Chemical Name: Tetrabromobisphenol A (TBBPA)
Trade Name(s): BA-59P, CN-614
CAS No: 79-94-7
Lab Study ID No: Inveresk 20892 (Particle Size Determination)

FINAL REPORT ACTION ITEM CHECK-OFF LIST

☒ Reviewed for possible:
- ☐ FIFRA 6 (a) (2) and/or
- ☒ TSCA Section 8 (e) reporting

☐ Copy of FIFRA 6 (a) (2) and/or TSCA Section 8 (e) letter to the following Agency(ies), if applicable:
- ☐ EPA-FIFRA
- ☐ EPA-TSCA
- ☐ California [FIFRA 6 (a) (2)s]
- ☐ Other States [FIFRA 6 (a) (2)s]: _____

☐ Confidentiality Statement page addressed, signed, and dated in FIFRA reports

☐ GLP Compliance page signed and dated in FIFRA reports

☐ Flagging Statement page addressed, signed and dated in FIFRA reports

☒ Copy of report submitted to the Agency(ies) in conjunction and/or support of one or more of the following:
- ☐ TSCA Consent Order/Agreement
- ☐ FIFRA Registration or Re-registration
- ☐ California Registration
- ☒ EU Notification
- ☐ Japanese MITI Notification
- ☐ Japanese MAFF Notification
- ☐ Canadian (DSL) Notification
- ☐ FIFRA 6 (a) (2) Submission
- ☐ TSCA 8 (e) Submission
- ☐ TSCA 8 (d) Data-Call-In
- ☐ PMN Submission
- ☐ Other: _____

☒ All information regarding the chemical and the study report entered into the IUCLID Toxicity Data Base

☒ Study Report reviewed for MSDS information — copied to product file for future update JJV 3/8/02

☒ Copy of Cover & Summary report pages to Business Unit MSDS information center (domestic and international) Dieter + Peter

☐ Active Study file merged with final report in Regulatory Affairs file room

Inveresk Report Number 20892

Tetrabromobisphenol A
Determination of the Particle Size of Tetrabromobisphenol A (TBBPA) by Low Angle Laser Light Scattering (LALLS) using the Malvern Mastersizer X

Study Initiation Date: ***11 April 2001***
Study Completion Date: ***01 February 2002***

Authors

G Johnston
K Fisher

Sponsor:

Great Lakes Chemical Corporation
1801 US Highway 52 West
West Lafayette, IN
47906-5310
USA

Performing Laboratory:

Inveresk Research
Tranent
EH33 2NE
Scotland

Final Page of Report: 25

Contents

Authentication

'I, the undersigned, hereby declare that this work was performed under my direction and in accordance with the OECD Principles of Good Laboratory Practice as set forth by the United Kingdom Department of Health. The study was conducted according to the procedures herein described and this report represents a true and accurate record of the results obtained.'

K Fisher

K Fisher BSc CChem MRSC
Study Director

04 February 2002.

Date

Quality Assurance Statement

The conduct of this study has been subjected to periodic inspections by the Inveresk Research Quality Assurance Unit. The dates of inspection are given below.

Date of QA Inspection	Phase	Date of Report to Management/ Study Director
23 April 2001	Protocol Review	25 April 2001
18 September 2001	Particle Size Determination	21 September 2001

The report has been audited by the Quality Assurance Personnel according to the appropriate Standard Operating Procedure(s). The report is considered to describe accurately the methods and procedures used in the study. The reported results accurately reflect the original data generated during the study.

D M Vieth BSc
Quality Assurance

22/JAN/2002
Date

Personnel Involved

Study Director:	K Fisher BSc CChem MRSC
Report Compilation:	G Johnston BSc
Senior Technician:	G Johnston BSc
Quality Assurance:	L C Turner BSc D M Vieth BSc

1 Summary

An assessment of the particle size range of the test item Tetrabromobisphenol A (TBBPA) has been conducted. The particle size range was determined by Low Angle Laser Light Scattering (LALLS) using a Malvern Mastersizer X.

1.1 Presentation

The sample presentation selected is based on the refractive indices of the test item and the dispersant medium. Initial tests were carried out using estimated refractive indices, then reprocessed once the correct refractive indices were known.

1.2 Assay

Duplicate aliquots of test item were dispersed in water, wetted with surfactant (Tween 20) then analysed on the Mastersizer X. Ten readings were taken for each sample. The overall mean D (v,0.5) (Mass Median Diameter) was 52.20 µm with a coefficient of variation of 3.19%. The overall mean D (v,0.1) was 27.06 µm with a coefficient of variation of 5.75%. All residuals were less than 1%.

1.3 Stability of Dispersion

An initial sample was assayed at 0, 10 and 20 min after dispersion in the small volume sample dispersion unit. Residuals and obscuration levels were consistent throughout. The D (v,0.5) and D (v,0.1) values for the sample showed little variation over time.

1.4 Respirable Fraction

Duplicate samples indicated that *ca* 4 % of the sample had a particle size of less than 15 µm.

1.5 Method Limitations

All particle size determinations are calculated using mathematical models to analyse the scattering pattern from the test sample. The resulting particle size data is based on spherical particles of equivalent volume. Inspection of the data residual provides some indication of the fit between the actual scattering pattern and that predicted by the applied presentation however a range of presentations are available.

2 Introduction

The Sponsor requested that Inveresk undertake particle sizing of the test item Tetrabromobisphenol A (TBBPA) by Low Angle Laser Light Scattering (LALLS). The analysis has been conducted to assess the proportion of material in the respiratory range (<15 µm).

Tetrabromobisphenol A (BA-59P) batch 0008J407C was supplied by the Sponsor and received at Inveresk on 23 April 2001. The material was assigned an expiry date of 25 April 2002 and stored at ambient laboratory temperature in the dark.

The work described in this report was performed in the Product Characterisation Laboratories of Inveresk Research, Tranent, EH33 2NE from September 2001 to October 2001. The study timings are as detailed below.

Study Initiation:	11 April 2001
Experimental Start Date:	17 September 2001
Experimental Completion Date:	04 October 2001
Study Completion Date:	Will be the date of the Study Director's signature on the Authentication page of the final report.

All data generated and recorded during this study, including a copy of the final report, will be stored in the Scientific Archives of Inveresk Research for 5 years after the issue of the final report. After the 5 year period the Sponsor will be consulted regarding the disposal, transfer or continued storage of the raw data.

3 Definitions

3.1 Low Angle Laser Light Scattering (LALLS).

When light is scattered by particles the pattern of light intensity obtained varies with scattering angle. Small particles scatter at large angles and large particles at small angles. In LALLS a He-Ne laser light source is passed through a flow cell containing a sample and focussed by lenses onto angular diode detectors. The scattering pattern obtained is then interpreted using mathematical models based on a knowledge of scattering theory and the physical properties of the particle to produce a distribution of particle size information.

3.2 Presentation

A presentation is a predicted scattering pattern from theoretical particles. The presentation chosen is based on the refractive index of the particles, their absorption and the refractive index of the sample dispersant media.

3.3 Residual

The residual is an indication of how closely the calculated data has been fitted to the measurement data and is expressed as a percentage. A residual of less than 1% shows good correlation.

3.4 Mass Median Diameter – D(v, 0.5)

The D(v, 0.5) is the size of particle at which 50% of the sample is smaller and 50% is larger than the stated size.

3.5 D(v, 0.1)

The D(v, 0.1) is the size of particle at which 10% of the sample is smaller and 90% is larger than the stated size.

3.6 Obscuration

The amount of sample passing through the laser beam is of great importance. Insufficient sample will not produce enough scattered light to be detected. Excessive amounts may result in multiple scattering. The Mastersizer determines the correct concentration of sample by measuring the amount of laser light lost by passing it through the sample. This is known as the obscuration and is given as a percentage. A suitable obscuration range is typically 10-40%.

4 Experimental Procedure

4.1 Particle Sizing

Duplicate aliquots of test item were dispersed in water, wetted with surfactant (Tween 20) then analysed on the Mastersizer X. Ten readings were taken for each sample. The mean D(v,0.5) (Mass Median Diameter) and mean D(v,0.1) were calculated.

4.2 Stability of Dispersion

A sample was dispersed in water, wetted with the surfactant then added to the small volume dispersion unit. The sample was assayed after 0, 10 and 20 min in the dispersion unit. Ten readings were taken of each sample. Graphs of D(v,0.5) and D(v,0.1) over time were plotted. The residuals and obscuration were monitored to check for dissolution of the sample over time.

4.3 Tetrabromobisphenol A (BA-59P)

Tetrabromobisphenol A (BA-49P) batch 0008J407C was supplied by the Sponsor and received at Inveresk on 23 April 2001. The material was assigned an expiry date of 25 April 2002 and stored at ambient laboratory temperature in the dark.

5 Results

5.1 Particle Sizing

The overall mean D(v,0.5) (Mass Median Diameter) was 52.20 µm with a coefficient of variation of 3.19%. The overall mean D(v,0.1) was 27.06 µm with a coefficient of variation of 5.75%. All residuals were less than 1%.

The data are presented in Table 1.

5.2 Stability of Dispersion

The D(v, 0.5) and D(v, 0.1) of the sample showed little variation over time. All residuals were less than 1% and the obscuration remained relatively constant throughout.

The data are presented in Table 2 and a plot of the D(v,0.5) and D(v,0.1) values is shown in Figure 1.

5.3 Respirable Fraction

A review of duplicate samples indicated that *ca* 4 % of the sample had a particle size of less than 15 µm.

6 Conclusion

Based on the available literature and experimental development a suitable presentation for the analysis of TBBPA has been developed.

An experimental assessment of the test samples showed that the samples were stable in the test media. The sample obscuration was found to be relatively constant and the residuals were consistently below 1%, indicating that the sample data was a good fit with the mathematical model appropriate to the chosen presentation.

Under these conditions the D(v, 0.5) was 52.20 µm and the D(v,0.1) was 27.06 µm. The data indicated that *ca* 4% of the sample had a particle size of less than 15 µm.

7 Tables

Table 1 Particle Sizing of Tetrabromobisphenol A

Sample Identity	Found D(v,0.5) (µm)	Mean D(v,0.5) (µm)	Coefficient of Variation (%)	Found D(v,0.1) (µm)	Mean D(v,0.1) (µm)	Coefficient of Variation (%)
BA-59P-1	55.20 53.79 53.46 53.92 53.59 53.58 53.68 53.55 53.54 53.48	53.78	0.97	27.07 28.86 28.69 28.84 28.68 28.82 28.70 28.62 28.59 28.48	28.54	1.85
BA-59P-2	50.85 50.58 50.63 50.43 50.80 50.72 50.51 50.50 50.49 50.60	50.61	0.28	26.07 25.60 25.64 25.55 25.63 25.48 25.55 25.43 25.49 25.49	25.59	0.71
Overall		52.20 µm	3.19%		27.06 µm	5.75%

Laboratory Notebook 08-1165 page 16

Presentation: 2QHD

Particle R.I = 1.729
Absorption = 0.1
Dispersant R.I. = 1.33

Table 2 ***Stability of Dispersion***

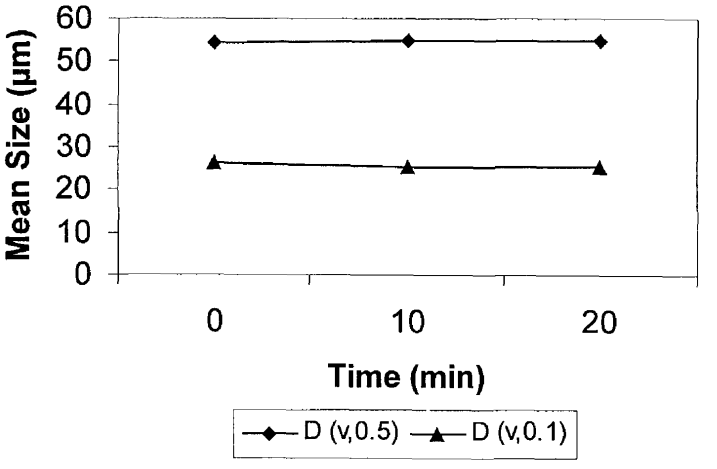
Time (min)	Found D(v,0.5) (µm)	Mean and Coefficient of Variation	Found D(v,0.1) (µm)	Mean and Coefficient of Variation
0	54.67 54.36 54.66 54.68 54.46 54.62 54.47 54.51 54.57 54.79	Mean =54.58 µm CoV = 0.24%	26.49 25 82 26.15 26.05 25.96 25.95 26.04 25.93 26.01 25.97	Mean = 26.04µm CoV = 0.70%
10	54.79 54.66 54.76 54.55 54.98 54.45 54.68 54.38 54.59 54.37	Mean = 54.62µm CoV = 0.35%	25.47 25.51 25.53 25.31 25.64 25 29 25.41 25.27 25.30 25.26	Mean = 25.40µm CoV = 0.52%
20	54.72 54.77 54.74 54.50 54.76 54.58 54.57 54.59 54.30 54.82	Mean = 54.64µm CoV = 0.29%	25.33 25.32 25.30 25.16 25.38 25.29 25.18 25.10 25.06 25.29	Mean = 25.24µm CoV = 0.43%

Laboratory notebook 08-1165 page 19, CoV = Coefficient of Variation

Presentation: 2QHD
Particle R.I. = 1.729
Absorption = 0.1
Dispersant R.I. = 1.33

8 Figures

Figure 1 Stability of Dispersion



9 Appendices

Appendix 1 Analytical Method No 4057: Particle Size

Analytical Method No:	4057
Assay:	Particle Size
Test Item:	Tetrabromobisphenol A
Approval:	K Fisher 04 February 2002

I Summary

An estimate of the particle size distribution of Tetrabromobisphenol A is conducted by determining the Mass Median Diameter (MMD) of an aqueous dispersion of the sample. The MMD was determined by Low Angle Laser Light Scattering using a Malvern Mastersizer X connected to a liquid dispersion unit.

II Reagents

1. Tetrabromobisphenol A (BA-59P), supplied by Sponsor
2. Milli-Q Water, prepared at Inveresk Research
3. Tween 20, supplied by Sigma

III Apparatus

1. Diffraction Particle Sizer: Malvern Mastersizer X
2. Malvern Small Volume Sample Dispersion Unit
3. Malvern Lens 300 mm
4. Analytical Balance, 4/5 figure Sartorius or equivalent

IV Preparation of Test Samples

Mix the supplied test item by repeatedly rotating the container 180° about its vertical and horizontal axes to ensure that the sample is uniform and avoid any sampling errors due to settling during transportation. Accurately weigh Tetrabromobisphenol A (*ca* 0.5 g) into a flask or beaker. Add Mill-Q water (50 ml) and one drop of Tween 20 to ensure wetting of the sample. Invert the sample until a homogenous dispersion is obtained.

Appendix 1
(continued)

V Instrument settings

Range Lens: 300 mm (Size Range 1.2 – 600 µm)
Beam Length: 2.4 mm
Presentation: 2QHD
Particle R.I. = 1.729
Absorption = 0.1
Dispersant R.I. = 1.33

Analysis Model: Polydisperse

Prior to the conduct of any test measurements the laser is switched on and allowed to equilibrate for at least 1 h. Laser alignment and background measurements are then conducted prior to the introduction of test samples.

VI Analysis of samples

Fill the Sample Dispersion Unit with Milli-Q water (100 ml). Set the stirrer speed on the Sample Dispersion Unit to 2500 r.p.m. Add aliquots of the sample solution to the Sample Dispersion Unit until a suitable obscuration level is obtained (typically 10-15%). Acquire the sample data using the conditions detailed in Section V. Typically the instrument will perform 10 runs during the determination of each sample. Inspect the data from each run to ensure that the chosen presentation is suitable for the sample under test (a residual of less than 1% shows good correlation) and record any trends in the data *eg* increases in the calculated mass median diameter D(v,0.5) or decreasing obscuration.

Report the mass median diameter obtained using the Mastersizer X as the mean of all D(v,0.5) values obtained for each sample. In addition the approximate percentage of the sample correlating to particle size of less than 15 µm, the range considered to be significant in terms of the respiratory fraction, is recorded. A typical Mastersizer Analysis Report is presented in Appendix 1, Figure 1.

Appendix 1 (continued)

Figure 1 Typical Mastersizer Analysis Report

MALVERN INSTRUMENTS MASTERSIZER

Result: Analysis Report

User Name: Gordon Johnston — Security Level: 0

Sample Details

Sample ID: BA-59P — Run Number: 44 — Measured: 17 Sep 2001 13:10
Sample File: 340578 — Record Number: 43 — Analysed: 4 Oct 2001 12:43
Sample Path: C:\SIZERX\DATA\ — Result Source: Analysed
Sample Notes: BA59P Preliminary investigation T10min

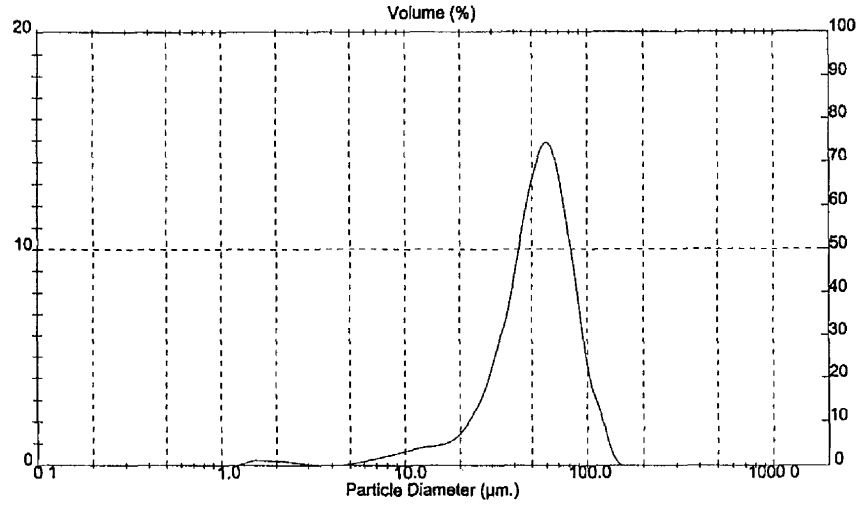
System Details

Range Lens: 300 mm — Beam Length: 2.40 mm — Sampler: MS1 — Obscuration: 12.8 %
Presentation: 2QHD — [Particle R.I = (1 7290, 0 1000); Dispersant R I = 1 3300] — Residual: 0 214 %
Analysis Model: Polydisperse
Modifications: None

Result Statistics

Distribution Type: Volume — Concentration = 0 0593 %Vol — Density = 1 000 g / cub. cm — Specific S.A. = 0 1791 sq m / g
Mean Diameters: — D (v, 0.1) = 25.53 um — D (v, 0 5) = 54.76 um — D (v, 0 9) = 88 48 um
D [4, 3] = 56 25 um — D [3, 2] = 33.50 um — Span = 1 149E+00 — Uniformity = 3 613E-01

Size Low (um)	In %	Size High (um)	Under%	Size Low (um)	In %	Size High (um)	Under%
0 50	0.13	1 32	0.13	25 46	4 74	31.01	14 89
1.32	0.24	1 60	0.38	31.01	7.86	37.79	22 55
1.60	0.28	1 95	0.66	37.79	12.46	46 03	35 01
1 95	0.24	2 38	0.90	46.03	17.29	56 09	52 29
2 38	0 14	2 90	1 05	56.09	19 00	68 33	71.27
2.90	0.04	3 53	1 09	68 33	15.22	83 26	86 48
3 53	0 00	4.30	1 09	83 26	8.92	101.44	95 40
4 30	0 05	5 24	1 15	101 44	3.77	123 59	99 18
5.24	0 20	6 39	1 35	123 59	0 81	150 57	100 00
6 39	0 42	7 78	1 77	150 57	0 00	183 44	100 00
7.78	0.64	9 48	2 40	183 44	0.00	223.51	100 00
9 48	0 87	11 55	3 28	223.51	0 00	272 31	100 00
11 55	1.07	14.08	4 35	272 31	0 00	331 77	100 00
14.08	1 20	17 15	5 55	331.77	0 00	404 21	100 00
17.15	1 62	20 90	7.18	404.21	0 00	492 47	100.00
20.90	2.77	25.46	9.95	492.47	0.00	600 00	100.00



Malvern Instruments Ltd.
Malvern, UK
Tel:=+[44] (0)1684-892456 Fax:+[44] (0)1684-892789

Mastersizer X Ver. 2.18
Serial Number: 33337-26

04 Oct 01 12:4

Appendix 2 Study Protocol

Inveresk Research
TRANENT EH33 2NE SCOTLAND
TELEPHONE: +44 (0) 1875 614545

Great Lakes Chemical Corporation
1801 US Highway 52 West
West Lafayette, IN
47906-5310
USA

05 April 2001

PROTOCOL TITLE:

Determination of the Particle Size of Tetrabromobisphenol A (TBBPA) by Low Angle Laser Light Scattering (LALLS) Using the Malvern Mastersizer X

INVERESK PROJECT NO:	340578
TEST MATERIAL:	Tetrabromobisphenol A (TBBPA)
INVERESK PROTOCOL CODE:	*Final*
STUDY DIRECTOR:	K Fisher BSc CChem MRSC

PROJECTED TIMINGS:

Start of Experimental Work:	April 2001
Completion of Experimental Work:	May 2001
Draft Report:	June 2001

STUDY DIRECTOR APPOINTED BY: _____ DATE: 11 April 2001
Inveresk Management

PROTOCOL APPROVED BY: K Fisher DATE: 11 April 2001
Study Director

PROTOCOL ACCEPTED BY: _____ DATE: 20 April 2001
Sponsor Representative

(No. of pages: 5 excluding front page)

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REGISTERED OFFICE ELPHINSTONE RESEARCH CENTRE TRANENT EH33 2NE
REGISTERED IN SCOTLAND NUMBER 81735

Appendix 2 (continued) Study Protocol

Inveresk Research

Inveresk 340578 *(Final)* 1

CONTENTS

Appendix 2 (continued) Study Protocol

Inveresk Research

Inveresk 340578 *(Final)* 2

DETERMINATION OF THE PARTICLE SIZE OF TETRABROMOBISPHENOL A (TBBPA) BY LOW ANGLE LASER LIGHT SCATTERING (LALLS) USING THE MALVERN MASTERSIZER X

INVERESK PROJECT NO. 340578

1 **INTRODUCTION AND STUDY OBJECTIVES**

1.1 Inveresk Research has been requested by the Sponsor to undertake a determination of Tetrabromobisphenol A (TBBPA) using Low Angle Laser Light Scattering.

2 **TEST MATERIAL**

2.1 The test material will be supplied by the Sponsor.

2.2 The test material will be stored in the dark at ambient room temperature unless otherwise instructed by the Sponsor.

2.3 The test material characterisation and handling procedures *etc.* will be supplied by the Sponsor prior to the commencement of the study via an MSDS.

3 **LOCATION OF STUDY**

3.1 The study will be conducted in the Department of Product Characterisation at:

Inveresk Research
Tranent
EH33 2NE
Scotland.

4 **EXPERIMENTAL PROCEDURE**

4.1 Preliminary Method Set Up

4.1.1 The particle size determination will be conducted using a Small Volume Sample Dispersion Unit. Preliminary investigations will be conducted to determine; a suitable dispersant; presentation, stirrer speed and lens for the determination of the particle size of the test material.

4.1.2 The use of surfactants and ultrasonication may be applied to the test sample to aid the preparation of a homogenous dispersion.

Appendix 2 (continued) Study Protocol

4.1.3 The repeatability of the measurement will be determined by obtaining 10 determinations of the same sample at initial measurement, following 10 minutes in the instrument and following 20 minutes in the instrument. The repeatability will be assessed from a review of the D(v, 0.5) values obtained and the obscuration.

4.1.4 The presentation used will be based on available information, the sample properties and the dispersant properties. The calculated residual will be <1%. If considered appropriate a volume concentration % sample will be prepared to check the accuracy of the presentation mode employed.

4.1.5 Once a suitable procedure has been established, duplicate samples of test material will be assayed.

5 **THEORY**

5.1 The Malvern Mastersizer X applies mathematical models and Mie theory to calculate the particle size distribution of a sample based on the scattering pattern obtained. In this technique all results are volume based and are expressed in terms of equivalent spheres. The D(v, 0.5) will be reported The D(v, 0.5) is the size of particle at which 50% of the sample is smaller and 50% is larger than the size. This value is also known as the Mass Median Diameter (MMD).

6 **INTERPRETATION**

6.1 The data generated by this technique is dependent on the mathematical model applied, sampling technique and choice of presentation. While each of these parameters will be optimised during the development of the measurement procedure, it must be noted that the particle size determination obtained should be considered as an indication of the particle size rather than absolute value for the sample. All particle size measurements are dependent on the conditions and the analytical technique used in its determination.

6 2 The relative density for the test material will be supplied by the Sponsor. The Mass Median Aerodynamic Diameter (MMAD) value will be determined by taking the MMD value times the square root of the relative density and including it as part of the report.

7 **GOOD LABORATORY PRACTICE**

7.1 The study will be conducted in accordance with the OECD Principles of Good Laboratory Practice as set forth by the United Kingdom Department of Health and as accepted by Regulatory Authorities throughout the European Community, United States of America (FDA and EPA) and Japan (MHLW, MAFF and MITI).

Appendix 2 (continued) Study Protocol

Inveresk Research

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7.2 All routine activities conducted during the course of this study are detailed in Inveresk Research's Standard Operating Procedures.

8 **QUALITY ASSURANCE**

8.1 Quality Assurance inspections will be carried out on critical phases in the execution of the study. Further inspections on routine, repetitive processes are also performed, although not necessarily on materials from this study.

8.2 The draft and final report will be audited before being forwarded or issued to the Sponsor.

8.3 These inspections and audits will be carried out by Quality Assurance personnel independent of staff involved in the study.

9 **PROTOCOL AMENDMENTS**

9.1 Changes to this protocol will be documented and the reason for the change stated, signed and dated by the Study Director. A copy of each amendment will be retained with the study protocol. Additionally, a copy of each amendment will be sent to the Sponsor for signature.

10 **REPORTS**

10.1 On completion of the study a draft report will be issued to the Sponsor. The report will incorporate:

Identification of the study, the test materials and any reference materials (if applicable)
Information concerning the Sponsor and the test facility
Experimental starting and completion dates
A Quality Assurance statement.
A Study Director/Principal Investigator statement
Description of materials and test methods
Results
Archive details
Protocol and amendments.

10.2 On receipt of approval or amendments to the draft report, the final report (3 copies - 2 bound, 1 unbound) will be issued to the Sponsor. If no comments are received from the Sponsor within 16 weeks from the date of issue of the draft report, the Sponsor will be contacted to request approval to issue the final report. If no response is forthcoming, Inveresk Research reserves the right to issue the final report.

Appendix 2 (continued) Study Protocol

Inveresk Research

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11 **ARCHIVE**

11.1 Inveresk Research will retain in its archive, for a period of five years (or for such shorter period as, in the opinion of Inveresk Research, the quality of the material affords evaluation) following the date of the final report, the undernoted materials relating to the project:

Protocol, protocol amendments and correspondence
Samples of test and reference materials (where appropriate)
Specimens (where appropriate)
All original data generated
Copy of the draft and final reports.

11.2 After the five year storage period, Inveresk Research will contact the Sponsor for instructions on the transfer, retention or disposal of materials. Fees for the disposal, transfer or continued retention of the materials will be invoiced to the Sponsor.

Compiled by: K Fisher
Date: April 2001

Appendix 3 Protocol Deviations

It should be noted that due to delays in obtaining the test item and knock on effects on the analytical schedule, the study schedule was not as detailed in the original protocol. In addition, the Mass Median Aerodynamic Diameter (MMAD) has not been calculated as the Sponsor was unable to provide information on the relative density of the test item.