6	F	246		
7	F	246		
8	F	247		
9	F	248		
10	F	254		
	MEAN	248		
	S.D.	3.3		
	#	5		

No entry indicates animal died before observation period

Concentration: 0.26 mg/l

An. #	Sex	Day 0	Day 7	Day 14
11	M	282	283	356
12	M	256	295	350
13	M	250	262	307
14	M	260	308	351
15	M	247	303	366
	MEAN	259	290	346
	S.D.	13.8	18.4	22.7
	#	5	5	5
16	F	209	214	242
17	F	265	267	289
18	F	210	228	245
19	F	219	224	251
20	F	210	218	238
	MEAN	223	230	253
	S.D.	24.0	21.3	20.7
	#	5	5	5

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Table 2 (cont'd): Body Weights (grams)

Concentration: 1.29 mg/l

An. #	Sex	Day 0	Day 7	Day 14
21	M	246	230	302
22	M	261	245	321
23	M	251	288	343
24	M	243	278	330
25	M	273	309	378
	MEAN	255	270	335
	S.D.	12.3	32.1	28.4
	#	5	5	5
26	F	209	211	216
27	F	218	229	249
28	F	216	225	247
29	F	220	229	253
30	F	219	222	244
	MEAN	216	223	242
	S.D.	4.4	7.4	14.8
	#	5	5	5

Study Title : Inhalation Toxicity in Rats
Project # : MB 06-15078.05
Test Article : [ ]
Protocol : 2300

Table 3: Necropsy Observations

Concentration: 3.25 mg/l

OBSERVATION	ANIMAL NUMBER/SEX	1/M	2/M	3/M	4/M	5/M	6/F	7/F	8/F	9/F	10/F
	Death/Sacrifice	D	D	D	D	D	D	D	D	D	D
Fur coated with test article		3	1		1	3	1	3	1	1	3
Chromodacryorrhea							3				
Nose/mouth: stained red			3	3	3		2		3	3	
Nose/mouth: wet			3	3	3		2		3	3	
Anogenital area: red									2	2	
Thymus: dark areas			1		3	1		1			
Lungs: darker than normal						3	3				
Lungs: red areas		3	3	3	3	3	3	3	3	3	3
Nasal Turbinates: red areas (thick clear substance)		3	3	3	3	3	3	3	2	2	3
Liver: pale areas						1	1	1		1	
Stomach: red					2		2	3	2		3
Stomach: distended with gas			2		3					2	
Intestines: red areas		2	2	2	1		3	2	2	2	3
Intestines: distended with mucous					2						
Intestines: yellow areas					2		2				
Cecum: distended with gas			2		2						

CODES:
D = death
1= slight or scattered
2= moderate or few
3= pronounced or many

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Study Title : **Inhalation Toxicity in Rats**
Project # : **MB 06-15078.05**
Test article :
Protocol : **2300**

Table 3 (cont'd): Necropsy Observations

Concentration: 0.26 mg/l

ANIMAL NUMBER/SEX	11/M	12/M	13/M	14/M	15/M	16/F	17/F	18/F	19/F	20/F
OBSERVATION Death/Sacrifice	S	S	S	S	S	S	S	S	S	S
Normal		X	X	X	X	X	X	X	X	
Edema on head	1									
Alopecia on forelimbs										2

Concentration: 1.29 mg/l

ANIMAL NUMBER/SEX	21/M	22/M	23/M	24/M	25/M	26/F	27/F	28/F	29/F	30/F
OBSERVATION Death/Sacrifice	S	S	S	S	S	S	S	S	S	S
Normal			X	X	X	X	X	X	X	X
Alopecia on face	1									
Kidneys: mottled		2								
Right Kidney: pale areas	1									

CODES:
S = sacrifice
X = observed
1= slight or scattered
2= moderate or few

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Study Title : Inhalation Toxicity in Rats
Project # : MB 06-15078.05
Test article : L
Protocol : 2300

Appendix 1: Chamber Conditions

Concentration: 3.25 mg/l

Time (minutes)	Airflow l/min	Temperature °C	Negative Pressure inches H_2O	Relative Humidity of Air Entering Chamber %
30	36	20.2	0.2	23
60	36	22.2	0.2	23
90	36	21.5	0.2	23
120	36	20.0	0.2	23
151	36	20.8	0.2	23
180	36	20.2	0.2	23
210	36	20.1	0.2	23
240	36	20.4	0.2	23

Concentration: 0.26 mg/l

Time (minutes)	Airflow l/min	Temperature °C	Negative Pressure inches H_2O	Relative Humidity of Air Entering Chamber %
30	25	20.8	0.4	23
60	25	20.5	0.4	23
90	25	21.1	0.4	23
119	25	21.2	0.4	23
154	25	21.1	0.4	23
180	25	20.6	0.4	23
208	25	20.0	0.4	23
238	24	20.3	0.4	23

Concentration: 1.29 mg/l

Time (minutes)	Airflow l/min	Temperature °C	Negative Pressure inches H_2O	Relative Humidity of Air Entering Chamber %
30	36	20.0	0.4	23
60	36	20.6	0.4	23
90	36	20.5	0.4	23
120	36	21.1	0.4	23
150	36	20.6	0.4	23
180	36	20.1	0.4	23
210	36	20.2	0.4	23
240	36	20.0	0.4	23

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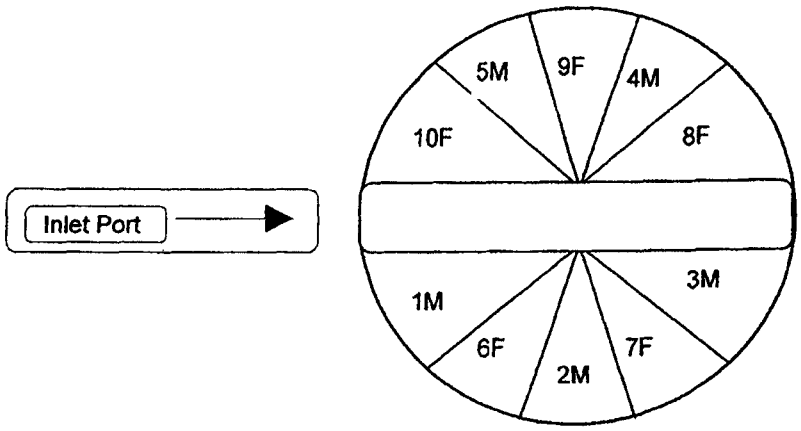
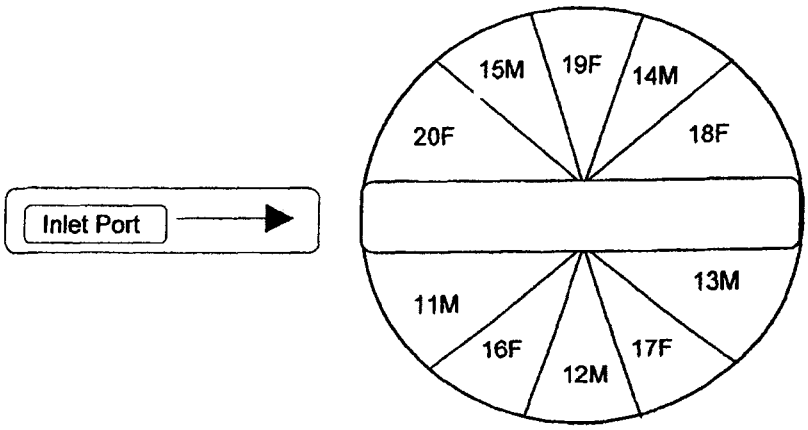
Project # : **MB 06-15078.05**
Test article : [illegible]
Protocol : **2300**

Appendix 2: Position of Rats in Exposure Chamber

Concentration: 3.25 mg/l



Concentration: 0.26 mg/l



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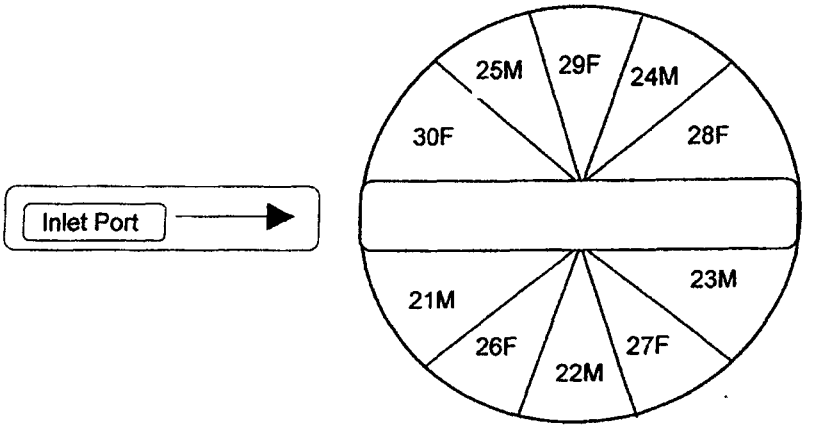
Study Title : Inhalation Toxicity in Rats
Project # : MB 06-15078.05
Test article :
Protocol : 2300

Appendix 2 (cont'd): Position of Rats in Exposure Chamber

Concentration: 1.29 mg/l



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Appendix 3: Chamber Concentrations

Total Solid Calculation

Sample #	Tare Weight (g)	Test Article Volume (cc)	Test Article + Tare Initial Weight (g)	Test Article + Tare Final Weight (g)	Final Weight/ Initial Weight
1	0.0908	0.1	0.2087	0.2041	0.96
2	0.0913	0.1	0.2132	0.2083	0.96
3	0.0918	0.1	0.2053	0.2008	0.96
				Mean	0.96
				SD	0.00
				n	3

Appendix 4: Concentration Determination

Concentration: 3.25 mg/l

Sample #	Measured Test Article (g)	Total Solid	Total Test Article* (g)	Air Volume Liters	Total Concentration (mg/l)
1	0.0160	0.96	0.0167	6	2.78
2	0.0184	0.96	0.0192	6	3.20
3	0.0360	0.96	0.0375	9.75	3.85
4	0.0214	0.96	0.0223	6	3.72
5	0.0155	0.96	0.0161	6	2.68
				Mean	3.25
				SD	0.53
				n	5

Concentration: 0.26 mg/l

Sample #	Measured Test Article (g)	Total Solid	Total Test Article* (g)	Air Volume Liters	Total Concentration (mg/l)
1	0.0010	0.96	0.0010	6	0.17
2	0.0009	0.96	0.0009	6	0.15
3	0.0016	0.96	0.0017	6	0.28
4	0.0016	0.96	0.0017	6	0.28
5	0.0006	0.96	0.0006	6	0.10
6	0.0014	0.96	0.0015	6	0.25
7	0.0015	0.96	0.0016	6	0.27
8	0.0008	0.96	0.0008	6	0.13
9	0.0014	0.96	0.0015	6	0.25
10	0.0038	0.96	0.0040	6	0.67
				Mean	0.26
				SD	0.16
				n	10

*Total Test Article = Measured Test Article/Total Solid

Appendix 4 (cont'd): Concentration Determination

Concentration: 1.29 mg/l

Sample #	Measured Test Article (g)	Total Solid	Total Test Article* (g)	Air Volume Liters	Total Concentration (mg/l)
1	0.0144	0.96	0.0150	6	2.50
2	0.0123	0.96	0.0128	6	2.13
3	0.0056	0.96	0.0058	6	0.97
4	0.0042	0.96	0.0044	6	0.73
5	0.0030	0.96	0.0031	6	0.52
6	0.0065	0.96	0.0068	6	1.13
7	0.0082	0.96	0.0085	6	1.42
8	0.0051	0.96	0.0053	6	0.88
				Mean	1.29
				SD	0.70
				n	8

*Total Test Article = Measured Test Article/Total Solid

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Study Title : **Inhalation Toxicity in Rats**
Project # : **MB 06-15078.05**
Test article : [redacted]
Protocol : **2300**

Appendix 5: Particle Size

Concentration: 3.25 mg/l - Run # 1

Effective Cut-off Diameter Micrometers	Initial Filter Weight (g)	Final Filter Weight (g)	Net Collected (g)	% of Total Weight in Size Range	Cumulative % Less Than Size Range
10.0	NA	NA	NA	NA	NA
9.0	NA	NA	NA	NA	NA
5.8	0.3020	0.3038	0.0018	6.25	100.00
4.7	0.2949	0.2979	0.0030	10.42	93.75
3.3	0.2949	0.2965	0.0016	5.56	83.33
2.1	0.2987	0.3004	0.0017	5.90	77.77
1.1	0.3286	0.3379	0.0093	32.29	71.87
0.7	0.3329	0.3443	0.0114	39.58	39.58
0.4	0.3227	0.3227	0.0000	0.00	0.00
0	0.3191	0.3191	0.0000	0.00	0.00
		Total:	0.0288		

16% Diameter - Micrometers =	0.455
50% Diameter - Micrometers =	1.03
84% Diameter - Micrometers =	2.36
Mass Mean Aerodynamic Diameter (MMAD) - Micrometers =	1.03
Geometric Standard Deviation = Square root of 84%/16% =	2.28
84%/50% =	2.29
50%/16% =	2.26

NA = not applicable

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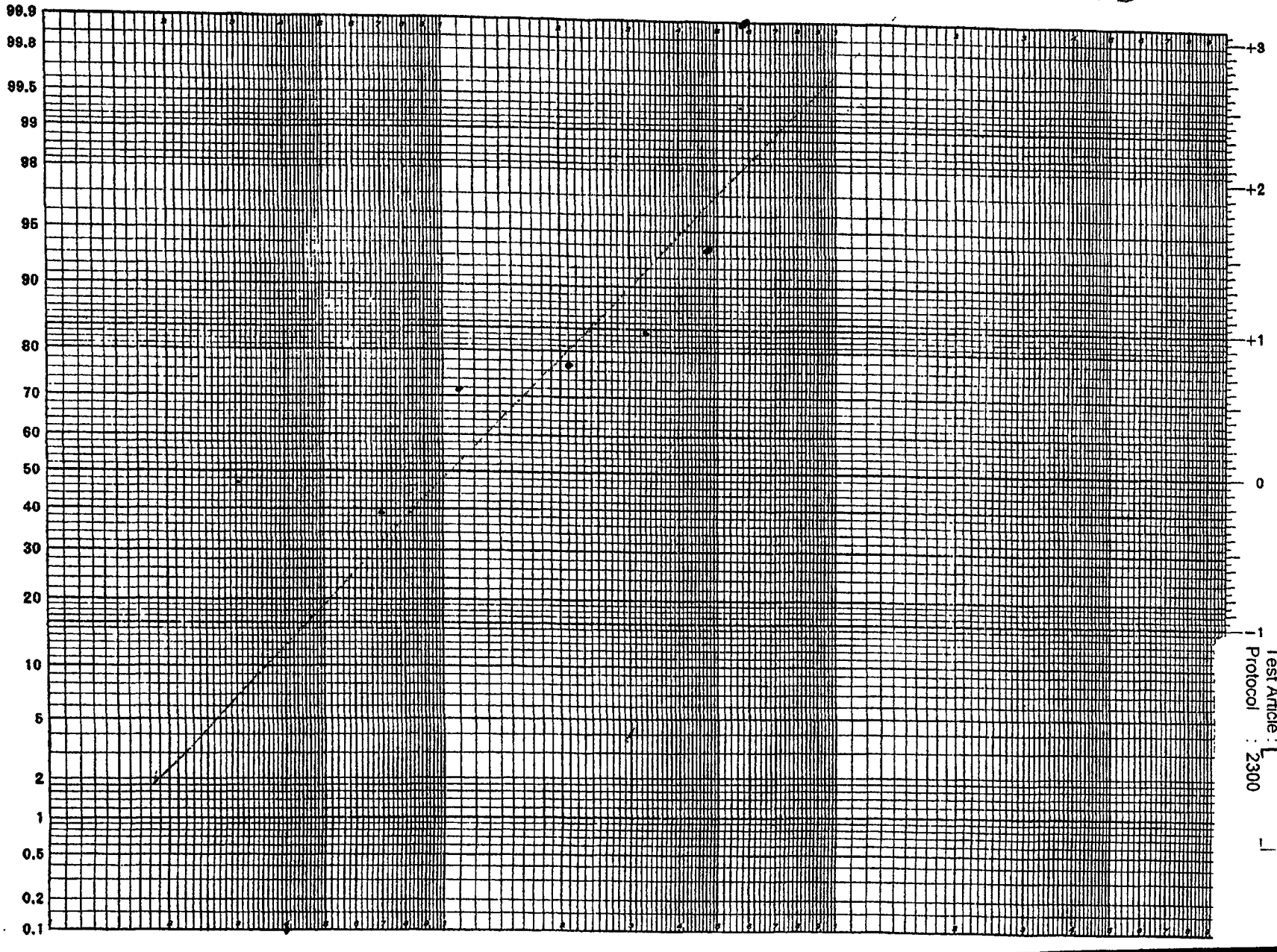
Bt#06-15078.05 Particle Size Analysis Run #1 Nov 10-06



Study Title : Inhalation Toxicity in F
Project # : MB 06-15078.05
Test Article : [ ]
Protocol : 2300

Study Title : **Inhalation Toxicity in Rats**
Project # : **MB 06-15078.05**
Test article :
Protocol : **2300**

Appendix 5 (cont'd): Particle Size

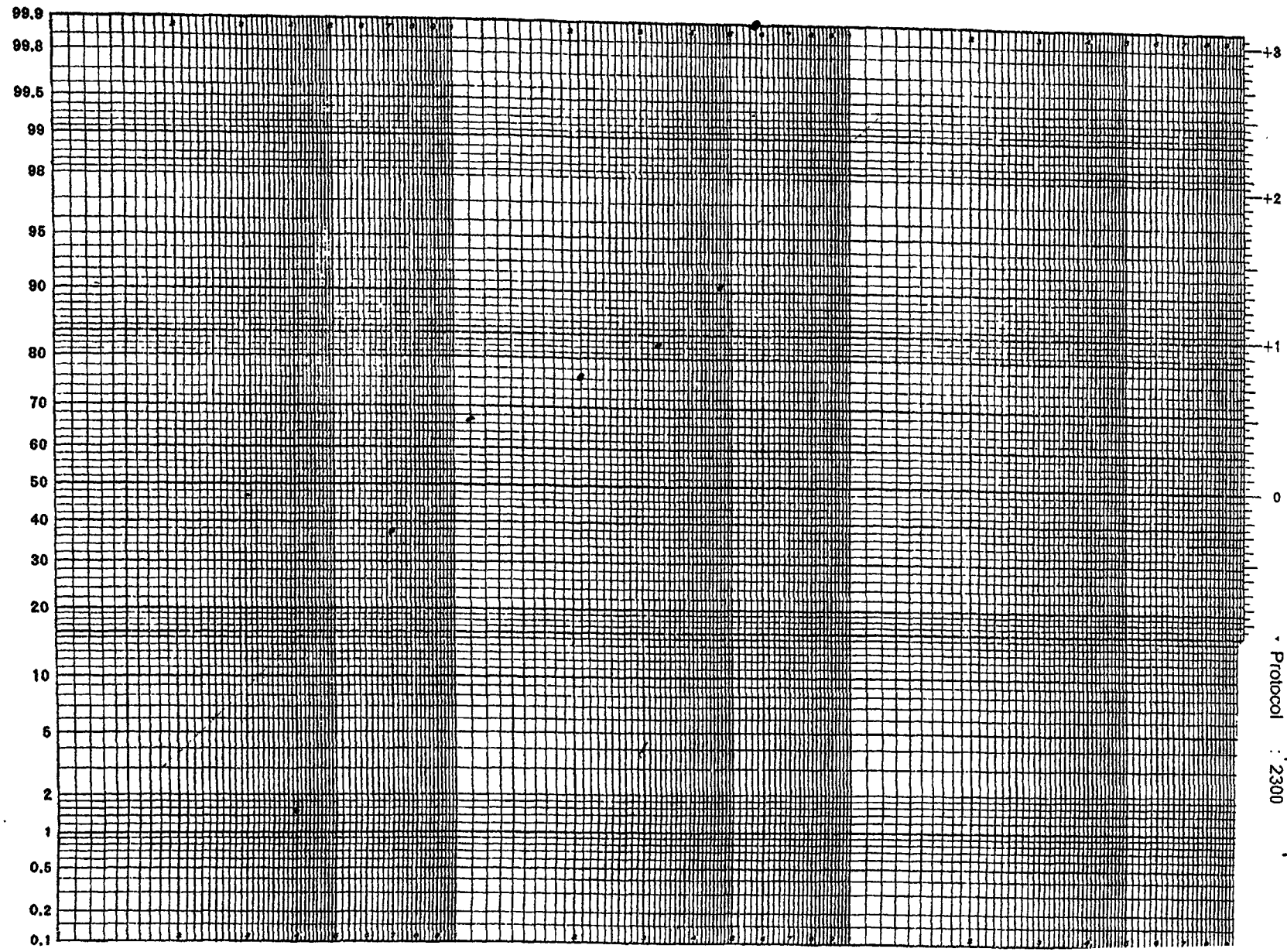
Concentration: 3.25 mg/l - Run # 2

Effective Cut-off Diameter Micrometers	Initial Filter Weight (g)	Final Filter Weight (g)	Net Collected (g)	% of Total Weight in Size Range	Cumulative % Less Than Size Range
10.0	NA	NA	NA	NA	NA
9.0	NA	NA	NA	NA	NA
5.8	0.2828	0.2848	0.0020	9.76	100.01
4.7	0.2742	0.2757	0.0015	7.32	90.25
3.3	0.3189	0.3203	0.0014	6.83	82.93
2.1	0.3207	0.3226	0.0019	9.27	76.10
1.1	0.3211	0.3271	0.0060	29.27	66.83
0.7	0.3195	0.3269	0.0074	36.10	37.56
0.4	0.3169	0.3172	0.0003	1.46	1.46
0	0.3196	0.3195	NA	0.00	0.00
		Total:	0.0205		

16% Diameter - Micrometers =	0.425
50% Diameter - Micrometers =	1.1
84% Diameter - Micrometers =	2.85
Mass Mean Aerodynamic Diameter (MMAD) - Micrometers =	1.1
Geometric Standard Deviation = Square root of 84%/16% =	2.59
84%/50% =	2.59
50%/16% =	2.59

NA = not applicable

LB#06-15078.05 Particle Size Analysis Run #2 Nov 10 '06



Study Title : Inhalation Toxicity in F
Project # : MB 06-15078.05
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Study Title : Inhalation Toxicity in Rats
Project # : MB 06-15078.05
Test article :
Protocol : 2300

Appendix 5 (cont'd): Particle Size

Concentration: 3.25 mg/l - Run # 3

Effective Cut-off Diameter Micrometers	Initial Filter Weight (g)	Final Filter Weight (g)	Net Collected (g)	% of Total Weight in Size Range	Cumulative % Less Than Size Range
10.0	NA	NA	NA	NA	NA
9.0	NA	NA	NA	NA	NA
5.8	0.2722	0.2750	0.0028	3.50	100.01
4.7	0.2776	0.2808	0.0032	4.00	96.51
3.3	0.3131	0.3376	0.0245	30.63	92.51
2.1	0.3154	0.3257	0.0103	12.88	61.88
1.1	0.3166	0.3330	0.0164	20.50	49.00
0.7	0.3158	0.3386	0.0228	28.50	28.50
0.4	0.3206	0.3204	NA	0.00	0.00
0	0.3223	0.3222	NA	0.00	0.00
		Total:	0.0800		

16% Diameter - Micrometers =	0.56
50% Diameter - Micrometers =	1.18
84% Diameter - Micrometers =	2.45
Mass Mean Aerodynamic Diameter (MMAD) - Micrometers =	1.18
Geometric Standard Deviation = Square root of 84%/16% =	2.09
84%/50% =	2.08
50%/16% =	2.11

NA = not applicable

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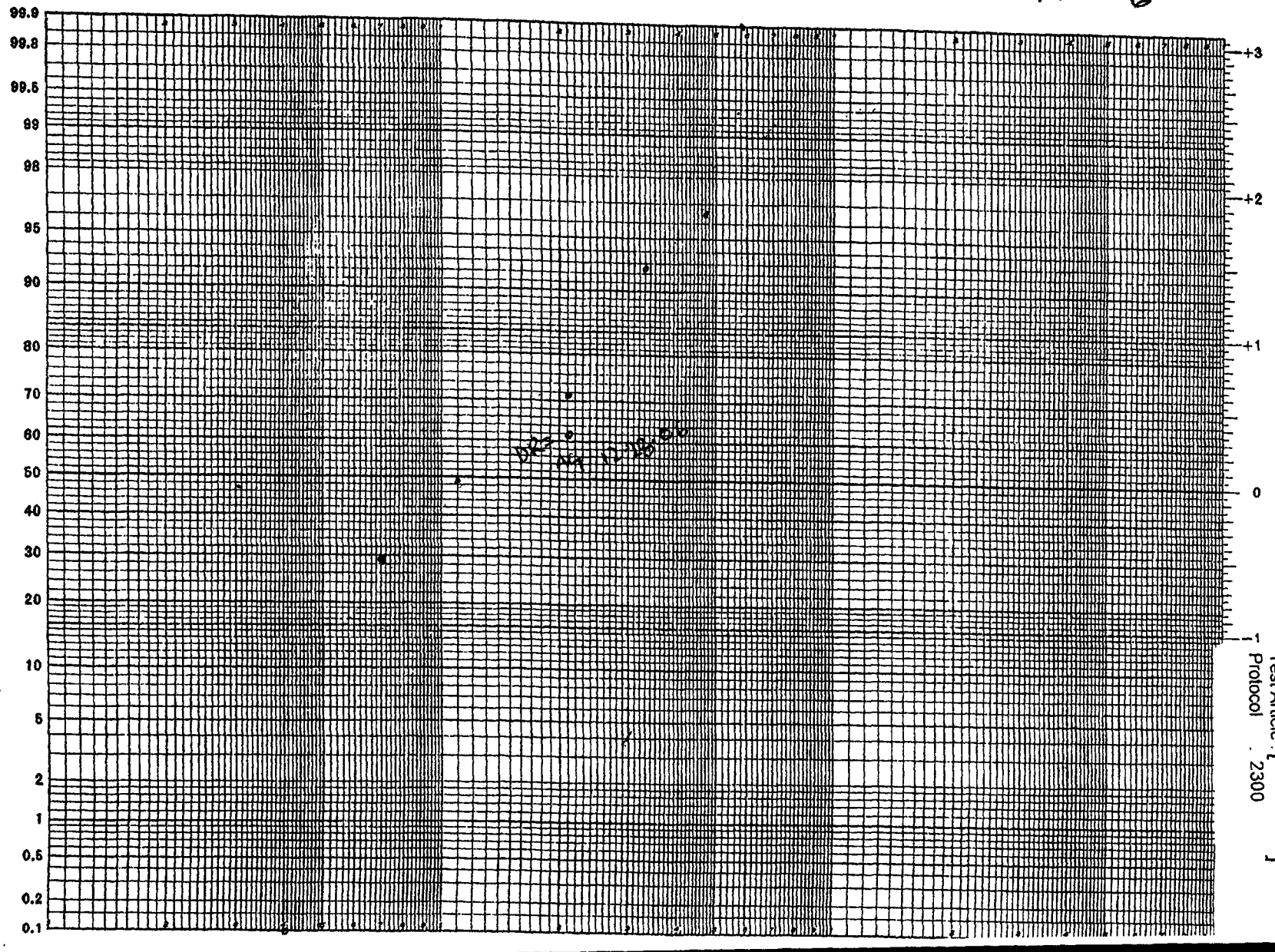
MB#06-15078.05 Particle Size Analysis Run #3 Nov 10 '06



Study Title : Inhalation Toxicity in
Project # : MB 06-15078.05
Test Article : [ ]
Protocol : 2300

Study Title : **Inhalation Toxicity in Rats**
Project # : **MB 06-15078.05**
Test article : [
Protocol : **2300**

Appendix 5 (cont'd): Particle Size

Concentration: 0.26 mg/l - Run # 1

Effective Cut-off Diameter Micrometers	Initial Filter Weight (g)	Final Filter Weight (g)	Net Collected (g)	% of Total Weight in Size Range	Cumulative % Less Than Size Range
10.0	NA	NA	NA	NA	NA
9.0	NA	NA	NA	NA	NA
5.8	0.2995	0.3026	0.0031	9.20	100.01
4.7	0.2916	0.2956	0.0040	11.87	90.81
3.3	0.3112	0.3146	0.0034	10.09	78.94
2.1	0.3108	0.3153	0.0045	13.35	68.85
1.1	0.3088	0.3187	0.0099	29.38	55.50
0.7	0.3103	0.3187	0.0084	24.93	26.12
0.4	0.3127	0.3131	0.0004	1.19	1.19
0	0.3184	0.3184	0.0000	0.00	0.00
		Total:	0.0337		

16% Diameter - Micrometers =	0.51
50% Diameter - Micrometers =	1.30
84% Diameter - Micrometers =	3.25
Mass Mean Aerodynamic Diameter (MMAD) - Micrometers =	1.30
Geometric Standard Deviation = Square root of 84%/16% =	2.52
84%/50% =	2.50
50%/16% =	2.55

NA = not applicable

Particle Size Determination for MB#06-15708.05 Run 1 Nov 15 '06

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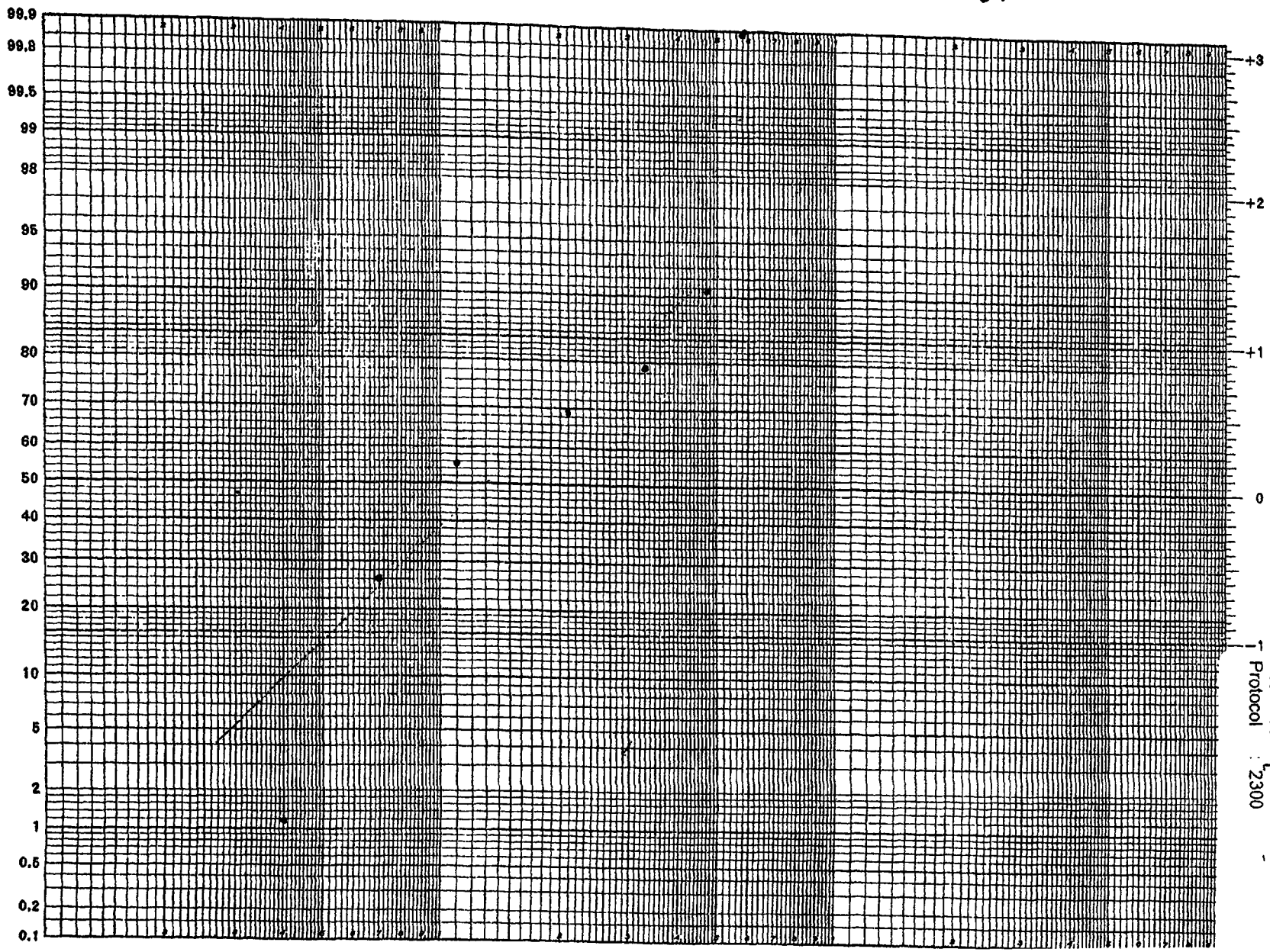

Study Title : Inhalation Toxicity in
Project # : MB 06-15078.05
Test Article :
Protocol : 2300

Study Title : Inhalation Toxicity in Rats
Project # : MB 06-15078.05
Test article : [
Protocol : 2300

Appendix 5 (cont'd): Particle Size

Concentration: 0.26 mg/l - Run # 2

Effective Cut-off Diameter Micrometers	Initial Filter Weight (g)	Final Filter Weight (g)	Net Collected (g)	% of Total Weight in Size Range	Cumulative % Less Than Size Range
10.0	NA	NA	NA	NA	NA
9.0	NA	NA	NA	NA	NA
5.8	0.2928	0.2960	0.0032	8.14	100.00
4.7	0.3003	0.3045	0.0042	10.69	91.86
3.3	0.3121	0.3152	0.0031	7.89	81.17
2.1	0.3150	0.3213	0.0063	16.03	73.28
1.1	0.3185	0.3293	0.0108	27.48	57.25
0.7	0.3128	0.3241	0.0113	28.75	29.77
0.4	0.3169	0.3173	0.0004	1.02	1.02
0	0.3128	0.3128	0.0000	0.00	0.00
		Total:	0.0393		

16% Diameter - Micrometers =	0.39
50% Diameter - Micrometers =	1.12
84% Diameter - Micrometers =	3.25
Mass Mean Aerodynamic Diameter (MMAD) - Micrometers =	1.12
Geometric Standard Deviation = Square root of 84%/16% =	2.89
84%/50% =	2.90
50%/16% =	2.87

NA = not applicable

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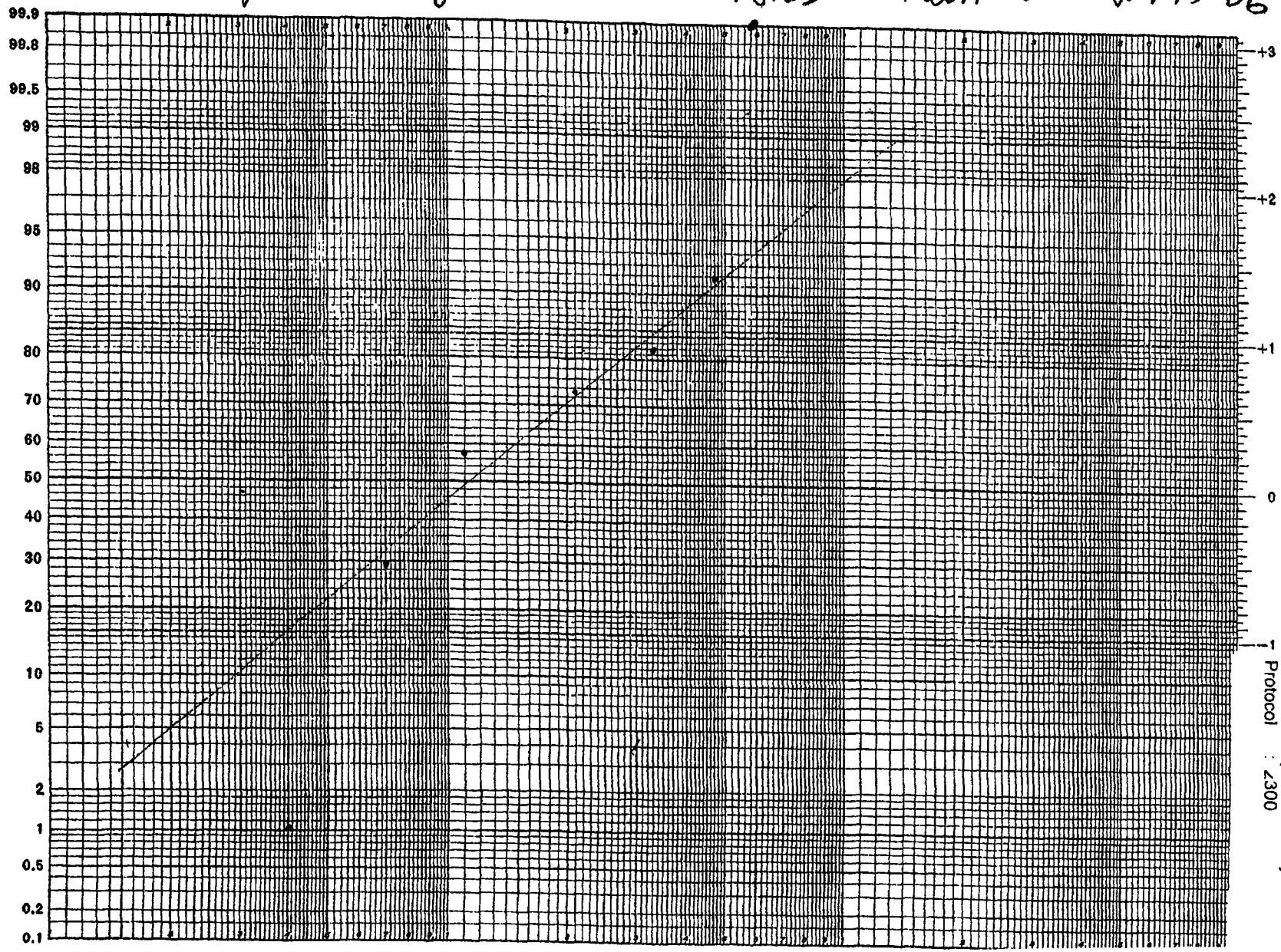
Determination of Particle Size for MB#06-15078.05 Run #2 Nov 15 06



Study Title : Inhalation Toxicity in
Project # : MB 06-15078.05
Test Article :
Protocol : 2300

Appendix 5 (cont'd): Particle Size

Concentration: 0.26 mg/l - Run # 3

Effective Cut-off Diameter Micrometers	Initial Filter Weight (g)	Final Filter Weight (g)	Net Collected (g)	% of Total Weight in Size Range	Cumulative % Less Than Size Range
10.0	NA	NA	NA	NA	NA
9.0	NA	NA	NA	NA	NA
5.8	0.2943	0.2954	0.0011	7.64	99.99
4.7	0.2878	0.2883	0.0005	3.47	92.35
3.3	0.3174	0.3179	0.0005	3.47	88.88
2.1	0.3189	0.3200	0.0011	7.64	85.41
1.1	0.3204	0.3254	0.0050	34.72	77.77
0.7	0.3190	0.3250	0.0060	41.67	43.05
0.4	0.3211	0.3212	0.0001	0.69	1.38
0	0.3236	0.3237	0.0001	0.69	0.69
		Total:	0.0144		

16% Diameter - Micrometers =	0.34
50% Diameter - Micrometers =	0.91
84% Diameter - Micrometers =	2.40
Mass Mean Aerodynamic Diameter (MMAD) - Micrometers =	0.91
Geometric Standard Deviation = Square root of 84%/16% =	2.66
84%/50% =	2.64
50%/16% =	2.67

NA = not applicable

Study Title : Inhalation Toxicity in I
Project # : MB 06-15078.05
Test Article : [illegible]
Protocol : 230u

article Size Determination

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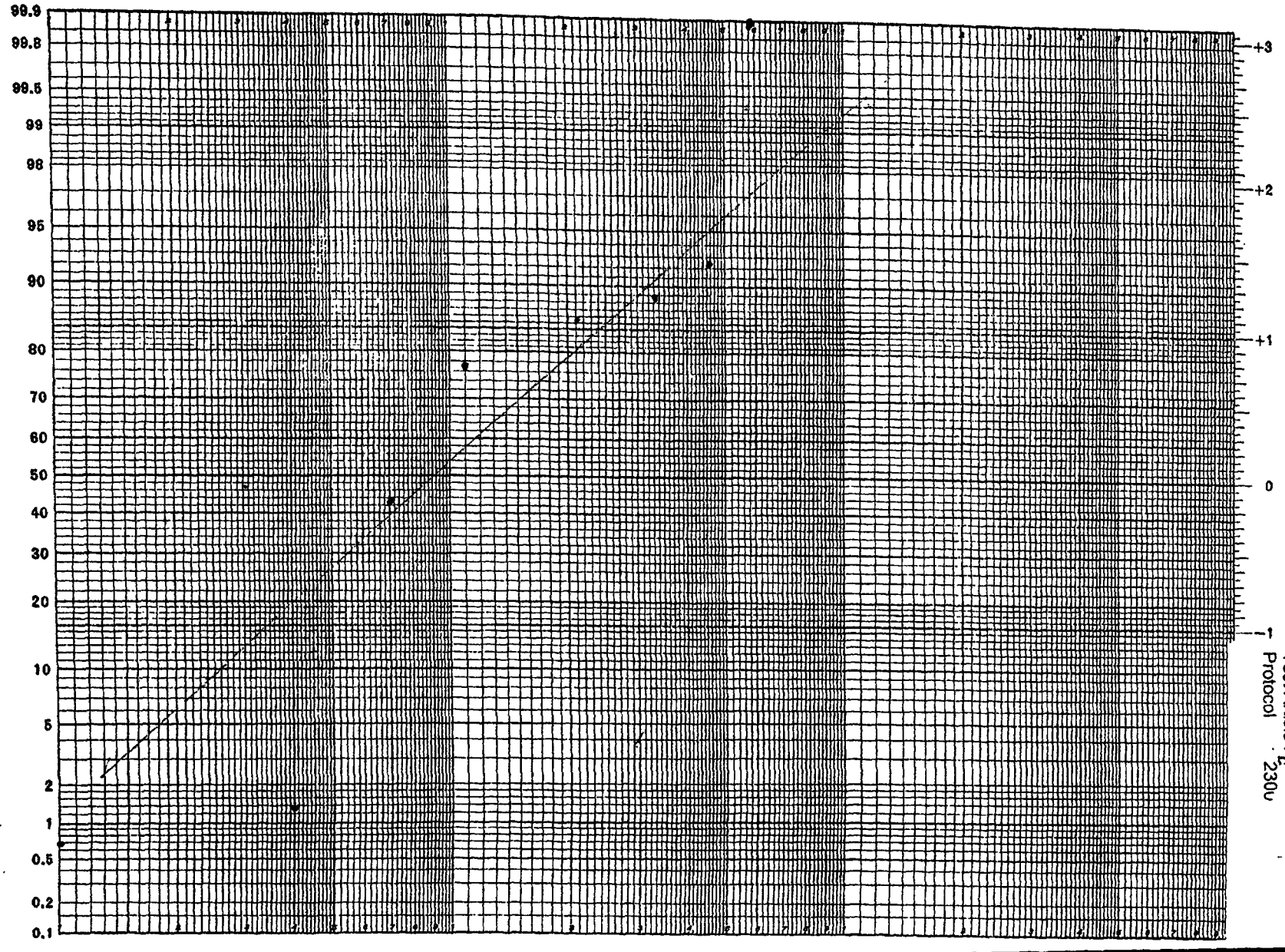
MB#06-15078.05 Run#3 Nov 15-06



Study Title : **Inhalation Toxicity in Rats**
Project # : **MB 06-15078.05**
Test article : [redacted]
Protocol : **2300**

Appendix 5(cont'd): Particle Size

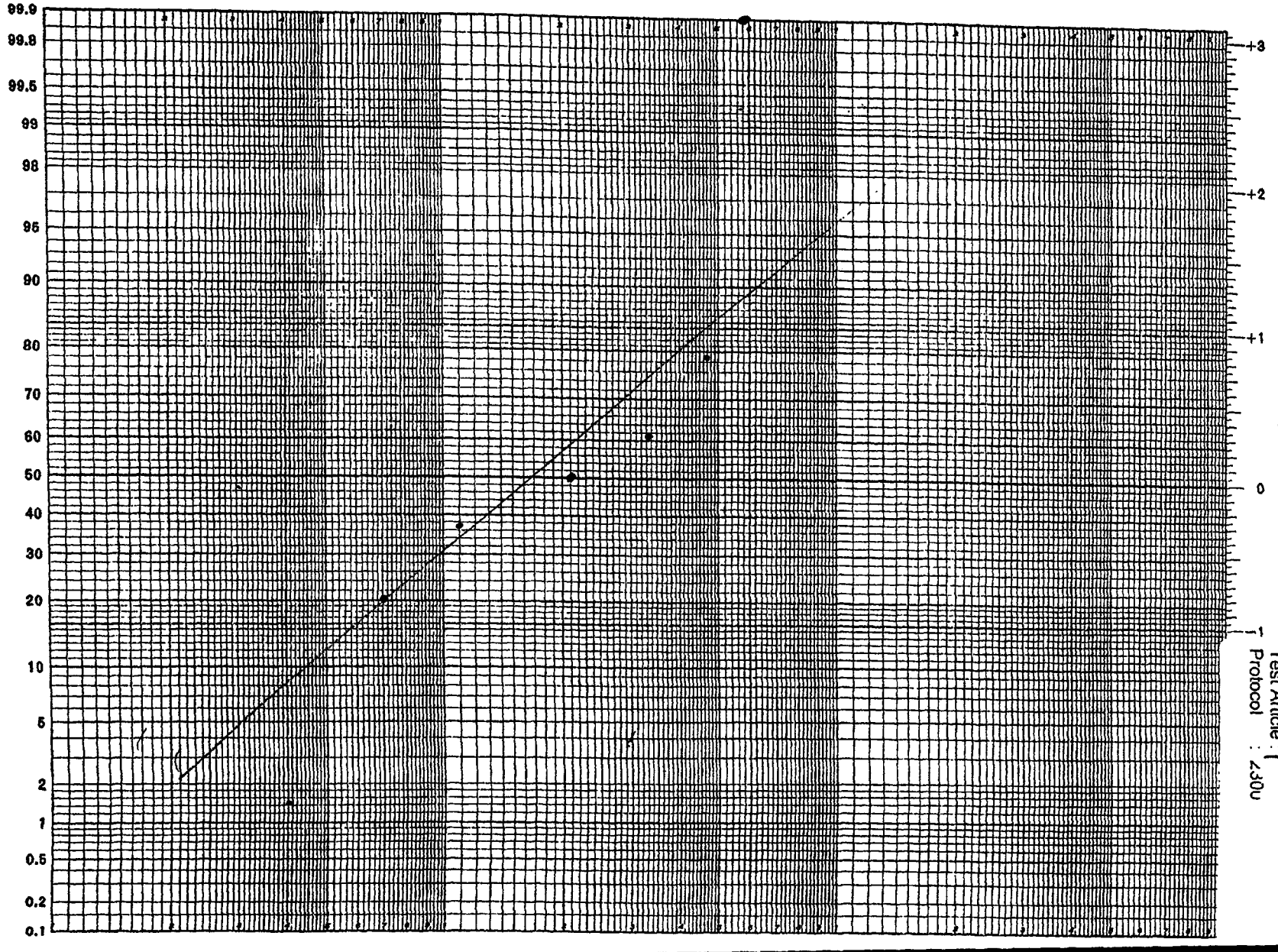
Concentration: 1.29 mg/l - Run # 1

Effective Cut-off Diameter Micrometers	Initial Filter Weight (g)	Final Filter Weight (g)	Net Collected (g)	% of Total Weight in Size Range	Cumulative % Less Than Size Range
10.0	NA	NA	NA	NA	NA
9.0	NA	NA	NA	NA	NA
5.8	0.2962	0.3020	0.0058	21.17	99.99
4.7	0.3007	0.3055	0.0048	17.52	78.82
3.3	0.3062	0.3093	0.0031	11.31	61.30
2.1	0.3078	0.3113	0.0035	12.77	49.99
1.1	0.3057	0.3104	0.0047	17.15	37.22
0.7	0.3110	0.3161	0.0051	18.61	20.07
0.4	0.3203	0.3207	0.0004	1.46	1.46
0	0.3072	0.3072	0.0000	0.00	0.00
		Total:	0.0274		

16% Diameter - Micrometers =	0.60
50% Diameter - Micrometers =	1.67
84% Diameter - Micrometers =	4.65
Mass Mean Aerodynamic Diameter (MMAD) - Micrometers =	1.67
Geometric Standard Deviation = Square root of 84%/16% =	2.78
84%/50% =	2.78
50%/16% =	2.78

NA = not applicable

Particle Size Determination for MB#06-15078.05 Run 1 Nov 30 06



Study Title : Inhalation Toxicity in I
Project # : MB 06-15078.05
Test Article : [illegible]
Protocol : 230U

Appendix 5 (cont'd): Particle Size

Concentration: 1.29 mg/l - Run # 2

Effective Cut-off Diameter Micrometers	Initial Filter Weight (g)	Final Filter Weight (g)	Net Collected (g)	% of Total Weight in Size Range	Cumulative % Less Than Size Range
10.0	NA	NA	NA	NA	NA
9.0	NA	NA	NA	NA	NA
5.8	0.2950	0.2987	0.0037	17.79	100.01
4.7	0.2961	0.3001	0.0040	19.23	82.22
3.3	0.2930	0.2953	0.0023	11.06	62.99
2.1	0.2953	0.2977	0.0024	11.54	51.93
1.1	0.2981	0.3017	0.0036	17.31	40.39
0.7	0.2983	0.3031	0.0048	23.08	23.08
0.4	0.3013	0.3013	0.0000	0.00	0.00
0	0.2924	0.2924	0.0000	0.00	0.00
		Total:	0.0208		

16% Diameter - Micrometers =	0.45
50% Diameter - Micrometers =	1.57
84% Diameter - Micrometers =	5.40
Mass Mean Aerodynamic Diameter (MMAD) - Micrometers =	1.57
Geometric Standard Deviation = Square root of 84%/16% =	3.46
84%/50% =	3.44
50%/16% =	3.49

NA = not applicable

Particle Size Determination for MB #06-15078.05

Run 2 Nov 30 '06

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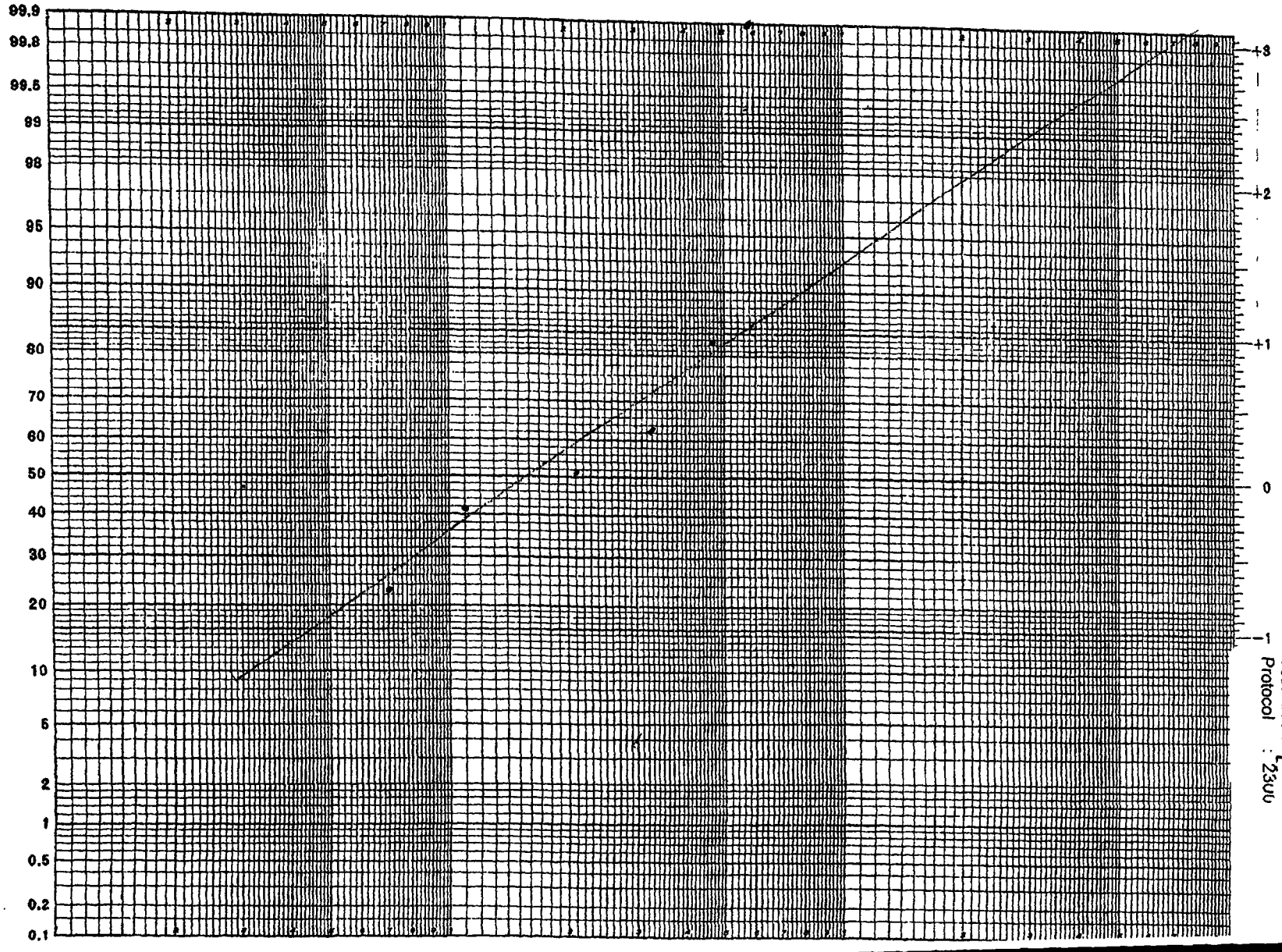

Study Title : Inhalation Toxicity in
Project # : MB 06-15078.05
Test Article : [
Protocol : 2300

Study Title : Inhalation Toxicity in Rats
Project # : MB 06-15078.05
Test article :
Protocol : 2300

Appendix 5 (cont'd): Particle Size

Concentration: 1.29 mg/l - Run # 3

Effective Cut-off Diameter Micrometers	Initial Filter Weight (g)	Final Filter Weight (g)	Net Collected (g)	% of Total Weight in Size Range	Cumulative % Less Than Size Range
10.0	NA	NA	NA	NA	NA
9.0	NA	NA	NA	NA	NA
5.8	0.2957	0.2972	0.0015	10.64	100.00
4.7	0.2953	0.2961	0.0008	5.67	89.36
3.3	0.3089	0.3098	0.0009	6.38	83.69
2.1	0.3070	0.3083	0.0013	9.22	77.31
1.1	0 3090	0.3131	0.0041	29.08	68.09
0.7	0.2966	0.3021	0.0055	39.01	39.01
0.4	0.2909	0.2909	0.0000	0.00	0.00
0	0.2951	0.2951	0.0000	0.00	0.00
		Total:	0.0141		

16% Diameter - Micrometers =	0.35
50% Diameter - Micrometers =	1.00
84% Diameter - Micrometers =	2.85
Mass Mean Aerodynamic Diameter (MMAD) - Micrometers =	1.00
Geometric Standard Deviation = Square root of 84%/16% =	2.85
84%/50% =	2.85
50%/16% =	2.86

Y3 213 HQ
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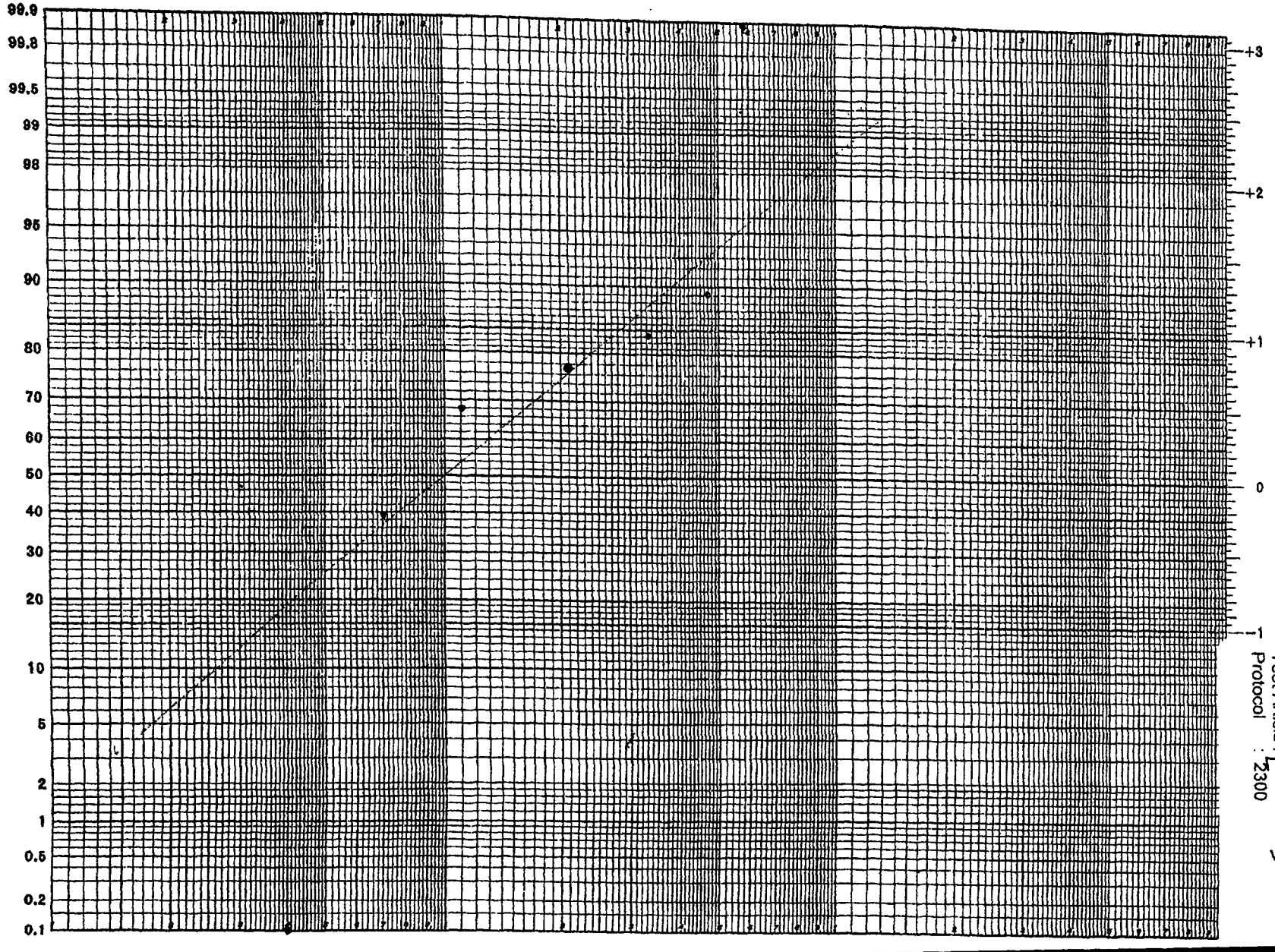
Particle Size Determination for MB#06-15078.05

Nov 30 '06



Study Title : Inhalation Toxicity in
Project # : MB 06-15078.05
Test Article : 2300
Protocol :

MB Research Laboratories

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phone (215) 536-4110
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TEST ARTICLE CHARACTERIZATION INFORMATION

In compliance with Good Laboratory Practice (GLP) regulations, a characterization of the test article is required in support of data submissions and should include identity, strength, purity, composition, stability and uniformity. This data must be reviewed by the Study Director prior to study initiation and included in the final report. (EPA 40 CFR 160.105 and 792.105; FDA 21 CFR 58.105, OECD 6.2).

In addition, the test article characterization should be performed in compliance with the Good Laboratory Practices.

Accordingly, please supply the following information for each test article submitted:

Test Article Identity : [redacted]

Strength : [redacted]

Purity : [redacted]

Composition : [redacted]

Stability : Stable under normal conditions

Uniformity : uniform

__ This characterization **was** conducted under GLPs *(or)*

X This characterization **was not** conducted under GLPs

BY: Kelly Magnuson (signature) FOR: Nalco Company (company)

10/16/06 (date)

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Study Title : **Inhalation Toxicity in Rats**
Project # : **MB 06-15078.05**
Test article : [illegible]
Protocol : 2560

QUALITY ASSURANCE EVALUATION

The Quality Assurance Unit has inspected an in-life phase of this study, audited the raw data and the report and determined that the methods and results contained herein accurately reflect the raw data. No changes/modifications from the approved protocol or Standard Operating Procedures were made without proper authorization and documentation. A summary of the compliance inspections is presented below.

Date of Inspection	Phase	Performed By	Date Findings Reported to Mgmt.	Sty. Dir.
11/10/06	Dosing administration	William J. Kintigh		
12/27/06	Raw data audit	William J. Kintigh		
02/01/07	Draft report audit	William J. Kintigh		
	Final report audit			

A complete Quality Assurance Evaluation statement will be included with the final report.

William J. Kintigh, B.S. Date
Quality Assurance Unit