# 1



Laboratory Component: Urinary Phthalates

Survey Years: 2003 to 2004

SAS Export File: L24PH\_C.XPT



First Release: January 2008 Last Revised: N/A

## NHANES 2003–2004 Data Documentation

Laboratory Assessment: Lab 24 Urinary Phthalates Years of Coverage: 2003–2004 First Published: January 2008

Component	Urinary Phthalates
Description	Phthalate acid esters (phthalates) are used extensively as plasticizers in a wide range of applications such as children's toys, food packaging, and medical supplies. Because some of these compounds are known to be estrogenic and have been associated with a host of health problems in rats, such as cancers and teratogenicity, governments in Europe and Japan have become increasingly concerned about levels in food packaging materials and children's toys. Biomeasures of phthalates in humans are necessary to evaluate potential human health threats from exposure to these chemicals.
Eligible Sample	Participants aged 6 years and older who met the subsample requirements.
Description of Laboratory Methodology	The test principle utilizes high performance liquid chromatography- electrospray ionization-tandem mass spectrometry (HPLC-ESI-MS/MS) for the quantitative detection in urine of the following phthalate metabolites: monomethyl phthalate (mMP), monoethyl phthalate (mEP), monobutyl phthalate (mBP), mono-isobutyl phthalate (miBP), mono (3-carboxypropyl) phthalate (mCPP), monocyclohexyl phthalate (mCHP), mono (2-ethylhexyl) phthalate (mEHP), monoocycl phthalate (mOP), monolearzyl phthalate (mBZP), monoisononyl phthalate (mNP), mono(2-ethyl-5-oxohexyl) phthalate (mEOHP), mono(2-ethyl-5-oxohexyl) phthalate (mEOHP), mono(2-ethyl-5-hydroxyhexyl) phthalate (mEHHP), and mono(2-ethyl-5-carboxypentyl) phthalate (mECPP) [1]. Urine samples are processed using enzymatic deconjugation of the glucuronidated phthalate monoesters followed by on-line solid phase extraction (SPE) coupled with reversed phase HPLC-ESI-MS/MS. Assay precision is improved by incorporating isotopically-labeled internal standards for each of the phthalate metabolites. In addition, 4-methyl umbelliferone glucuronide is used to monitor deconjugation efficiency. This selective method allows for rapid detection of up to fifteen monoester metabolites of commonly used phthalate diesters in human urine with limits of detection in the low parts per billion (ppb) ranges.

### Laboratory Quality Control and Monitoring

Urine specimens are processed, stored, and shipped to the Division of Laboratory Sciences, National Center for Environmental Health, Centers for Disease Control and Prevention for analysis.

Detailed specimen collection and processing instructions are discussed in the NHANES Laboratory/Medical Technologists Procedures Manual (LPM). Vials are stored under appropriate frozen (–20°C) conditions until they are shipped to National Center for Environmental Health for testing.

### Mobile Examination Centers (MECs)

Laboratory team performance is monitored using several techniques. NCHS and contract consultants use a structured quality assurance evaluation during unscheduled visits to evaluate both the quality of the laboratory work and the quality-control procedures. Each laboratory staff person is observed for equipment operation, specimen collection and preparation; testing procedures and constructive feedback are given to each staff. Formal retraining sessions are conducted annually to ensure that required skill levels were maintained.

The NHANES QA/QC protocols meet the 1988 Clinical Laboratory Improvement Act mandates. Detailed QA/QC instructions are discussed in the NHANES LPM.

### **Analytical Laboratories**

NHANES uses several methods to monitor the quality of the analyses performed by the laboratories. In the MEC, these methods include performing blind split samples collected on "dry run" sessions. In addition, contract laboratories randomly perform repeat testing on 2.0% of all specimens.

NCEH developed and distributed a quality control protocol for all the laboratories which outlined the Westgard rules used when running NHANES specimens. Any problems encountered during shipping or receipt of specimens, instrument calibration, reagents, and any special considerations are submitted to NCHS and Westat. Summary statistics for each control pool, QC graphs, are reviewed by NCHS for trends or shifts in the data. The laboratories are required to explain any identified areas of concern.

All QC procedures recommended by the manufacturers were followed.

Reported results for all assays meet the Division of Laboratory Sciences' quality control and quality assurance performance criteria for accuracy and precision (similar to specifications outlined by Westgard (1981).

### Analytic Notes

### Subsample weights

Measures of urinary environmentals were measured in a one third subsample of persons 6 years and over. Special sample weights are required to analyze these data properly. Specific sample weights for this subsample are included in this data file and should be used when analyzing these data.

### Variance estimation

The analysis of NHANES 2003-2004 laboratory data must be conducted with the key survey design and basic demographic variables. The NHANES 2003-2004 Demographic Data File contains demographic and sample design variables. The recommended procedure for variance estimation requires use of stratum and PSU variables (SDMVSTRA and SDMVPSU, respectively) in the demographic data file.

### Links to NHANES Data Files

This laboratory data file can be linked to the other NHANES 2003-2004 data files using the unique survey participant identifier SEQN.

### **Detection Limits**

The detection limits were constant for all of the analytes in the data set. Two variables are provided for each of these analytes. The variable named URD\_\_\_LC indicates whether the result was below the limit of detection. There are two values: "0" and "1"". "0" means that the result was at or above the limit of detection. "1" indicates that the result was below the limit of detection.

The other variable named URX\_\_\_\_ provides the analytic result for that analyte.

The lower limit of detections for the environmental phthalates is

Analyte	Item Id	Limit of
		Detection(LLOD)
Mono-2-ethyl-5- carboxypentyl phthalate	URXECP	0.25
Mono-n-butyl phthalate (ng/mL)	URXMBP	0.40
Mono-(3- carboxypropyl) phthalate (ng/mL)	URXMC1	0.16
Mono-cyclohexyl Phthalate (ng/mL)	URXMCP	0.20
Mono-ethyl phthalate (ng/mL)	URXMEP	0.40
Mono-(2-ethyl-5- hydroxyhexyl) (ng/mL)	URXMHH	0.32
Mono-(2-ethyl)-hexyl phthalate (ng/mL)	URXMHP	0.90
Mono-isobutyl pthalate (ng/mL)	URXMIB	0.26
Mono-n-methyl phthalate (ng/mL)	URXMNM	1.0
Mono-isononyl phthalate (ng/mL)	URXMNP	1.0
Mono-(2-ethyl-5- oxohexyl) (ng/mL)	URXMOH	0.45
Mono-n-octyl phthalate (ng/mL)	URXMOP	1.0
Mono-benzyl phthalate (ng/mL)	URXMZP	0.11

Please refer to the Analytic Guidelines for further details on the use of sample weights and other analytic issues.

**References** 1. K. Kato, M.J. Silva, L.L. Needham, A.M. Calafat, Anal. Chem. 77 (2005) 2985.

### **Locator Fields**

Title: Lab 24 Urinary Phthalates

Contact Number: 1-866-441-NCHS

Years of Content: 2003–2004

First Published: January 2008

Revised: N/A

Access Constraints: None

Use Constraints: None

Geographic Coverage: National

Subject: Urinary Phthalates

Record Source: NHANES 2003–2004

Survey Methodology: NHANES 2003–2004 is a stratified multistage probability sample of the civilian

non-institutionalized population of the U.S.

Medium: NHANES Web site; SAS transport files

# National Health and Nutrition Examination Survey Codebook for Data Production (2003-2004)

# Urinary Phthalates (L24PH\_C) Person Level Data

First Published: January 2008 Last Revised: N/A



SEQN	Target				
	B(6 Yrs. to 150 Yrs.)				
Hard Edits	SAS Label				
	Respondent sequence number				
English Text: Respondent sequence number.					
English Instructions:					

WTSB2YR		Τ	arget			
W10 <b>D2</b> 1K		B(6 Yrs. to 150 Yrs.)				
Hard Edits		SAS Label				
	7	Two-year MEC weights of subsample B				
English Text: Two-year	MEC weights of subsample	В				
English Instructions:						
Code or Value	Description	Count	Cumulative	Skip to Item		
0 to 435025.30254	Range of Values	2697	2697			
•	Missing	0	2697			

URXMBP		Target			
		B(6 Yrs. to 150 Yrs.)			
Hard Edits SAS Label					
		Mono-n-butyl phthalate			
English Text: Mono-n-b	outyl phtha	late (ng/mL)			
English Instructions:					
Code or Value	De	escription	Count	Cumulative	Skip to Item
0.3 to 5143.2	Rang	ge of Values	2605	2605	
· · ·	-	Missing	92	2697	

URDMBPL	C	Target				
			to 150 Yrs.)			
Hard Edit	S	SAS Label				
		Mono-n-butyl phthalate comment code				
English Text: mono-	n-butyl phthalate comment co	de				
<b>English Instructions</b>	:					
Code or Value	Description	Count	Cumulative	Skip to Item		
0	At or above the detection lin	ve the detection limit 2593 2593				
1	Below lower detection lim	it 12	2605			
	Missing	92	2697			

URXMCP		Target				
		B(6 Yrs. to 150 Yrs.)				
Hard Edits		SAS Label				
		Mono-cyclo	hexyl phthalate			
English Text: Mono-cyc	clohexyl phthalate (ng/mL)					
English Instructions:						
Code or Value	Description	Count	Cumulative	Skip to Item		
0.1 to 31	Range of Values	ange of Values 2605 2605				
	Missing					

URDMCPI	.C	Target				
			to 150 Yrs.)			
Hard Edit	s	SAS Label				
		Mono-cyclohexyl phthalate comment				
English Text: mono-	cyclohexyl phthalate comment co	yl phthalate comment code				
English Instructions	:					
Code or Value	Description	Count	Cumulative	Skip to Item		
0	At or above the detection limit	e the detection limit 281 281				
1	Below lower detection limit	ower detection limit 2324 2605				
•	Missing	92	2697			

URXMEP		Target				
		B(6 Yrs. to 150 Yrs.)				
Hard Edits		SAS Label				
		Mono-etl	nyl phthalate			
English Text: Mono-eth	yl phthalate (ng/mL)					
English Instructions:						
Code or Value	Description	Count	Cumulative	Skip to Item		
3.5 to 46347	Range of Values	2605	2605			
•	Missing	Missing 92 2697				

URDMEPI	C	Target				
		B(6 Yrs.	to 150 Yrs.)			
Hard Edit	s	SAS Label				
	1	Mono-ethyl phtha	alate comment code	e		
English Text: mono-	ethyl phthalate comment code					
English Instructions	:					
Code or Value	Description	Count	Cumulative	Skip to Item		
0	At or above the detection limit	ve the detection limit 2605 2605				
1	Below lower detection limit	0	2605			
	Missing	92	2697			

URXMHP		Target   B(6 Yrs. to 150 Yrs.)				
Hard Edits		SAS Label				
		Mono-(2-ethyl)-hexyl phthalate				
English Text: Mono-(2-	ethyl)-hexyl phthalate (ng/mI	L)				
English Instructions:						
Code or Value	Description	Count	Cumulative	Skip to Item		
0.6 to 718	Range of Values	2605	2605			
. Missing		92	2697			

URDMHPLC		Target				
				to 150 Yrs.)		
Hard Edit	s	SAS Label				
		Mor	no-(2-ethyl)-hex	yl phthalate comm	ent	
English Text: Mono-	(2-ethyl)-hex	yl phthalate comment	code			
<b>English Instructions</b>	:					
Code or Value	De	escription	Count	Cumulative	Skip to Item	
0	At or above	e the detection limit				
1	Below low	ver detection limit	779	2605		
· ·		Missing	92	2697		

URXMNP		TargetB(6 Yrs. to 150 Yrs.)				
Hard Edits		SAS Label				
		Mono-isononyl phthalate				
English Text: Mono-iso	nonyl phthalate (ng/mL)					
English Instructions:						
Code or Value	Description	Count	Cumulative	Skip to Item		
0.7 to 29.1	Range of Values	2605	2605			
· .	Missing	92	2697			

URDMNPI	URDMNPLC		Target				
			B(6 Yrs.	to 150 Yrs.)			
Hard Edit	s	SAS Label					
		Mono-isononyl phthalate comment code			ode		
English Text: Mono-	English Text: Mono-isononyl phthalate comment code						
<b>English Instructions</b>	•						
Code or Value	D	escription	Count	Cumulative	Skip to Item		
0	At or abov	e the detection limit	152	152			
1	Below lo	wer detection limit	2453	2605			
•		Missing	92	2697			

URXMOP		TargetB(6 Yrs. to 150 Yrs.)				
Hard Edits		SAS Label				
		Mono-n-octyl phthalate				
English Text: Mono-n-o	octyl phthalate (ng/mL)					
English Instructions:						
Code or Value	Description	Count	Cumulative	Skip to Item		
0.7 to 16.2	Range of Values	2605	2605			
	Missing	92	2697			

URDMOPI	URDMOPLC		Target				
		B(6 Yrs.	to 150 Yrs.)				
Hard Edit	s	SAS Label					
		Mono-n-octyl phthalate comment code					
English Text: Mono-	English Text: Mono-n-octyl phthalate comment code						
<b>English Instructions</b>	:						
Code or Value	Description	Description Count Cumulative Skip to Item					
0	At or above the detection limit	t 27	27				
1	Below lower detection limit	2578	2605				
•	Missing	92	2697				

URXMZP		TargetB(6 Yrs. to 150 Yrs.)				
Hard Edits		SAS Label				
		Mono-benzyl phthalate				
English Text: Mono-ber	nzyl phthalate (ng/mL)					
English Instructions:						
Code or Value	Description	Count	Cumulative	Skip to Item		
0.1 to 1197.6	Range of Values	2605	2605			
	Missing	92	2697			

URDMZPI	URDMZPLC		Target			
		B(6 Yrs.	to 150 Yrs.)			
Hard Edit	s	SAS Label				
	M	Mono-benzyl phthalate comment code				
English Text: Mono-	English Text: Mono-benzyl phthalate comment code					
English Instructions	:					
Code or Value	Description	Description Count Cumulative Skip to Item				
0	At or above the detection limit	2596	2596			
1	Below lower detection limit	9	2605			
•	Missing	92	2697			

URXMNM		Target				
		B(6 Yrs. to 150 Yrs.)				
Hard Edits		SAS Label				
		Mono-n-methyl phthalate				
English Text: Mono-n-r	nethyl phthalate (ng/mL)					
English Instructions:						
Code or Value	Description	Count	Cumulative	Skip to Item		
0.7 to 1170.3	Range of Values	2605	2605			
	Missing	92	2697			

URDMNMI	LC	Ta					
		B(6 Yrs. to 150 Yrs.)					
Hard Edit	s	SAS Label					
	Ma	Mono-n-methyl phthalate comment code					
English Text: Mono-	English Text: Mono-n-methyl phthalate comment code						
<b>English Instructions</b>	:						
Code or Value	Description	Description Count Cumulative Skip to Iter					
0	At or above the detection limit	1497	1497				
1	Below lower detection limit	1108	2605				
	Missing	92	2697				

URXMC1		Target			
URMMUU		B(6 Yrs. to 150 Yrs.)			
Hard Edits		SAS Label			
		Mono-(3-carboxypropyl) phthalate			
nglish Text: Mono-(3-	carboxypropyl) phthalate (ng/	/mL)			
nglish Instructions:					
Code or Value	Description	Count	Cumulative	Skip to Item	
0.1 to 389.1	Range of Values	2605	2605		
		92	2697		

URDMC11	URDMC1LC		Target			
Cindineit			B(6 Yrs.	to 150 Yrs.)		
Hard Edit	s	SAS Label				
		Mono-(3-carboxypropyl) phthalate cmt				
English Text: Mono-	English Text: Mono-(3-carboxypropyl) phthalate comment code					
<b>English Instructions</b>	:					
Code or Value	D	escription	Count	Cumulative	Skip to Item	
0	At or abov	e the detection limit	2569	2569		
1	Below lo	wer detection limit	36	2605		
· ·		Missing	92	2697		

URXMHH		TargetB(6 Yrs. to 150 Yrs.)				
Hard Edits		SAS Label				
	M	Mono-(2-ethyl-5-hydroxyhexyl) phthalate				
English Text: Mono-(2-	ethyl-5-hydroxyhexyl) phthal	ate (ng/mL)				
English Instructions:						
Code or Value	Description	Count	Cumulative	Skip to Item		
0.2 to 3141.4	Range of Values	2605	2605			
	Missing	92	2697			

URDMHH	URDMHHLC		Target				
		B(6 Yrs.	B(6 Yrs. to 150 Yrs.)				
Hard Edit	s	SAS Label					
	N	Mono(2ethyl5hydroxyhexyl) phthalate cmt					
English Text: Mono-	English Text: Mono-(2-ethyl-5-hydroxyhexyl) phthalate comment code						
<b>English Instructions</b>	:						
Code or Value	Description	Description Count Cumulative Skip to I					
0	At or above the detection lim	it 2598	2598				
1	Below lower detection limit	. 7	2605				
•	Missing	92	2697				

URXMOH		Target     B(6 Yrs. to 150 Yrs.)     SAS Label     Mono-(2-ethyl-5-oxohexl) phthalate			
UMMOII					
Hard Edits					
nglish Text: Mono-(2-	ethyl-5-oxohexl) phthalate (n	g/mL)			
nglish Instructions:					
Code or Value	Description	Count	Cumulative	Skip to Item	
0.4 to 1953.5	Range of Values	2605	2605		
	Missing	92	2697		

URDMOHI		Target			
		B(6 Yrs. to 150 Yrs.)			
Hard Edit	SAS Label				
	Мо	Mono-(2-ethyl-5-oxohexl) phthalate comnt			
English Text: Mono-	(2-ethyl-5-oxohexyl) phthalate co	mment code			
<b>English Instructions</b>	:				
Code or Value	Description	Count	Cumulative	Skip to Item	
0	At or above the detection limit	2583	2583		
1	Below lower detection limit	22	2605		
	Missing	92	2697		

URXMIB		Target     B(6 Yrs. to 150 Yrs.)     SAS Label     Mono-isobutyl phthalate			
CRAMID					
Hard Edits					
English Text: Mono-iso	butyl phthalate (ng/mL)				
English Instructions:					
Code or Value	Description	Count	Cumulative	Skip to Item	
0.2 to 359.1	Range of Values	2605	2605		
•	Missing	92	2697		

URDMIBLC		Target			
		B(6 Yrs. to 150 Yrs.)			
Hard Edit	SAS Label				
		Mono-isobutyl phthalate comment code			
English Text: Mono-	-isobutyl phtł	nalate comment code			
English Instructions	•				
Code or Value	D	escription	Count	Cumulative	Skip to Item
0	At or abov	e the detection limit	2539	2539	
1	Below lo	wer detection limit	66	2605	
•		Missing	92	2697	

URXECP		Target     B(6 Yrs. to 150 Yrs.)     SAS Label     Mono-2-ethyl-5-carboxypentyl phthalate			
00-					
Hard Edits					
	Ν				
English Text: mono-2-e	thyl-5-carboxypentyl phthala	te (ng/mL)			
English Instructions:					
Code or Value	Description	Count	Cumulative	Skip to Item	
0.2 to 2886.9	Range of Values	2605	2605		
•	Missing	92	2697		

URDECPLC		Target			
			B(6 Yrs. to 150 Yrs.)		
Hard Edit	S	SAS Label			
		Mono-2-ethyl-5carboxypentyl phthalate cm			e cm
English Text: mono-	2-ethyl-5-ca	rboxypentyl phthalate co	omment code		
<b>English Instructions</b>	:				
Code or Value	I	Description	Count	Cumulative	Skip to Item
0	At or above	ve the detection limit	2604	2604	
1	Below lo	ower detection limit	1	2605	
•		Missing	92	2697	

URXUCR		Target   B(6 Yrs. to 150 Yrs.)				
UNACCA						
Hard Edits		SAS Label				
		Creatinine, urine (mg/dL)				
nglish Text: Creatinin	e, urine (mg/dL)					
nglish Instructions:						
Code or Value	Description	Count	Cumulative	Skip to Item		
9 to 882	Range of Values	2623	2623			
i	Missing	74	2697			