



**US Environmental Protection Agency  
Office of Pesticide Programs**

**Multi-Generation Reproduction  
Studies**

**July 2002**

U.S. Environmental Protection Agency

Office of Pesticide Programs

Electronic Submission Guidance

**Standard Format for Electronic Submission of  
Supplemental Data Files in Support of**

**Multi-Generation  
Reproduction Studies**

July 31, 2002

The following formats and instructions are designed to be used as an example or guide for registrants to format electronic files for submission of animal toxicology data to the USEPA Office of Pesticide Programs for review in support of registration and re-registration of pesticides. They are based upon, and are intended to be consistent with, similar guidance published by the Food and Drug Administration (FDA).

The USEPA Office of Pesticide Programs has identified SAS Transport as the preferred means of supplying the supplemental data. SAS Transport Format, published by the SAS Institute, allows data to be translated to other commonly used formats without the need for other programs from the SAS Institute or other specific vendors. It is compatible with widely used spreadsheet and statistical software. Additionally, SAS transport files can be readily transferred to common database applications.

There are two SAS transport file formats: The open source version 5 XPORT and proprietary version 6 CPORT. In keeping with federal guidelines, OPP is specifying use of version 5 XPORT. Technical specifications for the XPORT Transport format may be found on the SAS Institute web site under [Technical Document TS-140](#).

The following data definition tables, developed jointly by OPP and Bayer Corp., should be used when submitting supplemental toxicity data. If changes are made to the data definition, an updated data definition table should be supplied in PDF format and include variable name, a description of the variable, type of variable, and codes used. A single transport file should be supplied for each dataset.

## Table of Contents

PARENTAL DATA FOR FIRST GENERATION (F0)	
Dataset	Description of dataset
MORTAL0	Mortality information.
SIGNS0	Clinical signs.
WEIGHTS0	Body weights.
FOOD0	Food consumption.
TESTSUB0	Test substance intake.
DOSING0	Dosing regimen * <b><i>For studies conducted with oral gavage.</i></b>
MACRO0	Gross pathology findings (Macroscopic examination of tissues).
ORGANWT0	Organ weights.
SPERM0	Sperm measures.
MICRO0	Microscopic findings (Histopathology).
PRECYC0	Pre-mating cycle stages.
ESTROUS0	Estrous cycle.
PAIRED0	Animals paired.
MATED0	Animals mated.
PRECOIT0	Precoital interval.
PREG0	Pregnancy status.
GESTUR0	Duration of gestation.
OTHER0	Other datasets as needed.

<b>PARENTAL DATA FOR SECOND GENERATION (F1)</b>	
<b>Dataset</b>	<b>Description of dataset</b>
MORTAL1	Mortality information.
SIGNS1	Clinical signs.
WEIGHTS1	Body weights.
FOOD1	Food consumption.
TESTSUB1	Test substance intake.
DOSING1	Dosing regimen * <b><i>For studies conducted with oral gavage.</i></b>
MACRO1	Gross pathology findings (Macroscopic examination of tissues).
ORGANWT1	Organ weights.
SPERM1	Sperm measures.
MICRO1	Microscopic findings (Histopathology).
PRECYC1	Pre-mating cycle stages.
ESTROUS1	Estrous cycle.
PAIRED1	Animals paired.
MATED1	Animals mated.
PRECOIT1	Precoital interval.
PREG1	Pregnancy status.
GESDUR1	Duration of gestation.
OTHER1	Other datasets as needed.

<b>OFFSPRING DATA FOR FIRST GENERATION (F0)</b>	
<b>Dataset</b>	<b>Description of dataset</b>
OMORTAL0	Mortality information.
OSIGNS0	Clinical signs.
PUPWT0	Pup weights.
ANODIST0	Anogenital distance (F2, if triggered).
SEXMAT0	Age at sexual maturity (vaginal opening/preputial separation).
LITTER0	Litter information: No. live pups, No. dead pups.
OMACRO0	Gross pathology findings (Macroscopic examination of tissues).
OORGWT0	Organ weights.
OMICRO0	Microscopic observations (Histopathology).
OTHER0	Other datasets as needed.

<b>OFFSPRING DATA FOR SECOND GENERATION (F1)</b>	
<b>Dataset</b>	<b>Description of dataset</b>
OMORTAL1	Mortality information.
OSIGNS1	Clinical signs.
PUPWT1	Pup weights.
ANODIST1	Anogenital distance (F2, if triggered).
SEXMAT1	Age at sexual maturity (vaginal opening/preputial separation).
LITTER1	Litter information: No. live pups, No. dead pups.
OMACRO1	Gross pathology findings (Macroscopic examination of tissues).
OORGWT1	Organ weights.
OMICRO1	Microscopic observations (Histopathology).
OTHER1	Other datasets as needed.

**Mortality Data for Each Animal (MORTAL0.V5X, MORTAL1.V5X)**

Variable	Label	Type	Codes and Comments
STUDYNUM	Study Number	Char	
SPECIES	Animal Species	Char	M = mouse, R = rat, D = dog.
ANIMLNUM	Animal Number	Char	
SEX	Sex	Char	F = female.
DOSEGP	Dose Group	Num	Use 0, 1, 2, 3, 4, etc. in ascending order from control.
DOSETEXT	Dose Group Representation	Char	PPM, mg/kg etc. plus dose level (e. g. 50 mg/kg).
DOSEVAL	Numeric Dose Value	Num	In 50 mg/kg example above, DOSEVAL would equal 50.
DTHSACST	Death or Sac Status	Num	
DTHDESC	Description of Death or Sac Status	Char	Use to define DTHSACST codes.
WEIGHT	Terminal Body Weight	Num	
UNIT	Unit of Measurement	Char	
EXCLUDE	Is This Record Excluded from Summaries?	Char	'YES' if record should be excluded. Blank (" ") if record should NOT be excluded.
EXCCODE	Exclusion Code	Char	(if codes are used.)
EXCDESC	Exclusion Description or Reason	Char	Text Description.

**Clinical Signs for Each Animal (SIGNS0.V5X, SIGNS1.V5X)**

Variable	Label	Type	Codes and Comments
STUDYNUM	Study Number	Char	
SPECIES	Animal Species	Char	M = mouse, R = rat, D = dog.
ANIMLNUM	Animal Number	Char	
SEX	Sex	Char	M = male, F = female.
DOSEGP	Dose Group	Num	Use 0, 1, 2, 3, 4, etc. in ascending order from control.
DOSETEXT	Dose Group Representation	Char	PPM, mg/kg etc. plus dose level (e. g. 50 mg/kg).
DOSEVAL	Numeric Dose Value	Num	In 50 mg/kg example above, DOSEVAL would equal 50.
DAYS	Day of Clinical Sign	Num	
SIGN	Clinical Sign	Char	
START	Days on Drug Sign First Seen	Num	
SEVERITY	Severity	Char	
EXCLUDE	Is This Record Excluded from Summaries?	Char	'YES' if record should be excluded. Blank (" ") if record should NOT be excluded.
EXCCODE	Exclusion Code	Char	(if codes are used.)
EXCDESC	Exclusion Description or Reason	Char	Text Description.



**Body Weights for Each Animal (WEIGHTS0.V5X, WEIGHTS1.V5X)**

Variable	Label	Type	Codes and Comments
STUDYNUM	Study Number	Char	
SPECIES	Animal Species	Char	M = mouse, R = rat, D = dog.
ANIMLNUM	Animal Number	Char	
SEX	Sex	Char	M = male, F = female.
DOSEGP	Dose Group	Num	Use 0, 1, 2, 3, 4, etc, in ascending order from control.
DOSETEXT	Dose Group Representation	Char	PPM, mg/kg etc. plus dose level (e. g. 50 mg/kg).
DOSEVAL	Numeric Dose Value	Num	In 50 mg/kg example above, DOSEVAL would equal 50.
PERIOD	Period Pertaining to Days	Char	Example: P = Premating, G = Gestation, L = Lactation.
DAYS	Day of Measurement	Num	
WEIGHT	Body Weight	Num	
UNIT	Unit of Weight Measurement	Char	g = gram, kg = kilograms, etc.
EXCLUDE	Is This Record Excluded from Summaries?	Char	'YES' if record should be excluded. Blank (" ") if record should NOT be excluded.
EXCCODE	Exclusion Code	Char	NM, etc. (if codes are used).
EXCDESC	Exclusion Description or Reason	Char	Not Measured, etc.

**Food Consumption for Each Animal (FOOD0.V5X, FOOD1.V5X)**

Variable	Label	Type	Codes and Comment
STUDYNUM	Study Number	Char	
SPECIES	Animal Species	Char	M = mouse, R = rat, D = dog.
ANIMLNUM	Animal Number	Char	
SEX	Sex	Char	M = male, F = female.
DOSEGP	Dose Group	Num	Example: 0, 1, 2, 3, 4, etc. in ascending order from control.
DOSETEXT	Dose Group Representation	Char	PPM, mg/kg etc. plus dose level (e. g. 50 mg/kg).
DOSEVAL	Numeric Dose Value	Num	In 50 mg/kg example above, DOSEVAL would equal 50.
PERIOD	Period Pertaining to Days	Char	Example: P=Premating, G=Gestation, L=Lactation.
DAYS	Day of Measurement	Num	
FFED	Food Fed	Num	
FLEFT	Food Left	Num	
PREVFED	Previous Day's Food Fed	Num	
DAYDIFF	Number of Days From Previous Measurement	Num	
UNIT	Unit of Measurement	Char	g = gram, kg = kilograms, etc.
EXCLUDE	Is This Record Excluded from Summaries?	Char	'YES' if record should be excluded. Blank (" ") if record should NOT be excluded.
EXCCODE	Exclusion Code	Char	S, NM, O, etc. (if codes are used).
EXCDESC	Exclusion Description or Reason	Char	Spiller, Not Measured, Outlier, etc.

**Test Substance Intake (TESTSUB0.V5X, TESTSUB1.V5X)**

Variable	Label	Type	Codes and Comments
STUDYNUM	Study Number	Char	
SPECIES	Species	Char	
ANIMLNUM	Animal Number	Char	
SEX	Sex	Char	M = male, F = female.
DOSEGP	Dose Group	Num	Use 0, 1, 2, 3, 4, etc. in ascending order from control.
DOSETEXT	Dose Group Representation	Char	PPM, mg/kg etc. plus dose level (e. g. 50 mg/kg).
DOSEVAL	Numeric Dose Value	Num	In 50 mg/kg example above, DOSEVAL would equal 50.
PERIOD	Period Pertaining to Days	Char	Example: P = Premating, G = Gestation, L = Lactation.
DAYS	Days on Drug at Observation	Num	
INTAKE	Test Substance Intake	Num	
UNIT	Unit of Weight Measurement	Char	g = gram, kg = kilograms, etc.
AI	Active Ingredient	Num	

**Test Substance Intake (DOSING0.V5X, DOSING1.V5X)**

Variable	Label	Type	Codes and Comments
STUDYNUM	Study Number	Char	
SPECIES	Species	Char	
ANIMLNUM	Animal Number	Char	
SEX	Sex	Char	M = male, F = female.
DOSEGP	Dose Group	Num	Use 0, 1, 2, 3, 4, etc. in ascending order from control.
DOSETEXT	Dose Group Representation	Char	PPM, mg/kg etc. plus dose level (e. g. 50 mg/kg).
DOSEVAL	Numeric Dose Value	Num	In 50 mg/kg example above, DOSEVAL would equal 50.
PERIOD	Period Pertaining to Days	Char	Example: P = Premating, G = Gestation, L = Lactation.
DOSEDATE	Date of Dosing	Num	
DOSETIME	Time of Dosing	Num	
BODYWT	Body Weight	Num	
WTUNIT	Body Weight Units	Num	g = grams, kg = kilograms, etc.
VOLUME	Volume Administered	Num	
VOLUNIT	Unit of Volume	Char	ml, etc.

**Macroscopic Findings for Each Animal (MACRO0.V5X, MACRO1.V5X)**

Variable	Label	Type	Codes and Comments
STUDYNUM	Study Number	Char	
SPECIES	Animal Species	Char	M = mouse, R = rat, D = dog.
ANIMLNUM	Animal Number	Char	
SEX	Sex	Char	M = male, F = female.
DOSEGP	Dose Group	Num	Use 0, 1, 2, 3, 4, etc. in ascending order from control.
DOSETEXT	Dose Group Representation	Char	PPM, mg/kg etc. plus dose level (e. g. 50 mg/kg).
DOSEVAL	Numeric Dose Value	Num	In 50 mg/kg example above, DOSEVAL would equal 50.
OBS_DATE	Date of Observation	Char	
ORGANNAM	Name of Organ	Char	
MACRO	Macroscopic Findings	Char	Do not include comments associated with findings. Full details for abnormal findings should be described in study report.
MODIFIER	Modifier	Char	
GRADE	Grade or Severity of Abnormality	Char	
EXCLUDE	Is This Record Excluded from Summaries?	Char	'YES' if record should be excluded. Blank (" ") if record should NOT be excluded.
EXCCODE	Exclusion Code	Char	(if codes are used.)
EXCDESC	Exclusion Description or Reason	Char	Text Description.

**Organ Weight for Every Organ Examined for Each Animal  
(ORGANWT0.V5X, ORGANWT1.V5X)**

Variable	Label	Type	Codes and Comments
STUDYNUM	Study Number	Char	
SPECIES	Animal Species	Char	M = mouse, R = rat, D = dog.
ANIMLNUM	Animal Number	Char	
SEX	Sex	Char	M = male, F = female.
DOSEGP	Dose Group	Num	Use 0, 1, 2, 3, 4, etc. in ascending order from control.
DOSETEXT	Dose Group Representation	Char	PPM, mg/kg etc. plus dose level (e. g. 50 mg/kg).
DOSEVAL	Numeric Dose Value	Num	In 50 mg/kg example above, DOSEVAL would equal 50.
FNLBDYWT	Final Body Weight	Num	
UNITBODW	Body Weight Units	Num	
DAYS	Days on Drug at Observation	Num	
ORGANNAM	Organ Name	Num	
ORGANWT	Weight of Organ	Num	
UNIT	Organ Weight Unit of Measurement	Char	
EXCLUDE	Is This Record Excluded from Summaries?	Char	'YES' if record should be excluded. Blank (" ") if record should NOT be excluded.
EXCCODE	Exclusion Code	Char	(if codes are used.)
EXCDESC	Exclusion Description or Reason	Char	Text Description.

**Sperm Measures for Each Animal (SPERM0.V5X, SPERM1.V5X)**

<b>Variable</b>	<b>Label</b>	<b>Type</b>	<b>Codes and Comments</b>
STUDYNUM	Study Number	Char	
SPECIES	Species	Char	
ANIMLNUM	Animal Number	Char	
SEX	Sex	Char	M = male, F = female.
DOSEGP	Dose Group	Num	Use 0, 1, 2, 3, 4, etc. in ascending order from control.
DOSETEXT	Dose Group Representation	Char	PPM, mg/kg etc. plus dose level (e. g. 50 mg/kg)
DOSEVAL	Numeric Dose Value	Num	In 50 mg/kg example above, DOSEVAL would equal 50.

**Microscopic Findings (histopathology) for Each Animal (MICRO0.V5X, MICRO1.V5X)**

Variable	Label	Type	Codes and Comments
STUDYNUM	Study Number	Char	
SPECIES	Animal Species	Char	M = mouse, R = rat, D = dog.
ANIMLNUM	Animal Number	Char	
SEX	Sex	Char	M = male, F = female.
DOSEGP	Dose Group	Num	Use 0, 1, 2, 3, 4, etc, in ascending order from control.
DOSETEXT	Dose Group Representation	Char	PPM, mg/kg etc. plus dose level (e. g. 50 mg/kg).
DOSEVAL	Numeric Dose Value	Num	In 50 mg/kg example above, DOSEVAL would equal 50.
ORGANNAM	Name of Organ	Char	
MICRO	Microscopic Findings	Char	Do not include comments associated with findings. Full details for abnormal findings should be described in study report.
GRADE	Grade or Severity of Abnormality	Char	
TUMOR	Tumor flag	Char	None, Benign, Malignant, or Indeterminate.
EXCLUDE	Is This Record Excluded from Summaries?	Char	'YES' if record should be excluded. Blank (" ") if record should NOT be excluded.
EXCCODE	Exclusion Code	Char	(if codes are used.)
EXCDESC	Exclusion Description or Reason	Char	Text Description.



**Estrous Cyclicity Data: Pre-mating (PREEST0.V5X, PREEST1.V5X)**

<b>Variable</b>	<b>Label</b>	<b>Type</b>	<b>Codes and Comments</b>
STUDYNUM	Study Number	Char	
SPECIES	Species	Char	M = mouse, R = rat, D = dog.
ANIMLNUM	Animal Number	Char	
SEX	Sex	Char	M = male, F = female.
DOSEGP	Dose Group	Num	Use 0, 1, 2, 3, 4, etc, in ascending order from control.
DOSETEXT	Dose Group Representation	Char	PPM, mg/kg etc. plus dose level (e. g. 50 mg/kg).
DOSEVAL	Numeric Dose Value	Num	In 50 mg/kg example above, DOSEVAL would equal 50.
DAYS	Day of Estrous Stage Evaluation	Num	
ESTSTAGE	Estrous Stage	Char	

**Estrous Cyclicity Data (ESTROUS0.V5X, ESTROUS1.V5X)**

<b>Variable</b>	<b>Label</b>	<b>Type</b>	<b>Codes and Comments</b>
STUDYNUM	Study Number	Char	
SPECIES	Species	Char	M = mouse, R = rat, D = dog.
ANIMLNUM	Animal Number	Char	
SEX	Sex	Char	M = male, F = female.
DOSEGP	Dose Group	Num	Use 0, 1, 2, 3, 4, etc, in ascending order from control.
DOSETEXT	Dose Group Representation	Char	PPM, mg/kg etc. plus dose level (e. g. 50 mg/kg).
DOSEVAL	Numeric Dose Value	Num	In 50 mg/kg example above, DOSEVAL would equal 50.
DAYS	Day of Estrous Evaluation	Num	
ESTSTAGE	Estrous Stage	Char	

**Animals Paired (PAIRED0.V5X, PAIRED1.V5X)**

Variable	Label	Type	Codes and Comments
STUDYNUM	Study Number	Char	
SPECIES	Species	Char	M = mouse, R = rat, D = dog.
DAMNUM	Dam Number	Char	
DOSEGP	Dose Group	Num	Use 0, 1, 2, 3, 4, etc, in ascending order from control.
DOSETEXT	Dose Group Representation	Char	PPM, mg/kg etc. plus dose level (e. g. 50 mg/kg).
DOSEVAL	Numeric Dose Value	Num	In 50 mg/kg example above, DOSEVAL would equal 50.
MALENUM	Sire Number	Char	
ALTMALE	Alternate Male Number	Char	
MATESTAT	Mating Status	Char	
OUTCOME	Outcome	Char	

**Animals Mated (MATED0.V5X, MATED1.V5X)**

<b>Variable</b>	<b>Label</b>	<b>Type</b>	<b>Codes and Comments</b>
STUDYNUM	Study Number	Char	
SPECIES	Species	Char	M = mouse, R = rat, D = dog.
ANIMLNUM	Animal Number	Char	
SEX	Sex	Char	M = male, F = female.
DOSEGP	Dose Group	Num	Use 0, 1, 2, 3, 4, etc, in ascending order from control.
DOSETEXT	Dose Group Representation	Char	PPM, mg/kg etc. plus dose level (e. g. 50 mg/kg).
DOSEVAL	Numeric Dose Value	Num	In 50 mg/kg example above, DOSEVAL would equal 50.
DATEPREG	Date Pregnant	Num	

**Precoital Interval Data (PRECOIT0.V5X, PRECOIT1.V5X)**

<b>Variable</b>	<b>Label</b>	<b>Type</b>	<b>Codes and Comments</b>
STUDYNUM	Study Number	Char	
SPECIES	Species	Char	M = mouse, R = rat, D = dog.
ANIMLNUM	Animal Number	Char	
SEX	Sex	Char	M = male, F = female.
DOSEGP	Dose Group	Num	Use 0, 1, 2, 3, 4, etc, in ascending order from control.
DOSETEXT	Dose Group Representation	Char	PPM, mg/kg etc. plus dose level (e. g. 50 mg/kg).
DOSEVAL	Numeric Dose Value	Num	In 50 mg/kg example above, DOSEVAL would equal 50.

**Pregnancy Status (PREG0.V5X, PREG1.V5X)**

Variable	Label	Type	Codes and Comments
STUDYNUM	Study Number	Char	
SPECIES	Species	Char	M = mouse, R = rat, D = dog.
ANIMLNUM	Animal Number	Char	
SEX	Sex	Char	F = female.
DOSEGP	Dose Group	Num	Use 0, 1, 2, 3, 4, etc, in ascending order from control.
DOSETEXT	Dose Group Representation	Char	PPM, mg/kg etc. plus dose level (e. g. 50 mg/kg).
DOSEVAL	Numeric Dose Value	Num	In 50 mg/kg example above, DOSEVAL would equal 50.
DATEPREG	Date Pregnant	Num	
SCHEDSAC	Scheduled Sac Date	Num	
DTHDATE	Actual Death Date	Num	
DELTYPE	Delivery Type	Char	
PREGSTAT	Pregnancy Status	Char	
DELDATE	Date of Delivery	Char	

**Duration of Gestation (GESTDUR0.V5X, GESTDUR1.V5X)**

<b>Variable</b>	<b>Label</b>	<b>Type</b>	<b>Codes and Comments</b>
STUDYNUM	Study Number	Char	
SPECIES	Species	Char	M = mouse, R = rat, D = dog.
ANIMLNUM	Animal Number	Char	
SEX	Sex	Char	F = female.
DOSEGP	Dose Group	Num	Use 0, 1, 2, 3, 4, etc, in ascending order from control.
DOSETEXT	Dose Group Representation	Char	PPM, mg/kg etc. plus dose level (e. g. 50 mg/kg).
DOSEVAL	Numeric Dose Value	Num	In 50 mg/kg example above, DOSEVAL would equal 50.
GESTDUR	Duration of Gestation	Num	Duration in Days.

**Offspring Mortality Data for Each Animal (OMORTAL0.V5X, OMORTAL1.V5X)**

Variable	Label	Type	Codes and Comments
STUDYNUM	Study Number	Char	
SPECIES	Species	Char	M = mouse, R = rat, D = dog.
ANIMLNUM	Animal Number	Char	
PUPNUM	Pup Number	Num	
SEX	Sex	Char	M = male, F = female.
DOSEGP	Dose Group	Num	Use 0, 1, 2, 3, 4, etc, in ascending order from control.
DOSETEXT	Dose Group Representation	Char	PPM, mg/kg etc. plus dose level (e. g. 50 mg/kg).
DOSEVAL	Numeric Dose Value	Num	In 50 mg/kg example above, DOSEVAL would equal 50.
DTHSACST	Death or Sac Status	Num	
DTHDESC	Description of Death or Sac Status	Char	Use to define DTHSACST codes.
WEIGHT	Terminal Body Weight	Num	
UNIT	Unit of Measurement	Char	



**Clinical Signs for Each Animal (OSIGNS0.V5X, OSIGNS1.V5X)**

<b>Variable</b>	<b>Label</b>	<b>Type</b>	<b>Codes and Comments</b>
STUDYNUM	Study Number	Char	
SPECIES	Animal Species	Char	M = mouse, R = rat, D = dog
ANIMLNUM	Animal Number	Num	
PUPNUM	Pup Number	Num	
SEX	Sex	Char	M = male, F = female.
DOSEGP	Dose Group	Num	Use 0, 1, 2, 3, 4, etc, in ascending order from control.
DOSETEXT	Dose Group Representation	Char	PPM, mg/kg etc. plus dose level (e. g. 50 mg/kg).
DOSEVAL	Numeric Dose Value	Num	In 50 mg/kg example above, DOSEVAL would equal 50.
DAYS	Day of Clinical Sign	Num	
SIGN	Clinical Sign	Char	
START	Days on Drug Sign First Seen	Num	
SEVERITY	Severity	Char	
EXCLUDE	Is This Record Excluded from Summaries?	Char	'YES' if record should be excluded. Blank (" ") if record should NOT be excluded.
EXCCODE	Exclusion Code	Char	(if codes are used.)
EXCDESC	Exclusion Description or Reason	Char	Not Observed, etc.

**Body Weight Data for Each Pup (PUPWT.V5X)**

<b>Variable</b>	<b>Label</b>	<b>Type</b>	<b>Codes and Comments</b>
STUDYNUM	Study Number	Char	
SPECIES	Animal Species	Char	M = mouse, R = rat, D = dog.
ANIMLNUM	Animal Number	Num	
PUPNUM	Pup Number	Num	
SEX	Sex	Char	M = male, F = female.
DOSEGP	Dose Group	Num	Use 0, 1, 2, 3, 4, etc, in ascending order from control.
DOSETEXT	Dose Group Representation	Char	PPM, mg/kg etc. plus dose level (e. g. 50 mg/kg).
DOSEVAL	Numeric Dose Value	Num	In 50 mg/kg example above, DOSEVAL would equal 50.
DAYS	Day of Measurement	Num	
WEIGHT	Body Weight	Num	
UNIT	Unit of Weight Measurement	Char	g = gram, kg = kilograms, etc.
EXCLUDE	Is This Record Excluded from Summaries?	Char	'YES' if record should be excluded. Blank (" ") if record should NOT be excluded.
EXCCODE	Exclusion Code	Char	(if codes are used.)
EXCDESC	Exclusion Description or Reason	Char	Not Measured, etc.

**Anogenital Distance for Each Animal (SPERM0.V5X, SPERM1.V5X)**

<b>Variable</b>	<b>Label</b>	<b>Type</b>	<b>Codes and Comments</b>
STUDYNUM	Study Number	Char	
SPECIES	Species	Char	M = mouse, R = rat, D = dog.
ANIMLNUM	Animal Number	Char	
SEX	Sex	Char	M = male.
DOSEGP	Dose Group	Num	Use 0, 1, 2, 3, 4, etc, in ascending order from control.
DOSETEXT	Dose Group Representation	Char	PPM, mg/kg etc. plus dose level (e. g. 50 mg/kg).
DOSEVAL	Numeric Dose Value	Num	In 50 mg/kg example above, DOSEVAL would equal 50.

**Age at Sexual Maturity for Each Animal (SEXMAT0.V5X, SEXMAT1.V5X)**

Variable	Label	Type	Codes and Comments
STUDYNUM	Study Number	Char	
SPECIES	Species	Char	M = mouse, R = rat, D = dog.
ANIMLNUM	Animal Number	Char	
PUPNUM	Pup Number	Char	
SEX	Sex	Char	M = male, F = female.
DOSEGP	Dose Group	Num	Use 0, 1, 2, 3, 4, etc, in ascending order from control.
DOSETEXT	Dose Group Representation	Char	PPM, mg/kg etc. plus dose level (e. g. 50 mg/kg).
DOSEVAL	Numeric Dose Value	Num	In 50 mg/kg example above, DOSEVAL would equal 50.
AGE	Age at Sexual Maturity	Num	Age in Days (Relative to postnatal day 0).

**Litter Data (LITTER0.V5X, LITTER1.v5x)**

<b>Variable</b>	<b>Label</b>	<b>Type</b>	<b>Codes and Comments</b>
STUDYNUM	Study Number	Char	
SPECIES	Species	Char	M = mouse, R = rat, D = dog.
ANIMLNUM	Animal (Litter) Number	Char	
SEX	Sex	Char	F = female.
DOSEGP	Dose Group	Num	Use 0, 1, 2, 3, 4, etc, in ascending order from control.
DOSETEXT	Dose Group Representation	Char	PPM, mg/kg etc. plus dose level (e. g. 50 mg/kg).
DOSEVAL	Numeric Dose Value	Num	In 50 mg/kg example above, DOSEVAL would equal 50.
GESTLEN	Gestation Length in Days	Num	
LIVE	Number of Live Pups	Num	
DEAD	Number of Dead Pups	Num	
UNCERT	Uncertain	Num	
TOTAL	Total Number of pups	Num	
IMPLANTS	Number of Implants	Num	
MALE	Number of Male Pups	Num	
FEMALE	Number of Female Pups	Num	

**Macroscopic Findings (OMACRO0.V5X, OMACRO1.V5X)**

Variable	Label	Type	Codes and Comments
STUDYNUM	Study Nnumber	Char	
SPECIES	Animal Species	Char	M = mouse, R = rat, D = dog.
ANIMLNUM	Animal Number	Char	
PUPNUM	Pup Number	Num	
SEX	Sex	Char	M = male, F = female.
DOSEGP	Dose Group	Num	Use 0, 1, 2, 3, 4, etc, in ascending order from control.
DOSETEXT	Dose Group Representation	Char	PPM, mg/kg etc. plus dose level (e. g. 50 mg/kg).
DOSEVAL	Numeric Dose Value	Num	In 50 mg/kg example above, DOSEVAL would equal 50.
OBS_DATE	Date of Observation	Char	
ORGANNAM	Name of Organ	Char	
MACRO	Macroscopic Findings	Char	Do not include comments associated with findings. Full details for abnormal findings should be described in study report.
MODIFIER	Modifier	Char	
GRADE	Grade or Severity of Abnormality	Char	
EXCLUDE	Is This Record Excluded from Summaries?	Char	'YES' if record should be excluded. Blank (" ") if record should NOT be excluded.
EXCCODE	Exclusion Code	Char	(if codes are used.)
EXCDESC	Exclusion Description or Reason	Char	Text Description.

**Organ Weight for Every Organ Examined for Each Offspring Animal  
(OORGWT0.V5X, OORGWT1.V5X)**

Variable	Label	Type	Codes and Comments
STUDYNUM	Study Number	Char	
SPECIES	Animal Species	Char	M = mouse, R = rat, D = dog.
ANIMLNUM	Animal Number	Char	
PUPNUM	Pup Number	Num	
SEX	Sex	Char	M = male, F = female.
DOSEGP	Dose Group	Num	Use 0, 1, 2, 3, 4, etc. in ascending order from control. Provide the dosing for each group
DOSETEXT	Dose Group Representation	Char	PPM, mg/kg etc. plus dose level (e. g. 50 mg/kg).
DOSEVAL	Numeric Dose Value	Num	In 50 mg/kg example above, DOSEVAL would equal 50.
FNLBDYWT	Final Body Weight	Num	
UNITBODW	Body Weight Units	Num	
DAYS	Days on Drug at Observation	Num	
ORGANNAM	Organ Name	Char	
ORGANWT	Weight of Organ	Num	
UNIT	Organ Weight Unit of Measurement	Char	
EXCLUDE	Is This Record Excluded from Summaries?	Char	'YES' if record should be excluded. Blank (" ") if record should NOT be excluded.
EXCCODE	Exclusion Code	Char	(if codes are used.)
EXCDESC	Exclusion Description or Reason	Char	Text Description.

**Microscopic Findings (histopathology) for Each Animal (OMICRO0.V5X, OMICRO1.V5X)**

Variable	Label	Type	Codes and Comments
STUDYNUM	Study Number	Char	
SPECIES	Animal Species	Char	M = mouse, R = rat, D = dog.
ANIMLNUM	Animal Number	Char	
PUPNUM	Pup Number	Num	
SEX	Sex	Char	M = male, F = female.
DOSEGP	Dose Group	Num	Use 0, 1, 2, 3, 4, . . . in ascending order from control. Provide the dosing for each group
DOSETEXT	Dose Group Representation	Char	PPM, mg/kg etc. plus dose level (e. g. 50 mg/kg).
DOSEVAL	Numeric Dose Value	Num	In 50 mg/kg example above, DOSEVAL would equal 50.
ORGANNAM	Name of Organ	Char	
MICRO	Microscopic Findings	Char	Do not include comments associated with findings. Full details for abnormal findings should be described in study report.
GRADE	Grade or Severity of Abnormality	Char	
TUMOR	Tumor Flag	Char	None, Benign, Malignant, or Indeterminate.
EXCLUDE	Is This Record Excluded from Summaries?	Char	'YES' if record should be excluded. Blank (" ") if record should NOT be excluded.
EXCCODE	Exclusion Code	Char	(if codes are used.)
EXCDESC	Exclusion Description or Reason	Char	Text Description.