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STUDY TITLE

Report

Paliogen Violet 5011

Reproduction/Developmental Toxicity Screening Test in Wistar Rats
Oral Administration (Gavage)

TEST GUIDELINES

OECD 421
OPPTS 870.3550

AUTHORS

[redacted]

STUDY COMPLETION DATE

22 Apr 2013

TEST FACILITY

BASF SE
[redacted]

TEST FACILITY PROJECT IDENTIFICATION

Project No. 80R0223/11C162

SPONSOR

BASF SE
[redacted]

PART I OF III (REPORT SECTION AND SUMMARY TABLES)

The following statement is for US EPA submissions only:

STATEMENT OF NO DATA CONFIDENTIALITY CLAIMS

No claim of confidentiality, on any basis whatsoever, is made for any information contained in this document. I acknowledge that information not designated as within the scope of FIFRA sec.10(d)(1)(A), (B) or (C) and which pertains to a registered or previous registered pesticide is not entitled to confidential treatment and may be released to the public, subject to the provisions regarding disclosure to multinational entities under FIFRA 10(g).

Submitter: ..... Date: .....

Typed Name of Signer:

Typed Name of Company: [redacted]

GLP COMPLIANCE STATEMENT

This study was conducted in accordance with the OECD Principles of Good Laboratory Practice and the GLP Principles of the German "Chemikaliengesetz" (Chemicals Act) which meet the United States Environmental Protection Agency Good Laboratory Practice Standards [40 CFR Part 160 (FIFRA) and Part 792 (TSCA)], with the exception that recognized differences exist between the GLP Principles/Standards of OECD and the Principles/Standards of FIFRA and TSCA.

Study Director: [redacted] Date: 22 April 2013

Typed name of Study Director: [redacted]

Typed name of Laboratory: BASF SE [redacted]

To be filled for USA EPA submission only:

Sponsor: _____ Date: _____

Typed Name of Sponsor: _____

Typed Name of Company: _____

Submitter: _____ Date _____

Typed Name of Submitter: _____

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The following statement is for US EPA submissions only:

FLAGGING CRITERIA

I have applied the criteria of 40 CFR 158.34/40 CFR 161.34 for flagging studies for potential adverse effects to the results of the attached study. This study neither meets nor exceeds any of the applicable criteria.

Submitter: ..... Date: .....

Typed Name of Signer:

Typed Name of Company: [redacted]

SIGNATURE PAGE

Study Director: [redacted] April 2013

Pathology: [redacted] 17. Apr 2013

Management: [redacted] April, 2013

CONTRIBUTORS TO THE STUDY / SUPERVISORY LABORATORY PERSONNEL

Head of Experimental Toxicology and Ecology:	[redacted]
Study Director:	[redacted]
Pathology:	[redacted]
Data Processing:	[redacted]
Statistics:	[redacted]
Quality Assurance Unit (QAU):	[redacted]
Coordination QAU:	[redacted]
Laboratory Mechanistic Tox. Rodent:	[redacted]
Pathology:	[redacted]
Histopathology:	[redacted]

STATEMENT OF THE QUALITY ASSURANCE UNIT

The Quality Assurance Unit (QAU) inspected the study and reported any inspection results to the Study Director and to Management.

The final report reflects the raw data.

Phase of study	Date of inspection (mm-dd-yyyy)	Reported to Study Director and to Management (mm-dd-yyyy)
Study Plan:	06-22-2012	06-22-2012
Conduct of study:	07-09-2012	07-09-2012
	08-02-2012	08-02-2012
	08-08-2012	08-08-2012
	08-14-2012	08-14-2012
Report:	04-10-2013	04-10-2013

Ludwigshafen, 22 April 2013

[redacted]

GLP CERTIFICATE (FROM THE COMPETENT AUTHORITY)

RheinlandPfalz

Gute Laborpraxis / Good Laboratory Practice

GLP-Bescheinigung / Statement of GLP Compliance

(gem. /according to § 19 Abs. 1 Chemikaliengesetz)

Eine GLP-Inspektion zur Überwachung und der Einhaltung der GLP-Grundsätze gemäß Chemikaliengesetz bzw. Richtlinie 2004/9/EG wurde durchgeführt in:

Assessment of conformity with GLP according to Chemikaliengesetz and Directive 2004/9/EC at::

Prüfeinrichtung / Test facility

[redacted] BASF SE [redacted]

Prüfung nach Kategorien / Areas of Expertise
(gem. / according ChemVwV-GLP Nr. 5.3/OECD guidance)
1,2,3,4,5,8,9
Kat. 9 – Biochemische und pathologische Untersuchungen zu Wirkmechanismen / Biochemical and pathological examinations concerning mode of action

Datum der Inspektion / Date of Inspection
(Tag.Monat Jahr / day.month year)
19.05.2009 & 06. bis 08.07.2009

Die genannte Prüfeinrichtung befindet sich im nationalen GLP-Überwachungsverfahren und wird regelmäßig auf Einhaltung der GLP-Grundsätze überwacht.

The above mentioned test facility is included in the national GLP Compliance Programme and is inspected on a regular basis.

Auf der Grundlage des Inspektionsberichtes wird hiermit bestätigt, dass in dieser Prüfeinrichtung die oben genannten Prüfungen unter Einhaltung der GLP-Grundsätze durchgeführt werden können.
Eine erneute behördliche Überprüfung der Einhaltung der GLP-Grundsätze durch die Prüfeinrichtung ist so rechtzeitig zu beantragen, dass die Folgeinspektion spätestens vier Jahre nach dem Beginn der o.g. Inspektion stattfinden kann. Ohne diesen Antrag wird die Prüfeinrichtung nach Ablauf der Frist aus dem deutschen GLP-Überwachungsprogramm genommen und diese GLP-Bescheinigung verliert ihre Gültigkeit:

Based on the inspection report it can be confirmed, that the test facility is able to conduct the aforementioned studies in compliance with the Principles of GLP.

Verification of the compliance of the test facility with the Priciples of the GLP has to be applied for in time to allow for a follow-up inspection to take place within four years after commencing the above mentioned inspection. Elapsing this term, the test facility will be taken out of the German GLP-Monitoring Programme and this GLP Certificate becomes invalid.

Unterschrift, Datum / Signature, Date

[redacted] .2009

and function of responsible person)

Siegel

[redacted]

(Name und Adresse der GLP-Überwachungsbehörde / Name and adress of the GLP Monitoring Authority)

Landesamt für Umwelt, Wasserwirtschaft und Gewerbeaufsicht

CONTENTS OF PART I (REPORT SECTION AND SUMMARY TABLES)

8. APPENDIX

8.1. LIST OF ABBREVIATIONS USED IN TABLES CLINICAL EXAMINATIONS

8.2. LIST OF ABBREVIATIONS USED IN TABLES PATHOLOGY

Part A:
CLINICAL EXAMINATIONS AND EXAMINATION OF REPRODUCTIVE PERFORMANCE
(MEAN VALUES AND SUMMARY TABLES)

Part B:
PATHOLOGY (MEAN VALUES AND SUMMARY TABLES)

The tables with individual values/findings (excluding tables for "pup body weight change") can be found in PART II. Further information (detailed analytical results and historical control data) are included in PART III (Supplement).

CONTENTS OF PART II (TABLES SECTION, INDIVIDUAL VALUES AND OBSERVATIONS)

CONTENTS OF PART III (SUPPLEMENT)

THIS REPORT CONSISTS OF PART I, II AND III.

1. SUMMARY

1.1. METHODS

Paliogen Violet 5011 was administered orally via gavage to groups of 10 male and 10 female Wistar rats (F0 animals) at dose levels of 0 mg/kg bw/d (test group 0), 100 mg/kg bw/d (test group 1), 300 mg/kg bw/d (test group 2) and 1000 mg/kg bw/d (test group 3).

The objective of the study was to detect possible effects of the test substance on the integrity and performance of male and female reproductive systems including gonadal function, mating behavior, conception, gestation and parturition. Furthermore, it was intended to obtain information about the general toxicological profile including target organs and the no observed adverse effect level (NOAEL) after repeated oral administration. The duration of treatment covered a 2 week premating period and mating in both sexes (mating pairs were from the same dose group) as well as entire gestation and 4 days of lactation period in females up to one day prior to the day of schedule sacrifice of the animals.

1.2. OBSERVATIONS

The parents' and the pups' state of health was checked each day, and parental animals were examined for their mating and reproductive performances.

F0 animals were mated 13 days after the beginning of treatment to produce a litter (F1 generation pups). As soon as sperm was detected in the vaginal smear, mating was discontinued. F0 animals were examined for their reproductive performance including determinations of the number of implantations and the calculation of the postimplantation loss in all F0 females.

Food consumption of the F0 parents was determined regularly once weekly before the mating period, as well as in dams during gestation (days 0 - 7, 7 - 14, 14 - 20) and lactation (days 1 - 4).

In general, the body weights of F0 animals were determined once a week. However, during gestation and lactation, F0 females were weighed on gestation days (GD) 0, 7, 14 and 20, and on postnatal days (PND) 0 and 4.

The pups were sexed and examined for macroscopically evident changes on PND 0. They were weighed on PND 1 and PND 4 and their viability was recorded. At necropsy on PND 4, all pups were sacrificed under isoflurane anesthesia with CO_2 and examined macroscopically for external and visceral findings at necropsy.

All F0 parental animals were sacrificed by decapitation under isoflurane anesthesia, and were assessed by gross pathology. Weights of selected organs were recorded and a histopathological examination was performed.

1.3. RESULTS

1.3.1. Analyses

The various analyses:

- demonstrated the stability of the test substance in the vehicle (drinking water) over a period of 7 days at room temperature
- the correctness of the prepared concentrations and the homogeneity of the test substance preparations in drinking water

1.3.2. Effects

The following test substance-related adverse effects/findings were noted:

Test group 3: 1000 mg/kg bw/d

F0 PARENTAL ANIMALS
CLINICAL EXAMINATIONS/ REPRODUCTIVE PERFORMANCE/ PATHOLOGY

- No test substance-related adverse findings were observed.

F1 PUPS
CLINICAL EXAMINATIONS/ GROSS FINDINGS

- No test substance-related adverse findings were observed.

Test group 2: 300 mg/kg bw/d

F0 PARENTAL ANIMALS
CLINICAL EXAMINATIONS/ REPRODUCTIVE PERFORMANCE/ PATHOLOGY

- No test substance-related adverse findings were observed.

F1 PUPS
CLINICAL EXAMINATIONS/ GROSS FINDINGS

- No test substance-related adverse findings were observed.

Test group 1: 100 mg/kg bw/d

F0 PARENTAL ANIMALS
CLINICAL EXAMINATIONS/ REPRODUCTIVE PERFORMANCE/ PATHOLOGY

- No test substance-related adverse findings were observed.

F1 PUPS
CLINICAL EXAMINATIONS/ GROSS FINDINGS

- No test substance-related adverse findings were observed.

1.4. CONCLUSION

Thus, under the conditions of this modified reproduction/developmental toxicity screening test the **NOAEL** (no observed adverse effect level) for **reproductive performance** and **fertility** was 1000 mg/kg bw/d.

The **NOAEL** for **developmental toxicity** in the F1 progeny was found to be 1000 mg/kg bw/d.

The **NOAEL** for **general, systemic toxicity** was 1000 mg/kg bw/d.

2. INTRODUCTION

2.1. OBJECTIVES

The aim of this study was to obtain initial information on the possible effects of Paliogen Violet 5011 on the integrity and performance of the male and female reproductive systems including gonadal function, mating behavior, conception, gestation and parturition. Furthermore, information about the general toxicological profile including target organs and no-observed-adverse-effect-level (NOAEL) after repeated oral administration should be elucidated.

2.2. SELECTION OF DOSES

At the request of the sponsor, the following nominal dose levels were selected:

100	mg/kg body weight/day	as low dose level
300	mg/kg body weight/day	as mid dose level
1000	mg/kg body weight/day	as high dose level

2.3. TEST GUIDELINES

The study was carried out in accordance with the requirements of the following test guidelines:

- OECD Guideline for the Testing of Chemicals; No. 421 (SIDS): Reproduction/Developmental Toxicity Screening Test, (27 Jul 1995)
- EPA, Health Effects Test Guidelines; OPPTS 870.3550: Reproduction/Developmental Toxicity Screening Test, (Jul 2000)

2.4. STUDY DATES

Date	Phase of study/ Examination	Study day
26 Jun 2012	Study initiation date: signature of study director	
26 Jun 2012	Supply of animals/beginning of acclimatization period/experimental starting date	-6
02 Jul 2012	End of acclimatization period and beginning of administration period	0
15 Jul 2012	First mating of parental animals for the formation of F1 generation pups	13
01 Aug 2012	End of administration period of males	30
02 Aug 2012	Sacrifice* of parental males	31
from 06 Aug 2012 onwards	Parturition of F1 generation pups postnatal day (PND) 0	from 35 onwards
from 10 Aug 2012 onwards	Sacrifice of F1 litter PND 4	from 39 onwards
27 Aug 2012	End of administration period of females	56
28 Aug 2012	Sacrifice* of parental females	57
07 Mar 2013	Experimental completion date (draft report to QAU**)	

* Before necropsy food was withdrawn for about 16-20 hours.
** QAU = Quality Assurance Unit

2.5. RETENTION OF RECORDS

GLP-relevant records and materials are stored at BASF SE for at least the period of time specified in the GLP principles. Details concerning responsibilities or locations of archiving can be seen from the respective SOPs and from the raw data.

2.6. ANIMAL WELFARE

This study was performed in an AAALAC-approved laboratory in accordance with the German Animal Welfare Act and the effective European Council Directive.

3. MATERIAL AND METHODS

3.1. TEST ITEM

The analyses of the test item (= test substance) have been carried out at Competence Center Analytics, BASF SE, 67056 Ludwigshafen, Germany.
The sponsor is responsible for compliance for all test substance information and their storage, except for those test substance investigations commissioned by the test facility.

Name of test substance:	Paliogen Violet 5011
Test substance No.:	11/0223-1
Batch No.	P 100012
CAS No.:	81-33-4
Purity:	The characterization (Study no. 11L00104) showed the expected values for the test substance
Homogeneity:	given (visually)
Stability:	The stability of the test substance under storage conditions over the test period was guaranteed by the sponsor, and the sponsor holds this responsibility

ADDITIONAL TEST ITEM INFORMATION

Date of production:	18 Nov 2010
Expiry date:	18 Nov 2020
Physical state/ appearance:	solid, violet
Storage conditions:	room temperature

3.2. TEST SYSTEM

Test system and strain:	Wistar Rat; Crl:WI(Han) All animals were free from clinical signs of disease at the start of the study. The females were nulliparous and non-pregnant at the beginning of the study. According to a written statement from the breeder, male and female animals were derived from different litters. This was necessary to rule out the possibility of sibling mating
Reason for species selection:	The rat is the preferred animal species for reproduction studies according to the various test guidelines and the Wistar strain was selected.
Age (at supply); sex:	10-11 weeks (males/females)
Supplier:	Charles River Laboratories, [redacted]
Identification:	The rats of the parental generation (F0 animals) were identified clearly by ear tattoo. All live pups were identified by skin tattoo on PND 1.

3.3. HOUSING AND DIET

During the study period, the rats were housed individually in Makrolon type M III cages supplied by Becker & Co., Castrop-Rauxel, Germany (floor area of about 800 cm²), with the following exceptions:

- During overnight matings, male and female mating partners were housed together in Makrolon type M III cages.
- Pregnant animals and their litters were housed together until PND 4 (end of lactation).

Pregnant females were provided with nesting material (cellulose wadding) toward the end of gestation.

Dust-free wooden bedding was used in this study (the present supplier is documented in the raw data). Wooden gnawing blocks (Type NGM E-022) supplied by Abedd® Lab. and Vet. Service GmbH, Vienna, Austria, were added for environmental enrichment.

The cages with the test animals were arranged on the racks in such a way that uniform experimental conditions (ventilation and light) were ensured.

The animals were housed in a fully air-conditioned room. Central air-conditioning guaranteed a range of 20-24°C for temperature and of 30-70% for relative humidity and 15 air changes per hour. The day/night cycle was 12 hours (12 hours light from 06.00-18.00h, 12 hours dark from 18.00-06.00h). There were no or only minimal deviations from these limits.

The animal room was completely disinfected prior to the study using a disinfector ("AUTEX", fully automatic, formalin-ammonia-based terminal disinfector). The floor and the walls were cleaned once a week with water containing an appropriate disinfectant.

The food used was ground Kliba maintenance diet mouse-rat "GLP", meal, supplied by Provimi Kliba SA, Kaiseraugst, Switzerland. Food and drinking water (from water bottles) were available ad libitum.

3.4. TEST GROUPS AND DOSES/CONCENTRATIONS

F0 generation parental animals

Test group	Dose (mg/kg body weight/day)	Concentration (g/100ml)	Dose volume (ml/kg body weight/day)	Number of animals		Animal No.	
				Male	Female	Male	Female
0	0	0	10*)	10	10	1 - 10	101 - 110
1	100	1.0	10**)	10	10	11 - 20	111 - 120
2	300	3.0	10**)	10	10	21 - 30	121 - 130
3	1000	10.0	10**)	10	10	31 - 40	131 - 140

*) drinking water
**) Test substance preparations in drinking water

3.5. TEST SUBSTANCE PREPARATIONS AND PREPARATION FREQUENCY

Paliogen Violet 5011 was applied as a suspension. To prepare this suspension, the appropriate amount of test substance was weighed out depending on the desired concentration. Then, drinking water was filled up to the desired volume, subsequently released with a high speed homogenizer. During administration of the test substance, preparations were kept homogeneous by stirring with a magnetic stirrer. The test substance preparations were produced at least once a week.

3.6. ANALYSES

3.6.1. Analyses of the test substance preparations

The analyses of the test substance preparations were carried out as a separate study at the test facility Competence Center Analytics of BASF SE, 67056 Ludwigshafen, Germany, under the responsibility of a Study Director of this test facility. The study was carried out in compliance with the Principles of Good Laboratory Practice.

The stability of the test substance in drinking water for a period of 7 days at room temperature was proven before the start of the study (Project No.: 11L00365; see PART III, Supplement).

At the beginning of the administration period samples were taken from the lowest and highest concentration for homogeneity analysis (were also used for concentration control). From the mid concentration a concentration control analysis was carried out. At the end of the administration period concentration control analyses of the test substance preparations were performed in samples of all concentrations (PART III, Supplement).

3.6.2. Analytical methods

The methods used for the analytical investigations of the test substance preparations can be found in PART III (Supplement).

3.6.3. Food analyses

The supplier assayed the food used in the study for chemical and microbiological contaminants.

3.6.4. Drinking water analyses

The drinking water is regularly assayed for chemical contaminants by the municipal authorities of Frankenthal and by the Environmental Analytics Water/Steam Monitoring Department of BASF SE as well as for the presence of microorganisms by a contract laboratory.

3.6.5. Bedding and enrichment analyses

The bedding and the enrichment are regularly assayed for contaminants (chlorinated hydrocarbons and heavy metals).

3.7. EXPERIMENTAL PROCEDURE

3.7.1. F0 generation parental animals and their progeny

On the day of arrival the animals were subjected to an acclimatization period during which they received ground diet and drinking water ad libitum. The animals were distributed according to weight among the individual test groups, separated by sex. The weight variation of the animals used did not exceed 20 percent of the mean weight of each sex. The list of randomization instructions was compiled with a computer.

At the start of the administration period (study day 0) the rats were 11-12 weeks old.

After the acclimatization period, the test substance was administered orally via gavage to the F0 generation parental animals daily. The animals of the control group received vehicle (drinking water) only.

Fourteen days after the beginning of treatment, males and females from the same test group were mated overnight in a ratio of 1:1 (details of pairing see 3.7.2.).

3.7.2. Mating of F0 generation parental animals

In general, each of the male and female animals was mated overnight in a 1:1 ratio for a maximum of 2 weeks. Throughout the mating period, each female animal was paired with a predetermined male animal from the same test group.

The animals were paired by placing the female in the cage of the male mating partner from about 16.00 h until 07.00 - 09.00 h of the following morning. Deviations from the specified times were possible on weekends and public holidays and were reported in the raw data. A vaginal smear was prepared after each mating and examined for the presence of sperm. If sperm was detected, pairing of the animals was discontinued. The day on which sperm was detected was denoted gestation day (GD) 0 and the following day "GD 1".

3.8. CLINICAL EXAMINATIONS AND EXAMINATION OF REPRODUCTIVE PERFORMANCE

3.8.1. Parental animals

3.8.1.1. Mortality

A check for moribund and dead animals was made twice daily on working days and once daily on Saturdays, Sundays and public holidays. If animals were in a moribund state, they were sacrificed and necropsied.

3.8.1.2. Clinical observations

A cageside examination was conducted at least once daily for any signs of morbidity, pertinent behavioral changes and signs of overt toxicity. Abnormalities and changes were documented daily for each affected animal.

The parturition and lactation behavior of the dams was generally evaluated in the mornings in combination with the daily clinical inspection of the dams. Only particular findings (e.g. inability to deliver) were documented on an individual dam basis.

On weekdays (except public holidays) the parturition behavior of the dams was inspected in the afternoons in addition to the evaluations in the mornings.

The day of littering was considered the 24-hour period from about 15.00 h of one day until about 15.00 h of the following day.

3.8.1.3. Food consumption

Generally, food consumption was determined once a week for male and female parental animals, with the following exceptions:

- Food consumption was not determined during the mating period (male and female F0 animals).
- Food consumption of the F0 females with evidence of sperm was determined for GD 0-7, 7-14 and 14-20.
- Food consumption of F0 females, which gave birth to a litter was determined for PND 1-4.

Food consumption was not determined in females without positive evidence of sperm (during the mating period of dams used in parallel) and females without litter (during the lactation period of dams used in parallel) and in males after the premating period.

3.8.1.4. Body weight data

In general, the body weight of the male and female parental animals was determined once a week at the same time of the day (in the morning) until sacrifice.

The body weight change of the animals was calculated from these results.

The following exceptions are notable for the female animals:

- During the mating period the parental females were weighed on the day of positive evidence of sperm (GD 0) and on GD 7, 14 and 20.
- Females with litter were weighed on the day of parturition (PND 0) and on PND 4.
- Females without litter, waiting for necropsy, were weighed weekly. These body weight data were solely used for the calculations of the dose volume; therefore these values are only documented in the Individual Tables (PART II).
- Females between PND 4 and sacrifice were weighed once a week.

3.8.1.5. Male reproduction data

The pairing partners, the number of mating days until vaginal sperm was detected in the female animals, and the gestational status of the females were recorded for F0 breeding pairs.

For the males, mating and fertility indices were calculated for F1 litters according to the following formulas:

$$\textbf{Male mating index (\%)} = \frac{\text{number of males with confirmed mating*}}{\text{number of males placed with females}} \times 100$$

*defined by a female with vaginal sperm or with implants in utero

$$\textbf{Male fertility index (\%)} = \frac{\text{number of males proving their fertility*}}{\text{number of males placed with females}} \times 100$$

* defined by a female with implants in utero

3.8.1.6. Female reproduction and delivery data

The pairing partners, the number of mating days until vaginal sperm were detected and gestational status were recorded for F0 females.

For the females, mating, fertility and gestation indices were calculated for F1 litters according to the following formulas:

$$\textbf{Female mating index (\%)} = \frac{\text{number of females mated*}}{\text{number of females placed with males}} \times 100$$

* defined as the number of females with vaginal sperm or with implants in utero

$$\textbf{Female fertility index (\%)} = \frac{\text{number of females pregnant*}}{\text{number of females mated**}} \times 100$$

* defined as the number of females with implants in utero
** defined as the number of females with vaginal sperm or with implants in utero

$$\textbf{Gestation index (\%)} = \frac{\text{number of females with live pups on the day of birth}}{\text{number of females pregnant*}} \times 100$$

* defined as the number of females with implants in utero

The total number of pups delivered and the number of liveborn and stillborn pups were noted, and the live birth index was calculated for F1 litters according to the following formula:

$$\textbf{Live birth index (\%)} = \frac{\text{number of liveborn pups at birth}}{\text{total number of pups born}} \times 100$$

The implantations were counted[1] and the postimplantation loss (in %) was calculated according the following formula:

$$\text{Post implantation loss (\%)} = \frac{\text{number of implantations} - \text{number of pups delivered}}{\text{number of implantations}} \times 100$$

[1] To determine the number of implantation sites, the apparently non-pregnant uteri were stained for about 5 minutes in 1% ammonium sulfide solution according to the method of SALEWSKI (Salewski, E.; 1964). Then the uteri were rinsed carefully under NaCl solution. Thereafter the implantation sites were recorded for calculation of the postimplantation loss.

3.8.2. Litter/Pups

3.8.2.1. Litter data

3.8.2.1.1. Pup number and status at delivery

All pups delivered from the F0 parents were examined as soon as possible on the day of birth to determine the total number of pups and the number of liveborn and stillborn pups in each litter. Pups, which died before the first determination of their status on the day of birth, were defined as stillborn pups.

3.8.2.1.2. Pup viability/mortality

In general, a check was made for any dead or moribund pups twice daily on workdays (once in the morning and once in the afternoon) or as a rule, only in the morning on Saturdays, Sundays or public holidays.

The number and percentage of dead pups on the day of birth (PND 0) and of pups dying between PND 1 - 4 (lactation period) were determined. Pups which died accidentally or were sacrificed due to maternal death were not included in these calculations. The number of live pups/litter was calculated on the day after birth, and on lactation day 4. The viability index was calculated according to the following formula:

$$\textbf{Viability index (\%)} = \frac{\text{number of live pups on day 4 after birth}}{\text{number of live pups on the day of birth}} \times 100$$

3.8.2.1.3. Sex ratio

On the day of birth (PND 0) the sex of the pups was determined by observing the distance between the anus and the base of the genital tubercle; normally, the anogenital distance is considerably greater in male than in female pups. The sex of the pups was finally confirmed at necropsy.

The sex ratio was calculated at day 0 and day 4 after birth according to the following formula:

$$\textbf{Sex ratio} = \frac{\text{number of live male or female pups on day 0/4}}{\text{number of live male and female pups on day 0/4}} \times 100$$

3.8.2.2. Pup clinical observations

The live pups were examined daily for clinical symptoms (including gross-morphological findings) during the clinical inspection of the dams.

3.8.2.3. Pup body weight data

The pups were weighed on the day after birth (PND 1) and on PND 4.

Pups' body weight change was calculated from these results.

The individual weights were always determined at about the same time of the day (in the morning).

In the summary tables pup body weights and pup body weight change are listed for males, females and males + females.

“Runts” were defined on the basis of the body weights on PND 1. "Runts" are pups that weigh less than 75% of the mean weight of the respective control pups.

3.8.2.4. Pup necropsy observations

All pups with scheduled sacrifice on PND 4 were sacrificed under isoflurane anesthesia with CO_2. All pups were examined externally and eviscerated; their organs were assessed macroscopically.

All stillborn pups and all pups that died before PND 4 were examined externally, eviscerated and their organs were assessed macroscopically.

All pups without notable findings or abnormalities were discarded after their macroscopic evaluation. Animals with notable findings or abnormalities were evaluated on a case-by-case basis, depending on the type of finding noted.

3.8.3. Statistics of the clinical examinations

Statistical analyses were performed according to following tables:

Parameter	Statistical test	Markers in the tables	References
Food consumption (parental animals), body weight and body weight change (parental animals and pups; for the pup weights, the litter means were used), gestation days, implantation sites, pups delivered, live pups day x	Simultaneous comparison of all dose groups with the control group using the DUNNETT test (two-sided) for the hypothesis of equal means	* for $p \leq 0.05$ ** for $p \leq 0.01$	Dunnett, C.W. (1955): A multiple comparison procedure for comparing several treatments with a control. JASA, Vol. 50, 1096-1121 Dunnett, C.W. (1964). New tables for multiple comparisons with a control. Biometrics, Vol. 20, 482-491
Male and female mating indices, male and female fertility indices, gestation index, females delivering, females with liveborn pups, females with stillborn pups, females with all stillborn pups,	Pair-wise comparison of each dose group with the control group using FISHER'S EXACT test (one-sided) for the hypothesis of equal proportions †	* for $p \leq 0.05$ ** for $p \leq 0.01$	Siegel S. (1956): Non-parametric statistics for behavioural sciences. McGraw-Hill New York
Mating days until day 0 pc	Pair-wise comparison of the dose group with the control group using the WILCOXON test (one-sided+) with BONFERRONI-HOLM adjustment for the hypothesis of equal medians	* for $p \leq 0.05$ ** for $p \leq 0.01$	Siegel S. (1956): Non-parametric statistics for behavioral sciences. McGraw-Hill New York Holm (1979): A Simple Sequentially Rejective Multiple Test Procedure. Scand. J. Statist, 6, 65-70
Viability Index	Pair-wise comparison of the dose group with the control group using the WILCOXON test (one-sided-) with BONFERRONI-HOLM adjustment for the hypothesis of equal medians	* for $p \leq 0.05$ ** for $p \leq 0.01$	Siegel S. (1956): Non-parametric statistics for behavioral sciences. McGraw-Hill New York Holm (1979): A Simple Sequentially Rejective Multiple Test Procedure. Scand. J. Statist, 6, 65-70

† Although the Fisher's exact test (one-sided+ and one-sided - separately) was chosen for all dichotomous endpoints, the Chi-Square test was performed accidentally for some endpoints (see Summary tables in part III). In this case the data for the parameters in the table above were separately re-analyzed with the Fisher's exact test using SAS ® Version 9.2 (included in raw data). Summary Delivery Table and Summary Mating Table in part I were created without statistics for the dichotomous data for clarity reasons, but any statistical significance concerning dichotomous data in part III and with SAS analysis are described in the textual part of the report.

3.9. PATHOLOGY

3.9.1. Necropsy

All animals were sacrificed by decapitation under isoflurane anesthesia. The exsanguinated animals were necropsied and assessed by gross pathology, special attention being given to the reproductive organs.

3.9.2. Weight parameters

Weight assessment was carried out on all animals. The following weights were determined:

1. Anesthetized animals
2. Epididymides
3. Testes

3.9.3. Organ / Tissue fixation

The following organs / tissues of all parental animals were preserved in neutral-buffered 4% formaldehyde or in modified Davidson's solution:

1. All gross lesions
2. Cervix
3. Coagulating glands
4. Epididymides (modified Davidson's solution)
5. Ovaries (modified Davidson's solution)
6. Oviducts
7. Prostate gland
8. Seminal vesicles
9. Testes (modified Davidson's solution)
10. Uterus
11. Vagina

3.9.4. Histopathology

After the organs were fixed, processing, examination by light microscopy and evaluation of findings were performed according to the following table:

Organ samples	Test group			
	0	1	2	3
1. Epididymides	A1			A1
2. Ovaries	A1			A1
3. Testes	A1			A1

METHODS/SCOPE OF EXAMINATIONS:

A = Hematoxylin-eosin (H&E)
1 = all animals per group

Special attention was given on the stages of spermatogenesis in the testes.

3.9.5. Statistics of pathology

Parameters	Statistical test	Markers in the tables	References
Weight parameters	Non-parametric one-way analysis using KRUSKAL-WALLIS test (two-sided). If the resulting p-value was equal or less than 0.05, a pair wise comparison of each dose group with the control group was performed using the WILCOXON test for the hypothesis of equal medians	* for $p \leq 0.05$ ** for $p \leq 0.01$	HETTMANNSPERGER, T.P. (1984): Statistical Inference based on Ranks, John Wiley & Sons New York, 132-140. International Mathematical and Statistical Libraries, Inc., 2500 Park West Tower One, Houston, Texas 77042-3020, USA, nakl-1 - nakl-3 MILLER, R.G. (1981): Simultaneous Statistical Inference Springer-Verlag New York Inc., 165-167 NIJENHUIS, A. and S.W. WILF (1978): Combinatorial Algorithms, Academic Press, New York, 32-33

4. RESULTS

Throughout the chapter "results", the term "significant" implies that the inter-group differences have attained *statistical* significance ($p \leq 0.05$) when compared with the control group.

4.1. ANALYSES

4.1.1. Stability analysis

The stability of the test substance in drinking water was demonstrated over a period of 7 days at room temperature. As the mixtures were stored no longer than this time period, the stability was guaranteed (see PART III, Supplement).

4.1.2. Homogeneity control analyses

The samples were homogenous within the different levels of concentration.

4.1.3. Concentration control analyses

The concentration control analyses of all concentrations revealed that the values were in the expected range of the target concentrations, i.e. were always in a range of about 90-110% of the nominal concentrations. These results demonstrate the correctness of the concentrations of Paliogen Violet 5011 (PART III, Supplement).

4.1.4. Food analyses

On the basis of duration of use and the analytical findings with respect to chemical and microbiological contaminants the diet was found to be suitable. Fed. Reg. Vol. 44, No. 91 of 09 May 1979, p. 27354 (EPA), served as a guideline for maximum tolerable chemical contaminants. The number of microorganisms did not exceed 1×10^5/g food. Individual results can be found in the archives of the Experimental Toxicology and Ecology of BASF SE.

4.1.5. Drinking water analyses

On the basis of the analytical findings the drinking water was found to be suitable. German "Trinkwasserverordnung" (Drinking Water Regulation) served as a guideline for maximum tolerable contaminants. Individual results can be found in the archives of the Experimental Toxicology and Ecology of BASF SE.

4.1.6. Bedding and enrichment analyses

On the basis of the analytical findings the bedding and the enrichment are found to be suitable. Levels given in Lab. Animal, Nov-Dec 1979, pp. 24-34, served as a guideline for maximum tolerable contaminants. Individual results are to be found in the archives of the Experimental Toxicology and Ecology of BASF SE.

4.2. CLINICAL EXAMINATIONS AND EXAMINATION OF REPRODUCTIVE PERFORMANCE

Summary tables of the results are given in the Appendix of PART I; individual values are given in Part A of PART II.
Descriptive statistical measures are calculated without rounding by the computer system using the original individual values. Any calculation of measures using the rounded values given in the tables may result in discrepancies in comparison with the measures calculated by the system.

4.2.1. Parental clinical examinations and examination of reproductive performance

4.2.1.1. Mortality

There were no mortalities in any of the test groups.

4.2.1.2. Clinical observations
(Tables IA1 – IA7)

All male and female animals of test group 2 (300 mg/kg bw/d) and 3 (1000 mg/kg bw/d) showed black discolored feces from study day 1 until the end of the administration period.
During gestation period on study days 41-43 one female animal (No. 122) of test group 2 (300 mg/kg bw/d) showed palpable mass in the abdominal region. Because of a single occurrence and no other clinical observation in this animal this finding was assessed as being incidental.

Two sperm positive females of the control group (Nos. 106 and 107) and each one sperm positive female of test group 1, 2 and 3 (Nos. 111, 122 and 139 – 100, 300, 1000 mg/kg bw/d) did not deliver F1 pups.

4.2.1.3. Food consumption
(Tables IA8 – IA11)

Food consumption of the male animals in test group 1 (100 mg/kg bw/d) was slightly decreased in the premating phase from study days 7-13 (-5.9%) and in the entire premating phase (-5.9%). Because of a single incidence this finding was assessed as being incidental.

4.2.1.4. Body weight data

(Tables IA12 – IA21; Figures 4.2.1.4.1. - 4.2.1.4.4.)

Mean body weights of the F0 males and females in all test groups were comparable to the concurrent control group throughout the entire study period.
The mean body weight gain of the F0 males in test group 2 in the entire premating phase was statistically significantly decreased (-37.4%). The mean body weight gain of the F0 females in test group 1 in the gestation period from study day 7 to 14 was statistically significantly increased (+24.2%). Because of single incidences and no dose response relationship these findings were assessed as being incidental.

Figure 4.2.1.4.1.: Mean body weight of F0 males during premating

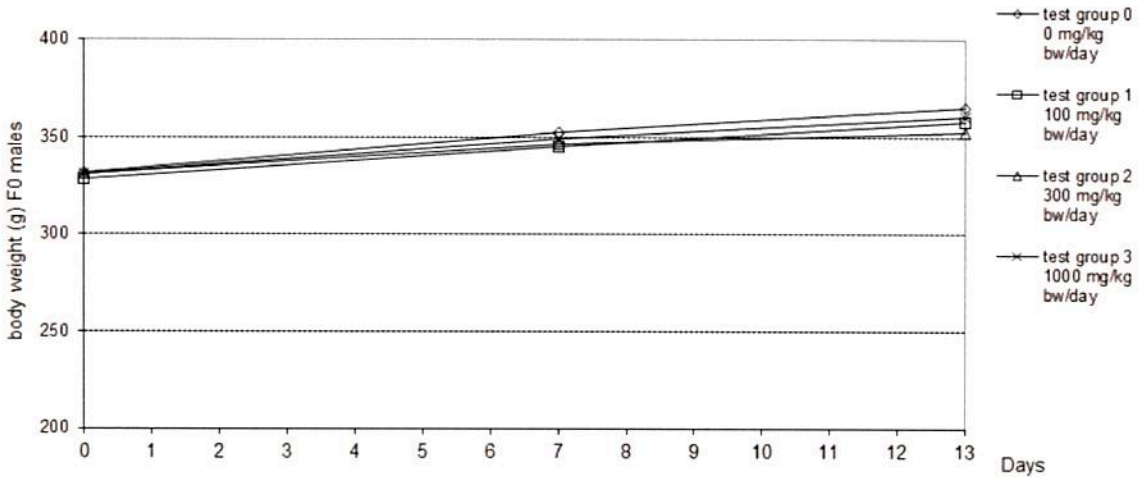


Figure 4.2.1.4.2.: Mean body weight of females during premating

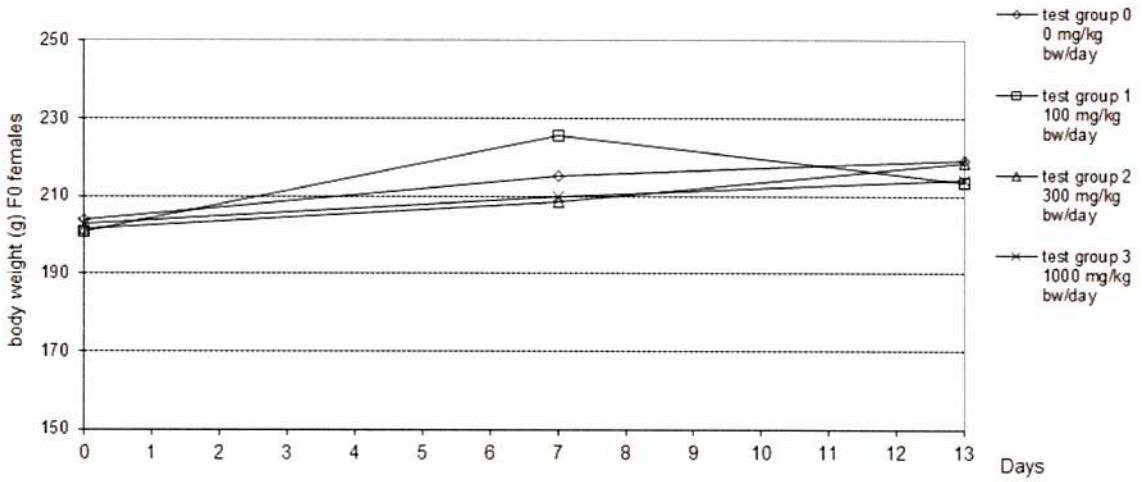


Figure 4.2.1.4.3.: Mean body weight of F0 females during gestation of F1 litter

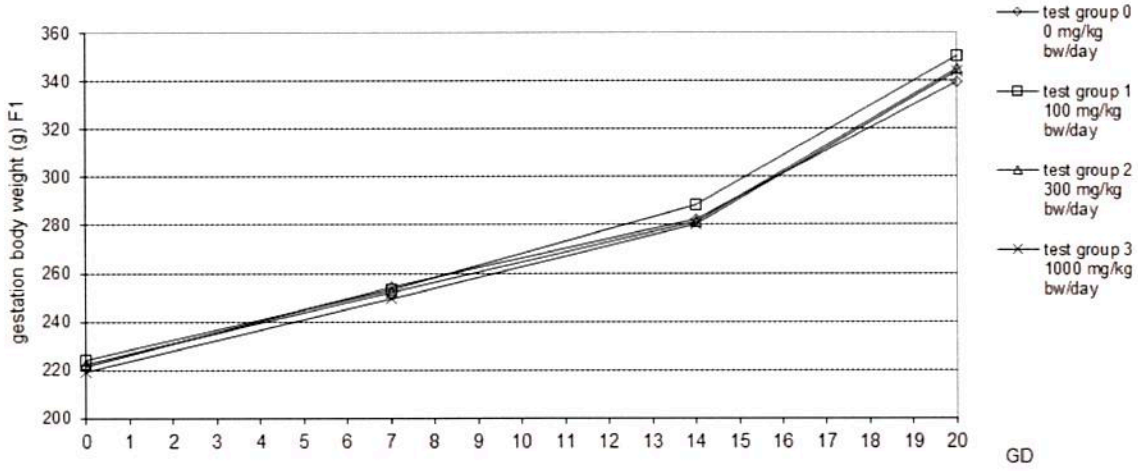
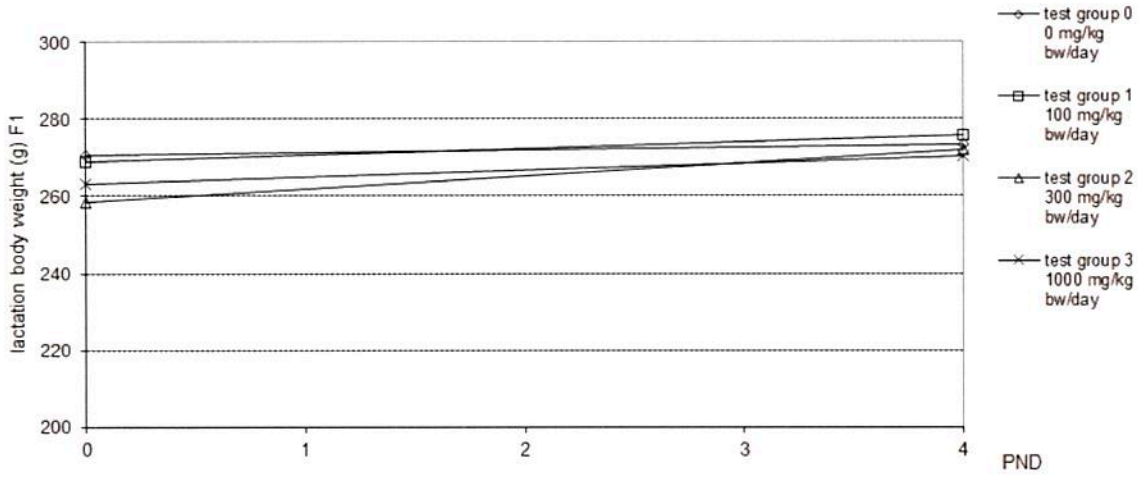


Figure 4.2.1.4.4.: Mean body weight of F0 females during lactation of F1 litter



4.2.1.5. Male reproduction data
(Table IA 22)

The male mating index was 100% in all test groups.

Fertility was proven for most of the F0 parental males within the scheduled mating interval to produce F1 litter.

Two males of the control group (Nos. 6 and 7 mated with females Nos. 106 and 107), one male of test group 1 (No. 11 mated with female No. 111 – 100 mg/kg bw/d), one male of test group 2 (No. 22 mated with female No. 122 – 300 mg/kg bw/d) and one male of test group 3 (No 39 mated with female No. 139 – 1000 mg/kg bw/d) did not generate F1 pups.

Thus, the male fertility index was 80% in the control group and 90% in all test groups. This reflects the normal range of biological variation inherent in the strain of rats used for this study (see Tab. 4.2.1.5.1.).

Tab. 4.2.1.5.1.: Male fertility indices for F0 males

	Test group 0 (0 mg/kg bw/d)	Test group 1 (100 mg/kg bw/d)	Test group 2 (300 mg/kg bw/d)	Test group 3 (1000 mg/kg bw/d)
Male fertility index [%]	80	90	90	90

* $p \leq 0.05$; ** $p \leq 0.01$

4.2.1.6. Female reproduction and delivery data
(Tables IA22 – IA25)

4.2.1.6.1. Female mating index

The female mating index calculated after the mating period for F1 litter was 100% in all test groups.

The mean duration until sperm was detected (GD 0) was 2.7, 2.9, 3.1 and 3.2 days in test groups 0 - 3. This finding reflected the normal range of biological variation inherent in the strain of rats used for this study as all respective values were within the range of the historical control data (PART III, Supplement).

All sperm positive rats delivered pups or had implants in utero with the following exception:

- Control group females Nos. 106 and 107 (mated with male No. 6 and 7) did not become pregnant.
- Low-dose female No. 111 (mated with male No. 11) did not become pregnant.
- Mid-dose female No. 122 (mated with male No. 22) did not become pregnant.
- High-dose female No. 139 (mated with male No. 39) did not become pregnant.

4.2.1.6.2. Female fertility index

The female fertility index was 80% in the control group and 90% in all test groups (Tab. 4.2.1.6.2.1.). These values reflect the normal range of biological variation inherent in the strain of rats used for this study.

Tab. 4.2.1.6.2.1.: Fertility indices for F0 females

	Test group 0 (0 mg/kg bw/d)	Test group 1 (100 mg/kg bw/d)	Test group 2 (300 mg/kg bw/d)	Test group 3 (1000 mg/kg bw/d)
Female fertility index [%]	80	90	90	90

* $p \leq 0.05$; ** $p \leq 0.01$

The mean duration of gestation was similar in all test groups (22.1 days in the control group, 22 days in test group 1, 22.2 days in test group 2 and 22 days in test group 3).

4.2.1.6.3. Gestation index

The gestation index was 100% in all test groups.

4.2.1.6.4. Live birth indices

The liveborn birth index was 98.8% in the control group, 96.5 in test group 1, 99.2 in test group 2 and 99.1% in test group 3. These values reflect the normal range of biological variation inherent in the strain of rats used for this study.

4.2.1.6.5. Postimplantation loss

The postimplantation loss was 8.86% in test group 0, 7.90% in test group 1, 1.78% in test group 2 and 4.28% in test group 3.
These findings reflected the normal range of biological variation inherent in the strain of rats used for this study as all respective values were within the range of the historical control data (PART III, Supplement).

4.2.2. F1 generation litter/pups

4.2.2.1. Litter data

(Tables IA25 – IA28)

4.2.2.1.1. Pup number and status at delivery

The mean number of delivered F1 pups was 10.6 in test group 0, 12.7 in test group 1, 13.1 in test group 2 and 12.7 in test group 3.

4.2.2.1.2. Pup viability/mortality

The viability index indicating pup mortality during lactation (PND 0 - 4) was 100% in all test groups.

4.2.2.1.3. Sex ratio

The sex distribution and sex ratios of live F1 pups on the day of birth and PND 4 did not show substantial differences between the control and the test substance-treated groups; slight differences were regarded to be spontaneous in nature (see Tab. 4.2.2.1.3.1.).

Tab. 4.2.2.1.3.1. Sex ratio of live F1 pups

PND 0	Test group 0 (0 mg/kg bw/d)	Test group 1 (100 mg/kg bw/d)	Test group 2 (300 mg/kg bw/d)	Test group 3 (1000 mg/kg bw/d)
Live males [%]	48.8	57.3	41.9	42.5
Live females [%]	51.2	42.7	58.1	57.5
PND 4				
Live males [%]	48.8	57.3	41.9	42.5
Live females [%]	51.2	42.7	58.1	57.5

Sex ratio data were calculated using the individual values concerning pup status (see PART II, Part A, Tabs. IIA-116 – IIA-153).

4.2.2.2. Pup clinical observations
(Tables IA29 – IA30)

The surviving F1 pups of any test group did not show adverse clinical signs up to scheduled sacrifice on PND 4.

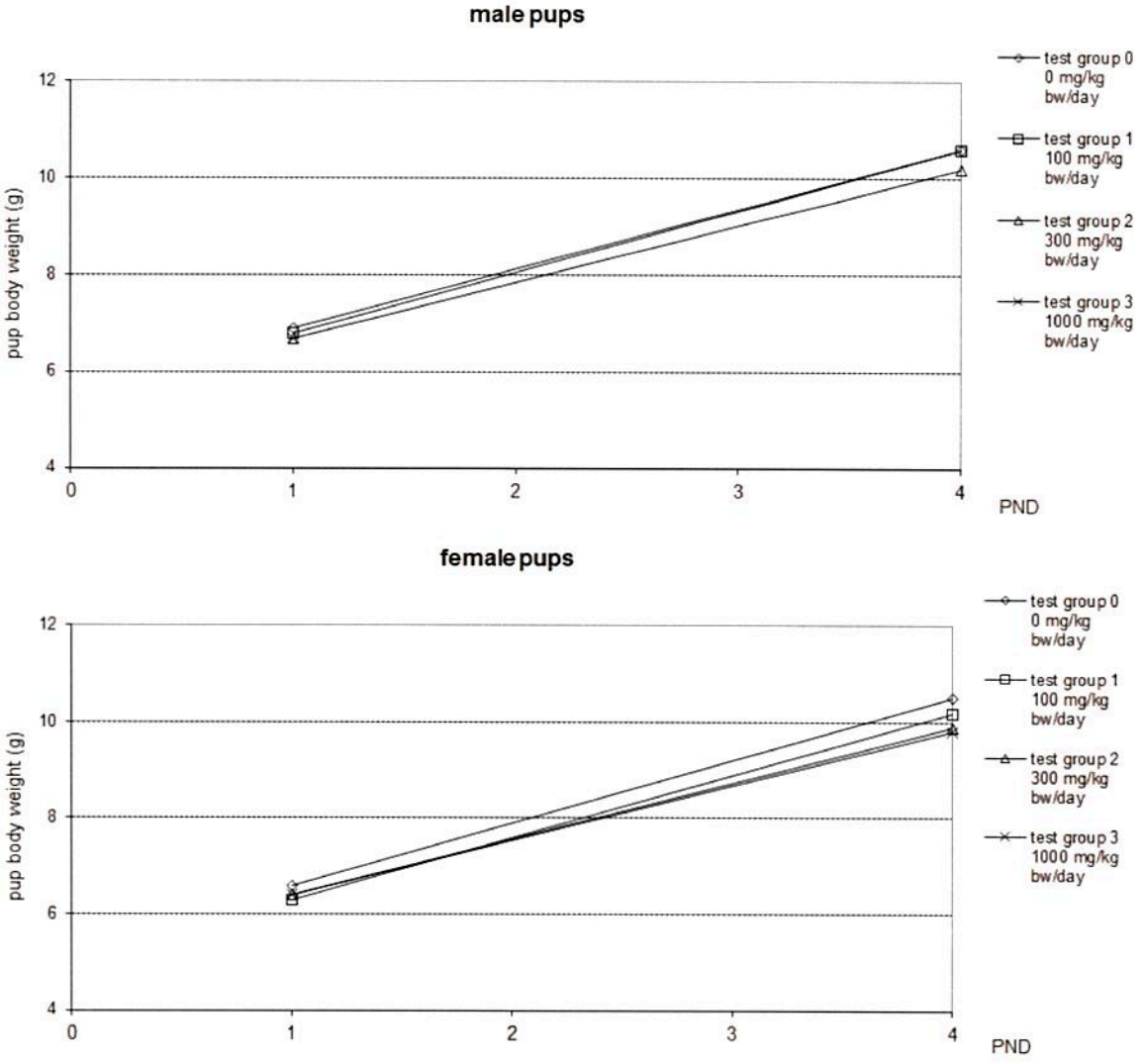
4.2.2.3. Pup body weight data
(Tables IA31 – IA33; Figure 4.2.2.3.1.)

Mean pup body weights/pup body weight changes of all pups in all test groups were comparable to the control group.

Two male runts were seen in test group 0. Each one female runt was seen in test group 1 and 2 (100 and 300 mg/kg bw/d).

These findings reflected the normal range of biological variation inherent in the strain of rats used for this study as all respective values were within the range of the historical control data (PART III, Supplement).

Figure 4.2.2.3.1. Mean body weight of F1 pups



4.2.2.4. Pup necropsy observations

(Table IA34 – IA35)

One male and one female F1 pup of test group 1 showed post mortem autolysis. Each one female F1 pup of test group 2 and 3 (300 and 1000 mg/kg bw/d) showed an empty stomach.

This finding was assessed as being spontaneous in nature and without biological relevance.

4.3. PATHOLOGY

Summary tables of the results can be found in Part B of PART I; individual tables can be found in Part B of PART II.

4.3.1. Weight parameters

(Tables IB 1 - 3)

All mean weight parameters did not show significant differences when compared to the control groups.

4.3.2. Gross lesions

(Table IB 4)

The following relevant gross findings were observed (incidence is given in the table below):

	Male animals				Female animals			
Test group (mg/kg bw/day)	**0** (0)	**1** (100)	**2** (300)	**3** (1000)	**0** (0)	**1** (100)	**2** (300)	**3** (1000)
No of animals	10	10	10	10	10	10	10	10
Glandular stomach Discoloration of contents			8	6				10
Jejunum Discoloration of contents			10	10			10	10
Colon Discoloration of contents			10	10			10	10

Several animals of test group 2 and 3 revealed a black discoloration of the contents of the glandular stomach, jejunum and colon. These findings are regarded to be treatment related.

All other gross lesions noted were single observations and they were regarded to have developed spontaneously and unrelated to compound and treatment.

4.3.3. Histopathology

(Tables IC 5)

The discoloration of the content in the digestive tract was regarded to be a consequence to the oral intake of the test substance which is of violet color. Therefore, the gross findings in the remaining animals were not investigated in addition.

All other findings noted were either single observations or they were biologically equally distributed between control and treatment group. All of them were considered to be incidental or spontaneous in origin and without any relation to treatment.

5. DISCUSSION

Paliogen Violet 5011 was administered orally by gavage to groups of 10 male and 10 female Wistar rats (F0 animals) at dose levels of 100, 300 and 1000 mg/kg bw/d.

Regarding clinical examinations, no signs of general systemic toxicity were observed in male or female parental animals of all test groups (100, 300 and 1000 mg/kg bw/d) during the entire study period. All male and female animals of test group 2 (300 mg/kg bw/d) and 3 (1000 mg/kg bw/d) showed black discolored feces from study day 1 until the end of the administration period. This finding was substance-related due to the dark violet color of the dye stuff.

Regarding fertility and reproductive performance, no signs of toxicity were observed in male or female parental animals of all test groups (100, 300 and 1000 mg/kg bw/d) during the entire study.

Regarding developmental toxicity, no signs of toxicity were observed in male or female pups of all test groups (100, 300 and 1000 mg/kg bw/d)

Regarding pathology, macroscopically black discoloration of the content of the digestive tract in numerous animals was observed. Beside the discoloration no signs of toxicity in the respective tissues were noted macroscopically. This finding is regarded to be a consequence to the oral intake of the violet test substance and therefore treatment related but not adverse in nature. All other findings were considered to be incidental or spontaneous in origin and without any relation to treatment.

6. CONCLUSION

Thus, under the conditions of this modified reproduction/developmental toxicity screening test the **NOAEL** (no observed adverse effect level) for **reproductive performance** and **fertility** was 1000 mg/kg bw/d

The **NOAEL** for **developmental toxicity** in the F1 progeny was found to be 1000 mg/kg bw/d.

The **NOAEL** for **general, systemic toxicity** was 1000 mg/kg bw/d.

7. REFERENCES

ECETOC Technical Report No 85: Recognition of, and Differentiation between Adverse and Non-adverse Effects in Toxicology Studies, 2002

NIJENHUIS, A.; WILF, H.S. Random permutation of n letters. Combinatorial Algorithms, Academic Press, New York, San Francisco, London, 62-64 (1978)

SALEWSKI, E. Färbemethode zum makroskopischen Nachweis von Implantationsstellen am Uterus der Ratte. Naunyn-Schmiedeberg's Arch. exp. Path. Pharmak. 247, 367-368 (1964)

8. APPENDIX

The following list contains abbreviations and definitions generally used in reports for this study type. This report will not necessarily use all expressions listed below.

8.1. LIST OF ABBREVIATIONS USED IN TABLES CLINICAL EXAMINATIONS

%	=	percent
%dev	=	deviation in percent
Animal No.	=	animal number
anm	=	animal
AT	=	after treatment
BT	=	before treatment
Bw or bw	=	body weight
cm	=	centimeter
Control	=	control animals
d	=	day
DCO	=	detailed clinical observation
F	=	female animals
FST	=	landing foot-splay test
g	=	weight in gram
GS F	=	grip strength forelimbs
GS H	=	grip strength hindlimbs
h	=	hour
Interr.	=	beam Interrupts
Interv.	=	Interval
kg or KG	=	kilogram
M	=	male animals or mean value
mg/kg bw/d	=	milligrams per kilogram bodyweight per day
mg or MG	=	milligram
min.	=	minute
N	=	number of animals for determining M and SD
NaCl	=	sodium chloride
NAD	=	nothing abnormal detected
NM	=	not measured
ppm	=	parts per million
p.c.	=	post coitum
Rear	=	rearing
S.d. or SD	=	standard deviation
Vs	=	Versus
Deviation Vs Control	=	deviation versus control in percent

8.2. LIST OF ABBREVIATIONS USED IN TABLES PATHOLOGY

F	=	female animals
F1	=	final sacrifice groups (main groups)
g	=	weight determination in grams
M	=	male animals (under sex); mean value (on weight level)
mg	=	weight determination in milligrams
mg/kg	=	milligram per kilogram
n	=	number of values measured for the determination of mean value and standard deviation
NAD	=	number of animals without gross lesions
ppm	=	parts per million under dose level
SD	=	standard deviation
s	=	suspect weight (not included in the mean weights)
%	=	percentage related to the reference weight in relative organ weight calculations

Codes for the status at necropsy:

P	=	planned sacrifice
K	=	sacrificed in a moribund state
S	=	spontaneous death

Codes used at finding level:

The codes are used for a grading system which takes into consideration either the severity or the number or the size of a microscopic finding.

	Severity	Number	Size
Grade 1	Minimal	Very few	Very small
Grade 2	Slight	Few	Small
Grade 3	Moderate	Moderate number	Moderate size
Grade 4	Marked; severe	Many	Large
Grade 5	Massive; extreme	Extensive number	Extensive size

Whenever a grading was not used, the microscopic finding was indicated to be present (P).

IA 1
28-Feb-2013 12:00
ToxData© System 3.0

Study 80R0223/11C162

Summary - Clinical Observation

Sex: **Male** - Phase: **Pre-mating**

			Test Group 0/ M 0 mg/kg bw/d	Test Group 1/ M 100 mg/kg bw/d	Test Group 2/ M 300 mg/kg bw/d	Test Group 3/ M 1000 mg/kg bw/d
	Animals examined	N	10	10	10	10
	Animals with signs	N	0	0	10	10
day 0 -> 13	feces *discolored feces*	N	0	0	10	10
	normal *NAD*	N	10	10	10	10

IA 2
28-Feb-2013 12:02
ToxData© System 3.0

Study 80R0223/11C162

Summary - Clinical Observation

Sex: **Female** - Phase: **Pre-mating**

			Test Group 0/ F 0 mg/kg bw/d	Test Group 1/ F 100 mg/kg bw/d	Test Group 2/ F 300 mg/kg bw/d	Test Group 3/ F 1000 mg/kg bw/d
day 0 -> 13	Animals examined	N	10	10	10	10
	Animals with signs	N	0	0	10	10
	feces	N	0	0	10	10
	discolored feces					
	normal	N	10	10	10	10
	NAD					

IA 3

Study 80R0223/11C162

28-Feb-2013 12:06

ToxData© System 3.0

Summary - Clinical Observation

Sex: **Male** - Phase: **Mating**

			Test Group 0/ M 0 mg/kg bw/d	Test Group 1/ M 100 mg/kg bw/d	Test Group 2/ M 300 mg/kg bw/d	Test Group 3/ M 1000 mg/kg bw/d
	Animals examined	N	10	10	10	10
	Animals with signs	N	0	0	10	10
day 1 -> 14	feces	N	0	0	10	10
	discolored feces					
	normal	N	10	10	0	0
	NAD					

IA 4
28-Feb-2013 12:07
ToxData© System 3.0

Study 80R0223/11C162

Summary - Clinical Observation

Sex: **Female** - Phase: **Mating**

			Test Group 0/ F 0 mg/kg bw/d	Test Group 1/ F 100 mg/kg bw/d	Test Group 2/ F 300 mg/kg bw/d	Test Group 3/ F 1000 mg/kg bw/d
day 1 -> 14	Animals examined	N	10	10	10	10
	Animals with signs	N	0	0	10	10
	feces	N	0	0	10	10
	discolored feces					
	normal	N	10	10	0	0
	NAD					

IA 5
28-Feb-2013 12:09
ToxData© System 3.0

Study 80R0223/11C162

Summary - Clinical Observation

Sex: **Male** - Phase: **Post-mating**

			Test Group 0/ M 0 mg/kg bw/d	Test Group 1/ M 100 mg/kg bw/d	Test Group 2/ M 300 mg/kg bw/d	Test Group 3/ M 1000 mg/kg bw/d
	Animals examined	N	10	10	10	10
	Animals with signs	N	0	0	10	10
day 0 -> 3	dead	N	10	10	10	10
	sacrificed scheduled					
	feces	N	0	0	10	10
	discolored feces					
	normal	N	10	10	0	0
	NAD					

IA 6
04-Mar-2013 12:19
ToxData© System 3.0

Study 80R0223/11C162

Summary - Clinical Observation

Sex: **Female** - Phase: **Gestation**

			Test Group 0/ F 0 mg/kg bw/d	Test Group 1/ F 100 mg/kg bw/d	Test Group 2/ F 300 mg/kg bw/d	Test Group 3/ F 1000 mg/kg bw/d
day 0 -> 44	Animals examined	N	10	10	10	10
	Animals with signs	N	0	0	10	10
		%	0.0	0.0	100.0	100.0
	dead	N	2	1	1	1
	sacrificed scheduled	%	20.0	10.0	10.0	10.0
	feces	N	0	0	10	10
	discolored feces	%	0.0	0.0	100.0	100.0
	mass	N	0	0	1	0
	palpable in abdomen	%	0.0	0.0	10.0	0.0
	normal	N	10	10	0	0
	NAD	%	100.0	100.0	0.0	0.0

IA 7
04-Mar-2013 12:20
ToxData© System 3.0

Study 80R0223/11C162

Summary - Clinical Observation

Sex: **Female** - Phase: **Lactation**

			Test Group 0/ F 0 mg/kg bw/d	Test Group 1/ F 100 mg/kg bw/d	Test Group 2/ F 300 mg/kg bw/d	Test Group 3/ F 1000 mg/kg bw/d
day 0 -> 23	Animals examined	N	8	9	9	9
	Animals with signs	N	0	0	9	9
		%	0.0	0.0	100.0	100.0
	dead	N	8	9	9	9
	sacrificed scheduled	%	100.0	100.0	100.0	100.0
	feces	N	0	0	9	9
	discolored feces	%	0.0	0.0	100.0	100.0
	normal	N	8	9	0	0
	NAD	%	100.0	100.0	0.0	0.0

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Study 80R0223/11C162

Summary Food Consumption Per Day

Sex: **Male** - Phase: **Pre-mating**

		Test Group 0/ M 0 mg/kg bw/d	Test Group 1/ M 100 mg/kg bw/d	Test Group 2/ M 300 mg/kg bw/d	Test Group 3/ M 1000 mg/kg bw/d
d 0 -> 7	**Mean [g]**	23.2 n	21.9	22.6	22.9
	S.d.	1.3	0.8	1.7	1.1
	N	10	10	10	10
	Deviation Vs Control		-5.7	-2.6	-1.5
d 7 -> 13	**Mean [g]**	23.5 n	22.2 *	22.8	23.0
	S.d.	1.1	0.8	1.5	1.0
	N	10	10	10	10
	Deviation Vs Control		-5.9	-3.1	-2.4
d 0 -> 13	**Mean [g]**	23.4 n	22.0 *	22.7	22.9
	S.d.	1.2	0.7	1.6	1.0
	N	10	10	10	10
	Deviation Vs Control		-5.9	-2.9	-2.0

Statistic Profile = Dunnett test (two-sided), * p<=0.05, ** p <=0.01, X = Group excluded from statistics
d = day; n=DUNNETT

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Study 80R0223/11C162

Summary Food Consumption Per Day

Sex: **Female** - Phase: **Pre-mating**

		Test Group 0/ F 0 mg/kg bw/d	Test Group 1/ F 100 mg/kg bw/d	Test Group 2/ F 300 mg/kg bw/d	Test Group 3/ F 1000 mg/kg bw/d
d 0 -> 7	**Mean [g]**	16.6 n	16.3	16.1	16.4
	S.d.	0.7	1.2	0.8	1.1
	N	10	10	10	10
	Deviation Vs Control		-2.3	-3.4	-1.5
d 7 -> 13	**Mean [g]**	17.2 n	17.0	16.9	16.7
	S.d.	0.6	1.2	0.9	1.2
	N	10	10	10	10
	Deviation Vs Control		-1.0	-1.6	-2.7
d 0 -> 13	**Mean [g]**	16.9 n	16.6	16.5	16.6
	S.d.	0.6	1.2	0.7	1.0
	N	10	10	10	10
	Deviation Vs Control		-1.7	-2.4	-2.0

Statistic Profile = Dunnett test (two-sided), * p<=0.05, ** p <=0.01, X = Group excluded from statistics
d = day; n=DUNNETT

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Study 80R0223/11C162

Summary Food Consumption Per Day

Sex: **Female** - Phase: **Gestation**

		Test Group 0/ F 0 mg/kg bw/d	Test Group 1/ F 100 mg/kg bw/d	Test Group 2/ F 300 mg/kg bw/d	Test Group 3/ F 1000 mg/kg bw/d
d 0 -> 7	**Mean [g]**	21.1 n	21.2	20.9	20.6
	S.d.	1.1	1.7	1.6	0.9
	N	10	10	10	10
	Deviation Vs Control		0.8	-1.0	-2.4
d 7 -> 14	**Mean [g]**	22.1 n	23.3	22.8	22.6
	S.d.	1.4	2.2	1.6	1.8
	N	10	10	10	10
	Deviation Vs Control		5.1	2.8	1.9
d 14 -> 20	**Mean [g]**	22.5 n	23.5	22.7	23.7
	S.d.	3.5	3.3	2.6	2.5
	N	10	10	10	10
	Deviation Vs Control		4.3	0.7	5.2
d 0 -> 20	**Mean [g]**	21.9 n	22.6	22.1	22.2
	S.d.	1.7	2.1	1.3	1.5
	N	10	10	10	10
	Deviation Vs Control		3.5	0.9	1.5

Statistic Profile = Dunnett test (two-sided), * p<=0.05, ** p <=0.01, X = Group excluded from statistics
d = day; n=DUNNETT

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Study 80R0223/11C162

Summary Food Consumption Per Day

Sex: **Female** - Phase: **Lactation**

		Test Group 0/ F 0 mg/kg bw/d	Test Group 1/ F 100 mg/kg bw/d	Test Group 2/ F 300 mg/kg bw/d	Test Group 3/ F 1000 mg/kg bw/d
d 1 -> 4	**Mean [g]**	32.9 n	35.9	35.8	35.2
	S.d.	7.0	4.7	3.2	3.8
	N	8	9	9	9
	Deviation Vs Control		9.0	8.6	6.8

Statistic Profile = Dunnett test (two-sided), * p<=0.05, ** p <=0.01, X = Group excluded from statistics
d = day; n=DUNNETT

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Study 80R0223/11C162

Summary Body Weights - BW / Body Weights [g]

Sex: **Male** - Phase: **Pre-mating**

		Test Group 0/ M 0 mg/kg bw/d	Test Group 1/ M 100 mg/kg bw/d	Test Group 2/ M 300 mg/kg bw/d	Test Group 3/ M 1000 mg/kg bw/d
day 0	**Mean**	332.1 n	328.5	331.5	331.3
	S.d.	9.2	9.9	10.4	11.2
	N	10	10	10	10
	Deviation Vs Control		-1.1	-0.2	-0.3
day 7	**Mean**	352.5 n	345.2	346.8	349.0
	S.d.	10.7	13.1	12.8	12.0
	N	10	10	10	10
	Deviation Vs Control		-2.1	-1.6	-1.0
day 13	**Mean**	365.5 n	358.1	352.4	360.4
	S.d.	11.3	14.2	19.4	15.7
	N	10	10	10	10
	Deviation Vs Control		-2.0	-3.6	-1.4

Statistic Profile = Dunnett test (two-sided), * p<=0.05, ** p <=0.01, X = Group excluded from statistics
n=DUNNETT

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Study 80R0223/11C162

Summary Body Weights - BW / Body Weights [g]

Sex: **Female** - Phase: **Pre-mating**

		Test Group 0/ F 0 mg/kg bw/d	Test Group 1/ F 100 mg/kg bw/d	Test Group 2/ F 300 mg/kg bw/d	Test Group 3/ F 1000 mg/kg bw/d
day 0	**Mean**	203.9 n	200.9	201.6	202.9
	S.d.	10.1	6.0	10.1	5.5
	N	10	10	10	10
	Deviation Vs Control		-1.5	-1.1	-0.5
day 7	**Mean**	215.4 n	225.8	208.7	209.9
	S.d.	11.5	49.9	12.2	8.0
	N	10	10	10	10
	Deviation Vs Control		4.8	-3.1	-2.6
day 13	**Mean**	219.3 n	213.6	218.5	214.1
	S.d.	9.7	10.3	6.4	9.7
	N	10	10	10	10
	Deviation Vs Control		-2.6	-0.4	-2.4

Statistic Profile = Dunnett test (two-sided), * p<=0.05, ** p <=0.01, X = Group excluded from statistics
n=DUNNETT

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Study 80R0223/11C162

Summary Body Weights - BW / Body Weights [g]

Sex: **Male** - Phase: **Mating**

		Test Group 0/ M 0 mg/kg bw/d	Test Group 1/ M 100 mg/kg bw/d	Test Group 2/ M 300 mg/kg bw/d	Test Group 3/ M 1000 mg/kg bw/d
day 8	Mean	376.0 n	369.4	367.6	372.5
	S.d.	13.6	15.1	15.0	16.2
	N	10	10	10	10
	Deviation Vs Control		-1.8	-2.2	-0.9

Statistic Profile = Dunnett test (two-sided), * p<=0.05, ** p <=0.01, X = Group excluded from statistics
n=DUNNETT

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Study 80R0223/11C162

Summary Body Weights - BW / Body Weights [g]

Sex: **Female** - Phase: **Gestation**

		Test Group 0/ F 0 mg/kg bw/d	Test Group 1/ F 100 mg/kg bw/d	Test Group 2/ F 300 mg/kg bw/d	Test Group 3/ F 1000 mg/kg bw/d
day 0	**Mean**	221.4 n	224.0	222.5	219.3
	S.d.	12.8	7.0	9.9	8.7
	N	8	9	9	9
	Deviation Vs Control		1.2	0.5	-0.9
day 7	**Mean**	254.2 n	253.3	252.1	249.7
	S.d.	13.2	8.6	8.7	8.6
	N	8	9	9	9
	Deviation Vs Control		-0.4	-0.8	-1.8
day 14	**Mean**	282.2 n	288.1	281.4	280.4
	S.d.	14.1	10.6	12.4	7.6
	N	8	9	9	9
	Deviation Vs Control		2.1	-0.3	-0.6
day 20	**Mean**	339.4 n	350.6	345.3	343.8
	S.d.	28.9	9.8	20.3	14.9
	N	8	9	9	9
	Deviation Vs Control		3.3	1.8	1.3

Statistic Profile = Dunnett test (two-sided), * p<=0.05, ** p <=0.01, X = Group excluded from statistics
n=DUNNETT

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Study 80R0223/11C162

Summary Body Weights - BW / Body Weights [g]

Sex: **Female** - Phase: **Lactation**

		Test Group 0/ F 0 mg/kg bw/d	Test Group 1/ F 100 mg/kg bw/d	Test Group 2/ F 300 mg/kg bw/d	Test Group 3/ F 1000 mg/kg bw/d
day 0	**Mean**	270.8 n	269.1	258.3	263.1
	S.d.	11.8	11.8	8.7	14.5
	N	8	9	9	9
	Deviation Vs Control		-0.6	-4.6	-2.8
day 4	**Mean**	273.5 n	275.8	272.1	270.4
	S.d.	19.3	9.9	12.7	10.0
	N	8	9	9	9
	Deviation Vs Control		0.9	-0.5	-1.1

Statistic Profile = Dunnett test (two-sided), * p<=0.05, ** p <=0.01, X = Group excluded from statistics
n=DUNNETT

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Study 80R0223/11C162

Summary Body Weights - BW / Body Weights [g]

Sex: **Male** - Phase: **Post-mating**

		Test Group 0/ M 0 mg/kg bw/d	Test Group 1/ M 100 mg/kg bw/d	Test Group 2/ M 300 mg/kg bw/d	Test Group 3/ M 1000 mg/kg bw/d
day 0	**Mean**	388.4 n	381.3	381.0	382.3
	S.d.	13.3	17.9	20.8	20.4
	N	10	10	10	10
	Deviation Vs Control		-1.8	-1.9	-1.6

Statistic Profile = Dunnett test (two-sided), * p<=0.05, ** p <=0.01, X = Group excluded from statistics
n=DUNNETT

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Study 80R0223/11C162

Summary Changes Body Weights - BW / Body Weights [g]

Sex: **Male** - Phase: **Pre-mating**

		Test Group 0/ M 0 mg/kg bw/d	Test Group 1/ M 100 mg/kg bw/d	Test Group 2/ M 300 mg/kg bw/d	Test Group 3/ M 1000 mg/kg bw/d
d 0 -> 7	**Mean**	20.4 n	16.7	15.2	17.8
	S.d.	3.6	4.7	7.6	4.4
	N	10	10	10	10
	Deviation Vs Control		-17.9	-25.1	-12.7
d 7 -> 13	**Mean**	13.0 n	12.9	5.6	11.4
	S.d.	4.2	2.9	11.1	5.9
	N	10	10	10	10
	Deviation Vs Control		-0.1	-56.6	-12.2
d 0 -> 13	**Mean**	33.3 n	29.7	20.9 **	29.2
	S.d.	6.0	6.5	12.6	7.3
	N	10	10	10	10
	Deviation Vs Control		-11.0	-37.4	-12.5

Statistic Profile = Dunnett test (two-sided), * p<=0.05, ** p <=0.01, X = Group excluded from statistics
d = day; n=DUNNETT

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Study 80R0223/11C162

Summary Changes Body Weights - BW / Body Weights [g]

Sex: **Female** - Phase: **Pre-mating**

		Test Group 0/ F 0 mg/kg bw/d	Test Group 1/ F 100 mg/kg bw/d	Test Group 2/ F 300 mg/kg bw/d	Test Group 3/ F 1000 mg/kg bw/d
d 0 -> 7	**Mean**	11.5 n	24.9	7.1	6.9
	S.d.	5.5	47.9	6.5	4.9
	N	10	10	10	10
	Deviation Vs Control		116.2	-38.6	-39.7
d 7 -> 13	**Mean**	3.9 n	-12.2	9.8	4.2
	S.d.	8.0	50.4	10.0	12.8
	N	10	10	10	10
	Deviation Vs Control		-409.1	147.7	7.4
d 0 -> 13	**Mean**	15.4 n	12.7	16.8	11.2
	S.d.	6.7	8.9	6.6	10.4
	N	10	10	10	10
	Deviation Vs Control		-17.7	8.9	-27.7

Statistic Profile = Dunnett test (two-sided), * p<=0.05, ** p <=0.01, X = Group excluded from statistics
d = day; n=DUNNETT

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Study 80R0223/11C162

Summary Changes Body Weights - BW / Body Weights [g]

Sex: **Female** - Phase: **Gestation**

		Test Group 0/ F 0 mg/kg bw/d	Test Group 1/ F 100 mg/kg bw/d	Test Group 2/ F 300 mg/kg bw/d	Test Group 3/ F 1000 mg/kg bw/d
d 0 -> 7	**Mean**	32.8 n	29.3	29.6	30.4
	S.d.	7.5	2.9	5.8	5.1
	N	8	9	9	9
	Deviation Vs Control		-10.7	-10.0	-7.3
d 7 -> 14	**Mean**	28.0 n	34.7 *	29.3	30.7
	S.d.	2.5	3.8	6.8	5.9
	N	8	9	9	9
	Deviation Vs Control		24.2	4.8	9.7
d 14 -> 20	**Mean**	57.2 n	62.5	63.9	63.4
	S.d.	17.6	6.8	9.8	8.1
	N	8	9	9	9
	Deviation Vs Control		9.3	11.7	10.8
d 0 -> 20	**Mean**	118.0 n	126.6	122.8	124.5
	S.d.	25.1	7.2	19.2	11.9
	N	8	9	9	9
	Deviation Vs Control		7.3	4.0	5.5

Statistic Profile = Dunnett test (two-sided), * p<=0.05, ** p <=0.01, X = Group excluded from statistics
d = day; n=DUNNETT

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Study 80R0223/11C162

Summary Changes Body Weights - BW / Body Weights [g]

Sex: **Female** - Phase: **Lactation**

		Test Group 0/ F 0 mg/kg bw/d	Test Group 1/ F 100 mg/kg bw/d	Test Group 2/ F 300 mg/kg bw/d	Test Group 3/ F 1000 mg/kg bw/d
d 0 -> 4	**Mean**	2.7 n	6.7	13.8	7.3
	S.d.	13.1	16.2	10.8	14.6
	N	8	9	9	9
	Deviation Vs Control		150.5	413.5	170.4

Statistic Profile = Dunnett test (two-sided), * p<=0.05, ** p <=0.01, X = Group excluded from statistics
d = day; n=DUNNETT

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Study 80R0223/11C162

Summary Mating Report

		Test Group 0/ F 0 mg/kg bw/d	Test Group 1/ F 100 mg/kg bw/d	Test Group 2/ F 300 mg/kg bw/d	Test Group 3/ F 1000 mg/kg bw/d
No. of females mated	N	10	10	10	10
- Inseminated	N	10	10	10	10
Female mating index	%	100.0	100.0	100.0	100.0
-- Pregnant	N	8	9	9	9
Female fertility index	%	80.0	90.0	90.0	90.0
No. of males mated	N	10	10	10	10
- With inseminated females	N	10	10	10	10
Male mating index	%	100.0	100.0	100.0	100.0
- With pregnant females	N	8	9	9	9
Male fertility index	%	80.0	90.0	90.0	90.0
Females with defined Day 0 pc	N	10	10	10	10
Mating days until Day 0 pc	Mean	2.7 x+	2.9	3.1	3.2
	S.d.	1.3	1.1	3.2	4.0
Days 0 To 4	N	10	10	9	9
	%	100.0	100.0	90.0	90.0
Days 5 To 9	N	0	0	0	0
	%	0.0	0.0	0.0	0.0
Days 10 To 14	N	0	0	1	1
	%	0.0	0.0	10.0	10.0

Statistic Profile = Wilcoxon with Bonferroni-Holm (one-sided+), * p<=0.05, ** p <=0.01, X = Group excluded from statistics
x=WILCOX

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Study 80R0223/11C162

Summary Pregnancy Status Report - Reproduction F0

Sex: **Female**

		Test Group 0/ F 0 mg/kg bw/d	Test Group 1/ F 100 mg/kg bw/d	Test Group 2/ F 300 mg/kg bw/d	Test Group 3/ F 1000 mg/kg bw/d
No. of females at start	N	10	10	10	10
No. of females mated	N	10	10	10	10
Without evidence of mating	N	0	0	0	0
- Pregnant	N	0	0	0	0
- Not pregnant	N	0	0	0	0
Females with defined Day 0 pc	N	10	10	10	10
Pregnant	N	8	9	9	9
- sacrificed scheduled	N	8	9	9	9
Not pregnant	N	2	1	1	1
- sacrificed scheduled	N	2	1	1	1
Pregnant, not delivering	N	0	0	0	0
Delivering	N	8	9	9	9
-- With liveborn pups	N	8	9	9	9
	%	100.0	100.0	100.0	100.0
-- With all pups stillborn	N	0	0	0	0
	%	0.0	0.0	0.0	0.0

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Study 80R0223/11C162

Summary Delivery Report

Sex: **Female**

		Test Group 0/ F 0 mg/kg bw/d	Test Group 1/ F 100 mg/kg bw/d	Test Group 2/ F 300 mg/kg bw/d	Test Group 3/ F 1000 mg/kg bw/d
No. of females at start	N	10	10	10	10
No. of females mated	N	10	10	10	10
Pregnant	N	8	9	9	9
Dead	N	0	0	0	0
Without delivery	N	2	1	1	1
- Pregnant	N	0	0	0	0
- Not pregnant	N	2	1	1	1
-- Delivering	N	8	9	9	9
	%	100.0	100.0	100.0	100.0
-- With liveborn pups	N	8	9	9	9
Gestation Index	%	100.0	100.0	100.0	100.0
Gestation days	Mean	22.1 n	22.0	22.2	22.0
	S.d.	0.4	0.0	0.4	0.5
	N	8	9	9	9
-- With stillborn pups	N	1	3	1	1
	%	12.5	33.3	11.1	11.1
-- With all pups stillborn	N	0	0	0	0
	%	0.0	0.0	0.0	0.0

Statistic Profile = Dunnett test (two-sided), * p<=0.05, ** p <=0.01, X = Group excluded from statistics
n=DUNNETT

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01-Mar-2013 08:40
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Study 80R0223/11C162

Summary Litter Report - Pup Status

Sex: **Female**

		Test Group 0/ F 0 mg/kg bw/d	Test Group 1/ F 100 mg/kg bw/d	Test Group 2/ F 300 mg/kg bw/d	Test Group 3/ F 1000 mg/kg bw/d
Total number of litters	N	8	9	9	9
With liveborn pups	N	8	9	9	9
	%	100.0	100.0	100.0	100.0
With stillborn pups	N	1	3	1	1
	%	12.5	33.3	11.1	11.1
With all pups stillborn	N	0	0	0	0
	%	0.0	0.0	0.0	0.0
Implantation Sites	N	94	124	120	119
	Mean	11.8 n	13.8	13.3	13.2
	S.d.	4.5	1.5	2.4	0.8
Pups delivered	N	85	114	118	114
	Mean	10.6 n	12.7	13.1	12.7
	S.d.	4.2	1.6	2.5	1.2
Postimplantation Loss	Mean%	8.86	7.90	1.78	4.28
Pups liveborn	N	84	110	117	113
	%	98.8	96.5	99.2	99.1
Pups stillborn	N	1	4	1	1
	%	1.2	3.5	0.8	0.9
Perinatal Loss	Mean%	0.89	3.56	0.62	0.93

Statistic Profile = Dunnett test (two-sided), * p<=0.05, ** p <=0.01, X = Group excluded from statistics
n=DUNNETT

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01-Mar-2013 08:40
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Study 80R0223/11C162

Summary Litter Report - Dead Pups

Sex: **Female**

		Test Group 0/ F 0 mg/kg bw/d	Test Group 1/ F 100 mg/kg bw/d	Test Group 2/ F 300 mg/kg bw/d	Test Group 3/ F 1000 mg/kg bw/d
Litters with liveborn pups	N	8	9	9	9
Pups delivered	N	85	114	118	114
stillborn / Dead	N	1	4	1	1
	%	1.2	3.5	0.8	0.9
Alive / Alive	N	84	110	117	113
	%	98.8	96.5	99.2	99.1
sacrificed scheduled / Dead	N	84	110	117	113
	%	98.8	96.5	99.2	99.1
Litters not surviving Day 4	N	0	0	0	0

Statistic Profile = Dunnett test (two-sided), * p<=0.05, ** p <=0.01, X = Group excluded from statistics

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Study 80R0223/11C162

Summary Litter Report - Pups Died

Sex: **Female**

		Test Group 0/ F 0 mg/kg bw/d	Test Group 1/ F 100 mg/kg bw/d	Test Group 2/ F 300 mg/kg bw/d	Test Group 3/ F 1000 mg/kg bw/d
Litters with liveborn pups	N	8	9	9	9
Pups delivered	N	85	114	118	114
Day 0	N	0	0	0	0
	%	0	0	0	0
Days 1 To 4	N	0	0	0	0
	%	0	0	0	0
Pups surviving days 0 To 4	N	84	110	117	113
Viability Index	Mean%	100.0 x-	100.0	100.0	100.0
	S.d.	0.0	0.0	0.0	0.0

Statistic Profile = Wilcoxon with Bonferroni-Holm (one-sided-), * p<=0.05, ** p <=0.01, X = Group excluded from statistics
x=WILCOX

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01-Mar-2013 08:40
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Study 80R0223/11C162

Summary Litter Report - Live Pups/Litter

Sex: **Female**

		Test Group 0/ F 0 mg/kg bw/d	Test Group 1/ F 100 mg/kg bw/d	Test Group 2/ F 300 mg/kg bw/d	Test Group 3/ F 1000 mg/kg bw/d
Litters with liveborn pups	N	8	9	9	9
Pups delivered	N	85	114	118	114
Day 0	Mean	10.5 n	12.2	13.0	12.6
	S.d.	4.1	1.8	2.3	1.3
Day 4	Mean	10.5 n	12.2	13.0	12.6
	S.d.	4.1	1.8	2.3	1.3
% Live male Day 0	%	48.8	57.3	41.9	42.5
% Live female Day 0	%	51.2	42.7	58.1	57.5
% Live male Day 4	%	48.8	57.3	41.9	42.5
% Live female Day 4	%	51.2	42.7	58.1	57.5

Statistic Profile = Dunnett test (two-sided), * p<=0.05, ** p <=0.01, X = Group excluded from statistics
n=DUNNETT

IA 29
Study 80R0223/11C162 28-Feb-2013 14:01
ToxData© System 3.0

Summary - Clinical Observation

Sex: **Male** - Phase: **Lactation Pup**

			Test Group 0/ M 0 mg/kg bw/d	Test Group 1/ M 100 mg/kg bw/d	Test Group 2/ M 300 mg/kg bw/d	Test Group 3/ M 1000 mg/kg bw/d
	Animals examined	N	42	64	49	49
	Animals with signs	N	1	1	0	1
day 0 -> 4	reproduction *not assessed (died)*	N	1	1	0	1
	normal *NAD*	N	41	63	49	48

IA 30
Study 80R0223/11C162 28-Feb-2013 14:01
ToxData© System 3.0

Summary - Clinical Observation

Sex: **Female** - Phase: **Lactation Pup**

			Test Group 0/ F 0 mg/kg bw/d	Test Group 1/ F 100 mg/kg bw/d	Test Group 2/ F 300 mg/kg bw/d	Test Group 3/ F 1000 mg/kg bw/d
	Animals examined	N	43	50	69	65
	Animals with signs	N	0	3	1	0
day 0 -> 4	reproduction *not assessed (died)*	N	0	3	1	0
	normal *NAD*	N	43	47	68	65

IA 31
28-Feb-2013 14:07
ToxData© System 3.0

Study 80R0223/11C162

Summary Pup Report Body Weights - BW / Body Weights [g]

Phase: **Lactation Pup**

		Test Group 0/ F 0 mg/kg bw/d	Test Group 1/ F 100 mg/kg bw/d	Test Group 2/ F 300 mg/kg bw/d	Test Group 3/ F 1000 mg/kg bw/d
day 1 Runt	**Males**	2	0	0	0
	Females	0	1	1	0
day 1 Males	**Mean**	6.9 n	6.8	6.7	6.7
	S.d.	0.5	0.3	0.8	0.3
	N	8	9	9	9
	Deviation Vs Control		-1.9	-2.9	-2.5
day 1 Females	**Mean**	6.6 n	6.3	6.4	6.4
	S.d.	0.7	0.4	0.7	0.2
	N	8	9	9	9
	Deviation Vs Control		-4.2	-3.4	-4.1
day 1 Males + Females	**Mean**	6.8 n	6.6	6.5	6.5
	S.d.	0.6	0.3	0.7	0.2
	N	8	9	9	9
	Deviation Vs Control		-2.7	-3.7	-3.6

Statistic Profile = Dunnett test (two-sided), * p<=0.05, ** p <=0.01, X = Group excluded from statistics
n=DUNNETT

IA 32
28-Feb-2013 14:07
ToxData© System 3.0

Study 80R0223/11C162

Summary Pup Report Body Weights - BW / Body Weights [g]

Phase: **Lactation Pup**

		Test Group 0/ F 0 mg/kg bw/d	Test Group 1/ F 100 mg/kg bw/d	Test Group 2/ F 300 mg/kg bw/d	Test Group 3/ F 1000 mg/kg bw/d
day 4 Males	**Mean**	10.6 n	10.6	10.2	10.1
	S.d.	1.0	0.8	1.1	0.6
	N	8	9	9	9
	Deviation Vs Control		0.1	-3.9	-4.6
day 4 Females	**Mean**	10.5 n	10.2	9.9	9.8
	S.d.	1.3	0.8	1.0	0.5
	N	8	9	9	9
	Deviation Vs Control		-2.9	-5.9	-6.8
day 4 Males + Females	**Mean**	10.5 n	10.4	10.0	9.9
	S.d.	1.1	0.7	1.1	0.5
	N	8	9	9	9
	Deviation Vs Control		-1.2	-4.9	-5.7

Statistic Profile = Dunnett test (two-sided), * p<=0.05, ** p <=0.01, X = Group excluded from statistics
n=DUNNETT

IA 33
28-Feb-2013 14:08
ToxData© System 3.0

Study 80R0223/11C162

Summary Pup Changes Report Body Weights - BW / Body Weights [g]

Phase: **Lactation Pup**

		Test Group 0/ F 0 mg/kg bw/d	Test Group 1/ F 100 mg/kg bw/d	Test Group 2/ F 300 mg/kg bw/d	Test Group 3/ F 1000 mg/kg bw/d
d 1 -> 4 Males	**Mean**	3.7 n	3.9	3.5	3.4
	S.d.	0.6	0.6	0.4	0.4
	N	8	9	9	9
	Deviation Vs Control		3.9	-5.6	-8.4
d 1 -> 4 Females	**Mean**	3.9 n	3.8	3.5	3.4
	S.d.	0.7	0.6	0.4	0.4
	N	8	9	9	9
	Deviation Vs Control		-0.6	-10.2	-11.5
d 1 -> 4 Males + Females	**Mean**	3.8 n	3.8	3.5	3.4
	S.d.	0.6	0.5	0.4	0.4
	N	8	9	9	9
	Deviation Vs Control		1.6	-7.2	-9.5

Statistic Profile = Dunnett test (two-sided), * p<=0.05, ** p <=0.01, X = Group excluded from statistics
d = day; n=DUNNETT

IA 34
28-Feb-2013 14:10
ToxData© System 3.0

Study 80R0223/11C162

Summary - Pup Necropsy Observation

Sex: **Male** - Phase: **Lactation Pup**

			Test Group 0/ M 0 mg/kg bw/d	Test Group 1/ M 100 mg/kg bw/d	Test Group 2/ M 300 mg/kg bw/d	Test Group 3/ M 1000 mg/kg bw/d
	Animals examined	N	42	64	49	49
	Animals with signs	N	0	1	0	0
		%	0.0	1.6	0.0	0.0
day 0 -> 4	General	N	0	1	0	0
	Post mortem autolysis	%	0.0	1.6	0.0	0.0
	normal	N	42	63	49	49
	NAD	%	100.0	98.4	100.0	100.0

IA 35
28-Feb-2013 14:10
ToxData© System 3.0

Study 80R0223/11C162

Summary - Pup Necropsy Observation

Sex: **Female** - Phase: **Lactation Pup**

			Test Group 0/ F 0 mg/kg bw/d	Test Group 1/ F 100 mg/kg bw/d	Test Group 2/ F 300 mg/kg bw/d	Test Group 3/ F 1000 mg/kg bw/d
day 0 -> 4	Animals examined	N	43	50	69	65
	Animals with signs	N	0	1	1	1
		%	0.0	2.0	1.4	1.5
	General	N	0	1	0	0
	Post mortem autolysis	%	0.0	2.0	0.0	0.0
	Stomach	N	0	0	1	1
	empty	%	0.0	0.0	1.4	1.5
	normal	N	43	49	68	64
	NAD	%	100.0	98.0	98.6	98.5

BASF PATHOLOGY REPORT IB- 80R0223/11C162 1/5

Reproduction/Developmental Toxicity Screening Test in Wistar Rats - Oral Administration (Gavage) 10.Apr.2013 SIBU

ABSOLUTE WEIGHTS - MEAN VALUES (MALE)

Sacrifice			F1			
Sex			M			
Group			0	1	2	3
Terminal body weight	g	M	375.93	368.26	364.3	369.25
		% dev	100	98	97	98
		SD	12.333	15.587	21.722	20.835
		n	10	10	10	10
Epididymides	g	M	1.139	1.067	1.12	1.123
		% dev	100	94	98	99
		SD	0.083	0.151	0.077	0.081
		n	10	10	10	10
Testes	g	M	3.644	3.427	3.518	3.63
		% dev	100	94	97	100
		SD	0.122	0.539	0.294	0.312
		n	10	10	10	10

*: P <= 0.05, **: P <= 0.01
Kruskal-Wallis H and Wilcoxon test, two sided

BASF PATHOLOGY REPORT IB- 2/5
80R0223/11C162
Reproduction/Developmental Toxicity Screening Test in Wistar Rats - Oral Administration (Gavage) 10.Apr.2013 SIBU

ABSOLUTE WEIGHTS - MEAN VALUES (FEMALE)

Sacrifice			F1			
Sex			F			
Group			0	1	2	3
Terminal body weight	g	M	251.07	247.78	253.51	248.53
		% dev	100	99	101	99
		SD	15.016	10.561	28.391	8.589
		n	10	10	10	10

*: P <= 0.05, **: P <= 0.01
Kruskal-Wallis H and Wilcoxon test, two sided

BASF PATHOLOGY REPORT IB- 3/5
80R0223/11C162
Reproduction/Developmental Toxicity Screening Test in Wistar Rats - Oral Administration (Gavage) 10.Apr.2013 SIBU

RELATIVE WEIGHTS - MEAN VALUES (MALE)

Sacrifice			F1			
Sex			M			
Group			0	1	2	3
Terminal body weight	%	M	100.0	100.0	100.0	100.0
		% dev	100	100	100	100
		n	10	10	10	10
Epididymides	%	M	0.303	0.29	0.309	0.305
		% dev	100	96	102	101
		SD	0.018	0.043	0.03	0.028
		n	10	10	10	10
Testes	%	M	0.97	0.932	0.968	0.986
		% dev	100	96	100	102
		SD	0.042	0.151	0.092	0.107
		n	10	10	10	10

*: P <= 0.05, **: P <= 0.01
Kruskal-Wallis H and Wilcoxon test, two sided

BASF PATHOLOGY REPORT IB- 4/5
80R0223/11C162
Reproduction/Developmental Toxicity Screening Test in Wistar Rats - Oral Administration (Gavage) 10.Apr.2013 SIBU

INCIDENCE OF GROSS LESIONS

Sacrifice	F1							
Sex	M				F			
Group	0	1	2	3	0	1	2	3
Animals in selected group	10	10	10	10	10	10	10	10
No abnormalities	8	9	.	.	8	9	.	.
General Observations	.	.	.	.	.	.	.	.
No offspring	2	1	1	1	.	.	.	.
Not pregnant	.	.	.	.	2	1	1	1
Colon	.	.	.	.	.	.	.	.
Discoloration of contents	.	.	10	10	.	.	10	10
Epididymides	.	.	.	.	.	.	.	.
Organ size reduced	.	1	.	.	.	.	.	.
Glandular stomach	.	.	.	.	.	.	.	.
Discoloration of contents	.	.	8	6	.	.	.	10
Jejunum	.	.	.	.	.	.	.	.
Discoloration of contents	.	.	10	10	.	.	10	10
Oviducts	.	.	.	.	.	.	.	.
Cyst	.	.	.	.	.	.	.	1
Testes	.	.	.	.	.	.	.	.
Organ size reduced	.	1	.	.	.	.	.	.
Uterus	.	.	.	.	.	.	.	.
Dilation	.	.	.	.	.	.	1	.

BASF PATHOLOGY REPORT IB- 5/5
80R0223/11C162
Reproduction/Developmental Toxicity Screening Test in Wistar Rats - Oral Administration (Gavage) 10.Apr.2013 SIBU

INCIDENCE OF ALL MICROSCOPIC FINDINGS

Sacrifice		F1							
Sex		M				F			
Group		0	1	2	3	0	1	2	3
Animals in selected group		10	10	10	10	10	10	10	10
Epididymides	exam.	10	.	.	10	.	.	.	.
Infiltration, lymphoid, (m)f		4	.	.	5	.	.	.	.
Ovaries	exam.	.	.	.	.	10	.	.	10
Corpora lutea present		.	.	.	.	10	.	.	10
Testes	exam.	10	.	.	10	.	.	.	.

STUDY TITLE

Report

Paliogen Violet 5011

Modified Reproduction/Developmental Toxicity Screening Test in Wistar Rats
Oral Administration (Gavage)

TEST FACILITY

BASF SE
[redacted]

TEST FACILITY PROJECT IDENTIFICATION

Project No. 80R0223/11C162

PART II OF III
(TABLES SECTION, INDIVIDUAL VALUES)

CONTENTS OF PART II (TABLES SECTION, INDIVIDUAL VALUES AND OBSERVATIONS)

Tables

Part B:
PATHOLOGY (INDIVIDUAL VALUES)

IIA 1
28-Feb-2013 14:25
ToxData© System 3.0

Study 80R0223/11C162

Individual Signs - Clinical Observation

Sex: **Male** - Phase: **Pre-mating**

Dose Group	Animal Number	Sign Type	Sign	Modifier	Remark	First Day	Last Day	Duration [Days]
[redacted]								

IIA 2
28-Feb-2013 14:26
ToxData© System 3.0

Study 80R0223/11C162

Individual Signs - Clinical Observation

Sex: **Male** - Phase: **Pre-mating**

Dose Group	Animal Number	Sign Type	Sign	Modifier	Remark	First Day	Last Day	Duration [Days]
[redacted]								

IIA 3
28-Feb-2013 14:26
ToxData© System 3.0

Study 80R0223/11C162

Individual Signs - Clinical Observation

Sex: **Male** - Phase: **Pre-mating**

Dose Group	Animal Number	Sign Type	Sign	Modifier	Remark	First Day	Last Day	Duration [Days]
[redacted]								

IIA 4
28-Feb-2013 14:26
ToxData© System 3.0

Study 80R0223/11C162

Individual Signs - Clinical Observation

Sex: **Male** - Phase: **Pre-mating**

Dose Group	Animal Number	Sign Type	Sign	Modifier	Remark	First Day	Last Day	Duration [Days]
[redacted]								

IIA 5
28-Feb-2013 14:26
ToxData© System 3.0

Study 80R0223/11C162

Individual Signs - Clinical Observation

Sex: **Female** - Phase: **Pre-mating**

Dose Group	Animal Number	Sign Type	Sign	Modifier	Remark	First Day	Last Day	Duration [Days]
[redacted]								

PG=Pregnant; NPI=GD 0; No Implants; No Pups

IIA 6
28-Feb-2013 14:26
ToxData© System 3.0

Study 80R0223/11C162

C

Individual Signs - Clinical Observation

Sex: **Female** - Phase: **Pre-mating**

Dose Group	Animal Number	Sign Type	Sign	Modifier	Remark	First Day	Last Day	Duration [Days]
[redacted]								

PG=Pregnant; NPI=GD 0; No Implants; No Pups

IIA 7
28-Feb-2013 14:26
ToxData© System 3.0

Study 80R0223/11C162

Individual Signs - Clinical Observation

Sex: **Female** - Phase: **Pre-mating**

Dose Group	Animal Number	Sign Type	Sign	Modifier	Remark	FirstDay	LastDay	Duration [Days]
[redacted]								

PG=Pregnant; NPI=GD 0; No Implants; No Pups

IIA 8
28-Feb-2013 14:26
ToxData© System 3.0

Study 80R0223/11C162

Individual Signs - Clinical Observation

Sex: **Female** - Phase: **Pre-mating**

Dose Group	Animal Number	Sign Type	Sign	Modifier	Remark	First Day	Last Day	Duration [Days]
[redacted]								

PG=Pregnant; NPI=GD 0; No Implants; No Pups

IIA 9

28-Feb-2013 14:31

ToxData© System 3.0

Study 80R0223/11C162

Individual Signs - Clinical Observation

Sex: **Male** - Phase: **Mating**

Dose Group	Animal Number	Sign Type	Sign	Modifier	Remark	First Day	Last Day	Duration [Days]
[redacted]								

IIA 10
28-Feb-2013 14:31
ToxData© System 3.0

Study 80R0223/11C162

Individual Signs - Clinical Observation

Sex: **Male** - Phase: **Mating**

Dose Group	Animal Number	Sign Type	Sign	Modifier	Remark	First Day	Last Day	Duration [Days]
[redacted]								

IIA 11
28-Feb-2013 14:31
ToxData© System 3.0

Study 80R0223/11C162

Individual Signs - Clinical Observation

Sex: **Male** - Phase: **Mating**

Dose Group	Animal Number	Sign Type	Sign	Modifier	Remark	First Day	Last Day	Duration [Days]
[redacted]								

IIA 12
28-Feb-2013 14:31
ToxData© System 3.0

Study 80R0223/11C162

Individual Signs - Clinical Observation

Sex: **Male** - Phase: **Mating**

Dose Group	Animal Number	Sign Type	Sign	Modifier	Remark	First Day	Last Day	Duration [Days]
[redacted]								

IIA 13
28-Feb-2013 14:31
ToxData© System 3.0

Study 80R0223/11C162

Individual Signs - Clinical Observation

Sex: **Female** - Phase: **Mating**

Dose Group	Animal Number	Sign Type	Sign	Modifier	Remark	First Day	Last Day	Duration [Days]
[redacted]								

PG=Pregnant; NPI=GD 0; No Implants; No Pups

IIA 14
28-Feb-2013 14:31
ToxData© System 3.0

Study 80R0223/11C162

Individual Signs - Clinical Observation

Sex: **Female** - Phase: **Mating**

Dose Group	Animal Number	Sign Type	Sign	Modifier	Remark	First Day	Last Day	Duration [Days]
[redacted]								

PG=Pregnant; NPI=GD 0; No Implants; No Pups

IIA 15
28-Feb-2013 14:31
ToxData© System 3.0

Study 80R0223/11C162

Individual Signs - Clinical Observation

Sex: **Female** - Phase: **Mating**

Dose Group	Animal Number	Sign Type	Sign	Modifier	Remark	First Day	Last Day	Duration [Days]
[redacted]								

PG=Pregnant; NPI=GD 0; No Implants; No Pups

IIA 16
28-Feb-2013 14:31
ToxData© System 3.0

Study 80R0223/11C162

Individual Signs - Clinical Observation

Sex: **Female** - Phase: **Mating**

Dose Group	Animal Number	Sign Type	Sign	Modifier	Remark	First Day	Last Day	Duration [Days]
[redacted]								

PG=Pregnant; NPI=GD 0; No Implants; No Pups

IIA 17
01-Mar-2013 15:34
ToxData© System 3.0

Study 80R0223/11C162

Individual Signs - Clinical Observation

Sex: **Male** - Phase: **Post-mating**

Dose Group	Animal Number	Sign Type	Sign	Modifier	Remark	First Day	Last Day	Duration [Days]
[redacted]								

IIA 18
01-Mar-2013 15:34
ToxData© System 3.0

Study 80R0223/11C162

Individual Signs - Clinical Observation

Sex: **Male** - Phase: **Post-mating**

Dose Group	Animal Number	Sign Type	Sign	Modifier	Remark	First Day	Last Day	Duration [Days]
[redacted]								

IIA 19
01-Mar-2013 15:34
ToxData© System 3.0

Study 80R0223/11C162

Individual Signs - Clinical Observation

Sex: **Male** - Phase: **Post-mating**

Dose Group	Animal Number	Sign Type	Sign	Modifier	Remark	First Day	Last Day	Duration [Days]
[redacted]								

IIA 20
01-Mar-2013 15:34
ToxData© System 3.0

Study 80R0223/11C162

Individual Signs - Clinical Observation

Sex: **Male** - Phase: **Post-mating**

Dose Group	Animal Number	Sign Type	Sign	Modifier	Remark	First Day	Last Day	Duration [Days]
[redacted]								

IIA 21
04-Mar-2013 09:41
ToxData© System 3.0

Study 80R0223/11C162

Individual Signs - Clinical Observation

Sex: **Female** - Phase: **Gestation**

Dose Group	Animal Number	Sign Type	Sign	Modifier	Remark	First Day	Last Day	Duration [Days]
[redacted]								

PG=Pregnant; NPI=GD 0; No Implants; No Pups

IIA 22
04-Mar-2013 09:41
ToxData© System 3.0

Study 80R0223/11C162

Individual Signs - Clinical Observation

Sex: **Female** - Phase: **Gestation**

Dose Group	Animal Number	Sign Type	Sign	Modifier	Remark	FirstLastDuration Day Day [Days]
[redacted]						

PG=Pregnant; NPI=GD 0; No Implants; No Pups

IIA 23
04-Mar-2013 09:41
ToxData© System 3.0

Study 80R0223/11C162

Individual Signs - Clinical Observation

Sex: **Female** - Phase: **Gestation**

Dose Group	Animal Number	Sign Type	Sign	Modifier	Remark	First Day	Last Day	Duration [Days]
[redacted]								

PG=Pregnant; NPI=GD 0; No Implants; No Pups

IIA 24
04-Mar-2013 09:41
ToxData© System 3.0

Study 80R0223/11C162

Individual Signs - Clinical Observation

Sex: **Female** - Phase: **Gestation**

Dose Group	Animal Number	Sign Type	Sign	Modifier	Remark	First Day	Last Day	Duration [Days]
[redacted]								

PG=Pregnant; NPI=GD 0; No Implants; No Pups

IIA 25
01-Mar-2013 16:02
ToxData© System 3.0

Study 80R0223/11C162

Individual Signs - Clinical Observation

Sex: **Female** - Phase: **Lactation**

Dose Group	Animal Number	Sign Type	Sign	Modifier	Remark	First Day	Last Day	Duration [Days]
[redacted]								

PG=Pregnant

IIA 26
01-Mar-2013 16:02
ToxData© System 3.0

Study 80R0223/11C162

Individual Signs - Clinical Observation

Sex: **Female** - Phase: **Lactation**

Dose Group	Animal Number	Sign Type	Sign	Modifier	Remark	First Day	Last Day	Duration [Days]
[redacted]								

PG=Pregnant

IIA 27
01-Mar-2013 16:02
ToxData© System 3.0

Study 80R0223/11C162

Individual Signs - Clinical Observation

Sex: **Female** - Phase: **Lactation**

Dose Group	Animal Number	Sign Type	Sign	Modifier	Remark	First Day	Last Day	Duration [Days]
[redacted]								

PG=Pregnant

IIA 28
01-Mar-2013 16:02
ToxData© System 3.0

Study 80R0223/11C162

Individual Signs - Clinical Observation

Sex: **Female** - Phase: **Lactation**

Dose Group	Animal Number	Sign Type	Sign	Modifier	Remark	First Day	Last Day	Duration [Days]
[redacted]								

PG=Pregnant

IIA 29
04-Mar-2013 08:19
ToxData© System 3.0

Study 80R0223/11C162

Individual Food Consumption Per Day [g/Day]

Sex: **Male** - Phase: **Pre-mating**

Group	Cage	Animals	d 0 -> 7	d 7 -> 13
[redacted]				

d = day

IIA 30
04-Mar-2013 08:19
ToxData© System 3.0

Study 80R0223/11C162

Individual Food Consumption Per Day [g/Day]

Sex: **Male** - Phase: **Pre-mating**

Group	Cage	Animals	d 0 -> 7	d 7 -> 13
[redacted]				

d = day

IIA 31
04-Mar-2013 08:19
ToxData© System 3.0

Study 80R0223/11C162

Individual Food Consumption Per Day [g/Day]

Sex: **Male** - Phase: **Pre-mating**

Group	Cage	Animals	d 0 -> 7	d 7 -> 13
[redacted]				

d = day

IIA 32
04-Mar-2013 08:19
ToxData© System 3.0

Study 80R0223/11C162

Individual Food Consumption Per Day [g/Day]

Sex: **Male** - Phase: **Pre-mating**

Group	Cage	Animals	d 0 -> 7	d 7 -> 13
[redacted]				

d = day

IIA 33
04-Mar-2013 08:19
ToxData© System 3.0

Study 80R0223/11C162

Individual Food Consumption Per Day [g/Day]

Sex: **Female** - Phase: **Pre-mating**

Group	Cage	Animals	d 0 -> 7	d 7 -> 13
[redacted]				

d = day

IIA 34
04-Mar-2013 08:19
ToxData© System 3.0

Study 80R0223/11C162

Individual Food Consumption Per Day [g/Day]

Sex: **Female** - Phase: **Pre-mating**

Group	Cage	Animals	d 0 -> 7	d 7 -> 13
[redacted]				

d = day

IIA 35
04-Mar-2013 08:19
ToxData© System 3.0

Study 80R0223/11C162

Individual Food Consumption Per Day [g/Day]

Sex: **Female** - Phase: **Pre-mating**

Group	Cage	Animals	d 0 -> 7	d 7 -> 13
[redacted]				

d = day

IIA 36
04-Mar-2013 08:19
ToxData© System 3.0

Study 80R0223/11C162

Individual Food Consumption Per Day [g/Day]

Sex: **Female** - Phase: **Pre-mating**

Group	Cage	Animals	d 0 -> 7	d 7 -> 13
[redacted]				

d = day

IIA 37
04-Mar-2013 09:38
ToxData© System 3.0

Study 80R0223/11C162

Individual Food Consumption Per Day [g/Day]

Sex: **Female** - Phase: **Gestation**

Group	Cage	Animals	d 0 -> 7	d 7 -> 14	d 14 -> 20
[redacted]					

d = day

IIA 38
04-Mar-2013 09:38
ToxData© System 3.0

Study 80R0223/11C162

Individual Food Consumption Per Day [g/Day]

Sex: **Female** - Phase: **Gestation**

Group	Cage	Animals	d 0 -> 7	d 7 -> 14	d 14 -> 20
[redacted]					

d = day

IIA 39
04-Mar-2013 09:38
ToxData© System 3.0

Study 80R0223/11C162

Individual Food Consumption Per Day [g/Day]

Sex: **Female** - Phase: **Gestation**

Group	Cage	Animals	d 0 -> 7	d 7 -> 14	d 14 -> 20
[redacted]					

d = day

IIA 40
04-Mar-2013 09:38
ToxData© System 3.0

Study 80R0223/11C162

Individual Food Consumption Per Day [g/Day]

Sex: **Female** - Phase: **Gestation**

Group	Cage	Animals	d 0 -> 7	d 7 -> 14	d 14 -> 20
[redacted]					

d = day

IIA 41
04-Mar-2013 08:22
ToxData© System 3.0

Study 80R0223/11C162

Individual Food Consumption Per Day [g/Day]

Sex: **Female** - Phase: **Lactation**

Group	Cage	Animals	d 1 -> 4
[redacted]			

d = day

IIA 42
04-Mar-2013 08:22
ToxData© System 3.0

Study 80R0223/11C162

Individual Food Consumption Per Day [g/Day]

Sex: **Female** - Phase: **Lactation**

Group	Cage	Animals	d 1 -> 4
[redacted]			

d = day

IIA 43
04-Mar-2013 08:22
ToxData© System 3.0

Study 80R0223/11C162

Individual Food Consumption Per Day [g/Day]

Sex: **Female** - Phase: **Lactation**

Group	Cage	Animals	d 1 -> 4
[redacted]			

d = day

IIA 44
04-Mar-2013 08:22
ToxData© System 3.0

Study 80R0223/11C162

Individual Food Consumption Per Day [g/Day]

Sex: **Female** - Phase: **Lactation**

Group	Cage	Animals	d 1 -> 4
[redacted]			

d = day

IIA 45
04-Mar-2013 08:29
ToxData© System 3.0

Study 80R0223/11C162

Individual Body Weights - BW / Body Weights [g]

Sex: **Male** - Phase: **Pre-mating**

Dose Group	Animal Number	day 0	day 7	day 13
[redacted]				

IIA 46
04-Mar-2013 08:29
ToxData© System 3.0

Study 80R0223/11C162

Individual Body Weights - BW / Body Weights [g]

Sex: **Male** - Phase: **Pre-mating**

Dose Group	Animal Number	day 0	day 7	day 13
[redacted]				

IIA 47
04-Mar-2013 08:29
ToxData© System 3.0

Study 80R0223/11C162

Individual Body Weights - BW / Body Weights [g]

Sex: **Male** - Phase: **Pre-mating**

Dose Group	Animal Number	day 0	day 7	day 13
[redacted]				

IIA 48
04-Mar-2013 08:29
ToxData© System 3.0

Study 80R0223/11C162

Individual Body Weights - BW / Body Weights [g]

Sex: **Male** - Phase: **Pre-mating**

Dose Group	Animal Number	day 0	day 7	day 13
[redacted]				

IIA 49
04-Mar-2013 08:29
ToxData© System 3.0

Study 80R0223/11C162

Individual Body Weights - BW / Body Weights [g]

Sex: **Female** - Phase: **Pre-mating**

Dose Group	Animal Number	day 0	day 7	day 13
[redacted]				

PG=Pregnant; NPI=GD 0; No Implants; No Pups

IIA 50
04-Mar-2013 08:29
ToxData© System 3.0

Study 80R0223/11C162

Individual Body Weights - BW / Body Weights [g]

Sex: **Female** - Phase: **Pre-mating**

Dose Group	Animal Number	day 0	day 7	day 13
[redacted]				

NPI=GD 0; No Implants; No Pups; PG=Pregnant

IIA 51
04-Mar-2013 08:29
ToxData© System 3.0

Study 80R0223/11C162

Individual Body Weights - BW / Body Weights [g]

Sex: **Female** - Phase: **Pre-mating**

Dose Group	Animal Number	day 0	day 7	day 13
[redacted]				

PG=Pregnant; NPI=GD 0; No Implants; No Pups

IIA 52
04-Mar-2013 08:29
ToxData© System 3.0

Study 80R0223/11C162

Individual Body Weights - BW / Body Weights [g]

Sex: **Female** - Phase: **Pre-mating**

Dose Group	Animal Number	day 0	day 7	day 13
[redacted]				

PG=Pregnant; NPI=GD 0; No Implants; No Pups

IIA 53
04-Mar-2013 08:36
ToxData© System 3.0

Study 80R0223/11C162

Individual Body Weights - BW / Body Weights [g]

Sex: **Male** - Phase: **Mating**

Dose Group	Animal Number	day 8
[redacted]		

IIA 54
04-Mar-2013 08:36
ToxData© System 3.0

Study 80R0223/11C162

Individual Body Weights - BW / Body Weights [g]

Sex: **Male** - Phase: **Mating**

Dose Group	Animal Number	day 8
[redacted]		

IIA 55
04-Mar-2013 08:36
ToxData© System 3.0

Study 80R0223/11C162

Individual Body Weights - BW / Body Weights [g]

Sex: **Male** - Phase: **Mating**

Dose Group	Animal Number	day 8
[redacted]		

IIA 56
04-Mar-2013 08:36
ToxData© System 3.0

Study 80R0223/11C162

Individual Body Weights - BW / Body Weights [g]

Sex: **Male** - Phase: **Mating**

Dose Group	Animal Number	day 8
[redacted]		

IIA 57
04-Mar-2013 08:37
ToxData© System 3.0

Study 80R0223/11C162

Individual Body Weights - BW / Body Weights [g]

Sex: **Female** - Phase: **Mating**

Dose Group	Animal Number	day 8
[redacted]		

PG=Pregnant; NPI=GD 0; No Implants; No Pups
NS = No More Scheduled

IIA 58
04-Mar-2013 08:37
ToxData© System 3.0

Study 80R0223/11C162

Individual Body Weights - BW / Body Weights [g]

Sex: **Female** - Phase: **Mating**

Dose Group	Animal Number	day 8
[redacted]		

NPI=GD 0; No Implants; No Pups; PG=Pregnant
NS = No More Scheduled

IIA 59
04-Mar-2013 08:37
ToxData© System 3.0

Study 80R0223/11C162

Individual Body Weights - BW / Body Weights [g]

Sex: **Female** - Phase: **Mating**

Dose Group	Animal Number	day 8
[redacted]		

PG=Pregnant; NPI=GD 0; No Implants; No Pups
NS = No More Scheduled

IIA 60
04-Mar-2013 08:37
ToxData© System 3.0

Study 80R0223/11C162

Individual Body Weights - BW / Body Weights [g]

Sex: **Female** - Phase: **Mating**

Dose Group	Animal Number	day 8
[redacted]		

PG=Pregnant; NPI=GD 0; No Implants; No Pups
NS = No More Scheduled

IIA 61
04-Mar-2013 08:41
ToxData© System 3.0

Study 80R0223/11C162

Individual Body Weights - BW / Body Weights [g]

Sex: **Male** - Phase: **Post-mating**

Dose Group	Animal Number	day 0
[redacted]		

IIA 62
04-Mar-2013 08:41
ToxData© System 3.0

Study 80R0223/11C162

Individual Body Weights - BW / Body Weights [g]

Sex: **Male** - Phase: **Post-mating**

Dose Group	Animal Number	day 0
[redacted]		

IIA 63
04-Mar-2013 08:41
ToxData© System 3.0

Study 80R0223/11C162

Individual Body Weights - BW / Body Weights [g]

Sex: **Male** - Phase: **Post-mating**

Dose Group	Animal Number	day 0
[redacted]		

IIA 64
04-Mar-2013 08:41
ToxData© System 3.0

Study 80R0223/11C162

Individual Body Weights - BW / Body Weights [g]

Sex: **Male** - Phase: **Post-mating**

Dose Group	Animal Number	day 0
[redacted]		

IIA 65
04-Mar-2013 09:37
ToxData© System 3.0

Study 80R0223/11C162

Individual Body Weights - BW / Body Weights [g]

Sex: **Female** - Phase: **Gestation**

Dose Group	Animal Number	day 0	day 7	day 14	day 20
[redacted]					

PG=Pregnant; NPI=GD 0; No Implants; No Pups

IIA 66
04-Mar-2013 09:37
ToxData© System 3.0

Study 80R0223/11C162

Individual Body Weights - BW / Body Weights [g]

Sex: **Female** - Phase: **Gestation**

Dose Group	Animal Number	day 0	day 7	day 14	day 20
[redacted]					

NPI=GD 0; No Implants; No Pups; PG=Pregnant

IIA 67
04-Mar-2013 09:37
ToxData© System 3.0

Study 80R0223/11C162

Individual Body Weights - BW / Body Weights [g]

Sex: **Female** - Phase: **Gestation**

Dose Group	Animal Number	day 0	day 7	day 14	day 20
[redacted]					

PG=Pregnant; NPI=GD 0; No Implants; No Pups

IIA 68
04-Mar-2013 09:37
ToxData© System 3.0

Study 80R0223/11C162

Individual Body Weights - BW / Body Weights [g]

Sex: **Female** - Phase: **Gestation**

Dose Group	Animal Number	day 0	day 7	day 14	day 20
[redacted]					

PG=Pregnant; NPI=GD 0; No Implants; No Pups

IIA 69
04-Mar-2013 08:44
ToxData© System 3.0

Study 80R0223/11C162

Individual Body Weights - BW / Body Weights [g]

Sex: **Female** - Phase: **Lactation**

Dose Group	Animal Number	day 0	day 4	day 7	day 14	day 21
[redacted]						

PG=Pregnant
NS = No More Scheduled

IIA 70
04-Mar-2013 08:44
ToxData© System 3.0

Study 80R0223/11C162

Individual Body Weights - BW / Body Weights [g]

Sex: **Female** - Phase: **Lactation**

Dose Group	Animal Number	day 0	day 4	day 7	day 14	day 21
[redacted]						

PG=Pregnant
NS = No More Scheduled

IIA 71
04-Mar-2013 08:44
ToxData© System 3.0

Study 80R0223/11C162

Individual Body Weights - BW / Body Weights [g]

Sex: **Female** - Phase: **Lactation**

Dose Group	Animal Number	day 0	day 4	day 7	day 14	day 21
[redacted]						

PG=Pregnant
NS = No More Scheduled

IIA 72
04-Mar-2013 08:44
ToxData© System 3.0

Study 80R0223/11C162

Individual Body Weights - BW / Body Weights [g]

Sex: **Female** - Phase: **Lactation**

Dose Group	Animal Number	day 0	day 4	day 7	day 14	day 21
[redacted]						

PG=Pregnant
NS = No More Scheduled

IIA 73
04-Mar-2013 08:47
ToxData© System 3.0

Study 80R0223/11C162

Individual Changes Body Weights - BW / Body Weights [g]

Sex: **Male** - Phase: **Pre-mating**

Dose Group	Animal Number	d 0 -> 7	d 7 -> 13	d 0 -> 13
[redacted]				

d = day

IIA 74
04-Mar-2013 08:47
ToxData© System 3.0

Study 80R0223/11C162

Individual Changes Body Weights - BW / Body Weights [g]

Sex: **Male** - Phase: **Pre-mating**

Dose Group	Animal Number	d 0 -> 7	d 7 -> 13	d 0 -> 13
[redacted]				

d = day

IIA 75
04-Mar-2013 08:47
ToxData© System 3.0

Study 80R0223/11C162

Individual Changes Body Weights - BW / Body Weights [g]

Sex: **Male** - Phase: **Pre-mating**

Dose Group	Animal Number	d 0 -> 7	d 7 -> 13	d 0 -> 13
[redacted]				

d = day

IIA 76
04-Mar-2013 08:47
ToxData© System 3.0

Study 80R0223/11C162

Individual Changes Body Weights - BW / Body Weights [g]

Sex: **Male** - Phase: **Pre-mating**

Dose Group	Animal Number	d 0 -> 7	d 7 -> 13	d 0 -> 13
[redacted]				

d = day

IIA 77
04-Mar-2013 08:47
ToxData© System 3.0

Study 80R0223/11C162

Individual Changes Body Weights - BW / Body Weights [g]

Sex: **Female** - Phase: **Pre-mating**

Dose Group	Animal Number	d 0 -> 7	d 7 -> 13	d 0 -> 13
[redacted]				

PG=Pregnant; NPI=GD 0; No Implants; No Pups
d = day

IIA 78
04-Mar-2013 08:47
ToxData© System 3.0

Study 80R0223/11C162

Individual Changes Body Weights - BW / Body Weights [g]

Sex: **Female** - Phase: **Pre-mating**

Dose Group	Animal Number	d 0 -> 7	d 7 -> 13	d 0 -> 13
[redacted]				

NPI=GD 0; No Implants; No Pups; PG=Pregnant
d = day

IIA 79
04-Mar-2013 08:47
ToxData© System 3.0

Study 80R0223/11C162

Individual Changes Body Weights - BW / Body Weights [g]

Sex: **Female** - Phase: **Pre-mating**

Dose Group	Animal Number	d 0 -> 7	d 7 -> 13	d 0 -> 13
[redacted]				

PG=Pregnant; NPI=GD 0; No Implants; No Pups
d = day

IIA 80
04-Mar-2013 08:47
ToxData© System 3.0

Study 80R0223/11C162

Individual Changes Body Weights - BW / Body Weights [g]

Sex: **Female** - Phase: **Pre-mating**

Dose Group	Animal Number	d 0 -> 7	d 7 -> 13	d 0 -> 13
[redacted]				

PG=Pregnant; NPl=GD 0; No Implants; No Pups
d = day

IIA 81
04-Mar-2013 08:56
ToxData© System 3.0

Study 80R0223/11C162

Individual Changes Body Weights - BW / Body Weights [g]

Sex: **Female** - Phase: **Gestation**

Dose Group	Animal Number	d 0 -> 7	d 7 -> 14	d 14 -> 20	d 20 -> 28	d 28 -> 35	d 35 -> 42
[redacted]							

PG=Pregnant; NPI=GD 0; No Implants; No Pups
d = day; NS = No More Scheduled

IIA 82
04-Mar-2013 08:56
ToxData© System 3.0

Study 80R0223/11C162

Individual Changes Body Weights - BW / Body Weights [g]

Sex: **Female** - Phase: **Gestation**

Dose Group	Animal Number	d 0 -> 7	d 7 -> 14	d 14 -> 20	d 20 -> 28	d 28 -> 35	d 35 -> 42
[redacted]							

NPI=GD 0; No Implants; No Pups; PG=Pregnant
d = day; NS = No More Scheduled

IIA 83
04-Mar-2013 08:56
ToxData© System 3.0

Study 80R0223/11C162

Individual Changes Body Weights - BW / Body Weights [g]

Sex: **Female** - Phase: **Gestation**

Dose Group	Animal Number	d 0 -> 7	d 7 -> 14	d 14 -> 20	d 20 -> 28	d 28 -> 35	d 35 -> 42
[redacted]							

PG=Pregnant; NPI=GD 0; No Implants; No Pups
d = day; NS = No More Scheduled

IIA 84
04-Mar-2013 08:56
ToxData© System 3.0

Study 80R0223/11C162

Individual Changes Body Weights - BW / Body Weights [g]

Sex: **Female** - Phase: **Gestation**

Dose Group	Animal Number	d 0 -> 7	d 7 -> 14	d 14 -> 20	d 20 -> 28	d 28 -> 35	d 35 -> 42
[redacted]							

PG=Pregnant; NPI=GD 0; No Implants; No Pups
d = day; NS = No More Scheduled

IIA 85
04-Mar-2013 09:00
ToxData© System 3.0

Study 80R0223/11C162

Individual Changes Body Weights - BW / Body Weights [g]

Sex: **Female** - Phase: **Lactation**

Dose Group	Animal Number	d 0 -> 4	d 4 -> 7	d 7 -> 14	d 14 -> 21
[redacted]					

PG=Pregnant
d = day; NS = No More Scheduled

IIA 86
04-Mar-2013 09:00
ToxData© System 3.0

Study 80R0223/11C162

Individual Changes Body Weights - BW / Body Weights [g]

Sex: **Female** - Phase: **Lactation**

Dose Group	Animal Number	d 0 -> 4	d 4 -> 7	d 7 -> 14	d 14 -> 21
[redacted]					

PG=Pregnant
d = day; NS = No More Scheduled

IIA 87
04-Mar-2013 09:00
ToxData© System 3.0

Study 80R0223/11C162

Individual Changes Body Weights - BW / Body Weights [g]

Sex: **Female** - Phase: **Lactation**

Dose Group	Animal Number	d 0 -> 4	d 4 -> 7	d 7 -> 14	d 14 -> 21
[redacted]					

PG=Pregnant
d = day; NS = No More Scheduled

IIA 88
04-Mar-2013 09:00
ToxData© System 3.0

Study 80R0223/11C162

Individual Changes Body Weights - BW / Body Weights [g]

Sex: **Female** - Phase: **Lactation**

Dose Group	Animal Number	d 0 -> 4	d 4 -> 7	d 7 -> 14	d 14 -> 21
[redacted]					

PG=Pregnant
d = day; NS = No More Scheduled

IIA 89
04-Mar-2013 09:43
ToxData© System 3.0

Study 80R0223/11C162

Individual Coupling Report

Sex: **Female**

Group	Female	Male	Pre-mating Date	Mating Date	Insemination Date	Mating Days	Delivery Date	Gestation Days	Pregnant Status
[redacted]									

IIA 90
04-Mar-2013 09:43
ToxData© System 3.0

Study 80R0223/11C162

Individual Coupling Report

Sex: **Female**

Group	Female	Male	Pre-mating Date	Mating Date	Insemination Date	Mating Days	Delivery Date	Gestation Days	Pregnant Status
[redacted]									

IIA 91
04-Mar-2013 09:43
ToxData© System 3.0

Study 80R0223/11C162

Individual Coupling Report

Sex: **Female**

Group	Female	Male	Pre-mating Date	Mating Date	Insemination Date	Mating Days	Delivery Date	Gestation Days	Pregnant Status
[redacted]									

IIA 92
04-Mar-2013 09:43
ToxData© System 3.0

Study 80R0223/11C162

Individual Coupling Report

Sex: **Female**

Group	Female	Male	Pre-mating Date	Mating Date	Insemination Date	Mating Days	Delivery Date	Gestation Days	Pregnant Status
[redacted]									

IIA 93
04-Mar-2013 09:44
ToxData© System 3.0

Study 80R0223/11C162

Individual Delivery Report

Sex: **Female**

Group	Female	Pregnant Status	Gestation Days	Dead N	Alive N	Total N	Implantation Sites N	Post Implantation Loss %	Live Birth Index %
[redacted]									

IIA 94

04-Mar-2013 09:44

ToxData© System 3.0

Study 80R0223/11C162

Individual Delivery Report

Sex: **Female**

Group	Female		Pregnant Status	Gestation Days	Dead N	Alive N	Total N	Implantation Sites N	Post Implantation Loss %	Live Birth Index %
[redacted]										

IIA 95
04-Mar-2013 09:44
ToxData© System 3.0

Study 80R0223/11C162

Individual Delivery Report

Sex: **Female**

Group	Female		Pregnant Status	Gestation Days	Dead N	Alive N	Total N	Implantation Sites N	Post Implantation Loss %	Live Birth Index %
[redacted]										

IIA 96
04-Mar-2013 09:44
ToxData© System 3.0

Study 80R0223/11C162

Individual Delivery Report

Sex: **Female**

Group		Pregnant Status	Gestation Days	Dead N	Alive N	Total N	Implantation Sites N	Post Implantation Loss %	Live Birth Index %
[redacted]									

IIA 97
04-Mar-2013 09:48
ToxData© System 3.0

Study 80R0223/11C162

Individual Signs - Clinical Observation

Litter Group	Litter	Animal Number	Sex	Sign Type	Sign	Modifier	Remark	First Day	Last Day	Duration [Days]
[redacted]										

IIA 98
04-Mar-2013 09:48
ToxData© System 3.0

Study 80R0223/11C162

Individual Signs - Clinical Observation

Litter Group	Litter	Animal Number	Sex	Sign Type	Sign	Modifier	Remark	First Day	Last Day	Duration [Days]
[redacted]										

IIA 99
04-Mar-2013 09:48
ToxData© System 3.0

Study 80R0223/11C162

Individual Signs - Clinical Observation

Litter Group	Animal Litter	Animal Number	Sex	Sign Type	Sign	Modifier	Remark	First Day	Last Day	Duration [Days]
[redacted]										

IIA 100
04-Mar-2013 09:48
ToxData© System 3.0

Study 80R0223/11C162

Individual Signs - Clinical Observation

Litter Group	Litter	Animal Number	Sex	Sign Type	Sign	Modifier	Remark	First Day	Last Day	Duration [Days]
[redacted]										

IIA 101
04-Mar-2013 09:48
ToxData© System 3.0

Study 80R0223/11C162

Individual Signs - Clinical Observation

Litter Group	Litter	Animal Number	Sex	Sign Type	Sign	Modifier	Remark	First Day	Last Day	Duration [Days]
[redacted]										

IIA 102
04-Mar-2013 09:48
ToxData© System 3.0

Study 80R0223/11C162

Individual Signs - Clinical Observation

Litter Group	Litter	Animal Number	Sex	Sign Type	Sign	Modifier	Remark	First Day	Last Day	Duration [Days]
[redacted]										

IIA 103
04-Mar-2013 09:48
ToxData© System 3.0

Study 80R0223/11C162

Individual Signs - Clinical Observation

Litter Group	Litter	Animal Number	Sex	Sign Type	Sign	Modifier	Remark	First Day	Last Day	Duration [Days]
[redacted]										

IIA 104
04-Mar-2013 09:48
ToxData© System 3.0

Study 80R0223/11C162

Individual Signs - Clinical Observation

Litter Group	Litter	Animal Number	Sex	Sign Type	Sign	Modifier	Remark	First Day	Last Day	Duration [Days]
[redacted]										

IIA 105
04-Mar-2013 09:48
ToxData© System 3.0

Study 80R0223/11C162

Individual Signs - Clinical Observation

Litter Group	Litter	Animal Number	Sex	Sign Type	Sign	Modifier	Remark	First Day	Last Day	Duration [Days]
[redacted]										

IIA 106
04-Mar-2013 09:48
ToxData© System 3.0

Study 80R0223/11C162

Individual Signs - Clinical Observation

Litter Group	Litter	Animal Number	Sex	Sign Type	Sign	Modifier	Remark	First Day	Last Day	Duration [Days]
[redacted]										

IIA 107
04-Mar-2013 09:48
ToxData© System 3.0

Study 80R0223/11C162

Individual Signs - Clinical Observation

Litter Group	Litter	Animal Number	Sex	Sign Type	Sign	Modifier	Remark	First Day	Last Day	Duration [Days]
[redacted]										

IIA 108
04-Mar-2013 09:48
ToxData© System 3.0

Study 80R0223/11C162

Individual Signs - Clinical Observation

Litter Group	Animal Litter	Animal Number	Sex	Sign Type	Sign	Modifier	Remark	First Day	Last Day	Duration [Days]
[redacted]										

IIA 109
04-Mar-2013 09:48
ToxData© System 3.0

Study 80R0223/11C162

Individual Signs - Clinical Observation

Litter Group	Litter	Animal Number	Sex	Sign Type	Sign	Modifier	Remark	First Day	Last Day	Duration [Days]
[redacted]										

IIA 110
04-Mar-2013 09:48
ToxData© System 3.0

Study 80R0223/11C162

Individual Signs - Clinical Observation

Litter Group	Animal Litter	Animal Number	Sex	Sign Type	Sign	Modifier	Remark	First Day	Last Day	Duration [Days]
[redacted]										

IIA 111
04-Mar-2013 09:48
ToxData© System 3.0

Study 80R0223/11C162

Individual Signs - Clinical Observation

Litter Group	Litter	Animal Number	Sex	Sign Type	Sign	Modifier	Remark	First Day	Last Day	Duration [Days]
[redacted]										

IIA 112
04-Mar-2013 09:48
ToxData© System 3.0

Study 80R0223/11C162

Individual Signs - Clinical Observation

Litter Group	Animal Litter	Animal Number	Sex	Sign Type	Sign	Modifier	Remark	First Day	Last Day	Duration [Days]
[redacted]										

IIA 113
04-Mar-2013 09:48
ToxData© System 3.0

Study 80R0223/11C162

Individual Signs - Clinical Observation

Litter Group	Litter	Animal Number	Sex	Sign Type	Sign	Modifier	Remark	First Day	Last Day	Duration [Days]
[redacted]										

IIA 114
04-Mar-2013 09:48
ToxData© System 3.0

Study 80R0223/11C162

Individual Signs - Clinical Observation

Litter Group	Litter	Animal Number	Sex	Sign Type	Sign	Modifier	Remark	First Day	Last Day	Duration [Days]
[redacted]										

IIA 115
04-Mar-2013 09:48
ToxData© System 3.0

Study 80R0223/11C162

Individual Signs - Clinical Observation

Litter Group	Litter	Animal Number	Sex	Sign Type	Sign	Modifier	Remark	First Day	Last Day	Duration [Days]
[redacted]										

IIA 116
04-Mar-2013 09:50
ToxData© System 3.0

Study 80R0223/11C162

Individual Signs - Pup Status

Litter Group	Litter	Animal Number	Sex	Sign Type	Sign	Modifier	Remark	First Day	Last Day	Duration [Days]
[redacted]										

IIA 117
04-Mar-2013 09:50
ToxData© System 3.0

Study 80R0223/11C162

Individual Signs - Pup Status

Litter Group	Litter	Animal Number	Sex	Sign Type	Sign	Modifier	Remark	First Day	Last Day	Duration [Days]
[redacted]										

IIA 118
04-Mar-2013 09:50
ToxData© System 3.0

Study 80R0223/11C162

Individual Signs - Pup Status

Litter Group	Litter	Animal Number	Sex	Sign Type	Sign	Modifier	Remark	First Day	Last Day	Duration [Days]
[redacted]										

IIA 119
04-Mar-2013 09:50
ToxData© System 3.0

Study 80R0223/11C162

Individual Signs - Pup Status

Litter Group	Litter	Animal Number	Sex	Sign Type	Sign	Modifier	Remark	First Day	Last Day	Duration [Days]
[redacted]										

IIA 120
04-Mar-2013 09:50
ToxData© System 3.0

Study 80R0223/11C162

Individual Signs - Pup Status

Litter Group	Litter	Animal Number	Sex	Sign Type	Sign	Modifier	Remark	First Day	Last Day	Duration [Days]
[redacted]										

IIA 121
04-Mar-2013 09:50
ToxData© System 3.0

Study 80R0223/11C162

Individual Signs - Pup Status

Litter Group	Litter	Animal Number	Sex	Sign Type	Sign	Modifier	Remark	First Day	Last Day	Duration [Days]
[redacted]										

IIA 122
04-Mar-2013 09:50
ToxData© System 3.0

Study 80R0223/11C162

Individual Signs - Pup Status

Litter Group	Litter	Animal Number	Sex	Sign Type	Sign	Modifier	Remark	First Day	Last Day	Duration [Days]
[redacted]										

IIA 123
04-Mar-2013 09:50
ToxData© System 3.0

Study 80R0223/11C162

Individual Signs - Pup Status

Litter Group	Litter	Animal Number	Sex	Sign Type	Sign	Modifier	Remark	First Day	Last Day	Duration [Days]
[redacted]										

IIA 124
04-Mar-2013 09:50
ToxData© System 3.0

Study 80R0223/11C162

Individual Signs - Pup Status

Litter Group	Litter	Animal Number	Sex	Sign Type	Sign	Modifier	Remark	First Day	Last Day	Duration [Days]
[redacted]										

IIA 125
04-Mar-2013 09:50
ToxData© System 3.0

Study 80R0223/11C162

Individual Signs - Pup Status

Litter Group	Litter	Animal Number	Sex	Sign Type	Sign	Modifier	Remark	First Day	Last Day	Duration [Days]
[redacted]										

IIA 126
04-Mar-2013 09:50
ToxData© System 3.0

Study 80R0223/11C162

Individual Signs - Pup Status

Litter Group	Litter	Animal Number	Sex	Sign Type	Sign	Modifier	Remark	First Day	Last Day	Duration [Days]
[redacted]										

IIA 127
04-Mar-2013 09:50
ToxData© System 3.0

Study 80R0223/11C162

Individual Signs - Pup Status

Litter Group	Litter	Animal Number	Sex	Sign Type	Sign	Modifier	Remark	First Day	Last Day	Duration [Days]
[redacted]										

IIA 128
04-Mar-2013 09:50
ToxData© System 3.0

Study 80R0223/11C162

Individual Signs - Pup Status

Litter Group	Litter	Animal Number	Sex	Sign Type	Sign	Modifier	Remark	First Day	Last Day	Duration [Days]
[redacted]										

IIA 129
04-Mar-2013 09:50
ToxData© System 3.0

Study 80R0223/11C162

Individual Signs - Pup Status

Litter Group	Litter	Animal Number	Sex	Sign Type	Sign	Modifier	Remark	First Day	Last Day	Duration [Days]
[redacted]										

IIA 130
04-Mar-2013 09:50
ToxData© System 3.0

Study 80R0223/11C162

Individual Signs - Pup Status

Litter Group	Litter	Animal Number	Sex	Sign Type	Sign	Modifier	Remark	First Day	Last Day	Duration [Days]
[redacted]										

IIA 131
04-Mar-2013 09:50
ToxData© System 3.0

Study 80R0223/11C162

Individual Signs - Pup Status

Litter Group	Litter	Animal Number	Sex	Sign Type	Sign	Modifier	Remark	First Day	Last Day	Duration [Days]
[redacted]										

IIA 132
04-Mar-2013 09:50
ToxData© System 3.0

Study 80R0223/11C162

Individual Signs - Pup Status

Litter Group	Litter	Animal Number	Sex	Sign Type	Sign	Modifier	Remark	First Day	Last Day	Duration [Days]
[redacted]										

IIA 133
04-Mar-2013 09:50
ToxData© System 3.0

Study 80R0223/11C162

Individual Signs - Pup Status

Litter Group	Litter	Animal Number	Sex	Sign Type	Sign	Modifier	Remark	First Day	Last Day	Duration [Days]
[redacted]										

IIA 134
04-Mar-2013 09:50
ToxData© System 3.0

Study 80R0223/11C162

Individual Signs - Pup Status

Litter Group	Litter	Animal Number	Sex	Sign Type	Sign	Modifier	Remark	First Day	Last Day	Duration [Days]
[redacted]										

IIA 135
04-Mar-2013 09:50
ToxData© System 3.0

Study 80R0223/11C162

Individual Signs - Pup Status

Litter Group	Litter	Animal Number	Sex	Sign Type	Sign	Modifier	Remark	First Day	Last Day	Duration [Days]
[redacted]										

IIA 136
04-Mar-2013 09:50
ToxData© System 3.0

Study 80R0223/11C162

Individual Signs - Pup Status

Litter Group	Litter	Animal Number	Sex	Sign Type	Sign	Modifier	Remark	First Day	Last Day	Duration [Days]
[redacted]										

IIA 137
04-Mar-2013 09:50
ToxData© System 3.0

Study 80R0223/11C162

Individual Signs - Pup Status

Litter Group	Litter	Animal Number	Sex	Sign Type	Sign	Modifier	Remark	First Day	Last Day	Duration [Days]
[redacted]										

IIA 138
04-Mar-2013 09:50
ToxData© System 3.0

Study 80R0223/11C162

Individual Signs - Pup Status

Litter Group	Litter	Animal Number	Sex	Sign Type	Sign	Modifier	Remark	First Day	Last Day	Duration [Days]
[redacted]										

IIA 139
04-Mar-2013 09:50
ToxData© System 3.0

Study 80R0223/11C162

Individual Signs - Pup Status

Litter Group	Litter	Animal Number	Sex	Sign Type	Sign	Modifier	Remark	First Day	Last Day	Duration [Days]
[redacted]										

IIA 140
04-Mar-2013 09:50
ToxData© System 3.0

Study 80R0223/11C162

Individual Signs - Pup Status

Litter Group	Litter	Animal Number	Sex	Sign Type	Sign	Modifier	Remark	First Day	Last Day	Duration [Days]
[redacted]										

IIA 141
04-Mar-2013 09:50
ToxData© System 3.0

Study 80R0223/11C162

Individual Signs - Pup Status

Litter Group	Litter	Animal Number	Sex	Sign Type	Sign	Modifier	Remark	First Day	Last Day	Duration [Days]
[redacted]										

IIA 142
04-Mar-2013 09:50
ToxData© System 3.0

Study 80R0223/11C162

Individual Signs - Pup Status

Litter Group	Litter	Animal Number	Sex	Sign Type	Sign	Modifier	Remark	First Day	Last Day	Duration [Days]
[redacted]										

IIA 143
04-Mar-2013 09:50
ToxData© System 3.0

Study 80R0223/11C162

Individual Signs - Pup Status

Litter Group	Litter	Animal Number	Sex	Sign Type	Sign	Modifier	Remark	First Day	Last Day	Duration [Days]
[redacted]										

IIA 144
04-Mar-2013 09:50
ToxData© System 3.0

Study 80R0223/11C162

Individual Signs - Pup Status

Litter Group	Litter	Animal Number	Sex	Sign Type	Sign	Modifier	Remark	First Day	Last Day	Duration [Days]
[redacted]										

IIA 145
04-Mar-2013 09:50
ToxData© System 3.0

Study 80R0223/11C162

Individual Signs - Pup Status

Litter Group	Litter	Animal Number	Sex	Sign Type	Sign	Modifier	Remark	First Day	Last Day	Duration [Days]
[redacted]										

IIA 146
04-Mar-2013 09:50
ToxData© System 3.0

Study 80R0223/11C162

Individual Signs - Pup Status

Litter Group	Litter	Animal Number	Sex	Sign Type	Sign	Modifier	Remark	First Day	Last Day	Duration [Days]
[redacted]										

IIA 147
04-Mar-2013 09:50
ToxData© System 3.0

Study 80R0223/11C162

Individual Signs - Pup Status

Litter Group	Litter	Animal Number	Sex	Sign Type	Sign	Modifier	Remark	First Day	Last Day	Duration [Days]
[redacted]										

IIA 148
04-Mar-2013 09:50
ToxData© System 3.0

Study 80R0223/11C162

Individual Signs - Pup Status

Litter Group	Litter	Animal Number	Sex	Sign Type	Sign	Modifier	Remark	First Day	Last Day	Duration [Days]
[redacted]										

IIA 149
04-Mar-2013 09:50
ToxData© System 3.0

Study 80R0223/11C162

Individual Signs - Pup Status

Litter Group	Litter	Animal Number	Sex	Sign Type	Sign	Modifier	Remark	First Day	Last Day	Duration [Days]
[redacted]										

IIA 150
04-Mar-2013 09:50
ToxData© System 3.0

Study 80R0223/11C162

Individual Signs - Pup Status

Litter Group	Litter	Animal Number	Sex	Sign Type	Sign	Modifier	Remark	First Day	Last Day	Duration [Days]
[redacted]										

IIA 151
04-Mar-2013 09:50
ToxData© System 3.0

Study 80R0223/11C162

Individual Signs - Pup Status

Litter Group	Litter	Animal Number	Sex	Sign Type	Sign	Modifier	Remark	First Day	Last Day	Duration [Days]
[redacted]										

IIA 152
04-Mar-2013 09:50
ToxData© System 3.0

Study 80R0223/11C162

Individual Signs - Pup Status

Litter Group	Litter	Animal Number	Sex	Sign Type	Sign	Modifier	Remark	First Day	Last Day	Duration [Days]
[redacted]										

IIA 153
04-Mar-2013 09:50
ToxData© System 3.0

Study 80R0223/11C162

Individual Signs - Pup Status

Litter Group	Litter	Animal Number	Sex	Sign Type	Sign	Modifier	Remark	First Day	Last Day	Duration [Days]
[redacted]										

IIA 154
04-Mar-2013 09:53
ToxData© System 3.0

Study 80R0223/11C162

Individual Report By Litter Body Weights - BW / Body Weights [g]

Phase: **Lactation Pup**

Litter Group	Litter Number	Animal Number	Sex	day 1	day 4
[redacted]					

IIA 155
04-Mar-2013 09:53
ToxData© System 3.0

Study 80R0223/11C162

Individual Report By Litter Body Weights - BW / Body Weights [g]

Phase: **Lactation Pup**

Litter Group	Litter Number	Animal Number	Sex	day 1	day 4
[redacted]					

IIA 156
04-Mar-2013 09:53
ToxData© System 3.0

Study 80R0223/11C162

Individual Report By Litter Body Weights - BW / Body Weights [g]

Phase: **Lactation Pup**

Litter Group	Litter Number	Animal Number	Sex	day 1	day 4
[redacted]					

NS = No More Scheduled

IIA 157
04-Mar-2013 09:53
ToxData© System 3.0

Study 80R0223/11C162

Individual Report By Litter Body Weights - BW / Body Weights [g]

Phase: **Lactation Pup**

Litter Group	Litter Number	Animal Number	Sex	day 1	day 4
[redacted]					

r-RUNT = 25% less weight than the mean of the control

IIA 158
04-Mar-2013 09:53
ToxData© System 3.0

Study 80R0223/11C162

Individual Report By Litter Body Weights - BW / Body Weights [g]

Phase: **Lactation Pup**

Litter Group	Litter Number	Animal Number	Sex	day 1	day 4
[redacted]					

IIA 159
04-Mar-2013 09:53
ToxData© System 3.0

Study 80R0223/11C162

Individual Report By Litter Body Weights - BW / Body Weights [g]

Phase: **Lactation Pup**

Litter Group	Litter Number	Animal Number	Sex	day 1	day 4
[redacted]					

NS = No More Scheduled

IIA 160
04-Mar-2013 09:53
ToxData© System 3.0

Study 80R0223/11C162

Individual Report By Litter Body Weights - BW / Body Weights [g]

Phase: **Lactation Pup**

Litter Group	Litter Number	Animal Number	Sex	day 1	day 4
[redacted]					

IIA 161
04-Mar-2013 09:53
ToxData© System 3.0

Study 80R0223/11C162

Individual Report By Litter Body Weights - BW / Body Weights [g]

Phase: **Lactation Pup**

Litter Group	Litter Number	Animal Number	Sex	day 1	day 4
[redacted]					

r-RUNT = 25% less weight than the mean of the control; NS = No More Scheduled

IIA 162
04-Mar-2013 09:53
ToxData© System 3.0

Study 80R0223/11C162

Individual Report By Litter Body Weights - BW / Body Weights [g]

Phase: **Lactation Pup**

Litter Group	Litter Number	Animal Number	Sex	day 1	day 4
[redacted]					

NS = No More Scheduled

IIA 163
04-Mar-2013 09:53
ToxData© System 3.0

Study 80R0223/11C162

Individual Report By Litter Body Weights - BW / Body Weights [g]

Phase: **Lactation Pup**

Litter Group	Litter Number	Animal Number	Sex	day 1	day 4
[redacted]					

IIA 164
04-Mar-2013 09:53
ToxData© System 3.0

Study 80R0223/11C162

Individual Report By Litter Body Weights - BW / Body Weights [g]

Phase: **Lactation Pup**

Litter Group	Litter Number	Animal Number	Sex	day 1	day 4
[redacted]					

r-RUNT = 25% less weight than the mean of the control; NS = No More Scheduled

IIA 165
04-Mar-2013 09:53
ToxData© System 3.0

Study 80R0223/11C162

Individual Report By Litter Body Weights - BW / Body Weights [g]

Phase: **Lactation Pup**

Litter Group	Litter Number	Animal Number	Sex	day 1	day 4
[redacted]					

IIA 166
04-Mar-2013 09:53
ToxData© System 3.0

Study 80R0223/11C162

Individual Report By Litter Body Weights - BW / Body Weights [g]

Phase: **Lactation Pup**

Litter Group	Litter Number	Animal Number	Sex	day 1	day 4
[redacted]					

IIA 167
04-Mar-2013 09:53
ToxData© System 3.0

Study 80R0223/11C162

Individual Report By Litter Body Weights - BW / Body Weights [g]

Phase: **Lactation Pup**

Litter Group	Litter Number	Animal Number	Sex	day 1	day 4
[redacted]					

IIA 168
04-Mar-2013 09:53
ToxData© System 3.0

Study 80R0223/11C162

Individual Report By Litter Body Weights - BW / Body Weights [g]

Phase: **Lactation Pup**

Litter Group	Litter Number	Animal Number	Sex	day 1	day 4
[redacted]					

IIA 169
04-Mar-2013 09:53
ToxData© System 3.0

Study 80R0223/11C162

Individual Report By Litter Body Weights - BW / Body Weights [g]

Phase: **Lactation Pup**

Litter Group	Litter Number	Animal Number	Sex	day 1	day 4
[redacted]					

IIA 170
04-Mar-2013 09:53
ToxData© System 3.0

Study 80R0223/11C162

Individual Report By Litter Body Weights - BW / Body Weights [g]

Phase: **Lactation Pup**

Litter Group	Litter Number	Animal Number	Sex	day 1	day 4
[redacted]					

IIA 171
04-Mar-2013 09:53
ToxData© System 3.0

Study 80R0223/11C162

Individual Report By Litter Body Weights - BW / Body Weights [g]

Phase: **Lactation Pup**

Litter Group	Litter Number	Animal Number	Sex	day 1	day 4
[redacted]					

IIA 172
04-Mar-2013 09:53
ToxData© System 3.0

Study 80R0223/11C162

Individual Report By Litter Body Weights - BW / Body Weights [g]

Phase: **Lactation Pup**

Litter Group	Litter Number	Animal Number	Sex	day 1	day 4
[redacted]					

IIA 173
04-Mar-2013 09:53
ToxData© System 3.0

Study 80R0223/11C162

Individual Report By Litter Body Weights - BW / Body Weights [g]

Phase: **Lactation Pup**

Litter Group	Litter Number	Animal Number	Sex	day 1	day 4
[redacted]					

NS = No More Scheduled

IIA 174
04-Mar-2013 09:53
ToxData© System 3.0

Study 80R0223/11C162

Individual Report By Litter Body Weights - BW / Body Weights [g]

Phase: **Lactation Pup**

Litter Group	Litter Number	Animal Number	Sex	day 1	day 4
[redacted]					

IIA 175
04-Mar-2013 09:56
ToxData© System 3.0

Study 80R0223/11C162

Individual Changes Body Weights - BW / Body Weights [g]

Sex: **Male** - Phase: **Lactation Pup**

Dose Group	Animal Number	d 1 -> 4
[redacted]		

d = day

IIA 176
04-Mar-2013 09:56
ToxData© System 3.0

Study 80R0223/11C162

Individual Changes Body Weights - BW / Body Weights [g]

Sex: **Male** - Phase: **Lactation Pup**

Dose Group	Animal Number	d 1 -> 4
[redacted]		

d = day; NS = No More Scheduled

IIA 177
04-Mar-2013 09:56
ToxData© System 3.0

Study 80R0223/11C162

Individual Changes Body Weights - BW / Body Weights [g]

Sex: **Male** - Phase: **Lactation Pup**

Dose Group	Animal Number	d 1 -> 4
[redacted]		

d = day

IIA 178
04-Mar-2013 09:56
ToxData© System 3.0

Study 80R0223/11C162

Individual Changes Body Weights - BW / Body Weights [g]

Sex: **Male** - Phase: **Lactation Pup**

Dose Group	Animal Number	d 1 -> 4
[redacted]		

d = day

IIA 179
04-Mar-2013 09:56
ToxData© System 3.0

Study 80R0223/11C162

Individual Changes Body Weights - BW / Body Weights [g]

Sex: **Male** - Phase: **Lactation Pup**

Dose Group	Animal Number	d 1 -> 4
[redacted]		

d = day; NS = No More Scheduled

IIA 180
04-Mar-2013 09:56
ToxData© System 3.0

Study 80R0223/11C162

Individual Changes Body Weights - BW / Body Weights [g]

Sex: **Male** - Phase: **Lactation Pup**

Dose Group	Animal Number	d 1 -> 4
[redacted]		

d = day

IIA 181
04-Mar-2013 09:56
ToxData© System 3.0

Study 80R0223/11C162

Individual Changes Body Weights - BW / Body Weights [g]

Sex: **Male** - Phase: **Lactation Pup**

Dose Group	Animal Number	d 1 -> 4
[redacted]		

d = day

IIA 182
04-Mar-2013 09:56
ToxData© System 3.0

Study 80R0223/11C162

Individual Changes Body Weights - BW / Body Weights [g]

Sex: **Male** - Phase: **Lactation Pup**

Dose Group	Animal Number	d 1 -> 4
[redacted]		

d = day

IIA 183
04-Mar-2013 09:56
ToxData© System 3.0

Study 80R0223/11C162

Individual Changes Body Weights - BW / Body Weights [g]

Sex: **Male** - Phase: **Lactation Pup**

Dose Group	Animal Number	d 1 -> 4
[redacted]		

d = day

IIA 184
04-Mar-2013 09:56
ToxData© System 3.0

Study 80R0223/11C162

Individual Changes Body Weights - BW / Body Weights [g]

Sex: **Male** - Phase: **Lactation Pup**

Dose Group	Animal Number	d 1 -> 4
[redacted]		

d = day; NS = No More Scheduled

IIA 185
04-Mar-2013 09:56
ToxData© System 3.0

Study 80R0223/11C162

Individual Changes Body Weights - BW / Body Weights [g]

Sex: **Male** - Phase: **Lactation Pup**

Dose Group	Animal Number	d 1 -> 4
[redacted]		

d = day

IIA 186
04-Mar-2013 09:56
ToxData© System 3.0

Study 80R0223/11C162

Individual Changes Body Weights - BW / Body Weights [g]

Sex: **Female** - Phase: **Lactation Pup**

Dose Group	Animal Number	d 1 -> 4
[redacted]		

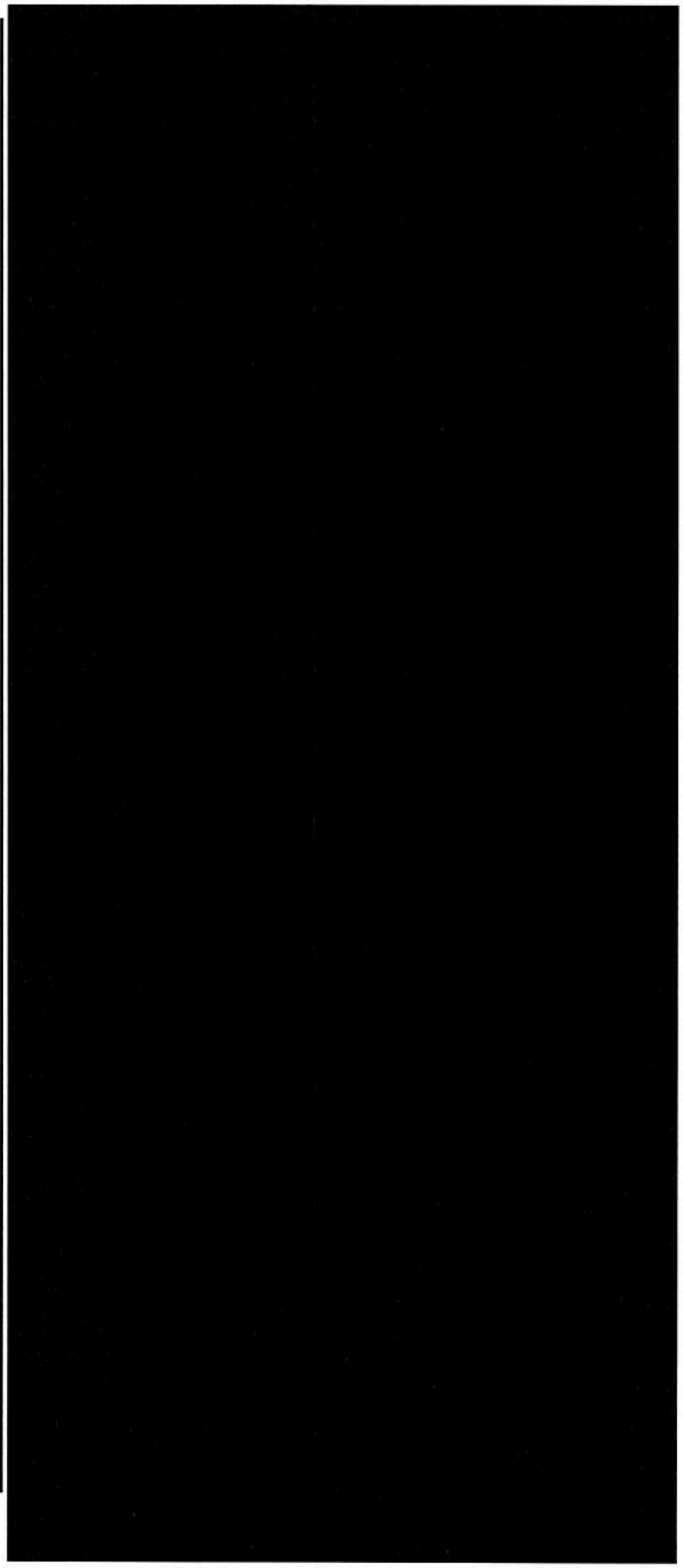
d = day

IIA 187
04-Mar-2013 09:56
ToxData© System 3.0

Study 80R0223/11C162

Individual Changes Body Weights - BW / Body Weights [g]

Sex: **Female** - Phase: **Lactation Pup**



Dose Group	Animal Number	d 1 -> 4

d = day

IIA 188
04-Mar-2013 09:56
ToxData© System 3.0

Study 80R0223/11C162

Individual Changes Body Weights - BW / Body Weights [g]

Sex: **Female** - Phase: **Lactation Pup**

Dose Group	Animal Number	d 1 -> 4
[redacted]		

d = day; NS = No More Scheduled

IIA 189
04-Mar-2013 09:56
ToxData© System 3.0

Study 80R0223/11C162

Individual Changes Body Weights - BW / Body Weights [g]

Sex: **Female** - Phase: **Lactation Pup**

Dose Group	Animal Number	d 1 -> 4
[redacted]		

d = day; NS = No More Scheduled

IIA 190
04-Mar-2013 09:56
ToxData© System 3.0

Study 80R0223/11C162

Individual Changes Body Weights - BW / Body Weights [g]

Sex: **Female** - Phase: **Lactation Pup**

Dose Group	Animal Number	d 1 -> 4
[redacted]		

d = day

IIA 191
04-Mar-2013 09:56
ToxData© System 3.0

Study 80R0223/11C162

Individual Changes Body Weights - BW / Body Weights [g]

Sex: **Female** - Phase: **Lactation Pup**

Dose Group	Animal Number	d 1 -> 4
[redacted]		

d = day; NS = No More Scheduled

IIA 192
04-Mar-2013 09:56
ToxData© System 3.0

Study 80R0223/11C162

Individual Changes Body Weights - BW / Body Weights [g]

Sex: **Female** - Phase: **Lactation Pup**

Dose Group	Animal Number	d 1 -> 4
[redacted]		

d = day

IIA 193
04-Mar-2013 09:56
ToxData© System 3.0

Study 80R0223/11C162

Individual Changes Body Weights - BW / Body Weights [g]

Sex: **Female** - Phase: **Lactation Pup**

Dose Group	Animal Number	d 1 -> 4
[redacted]		

d = day

IIA 194
04-Mar-2013 09:56
ToxData© System 3.0

Study 80R0223/11C162

Individual Changes Body Weights - BW / Body Weights [g]

Sex: **Female** - Phase: **Lactation Pup**

Dose Group	Animal Number	d 1 -> 4
[redacted]		

d = day

IIA 195
04-Mar-2013 09:56
ToxData© System 3.0

Study 80R0223/11C162

Individual Changes Body Weights - BW / Body Weights [g]

Sex: **Female** - Phase: **Lactation Pup**

Dose Group	Animal Number	d 1 -> 4
[redacted]		

d = day

IIA 196
04-Mar-2013 09:56
ToxData© System 3.0

Study 80R0223/11C162

Individual Changes Body Weights - BW / Body Weights [g]

Sex: **Female** - Phase: **Lactation Pup**

Dose Group	Animal Number	d 1 -> 4
[redacted]		

d = day

IIA 197
04-Mar-2013 09:56
ToxData© System 3.0

Study 80R0223/11C162

Individual Changes Body Weights - BW / Body Weights [g]

Sex: **Female** - Phase: **Lactation Pup**

Dose Group	Animal Number	d 1 -> 4
[redacted]		

d = day

IIA 198
04-Mar-2013 09:59
ToxData© System 3.0

Study 80R0223/11C162

Individual Signs - Pup Necropsy Observation

Litter Group	Litter	Animal Number	Sex	Sign Type	Sign	Modifier	Remark	First Day	Last Day	Duration [Days]
[redacted]										

IIA 199
04-Mar-2013 09:59
ToxData© System 3.0

Study 80R0223/11C162

Individual Signs - Pup Necropsy Observation

Litter Group	Litter	Animal Number	Sex	Sign Type	Sign	Modifier	Remark	First Day	Last Day	Duration [Days]
[redacted]										

IIA 200
04-Mar-2013 09:59
ToxData© System 3.0

Study 80R0223/11C162

Individual Signs - Pup Necropsy Observation

Litter Group	Litter	Animal Number	Sex	Sign Type	Sign	Modifier	Remark	First Day	Last Day	Duration [Days]
[redacted]										

IIA 201
04-Mar-2013 09:59
ToxData© System 3.0

Study 80R0223/11C162

Individual Signs - Pup Necropsy Observation

Litter Group	Litter	Animal Number	Sex	Sign Type	Sign	Modifier	Remark	First Day	Last Day	Duration [Days]
[redacted]										

IIA 202
04-Mar-2013 09:59
ToxData© System 3.0

Study 80R0223/11C162

Individual Signs - Pup Necropsy Observation

Litter Group	Litter	Animal Number	Sex	Sign Type	Sign	Modifier	Remark	First Day	Last Day	Duration [Days]
[redacted]										

IIA 203
04-Mar-2013 09:59
ToxData© System 3.0

Study 80R0223/11C162

Individual Signs - Pup Necropsy Observation

Litter Group	Litter	Animal Number	Sex	Sign Type	Sign	Modifier	Remark	First Day	Last Day	Duration [Days]
[redacted]										

IIA 204
04-Mar-2013 09:59
ToxData© System 3.0

Study 80R0223/11C162

Individual Signs - Pup Necropsy Observation

Litter Group	Litter	Animal Number	Sex	Sign Type	Sign	Modifier	Remark	First Day	Last Day	Duration [Days]
[redacted]										

IIA 205
04-Mar-2013 09:59
ToxData© System 3.0

Study 80R0223/11C162

Individual Signs - Pup Necropsy Observation

Litter Group	Litter	Animal Number	Sex	Sign Type	Sign	Modifier	Remark	First Day	Last Day	Duration [Days]
[redacted]										

IIA 206
04-Mar-2013 09:59
ToxData© System 3.0

Study 80R0223/11C162

Individual Signs - Pup Necropsy Observation

Litter Group	Litter	Animal Number	Sex	Sign Type	Sign	Modifier	Remark	First Day	Last Day	Duration [Days]
[redacted]										

IIA 207
04-Mar-2013 09:59
ToxData© System 3.0

Study 80R0223/11C162

Individual Signs - Pup Necropsy Observation

Litter Group	Litter	Animal Number	Sex	Sign Type	Sign	Modifier	Remark	First Day	Last Day	Duration [Days]
[redacted]										

IIA 208
04-Mar-2013 09:59
ToxData© System 3.0

Study 80R0223/11C162

Individual Signs - Pup Necropsy Observation

Litter Group	Litter	Animal Number	Sex	Sign Type	Sign	Modifier	Remark	First Day	Last Day	Duration [Days]
[redacted]										

IIA 209
04-Mar-2013 09:59
ToxData© System 3.0

Study 80R0223/11C162

Individual Signs - Pup Necropsy Observation

Litter Group	Litter	Animal Number	Sex	Sign Type	Sign	Modifier	Remark	First Day	Last Day	Duration [Days]
[redacted]										

IIA 210
04-Mar-2013 09:59
ToxData© System 3.0

Study 80R0223/11C162

Individual Signs - Pup Necropsy Observation

Litter Group	Litter	Animal Number	Sex	Sign Type	Sign	Modifier	Remark	First Day	Last Day	Duration [Days]
[redacted]										

IIA 211
04-Mar-2013 09:59
ToxData© System 3.0

Study 80R0223/11C162

Individual Signs - Pup Necropsy Observation

Litter Group	Litter	Animal Number	Sex	Sign Type	Sign	Modifier	Remark	First Day	Last Day	Duration [Days]
[redacted]										

IIA 212
04-Mar-2013 09:59
ToxData© System 3.0

Study 80R0223/11C162

Individual Signs - Pup Necropsy Observation

Litter Group	Litter	Animal Number	Sex	Sign Type	Sign	Modifier	Remark	First Day	Last Day	Duration [Days]
[redacted]										

IIA 213
04-Mar-2013 09:59
ToxData© System 3.0

Study 80R0223/11C162

Individual Signs - Pup Necropsy Observation

Litter Group	Litter	Animal Number	Sex	Sign Type	Sign	Modifier	Remark	First Day	Last Day	Duration [Days]
[redacted]										

IIA 214
04-Mar-2013 09:59
ToxData© System 3.0

Study 80R0223/11C162

Individual Signs - Pup Necropsy Observation

Litter Group	Litter	Animal Number	Sex	Sign Type	Sign	Modifier	Remark	First Day	Last Day	Duration [Days]
[redacted]										

IIA 215
04-Mar-2013 09:59
ToxData© System 3.0

Study 80R0223/11C162

Individual Signs - Pup Necropsy Observation

Litter Group	Litter	Animal Number	Sex	Sign Type	Sign	Modifier	Remark	First Day	Last Day	Duration [Days]
[redacted]										

IIA 216
04-Mar-2013 09:59
ToxData© System 3.0

Study 80R0223/11C162

Individual Signs - Pup Necropsy Observation

Litter Group	Litter	Animal Number	Sex	Sign Type	Sign	Modifier	Remark	First Day	Last Day	Duration [Days]
[redacted]										

BASF PATHOLOGY REPORT IIB- 1/63
80R0223/11C162
Reproduction/Developmental Toxicity Screening Test in Wistar Rats - Oral Administration (Gavage) 16.Oct.2012 SIBU

ABSOLUTE WEIGHTS - INDIVIDUAL VALUES

Sacrifice F1
Sex M
Group 0

	Term. body weight g	Epididymides g	Testes g
[redacted]			

BASF PATHOLOGY REPORT IIB- 2/63
80R0223/11C162
Reproduction/Developmental Toxicity Screening Test in Wistar Rats - Oral Administration (Gavage) 16.Oct.2012 SIBU

ABSOLUTE WEIGHTS - INDIVIDUAL VALUES

Sacrifice F1
Sex M
Group 1

	Term. body weight g	Epididymides g	Testes g
[redacted]			

BASF PATHOLOGY REPORT IIB- 3/63
80R0223/11C162

Reproduction/Developmental Toxicity Screening Test in Wistar Rats - Oral Administration (Gavage) 16.Oct.2012 SIBU

ABSOLUTE WEIGHTS - INDIVIDUAL VALUES

Sacrifice F1
Sex M
Group 2

	Term. body weight g	Epididymides g	Testes g
[redacted]			

BASF PATHOLOGY REPORT IIB- 4/63
80R0223/11C162
Reproduction/Developmental Toxicity Screening Test in Wistar Rats - Oral Administration (Gavage) 16.Oct.2012 SIBU

ABSOLUTE WEIGHTS - INDIVIDUAL VALUES

Sacrifice	F1
Sex	M
Group	3

Term. body weight g	Epididymides g	Testes g
[redacted]		

BASF PATHOLOGY REPORT IIB- 5/63
80R0223/11C162

Reproduction/Developmental Toxicity Screening Test in Wistar Rats - Oral Administration (Gavage) 16.Oct.2012 SIBU

ABSOLUTE WEIGHTS - INDIVIDUAL VALUES

Sacrifice	F1
Sex	F
Group	0

Term. body weight g
[redacted]

BASF PATHOLOGY REPORT IIB- 6/63
80R0223/11C162
Reproduction/Developmental Toxicity Screening Test in Wistar Rats - Oral Administration (Gavage) 16.Oct.2012 SIBU

ABSOLUTE WEIGHTS - INDIVIDUAL VALUES

Sacrifice	F1
Sex	F
Group	1

	Term. body weight g
[redacted]	

BASF PATHOLOGY REPORT IIB- 7/63
80R0223/11C162
Reproduction/Developmental Toxicity Screening Test in Wistar Rats - Oral Administration (Gavage) 16.Oct.2012 SIBU

ABSOLUTE WEIGHTS - INDIVIDUAL VALUES

Sacrifice	F1
Sex	F
Group	2

	Term. body weight g
[redacted]	

BASF PATHOLOGY REPORT IIB- 8/63
80R0223/11C162
Reproduction/Developmental Toxicity Screening Test in Wistar Rats - Oral Administration (Gavage) 16.Oct.2012 SIBU

ABSOLUTE WEIGHTS - INDIVIDUAL VALUES

Sacrifice F1
Sex F
Group 3

	Term. body weight g
[redacted]	

BASF PATHOLOGY REPORT IIB- 9/63
80R0223/11C162

Reproduction/Developmental Toxicity Screening Test in Wistar Rats - Oral Administration (Gavage) 16.Oct.2012 SIBU

RELATIVE WEIGHTS - INDIVIDUAL VALUES

Sacrifice F1
Sex M
Group 0

	Term. body weight	Epididymides	Testes
	%	%	%
[redacted]			

BASF PATHOLOGY REPORT IIB- 10/63
80R0223/11C162
Reproduction/Developmental Toxicity Screening Test in Wistar Rats - Oral Administration (Gavage) 16.Oct.2012 SIBU

RELATIVE WEIGHTS - INDIVIDUAL VALUES

Sacrifice F1
Sex M
Group 1

	Term. body weight %	Epididymides %	Testes %
[redacted]			

BASF PATHOLOGY REPORT IIB- 11/63
80R0223/11C162
Reproduction/Developmental Toxicity Screening Test in Wistar Rats - Oral Administration (Gavage) 16.Oct.2012 SIBU

RELATIVE WEIGHTS - INDIVIDUAL VALUES

Sacrifice F1
Sex M
Group 2

	Term. body weight %	Epididymides %	Testes %
[redacted]			

BASF PATHOLOGY REPORT IIB- 12/63
80R0223/11C162
Reproduction/Developmental Toxicity Screening Test in Wistar Rats - Oral Administration (Gavage) 16.Oct.2012 SIBU

RELATIVE WEIGHTS - INDIVIDUAL VALUES

Sacrifice F1
Sex M
Group 3

	Term. body weight %	Epididymides %	Testes %
[redacted]			

BASF PATHOLOGY REPORT IIB- 13/63
80R0223/11C162

Reproduction/Developmental Toxicity Screening Test in Wistar Rats - Oral Administration (Gavage) 16.Oct.2012 SIBU

RELATIVE WEIGHTS - INDIVIDUAL VALUES

Sacrifice	F1
Sex	F
Group	0

	Term. body weight %
[redacted]	

BASF PATHOLOGY REPORT IIB- 14/63
80R0223/11C162
Reproduction/Developmental Toxicity Screening Test in Wistar Rats - Oral Administration (Gavage) 16.Oct.2012 SIBU

RELATIVE WEIGHTS - INDIVIDUAL VALUES

Sacrifice	F1
Sex	F
Group	1

	Term. body weight %
[redacted]	

BASF PATHOLOGY REPORT IIB- 15/63
80R0223/11C162
Reproduction/Developmental Toxicity Screening Test in Wistar Rats - Oral Administration (Gavage) 16.Oct.2012 SIBU

RELATIVE WEIGHTS - INDIVIDUAL VALUES

Sacrifice	F1
Sex	F
Group	2

	Term. body weight %
[redacted]	

BASF PATHOLOGY REPORT IIB- 16/63
80R0223/11C162
Reproduction/Developmental Toxicity Screening Test in Wistar Rats - Oral Administration (Gavage) 16.Oct.2012 SIBU

RELATIVE WEIGHTS - INDIVIDUAL VALUES

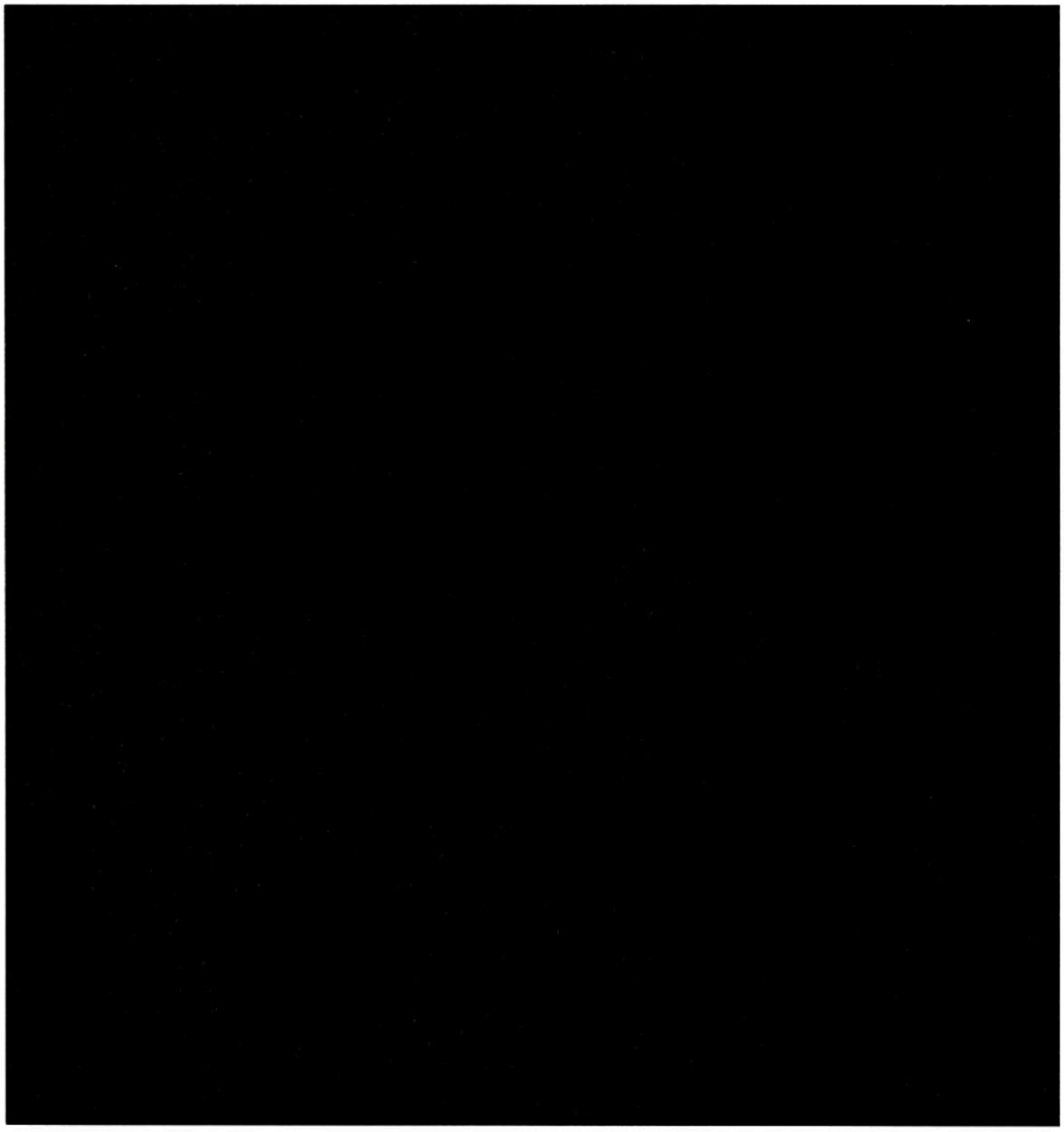
Sacrifice F1
Sex F
Group 3

	Term. body weight %
[redacted]	

BASF PATHOLOGY REPORT IIB- 17/63
80R0223/11C162

Reproduction/Developmental Toxicity Screening Test in Wistar Rats - Oral Administration (Gavage) 16.Oct.2012 SIBU

SINGLE ANIMAL SHEET
(GROSS LESIONS AND MICROSCOPIC FINDINGS)

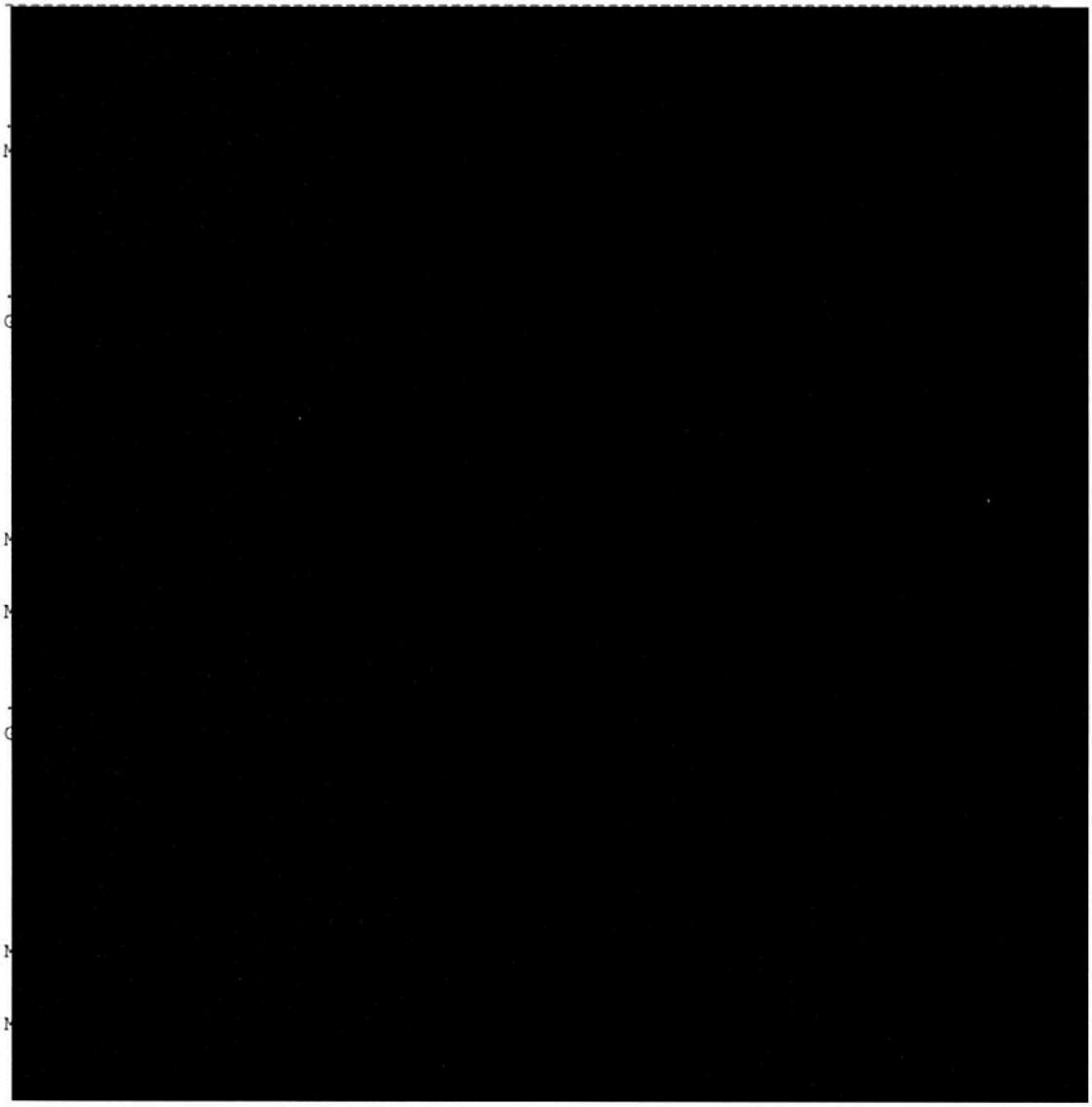


BASF	PATHOLOGY REPORT	IIB- 18/63 80R0223/11C162
Reproduction/Developmental Toxicity Screening Test in Wistar Rats - Oral Administration (Gavage)		16.Oct.2012 SIBU

SINGLE ANIMAL SHEET
(GROSS LESIONS AND MICROSCOPIC FINDINGS)

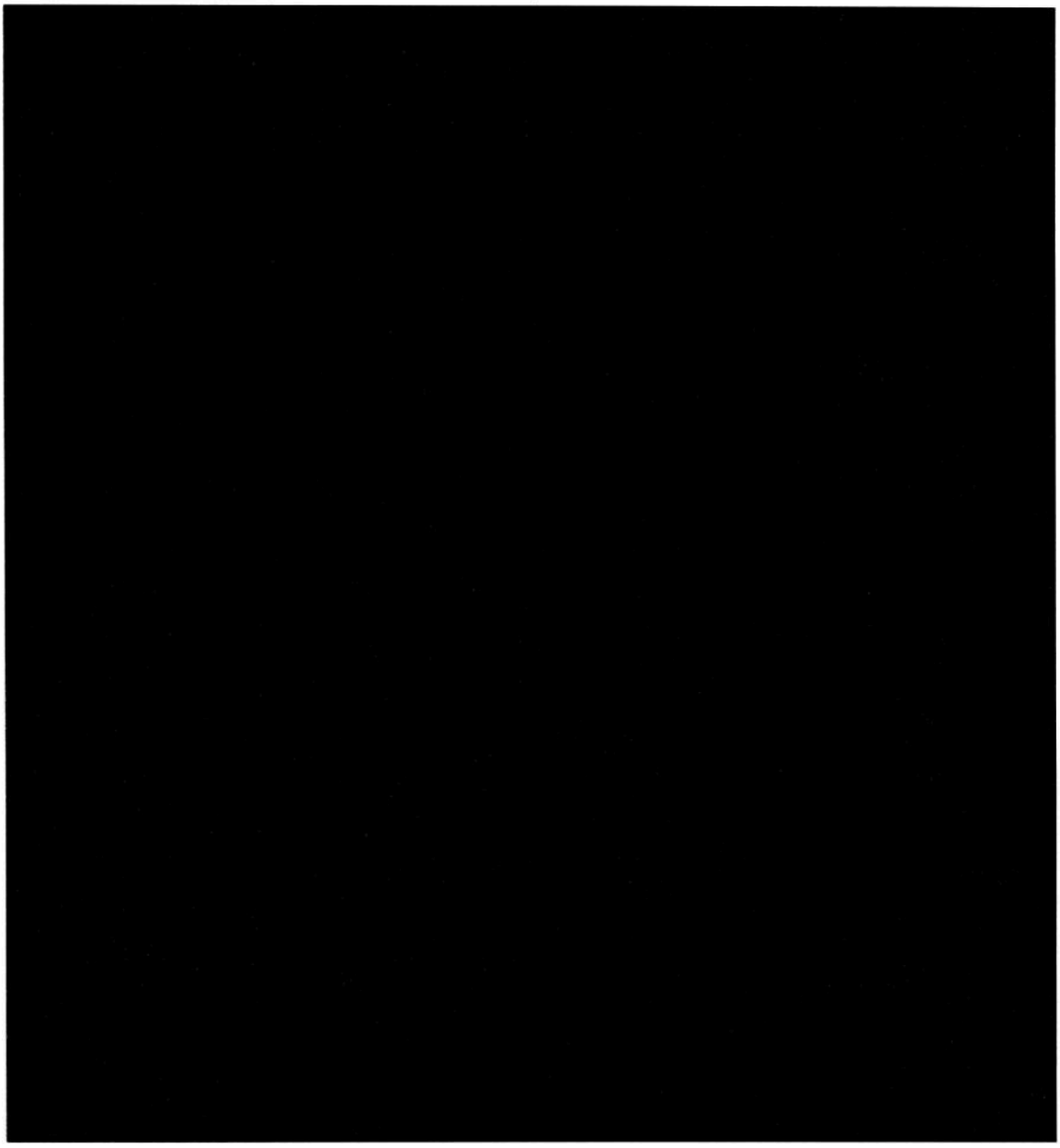
BASF	PATHOLOGY REPORT	IIB- 19/63 80R0223/11C162
Reproduction/Developmental Toxicity Screening Test in Wistar Rats - Oral Administration (Gavage)		16.Oct.2012 SIBU

SINGLE ANIMAL SHEET
(GROSS LESIONS AND MICROSCOPIC FINDINGS)



BASF	PATHOLOGY REPORT	IIB- 20/63 80R0223/11C162
Reproduction/Developmental Toxicity Screening Test in Wistar Rats - Oral Administration (Gavage)		16.Oct.2012 SIBU

SINGLE ANIMAL SHEET
(GROSS LESIONS AND MICROSCOPIC FINDINGS)



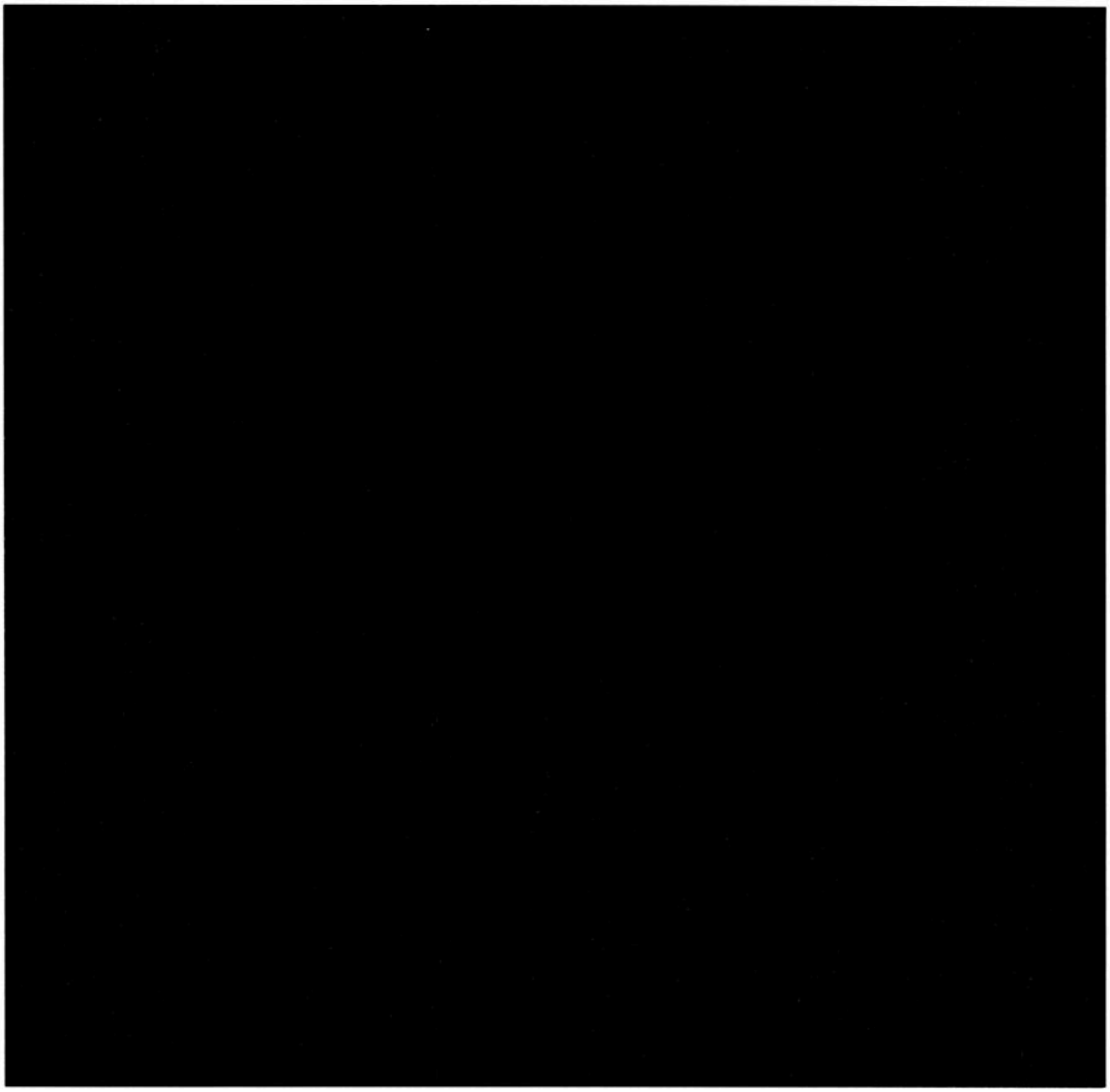
BASF	PATHOLOGY REPORT	IIB- 21/63 80R0223/11C162
Reproduction/Developmental Toxicity Screening Test in Wistar Rats - Oral Administration (Gavage)		16.Oct.2012 SIBU

SINGLE ANIMAL SHEET
(GROSS LESIONS AND MICROSCOPIC FINDINGS)

[redacted]

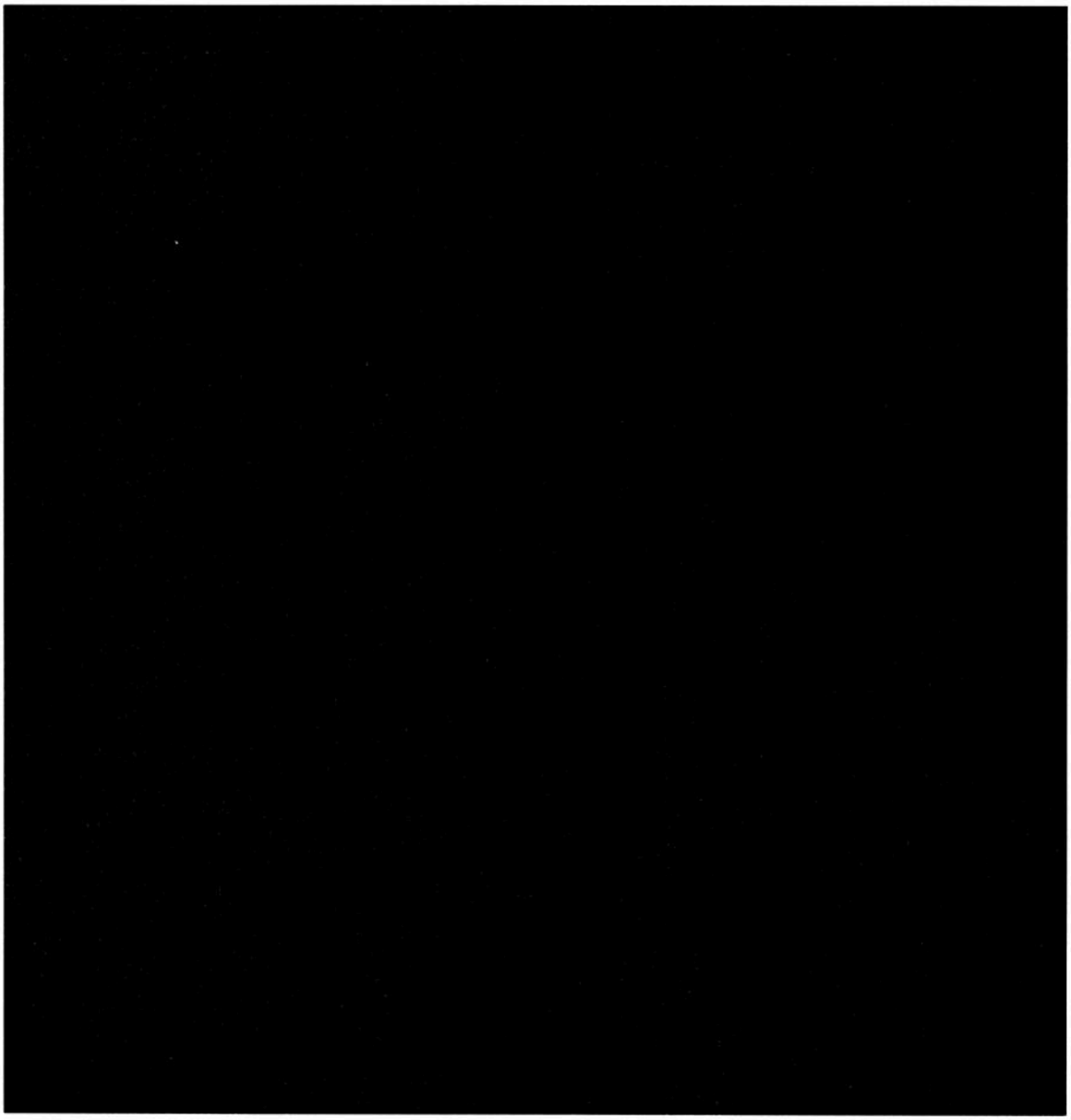
BASF	PATHOLOGY REPORT	IIB- 22/63 80R0223/11C162
Reproduction/Developmental Toxicity Screening Test in Wistar Rats - Oral Administration (Gavage)		16.Oct.2012 SIBU

SINGLE ANIMAL SHEET
(GROSS LESIONS AND MICROSCOPIC FINDINGS)



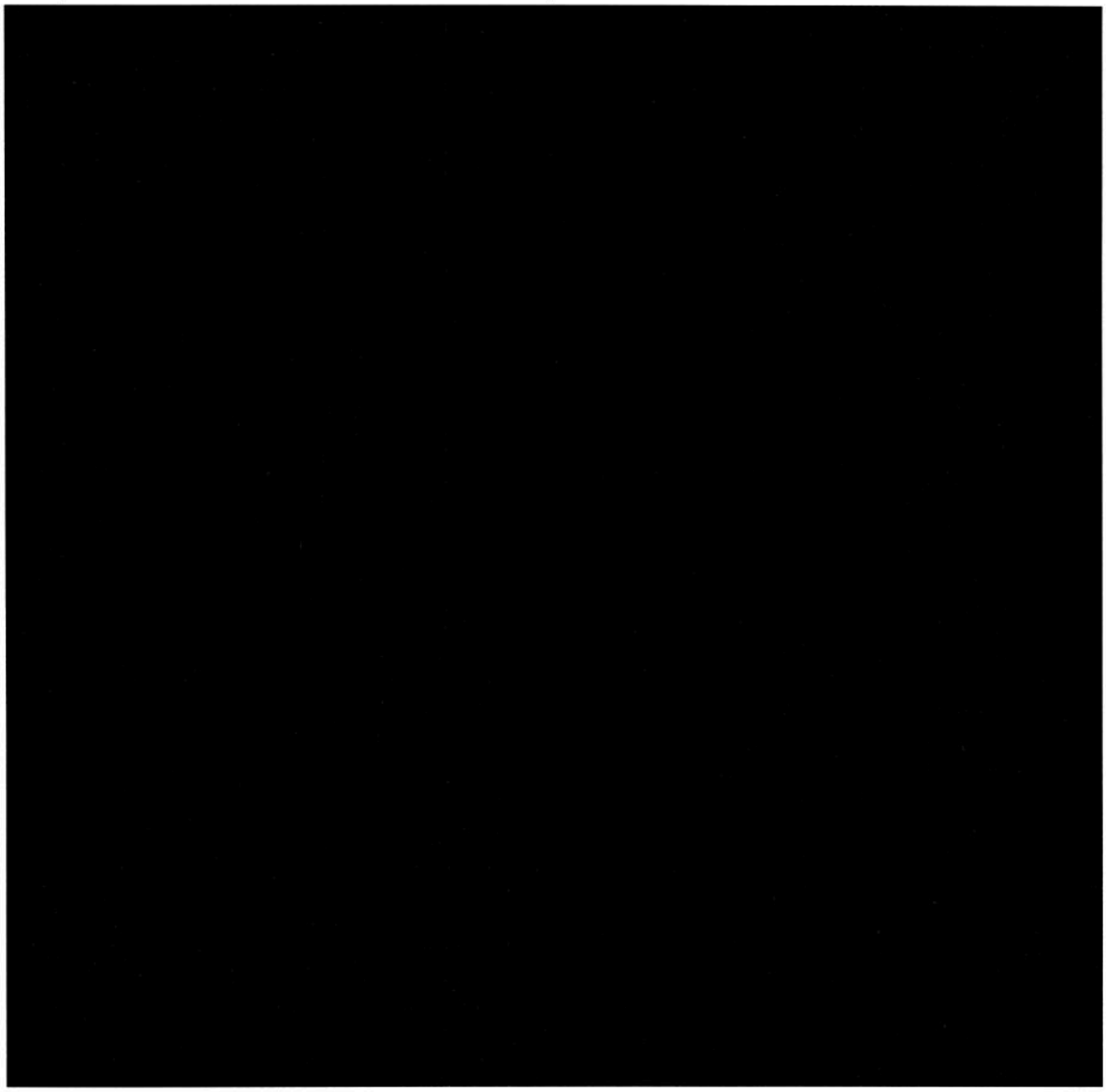
BASF	PATHOLOGY REPORT	IIB- 23/63 80R0223/11C162
Reproduction/Developmental Toxicity Screening Test in Wistar Rats - Oral Administration (Gavage)		16.Oct.2012 SIBU

SINGLE ANIMAL SHEET
(GROSS LESIONS AND MICROSCOPIC FINDINGS)



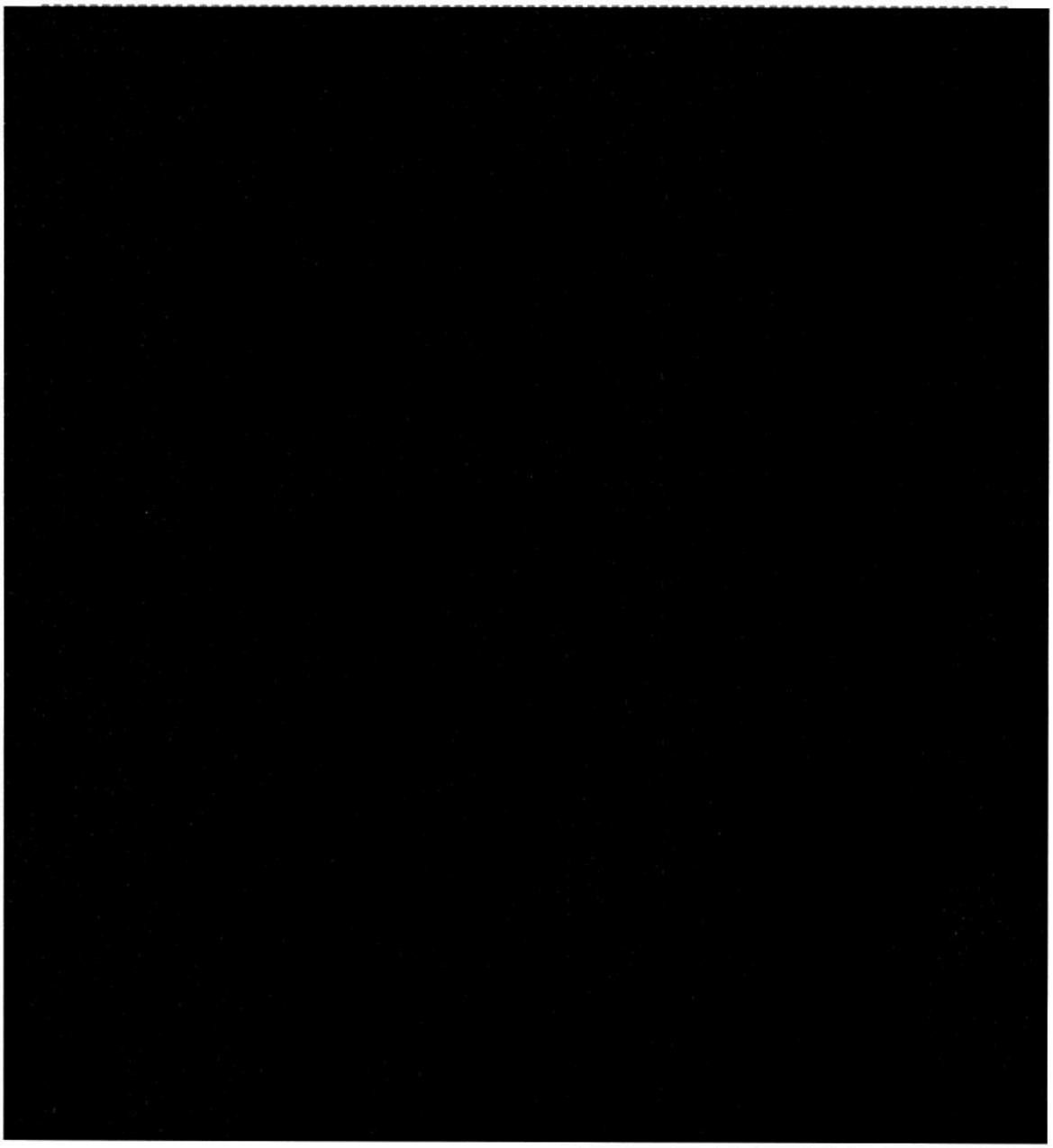
BASF	PATHOLOGY REPORT	IIB- 24/63 80R0223/11C162
Reproduction/Developmental Toxicity Screening Test in Wistar Rats - Oral Administration (Gavage)		16.Oct.2012 SIBU

SINGLE ANIMAL SHEET
(GROSS LESIONS AND MICROSCOPIC FINDINGS)



BASF	PATHOLOGY REPORT	IIB- 25/63 80R0223/11C162
Reproduction/Developmental Toxicity Screening Test in Wistar Rats - Oral Administration (Gavage)		16.Oct.2012 SIBU

SINGLE ANIMAL SHEET
(GROSS LESIONS AND MICROSCOPIC FINDINGS)



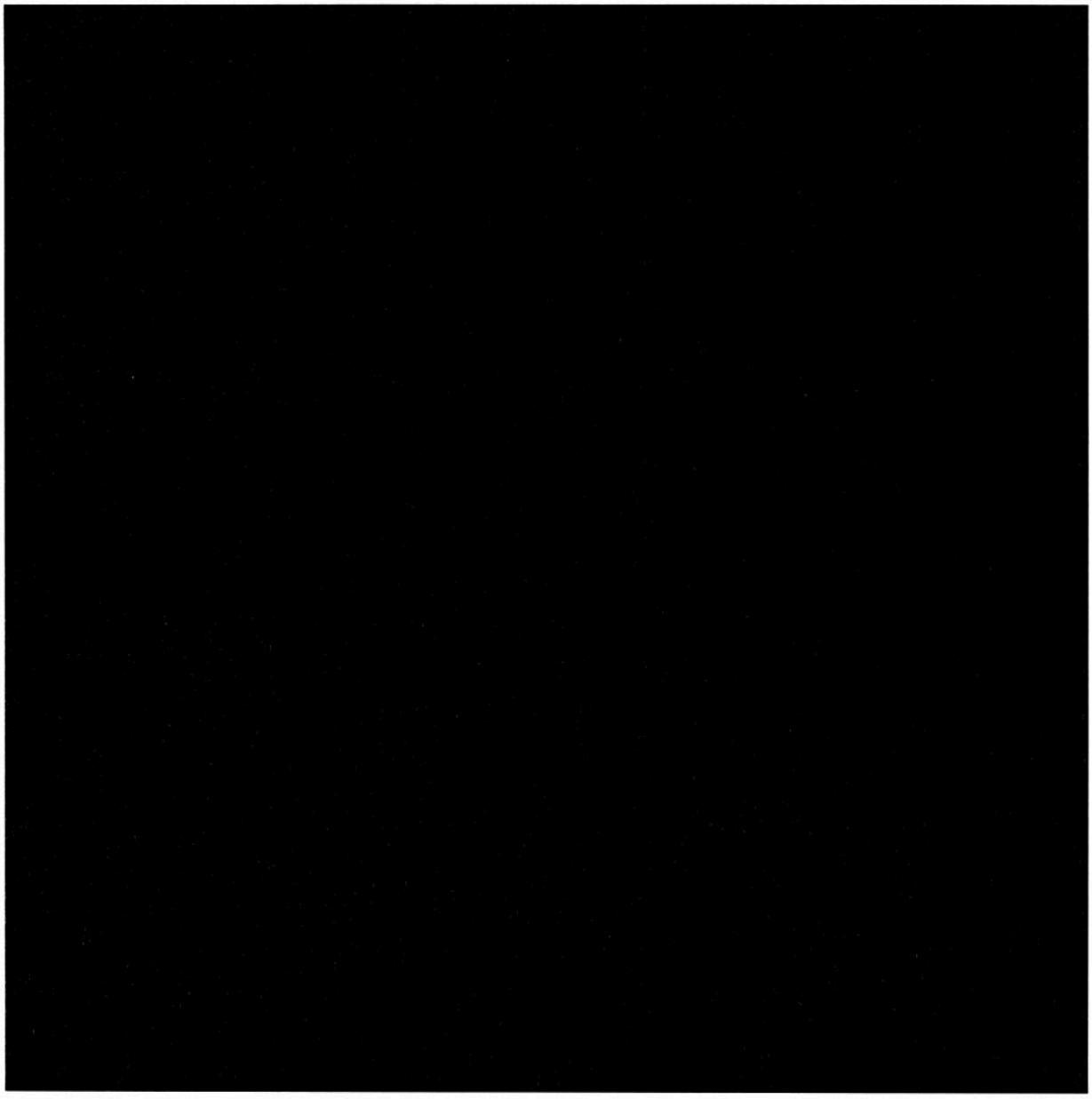
BASF	PATHOLOGY REPORT	IIB- 26/63 80R0223/11C162
Reproduction/Developmental Toxicity Screening Test in Wistar Rats - Oral Administration (Gavage)		16.Oct.2012 SIBU

SINGLE ANIMAL SHEET
(GROSS LESIONS AND MICROSCOPIC FINDINGS)

[redacted]

BASF	PATHOLOGY REPORT	IIB- 27/63 80R0223/11C162
Reproduction/Developmental Toxicity Screening Test in Wistar Rats - Oral Administration (Gavage)		16.Oct.2012 SIBU

SINGLE ANIMAL SHEET
(GROSS LESIONS AND MICROSCOPIC FINDINGS)



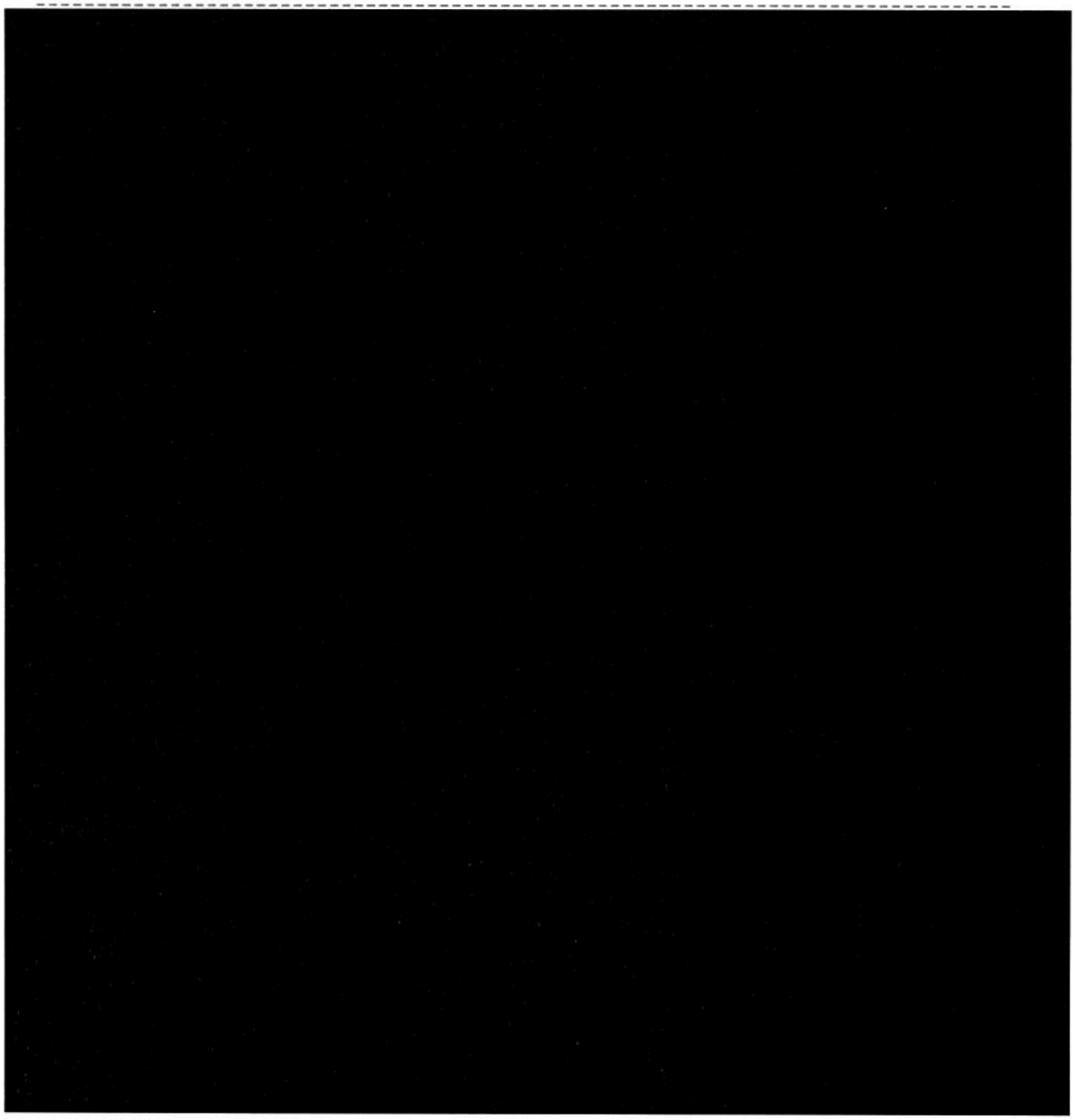
BASF	PATHOLOGY REPORT	IIB- 28/63 80R0223/11C162
Reproduction/Developmental Toxicity Screening Test in Wistar Rats - Oral Administration (Gavage)		16.Oct.2012 SIBU

SINGLE ANIMAL SHEET
(GROSS LESIONS AND MICROSCOPIC FINDINGS)

[redacted]

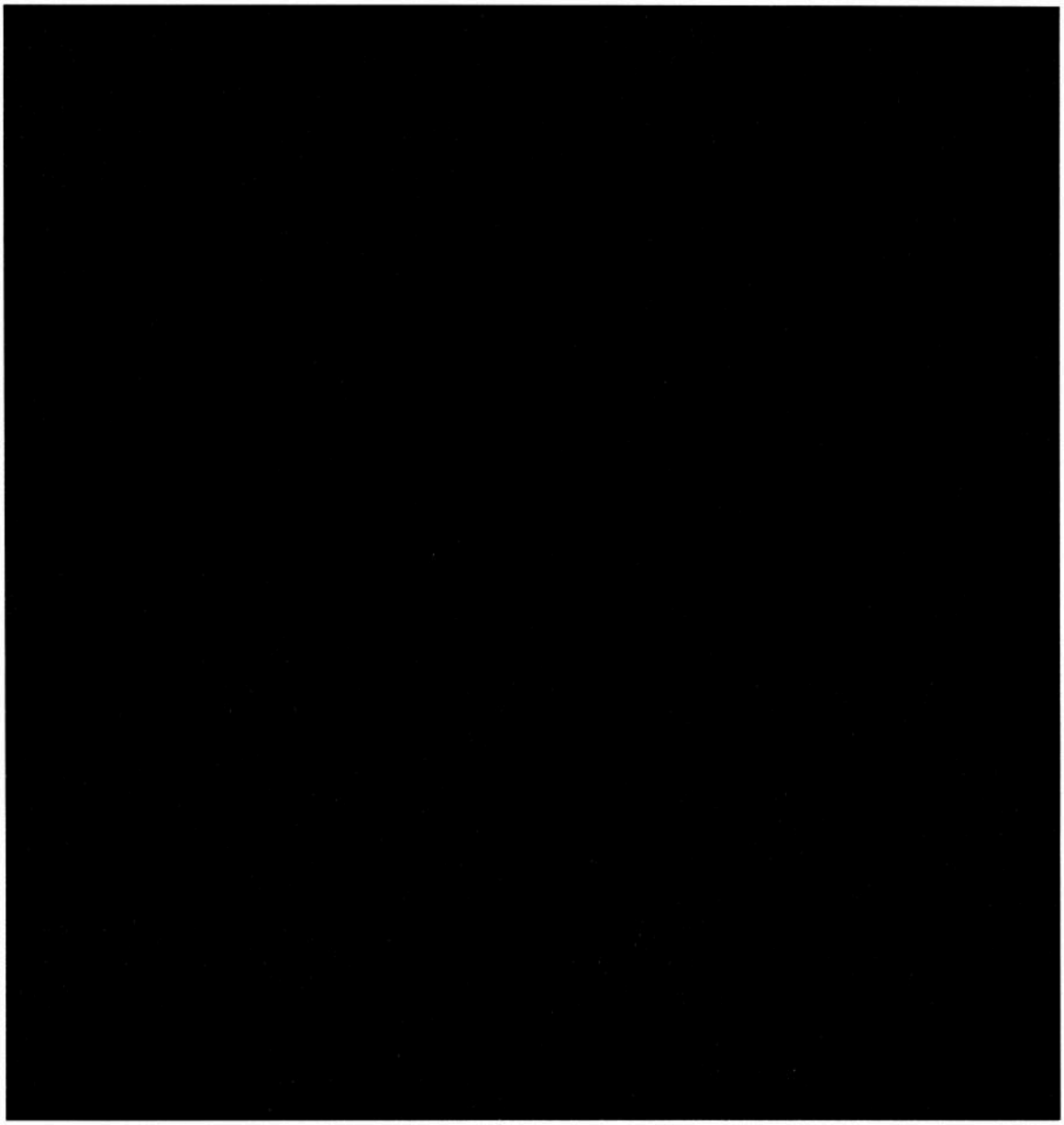
BASF	PATHOLOGY REPORT	IIB- 29/63 80R0223/11C162
Reproduction/Developmental Toxicity Screening Test in Wistar Rats - Oral Administration (Gavage)		16.Oct.2012 SIBU

SINGLE ANIMAL SHEET
(GROSS LESIONS AND MICROSCOPIC FINDINGS)



BASF	PATHOLOGY REPORT	IIB- 30/63 80R0223/11C162
Reproduction/Developmental Toxicity Screening Test in Wistar Rats - Oral Administration (Gavage)		16.Oct.2012 SIBU

SINGLE ANIMAL SHEET
(GROSS LESIONS AND MICROSCOPIC FINDINGS)



BASF	PATHOLOGY REPORT	IIB- 31/63 80R0223/11C162
Reproduction/Developmental Toxicity Screening Test in Wistar Rats - Oral Administration (Gavage)		16.Oct.2012 SIBU

SINGLE ANIMAL SHEET
(GROSS LESIONS AND MICROSCOPIC FINDINGS)

[redacted]

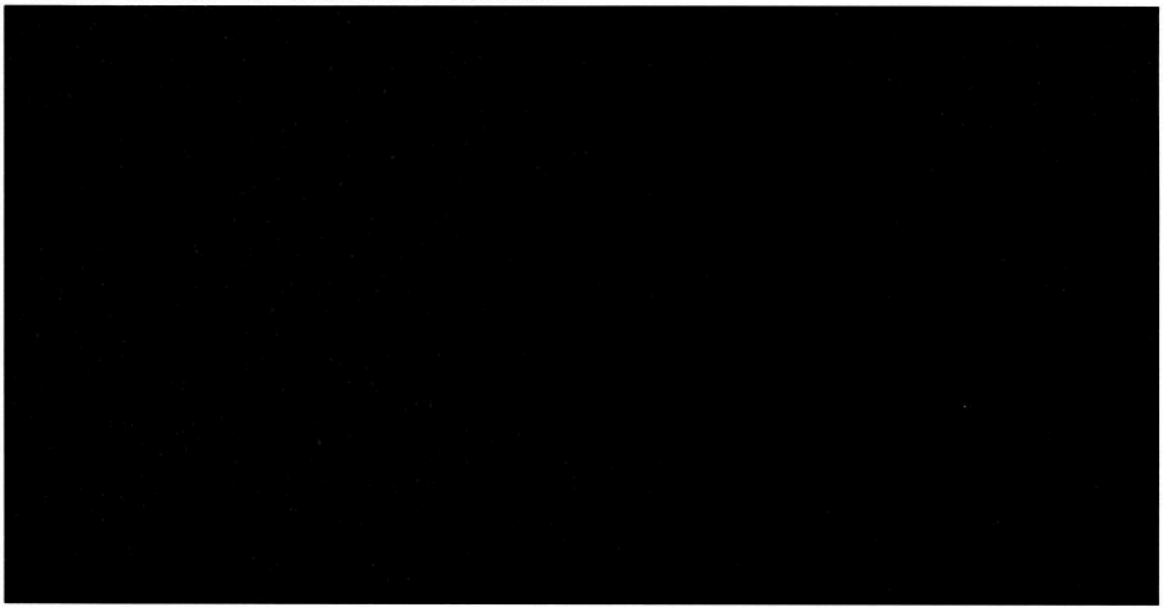
BASF	PATHOLOGY REPORT	IIB- 32/63 80R0223/11C162
Reproduction/Developmental Toxicity Screening Test in Wistar Rats - Oral Administration (Gavage)		16.Oct.2012 SIBU

SINGLE ANIMAL SHEET
(GROSS LESIONS AND MICROSCOPIC FINDINGS)

[redacted]

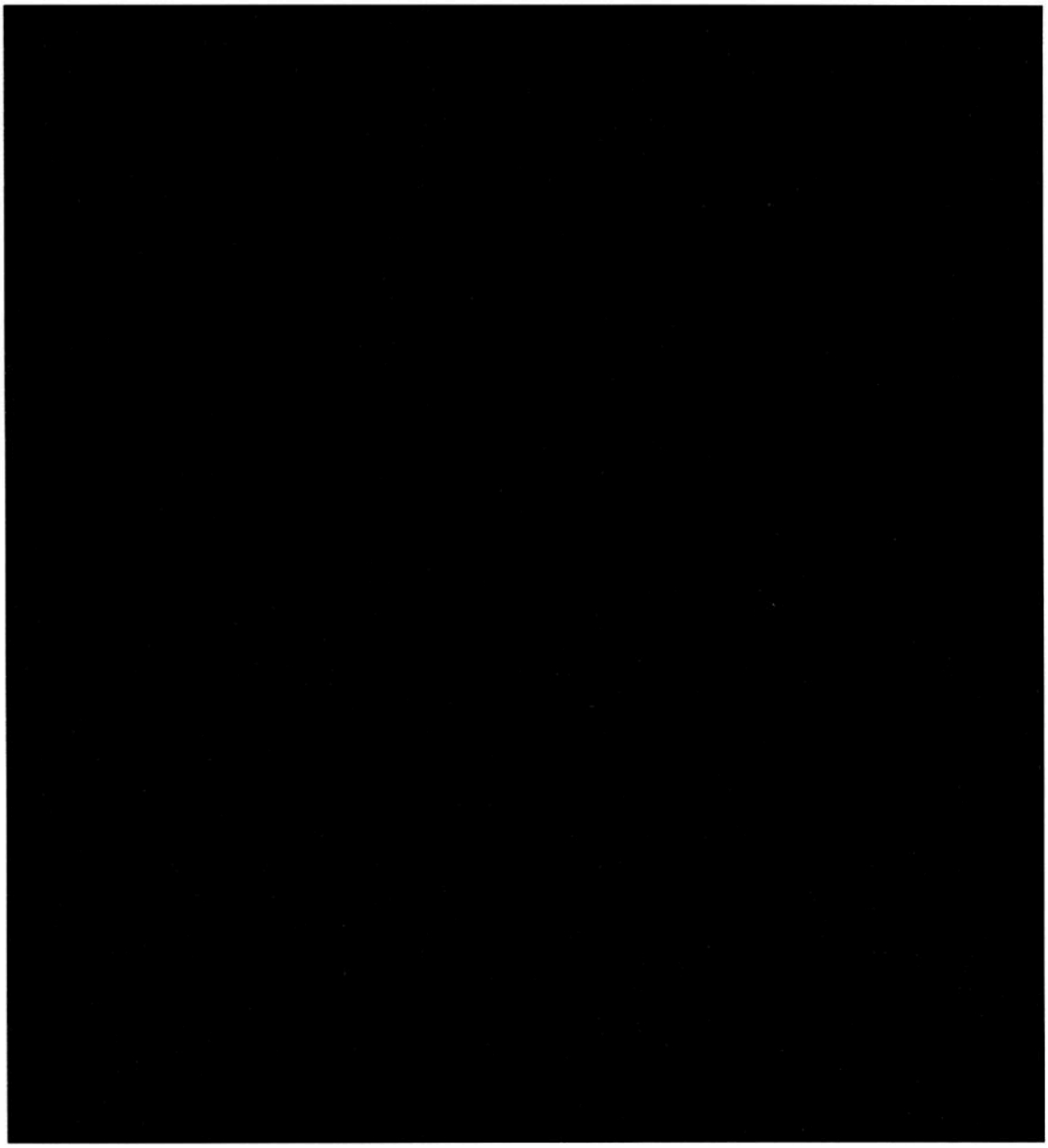
BASF	PATHOLOGY REPORT	IIB- 33/63 80R0223/11C162
Reproduction/Developmental Toxicity Screening Test in Wistar Rats - Oral Administration (Gavage)		16.Oct.2012 SIBU

SINGLE ANIMAL SHEET
(GROSS LESIONS AND MICROSCOPIC FINDINGS)



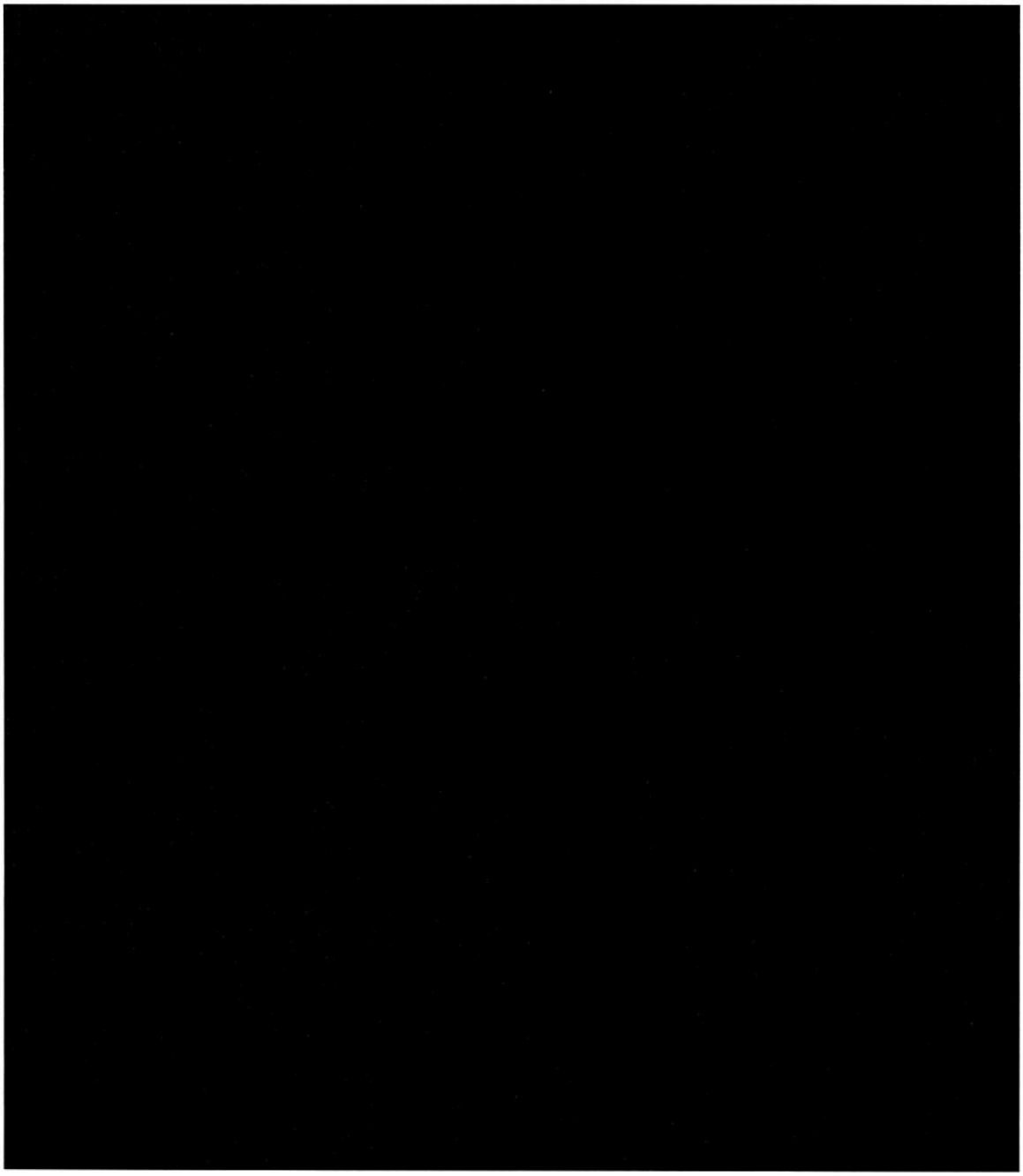
BASF	PATHOLOGY REPORT	IIB- 34/63 80R0223/11C162
Reproduction/Developmental Toxicity Screening Test in Wistar Rats - Oral Administration (Gavage)		16.Oct.2012 SIBU

SINGLE ANIMAL SHEET
(GROSS LESIONS AND MICROSCOPIC FINDINGS)



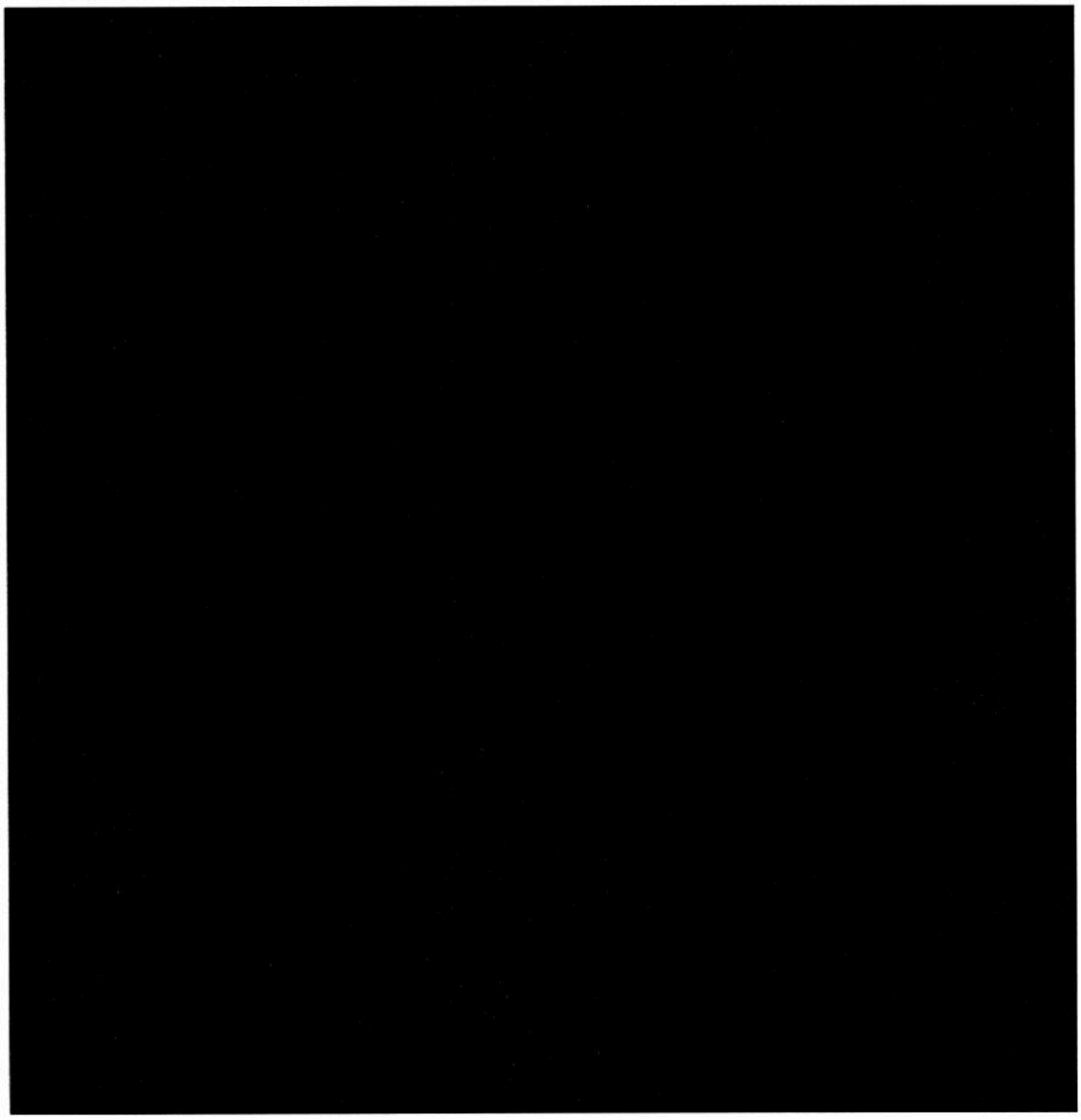
BASF	PATHOLOGY REPORT	IIB- 35/63 80R0223/11C162
Reproduction/Developmental Toxicity Screening Test in Wistar Rats - Oral Administration (Gavage)		16.Oct.2012 SIBU

SINGLE ANIMAL SHEET
(GROSS LESIONS AND MICROSCOPIC FINDINGS)



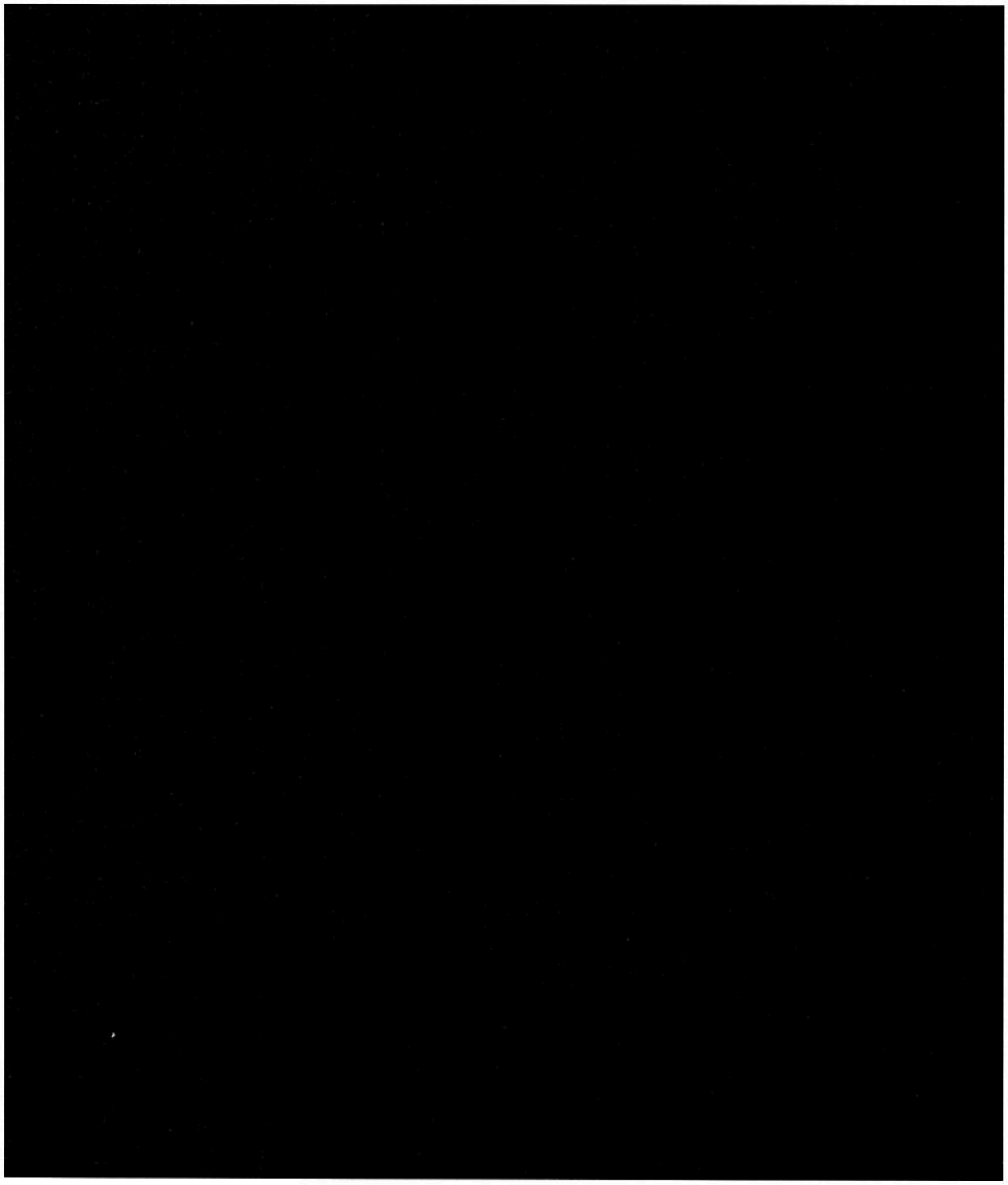
BASF	PATHOLOGY REPORT	IIB- 36/63 80R0223/11C162
Reproduction/Developmental Toxicity Screening Test in Wistar Rats - Oral Administration (Gavage)		16.Oct.2012 SIBU

SINGLE ANIMAL SHEET
(GROSS LESIONS AND MICROSCOPIC FINDINGS)



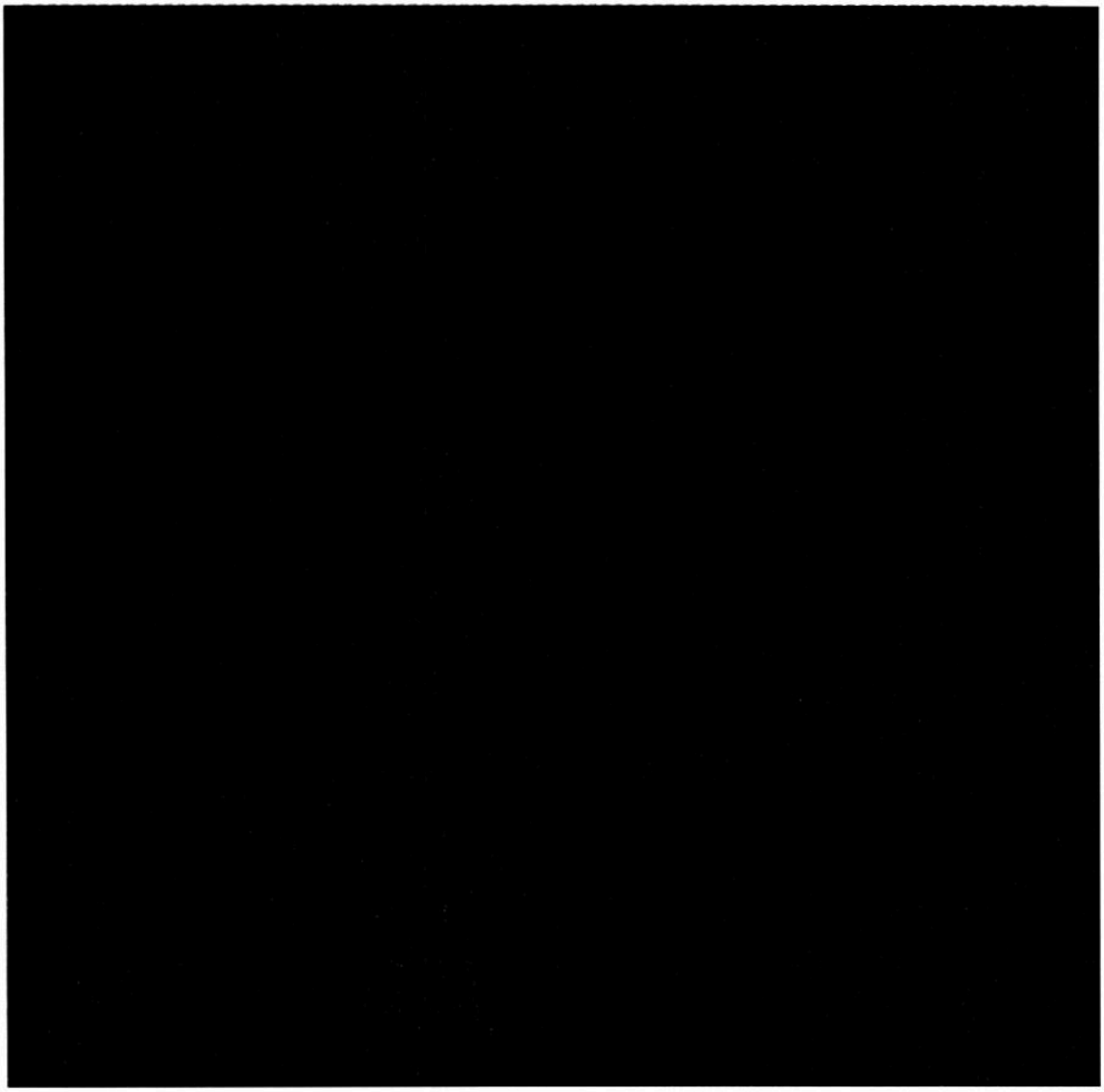
BASF	PATHOLOGY REPORT	IIB- 37/63 80R0223/11C162
Reproduction/Developmental Toxicity Screening Test in Wistar Rats - Oral Administration (Gavage)		16.Oct.2012 SIBU

SINGLE ANIMAL SHEET
(GROSS LESIONS AND MICROSCOPIC FINDINGS)



BASF	PATHOLOGY REPORT	IIB- 38/63 80R0223/11C162
Reproduction/Developmental Toxicity Screening Test in Wistar Rats - Oral Administration (Gavage)		16.Oct.2012 SIBU

SINGLE ANIMAL SHEET
(GROSS LESIONS AND MICROSCOPIC FINDINGS)



BASF	PATHOLOGY REPORT	IIB- 39/63 80R0223/11C162
Reproduction/Developmental Toxicity Screening Test in Wistar Rats - Oral Administration (Gavage)		16.Oct.2012 SIBU

SINGLE ANIMAL SHEET
(GROSS LESIONS AND MICROSCOPIC FINDINGS)

[redacted]

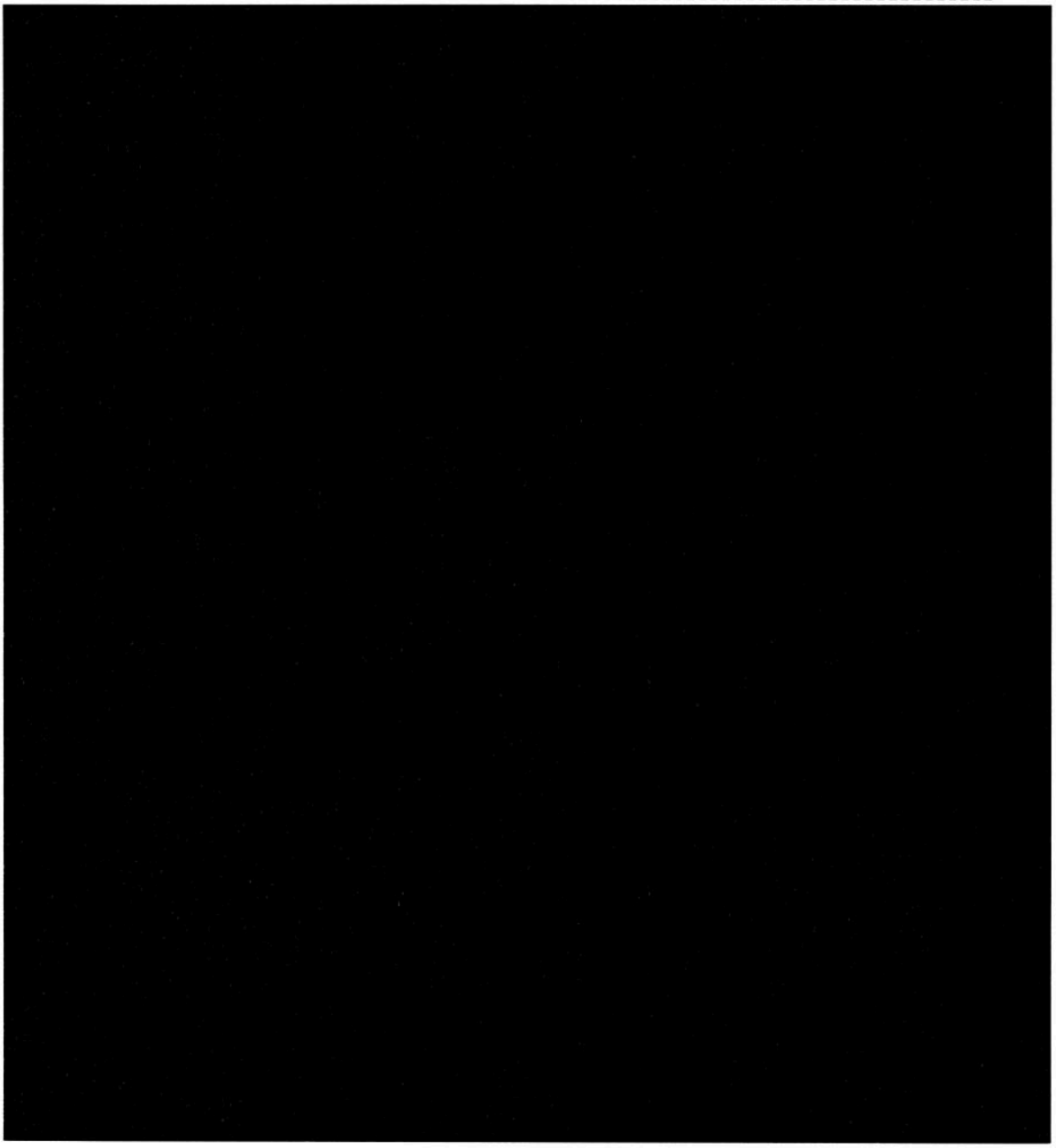
BASF	PATHOLOGY REPORT	IIB- 40/63 80R0223/11C162
Reproduction/Developmental Toxicity Screening Test in Wistar Rats - Oral Administration (Gavage)		16.Oct.2012 SIBU

SINGLE ANIMAL SHEET
(GROSS LESIONS AND MICROSCOPIC FINDINGS)

[redacted]

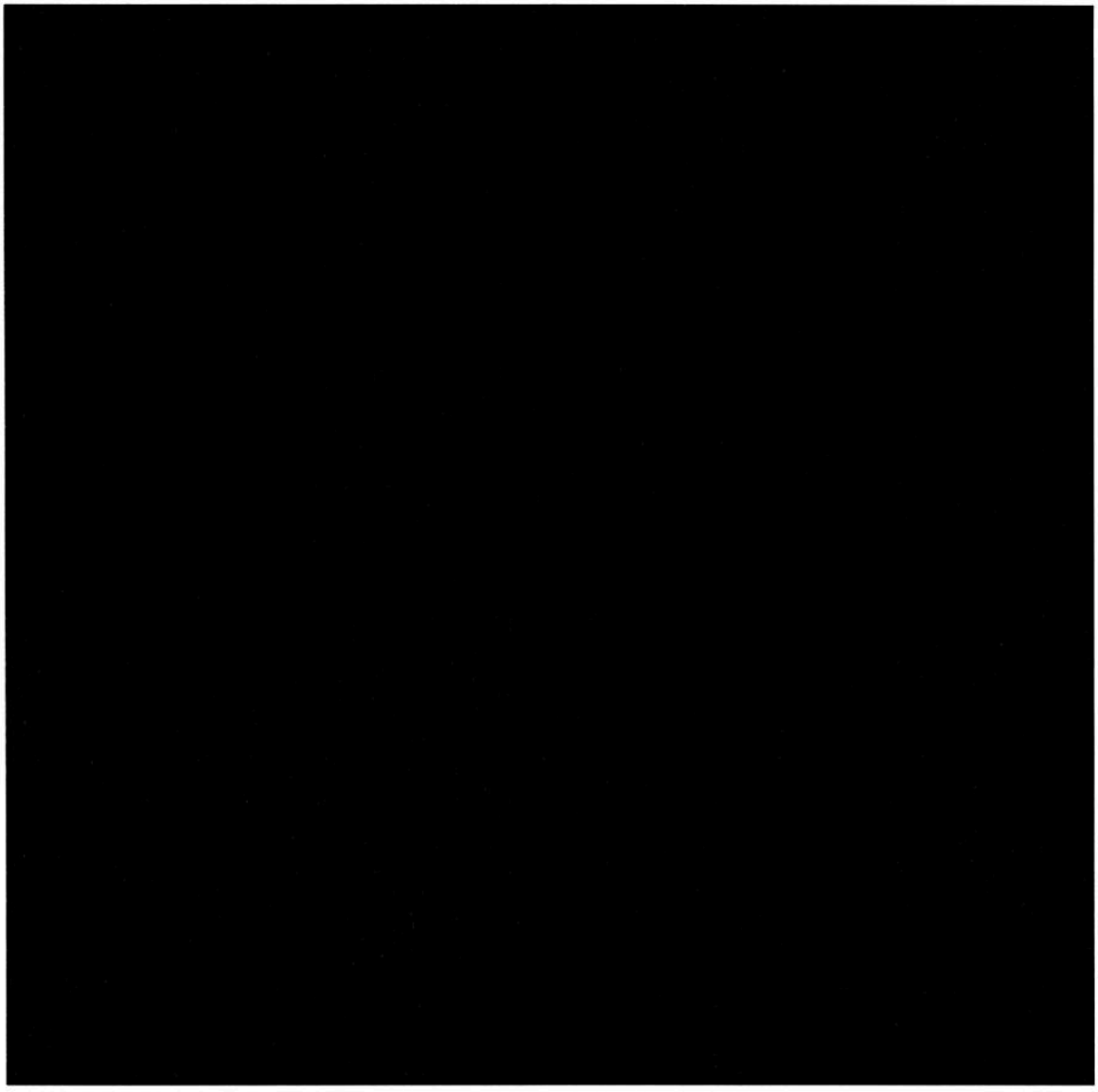
BASF	PATHOLOGY REPORT	IIB- 41/63 80R0223/11C162
Reproduction/Developmental Toxicity Screening Test in Wistar Rats - Oral Administration (Gavage)		16.Oct.2012 SIBU

SINGLE ANIMAL SHEET
(GROSS LESIONS AND MICROSCOPIC FINDINGS)



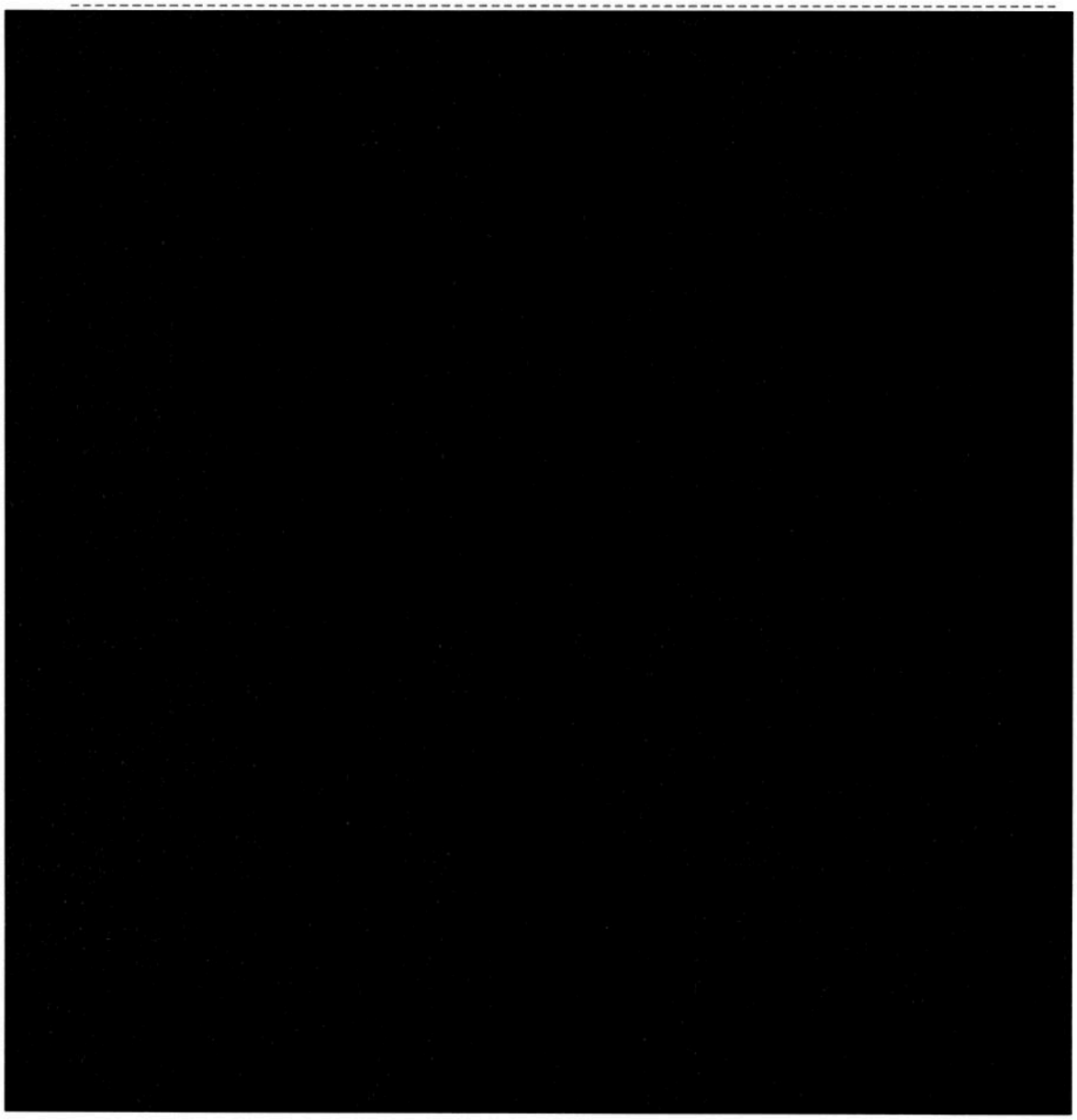
BASF	PATHOLOGY REPORT	IIB- 42/63 80R0223/11C162
Reproduction/Developmental Toxicity Screening Test in Wistar Rats - Oral Administration (Gavage)		16.Oct.2012 SIBU

SINGLE ANIMAL SHEET
(GROSS LESIONS AND MICROSCOPIC FINDINGS)



BASF	PATHOLOGY REPORT	IIB- 43/63 80R0223/11C162
Reproduction/Developmental Toxicity Screening Test in Wistar Rats - Oral Administration (Gavage)		16.Oct.2012 SIBU

SINGLE ANIMAL SHEET
(GROSS LESIONS AND MICROSCOPIC FINDINGS)



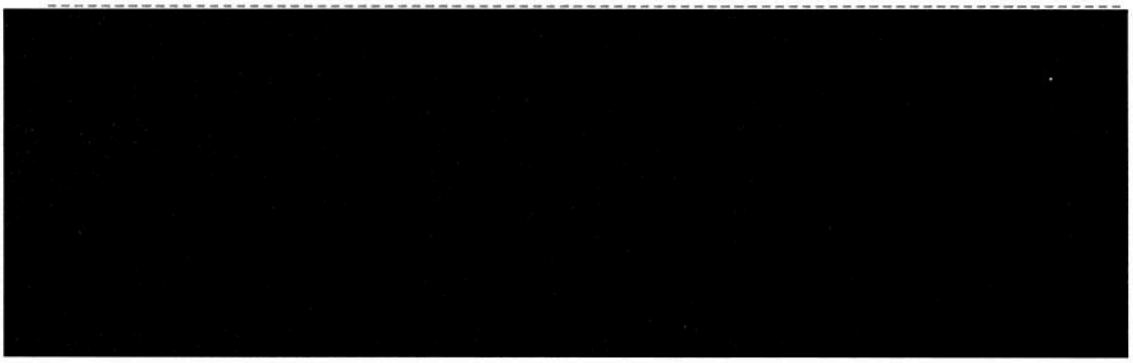
BASF	PATHOLOGY REPORT	IIB- 44/63 80R0223/11C162
Reproduction/Developmental Toxicity Screening Test in Wistar Rats - Oral Administration (Gavage)		16.Oct.2012 SIBU

SINGLE ANIMAL SHEET
(GROSS LESIONS AND MICROSCOPIC FINDINGS)

[redacted]

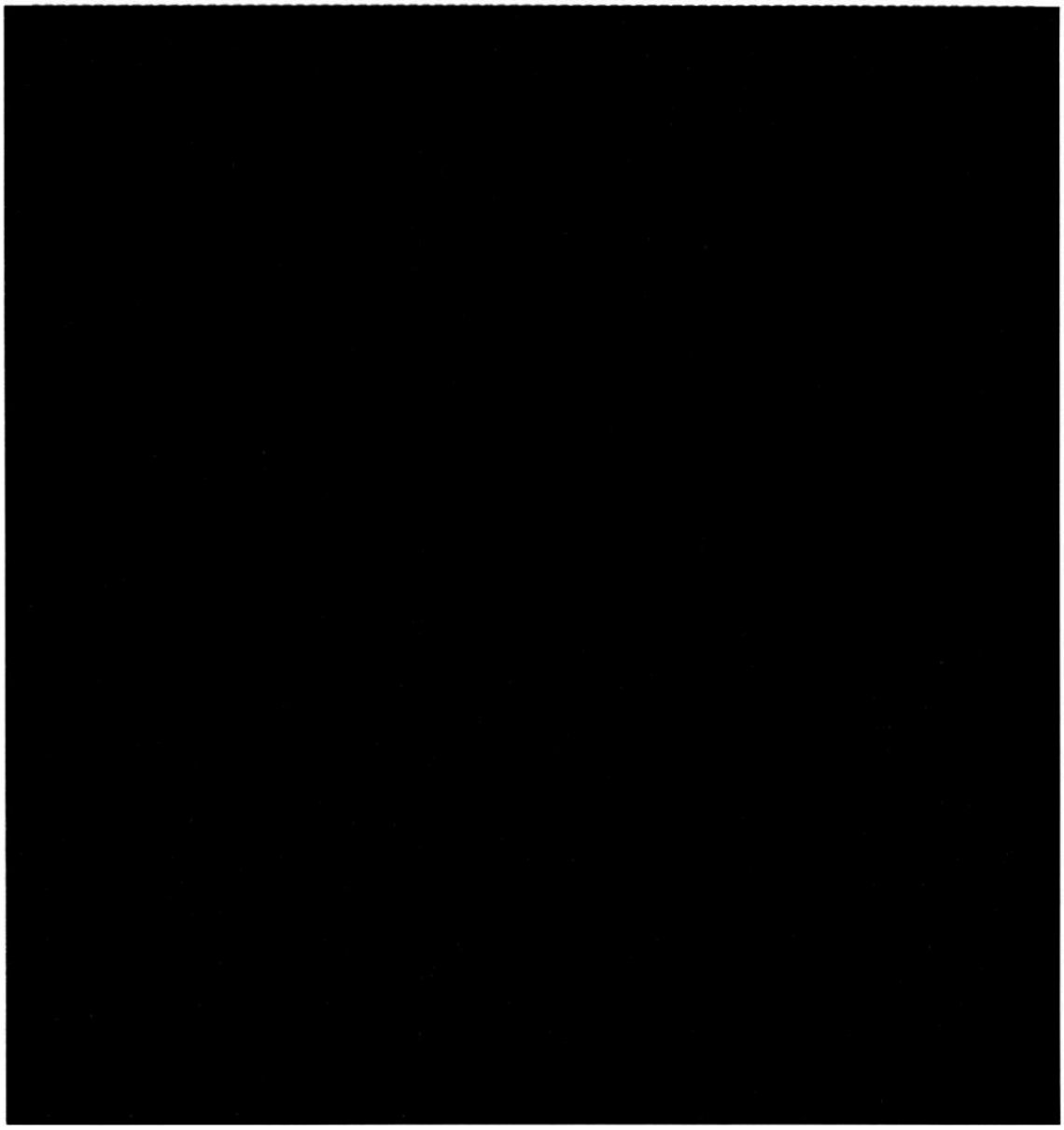
BASF	PATHOLOGY REPORT	IIB- 45/63 80R0223/11C162
Reproduction/Developmental Toxicity Screening Test in Wistar Rats - Oral Administration (Gavage)		16.Oct.2012 SIBU

SINGLE ANIMAL SHEET
(GROSS LESIONS AND MICROSCOPIC FINDINGS)



BASF	PATHOLOGY REPORT	IIB- 46/63 80R0223/11C162
Reproduction/Developmental Toxicity Screening Test in Wistar Rats - Oral Administration (Gavage)		16.Oct.2012 SIBU

SINGLE ANIMAL SHEET
(GROSS LESIONS AND MICROSCOPIC FINDINGS)



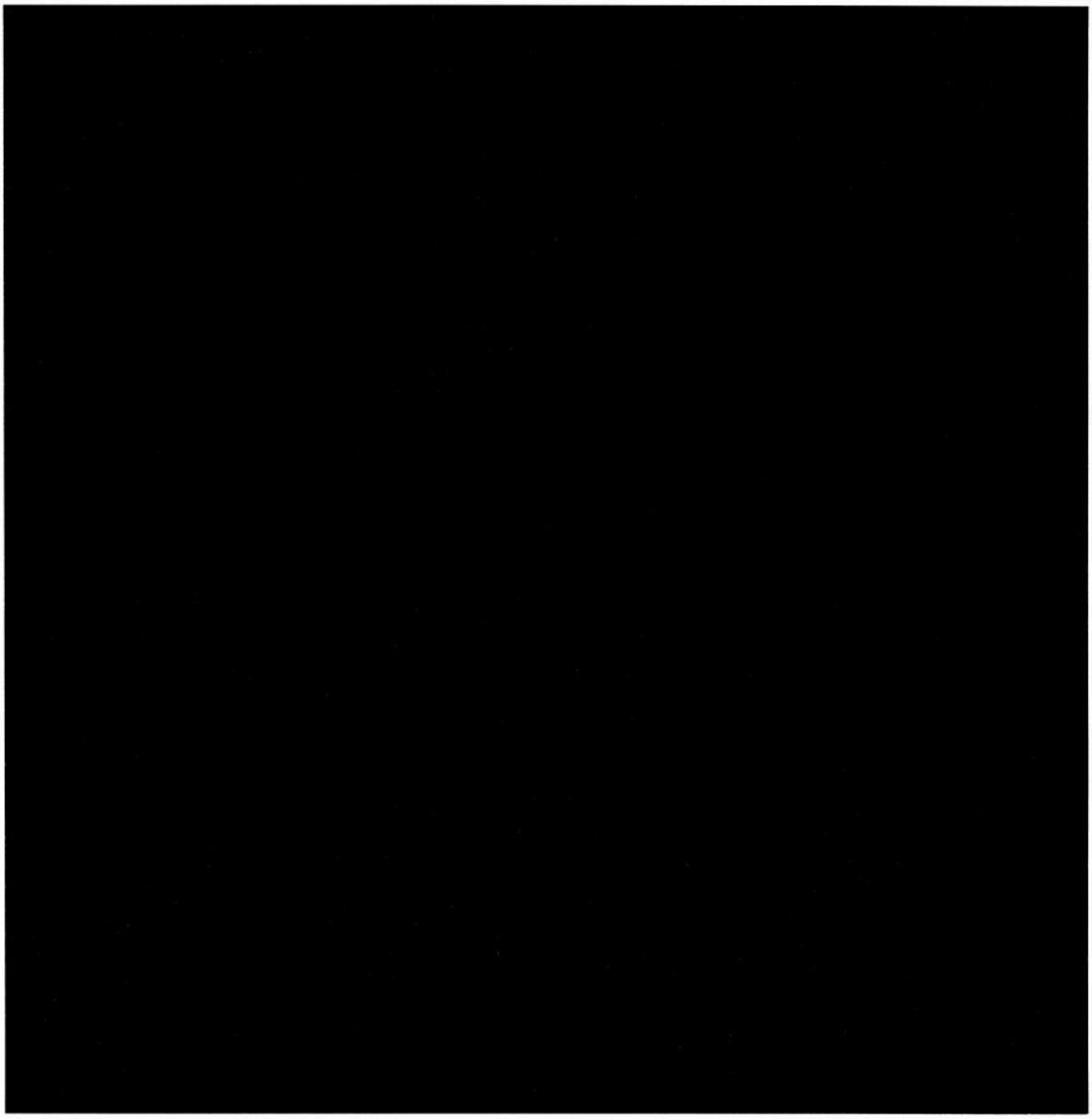
BASF	PATHOLOGY REPORT	IIB- 47/63 80R0223/11C162
Reproduction/Developmental Toxicity Screening Test in Wistar Rats - Oral Administration (Gavage)		16.Oct.2012 SIBU

SINGLE ANIMAL SHEET
(GROSS LESIONS AND MICROSCOPIC FINDINGS)

[redacted]

BASF	PATHOLOGY REPORT	IIB- 48/63 80R0223/11C162
Reproduction/Developmental Toxicity Screening Test in Wistar Rats - Oral Administration (Gavage)		16.Oct.2012 SIBU

SINGLE ANIMAL SHEET
(GROSS LESIONS AND MICROSCOPIC FINDINGS)



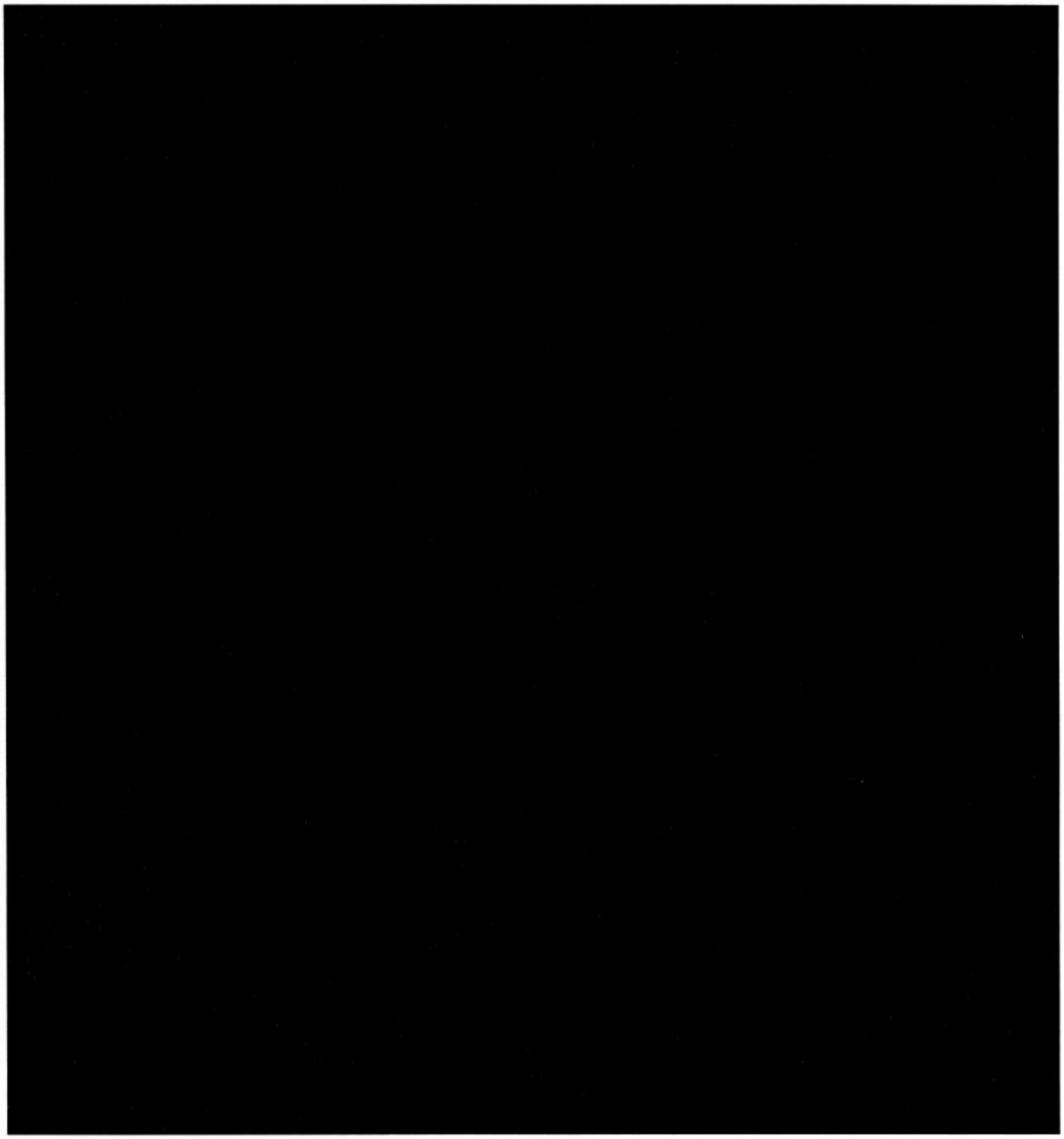
BASF	PATHOLOGY REPORT	IIB- 49/63 80R0223/11C162
Reproduction/Developmental Toxicity Screening Test in Wistar Rats - Oral Administration (Gavage)		16.Oct.2012 SIBU

SINGLE ANIMAL SHEET
(GROSS LESIONS AND MICROSCOPIC FINDINGS)

[redacted]

BASF	PATHOLOGY REPORT	IIB- 50/63 80R0223/11C162
Reproduction/Developmental Toxicity Screening Test in Wistar Rats - Oral Administration (Gavage)		16.Oct.2012 SIBU

SINGLE ANIMAL SHEET
(GROSS LESIONS AND MICROSCOPIC FINDINGS)



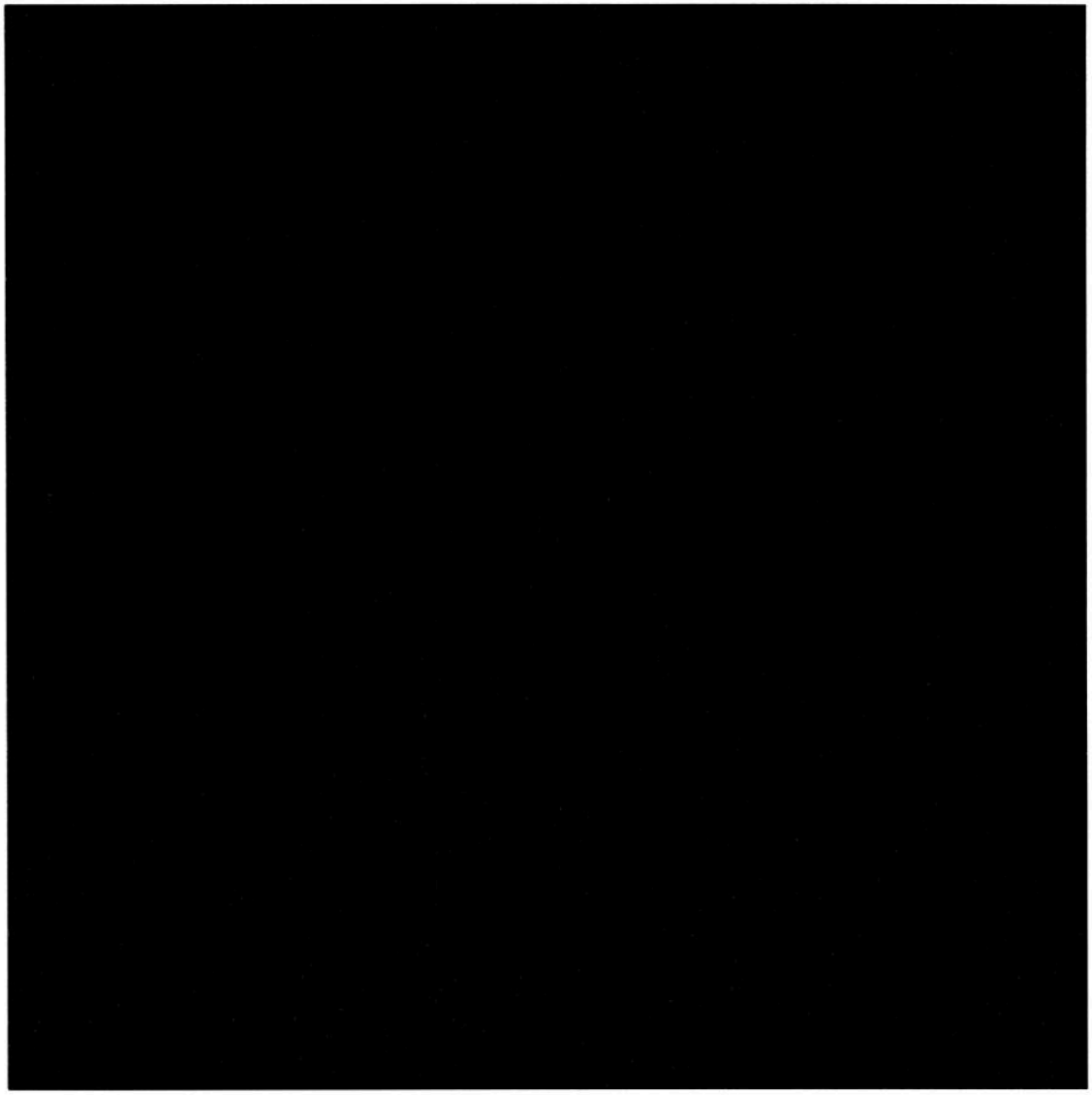
BASF	PATHOLOGY REPORT	IIB- 51/63 80R0223/11C162
Reproduction/Developmental Toxicity Screening Test in Wistar Rats - Oral Administration (Gavage)		16.Oct.2012 SIBU

SINGLE ANIMAL SHEET
(GROSS LESIONS AND MICROSCOPIC FINDINGS)

[redacted]

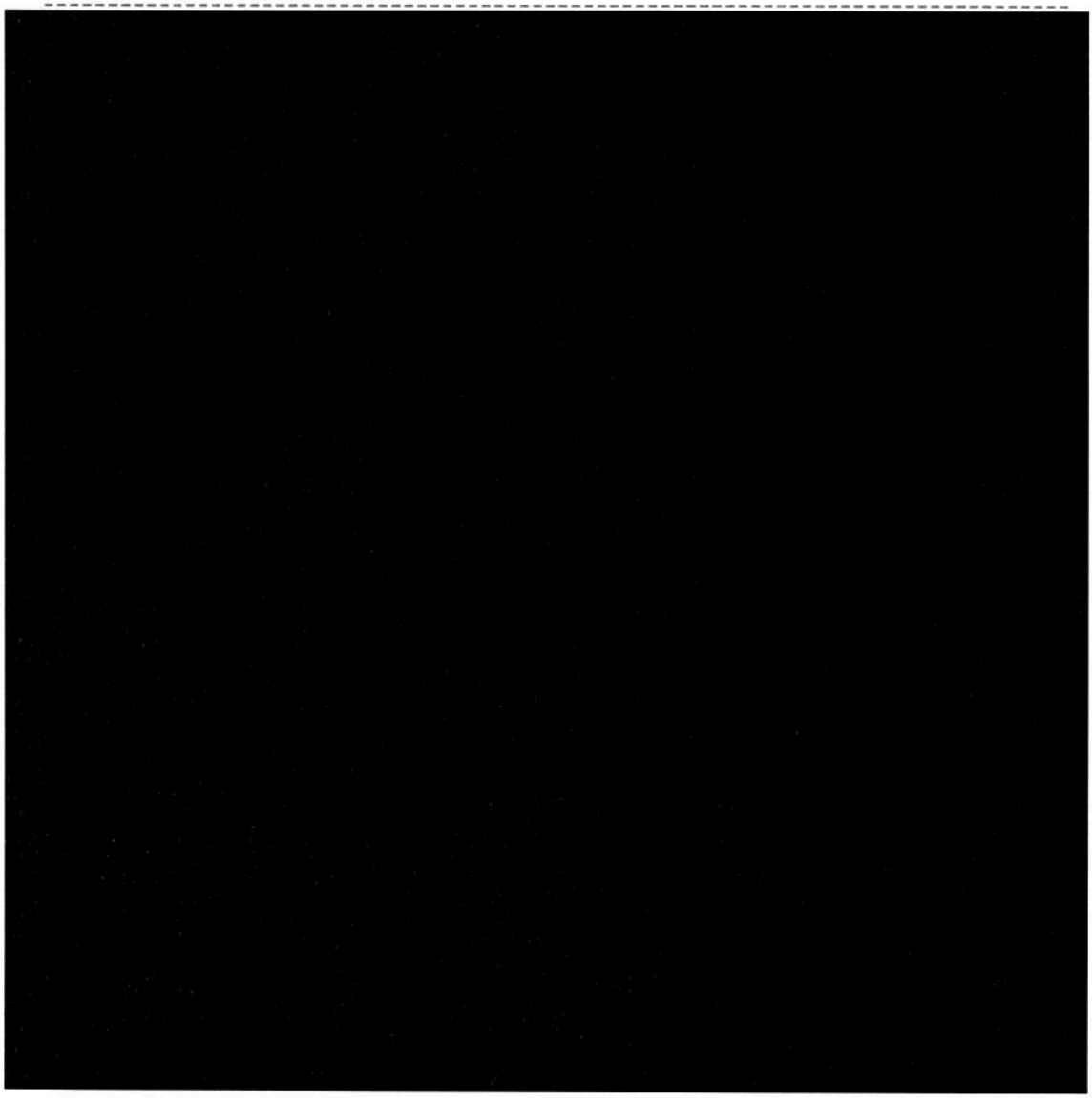
BASF	PATHOLOGY REPORT	IIB- 52/63 80R0223/11C162
Reproduction/Developmental Toxicity Screening Test in Wistar Rats - Oral Administration (Gavage)		16.Oct.2012 SIBU

SINGLE ANIMAL SHEET
(GROSS LESIONS AND MICROSCOPIC FINDINGS)



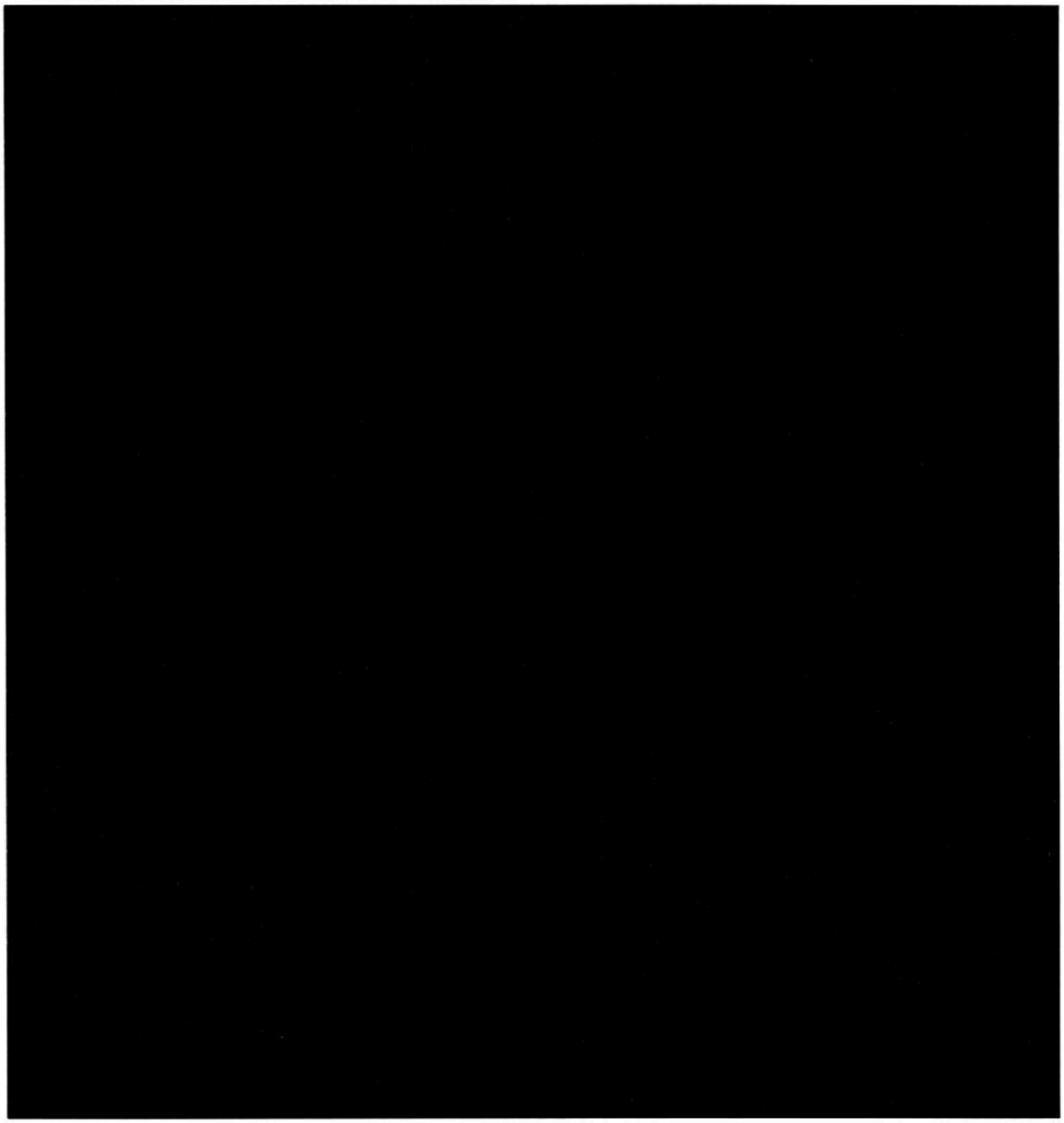
BASF	PATHOLOGY REPORT	IIB- 53/63 80R0223/11C162
Reproduction/Developmental Toxicity Screening Test in Wistar Rats - Oral Administration (Gavage)		16.Oct.2012 SIBU

SINGLE ANIMAL SHEET
(GROSS LESIONS AND MICROSCOPIC FINDINGS)



BASF	PATHOLOGY REPORT	IIB- 54/63 80R0223/11C162
Reproduction/Developmental Toxicity Screening Test in Wistar Rats - Oral Administration (Gavage)		16.Oct.2012 SIBU

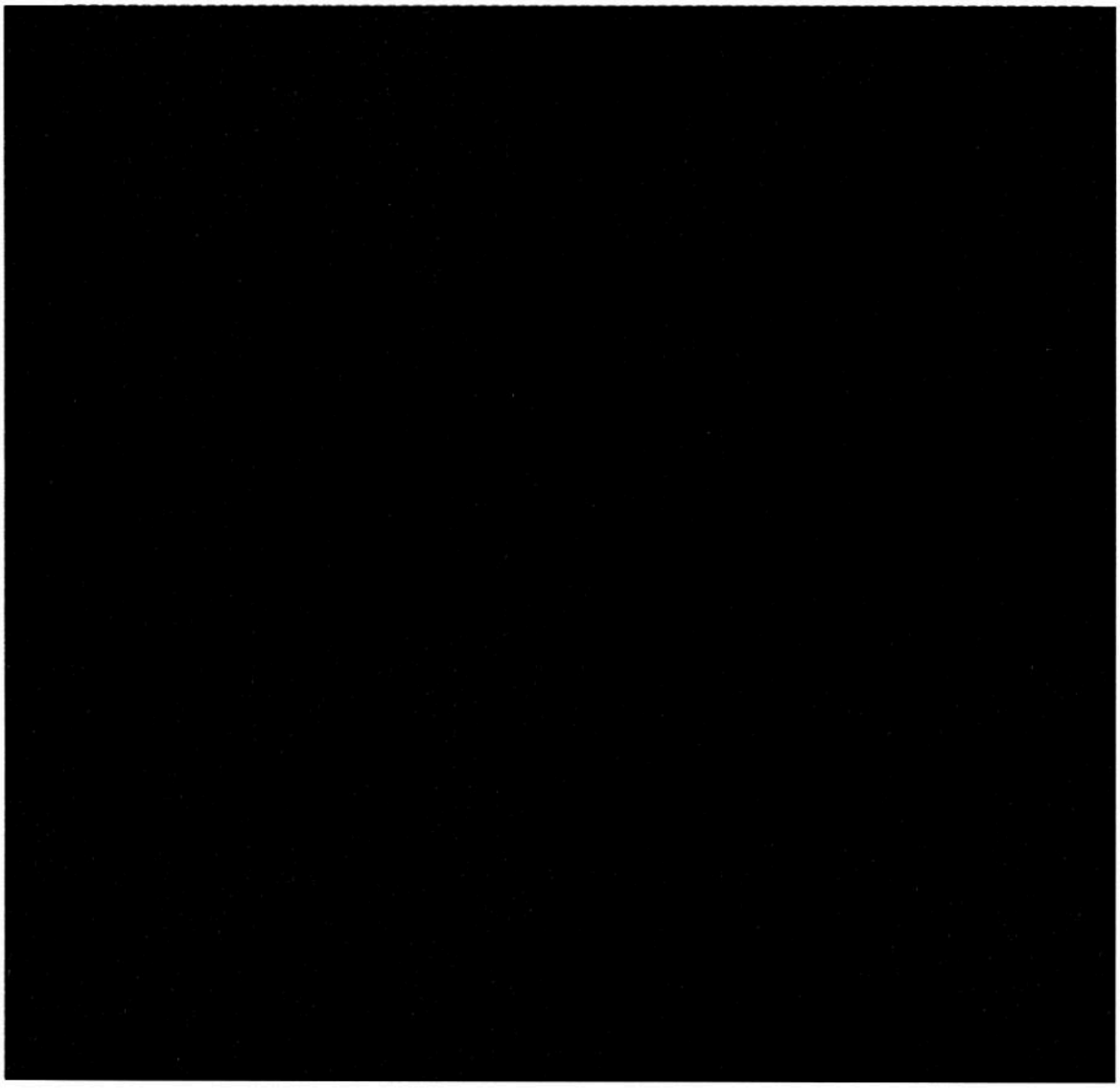
SINGLE ANIMAL SHEET
(GROSS LESIONS AND MICROSCOPIC FINDINGS)



BASF PATHOLOGY REPORT IIB- 55/63
80R0223/11C162

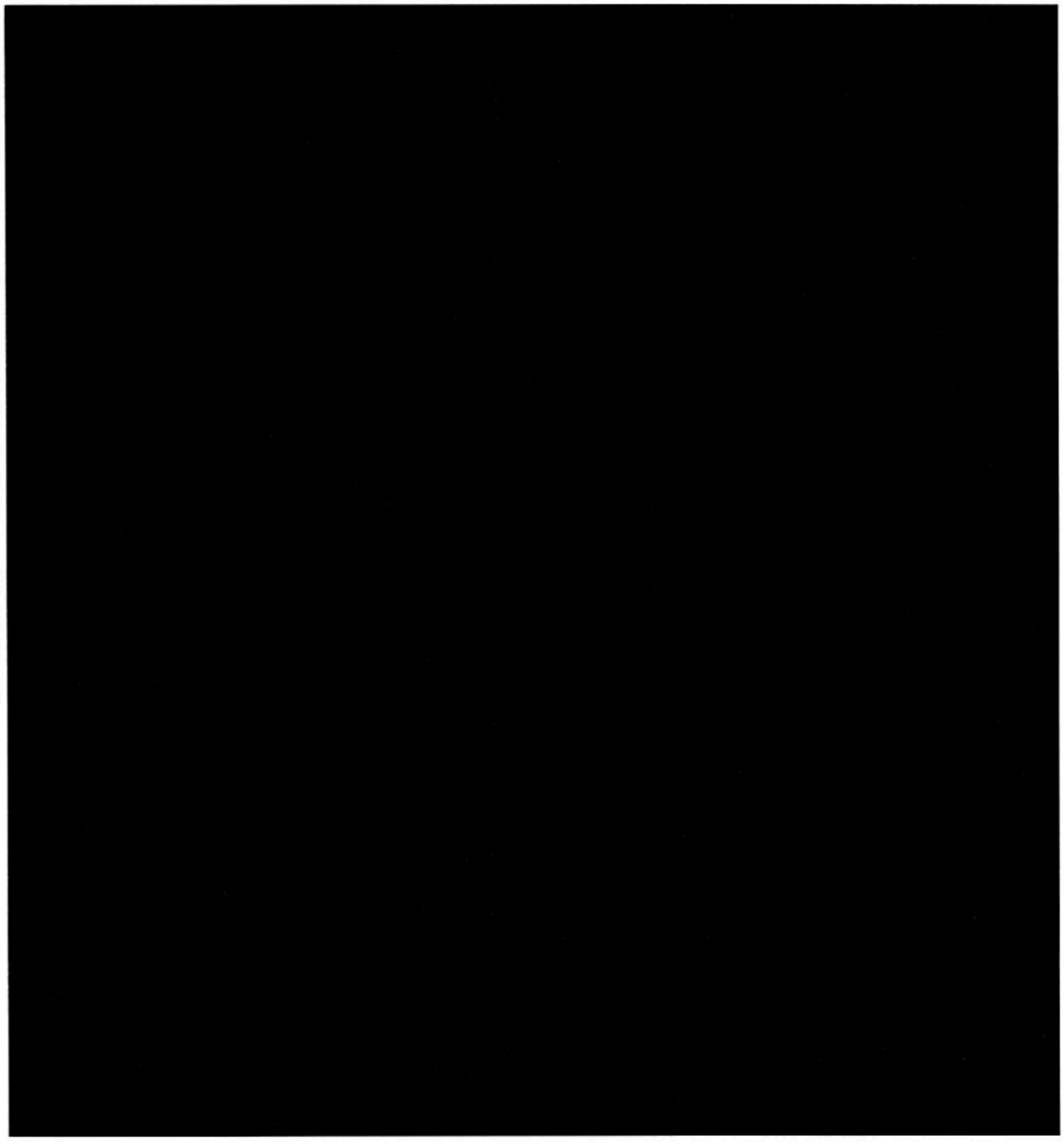
Reproduction/Developmental Toxicity Screening Test in Wistar Rats - Oral Administration (Gavage) 16.Oct.2012 SIBU

SINGLE ANIMAL SHEET
(GROSS LESIONS AND MICROSCOPIC FINDINGS)



BASF	PATHOLOGY REPORT	IIB- 56/63 80R0223/11C162
Reproduction/Developmental Toxicity Screening Test in Wistar Rats - Oral Administration (Gavage)		16.Oct.2012 SIBU

SINGLE ANIMAL SHEET
(GROSS LESIONS AND MICROSCOPIC FINDINGS)



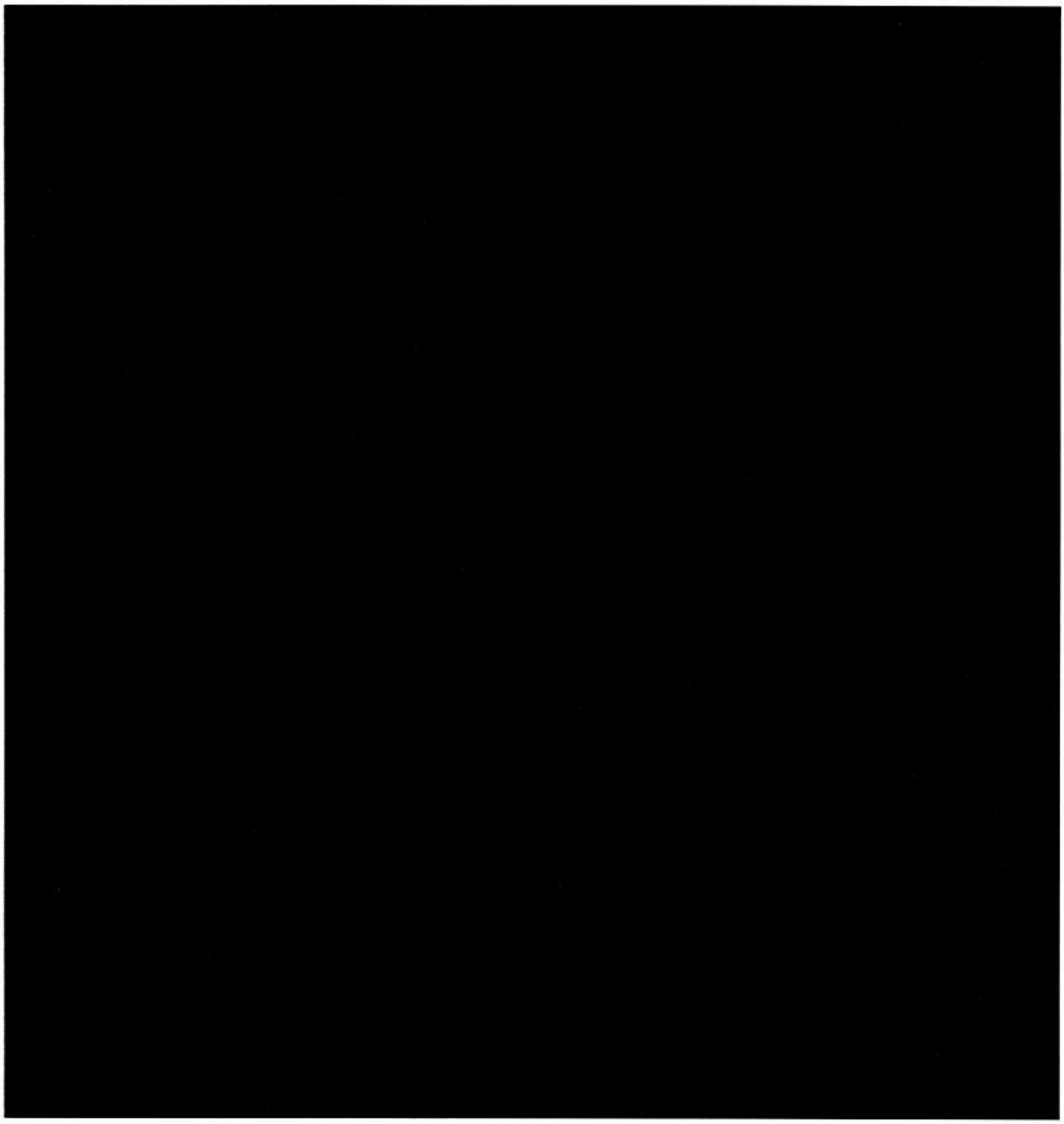
BASF	PATHOLOGY REPORT	IIB- 57/63 80R0223/11C162
Reproduction/Developmental Toxicity Screening Test in Wistar Rats - Oral Administration (Gavage)		16.Oct.2012 SIBU

SINGLE ANIMAL SHEET
(GROSS LESIONS AND MICROSCOPIC FINDINGS)

[redacted]

BASF	PATHOLOGY REPORT	IIB- 58/63 80R0223/11C162
Reproduction/Developmental Toxicity Screening Test in Wistar Rats - Oral Administration (Gavage)		16.Oct.2012 SIBU

SINGLE ANIMAL SHEET
(GROSS LESIONS AND MICROSCOPIC FINDINGS)



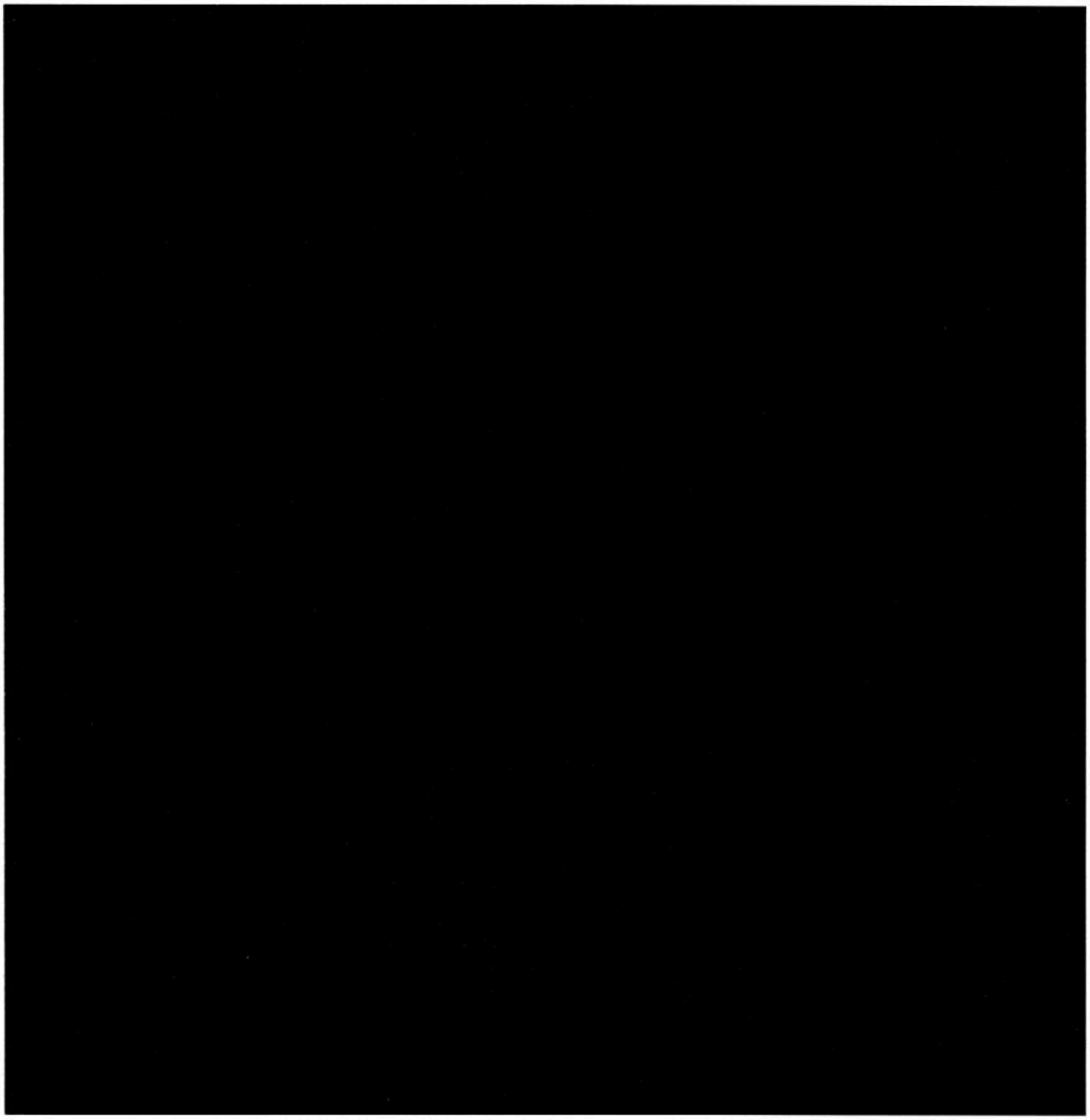
BASF	PATHOLOGY REPORT	IIB- 59/63 80R0223/11C162
Reproduction/Developmental Toxicity Screening Test in Wistar Rats - Oral Administration (Gavage)		16.Oct.2012 SIBU

SINGLE ANIMAL SHEET
(GROSS LESIONS AND MICROSCOPIC FINDINGS)

[redacted]

BASF	PATHOLOGY REPORT	IIB- 60/63 80R0223/11C162
Reproduction/Developmental Toxicity Screening Test in Wistar Rats - Oral Administration (Gavage)		16.Oct.2012 SIBU

SINGLE ANIMAL SHEET
(GROSS LESIONS AND MICROSCOPIC FINDINGS)



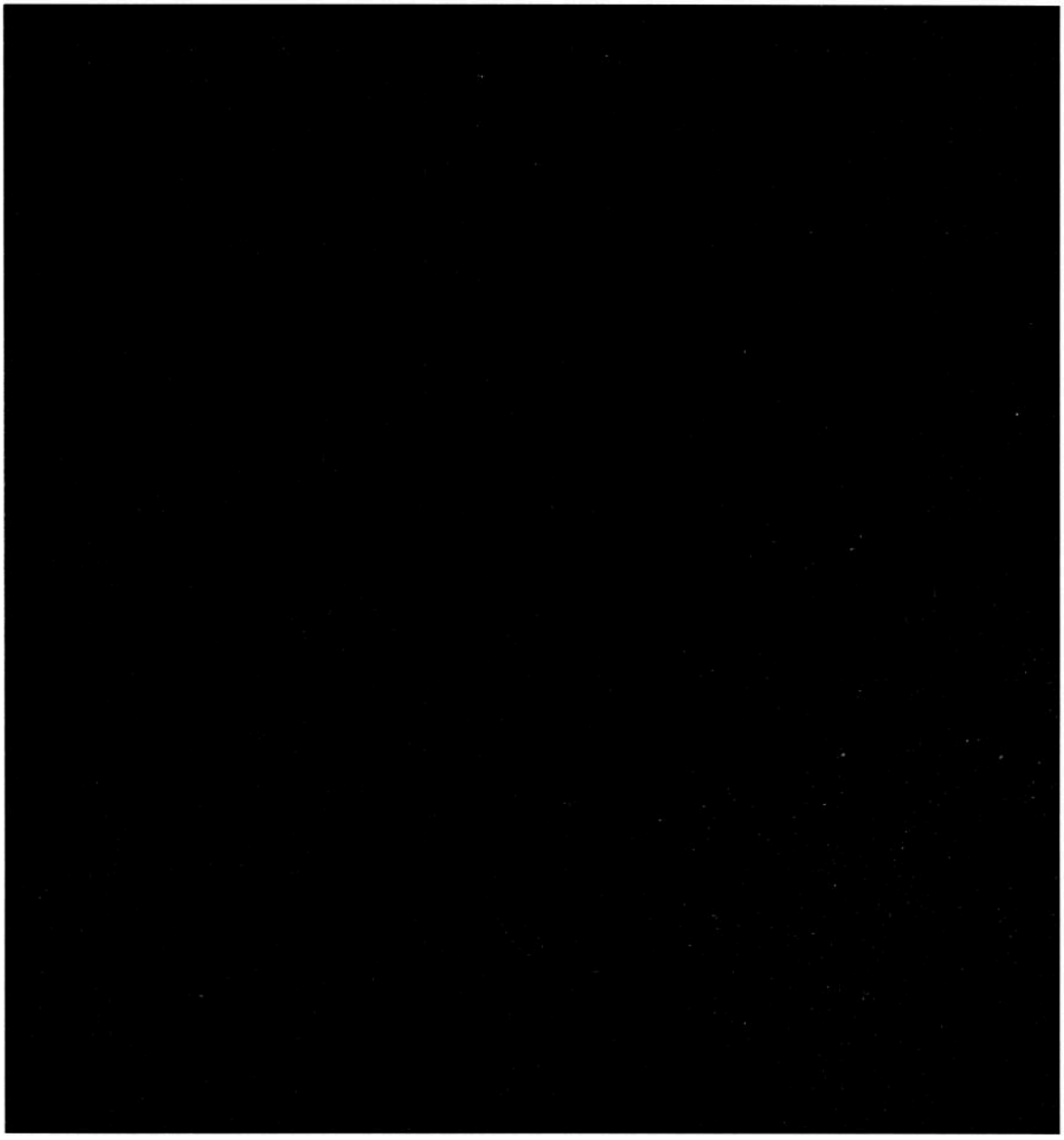
BASF	PATHOLOGY REPORT	IIB- 61/63 80R0223/11C162
Reproduction/Developmental Toxicity Screening Test in Wistar Rats - Oral Administration (Gavage)		16.Oct.2012 SIBU

SINGLE ANIMAL SHEET
(GROSS LESIONS AND MICROSCOPIC FINDINGS)

[redacted]

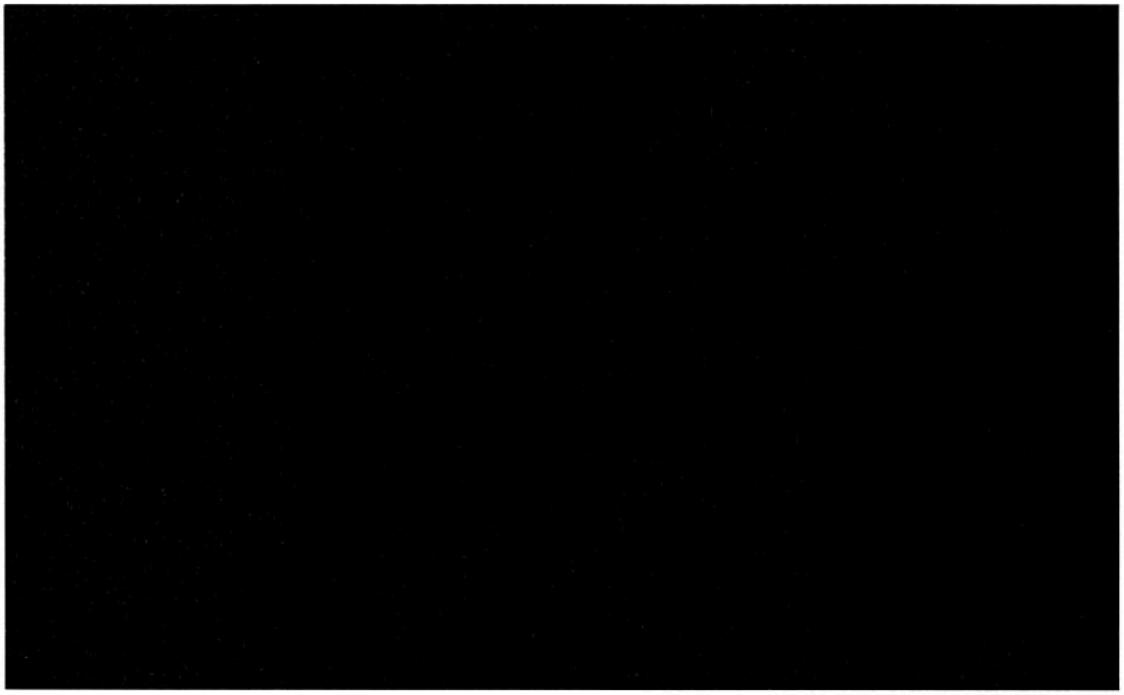
BASF	PATHOLOGY REPORT	IIB- 62/63 80R0223/11C162
Reproduction/Developmental Toxicity Screening Test in Wistar Rats - Oral Administration (Gavage)		16.Oct.2012 SIBU

SINGLE ANIMAL SHEET
(GROSS LESIONS AND MICROSCOPIC FINDINGS)



BASF	PATHOLOGY REPORT	IIB- 63/63 80R0223/11C162
Reproduction/Developmental Toxicity Screening Test in Wistar Rats - Oral Administration (Gavage)		16.Oct.2012 SIBU

SINGLE ANIMAL SHEET
(GROSS LESIONS AND MICROSCOPIC FINDINGS)



STUDY TITLE

Report

Paliogen Violet 5011

Reproduction/Developmental Toxicity Screening Test in Wistar Rats
Oral Administration (Gavage)

TEST FACILITY

BASF SE
[redacted]

TEST FACILITY PROJECT IDENTIFICATION

Project No. 80R0223/11C162

PART III OF III
(SUPPLEMENT)

CONTENTS OF PART III (SUPPLEMENT)

1. Tables and statistics

0
Study 80R0223/11C162 28-Feb-2013 13:40
ToxData© System 3.0

Summary Mating Report

		Test Group 0/ F 0 mg/kg bw/d	Test Group 1/ F 100 mg/kg bw/d	Test Group 2/ F 300 mg/kg bw/d	Test Group 3/ F 1000 mg/kg bw/d
No. of females mated	N	10	10	10	10
- Inseminated	N	10 c+	10	10	10
Female mating index	%	100.0	100.0	100.0	100.0
-- Pregnant	N	8 f+	9	9	9
Female fertility index	%	80.0	90.0	90.0	90.0
No. of males mated	N	10	10	10	10
- With inseminated females	N	10 f+	10	10	10
Male mating index	%	100.0	100.0	100.0	100.0
- With pregnant females	N	8 f+	9	9	9
Male fertility index	%	80.0	90.0	90.0	90.0
Females with defined Day 0 pc	N	10	10	10	10
Mating days until Day 0 pc	Mean	2.7 x+	2.9	3.1	3.2
	S.d.	1.3	1.1	3.2	4.0
	P-Value	@0.6513	1.0000	1.0000	1.0000
Days 0 To 4	N	10 f+	10	9	9
	%	100.0	100.0	90.0	90.0
Days 5 To 9	N	0 c+	0	0	0
	%	0.0	0.0	0.0	0.0
Days 10 To 14	N	0 c+	0	1	1
	%	0.0	0.0	10.0	10.0

Statistic Profile = Wilcoxon with Bonferroni-Holm (one-sided+), * p<=0.05, ** p <=0.01, X = Group excluded from statistics, @ = Global test
c=CHI-SQUARE, f=FISHER-EXACT; x=WILCOX

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Study 80R0223/11C162 28-Feb-2013 13:40
ToxData© System 3.0

Summary Mating Report

		Test Group 0/ F 0 mg/kg bw/d	Test Group 1/ F 100 mg/kg bw/d	Test Group 2/ F 300 mg/kg bw/d	Test Group 3/ F 1000 mg/kg bw/d
No. of females mated	N	10	10	10	10
- Inseminated	N	10 c-	10	10	10
Female mating index	%	100.0	100.0	100.0	100.0
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Female fertility index	%	80.0	90.0	90.0	90.0
No. of males mated	N	10	10	10	10
- With inseminated females	N	10 f-	10	10	10
Male mating index	%	100.0	100.0	100.0	100.0
- With pregnant females	N	8 f-	9	9	9
Male fertility index	%	80.0	90.0	90.0	90.0
Females with defined Day 0 pc	N	10	10	10	10
Mating days until Day 0 pc	Mean	2.7 x+	2.9	3.1	3.2
	S.d.	1.3	1.1	3.2	4.0
	P-Value	@0.6513	1.0000	1.0000	1.0000
Days 0 To 4	N	10 f-	10	9	9
	%	100.0	100.0	90.0	90.0
Days 5 To 9	N	0 c-	0	0	0
	%	0.0	0.0	0.0	0.0
Days 10 To 14	N	0 c-	0	1	1
	%	0.0	0.0	10.0	10.0

Statistic Profile = Wilcoxon with Bonferroni-Holm (one-sided+), * p<=0.05, ** p <=0.01, X = Group excluded from statistics, @ = Global test
c=CHI-SQUARE, f=FISHER-EXACT; x=WILCOX

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Study 80R0223/11C162
28-Feb-2013 13:47
ToxData© System 3.0

Summary Delivery Report

Sex: **Female**

		Test Group 0/ F 0 mg/kg bw/d	Test Group 1/ F 100 mg/kg bw/d	Test Group 2/ F 300 mg/kg bw/d	Test Group 3/ F 1000 mg/kg bw/d
No. of females at start	N	10	10	10	10
No. of females mated	N	10	10	10	10
Pregnant	N	8	9	9	9
Dead	N	0	0	0	0
Without delivery	N	2	1	1	1
- Pregnant	N	0	0	0	0
- Not pregnant	N	2	1	1	1
-- Delivering	N	8 f+	9	9	9
	%	100.0	100.0	100.0	100.0
-- With liveborn pups	N	8 f+	9	9	9
Gestation Index	%	100.0	100.0	100.0	100.0
Gestation days	Mean	22.1 n	22.0	22.2	22.0
	S.d.	0.4	0.0	0.4	0.5
	N	8	9	9	9
-- With stillborn pups	N	1 f+	3	1	1
	%	12.5	33.3	11.1	11.1
-- With all pups stillborn	N	0 c+	0	0	0
	%	0.0	0.0	0.0	0.0

Statistic Profile = Dunnett test (two-sided) + Fisher's exact test (one-sided+), * p<=0.05, ** p <=0.01, X = Group excluded from statistics
f=FISHER-EXACT; n=DUNNETT, c=CHI-SQUARE

0
Study 80R0223/11C162 28-Feb-2013 13:47
ToxData© System 3.0

Summary Delivery Report

Sex: **Female**

		Test Group 0/ F 0 mg/kg bw/d	Test Group 1/ F 100 mg/kg bw/d	Test Group 2/ F 300 mg/kg bw/d	Test Group 3/ F 1000 mg/kg bw/d
No. of females at start	N	10	10	10	10
No. of females mated	N	10	10	10	10
Pregnant	N	8	9	9	9
Dead	N	0	0	0	0
Without delivery	N	2	1	1	1
- Pregnant	N	0	0	0	0
- Not pregnant	N	2	1	1	1
-- Delivering	N	8 f-	9	9	9
	%	100.0	100.0	100.0	100.0
-- With liveborn pups	N	8 f-	9	9	9
Gestation Index	%	100.0	100.0	100.0	100.0
Gestation days	Mean	22.1 n	22.0	22.2	22.0
	S.d.	0.4	0.0	0.4	0.5
	N	8	9	9	9
-- With stillborn pups	N	1 f-	3	1	1
	%	12.5	33.3	11.1	11.1
-- With all pups stillborn	N	0 c-	0	0	0
	%	0.0	0.0	0.0	0.0

Statistic Profile = Dunnett test (two-sided) + Fisher's exact test (one-sided-), * p<=0.05, ** p <=0.01, X = Group excluded from statistics
f=FISHER-EXACT; n=DUNNETT, c=CHI-SQUARE

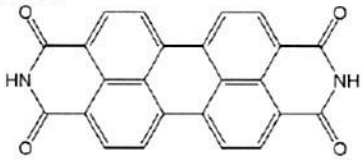
2. Analyses of the test substance and test substance preparations

Competence Center Analytics

Final Report

Characterization of "Paliogen Violet 5011" for REACH
Study No. 11L00104 (confidential)

BASF
The Chemical Company

Test item	"Paliogen Violet 5011"
Chemical identity	Anthra[2,1,9-def:6,5,10-d'e'f']diisoquinoline-1,3,8,10(2H,9H)-tetrone
Chemical structure	
Batch identification	P 100012
Date of production (test item)	Nov 18, 2010
Origin of test item	[redacted]
PSN	11/0223-1
CAS no.	81-33-4
Sponsor	[redacted]
Date of receipt of order	Mar 18, 2011
Date of receipt of test item	Mar 23, 2011
Testing facility	Competence Center Analytics, BASF SE, [redacted]
Study director	[redacted]
Storage cond. test item	Room temeprature
Test period	April 12 – June 30, 2011
Storage of records	GLP archives, Competence Center Analytics
Storage of sample of test item	[redacted] Competence Center Analytics

Summary of results

Appearance and homogeneity

The test item was a black powder with different grain sizes.

Identity (IR spectroscopy)

The IR spectrum shows the bands expected for the test item.

Identity (UV/VIS spectroscopy)

The specific absorbances ($A_{1\%1cm}$) and the specific absorptivities (ε') are compiled in the table below.

Wavelength *[nm]*	$A_{1\%1cm}$ (1)	ε' *[$l\,g^{-1}\,cm^{-1}$]*
219	1245 ± 4.1	125 ± 0.4
246	1571 ± 4.8	157 ± 0.5
406	202 ± 0.3	20 ±< 0.1
551	1135 ± 3.7	114± 0.4
595	2070 ± 8.5	207 ± 0.9

(1) The specific absorbance $A_{1\%1cm}$ is defined as the absorbance of a solution of the test item at a given wavelength, calculated for a concentration of 1.0 g / 100 ml and 1.0 cm pathlength using Beer's law.

Identity (NMR spectroscopy)

The ^{1}H- and ^{13}C-NMR spectra show the signals expected for the test item

Identity (Mass spectrometry)

The MALDI-spectrum shows the expected signals for the test item. A signal with Mr = 371 is not assignable to the proposed structure.

Elemental analysis (content of C,H,N,O)

Element	Values calculated for anhydrous test item (1) *[g/100 g]*	Values found (2) *[g/100 g]*
C	73.9	72.3
H	2.6	2.6
N	7.2	7.0
O	16.4	17.6

(1) Calculated for the pure, anhydrous test item $C_{24}H_{16}N_2O_4$, M = 390.353 g/mol.
(2) Mean values of 2 determinations.

The values found for H and N are in good agreement with the calculated values. There are deviations for the values found for C (-1.6 g/100g) and for O (+ 1.2 g/100g)

1 Appearance and homogeneity

Method	Visual inspection at room temperature
Result	The test item was a black powder with different grain sizes. It was apparently homogeneous
Date of test	April 12, 2011
Head of laboratory	[redacted]

2 Identity (IR spectroscopy)

Method	FTIR spectroscopy
Apparatus	FTIR spectrometer Nicolet 6700
Reagents	KBr (Merck, Darmstadt)
Sample preparation	The test item was measured as KBr pellet.
Test parameters	Measurement at room temperature; 32 scans; resolution: 4.0 cm^{-1}
Result	The IR spectrum of the test item is displayed on page 10. It shows the bands expected for the test item (for assignments see spectrum).
Date of test	May 13, 2011
Head of laboratory	[redacted]

3 Identity (UV/VIS spectroscopy)

Method	UV/VIS spectroscopy
Apparatus	UV/VIS spectrometer PerkinElmer Lambda 900
Reagents	Sulfuric acid (95-97 %, Merck, Darmstadt)
Sample preparation	For duplicate determination, approx. 1.1 mg and 1.7 mg of the test item were accurately weighed into 25 ml volumetric flasks and dissolved in conc. sulfuric acid. Homogenization was achieved by treatment in an ultrasonic bath (approx. 2 min) prior to measurement.
Test parameters	Cuvette: quartz, pathlength: 0.1 cm; data interval: 1.0 nm; slit width: 2.0 nm; scan speed: 125 nm/min; integration time: 0.44 s.

reference: conc. H_2SO_4; measurement at room temperature (approx. 25 °C).

Result

The UV/VIS spectrum of the test item in H_2SO_4 is displayed on page 11. In the spectral range of 200-800 nm, 5 bands were detected. The specific absorbances ($A_{1\%1cm}$) and the specific absorptivities (ε') are compiled in the table below.

Wavelength *[nm]*	$A_{1\%1cm}$ (1)	ε' *[l·g⁻¹·cm⁻¹]*
219	1245 ± 4.1	125 ± 0.4
246	1571 ± 4.8	157 ± 0.5
406	202 ± 0.3	20 ±< 0.1
551	1135 ± 3.7	114± 0.4
595	2070 ± 8.5	207 ± 0.9

(1) The specific absorbance $A_{1\%1cm}$ is defined as the absorbance of a solution of the test item at a given wavelength, calculated for a concentration of 1.0 g / 100 ml and 1.0 cm pathlength using Beer's law.

Date of test

June 29. 2011

Head of laboratory

[redacted]

4 Identity (NMR spectroscopy)

Method

^1H- and ^{13}C-NMR spectroscopy

Apparatus

NMR spectrometer Bruker DPX 399

Reagents

Solvent: D_2SO_4 (Euriso-top)
Frequency standard: hexamethyldisiloxane (HMDS, Merck)

Sample preparation

The test item was dissolved in D_2SO_4 containing HMDS.

Test parameters

Measuring frequencies: 400 MHz (^1H-NMR) and 101 MHz (^{13}C-NMR); measurements at approx. 27 °C; for further parameters see spectra on pages 12-13.

Result

The ^1H- and ^{13}C-NMR spectra are displayed on page 12 and page 13, respectively. The spectra show the signals expected for the test item.

Date of test

May 04 - May 06, 2011

Head of laboratory

[redacted]

5 Identity (Mass spectrometry)

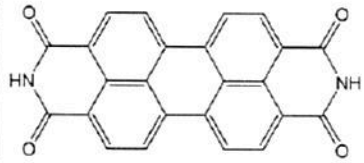
Method	Matrix-assisted laser desorption ionization mass spectrometry (MALDI-MS)
Apparatus	Bruker Reflex III
Reagents	2,5-Dihydroxybenzoic acid (DHB, Bruker Daltonics) H_2O Biochemica (Fluka) Acetonitrile (Chromasolv, >99.9%, Sigma-Aldrich) Formic acid (98-100 %, B. Kraft) Reference materials: Pepmix (containing 15 pmol/µl of Bradikinin fragment 1-7, 10 pmol/µl of Angiotensin I, 20 pmol/µl of Angiotensin II, 10 pmol/µl of Neurotensin and 20 pmol/µl of ACTH fragment 18-39, all components: Sigma)
Sample preparation	Small quantities of the test item and DHB (matrix) were thoroughly mixed in a mortar. For analysis, the mixture was transferred onto the sample holder (target).
Calibration	Calibration was done using an external standard (Pepmix, dissolved in an 49% acetonitrile / 50% water / 1% formic acid mixture). For calibration 1 µl Pepmix was mixed with 1 µl DHB solution on a spot of the target.

Test parameters

Ionization method	MALDI
N_2 laser	337 nm
Polarity	Cationic
Scan range (m/z)	100 - 4000
Laser attenuation	75-90%

Results

The MALDI-spectrum (see on page 14) shows the expected signals for the test item.
A signal with Mr = 371 is not assignable to the proposed structure.

Mr [1]	proposed structure[2]
390	

(1) Monoisotopic rel. molecular mass.
(2) The given structure was deduced from the molecular mass.

Date of test: June 03, 2011

Head of laboratory: [redacted]

6 Content of carbon, hydrogen and nitrogen

Method	Combustion of the test item in a stream of oxygen-containing helium; reduction of NO_x to N_2; determination of N_2, CO_2 and H_2O using a thermal conductivity detector (TCD).
Apparatus	Elementar vario EL cube
Reagents	Reaction gas: O_2 Carrier gas: He (approx. 230 ml/min) Combustion catalyst: CuO Reduction catalyst: Cu
Sample preparation	For duplicate determination, 2.17 mg and 3.57 mg of the test item were analyzed as obtained without further pre-treatment (no drying prior to measurement).
Test parameters	Combustion temperature: approx. 950 °C Reduction temperature: approx. 600 °C

Results

Element	Values calculated for anhydrous test item [1] *[g/100 g]*	Values found [2] *[g/100 g]*
C	73.9	72.3
H	2.6	2.6
N	7.2	7.0

(1) Calculated for the pure, anhydrous test item $C_{24}H_{12}N_2O_4$; M = 390.353 g/mol
(2) Mean values of 2 determinations.

The values for H and N check well; the value found for C is 1.6 g/100 g too low.

Date of test: June 24, 2011

Head of laboratory: [redacted]

7 Content of oxygen

Method: Pyrolysis of the test item in a stream of helium, conversion to CO with carbon black, separation of the resulting gas mixture by chromatography, measurement of the CO content using a thermal conductivity detector (TCD).

Apparatus: EuroVector EA 3000 equipped with an external high-temperature oven

Reagents:
Carrier gas: He (approx. 130 kPa)
Pyrolysis contact: carbon black / granulated carbon
Combustion additive: mixture of Teflon® powder and anthracene (4:1, m/m)

Sample preparation: For duplicate determination, 2.19 mg and 3.20 mg of the test item were analyzed as obtained without further pre-treatment (no drying prior to measurement).

Test parameters:
Oven temperature: approx. 1450 °C
Cooling trap: liquid nitrogen
Evaluation: external calibration

Result

Element	Value calculated for anhydrous test item [1] *[g/100 g]*	Value found [2] *[g/100 g]*
O	16.4	17.6

(1) Calculated for the pure, anhydrous test item $C_{24}H_{10}N_2O_4$; M = 390.353 g/mol.
(2) Mean values of 2 determinations.

The value found is 1.2 g/100g too high.

Date of test: June 30, 2011

Head of laboratory: [redacted]

[redacted]

Jul 26, 2011
Date

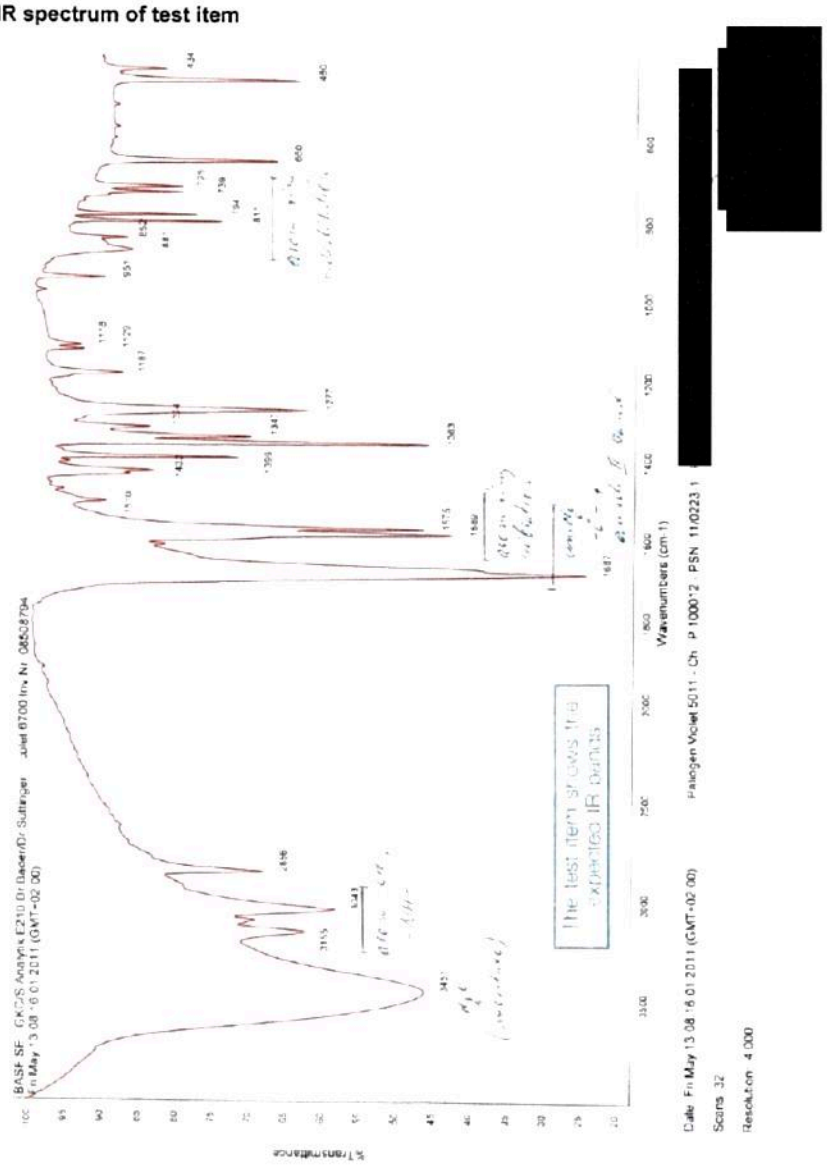
GLP Compliance Statement

This study was conducted in accordance with the OECD Principles of Good Laboratory Practice and the GLP Principles of the German "Chemikaliengesetz" (Chemicals Act).

[redacted]

Oct 26, 2011
Date

IR spectrum of test item

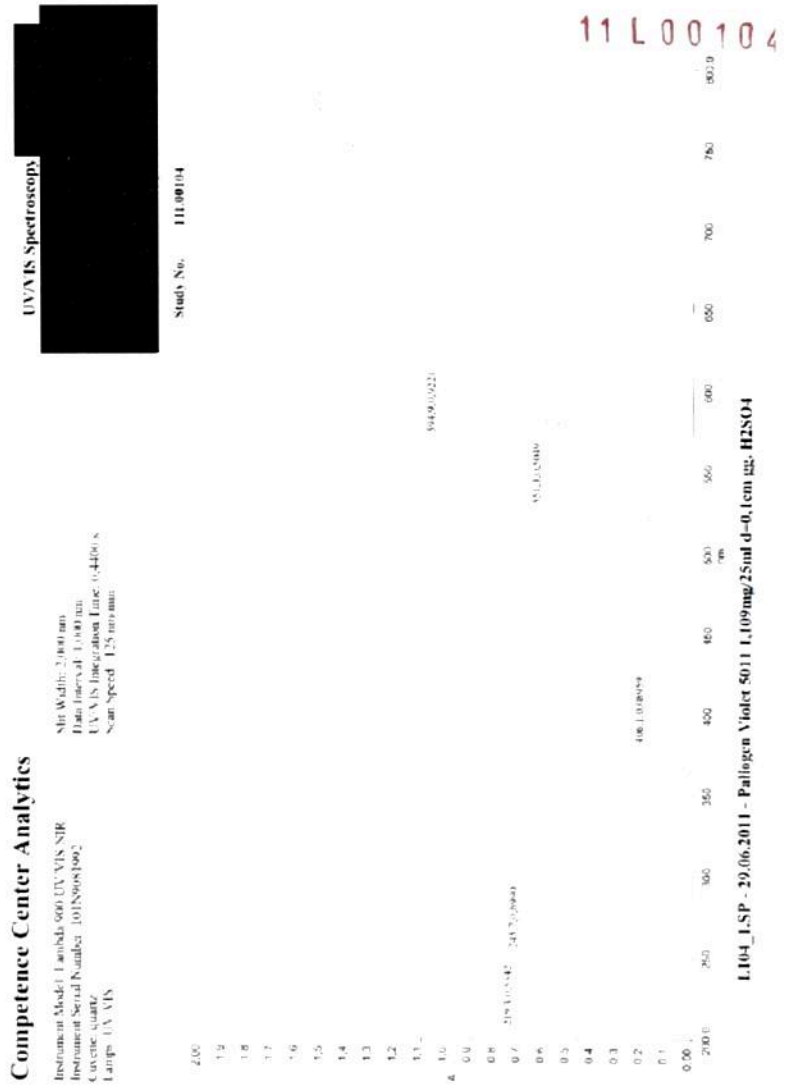


Competence Center Analytics

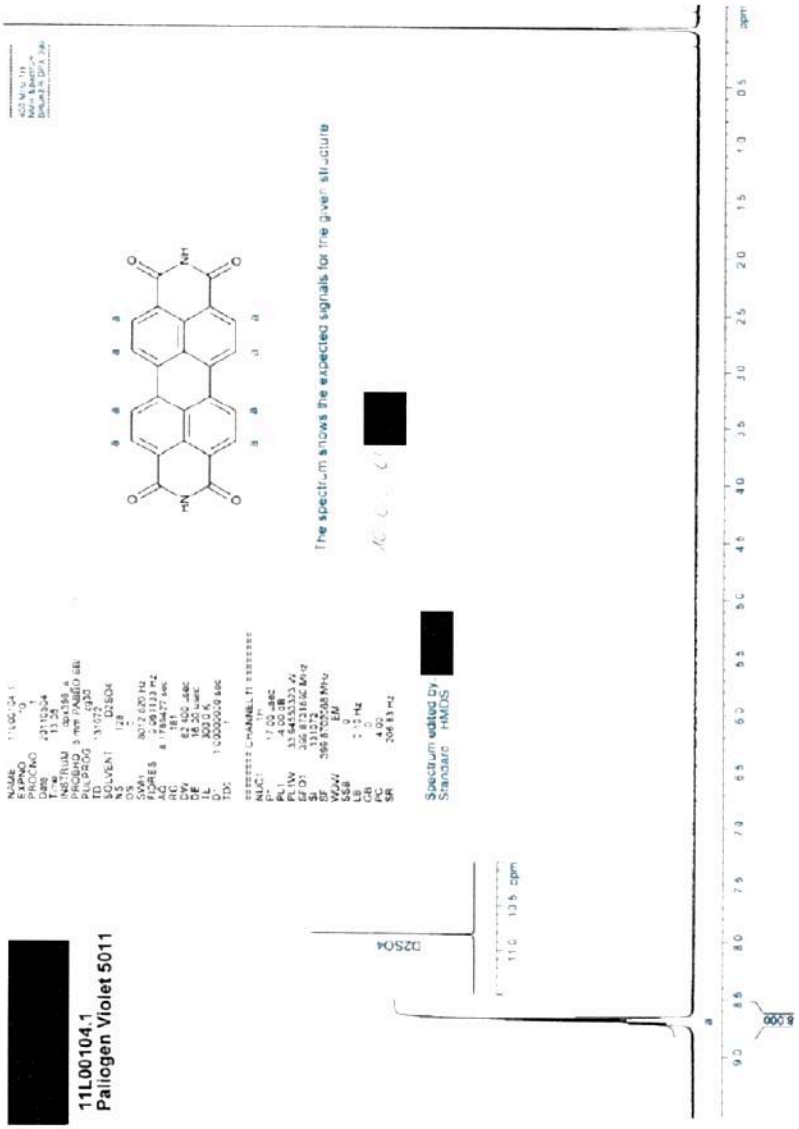
The Chemical Company

Final Report
Characterization of "Paliogen Violet 5011" for REACH
Study No. 11L00104 (confidential)

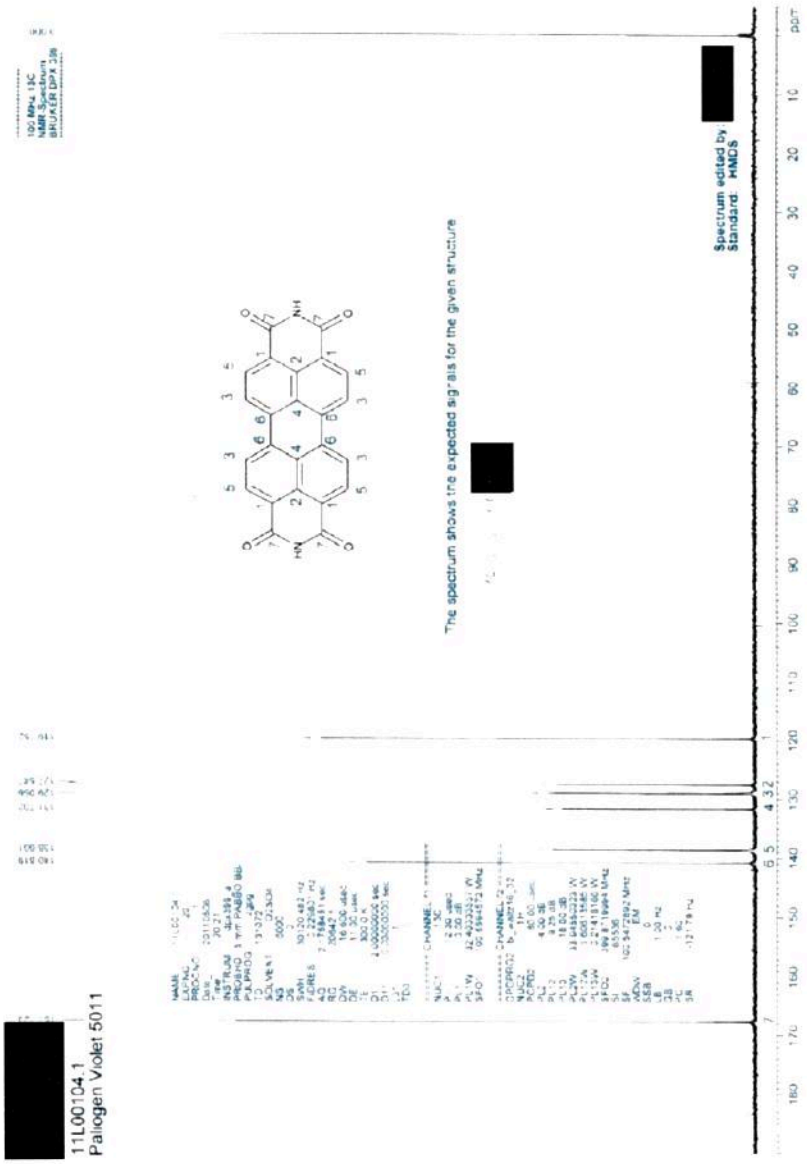
UV/VIS spectrum of test item



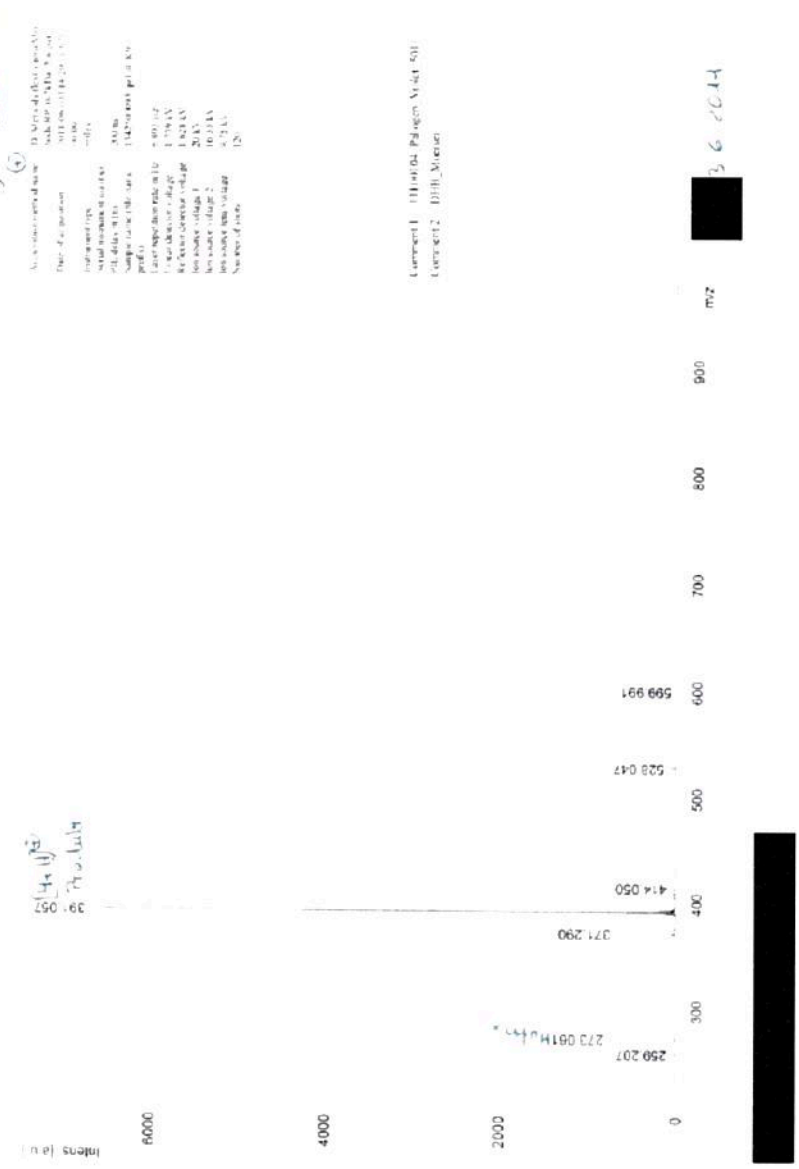
^{1}H-NMR spectrum of test item



^{13}C-NMR spectrum of test item



MS: MALDI spectrum of test item



STATEMENT OF THE QUALITY ASSURANCE UNIT

The Quality Assurance Unit inspects the laboratories of the department Competence Center Analytics in regular intervals. Besides these general inspections we inspected the following items of this study in accordance with the OECD Principles of Good Laboratory Practice and the GLP Principles of the German "Chemikaliengesetz" (Chemicals Act). Findings are reported to study director and to management.

Verification of study plan: Mar 29, 2011

Inspection of	Date of inspection	Reported to study director and management
Raw data:	Oct 05, 2011	Oct 05, 2011
Final report:	Oct 05, 2011	Oct 05, 2011

The final report reflects the raw data.

Ludwigshafen [redacted]

Oct 05, 2011
Date

Competence Center Analytics

Final Report

Stability of "Paliogen Violet 5011" in "Trinkwasser"
Study No. 11L00365 (confidential)

The Chemical Company

Test item	"Paliogen Violet 5011"
Batch identification	P 100012
Date of production (test item)	Nov 18, 2010
PSN	11/0223-1
Project no.	Unknown
Vehicle	"Trinkwasser"
Sponsor	[redacted]
Date of receipt of order	Aug 30, 2011
Date of receipt of test item	Aug 30, 2011
Testing facility	Competence Center Analytics, BASF SE, [redacted]
Study director	[redacted]
Storage cond. test item	Room temperature
Storage cond. vehicle	Room temperature
Test period	Dec 05 - 12, 2011
Storage of records	[redacted] Competence Center Analytics

Method	UV/VIS spectroscopy
Apparatus	UV/VIS spectrometer PerkinElmer Lambda 900
Reagents	Drinking water (vehicle; supplied by [redacted] Sulfuric acid (95-97 %; Merck)

Sample preparation

A total of 8 suspensions containing approx. 100 mg /100 ml of the test item in the vehicle were prepared (duplicate determination for storage times of 0 h, 4 h, 4 d and 7 d). To this end, for each sample approx. 10 mg of the test item were suspended in 10 ml of the vehicle (drinking water) in a 100 ml round-bottom flask. After shaking, the resulting mixtures were analyzed immediately ("0 h") and after storage for 4 h, 4 d and 7 d at room temperature according to the following procedure: The samples were evaporated *in vacuo* to dryness using a rotary evaporator (60 °C). Each residue obtained was dissolved in 25 ml of conc. sulfuric acid. The resulting solutions were diluted with H_2SO_4 prior to measurement (2nd measurement at 0 h: 1:100 v/v, all other measurements: 1:50 v/v).

Test parameters

Cuvettes: quartz, pathlength 1.0 cm; reference: H_2SO_4; scan speed: 125 nm/min; data interval: 1.0 nm; slit width: 2.0 nm; integration time: 0.44 sec; measurements at room temperature.

Results

The specific absorbances ($A_{1\%1cm}$) of the major bands at approx. 595 nm, 551 nm and 245 nm were evaluated. The values obtained are compiled in the table below. The UV/VIS spectra obtained from the samples at 0 h and 7 d are shown in Fig. 1 (page 4) and Fig. 2 (page 5), respectively.

Storage time	Sample name	$A_{1\%1cm}$ [a] at 595 nm	$A_{1\%1cm}$ [a] at 551 nm	$A_{1\%1cm}$ [a] at 245 nm
0 h	Probe 1; 100 mg /100 ml; 0 h; RT	2178.1	1190.7	1647.4
	Probe 2; 100 mg /100 ml; 0 h; RT	2066.9	1129.1	1576.2
	Mean value	2122.5 ± 55.6	1159.9 ± 30.8	1611.8 ± 35.6
4 h	Probe 3; 100 mg /100 ml; 4 h; RT	2003.5	1091.1	1470.4
	Probe 4; 100 mg /100 ml; 4 h; RT	2033.1	1110.5	1504.3
	Mean value	2018.3 ± 14.8	1100.8 ± 9.7	1487.4 ± 16.9
4d	Probe 5; 100 mg /100 ml; 4 d; RT	2020.2	1113.4	1539.4
	Probe 6; 100 mg /100 ml; 4 d; RT	2042.6	1115.8	1545.2
	Mean value	2031.4 ± 11.3	1114.6 ± 1.2	1542.3 ± 2.9
7d	Probe 7; 100 mg /100 ml; 7 d; RT	1966.8	1077.5	1492.4
	Probe 8; 100 mg /100 ml; 7 d; RT	1984.8	1086.8	1508.8
	Mean value	1975.8 ± 9.0	1082.2 ± 4.7	1500.6 ± 8.2

a) The specific absorbance ($A_{1\%1cm}$) is the absorbance at a given wavelength calculated for a concentration of 1 % (m/v) and a pathlength of 1.0 cm using Beer's law. Mean values and deviations were calculated from the unrounded values.

Discussion of results

The specific absorbances ($A_{1\%1cm}$), as calculated from all measurements, yielded mean values of x = 2037.0 (595 nm), x = 1114.4 (551 nm) and x = 1535.5 (245 nm). The deviation of the results for each storage time (mean value of duplicate determination) with respect to x are as follows:

0 h: 4.2 % (595 nm), 4.1 % (551 nm) and 5.0 % (245 nm)
4 h: 0.9 % (595 nm), 1.2 % (551 nm) and 3.1 % (245 nm)
4 d: 0.3 % (595 nm), 0.0 % (551 nm) and 0.4 % (245 nm)
7 d: 3.0 % (595 nm), 2.9 % (551 nm) and 2.3 % (245 nm)

The deviations show no correlation with the storage time and are well within the repeatability of the duplicate determinations. Moreover, the comparison of the spectra recorded at the various storage times reveals no significant spectral changes over time (see Fig. 1 and 2 for storage times of 0 h and 7 d).
Hence, on the basis of the UV/VIS measurements reported in this study, the test item is stable in the vehicle for at least 7 days at room temperature.

[redacted]

Jun 13, 2012
Date

Fig. 1. UV/VIS spectrum obtained after sample work-up (storage time: 0 h)

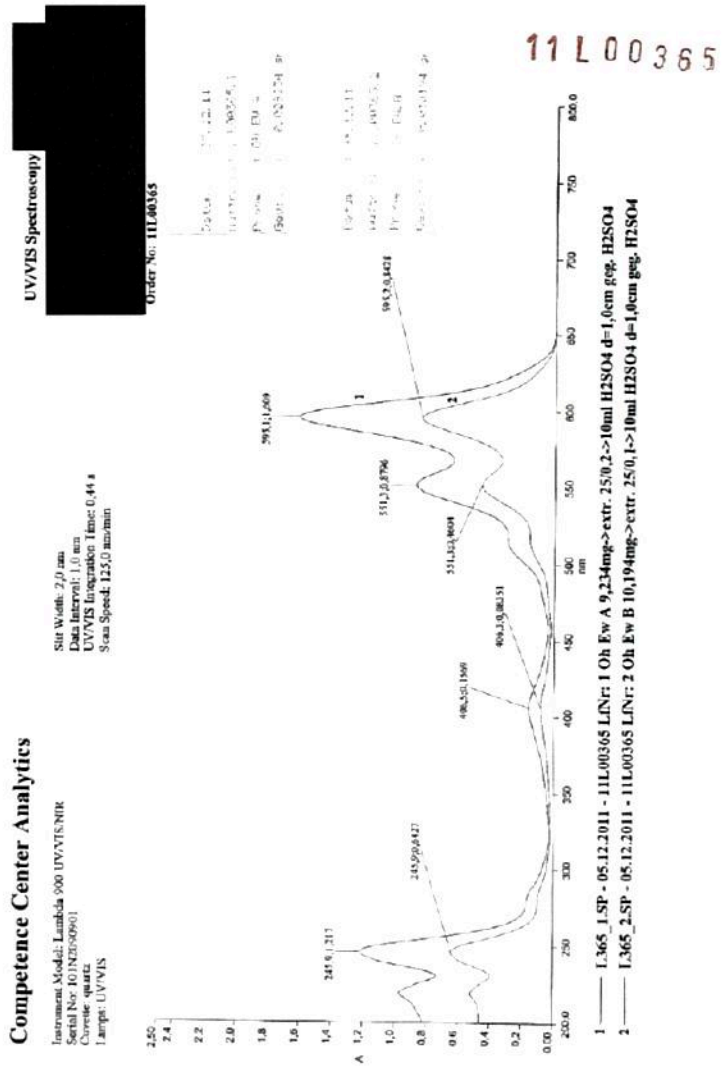
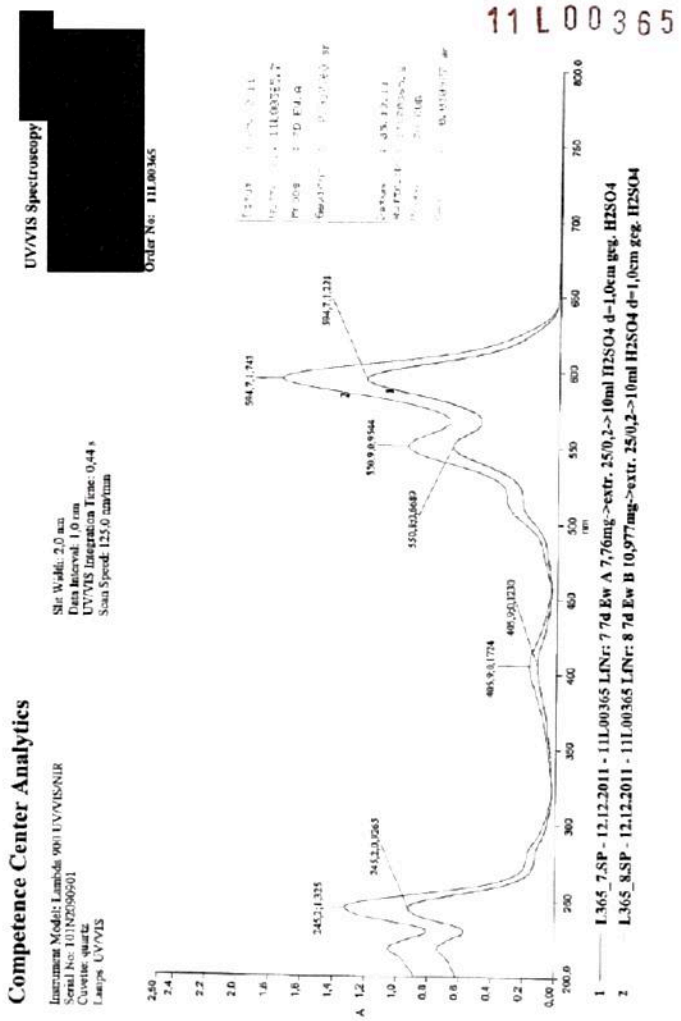


Fig. 2. UV/VIS spectrum obtained after sample work-up (storage time: 7 d)



Competence Center Analytics

BASF
The Chemical Company

Final Report
Stability of "Paliogen Violet 5011" in "Trinkwasser"
Study No. 11L00365 (confidential)

GLP Compliance Statement

This study was conducted in accordance with the OECD Principles of Good Laboratory Practice and the GLP Principles of the German "Chemikaliengesetz" (Chemicals Act).

[redacted]

Jun 13, 2012
Date

Statement of the Quality Assurance Unit

The Quality Assurance Unit inspects the laboratories of the department Competence Center Analytics in regular intervals. Besides these general inspections we inspected the following items of this study in accordance with the OECD Principles of Good Laboratory Practice and the GLP Principles of the German "Chemikaliengesetz" (Chemicals Act). Findings are reported to study director and to management.

Verification of study plan: Sep 14, 2011

Inspection of	Date of inspection	Reported to study director and to management
Raw data:	June 11, 2012	June 13, 2012
Final report:	June 11, 2012	June 13, 2012

The final report reflects the raw data.

Ludwigshafen [redacted]

June 13, 2012
Date

Competence Center Analytics

Final Report

Concentration control and homogeneity of "Paliogen Violet 5011" in "Drinking water"
Study No. 12L00270 (confidential)

BASF
The Chemical Company

Test item	"Paliogen Violet 5011"
Batch identification	P 100012
Date of production (test item)	Nov 18, 2010
PSN	11/0223-1
Project no.	80R0223/11C162
Vehicle	"Drinking water"
Sponsor	[redacted]
Date of receipt of order	Jul 02, 2012
Date of receipt of test item	Jul 02, 2012
Testing facility	Competence Center Analytics, BASF SE, [redacted]
Study director	[redacted]
Storage cond. samples	Freezer
Storage cond. test item	Freezer
Storage cond. vehicle	Freezer
Test period	Aug 06 - 15, 2012
Storage of records	[redacted] Competence Center Analytics

1 Content of test item (dry residue)

Determination: "Paliogen Violet 5011"

Method: Determination of the dry residue at 105 °C

Apparatus: Drying oven

Sample preparation: Each sample was transferred into a platinum dish. Subsequently, the vehicle was evaporated at 105 °C until a constant weight was achieved. The dish containing the dry residue was cooled down to room temperature in a desiccator.

Test parameters: Temperature: 105 °C

Results

Sample no.	Date of sample preparation	Date of sampling	Expected concentration *[g/100 ml]*	Value found *[g/100 g]*	Value found [1] *[g/100 ml]*	Deviation *[%]*
3	Jul 02, 2012	Jul 02, 2012	1	0.99	1.03	3.0
4	Jul 02, 2012	Jul 02, 2012	1	0.99	1.03	3.0
5	Jul 02, 2012	Jul 02, 2012	1	0.99	1.03	3.0
6	Jul 02, 2012	Jul 02, 2012	3	2.94	2.97	-1.0
7	Jul 02, 2012	Jul 02, 2012	10	9.22	9.81	-1.9
8	Jul 02, 2012	Jul 02, 2012	10	9.15	9.86	-1.4
9	Jul 02, 2012	Jul 02, 2012	10	9.17	9.83	-1.7

(1) The densities of the samples were each calculated using the sample masses determined in this study and the sample volumes of 3 ml each, as stated by the sponsor.

Discussion of results: The content of test item in the samples, as measured by determining the mass of the dry residues after evaporation of the vehicle, is in good agreement with the expected values (deviations ≤ 3 %). At a concentration level of 1 g/100 ml and 10 g/100 ml homogeneity was proved by these measurements.

Date of test: Aug 06 - 07, 2012

Head of laboratory: [redacted]

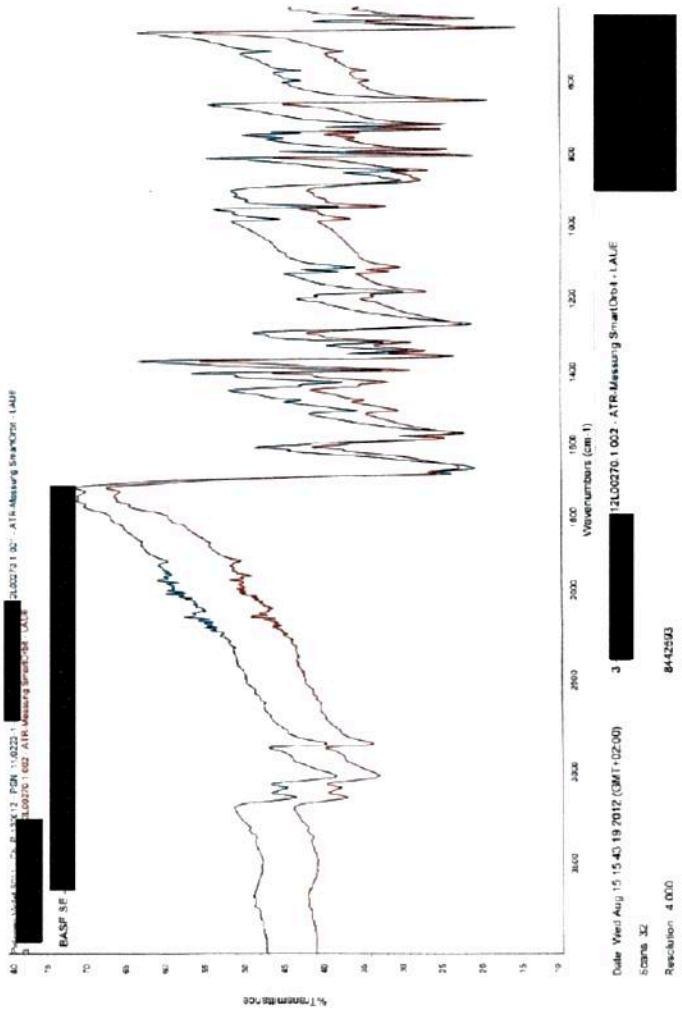
2 Identity (IR spectroscopy)

Method	IR spectroscopy
Apparatus	IR spectrometer Nicolet Nexus equipped with a SmartOrbit diamond ATR unit
Sample preparation	The samples (original test item and dry residues) were measured without further preparation.
Test parameters	Measurement at room temperature; 32 scans; resolution: 4.0 cm^{-1}
Results	The IR (ATR) spectra of the dry residues obtained after evaporation of the vehicle contained in the samples were compared with the IR spectrum of the original test item in order to examine whether the evaporation process has resulted in decomposition of the test item. Exemplarily, the IR spectra of the original test item and of the dry residue obtained from sample no. 3 are depicted in Fig. 1 (page 4). The comparison of the spectra proves that the test item did not undergo a significant chemical change during the evaporation process. Hence, the determination of the content of the test item in the samples by measuring the dry residues is feasible.
Date of test	Aug 15, 2012
Head of laboratory	[redacted]

[redacted]

Aug 22, 2012
Date

Fig. 1. IR spectra of the original test item (blue) and dry residue (red) obtained from sample no. 3



Competence Center Analytics

BASF
The Chemical Company

GLP Compliance Statement

This study was conducted in accordance with the OECD Principles of Good Laboratory Practice and the GLP Principles of the German "Chemikaliengesetz" (Chemicals Act).

[redacted]

Aug 22, 2012
Date

Statement of the Quality Assurance Unit

The Quality Assurance Unit inspects the laboratories of the department Competence Center Analytics in regular intervals. Besides these general inspections we inspected the following items of this study in accordance with the OECD Principles of Good Laboratory Practice and the GLP Principles of the German "Chemikaliengesetz" (Chemicals Act). Findings are reported to study director and to management.

Verification of study plan: July 24, 2012

Inspection of	Date of inspection	Reported to study director and to management
Raw data:	Aug 22, 2012	Aug 22, 2012
Final report:	Aug 22, 2012	Aug 22, 2012

The final report reflects the raw data.

Ludwigshafen [redacted]

Aug 22, 2012
Date

Competence Center Analytics

Final Report

Concentration control of "Paliogen Violet 5011" in "Drinking water"
Study No. 12L00332 (confidential)

BASF
The Chemical Company

Test item	"Paliogen Violet 5011"
Batch identification	P 100012
Date of production (test item)	Nov 18, 2010
PSN	11/0223-1
Project no.	80R0223/11C162
Vehicle	"Drinking water"
Sponsor	[redacted]
Date of receipt of order	Aug 20, 2012
Date of receipt of test item	Aug 20, 2012
Testing facility	Competence Center Analytics, BASF SE, [redacted]
Study director	[redacted]
Storage cond. samples	Freezer
Storage cond. test item	Freezer
Storage cond. vehicle	Freezer
Test period	Sep 04 - 19, 2012
Storage of records	[redacted] Competence Center Analytics

Competence Center Analytics

BASF
The Chemical Company

Final Report
Concentration control of "Paliogen Violet 5011" in "Drinking water"
Study No. 12L00332 (confidential)

1 Content of test item (dry residue)

Determination	"Paliogen Violet 5011"
Method	Determination of the dry residue at 105 °C
Apparatus	Drying oven
Sample preparation	Each sample was transferred into a platinum dish. Subsequently, the vehicle was evaporated at 105 °C until a constant weight was achieved. The dish containing the dry residue was cooled down to room temperature in a desiccator.
Test parameters	Temperature: 105 °C

Results

Sample no.	Date of sample preparation	Date of sampling	Expected concentration *[g/100 ml]*	Value found *[g/100 g]*	Value found (1) *[g/100 ml]*	Deviation *[%]*
12	Aug 20, 2012	Aug 20, 2012	1	1.04	1.05	5.0
13	Aug 20, 2012	Aug 20, 2012	3	3.01	3.09	3.0
14	Aug 20, 2012	Aug 20, 2012	10	9.91	10.50	5.0

(1) The density of each of the samples was calculated from the individual sample weight cetermined in this study and the sample volume of 3 ml each, as stated by the sponsor.

Discussion of results	The content of test item in the samples, as measured by determining the mass of the dry residues after evaporation of the vehicle, is in good agreement with the expected values (deviations ≤ 5.0 %).
Date of test	Sep 04 - 05, 2012
Head of laboratory	[redacted]

2 Identity (IR spectroscopy) of the dry residue

Method	IR spectroscopy
Apparatus	IR spectrometer Nicolet Nexus equipped with a SmartOrbit diamond ATR unit

Competence Center Analytics

BASF
The Chemical Company

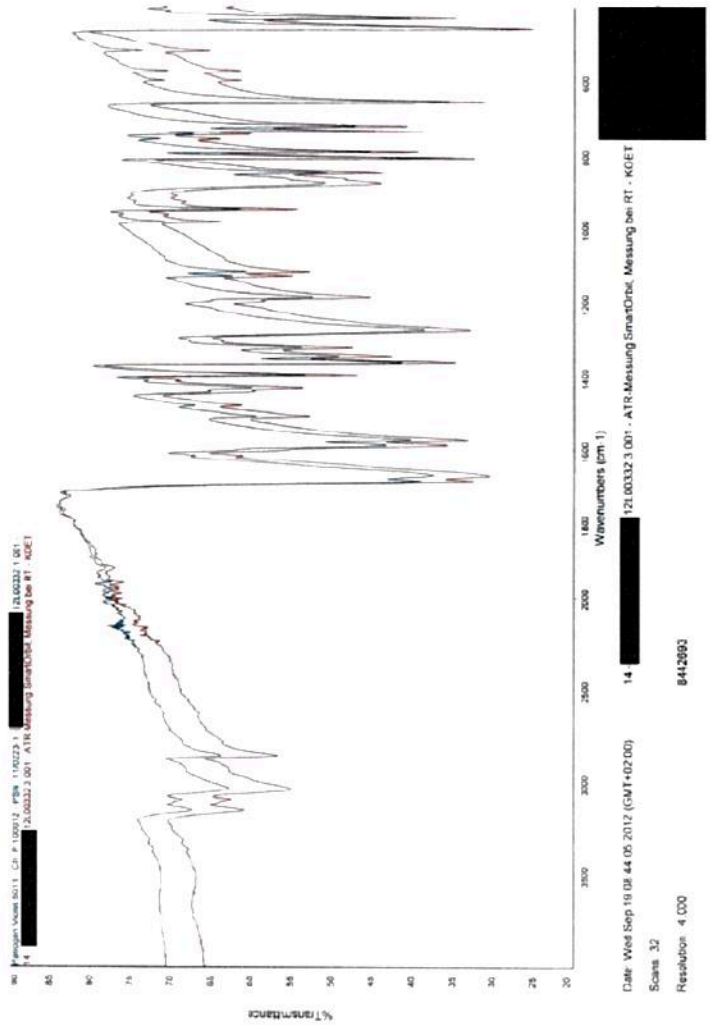
Final Report
Concentration control of "Paliogen Violet 5011" in "Drinking water"
Study No. 12L00332 (confidential)

Sample preparation	The samples (original test item and dry residues) were measured without further preparation.
Test parameters	Measurement at room temperature; 32 scans; resolution: 4.0 cm^{-1}
Results	The IR (ATR) spectra of the dry residues obtained after evaporation of the vehicle contained in the samples were compared with the IR spectrum of the original test item in order to examine whether the evaporation process has resulted in decomposition of the test item. Exemplarily, the IR spectra of the original test item and of the dry residue obtained from sample no. 14 (highest concentration) are depicted in Fig. 1 (page 4). The comparison of the spectra proves that the test item did not undergo a significant chemical change during the evaporation process. Hence, the determination of the content of the test item in the samples by measuring the dry residues is feasible.
Date of test	Sep 19, 2012
Head of laboratory	[redacted]

[redacted]

Feb 19, 2013
Date

Fig. 1. IR spectra of the original test item (blue) and dry residue (red) obtained from sample no. 14



Competence Center Analytics

The Chemical Company

Final Report
Concentration control of "Paliogen Violet 5011" in "Drinking water"
Study No. 12L00332 (confidential)

GLP Compliance Statement

This study was conducted in accordance with the OECD Principles of Good Laboratory Practice and the GLP Principles of the German "Chemikaliengesetz" (Chemicals Act).

[redacted]

Feb 19, 2013
Date

Competence Center Analytics

BASF
The Chemical Company

Final Report
Concentration control of "Paliogen Violet 5011" in "Drinking water"
Study No. 12L00332 (confidential)

Statement of the Quality Assurance Unit

The Quality Assurance Unit inspects the laboratories of the department Competence Center Analytics in regular intervals. Besides these general inspections we inspected the following items of this study in accordance with the OECD Principles of Good Laboratory Practice and the GLP Principles of the German "Chemikaliengesetz" (Chemicals Act). Findings are reported to study director and to management.

Verification of study plan: Aug 29, 2012

Inspection of	Date of inspection	Reported to study director and to management
Raw data:	Feb 19, 2013	Feb 19, 2013
Final report:	Feb 19, 2013	Feb 19, 2013

The final report reflects the raw data.

Ludwigshafen [redacted]

Feb 19, 2013
Date

3. Historical control data

5-MAR-13

HISTORICAL CONTROL DATA

TABLE :

SPECIES: RAT
STRAIN: WISTAR
SUPPLIER: CHARLES RIVER
FILENAME: 11C162

Study No./Control Group	Start Date	End Date	Route of Administration
98R002L1 1	2-JAN-12		GAVAGE
00140F1 1	7-JAN-05		GAVAGE
01075F1 1	29-APR-02		GAVAGE
01195F1 1	7-NOV-05		GAVAGE
01250F1 1	4-JAN-10		GAVAGE
04R001L1 1	14-FEB-10		GAVAGE
04028F1 1	21-FEB-05		GAVAGE
04029F1 1	18-OCT-04		GAVAGE
04052F1 1	25-APR-05		GAVAGE
04108F1 1	31-MAR-08		GAVAGE
04C027L1 1	10-OCT-11		GAVAGE
05031F1 1	17-OCT-05		GAVAGE
05039F1 1	20-FEB-06		GAVAGE
05117F1 1	5-OCT-09		GAVAGE
05122F1 1	9-NOV-09		DIET
05R009L1 1	7-NOV-11		INHALATION
07061F1 1	4-FEB-08		GAVAGE
07061X1 1	10-MAR-08		GAVAGE
07089F1 1	17-MAR-08		GAVAGE
07103F1 1	7-JUL-08		GAVAGE
07106F1 1	1-SEP-08		GAVAGE
07107F1 1	27-OCT-08		GAVAGE
07110F1 1	18-DEC-08		GAVAGE
07133F1 1	30-JUL-09		GAVAGE
07C029L1 1	10-MAY-11		GAVAGE
08042F1 1	10-NOV-09		DIET
09R001L1 1	4-FEB-10		INHALATION
09R002L1 1	25-JAN-10		GAVAGE
09035F1 1	28-SEP-09		GAVAGE
09048F1 1	12-OCT-09		GAVAGE
09052F1 1	19-OCT-09		GAVAGE
09061F1 1	14-DEC-09		DIET
09066F1 1	4-JAN-10		GAVAGE
09067F1 1	30-NOV-09		GAVAGE
09068F1 1	4-JAN-10		GAVAGE
09074F1 1	25-JAN-10		GAVAGE
10C002L1 1	3-MAY-10		GAVAGE
10C071L1 1	31-JAN-11		GAVAGE

5-MAR-13

TABLE :

HISTORICAL CONTROL DATA

SPECIES: RAT
STRAIN: WISTAR
SUPPLIER: CHARLES RIVER
FILENAME: 11C162

Study No./Control Group	Start Date	End Date	Route of Administration
10S073L1 1	21-MAR-11		GAVAGE
10S086L1 1	7-MAR-11		DIET
10S114L1 1	11-JUL-11		GAVAGE
11C017L1 1	22-AUG-11		GAVAGE
11C032L1 1	8-AUG-11		GAVAGE
11S030L1 1	29-AUG-11		GAVAGE
11S058L1 1	31-OCT-11		GAVAGE

5-MAR-13

SPECIES: RAT
STRAIN: WISTAR
SUPPLIER: CHARLES RIVER

TABLE :

HISTORICAL CONTROL DATA
MEAN MATERNAL BODY WEIGHTS DURING GESTATION GRAMS

NO. OF ANIMALS	MEAN	RANGE OF ACTUAL VALUES	95 % 2.5%	SPREAD 97.5%
[redacted]				

5-MAR-13

TABLE :

HISTORICAL CONTROL DATA

SPECIES RAT
STRAIN WISTAR
SUPPLIER CHARLES RIVER

MEAN MATERNAL BODY WEIGHTS DURING LACTATION -- GRAMS

NO. OF ANIMALS	MEAN	RANGE OF ACTUAL VALUES	95 % 2.5%	SPREAD 97.5%
[redacted]				

01-FEB-13

TABLE:

HISTORICAL CONTROL DATA

REPRODUCTION AND LITTER DATA

SPECIES RAT
STRAIN WISTAR
SUPPLIER CHARLES RIVER

STUDY NO.	MALE MATING INDEX [%]	MALE FERTILITY INDEX [%]	FEMALE MATING INDEX [%]	MATING DAYS – 0 P.C. [DAYS]	FEMALE FERTILITY INDEX [%]	DURATION OF GESTATION [DAYS]	IMPLANTATION SITES [MEAN]
98R002 L1	100	100	100	3.8	100	22.0	13.5
00140 F1	100	100	100	3.9	100	22.1	11.5
01075 F1	100	90	100	1.8	90	21.8	10.8
01195 F1	100	100	100	2.7	100	22.0	13.1
01250 F1	100	100	100	1.6	100	21.9	12.9
04028 F1	100	100	100	2.7	100	22.0	11.9
04029 F1	100	100	100	2.6	100	22.0	14.0
04052 F1	100	100	100	3.1	100	21.8	12.6
04108 F1	100	90	100	4.8	90	22.1	13.4
04C027 L1	100	100	100	2.6	100	21.9	13.4
04R001 L1	90	90	90	3.1	100	21.9	12.7
05031 F1	100	92	100	3.2	92	21.8	13.6
05039 F1	100	100	100	2.5	100	21.9	11.9
05117 F1	90	70	90	2.2	78	22.3	11.9
05122 F1	100	90	100	6.0	90	22.0	11.2
05R009 L1	100	90	100	3.1	90	22.3	9.8
07061 F1	100	80	100	3.4	80	22.0	12.6
X1	100	100	100	2.4	100	22.4	13.3
07089 F1	100	100	100	3.7	100	22.2	12.1

01-FEB-13

TABLE:

HISTORICAL CONTROL DATA

REPRODUCTION AND LITTER DATA

SPECIES RAT
STRAIN WISTAR
SUPPLIER CHARLES RIVER

STUDY NO.	MALE MATING INDEX [%]	MALE FERTILITY INDEX [%]	FEMALE MATING INDEX [%]	MATING DAYS – 0 P.C. [DAYS]	FEMALE FERTILITY INDEX [%]	DURATION OF GESTATION [DAYS]	IMPLANTATION SITES [MEAN]
07100 F1	100	90	100	3.4	90	22.1	13.0
07103 F1	100	100	100	2.3	100	22.2	14.1
07106 F1	100	90	100	3.4	90	22.0	14.4
07107 F1	100	100	100	2.4	100	21.9	13.6
07110 F1	100	90	100	2.4	90	22.1	11.6
07133 F1	100	100	100	2.5	100	21.9	11.4
07C029 L1	100	90	100	3.9	90	22.0	11.8
08042 F1	100	90	100	2.9	90	22.0	12.0
08065 F1	100	100	100	2.2	100	22.2	13.5
09035 F1	100	100	100	3.7	100	21.8	11.7
09048 F1	100	100	100	2.7	100	22.0	10.9
09052 F1	100	100	100	2.9	100	21.6	12.7
09061 F1	100	100	100	4.2	100	22.2	11.9
09066 F1	100	100	100	2.0	100	22.0	14.2
09067 F1	100	90	100	3.7	90	22.0	11.8
09068 F1	100	100	100	2.4	100	22.2	12.9

01-FEB-13

TABLE:

HISTORICAL CONTROL DATA

REPRODUCTION AND LITTER DATA

SPECIES RAT
STRAIN WISTAR
SUPPLIER CHARLES RIVER

STUDY NO.	MALE MATING INDEX [%]	MALE FERTILITY INDEX [%]	FEMALE MATING INDEX [%]	MATING DAYS – 0 P.C. [DAYS]	FEMALE FERTILITY INDEX [%]	DURATION OF GESTATION [DAYS]	IMPLANTATION SITES [MEAN]
09074 F1	100	80	100	3.2	80	22.0	13.0
09C003 L1	100	100	100	2.7	100	21.9	13.8
09C004 L1	100	90	100	3.1	90	22.2	13.8
09C017 L1	100	100	100	2.6	100	22.4	12.1
09R001 L1	100	100	100	3.1	100	22.2	10.6
09R002 L1	100	90	100	3.9	90	21.9	12.9
10C002 L1	100	100	100	2.6	100	22.2	12.7
10C071 L1	100	100	100	2.1	100	22.1	12.5
10S027 L1	100	90	100	3.2	90	22.1	13.0
10S073 L1	100	70	100	2.2	70	22.1	--[1]
10S086 L1	100	100	100	4.1	100	22.3	--[1]
10S114 L1	80	80	80	3.8	100	22.0	13.9
11C017 L1	100	90	100	2.6	90	21.9	12.3
11C032 L1	100	100	100	3.6	100	21.9	13.4
11S030 L1	100	90	100	3.8	90	22.1	11.2
11S058 L1	100	100	100	3.1	100	22.2	11.2
RANGE Min.	80	70	80	1.6	70	21.6	10.6
Max.	100	100	100	6.0	100	22.4	14.4

1) No Data available

01-FEB-13

TABLE:

HISTORICAL CONTROL DATA

REPRODUCTION AND LITTER DATA

SPECIES RAT
STRAIN WISTAR
SUPPLIER CHARLES RIVER

STUDY NO.	%POSTIMPLAN-TATION LOSS [MEAN]	GESTATION INDEX [%]	PUPS DEL/DAM [MEAN]	PUPS STILLBORN [%]	LIVE BIRTH INDEX [%]	VIABILITY INDEX DAYS 0 TO 4 [%]
98R002 L1	10.7	100	12.0	0.0	100	99
00140 F1	6.8	100	10.7	0.9	99	100
01075 F1	4.7	89	10.3	1.2	99	99
01195 F1	5.9	100	12.4	1.0	99	99
01250 F1	6.0	100	12.1	0.8	99	99
04028 F1	14.5	90	12.1	4.6	95	100
04029 F1	5.6	100	13.2	1.5	98	99
04052 F1	8.0	100	11.6	0.0	100	100
04108 F1	5.4	100	12.8	6.1	94	100
04C027 L1	18.3	90	11.9	0.0	100	100
04R001 L1	2.2	100	12.3	0.9	99	98
05031 F1	5.5	100	12.9	0.0	100	98
05039 F1	6.6	92	11.0	0.8	99	100
05117 F1	5.4	100	11.3	1.3	99	99
05122 F1	4.7	100	10.7	0.0	100	100
05R009 L1	5.0	100	9.2	1.2	99	99
07061 F1	8.1	100	11.6	0.0	100	100
X1	5.5	100	12.6	0.0	100	99
07089 F1	11.6	90	13.1	4.2	96	97

01-FEB-13

TABLE:

HISTORICAL CONTROL DATA

REPRODUCTION AND LITTER DATA

SPECIES RAT
STRAIN WISTAR
SUPPLIER CHARLES RIVER

STUDY NO.	%POSTIMPLANTATION LOSS [MEAN]	GESTATION INDEX [%]	PUPS DEL/DAM [MEAN]	PUPS STILLBORN [%]	LIVE BIRTH INDEX [%]	VIABILITY INDEX DAYS 0 TO 4 [%]
07100 F1	4.1	100	12.4	0.9	99	99
07103 F1	3.5	100	13.6	5.1	95	99
07106 F1	1.9	100	14.1	0.8	99	99
07107 F1	0.7	100	13.5	0.0	100	99
07110 F1	14.6	89	12.4	0.0	100	100
07133 F1	6.6	100	10.6	0.8	99	100
07C029 L1	1.7	100	11.6	0.0	100	99
08042 F1	1.0	100	11.9	0.0	100	97
08065 F1	3.7	100	13.0	6.9	93	83
09035 F1	6.1	100	11.0	0.0	100	99
09048 F1	2.6	100	10.6	0.0	100	100
09052 F1	4.9	100	12.1	0.0	100	100
09061 F1	3.7	100	11.5	0.9	99	99
09066 F1	5.3	100	13.5	3.7	96	98
09067 F1	6.2	100	11.0	1.0	99	100
09068 F1	6.3	100	12.1	0.0	100	100

01-FEB-13

TABLE:

HISTORICAL CONTROL DATA

REPRODUCTION AND LITTER DATA

SPECIES RAT
STRAIN WISTAR
SUPPLIER CHARLES RIVER

STUDY NO.	%POSTIMPLAN-TATION LOSS [MEAN]	GESTATION INDEX [%]	PUPS DEL/DAM [MEAN]	PUPS STILLBORN [%]	LIVE BIRTH INDEX [%]	VIABILITY INDEX DAYS 0 TO 4 [%]
09074 F1	6.8	100	12.1	1.0	99	99
09C003 L1	7.8	100	12.8	0.0	100	100
09C004 L1	0.8	100	13.7	4.1	96	96
09C017 L1	4.3	100	11.5	0.0	100	99
09R001 L1	12.6	100	9.3	0.0	100	100
09R002 L1	5.6	100	12.2	7.3	93	98
10C002 L1	9.3	100	11.7	1.7	98	100
10C071 L1	5.4	100	11.8	0.0	100	99
10S027 L1	6.1	100	12.2	0.9	99	100
10S073 L1	--[1)]	100	12.1	1.2	99	99
10S086 L1	--[1)]	100	10.9	0.0	100	100
10S114 L1	1.0	100	13.8	0.0	100	99
11C017 L1	2.8	100	12.0	0.0	100	99
11C032 L1	2.1	100	13.1	0.8	99	99
11S030 L1	13.8	89	12.0	0.0	100	100
11S058 L1	4.8	100	10.6	0.0	100	99
RANGE Min.	0.7	89	9.3	0.0	93	83
Max.	18.3	100	14.1	7.3	100	100

1) No Data available

5-MAR-13

TABLE :

HISTORICAL CONTROL DATA

PUP WEIGHTS - grams

SPECIES RAT

STRAIN WISTAR

SUPPLIER CHARLES RIVER

DAY	NO. OF LITTERS	MEAN	RANGE OF LITTER MEANS	RANGE OF STUDY MEANS
[redacted]				

5-MAR-13

TABLE :

HISTORICAL CONTROL DATA

PUP NECROPSY OBSERVATIONS

SPECIES RAT

STRAIN WISTAR

SUPPLIER CHARLES RIVER

[redacted]