Todd Steveson

SOLICITATION/CONTRACT/ORDER FOR COMMERCIAL ITEM

OFFEROR TO COMPLETE BLOCKS 12, 17, 23, 24, & 30

1. REQUISITION NUMBER	PAGE	OF
REQ-4500-10-0011	1	2

2. CONTRACT NO.	3. AWARD/ EFFECTIVE DATE	4. ORDER NUMBER	5. SOLICITATION NUMBER	6. SOLICITATION ISSUE DATE
CPSC-D-06-0006	09/02/2010	0012		

7. FOR SOLICITATION INFORMATION CALL:	a. NAME	b. TELEPHONE NUMBER (No collect calls)	8. OFFER DUE DATE/LOCAL TIME
	Kim Miles	301-504-7018	

9. ISSUED BY CODE FMPS

CONSUMER PRODUCT SAFETY COMMISSION
DIV OF PROCUREMENT SERVICES
4330 EAST WEST HWY
ROOM 517
BETHESDA MD 20814

10. THIS ACQUISITION IS

☒ UNRESTRICTED OR ☐ SET ASIDE: % FOR:

☐ SMALL BUSINESS ☐ EMERGING SMALL BUSINESS

NAICS: ☐ HUBZONE SMALL BUSINESS ☐ SOLE SOURCE

SIZE STANDARD: ☐ SERVICE-DISABLED VETERAN-OWNED SMALL BUSINESS ☐ 8(A)

11. DELIVERY FOR FOB DESTINATION UNLESS BLOCK IS MARKED	12. DISCOUNT TERMS	13a. THIS CONTRACT IS A RATED ORDER UNDER DPAS (15 CFR 700)	13b. RATING / 14. METHOD OF SOLICITATION
☐ SEE SCHEDULE	Net 30	☐	☒ RFQ ☐ IFB ☐ RFP

15. DELIVER TO CODE HS

CONSUMER PRODUCT SAFETY COMMISSION
DIRECTORATE FOR HEALTH SCIENCES
4330 EASTWEST HIGHWAY
ROOM 600
BETHESDA MD 20814

16. ADMINISTERED BY CODE FMPS

CONSUMER PRODUCT SAFETY COMMISSION
DIV OF PROCUREMENT SERVICES
4330 EAST WEST HWY
ROOM 517
BETHESDA MD 20814

17a. CONTRACTOR/ OFFEROR CODE [redacted] FACILITY CODE

VERSAR INC
ATTN PAUL KENDALL
6850 VERSAR CENTER STE 1
SPRINGFIELD VA 22151-4196

TELEPHONE NO. 703) 642-6849

☐ 17b. CHECK IF REMITTANCE IS DIFFERENT AND PUT SUCH ADDRESS IN OFFER

18a. PAYMENT WILL BE MADE BY CODE FMFS

CONSUMER PRODUCT SAFETY COMMISSION
DIVISION OF FINANCIAL SERVICES
4330 EAST WEST HWY
ROOM 522
BETHESDA MD 20814

18b. SUBMIT INVOICES TO ADDRESS SHOWN IN BLOCK 18a UNLESS BLOCK BELOW IS CHECKED ☐ SEE ADDENDUM

19. ITEM NO.	20. SCHEDULE OF SUPPLIES/SERVICES	21. QUANTITY	22. UNIT	23. UNIT PRICE	24. AMOUNT
	DUNS Number: [redacted] TASK ORDER 0012 The contractor shall provide toxicology Review Services in accordance with CPSC-D-06-0006, line item 0008 and the attached task order description of services.				
0001	Toxicology Review Services for Tier I and Tier II chemicals only. Services are for "High Continued ... *(Use Reverse and/or Attach Additional Sheets as Necessary)*	[redacted]	EA	[redacted]	177,835.00

25. ACCOUNTING AND APPROPRIATION DATA
0100A10DPS 2010 2370600000 EXHR004500 252H0

26. TOTAL AWARD AMOUNT *(For Govt. Use Only)*
$181,835.00

☐ 27a. SOLICITATION INCORPORATES BY REFERENCE FAR 52.212-1, 52.212-4. FAR 52.212-3 AND 52.212-5 ARE ATTACHED. ADDENDA ☐ ARE ☐ ARE NOT ATTACHED.

☒ 27b. CONTRACT/PURCHASE ORDER INCORPORATES BY REFERENCE FAR 52.212-4. FAR 52.212-5 IS ATTACHED. ADDENDA ☐ ARE ☒ ARE NOT ATTACHED.

☐ 28. CONTRACTOR IS REQUIRED TO SIGN THIS DOCUMENT AND RETURN _____ COPIES TO ISSUING OFFICE. CONTRACTOR AGREES TO FURNISH AND DELIVER ALL ITEMS SET FORTH OR OTHERWISE IDENTIFIED ABOVE AND ON ANY ADDITIONAL SHEETS SUBJECT TO THE TERMS AND CONDITIONS SPECIFIED HEREIN.

☒ 29. AWARD OF CONTRACT REF. _____ OFFER DATED _____. YOUR OFFER ON SOLICITATION (BLOCK 5), INCLUDING ANY ADDITIONS OR CHANGES WHICH ARE SET FORTH HEREIN, IS ACCEPTED AS TO ITEMS:

30a. SIGNATURE OF OFFEROR/CONTRACTOR	31a. UNITED STATES OF AMERICA *(SIGNATURE OF CONTRACTING OFFICER)*
	Kim Miles

30b. NAME AND TITLE OF SIGNER *(Type or print)*	30c. DATE SIGNED	31b. NAME OF CONTRACTING OFFICER *(Type or print)*	31c. DATE SIGNED
		Kim Miles	9-2-10

AUTHORIZED FOR LOCAL REPRODUCTION
PREVIOUS EDITION IS NOT USABLE

STANDARD FORM 1449 (REV. 3/2005)
Prescribed by GSA - FAR (48 CFR) 53.212

19. ITEM NO.	20. SCHEDULE OF SUPPLIES/SERVICES	21. QUANTITY	22. UNIT	23. UNIT PRICE	24. AMOUNT
	Production Volume and Other Phthalates not Covered in the 2008 CPSIA". Tier I (4 chemicals) - [redacted] hours Tier II (6 chemicals) - [redacted] hours				
0002	Other direct cost associated with Tiers I & II	[redacted]	EA	[redacted]	4,000.00
	The total amount of award: $181,835.00. The obligation for this award is shown in box 26.				

32a. QUANTITY IN COLUMN 21 HAS BEEN

☐ RECEIVED ☐ INSPECTED ☐ ACCEPTED, AND CONFORMS TO THE CONTRACT, EXCEPT AS NOTED:

32b. SIGNATURE OF AUTHORIZED GOVERNMENT REPRESENTATIVE	32c. DATE	32d. PRINTED NAME AND TITLE OF AUTHORIZED GOVERNMENT REPRESENTATIVE

32e. MAILING ADDRESS OF AUTHORIZED GOVERNMENT REPRESENTATIVE	32f. TELEPHONE NUMBER OF AUTHORIZED GOVERNMENT REPRESENTATIVE
	32g. E-MAIL OF AUTHORIZED GOVERNMENT REPRESENTATIVE

33. SHIP NUMBER	34. VOUCHER NUMBER	35. AMOUNT VERIFIED CORRECT FOR	36. PAYMENT	37. CHECK NUMBER
☐ PARTIAL ☐ FINAL			☐ COMPLETE ☐ PARTIAL ☐ FINAL	

38. S/R ACCOUNT NUMBER	39. S/R VOUCHER NUMBER	40. PAID BY

41a. I CERTIFY THIS ACCOUNT IS CORRECT AND PROPER FOR PAYMENT		42a. RECEIVED BY *(Print)*	
41b. SIGNATURE AND TITLE OF CERTIFYING OFFICER	41c. DATE	42b. RECEIVED AT *(Location)*	
		42c. DATE REC'D *(YY/MM/DD)*	42d. TOTAL CONTAINERS

TASK DESCRIPTION

High Production Volume and Other Phthalates not Covered in the 2008 CPSIA

1. Background

Dialkyl *ortho*-phthalates (*o*-DAPs) are a class of commercially important compounds that are used primarily as plasticizers in polyvinyl chloride (PVC) and as solvents. *o*-DAPs have been used as plasticizers in many household products made from PVC, including floor and wall coverings and children's products such as soft plastic teethers, rattles, and toys. Lower molecular weight *o*-DAP's are used as solvents in inks, waxes, polishes, and coatings. *o*-DAPs are also present in medical devices, laboratory tubing, and cosmetics. *o*-DAPs are ubiquitous environmental contaminants; they are present in food, air, and water. *o*-DAP metabolites have been detected in the urine of all humans tested.

o-DAPs have been under increasing scrutiny due to their health effects in animal studies, which include reproductive and developmental toxicity, chronic organ toxicity, and cancer. Recent studies have presented suggestive evidence that *o*-DAPs may have reproductive and developmental effects in humans. A National Research Council subcommittee recently completed a report on methodology for assessing the possible combined effects of *o*-DAP exposure in humans.

The U.S. Consumer Product Safety Commission (CPSC) staff has recently focused its attention on a variety of *o*-DAPs as mandated by the Consumer Product Safety Improvement Act (CPSIA; 2008). CPSC staff have written hazard summaries for 6 phthalates outlined in the Act (Butyl benzyl, Dibutyl, Di (2-ethylhexyl), Di *n*-octyl, Disononyl, and Diisodecyl phthalate (BBP, DBP, DEHP, DnOP, DINP, DIDP, respectively). These six phthalates represent approximately 20% of phthalates produced in large quantities and less than 2% of phthalate chemicals currently on the market.

A Chronic Hazard Advisory Panel (CHAP) has been convened as mandated in the CPSIA to investigate the potential risks associated with individual phthalates (especially DnOP, DINP, DIDP), and all phthalates combined. Since the CPSC staff have only prepared hazard documents on 6 of the phthalates, the CHAP has requested that additional hazard information on other phthalates be compiled.

Five sources of information have been utilized by CPSC staff to determine which additional high production volume phthalates require investigation: 1) a TOXNET database search for publications, 2) U.S. phthalate production and consumption estimates (SRI marketing report, 2009), 3) listing as a High Production Volume (HPV) chemical by the U.S. EPA, 4) information on phthalates being actively monitored in biological media, and 5) hazard, exposure, or risk reports written by other agencies.

A) TOXNET was searched by CAS number (as of 05/14/10). Phthalates were ranked by the number of records in Toxicology Literature Online (TOXLINE). The number of records in Developmental and Reproductive Toxicology Database (DART), and Chemical Identification (ChemIDplus) are also given. (Table 1).

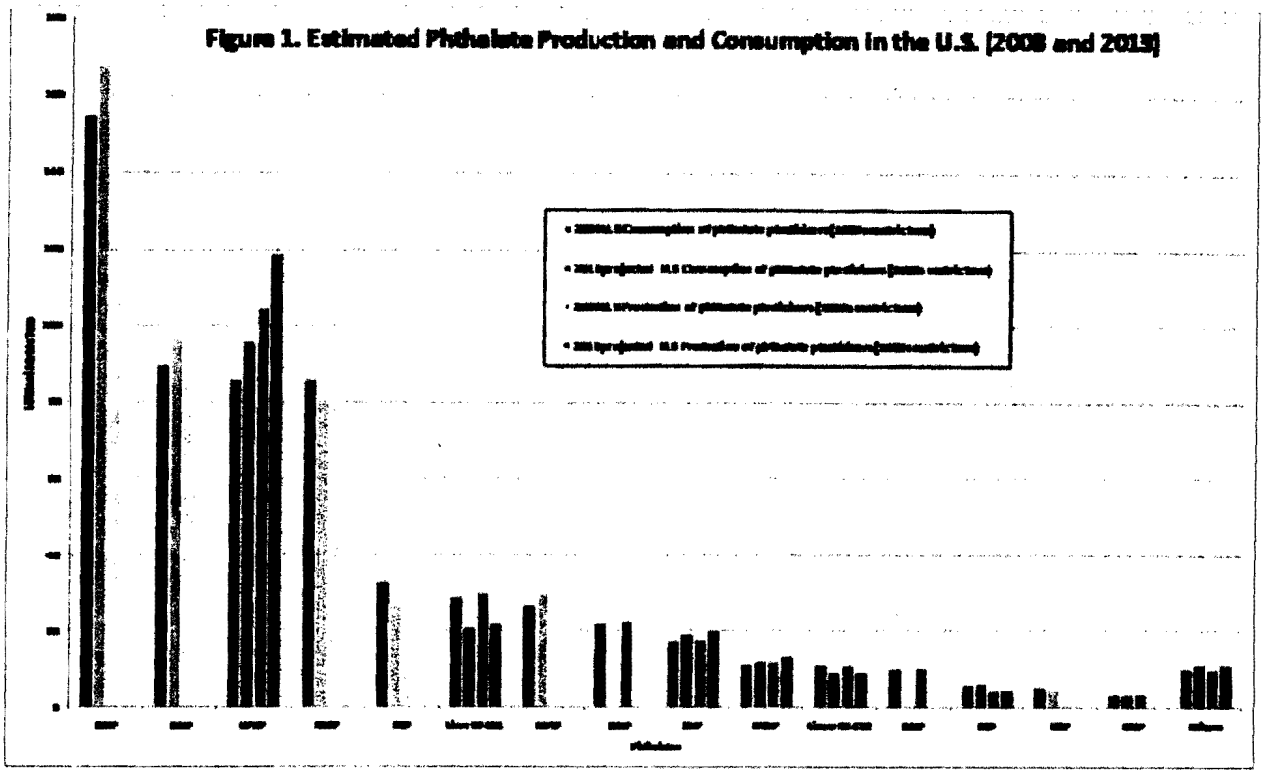
Table 1. Number of Publications for 38 phthalates as Shown in TOXLINE, DART, and ChemIDplus

#	CAS no.	Dialkyl *Ortho*-Phthalate (abbreviation)	TOXLINE	DART	Chem ID
3	84-66-2	1,2-Benzenedicarboxylic acid, diethyl ester (DEP)	884	58	1
4	131-11-3	1,2-Benzenedicarboxylic acid, dimethyl ester (DMP)	745	31	1
7	27554-26-3	1,2-Benzenedicarboxylic acid, diisooctyl ester (DIOP)	306	18	1
10	84-69-5	1,2-Benzenedicarboxylic acid, diisobutyl ester (DIBP)	161	15	1
11	119-06-2	1,2-Benzenedicarboxylic acid, ditridecyl ester (DTDP)	146	0	1
12	131-17-9	1,2-Benzenedicarboxylic acid, di-2-propenyl ester (DAP)	115	3	1
13	3648-20-2	1,2-Benzenedicarboxylic acid, diundecyl ester (DUP)	115	0	1
14	84-75-3	1,2-Benzenedicarboxylic acid, dihexyl ester	104	13	1
16	84-76-4	1,2-Benzenedicarboxylic acid, dinonyl ester (DNP)	90	0	1
17	117-82-8	1,2-Benzenedicarboxylic acid, bis(2-metoxyethyl) ester (DMEP)	89	25	1
18	131-18-0	1,2-Benzenedicarboxylic acid, dipentyl ester (diamyl phthalate)	89	18	1
19	84-61-7	1,2-Benzenedicarboxylic acid, dicyclohexyl ester	83	6	1
21	68515-51-5	1,2-Benzenedicarboxylic acid, di C6-C10 alkyl phthalate	49	0	1
22	68515-45-7	1,2-Benzenedicarboxylic acid, dinonyl ester, branched and linear	45	0	1
23	84-77-5	1,2-Benzenedicarboxylic acid, didecyl ester	38	0	1
24	68515-50-4	1,2-Benzenedicarboxylic acid, dihexyl ester, branched and linear	36	0	1
25	68515-47-9	1,2-Benzenedicarboxylic acid, di-C11-14-branched alkyl esters, C13-rich	34	0	1
26	68515-41-3	C7-C9 phthalate	15	0	1
27	71888-89-6	1,2-Benzenedicarboxylic acid, di-C6-8-branched alkyl esters, C7-rich (DiHP)	12	1	1
28	53306-54-0	1,2-Benzenedicarboxylic acid, di(2-propylheptyl) ester (DPHP)	9	0	1
30	68515-40-2	1,2-Benzenedicarboxylic acid, benzyl C7-9-branched and linear alkyl esters	3	0	1
31	68515-44-6	1,2-Benzenedicarboxylic acid, diheptyl ester, branched and linear	2	0	1
32	111381-89-6	1,2-Benzenedicarboxylic acid, heptyl nonyl ester, branched and linear	1	0	1
33	111381-90-9	1,2-Benzenedicarboxylic acid, heptyl undecyl ester, branched and linear	1	0	1
34	111381-91-0	1,2-Benzenedicarboxylic acid, nonyl undecyl ester, branched and linear	1	0	1
35	16883-83-3	1,2-Benzenedicarboxylic acid, 2,2-dimethyl-1-(1-methylethyl-3-(2-methyl-1-oxopropoxy) propyl phenylmethyl ester	-	-	-
36	68515-43-5	1,2-Benzenedicarboxylic acid, di-C9-11-branched and linear alkyl esters	-	-	-
37	68648-93-1	1,2-Benzenedicarboxylic acid, mixed decyl and hexyl and octyl diesters	-	-	-
38	85507-79-5	1,2-Benzenedicarboxylic acid, diundecyl ester, branched and linear	-	-	-

[a] Hazard documents have been prepared by CPSC staff on these phthalates (highlighted in orange).

Note: Rows in blue are terephthalates (DOTP is included in the Versar report on phthalate substitutes (http://www.cpsc.gov/ABOUT/Cpsia/phthalsub.pdf)

B) U.S. phthalate production and consumption were extracted from two SRI marketing reports on phthalates (2007, 2009) and ordered from highest to lowest (Figure 1). Bars in orange represent phthalates for which CPSC staff or contractors have already prepared hazard and exposure reports.



DINP – Diisononyl phthalate; DIDP – Diisodecyl phthalate; DPHP – Di (2-propylheptyl) phthalate; DEHP – Di (2-ethylhexyl) phthalate; BBP – Butyl benzyl phthalate; Linear C_9-C_{11} phthalates (includes C_9, C_{11}, $C_{9\text{-}11}$, and $C_{9\text{-}10\text{-}11}$); DOTP – Dioctyl terephthalate; DIHP – Diisoheptyl phthalate; DUP – Diundecyl phthalate; DTDP – Ditridecyl phthalate; DIDP – Diisodecyl phthalate; DEP – Diethyl phthalate; DBP – Di-*n*-butyl phthalate; DMP – Dimethyl phthalate, Others (includes benzyl, undecyl, dodecyl, dicyclohexyl, *n*-butyl cyclohexyl, *n*-butyl-2-ethylhexyl, diisobutyl, dicapryl, diethylene glycol and cyclohexyl-2-ethylhexyl phthalates and di-*n*-butyl terephthalates).

Note: Grouped bars in various shades of orange indicate phthalates for which hazard documents have already been prepared by CPSC staff or contractors.

C) U.S. high production volume (HPV) chemicals. Manufacturers have submitted test plans and robust summaries of the phthalates category as part of the U.S. EPA High Production Volume Challenge program. According to these reports, the phthalates listed below are HPV chemicals (Table 2).

Table 2. High Production Volume Phthalates

No.	CAS No.	Parent Dialkyl *Ortho*-Phthalate	Abbreviation
1	111381-89-6	1,2-Benzenedicarboxylic acid, heptyl nonyl ester, branched and linear	79P
2	111381-90-9	1,2-Benzenedicarboxylic acid, heptyl undecyl ester, branched and linear	711P
3	111381-91-0	1,2-Benzenedicarboxylic acid, nonyl undecyl ester, branched and linear	Din911P
6	131-11-3	1,2-Benzenedicarboxylic acid, dimethyl ester	DMP
7	16883-83-3	1,2-Benzenedicarboxylic acid, 2,2-dimethyl-1-(1-methylethyl-3-(2-methyl-1-oxopropoxy) propyl phenylmethyl ester	B84P
8	27554-26-3	1,2-Benzenedicarboxylic acid, diisooctyl ester	DIOP
10	3648-20-2	1,2-Benzenedicarboxylic acid, diundecyl ester	DUP
11	68515-40-2	1,2-Benzenedicarboxylic acid, benzyl C7-9-branched and linear alkyl esters	B79P
12	68515-43-5	1,2-Benzenedicarboxylic acid, di-C9-11-branched and linear alkyl esters	911P
13	68515-44-6	1,2-Benzenedicarboxylic acid, diheptyl ester, branched and linear	DinHP
14	68515-45-7	1,2-Benzenedicarboxylic acid, dinonyl ester, branched and linear	DNP
15	68515-47-9	1,2-Benzenedicarboxylic acid, di-C11-14-branched alkyl esters, C13-rich	DTDP
18	68515-50-4	1,2-Benzenedicarboxylic acid, dihexyl ester, branched and linear	DHP
19	68648-93-1	1,2-Benzenedicarboxylic acid, mixed decyl and hexyl and octyl diesters	610P
20	71888-89-6	1,2-Benzenedicarboxylic acid, di-C6-8-branched alkyl esters, C7-rich	DIHP
21	84-66-2	1,2-Benzenedicarboxylic acid, diethyl ester	DEP
23	84-77-5	1,2-Benzenedicarboxylic acid, didecyl ester	DDP
24	85507-79-5	1,2-Benzenedicarboxylic acid, diundecyl ester, branched and linear	DinUP

* Hazard documents have been prepared by CPSC staff on these phthalates (highlighted in orange)

D) Several state, national, and international programs are, or will be, monitoring metabolites of phthalates in biological fluids (Table 3).

Table 3. Biomonitoring for Phthalate Metabolites by Agency[b] and Project

No.	CAS no.	Parent Dialkyl *Ortho*-Phthalate (abbreviation)			MIREC		MIEEP		COPHES II
3	85-69-5	1,2-Benzenedicarboxylic acid, diisobutyl ester (DiBP)[a]	MiBP			MiBP		MiBP	
4	84-66-2	1,2-Benzenedicarboxylic acid, diethyl ester (DEP)	MEP	MEP	MEP	MEP	?	-	?
5	131-11-3	1,2-Benzenedicarboxylic acid, dimethyl ester (DMP)	MMP	MMP	MMP	MMP	?	-	?
9	84-61-7	1,2-Benzenedicarboxylic acid, dicyclohexyl ester	Dicyclo hexyl (MCHP)	Dicyclo hexyl (MCHP)	Dicyclo hexyl (MCHP)	Dicyclo hexyl (MCHP)	?	-	?

[a] Hazard documents have been prepared by CPSC staff on these phthalates (highlighted in orange).

[b] **NBS** - National Biomonitoring Survey (NHANES), **CHMS** - Canadian Health Measures Survey, **MIREC** - Canadian Maternal-Infant Research on Environmental Chemicals Survey, **CECBP** - CA Environmental Contaminants Biomonitoring Program, **MIEEP** - CA Maternal and Infant Environmental Exposure Project, **GerES** - German Environmental Survey, **COPHES II** - European Human Biomonitoring (?).

Note: Headers in red indicate that data is, or will be, available by the summer of 2010.

E) U.S. (CPSC, ATSDR, EPA IRIS, NTP-CERHR) and international (ECB, NICNAS, IUCLID) agencies have also published hazard reviews of phthalates (Table 4). These reviews vary in the amount of detail presented.

Table 4. Report Date by Agency[b] and Phthalate

No.	CAS no.	Parent Dialkyl *Ortho*-Phthalate (abbreviation)	CPSC	ATSDR	ECB	EPA IRIS	NTP-CERHR	NICNAS	IUCLID
3	84-66-2	1,2-Benzenedicarboxylic acid, diethyl ester (DEP)	-	1995	-	1993	-	2008	2000
4	131-11-3	1,2-Benzenedicarboxylic acid, dimethyl ester (DMP)	-	-	-	1994	-	2008	2000
7	27554-26-3	1,2-Benzenedicarboxylic acid, diisooctyl ester (DIOP)	-	-	-	-	-	2008	2000
9	84-69-5	1,2-Benzenedicarboxylic acid, diisobutyl ester (DIBP)	-	-	-	2011, 4th qtr	-	2008	2000
10	119-06-2	1,2-Benzenedicarboxylic acid, ditridecyl ester (DTDP)	-	-	-	-	-	2008	-
11	84-75-3	1,2-Benzenedicarboxylic acid, dihexyl ester (DHP)	-	-	-	-	2000 2003	2008	-
13	84-61-7	1,2-Benzenedicarboxylic acid, dicyclohexyl ester	-	-	-	-	-	2008	2000
15	68515-50-4	1,2-Benzenedicarboxylic acid, dihexyl ester, branched and linear	-	-	-	-	-	2008	-
16	68515-47-9	1,2-Benzenedicarboxylic acid, di-C11-14-branched alkyl esters, C13-rich	-	-	-	-	-	2008	2000
17	68515-41-3	1,2-Benzenedicarboxylic acid, di-C7-9-branched and linear alkyl esters	-	-	-	-	-	2008	2000
18	71888-89-6	1,2-Benzenedicarboxylic acid, di-C6-8-branched alkyl esters, C7-rich	-	-	-	-	-	2008	2000
19	53306-54-0	1,2-Benzenedicarboxylic acid, di(2-propylheptyl) ester (DPHP)	-	-	-	-	-	2003	-
20	68515-40-2	1,2-Benzenedicarboxylic acid, benzyl C7-9-branched and linear alkyl esters	-	-	-	-	-	-	2000
21	16883-83-3	1,2-Benzenedicarboxylic acid, 2,2-dimethyl-1-(1-methylethyl-3-(2-methyl-1-oxopropoxy) propyl phenylmethyl ester (DMMEMOPPPM)	-	-	-	-	-	-	2000
22	68515-43-5	1,2-Benzenedicarboxylic acid, di-C9-11-branched and linear alkyl esters	-	-	-	-	-	2008	2000
23	85507-79-5	1,2-Benzenedicarboxylic acid, diundecyl ester, branched and linear (DIUP)	-	-	-	-	-	2008	2000
24	68515-51-5	1,2-Benzenedicarboxylic acid, di C6-C10 alkyl phthalate	-	2007	-	-	-	2008	2000
25	84-76-4	1, 2 Benzenedicarboxylic acid, dinonyl ester (DNP)	-	-	-	-	-	2008	-
26	131-17-9	1, 2 Benzenedicarboxylic acid, di-2-propenyl ester (DAP)	-	-	-	-	-	2008	-
27	117-82-8	1, 2 Benzenedicarboxylic acid, bis(2-methoxyethyl) ester (DMEP)	-	-	-	-	-	2008	-
28	120-61-6	1, 4 Benzenedicarboxylic acid, dimethyl ester (DMT)	-	-	-	1995	-	2008	2000
29	3648-20-2	1, 2 Benzenedicarboxylic acid, diundecyl ester (DUP)	-	-	-	-	-	2008	2000
30	26761-40-0	1, 2 Benzenedicarboxylic acid, 1,2 diisodecyl ester (DIDP)	2010	-	2003	-	2000 2003	2008	2000
31	131-18-0	1, 2 Benzenedicarboxylic acid, dipentyl ester (diamyl phthalate)	-	-	-	2011, 4th qtr	-	-	-
32	4654-26-6	1,4-Benzenedicarboxylic acid, dioctyl ester (DOTP) [c]	2010	-	-	-	-	-	-

[a] Hazard documents have been prepared by CPSC staff on these phthalates (highlighted in orange)

[b] **CPSC** – Consumer Product Safety Commission, **ATSDR** – Agency for Toxic Substances and Disease Registry, **EPA IRIS** – Environmental Protection Agency Integrated Risk and Information System, **NTP-CERHR** – National Toxicology Program Center for the Evaluation of Risks to Human Reproduction, **ECB** – European Chemicals Bureau, **NICNAS** – National Industrial Chemicals Notification and Assessment Scheme (Australia) , **IUCLID** – International Uniform Chemical information Database

[c] Included in the Versar report on phthalate substitutes (http://www.cpsc.gov/ABOUT/Cpsia/phthalsub.pdf).

Phthalate Selection

Biomonitoring data exists or will be collected for DEP (84-66-2), DMP (131-11-3), and dicyclohexyl phthalate (84-61-7). For this reason, hazard and exposure data should be summarized for these compounds. Substantial amounts of literature (>500 articles) exist for DEP (84-66-2) and DMP (131-11-3), and these compounds have been reviewed by at least three federal or international agencies. Less literature exists for dicyclohexyl phthalate.

Production and consumption of phthalates is thought to be directly related to the amount of human exposure. Graphs for U.S. manufacturers suggest that the production and consumption of DPHP > Linear C_9-C_{11} > DOTP > DiHP > DUP > DTDP > Linear C_6-C_{12} > DIOP > DEP > DMP (excluding phthalates for which CPSC has done reports). Of these, DPHP has been reviewed by NICNAS, and "robust summaries" of toxicological studies are available. DTDP has been reviewed by NICNAS, and Linear C_9-C_{11}, DiHP, DUP, DIOP have been reviewed by NICNAS and IUCLID. Lesser amounts (<100 pubs) of literature exist for DPHP (53306-54-0), DOTP (4654-26-6), and DiHP (71888-89-6). Intermediate amounts (100-500 pubs) of literature exist for DUP (3648-20-2), DTDP (119-06-2), and DIOP (27554-26-3). Literature does not exist for Linear C_9-C_{11} phthalates (part of 68515-43-5). DOTP was included in the Versar report on phthalate substitutes (Versar 2010).

Phthalates that have been previously reviewed and summarized by CPSC staff (DEHP, DnOP, DBP, BBP, DINP, DIDP, DOTP) **will not be** selected for re-review by the contractor. In addition, terephthalates will not be included, because these do not appear to induce the male reproductive effects associated with the orthophthalates.

The candidate list of additional phthalates for review by the contractor will be based on a compilation of literature sources (SRI 2007, 2009; TOXLINE, DART, ChemIDplus, HPV, other agency reviews). A priority list was generated from these candidates.

1) Top priority was given to phthalates with potential human biomonitoring data. DEP (84-66-2), DMP (131-11-3), DiBP (84-69-5), and dicyclohexyl phthalate (84-61-7) have or are expected to have human biomonitoring data by the summer of 2010.

2) Top production and consumption volume as summarized by SRI (2007, 2009) was used as the second criterion to prioritize phthalates for additional review. Graphs for U.S. manufacturers suggest that the production and consumption of DPHP > Linear C_9-C_{11} > DiHP > DUP >

DTDP> DIOP>all other phthalates. Furthermore, the following compounds account for 90% of phthalate production or projected production from 2003-2013: BBP, DEHP, DIDP, diisoheptyl phthalate, DINP, DOTP, DPHP, DUP, linear C6-C12, and linear C7-C11 (SRI 2007, 2009).

3) Phthalates under review by the U.S. EPA: DMP, DEP, DBP, DiBP, diamyl phthalate, DINP, DIDP, DEHP, and DNOP. Removing the six that have been reviewed by the CPSC staff leaves DMP, DEP, DiBP, and diamyl phthalate.

4) Phthalates with both DART and TOXLINE references were used as a fourth criterion for prioritization.

5) Prioritization of the remaining phthalates was determined by the number of TOXLINE records, with preference given for those that were HPV chemicals (CAS numbers 68515-45-7, 84-77-5, 68515-50-4, 68515-47-9).

The order of priority for reports is listed below.

Table 3. CPSC Staff Prioritized List of Phthalates for Hazard, Exposure, and Risk Summarization								
Priority	CAS no.	Parent Dialkyl *Ortho*-Phthalate (abbreviation)	Number Projects w/ Biomonitoring	Relative Production Amount	HPV	Number Agency Summaries	TOXLINE	DART
1	84-66-2	1,2-Benzenedicarboxylic acid, diethyl ester (DEP)	4	7	HPV	4	884	58
2	131-11-3	1,2-Benzenedicarboxylic acid, dimethyl ester (DMP)	4	8	HPV	3	745	31
3	84-61-7	1,2-Benzenedicarboxylic acid, dicyclohexyl ester	4	.	.	2	83	6
4	84-69-5	1,2-Benzenedicarboxylic acid, diisobutyl ester (DIBP)	3	.	.	2*	161	15
5	53306-54-0	1,2-Benzenedicarboxylic acid, di(2-propylheptyl) ester (DPHP)	.	1	.	1	9	0
6	68515-43-5	1,2-Benzenedicarboxylic acid, di-C9-11-branched and linear alkyl esters	.	2	HPV	2	0	0
7	71888-89-6	1,2-Benzenedicarboxylic acid, di-C6-8-branched alkyl esters, C7-rich (DiHP)	.	3	HPV	2	12	1
8	3648-20-2	1, 2 Benzenedicarboxylic acid, diundecyl ester (DUP)	.	4	HPV	2	115	0
9	27554-26-3	1,2-Benzenedicarboxylic acid, diisooctyl ester (DIOP)	.	6	HPV	2	306	18
10	119-06-2	1,2-Benzenedicarboxylic acid, ditridecyl ester (DTDP)	.	5	.	1	146	0
11	131-18-0	1, 2 Benzenedicarboxylic acid, dipentyl ester (diamyl phthalate)	.	.	.	*	89	18
12	131-17-9	1, 2 Benzenedicarboxylic acid, di-2-propenyl ester (DAP)	.	.	.	1	115	3
13	117-82-8	1, 2 Benzenedicarboxylic acid, bis(2-methoxyethyl) ester (DMEP)	.	.	.	1	89	25
14	84-75-3	1,2-Benzenedicarboxylic acid, dihexyl ester (DHP)	.	.	.	3	104	13
15	68515-45-7	1,2-Benzenedicarboxylic acid, dinonyl ester, branched and linear	.	.	HPV	.	45	0
16	84-77-5	1,2-Benzenedicarboxylic acid, didecyl ester	.	.	HPV	.	38	0
17	68515-50-4	1,2-Benzenedicarboxylic acid, dihexyl ester, branched and linear	.	.	HPV	1	36	0
18	68515-47-9	1,2-Benzenedicarboxylic acid, di-C11-14-branched alkyl esters, C13-rich	.	.	HPV	2	34	0
19	84-76-4	1, 2 Benzenedicarboxylic acid, dinonyl ester (DNP)	.	.	.	1	90	0
20	68515-51-5	1,2-Benzenedicarboxylic acid, di C6-C10 alkyl phthalate	.	.	.	3	49	0
21	68515-41-3	1,2-Benzenedicarboxylic acid, di-C7-9-branched and linear alkyl esters	.	.	.	2	15	0
22	68515-40-2	1,2-Benzenedicarboxylic acid, benzyl C7-9-branched and linear alkyl esters	.	.	HPV	1	3	0
23	85507-79-5	1,2-Benzenedicarboxylic acid, diundecyl ester, branched and linear (DIUP)	.	.	HPV	2	0	0
24	16883-83-3	1,2-Benzenedicarboxylic acid, 2,2-dimethyl-1-(1-methylethyl-3-(2-methyl-1-oxopropoxy) propyl phenylmethyl ester (DMMEMOPPPM)	.	.	HPV	1	0	0
25	68515-44-6	1,2-Benzenedicarboxylic acid, diheptyl ester, branched and linear	.	.	HPV	.	2	0
26	111381-89-6	1,2-Benzenedicarboxylic acid, heptyl nonyl ester, branched and linear	.	.	HPV	.	1	0
27	111381-90-9	1,2-Benzenedicarboxylic acid, heptyl undecyl ester, branched and linear	.	.	HPV	.	1	0
28	111381-91-0	1,2-Benzenedicarboxylic acid, nonyl undecyl ester, branched and linear	.	.	HPV	.	1	0
29	68648-93-1	1,2-Benzenedicarboxylic acid, mixed decyl and hexyl and octyl diesters	.	.	HPV	.	0	0

* EPA report expected to be complete by 4th quarter, 2011

2. Objective

The objectives of this task are to summarize in type-writing the hazard data on selected *o*-DAP plasticizers outlined above.

3. Description of Task

The Contractor will:

- Meet with the Project Officer in person prior to beginning the task.
- Meet with the Project Officer either by phone or in person following the completion of each of the subtasks listed below to discuss progress on the task. The scope of the task may need to be narrowed or expanded, as appropriate.

(1) Select and obtain references for the selected plasticizers that include data relating to relevant physico-chemical properties **and** the potential for human and mammalian toxicity and exposure.

- The CPSC staff will provide a preliminary literature search by CAS number of TOXLINE, DART, and ChemID (see above) and related NLM bibliographic databases.

- The Contractor will supplement the preliminary literature search using any additional databases available and considering synonyms and chemical names in addition to the CAS number.

- The Contractor may rely on authoritative reviews for general toxicity and physic-chemical information, but should review key references on health effects. Key references include those that identify no adverse effect levels, lowest adverse effect levels, or dose response information for carcinogenicity, reproductive/developmental effects, or chronic organ toxicity.

- In reviewing the toxicity data, a higher priority will be given to studies relating to human toxicity. This will include data in humans, animal studies, and *in vitro* studies.

- Information on environmental effects (i.e. ecotoxicity, bioaccumulation, and biopersistence) is of secondary interest, unless other data do not exist and it can be related to human or mammalian toxicity.

(2) For each selected plasticizer, summarize the relevant references into a report.

- Reports shall break discussion points into the following format where possible. This format is not all inclusive and can be added to or subtracted from when information does or does not exist.

    - 1. Introduction
    - 2. Physico-chemical Characteristics
        - (to include basic physico-chemical data, Chemical Abstracts Service (CAS) numbers, chemical names, trade names, and synonyms as identified in ChemIDplus (http://chem.sis.nlm.nih.gov/chemidplus/chemidlite.jsp))
    - 3. Manufacture, Supply, and Use

- 4. Toxicokinetics
    - Absorption
    - Distribution
    - Metabolism
    - Excretion
- 5. Hazard Information
    - Acute Single Dose Toxicity
        - Acute oral toxicity
        - Acute dermal toxicity
        - Acute inhalation toxicity
        - Primary skin irritation
        - Primary eye irritation
        - Respiratory irritation
        - Sensitization
    - Acute, Subchronic, and Chronic Single- and Repeat-Dose Toxicity
        - Mortality
        - General effects (i.e., food or water consumption, body weight, clinical signs)
        - Gastrointestinal toxicity
        - Hepatotoxicity
        - Renal toxicity
        - Neurotoxicity
        - Respiratory toxicity
        - Endocrine activity
        - Thyroid toxicity
        - Reproductive toxicity
        - Prenatal, perinatal, and post-natal toxicity*
        - Carcinogenicity
            - Genotoxicity
            - Initiation and promotion
            - Carcinogenicity studies
    - Lowest Hazard Endpoints by Organ System and Exposure Duration
    - Overall Uncertainty
- 6. Exposure
- 7. Discussion
- 8. References

- Sections under "Hazard Information" should also discuss dosing duration (i.e. Acute, Subchronic, Chronic) when the information exists.

- Copies of references cited and the report(s) will be made available to the Contract Officer in electronic form where possible or paper form where electronic form is not available.

---

* Perinatal studies that include exposure during late gestation through lactation are of particular importance for phthalates. These studies should be highlighted where available.

- The report is subject to CPSC clearance procedures. The Contractor will work with the Contract office to address comments from CPSC reviewers.

- Grouping of phthalates by structural or other characteristics. Given the large number of phthalates, some with limited data, it may be practical, as well as helpful to the readers, to group phthalates with similar characteristics. For example, they may be grouped by degree of branching (linear, branched, or isomeric mixture), molecular weight, or chain length. On the other hand, some compounds are data rich; these may require individual reviews. The Contractor will group phthalates by an appropriate scheme after consulting with the project officer.

4. Deliverables or Performance

The Contractor shall provide the requested information in the form of a written report for each selected plasticizer to the CPSC Project Officer within one hundred and twenty (120) days after the initial meeting. The report shall be in the format of a scientific report with full citations, tables, and figures as discussed above. The reviewer shall e-mail the report to the Project Officer in a Microsoft Word (preferred) or WordPerfect file.

5. Delivery Schedule

Item(s)	Quantity	Delivery or Performance
The CPSC Project Officer and Contractor will meet in person to discuss and initiate the project	1	June 2010
The CPSC Project Officer will be available to consult with the Contractor by teleconference or in person.	As appropriate	At the completion of each subtask, or monthly, whichever comes first.
The Contractor shall submit a prioritized list of phthalates and phthalate groups to the CPSC Project Officer	1	Within 60 days after the initial teleconference or meeting
The CPSC Project Officer and Contractor will meet in person or by teleconference to select the phthalates and phthalate groups to be included in the final report.	1	Within 30 days after the CPSC Project Officer receives the list of candidate phthalate substitutes.
The Contractor shall submit a draft report in electronic format to the CPSC Project Officer.	1	Within 120 days after the phthalate substitute(s) are selected in consultation with the CPSC Project Officer.
The CPSC Project Officer will provide type-written comments or a document edited by "Track Changes" on the draft report to the Contractor.	1	Within 30 days after receipt of the draft final report.
The Contractor shall submit an electronic draft final report to the CPSC Project Officer.	The Contractor will revise the draft final report as appropriate.	Within 30 days after receipt of comments.
The CPSC Project Officer will submit the draft final report for CPSC clearance.	1	With 1 week following receipt.
The CPSC Project Officer will provide type-written comments or a document edited by "Track Changes" on the draft final report to the Contractor.	1	Within 1 week following receipt.
The Contractor will provide a final report	1	Within 10 days after receipt of comments.
Inspection and Acceptance	The Final report will be reviewed by the CPSC Project Officer	Within 30 days after receipt of the report

6. Place of Delivery

U.S. Consumer Product Safety Commission
4330 East West Highway
Bethesda, MD 20814

CPSC Project Officers and contact information:

Kent R. Carlson, Ph.D.
kcarlson@cpsc.gov
301-504-6812

Michael A. Babich, Ph.D.
mbabich@cpsc.gov
301-504-7253

7. Inspection and Acceptance

The Draft Final Toxicity Review report submitted to the U.S. Consumer Product Safety Commission will be reviewed within 30 days of receipt of the draft final report for any additional questions and/or comments. If returned to the Contractor as a result of the review, the Contractor shall address and/or revise their report accordingly and return the final version to the Project Officer within 30 days of receipt. The CPSC Project Officer will then have an additional 30 days to review the Final Toxicity Review report.

8. Requirement for CPSC Clearance

The final report is the property of the U.S. Consumer Product Safety Commission. The Contractor will not publish the final report, present the information at scientific meetings, or in any other way make the findings public in any form without the written permission of the Project Officer. Any publication must be cleared following CPSC procedures, as outlined in the Consumer Product Safety Act.