US Environmental Protection Agency Office of Pesticide Programs

Developmental Neurotoxicity (DNT) 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

Developmental Neurotoxicity (DNT) 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.

Standard Format for Electronic Submission of Supplemental Data Files
in Support of Developmental Neurotoxicity (DNT) Studies.

July 31, 2002

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STANDARD DATASET FOR MATERNAL ANIMALS	
Dataset	**Description**
MGWEIGHT	Gestation body weight.
MLWEIGHT	Lactation body weight.
MGFOOD	Gestation food consumption. *** For studies conducted with dietary administration**.
MLFOOD	Lactation food consumption. *** For studies conducted with dietary administration.**
MGSIGNS	Gestation clinical signs.
MLSIGNS	Lactation clinical signs.
MGESTDUR	Gestation duration.
MMORT	Mortality.
MFOBOBS	FOB – Observations.
MFOBNUM	FOB – Numeric parameters.
MMA	Motor activity.
[To be identified by Registrant]	Clinical biomarker data, e.g., ChE.
[To be identified by Registrant]	Other datasets as needed.

STANDARD DATASETS FOR OFFSPRING	
Dataset	**Description**
COUNT	Lactation pup count (live and dead).
LWEIGHT	Lactation body weight.
PWEIGHT	Postweaning body weight.
PSIGNS	Clinical signs.
PMORT	Mortality.
SEXMAT	Sexual maturation.
PFOBOBS	FOB – Observations.
PFOBNUM	FOB – Numeric parameters.
PMA	Motor activity.
AUD	Auditory startle.
PASSIVE	Passive avoidance (Learning & memory phases). **** Can include only one file for learning and memory depending on testing paradigm***.
WMAZE	Water ("M") maze (Learning & memory phases)**. **** Can include only one file for learning and memory depending on testing paradigm.***
BRWEIGHT	Brain weight.
BRMEASUR	Brain measurements.
GROSS	Gross pathology.
MICRO	Microscopic pathology.
MORPH	Morphometric analysis of brain.
[To be identified by Registrant]	Clinical biomarker data, e.g., ChE.
[To be identified by Registrant]	Other datasets as needed.

Gestation Body Weight Data for Each Maternal Animal (MGWEIGHT.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/mg).
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.

Lactation Body Weight Data for Each Maternal Animal (MLWEIGHT.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.

Gestation Food Consumption Data for Each Maternal Animal (MGFOOD.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	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.
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.

Lactation Food Consumption Data for Each Maternal Animal (MLFOOD.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	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.
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.

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Gestation Clinical Signs for Each Maternal Animal (MGSIGNS.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.

Lactation Clinical Signs for Each Maternal Animal (MLSIGNS.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.

Gestation Duration for Each Maternal Animal (MGESTDUR.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.
GESTDUR	Duration of Gestation	Num	Duration in Days.

Maternal Mortality Data for Each Animal (MMORT.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.

Maternal FOB Observations (MFOBOBS.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	Num	
DAY	Nominal Day of Observation	Char	
CATEGORY	Category of Observation	Char	
OBS	Observation	Char	
FINDING	Finding	Char	
SEVERITY	Severity	Char	
COLOR	Color	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.

Maternal FOB Numeric Parameters (MFOBNUM.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		
DAY	Nominal Day of Observation	Char	
CATEGORY	Category of Numeric Observation	Char	
OBS	Observation	Char	
FINDING	Finding	Char	
OBS	Observation	Char	
FINDING	Finding	Char	
VALUE	Result	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.

Maternal Motor Activity (MMA.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 Testing	Num	
DAY	Nominal Day of Testing	Num	
DURATION	Duration of Test	Num	
MAZENUM	Maze Number	Num	
BEAMNUM	Number of Beam Being Interrupted	Num	
BEAM_DUR	Duration of Beam Break	Num	msec.
B_TIME	Time of Beam Break	Num	hh:mm:ss
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.

Lactation Pup Count (Live and Dead) (COUNT.V5X)

Variable	Label	Type	Codes and Comments
STUDYNUM	Study Number	Char	
SPECIES	Species	Char	M = mouse, R = rat, D = dog.
LITTERNO	Litter (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.
DAY	Postnatal Day of Observation	Num	Example intervals: 0, 4 precull, 4 postcull, 7, 14, 21.
LIVE	Number of Live Pups	Num	Variables LIVE, DEAD, CULLED, and MISSING should represent the total number of pups on any given day.
DEAD	Number of Dead Pups	Num	
CULLED	Number of Culled Pups	Num	
MISSING	Number of Missing or Cannibalized Pups	Num	

Lactation Body Weight Data for Each Pup (LWEIGHT.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.
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.

Postweining Body Weight Data for Each Pup (PWEIGHT.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.
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.

Clinical Signs for Each Pup (PSIGNS.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.
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.

Mortality Data for Each Pup (PMORT.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.
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.

Sexual Maturation for Each Pup (SEXMAT.V5X)

Variable	Label	Type	Codes and Comments
STUDYNUM	Study Number	Char	
SPECIES	Species	Char	M = mouse, R = rat, D = dog.
LITTERNO	Litter (dam) Number	Char	
PUPNUM	Pup 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.
SEX	Pup Sex	Char	M = male, F = female.
DAY	Postnatal Day of Positive Finding	Num	Day of preputial separation (M) or vaginal opening (F).
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.

Pup FOB – Observations (PFOBOBS.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.
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	Num	
DAY	Nominal Day of Observation	Char	
CATEGORY	Category of Observation	Char	
OBS	Observation	Char	
FINDING	Finding	Char	
SEVERITY	Severity	Char	
COLOR	Color	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.

Pup FOB – Numeric Parameters (PFOBNUM.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.
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	Num	
DAY	Nominal Day of Observation	Char	
CATEGORY	Category of Numeric Observation	Char	
OBS	Observation	Char	
FINDING	Finding	Char	
VALUE	Result	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.

Pup Motor Activity (PMA.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.
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 Testing	Num	
DAY	Nominal Day of Testing	Num	
DURATION	Duration of Test	Num	
MAZENUM	Maze Number	Num	
BEAMNUM	Number of Beam Being Interrupted	Num	
BEAM_DUR	Duration of Beam Break	Num	msec.
B_TIME	Time of Beam Break	Num	hh:mm:ss
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.

Auditory Startle (AUD.V5X)

Variable	Label	Type	Codes and Comments
STUDYNUM	Study Number	Char	
SPECIES	Species	Char	M = mouse, R = rat, D = dog.
LITTERNO	Litter (dam) Number	Char	
PUPNUM	Pup 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.
SEX	Pup Sex	Char	M = male, F = female.
DAY	Postnatal Day of Testing	Num	Example testing days: 22, 60.
BLOCK	Block Number	Num	
TRIAL	Trial Number	Num	
LATENCY	Latency to Peak Response	Num	UNIT = Miliseconds.
DURATION	Response Duration	Num	UNIT = Miliseconds.
PEAKAMP	Peak Amplitude of Response	Num	UNIT = Grams.
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.

Passive Avoidance Learning & Memory Data for Each Pup (PASSIVE.V5X)

Variable	Label	Type	Codes and Comments
STUDYNUM	Study Number	Char	
SPECIES	Species	Char	M = mouse, R = rat, D = dog.
LITTERNO	Litter (dam) Number	Char	
PUPNUM	Pup Number	Num	
SEX	Pup 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.
DAY	Postnatal Day of Testing	Num	First test day = Learning, Second = Memory
TRIAL	Trial Number	Num	
MAXTRIAL	Maximum Number of Trials Allowed	Num	
TIME	Trial Time	Num	Length of the trial (how long did the trial last?)
MAXTIME	Maximum Time Allowed for a Trial	Num	How long will the animal be allowed to continue if the trial criterion is not met?
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.

Water ("M") Maze for Each Pup (Wmaze.V5X)

Variable	Label	Type	Codes and Comments
STUDYNUM	Study Number	Char	
SPECIES	Species	Char	M = mouse, R = rat, D = dog.
LITTERNO	Litter (dam) Number	Char	
PUPNUM	Pup 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.
SEX	Pup Sex	Char	M = male, F = female.
DAY	Postnatal Day of Testing	Num	First test day = Learning, Second = Memory.
TRIAL	Trial Number	Num	
TIME	Trial Time	Num	Length of the trial (how long did the trial last?)
MAXTIME	Maximum Time Allowed for a Trial	Num	How long will the animal be allowed to continue if trial criterion is not met?
ERRORS	No. of Errors	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.

Brain Weight Data for Each Pup (BRWEIGHT.V5X)

Variable	Label	Type	Codes and Comments
STUDYNUM	Study Number	Char	
SPECIES	Species	Char	M = mouse, R = rat, D = dog.
LITTERNO	Litter (dam) Number	Char	
PUPNUM	Pup 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.
DAY	Postnatal Day of Termination	Num	
SEX	Pup Sex	Char	M = male, F = female.
FIANLBW	Final Body Weight	Num	
BRAINWT	Absolute Whole Brain Weight	Num	
RATIO	Brain Weight to Body Weight Ratio	Num	BRAINWT / FINALBW.
REGIONWT	Regional Brain Weight Measurements	Num	One observation per row. Example regions: cerebellum, forebrain, hindbrain.
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.

Brain Measurement (Dimension) Data for Each Pup (BRMEASUR.V5X)

Variable	Label	Type	Codes and Comments
STUDYNUM	Study Number	Char	
SPECIES	Species	Char	M = mouse, R = rat, D = dog.
LITTERNO	Litter (dam) Number	Char	
PUPNUM	Pup 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.
DAY	Postnatal Day of Termination	Num	
SEX	Pup Sex	Char	M = male, F = female.
WIDTH	Width of Brain	Num	At designated morphological location.
LENGTH	Length of Brain	Num	At designated morphological location.
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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Gross Pathology Observations for Each Pup (GROSS.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.
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.

Microscopic Pathology Observations for Each Pup (Micro.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.
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.

Brain Morphometric Measurement Data for Each Pup (MORPH.V5X)

Variable	Label	Type	Codes and Comments
STUDYNUM	Study Number	Char	
SPECIES	Species	Char	M = mouse, R = rat, D = dog.
LITTERNO	Litter (dam) Number	Char	
PUPNUM	Pup Number	Num	
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.
DAY	Postnatal Day of Termination	Num	
SEX	Pup Sex	Char	M = male, F = female.
NEOCORT	Thickness in the Neocortex	Num	
HIPPO	Thickness in the Hippocampus	Num	
CEREBELL	Thickness in the Cerebellum	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.

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RBC Cholinesterase Data Observations for Each Pup (RBCChE.V5X)

Variable	Label	Type	Codes and Comments
STUDYNUM	Study Number	Char	
SPECIES	Species	Char	M = mouse, R = rat, D = dog.
LITTERNO	Litter (dam) Number	Char	
PUPNUM	Pup Number	Num	
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.
SEX	Pup Sex	Char	M = male, F = female.
DAY	Postnatal Day of Sample Collection	Num	Examples: PND 4, 11, 21, 60.
RBCChE	RBC Cholinesterase Measurement	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.