US Environmental Protection Agency
Office of Pesticide Programs

Prenatal Developmental Toxicity 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

Prenatal Developmental Toxicity 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

Dataset	Description of Dataset
MORTAL	Mortality information.
SIGNS	Clinical signs.
WEIGHTS	Body weights.
FOOD	Food consumption.
MACRO	Gross pathology findings (Macroscopic examination of tissues).
UTCARCWT	Uterine weight, carcass weight, adjusted body weight gain.
MATED	Animals mated.
PREGSTAT	Pregnancy status.

REPRODAT	Reproduction data:
	    No. Corpora Lutea,
	    No. Implantations,
	    No. Live fetuses,
	    No. Dead fetuses,
	    No. Resorptions – Early, Late.

FETDAT	Individual fetal data.
FETEXT	Individual fetal findings – External.
FETVISC	Individual fetal findings – Visceral.
FETSKEL	Individual fetal findings - Skeletal.
FETSK_I	Individual fetal findings – Skeletal incompletely evaluated litters.
PLANCENTA	Placental findings.
Other	Other datasets as needed.

Mortality Data for Each Animal (MORTAL.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 (SIGNS.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.
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 Weights for Each Animal (WEIGHTS.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.
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.

Food Consumption for Each Animal (FOOD.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.
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.

Macroscopic Findings for Each Animal (MACRO.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.
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.

Uterine Weight, Carcass Weight, and Adjusted Body Weight Gain for Each Animal (UTCARCwt.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.
UTERWT	Uterus Weight	Num	
CARCWT	Carcass Weight	Num	
WTCHG	Weight Change Day 0 to 20	Num	
ADJWTCHG	Adjusted Weight Change Day 0 to 20	Num	
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.

Animals Mated (MATED.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	
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.

Pregnancy Status (PREGSTAT.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	
ACTDEATH	Actual Death Date	Num	
DELTYPE	Delivery Type	Char	
PREGSTAT	Pregnancy Status	Char	
DELDATE	Date of Delivery	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.

Reproduction Data (REPRODAT.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.
CORLUTEA	Number of Corpora Lutea	Num	
IMPLANTS	Number of Implantations	Num	
FETUS_L	Number of Live Fetuses	Num	
FETUS_D	Number of Dead Fetuses	Num	
RESORP_E	Number of Resorptions - Early	Num	
RESORP_L	Number of Resorptions - Late	Num	
MALES	Number of Males	Num	
FEMALES	Number of Females	Num	
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.

Individual Fetal Data (FETDAT.V5X)

Variable	Label	Type	Codes and Comments
STUDYNUM	Study number	Char	
SPECIES	Species	Char	M = mouse, R = rat, D = dog.
ANIMLNUM	Dam (Litter) 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.
IMPNUM	Implant Number	Num	
LOCATION	Implant Location	Char	Right or Left.
FETNUM	Fetus number	Num	
FETSEX	Fetus sex	Char	M = male, F = female.
RESORP_E	Early Resorption?	Num	0=No, 1=Yes.
RESORP_L	Late Resorption?	Num	0=No, 1=Yes.
DEAD	Dead Fetus?	Num	0=No, 1=Yes.
FETWT	Fetal Weight	Num	Unit = grams.
PLACWT	Placental Weight	Num	Unit = grams.
FIXATION	Fixation Type	Char	S = Skeletal, V = Visceral.
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.

Individual Fetal Findings - External (FETEXT.V5X)

Variable	Label	Type	Codes and Comments
STUDYNUM	Study number	Char	
SPECIES	Species	Char	M = mouse, R = rat, D = dog.
ANIMLNUM	Dam (Litter) number	Char	
FETNUM	Fetus number	Num	
FETSEX	Fetus 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.
OBSDATE	Observation Date	Num	
DAYS	Nominal Day of Observation	Num	
ORGAN	Organ Name	Char	
OBS	Observation	Char	
MODIFIER	Modifier	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.

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Individual Fetal Findings - Visceral (FETVISC.V5X)

Variable	Label	Type	Codes and Comments
STUDYNUM	Study number	Char	
SPECIES	Species	Char	M = mouse, R = rat, D = dog.
ANIMLNUM	Dam (Litter) number	Char	
FETNUM	Fetus number	Num	
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.
OBSDATE	Observation Date	Num	
DAYS	Nominal Day of Observation	Num	
ORGAN	Organ Name	Char	
OBS	Observation	Char	
MODIFIER	Modifier	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.

Individual Fetal Findings - Skeletal (FETSKEL.V5X)

Variable	Label	Type	Codes and Comments
STUDYNUM	Study number	Char	
SPECIES	Species	Char	M = mouse, R = rat, D = dog.
ANIMLNUM	Dam (Litter) number	Char	
FETNUM	Fetus number	Num	
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.
OBSDATE	Observation Date	Num	
DAYS	Nominal Day of Observation	Num	
SKELSYS	Skeletal System	Char	
OBS	Observation	Char	
LOC1	1st Location	Char	
LOC2	2nd Location	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.

Placental Findings (PLACENTA.V5X)

Variable	Label	Type	Codes and Comments
STUDYNUM	Study number	Char	
SPECIES	Species	Char	M = mouse, R = rat, D = dog.
ANIMLNUM	Dam (Litter) number	Char	
FETNUM	Fetus number	Num	
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.
OBSDATE	Observation Date	Num	
DAYS	Nominal Day of Observation	Num	
OBS	Observation	Char	
MODIFIER	Modifier	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.