INTRODUCTION

Tris(1-chloro-2-propyl)phosphate (TCPP) belongs to a class of chemicals known as trisphosphates, more specifically, aliphatic halogenated trisphosphates (NICNAS, 2001). Trisphosphates are primarily used industrially as flame retardants, plasticizers, and solvents (NICNAS, 2001). TCPP is used as a flame retardant in polyurethane foam (OECD, 2000). Figure 1 provides the chemical structure for TCPP. A table of physicochemical properties is provided below (see Table 1).

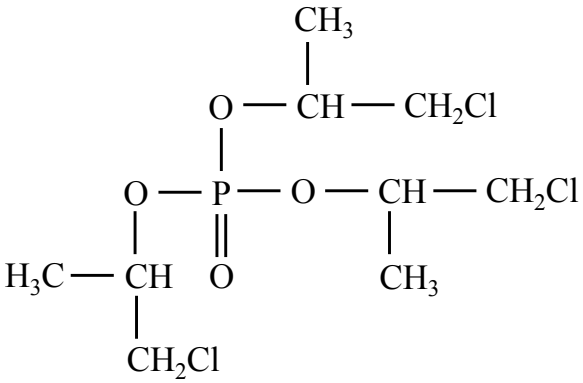


Figure 1. Tris(1-chloro-2-propyl)phosphate Structure

Table 1. Physicochemical Properties for TCPP (CASRN 13674-84-5)[a]

Property (unit)	Value
Boiling point (ºC)	Not available
Melting point (ºC)	−40
Density (g/cm^3)	1.29
Vapor pressure (Pa at 25ºC)	<260
pH (unitless)	Not available
Solubility in water (g/L at 20ºC)	1.6
Relative vapor density (air = 1)	Not available
Molecular weight (g/mol)	327.6

[a]NICNAS (2001).

No Reference Dose (RfD), Reference Concentration (RfC), or cancer assessment for TCPP is included on the EPA's Integrated Risk Information System (IRIS) database (U.S. EPA, 2011a) or on the Drinking Water Standards and Health Advisories List (U.S. EPA, 2009). No RfD or RfC values were reported in the Health Effects Assessment Summary Tables (HEAST) (U.S. EPA, 2011b). The Chemical Assessments and Related Activities (CARA) list did not include a Health and Environmental Effects Profile (HEEP) for TCPP (U.S. EPA, 1994a). The

Agency for Toxic Substances and Disease Registry (ATSDR) is in the process of reviewing the toxicity of TCPP in conjunction with other phosphate ester flame retardants, and a draft Toxicological Profile is available (ATSDR, 2009). No minimal risk levels were reported for TCPP due to lack of adequate information. The World Health Organization (WHO) reviewed the toxicity of TCPP in an Environmental Health Criteria document (IPCS, 1998) and indicated that adverse health effects are negligible due to low exposure risk. The California Environmental Protection Agency (CalEPA, 2008, 2009) has not derived toxicity values for exposure to TCPP. No occupational exposure limits for TCPP have been derived or recommended by the American Conference of Governmental Industrial Hygienists (ACGIH, 2011), proposed by the National Institute of Occupational Safety and Health (NIOSH, 2011), or adopted by the Occupational Safety and Health Administration (OSHA, 2006).

The HEAST (U.S. EPA, 2011b) does not report a cancer weight-of-evidence (WOE) classification or an oral slope factor for TCPP. The International Agency for Research on Cancer (IARC, 2011) has not reviewed the carcinogenic potential of TCPP. TCPP is not included in the *12th Report on Carcinogens* (NTP, 2011c). CalEPA (2008) has not derived a quantitative estimate of carcinogenic potential for TCPP.

Literature searches were conducted on sources published from 1900 through September 13, 2011 for studies relevant to the derivation of provisional toxicity values for tris(1-chloro-2-propyl)phosphate (TCPP), CAS No. 13674-84-5. Searches were conducted using EPA's Health and Environmental Research Online (HERO) database of scientific literature. HERO searches the following databases: AGRICOLA; American Chemical Society; BioOne; Cochrane Library; DOE: Energy Information Administration, Information Bridge, and Energy Citations Database; EBSCO: Academic Search Complete; GeoRef Preview; GPO: Government Printing Office; Informaworld; IngentaConnect; J-STAGE: Japan Science & Technology; JSTOR: Mathematics & Statistics and Life Sciences; NSCEP/NEPIS (EPA publications available through the National Service Center for Environmental Publications [NSCEP] and National Environmental Publications Internet Site [NEPIS] database); PubMed: MEDLINE and CANCERLIT databases; SAGE; Science Direct; Scirus; Scitopia; SpringerLink; TOXNET (Toxicology Data Network): ANEUPL, CCRIS, ChemIDplus, CIS, CRISP, DART, EMIC, EPIDEM, ETICBACK, FEDRIP, GENE-TOX, HAPAB, HEEP, HMTC, HSDB, IRIS, ITER, LactMed, Multi-Database Search, NIOSH, NTIS, PESTAB, PPBIB, RISKLINE, TRI; and TSCATS; Virtual Health Library; Web of Science (searches Current Contents database among others); World Health Organization; and Worldwide Science. The following databases outside of HERO were searched for health information: ACGIH, ATSDR, CalEPA, EPA IRIS, EPA HEAST, EPA HEEP, EPA OW, EPA TSCATS/TSCATS2, NIOSH, NTP, OSHA, and RTECS.

REVIEW OF POTENTIALLY RELEVANT DATA (CANCER AND NONCANCER)

Table 2 provides an overview of the relevant database for TCPP and includes all potentially relevant repeated short-term-, subchronic-, and chronic-duration studies. Principal studies are identified. The phrase "statistical significance," used throughout the document, indicates a p-value of <0.05.

Table 2. Summary of Potentially Relevant Data for TCPP (CASRN 13674-84-5)

Category	Number of Male/Female, Strain, Species, Study Type, Study Duration	Dosimetry[a]	Critical Effects	NOAEL[a]	BMDL/ BMCL[a]	LOAEL[a]	Reference (Comments)	Notes[b]
Human								
1. Oral (mg/kg-d)								
Subchronic	ND							
Chronic	ND							
Developmental	ND							
Reproductive	ND							
Carcinogenicity	ND							
2. Inhalation (mg/m^3)								
Subchronic	ND							
Chronic	ND							
Developmental	ND							
Reproductive	ND							
Carcinogenicity	ND							
Animal								
1. Oral (mg/kg-d)								
Subchronic	20/20, CD rat, diet, 90 d	Males: 0, 36, 112, 337, 944; Females: 0, 43, 120, 399, 1222[c] (Adjusted)	Increased liver weight in males[d]	ND	NDr	36[e]	Freudenthal and Henrich (1999) Compound used was 70% TCPP; doses are adjusted for TCPP content.	

Table 2. Summary of Potentially Relevant Data for TCPP (CASRN 13674-84-5)								
Category	**Number of Male/Female, Strain, Species, Study Type, Study Duration**	**Dosimetry[a]**	**Critical Effects**	**NOAEL[a]**	**BMDL/ BMCL[a]**	**LOAEL[a]**	**Reference (Comments)**	**Notes[b]**
	10/10 B6C3F$_1$ mice, diet, 14 wk	**Males: 0, 219, 456, 737, 2470, 4410** **Females: 0, 198, 420, 906, 1930, 3590 (Adjusted)**	**Decreased terminal body weight; increased relative liver weight in males** **Hepatocyte hypertrophy in males**	**219** **737**	**NDr** **138**	**456** **2470**	**NTP (2011a,b)**	**PS**
Chronic	ND							
Developmental	0/11−14, Wistar rat, diet, GD 0−20	0, 6.7, 69, 670 tris(chloropropyl)phosphate (Adjusted)	Missing 13th rib in fetuses	69[e]	278	670	Kawasaki et al. (1982)[f] Compound used was tris(chloro-propyl)phos-phate, a mixture that contains TCPP. Doses are not corrected for TCPP content because sufficient information was not available.	
Reproductive	ND							
Carcinogenicity	ND							
2. Inhalation (mg/m^3)								
Subchronic	ND							
Chronic	ND							
Developmental	ND							
Reproductive	ND							
Carcinogenicity	ND							

Table 2. Summary of Potentially Relevant Data for TCPP (CASRN 13674-84-5)

Category	Number of Male/Female, Strain, Species, Study Type, Study Duration	Dosimetry[a]	Critical Effects	NOAEL[a]	BMDL/ BMCL[a]	LOAEL[a]	Reference (Comments)	Notes[b]

[a]Dosimetry: NOAEL, BMDL/BMCL, and LOAEL values are converted to an adjusted daily dose (ADD in mg/kg-d) for oral noncancer effects. All long-term exposure values (4 wk and longer) are converted from a discontinuous to a continuous (weekly) exposure. Values from animal developmental studies are not adjusted to a continuous exposure.
[b]Notes: PS = Principal study.
[c]Compound tested was administered in the diet and stated to contain 70% TCPP; therefore, doses are adjusted by the formula:
$Dose_{ADJ}$ = [Dose in ppm × Average Food Consumption per Day × (1 ÷ Body Weight) × (Days Dosed ÷ Total Days)] × 0.7.
[d]The critical effect was not specified in the report, but the information provided indicates that it was liver weight.
[e]These values were not reported by the study authors but are determined by the data.
[f]This was published in a foreign journal, but a translation was provided by the National Institute of Health Science (NIHS, 1994).
ND = No data, NDr = Not determined.

Table B.6. Food Consumption, Liver Weight Change, and Hepatocyte Hypertrophy in Mice Treated with TCPP in the Diet for 14 Weeks[a]

	TCPP dose (ppm in diet [mg/kg-d])[b]					
Males	**0**	**1250 (219)**	**2500 (456)**	**5000 (737)**	**10,000 (2470)**	**20,000 (4410)**
Mean daily food consumption (g [% change from control])	4.6	4.8 (4)	4.8 (4)	5.2 (13)	5.9 (28)	5.0 (9)
Relative liver weight (% change from control)	N/A	5[c]	11[c]	21[c]	40[c]	94[c]
Hepatocyte hypertrophy (# affected/total)	0/10	0/10	3/10	4/10	10/10[d]	10/10[d]
	TCPP dose (ppm in diet [mg/kg-d])[b]					
Females	**0**	**1250 (198)**	**2500 (420)**	**5000 (906)**	**10,000 (1930)**	**20,000 (3590)**
Mean daily food consumption (g [% change from control])	3.3	3.5 (6)	3.6 (9)	3.8 (15)	3.7 (12)	3.4 (3)
Relative liver weight (% change from control)	N/A	4[c]	6	11[c]	19[c]	47[c]
Hepatocyte hypertrophy (# affected/total)	0/10	0/10	0/10	5/10[d]	10/10[d]	10/10[d]

[a]Source: NTP (2011a).
[b]Dose adjusted using food consumption and body weight data reported in the study.
[c]Statistically different from control at $p \leq 0.05$ as reported by study authors.
[d]Statistically different from control at $p \leq 0.05$ based on Fisher's Exact test performed for this review.
N/A: Not Applicable.

APPENDIX C. BMD OUTPUTS

MODEL-FITTING PROCEDURE FOR QUANTAL NONCANCER DATA

The model-fitting procedure for dichotomous noncancer data is as follows. All available dichotomous models in the EPA BMDS (version 2.1) are fit to the incidence data using the extra risk option. The multistage model is run for all polynomial degrees up to $n - 1$ (where n is the number of dose groups including control). Adequate model fit is judged by three criteria: goodness-of-fit p-value ($p > 0.1$), visual inspection of the dose-response curve, and scaled residual at the data point (except the control) closest to the predefined benchmark response (BMR). Among all the models providing adequate fit to the data, the lowest BMDL is selected as the POD when the difference between the BMDLs estimated from these models is more than 3-fold (unless it is an outlier); otherwise, the BMDL from the model with the lowest Akaike Information Criterion (AIC) is chosen. In accordance with EPA (2000) guidance, benchmark doses (BMDs) and lower bounds on the BMD (BMDLs) associated with a BMR of 10% extra risk are calculated for all models.

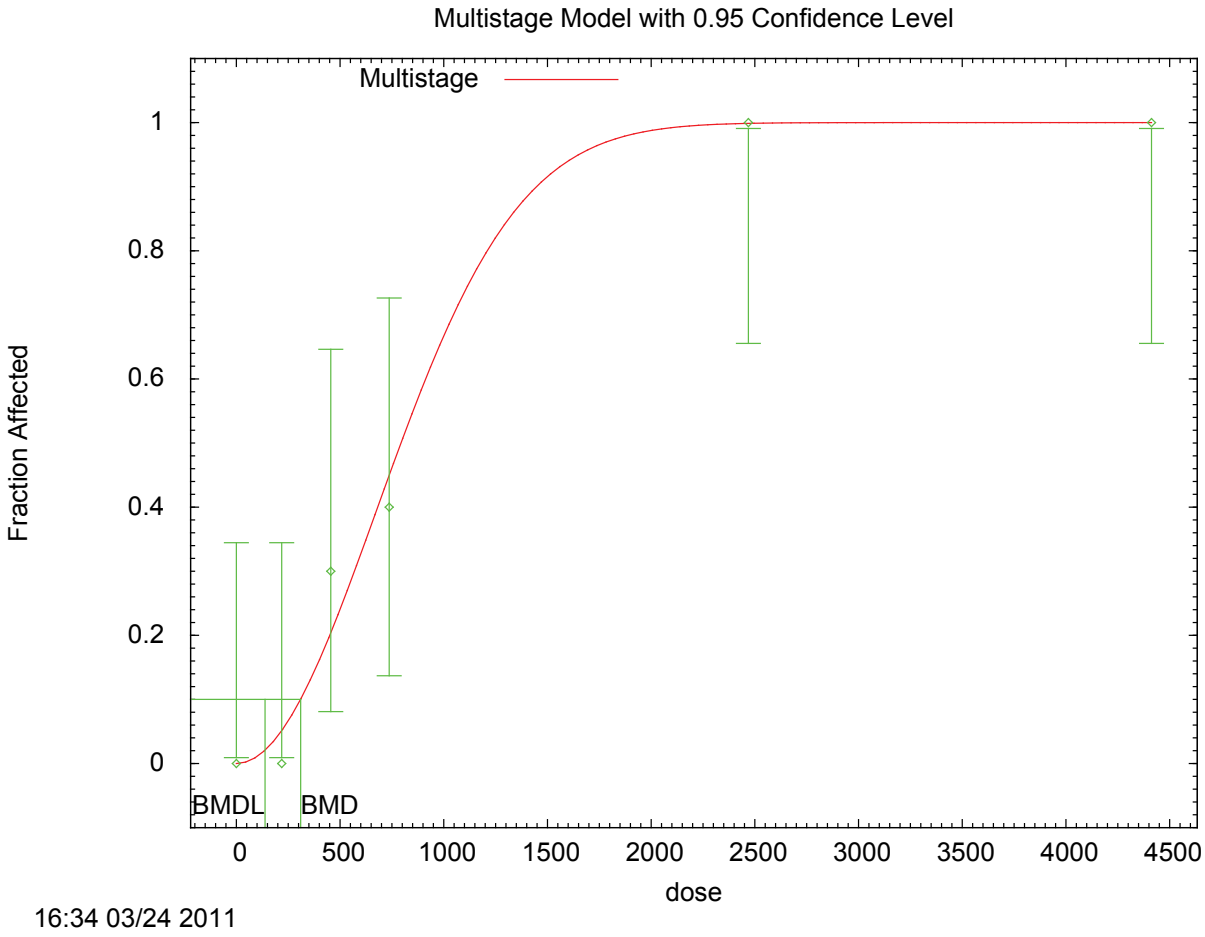
MODEL-FITTING RESULTS FOR HEPATOCYTE HYPERTROPHY IN MALE MICE (NTP, 2011a)

Applying the procedure outlined above to the data (see Table B.6) for hepatocyte hypertrophy in male mice exposed subchronically to TCPP via diet for 14 weeks (NTP, 2011a), all models provided adequate fit to the data (see Table C.1). However, the first-degree multistage model and the quantal-linear model provided poor fit in the low-dose region and were excluded from consideration. Of the remaining models, the $BMDL_{10}$s differed by less than 3-fold, so the model with the lowest AIC (second-degree multistage) was selected. The BMD_{10} and $BMDL_{10}$ for hepatocyte hypertrophy in male mice were 310 and 138 mg/kg-day, respectively. Figure C.1 shows the fit of the second degree multistage model to the data.

Table C.1. Model Predictions for the Incidence of Hepatocyte Hypertrophy in Male Mice Treated with TCPP in the Diet for 14 Weeks

Model	Degrees of Freedom	χ^2	χ^2 Goodness-of-Fit *p*-Value[a]	AIC	BMD_{10} (mg/kg-d)	$BMDL_{10}$ (mg/kg-d)
Gamma[b]	4	1.31	0.8593	31.2323	345.328	177.454
Logistic	4	2.3	0.6813	32.4306	380.604	252.026
Log-Logistic[c]	4	1.84	0.7647	31.858	363.451	220.08
Log-Probit[c]	4	1.44	0.8367	31.3251	360.007	225.345
Multistage (degree = 1)[d]	5	3.92	0.5611	34.6386	117.803	79.3911
Multistage (degree = 2)[d]	***5***	***1.22***	***0.9425***	***29.3711***	***310.099***	***138.32***
Multistage (degree = 3)[d]	4	1.25	0.8691	31.3627	315.472	123.483
Multistage (degree = 4)[d]	3	1.25	0.7419	33.3613	314.203	118.179
Multistage (degree = 5)[d]	4	1.23	0.8726	31.3542	312.626	116.479
Probit	4	1.99	0.738	32.0008	366.693	238.462
Weibull[b]	4	1.3	0.8612	31.3404	326.299	161.844
Quantal-Linear	5	3.92	0.5611	34.6386	117.803	79.3911

[a]Values <0.10 fail to meet conventional goodness-of-fit criteria.
[b]Power restricted to ≥1.
[c]Slope restricted to ≥1.
[d]Betas restricted to ≥0.
AIC = Akaike Information Criterion; BMD = maximum likelihood estimate of the dose/concentration associated with the selected benchmark response; BMDL = 95% lower confidence limit on the BMD.



BMDs and BMDLs indicated are associated with an extra risk of 10% and are in units of mg/kg-day (5 days/week).

Figure C.1. Fit of Multistage (degree = 2) Model to Data on Hepatocyte Hypertrophy in Male Mice Treated with TCPP in the Diet for 14 Weeks

MODEL-FITTING RESULTS FOR HEPATOCYTE HYPERTROPHY IN FEMALE MICE (NTP, 2011a)

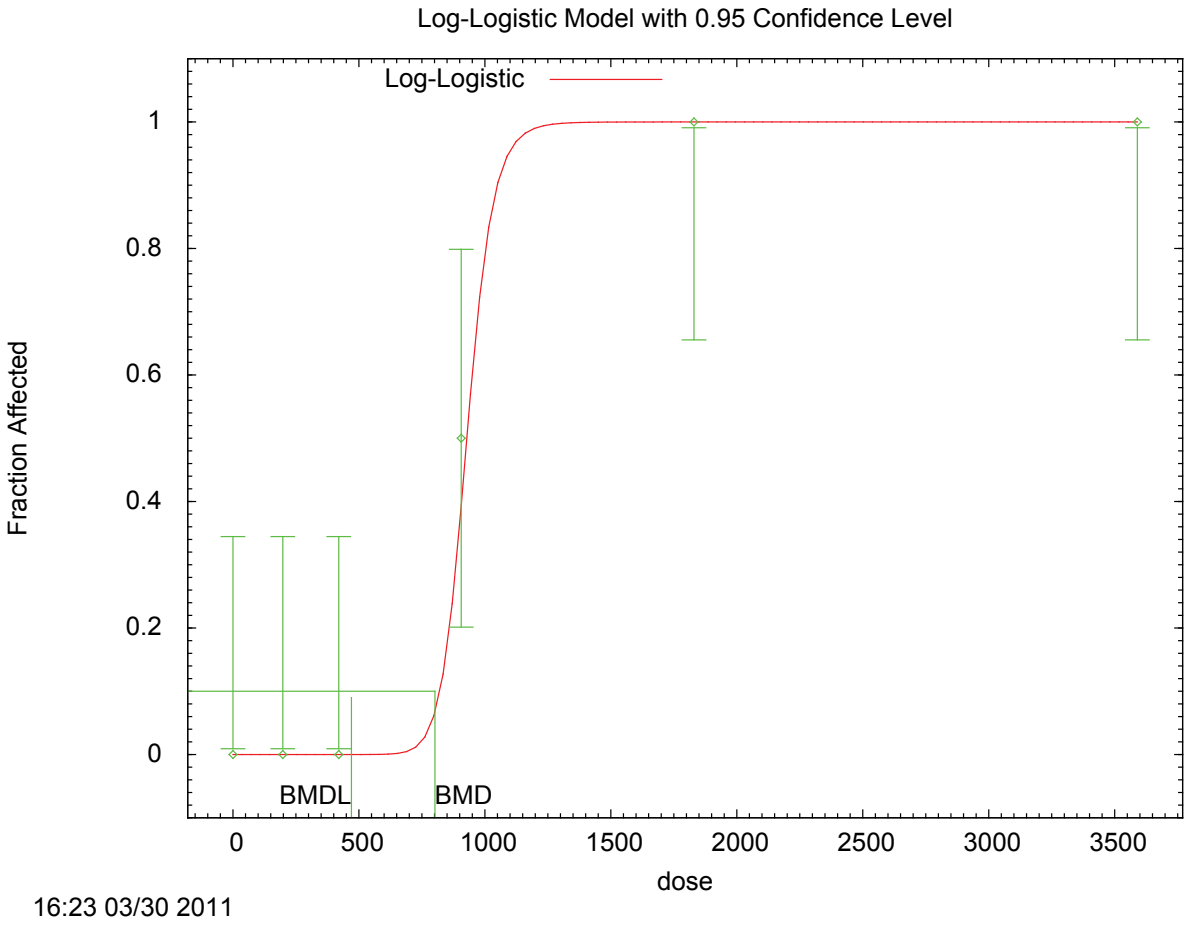
Applying the procedure outlined above to the data (see Table B.6) for hepatocyte hypertrophy in female mice exposed subchronically to TCPP via the diet for 14 weeks (NTP, 2011a), all models provided adequate fit to the data except for the first-degree multistage model, the Weibull model, and the quantal-linear model (see Table C.2). Of the remaining models, the $BMDL_{10}$s differed by less than 3-fold, so the model with the lowest AIC (log-logistic) was selected. The BMD_{10} and $BMDL_{10}$ for hepatocyte hypertrophy in female mice were 802 and 470 mg/kg-day, respectively. Figure C.2 shows the fit of the log-logistic model to the data.

Table C.2. Model Predictions for the Incidence of Hepatocyte Hypertrophy in Female Mice Treated with TCPP in the Diet for 14 Weeks

Model	Degrees of Freedom	χ^2	χ^2 Goodness-of-Fit *p*-Value[a]	AIC	BMD_{10} (mg/kg-d)	$BMDL_{10}$ (mg/kg-d)
Gamma[b]	5	0.02	1	15.9118	658.262	432.104
Logistic	4	0	1	17.8629	849.083	473.396
Log-Logistic[c]	***5***	***0***	***1***	***15.863***	***801.89***	***470.386***
Log-Probit[c]	4	0	1	17.8629	773.617	451.846
Multistage (degree = 1)[d]	5	9.34	0.0961	32.1341	124.7	85.3798
Multistage (degree = 2)[d]	5	2.57	0.7658	20.7235	353.942	243.55
Multistage (degree = 3)[d]	5	0.81	0.9764	17.4037	498.207	335.397
Multistage (degree = 4)[d]	5	0.34	0.9968	16.5128	575.256	375.808
Multistage (degree = 5)[d]	4	0.32	0.9888	18.4686	581.405	373.335
Probit	4	0	1	17.8629	795.498	440.581
Weibull[be]				13.8644		
Quantal-Linear	5	9.34	0.0961	32.1341	124.7	85.3798

[a]Values <0.10 fail to meet conventional goodness-of-fit criteria.
[b]Power restricted to ≥1.
[c]Slope restricted to ≥1.
[d]Betas restricted to ≥0.
[e]Model failed to reach convergence in the allowed number of iterations (250).

AIC = Akaike Information Criterion; BMD = maximum likelihood estimate of the dose/concentration associated with the selected benchmark response; BMDL = 95% lower confidence limit on the BMD.



BMDs and BMDLs indicated are associated with an extra risk of 10% and are in units of mg/kg-day (5 days/week).

Figure C.2. Fit of Log-logistic Model to Data on Hepatocyte Hypertrophy in Female Mice Treated with TCPP in the Diet for 14 Weeks

MODEL-FITTING PROCEDURE FOR CONTINUOUS DATA

The model-fitting procedure for continuous data is as follows. The simplest model (linear) in the EPA's BMD software (BMDS version 2.1.2) is first applied to the data while assuming constant variance. If the data are consistent with the assumption of constant variance ($p \geq 0.1$), then all of the available models are fit to the data while assuming constant variance. Among the models providing adequate fit to the means ($p \geq 0.1$), the one with the lowest AIC for the fitted model is selected for BMD derivation. If the test for constant variance is negative, the models are run again while applying the power model integrated into the BMDS to account for nonhomogenous variance. If the nonhomogenous variance model provides an adequate fit ($p \geq 0.1$) to the variance data, then a model is chosen for BMD derivation based on adequate fit to the means ($p \geq 0.1$) and lowest AIC. If the test for constant variance is negative and the nonhomogenous variance model does not provide an adequate fit to the variance data, then the data set is considered unsuitable for modeling.

MODEL-FITTING RESULTS FOR TERMINAL BODY WEIGHT IN MALE MICE (NTP, 2011b)

Applying the procedure outlined above to the data (see Table B.4) for terminal body weight in male mice exposed subchronically to TCPP via the diet for 14 weeks (NTP, 2011b), the variance was nonhomogenous and could not be modeled using the Power model in the BMD software (see Table C.3). Therefore, these data are unsuitable for modeling. However, terminal body weight and relative liver weight in male mice (which was also unsuitable for modeling due to lack of means and standard deviations in data reporting) provided the lowest LOAEL and NOAEL for the NTP (2011a,b) study. These values were 456 and 219 mg/kg-day, respectively. BMD modeling of the incidence of hepatocyte hypertrophy was possible, and the $BMDL_{10}$ (138 mg/kg-day) was lower than the NOAEL for liver and body weights. While the variance models did not fit for terminal body weight in male mice, three models provide adequate fit to the means (4^{th} and 5^{th} degree exponential models and the Hill model). Comparing the BMD_{10}s from these models (389−419 mg/kg-day) to the BMD_{10} for hepatocyte hypertrophy in males (310 mg/kg-day) confirms that hepatocyte hypertrophy is a more sensitive effect than decreased terminal body weight and, therefore, is an appropriate POD.

Table C.3. Model Predictions for Terminal Body Weight in Male Mice Treated with TCPP in the Diet for 14 Weeks[a]

Model	Variance *p*-Value[b]	Means *p*-Value[b]	AIC	BMD_{10} (mg/kg-d)	$BMDL_{10}$ (mg/kg-d)
Constant variance					
Exponential (degree = 2)	0.02296	0.004434	189.9877	1409.6	1164.08
Exponential (degree = 3)	0.02296	0.004434	189.9877	1409.6	1164.08
Exponential (degree = 4)	*0.02296*	*0.6846*	*178.345*	*407.283*	*266.856*
Exponential (degree = 5)	*0.02296*	*0.6846*	*178.345*	*407.283*	*266.856*
Hill[c]	*0.02296*	*0.6892*	*179.599717*	*419.41*	*244.768*
Linear[d]	0.02296	0.001763	192.06049	1603.47	1358.42
Polynomial[c]	0.02296	0.001763	192.06049	1603.47	1358.42
Power[c]	0.02296	0.001763	192.06049	1603.47	1358.42
Modeled variance					
Exponential (degree = 2)	0.01867	0.003127	191.5604	1455.97	1177.79
Exponential (degree = 3)	0.01867	0.003127	191.5604	1455.97	1177.79
Exponential (degree = 4)	*0.01867*	*0.6247*	*179.3946*	*389.155*	*245.682*
Exponential (degree = 5)	*0.01867*	*0.6247*	*179.3946*	*389.155*	*245.682*
Hill[c]	*0.01867*	*0.6216*	*180.590222*	*390.25*	*241.934*
Linear[d]	0.01867	0.00126	193.593512	1651.91	1373.53
Polynomial[c]	0.01867	0.00126	193.593512	1651.91	1373.53
Power[c]	0.01867	0.00126	193.593512	1651.91	1373.53

[a]NTP (2011b).
[b]Values <0.10 fail to meet conventional goodness-of-fit criteria.
[c]Power restricted to ≥1.
[d]Coefficients restricted to be positive.

MODEL-FITTING RESULTS FOR TERMINAL BODY WEIGHT IN FEMALE MICE (NTP, 2011b)

The data for terminal body weight in female mice cannot be modeled due to a nonmonotonic dose-response curve (see Table B.5).

APPENDIX D. REFERENCES

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