976	PD317_09	Num	8	12656
977	PD317_10	Num	8	12664
978	PD318_01	Num	8	12672
979	PD318_02	Num	8	12680
980	PD318_03	Num	8	12688
981	PD318_04	Num	8	12696
982	PD318_05	Num	8	12704
983	PD318_06	Num	8	12712
984	PD318_07	Num	8	12720
985	PD318_08	Num	8	12728
986	PD318_09	Num	8	12736
987	PD318_10	Num	8	12744
988	PD319_01	Num	8	12752
989	PD319_02	Num	8	12760
990	PD319_03	Num	8	12768
991	PD319_04	Num	8	12776
992	PD319_05	Num	8	12784
993	PD319_06	Num	8	12792
994	PD319_07	Num	8	12800
995	PD319_08	Num	8	12808
996	PD319_09	Num	8	12816
997	PD319_10	Num	8	12824
998	PD320_01	Num	8	12832
999	PD320_02	Num	8	12840
1000	PD320_03	Num	8	12848
1001	PD320_04	Num	8	12856
1002	PD320_05	Num	8	12864
1003	PD320_06	Num	8	12872
1004	PD320_07	Num	8	12880
1005	PD320_08	Num	8	12888
1006	PD320_09	Num	8	12896
1007	PD320_10	Num	8	12904
1008	PD321_01	Num	8	12912
1009	PD321_02	Num	8	12920
1010	PD321_03	Num	8	12928
1011	PD321_04	Num	8	12936
1012	PD321_05	Num	8	12944
1013	PD321_06	Num	8	12952
1014	PD321_07	Num	8	12960
1015	PD321_08	Num	8	12968
1016	PD321_09	Num	8	12976
1017	PD321_10	Num	8	12984
1018	PD322_01	Num	8	12992
1019	PD322_02	Num	8	13000
1020	PD322_03	Num	8	13008
1021	PD322_04	Num	8	13016
1022	PD322_05	Num	8	13024
1023	PD322_06	Num	8	13032
1024	PD322_07	Num	8	13040
1025	PD322_08	Num	8	13048
1026	PD322_09	Num	8	13056
1027	PD322_10	Num	8	13064
1028	PD323_01	Num	8	13072
1029	PD323_02	Num	8	13080
1030	PD323_03	Num	8	13088
1031	PD323_04	Num	8	13096
1032	PD323_05	Num	8	13104

1033	PD323_06	Num	8	13112
1034	PD323_07	Num	8	13120
1035	PD323_08	Num	8	13128
1036	PD323_09	Num	8	13136
1037	PD323_10	Num	8	13144
1038	PD324_01	Num	8	13152
1039	PD324_02	Num	8	13160
1040	PD324_03	Num	8	13168
1041	PD324_04	Num	8	13176
1042	PD324_05	Num	8	13184
1043	PD324_06	Num	8	13192
1044	PD324_07	Num	8	13200
1045	PD324_08	Num	8	13208
1046	PD324_09	Num	8	13216
1047	PD324_10	Num	8	13224
1048	PD325_01	Num	8	13232
1049	PD325_02	Num	8	13240
1050	PD325_03	Num	8	13248
1051	PD325_04	Num	8	13256
1052	PD325_05	Num	8	13264
1053	PD325_06	Num	8	13272
1054	PD325_07	Num	8	13280
1055	PD325_08	Num	8	13288
1056	PD325_09	Num	8	13296
1057	PD325_10	Num	8	13304
1058	PD326_01	Num	8	13312
1059	PD326_02	Num	8	13320
1060	PD326_03	Num	8	13328
1061	PD326_04	Num	8	13336
1062	PD326_05	Num	8	13344
1063	PD326_06	Num	8	13352
1064	PD326_07	Num	8	13360
1065	PD326_08	Num	8	13368
1066	PD326_09	Num	8	13376
1067	PD326_10	Num	8	13384
1068	PD327_01	Num	8	13392
1069	PD327_02	Num	8	13400
1070	PD327_03	Num	8	13408
1071	PD327_04	Num	8	13416
1072	PD327_05	Num	8	13424
1073	PD327_06	Num	8	13432
1074	PD327_07	Num	8	13440
1075	PD327_08	Num	8	13448
1076	PD327_09	Num	8	13456
1077	PD327_10	Num	8	13464
1078	PD328_01	Num	8	13472
1079	PD328_02	Num	8	13480
1080	PD328_03	Num	8	13488
1081	PD328_04	Num	8	13496
1082	PD328_05	Num	8	13504
1083	PD328_06	Num	8	13512
1084	PD328_07	Num	8	13520
1085	PD328_08	Num	8	13528
1086	PD328_09	Num	8	13536
1087	PD328_10	Num	8	13544
1088	PD329_01	Num	8	13552
1089	PD329_02	Num	8	13560

1090	PD329_03	Num	8	13568
1091	PD329_04	Num	8	13576
1092	PD329_05	Num	8	13584
1093	PD329_06	Num	8	13592
1094	PD329_07	Num	8	13600
1095	PD329_08	Num	8	13608
1096	PD329_09	Num	8	13616
1097	PD329_10	Num	8	13624
1098	PD330_01	Num	8	13632
1099	PD330_02	Num	8	13640
1100	PD330_03	Num	8	13648
1101	PD330_04	Num	8	13656
1102	PD330_05	Num	8	13664
1103	PD330_06	Num	8	13672
1104	PD330_07	Num	8	13680
1105	PD330_08	Num	8	13688
1106	PD330_09	Num	8	13696
1107	PD330_10	Num	8	13704
1108	PD331_01	Num	8	13712
1109	PD331_02	Num	8	13720
1110	PD331_03	Num	8	13728
1111	PD331_04	Num	8	13736
1112	PD331_05	Num	8	13744
1113	PD331_06	Num	8	13752
1114	PD331_07	Num	8	13760
1115	PD331_08	Num	8	13768
1116	PD331_09	Num	8	13776
1117	PD331_10	Num	8	13784
1118	PD332_01	Num	8	13792
1119	PD332_02	Num	8	13800
1120	PD332_03	Num	8	13808
1121	PD332_04	Num	8	13816
1122	PD332_05	Num	8	13824
1123	PD332_06	Num	8	13832
1124	PD401_01	Num	8	13840
1125	PD401_02	Num	8	13848
1126	PD401_03	Num	8	13856
1127	PD401_04	Num	8	13864
1128	PD401_05	Num	8	13872
1129	PD401_06	Num	8	13880
1130	PD401_07	Num	8	13888
1131	PD401_08	Num	8	13896
1132	PD401_09	Num	8	13904
1133	PD401_10	Num	8	13912
1134	PD402_01	Num	8	13920
1135	PD402_02	Num	8	13928
1136	PD402_03	Num	8	13936
1137	PD402_04	Num	8	13944
1138	PD402_05	Num	8	13952
1139	PD402_06	Num	8	13960
1140	PD402_07	Num	8	13968
1141	PD402_08	Num	8	13976
1142	PD402_09	Num	8	13984
1143	PD402_10	Num	8	13992
1144	PD403_01	Num	8	14000
1145	PD403_02	Num	8	14008
1146	PD403_03	Num	8	14016

1147	PD403_04	Num	8	14024
1148	PD403_05	Num	8	14032
1149	PD403_06	Num	8	14040
1150	PD403_07	Num	8	14048
1151	PD403_08	Num	8	14056
1152	PD403_09	Num	8	14064
1153	PD403_10	Num	8	14072
1154	PD404_01	Num	8	14080
1155	PD404_02	Num	8	14088
1156	PD404_03	Num	8	14096
1157	PD404_04	Num	8	14104
1158	PD404_05	Num	8	14112
1159	PD404_06	Num	8	14120
1160	PD404_07	Num	8	14128
1161	PD404_08	Num	8	14136
1162	PD404_09	Num	8	14144
1163	PD404_10	Num	8	14152
1164	PD405_01	Num	8	14160
1165	PD405_02	Num	8	14168
1166	PD405_03	Num	8	14176
1167	PD405_04	Num	8	14184
1168	PD405_05	Num	8	14192
1169	PD405_06	Num	8	14200
1170	PD405_07	Num	8	14208
1171	PD405_08	Num	8	14216
1172	PD405_09	Num	8	14224
1173	PD405_10	Num	8	14232
1174	PD406_01	Num	8	14240
1175	PD406_02	Num	8	14248
1176	PD406_03	Num	8	14256
1177	PD406_04	Num	8	14264
1178	PD406_05	Num	8	14272
1179	PD406_06	Num	8	14280
1180	PD406_07	Num	8	14288
1181	PD406_08	Num	8	14296
1182	PD406_09	Num	8	14304
1183	PD406_10	Num	8	14312
1184	PD407_01	Num	8	14320
1185	PD407_02	Num	8	14328
1186	PD407_03	Num	8	14336
1187	PD407_04	Num	8	14344
1188	PD407_05	Num	8	14352
1189	PD407_06	Num	8	14360
1190	PD407_07	Num	8	14368
1191	PD407_08	Num	8	14376
1192	PD407_09	Num	8	14384
1193	PD407_10	Num	8	14392
1194	PD408_01	Num	8	14400
1195	PD408_02	Num	8	14408
1196	PD408_03	Num	8	14416
1197	PD408_04	Num	8	14424
1198	PD408_05	Num	8	14432
1199	PD408_06	Num	8	14440
1200	PD408_07	Num	8	14448
1201	PD408_08	Num	8	14456
1202	PD408_09	Num	8	14464
1203	PD408_10	Num	8	14472

1204	PD409_01	Num	8	14480
1205	PD409_02	Num	8	14488
1206	PD409_03	Num	8	14496
1207	PD409_04	Num	8	14504
1208	PD409_05	Num	8	14512
1209	PD409_06	Num	8	14520
1210	PD409_07	Num	8	14528
1211	PD409_08	Num	8	14536
1212	PD409_09	Num	8	14544
1213	PD409_10	Num	8	14552
1214	PD410_01	Num	8	14560
1215	PD410_02	Num	8	14568
1216	PD410_03	Num	8	14576
1217	PD410_04	Num	8	14584
1218	PD410_05	Num	8	14592
1219	PD410_06	Num	8	14600
1220	PD410_07	Num	8	14608
1221	PD410_08	Num	8	14616
1222	PD410_09	Num	8	14624
1223	PD410_10	Num	8	14632
1224	PD411_01	Num	8	14640
1225	PD411_02	Num	8	14648
1226	PD411_03	Num	8	14656
1227	PD411_04	Num	8	14664
1228	PD411_05	Num	8	14672
1229	PD411_06	Num	8	14680
1230	PD411_07	Num	8	14688
1231	PD411_08	Num	8	14696
1232	PD411_09	Num	8	14704
1233	PD411_10	Num	8	14712
1234	PD412_01	Num	8	14720
1235	PD412_02	Num	8	14728
1236	PD412_03	Num	8	14736
1237	PD412_04	Num	8	14744
1238	PD412_05	Num	8	14752
1239	PD412_06	Num	8	14760
1240	PD412_07	Num	8	14768
1241	PD412_08	Num	8	14776
1242	PD412_09	Num	8	14784
1243	PD412_10	Num	8	14792
1244	PD413_01	Num	8	14800
1245	PD413_02	Num	8	14808
1246	PD413_03	Num	8	14816
1247	PD413_04	Num	8	14824
1248	PD413_05	Num	8	14832
1249	PD413_06	Num	8	14840
1250	PD413_07	Num	8	14848
1251	PD413_08	Num	8	14856
1252	PD413_09	Num	8	14864
1253	PD413_10	Num	8	14872
1254	PD414_01	Num	8	14880
1255	PD414_02	Num	8	14888
1256	PD414_03	Num	8	14896
1257	PD414_04	Num	8	14904
1258	PD414_05	Num	8	14912
1259	PD414_06	Num	8	14920
1260	PD414_07	Num	8	14928

1261	PD414_08	Num	8	14936
1262	PD414_09	Num	8	14944
1263	PD414_10	Num	8	14952
1264	PD415_01	Num	8	14960
1265	PD415_02	Num	8	14968
1266	PD415_03	Num	8	14976
1267	PD415_04	Num	8	14984
1268	PD415_05	Num	8	14992
1269	PD415_06	Num	8	15000
1270	PD415_07	Num	8	15008
1271	PD415_08	Num	8	15016
1272	PD415_09	Num	8	15024
1273	PD415_10	Num	8	15032
1274	PD416_01	Num	8	15040
1275	PD416_02	Num	8	15048
1276	PD416_03	Num	8	15056
1277	PD416_04	Num	8	15064
1278	PD416_05	Num	8	15072
1279	PD416_06	Num	8	15080
1280	PD416_07	Num	8	15088
1281	PD416_08	Num	8	15096
1282	PD416_09	Num	8	15104
1283	PD416_10	Num	8	15112
1284	PD417_01	Num	8	15120
1285	PD417_02	Num	8	15128
1286	PD417_03	Num	8	15136
1287	PD417_04	Num	8	15144
1288	PD417_05	Num	8	15152
1289	PD417_06	Num	8	15160
1290	PD417_07	Num	8	15168
1291	PD417_08	Num	8	15176
1292	PD417_09	Num	8	15184
1293	PD417_10	Num	8	15192
1294	PD418_01	Num	8	15200
1295	PD418_02	Num	8	15208
1296	PD418_03	Num	8	15216
1297	PD418_04	Num	8	15224
1298	PD418_05	Num	8	15232
1299	PD418_06	Num	8	15240
1300	PD418_07	Num	8	15248
1301	PD418_08	Num	8	15256
1302	PD418_09	Num	8	15264
1303	PD418_10	Num	8	15272
1304	PD419_01	Num	8	15280
1305	PD419_02	Num	8	15288
1306	PD419_03	Num	8	15296
1307	PD419_04	Num	8	15304
1308	PD419_05	Num	8	15312
1309	PD419_06	Num	8	15320
1310	PD419_07	Num	8	15328
1311	PD419_08	Num	8	15336
1312	PD419_09	Num	8	15344
1313	PD419_10	Num	8	15352
1314	PD420_01	Num	8	15360
1315	PD420_02	Num	8	15368
1316	PD420_03	Num	8	15376
1317	PD420_04	Num	8	15384

1318	PD420_05	Num	8	15392
1319	PD420_06	Num	8	15400
1320	PD420_07	Num	8	15408
1321	PD420_08	Num	8	15416
1322	PD420_09	Num	8	15424
1323	PD420_10	Num	8	15432
1324	PD421_01	Num	8	15440
1325	PD421_02	Num	8	15448
1326	PD421_03	Num	8	15456
1327	PD421_04	Num	8	15464
1328	PD421_05	Num	8	15472
1329	PD421_06	Num	8	15480
1330	PD421_07	Num	8	15488
1331	PD421_08	Num	8	15496
1332	PD421_09	Num	8	15504
1333	PD421_10	Num	8	15512
1334	PD422_01	Num	8	15520
1335	PD422_02	Num	8	15528
1336	PD422_03	Num	8	15536
1337	PD422_04	Num	8	15544
1338	PD422_05	Num	8	15552
1339	PD422_06	Num	8	15560
1340	PD422_07	Num	8	15568
1341	PD422_08	Num	8	15576
1342	PD422_09	Num	8	15584
1343	PD422_10	Num	8	15592
1344	PD423_01	Num	8	15600
1345	PD423_02	Num	8	15608
1346	PD423_03	Num	8	15616
1347	PD423_04	Num	8	15624
1348	PD423_05	Num	8	15632
1349	PD423_06	Num	8	15640
1350	PD423_07	Num	8	15648
1351	PD423_08	Num	8	15656
1352	PD423_09	Num	8	15664
1353	PD423_10	Num	8	15672
1354	PD424_01	Num	8	15680
1355	PD424_02	Num	8	15688
1356	PD424_03	Num	8	15696
1357	PD424_04	Num	8	15704
1358	PD424_05	Num	8	15712
1359	PD424_06	Num	8	15720
1360	PD424_07	Num	8	15728
1361	PD424_08	Num	8	15736
1362	PD424_09	Num	8	15744
1363	PD424_10	Num	8	15752
1364	PD425_01	Num	8	15760
1365	PD425_02	Num	8	15768
1366	PD425_03	Num	8	15776
1367	PD425_04	Num	8	15784
1368	PD425_05	Num	8	15792
1369	PD425_06	Num	8	15800
1370	PD425_07	Num	8	15808
1371	PD425_08	Num	8	15816
1372	PD425_09	Num	8	15824
1373	PD425_10	Num	8	15832
1374	PD426_01	Num	8	15840

1375	PD426_02	Num	8	15848
1376	PD426_03	Num	8	15856
1377	PD426_04	Num	8	15864
1378	PD426_05	Num	8	15872
1379	PD426_06	Num	8	15880
1380	PD426_07	Num	8	15888
1381	PD426_08	Num	8	15896
1382	PD426_09	Num	8	15904
1383	PD426_10	Num	8	15912
1384	PD427_01	Num	8	15920
1385	PD427_02	Num	8	15928
1386	PD427_03	Num	8	15936
1387	PD427_04	Num	8	15944
1388	PD427_05	Num	8	15952
1389	PD427_06	Num	8	15960
1390	PD427_07	Num	8	15968
1391	PD427_08	Num	8	15976
1392	PD427_09	Num	8	15984
1393	PD427_10	Num	8	15992
1394	PD428_01	Num	8	16000
1395	PD428_02	Num	8	16008
1396	PD428_03	Num	8	16016
1397	PD428_04	Num	8	16024
1398	PD428_05	Num	8	16032
1399	PD428_06	Num	8	16040
1400	PD428_07	Num	8	16048
1401	PD428_08	Num	8	16056
1402	PD428_09	Num	8	16064
1403	PD428_10	Num	8	16072
1404	PD429_01	Num	8	16080
1405	PD429_02	Num	8	16088
1406	PD429_03	Num	8	16096
1407	PD429_04	Num	8	16104
1408	PD429_05	Num	8	16112
1409	PD429_06	Num	8	16120
1410	PD429_07	Num	8	16128
1411	PD429_08	Num	8	16136
1412	PD429_09	Num	8	16144
1413	PD429_10	Num	8	16152
1414	PD430_01	Num	8	16160
1415	PD430_02	Num	8	16168
1416	PD430_03	Num	8	16176
1417	PD430_04	Num	8	16184
1418	PD430_05	Num	8	16192
1419	PD430_06	Num	8	16200
1420	PD430_07	Num	8	16208
1421	PD430_08	Num	8	16216
1422	PD430_09	Num	8	16224
1423	PD430_10	Num	8	16232
1424	PD431_01	Num	8	16240
1425	PD431_02	Num	8	16248
1426	PD431_03	Num	8	16256
1427	PD431_04	Num	8	16264
1428	PD431_05	Num	8	16272
1429	PD431_06	Num	8	16280
1430	PD431_07	Num	8	16288
1431	PD431_08	Num	8	16296

1432	PD431_09	Num	8	16304
1433	PD431_10	Num	8	16312
1434	PD432_01	Num	8	16320
1435	PD432_02	Num	8	16328
1436	PD432_03	Num	8	16336
1437	PD432_04	Num	8	16344
1438	PD432_05	Num	8	16352
1439	PD432_06	Num	8	16360
1440	PD432_07	Num	8	16368
1441	PD432_08	Num	8	16376
1442	PD432_09	Num	8	16384
1443	PD432_10	Num	8	16392
1444	PD433_01	Num	8	16400
1445	PD433_02	Num	8	16408
1446	PD433_03	Num	8	16416
1447	PD433_04	Num	8	16424
1448	PD433_05	Num	8	16432
1449	PD433_06	Num	8	16440
1450	PD433_07	Num	8	16448
1451	PD433_08	Num	8	16456
1452	PD433_09	Num	8	16464
1453	PD433_10	Num	8	16472
11	PRED5_1	Char	2	26
41	PRED5_2	Char	2	1239
82	PRED5_3	Char	2	3002
123	PRED5_4	Char	2	4621
217	PSUCODE	Char	8	6584
215	STRCODE	Char	5	6571
216	WEIGHT	Num	8	6576

The CONTENTS Procedure

Data Set Name:	C2.D5TIME	Observations:	491
Member Type:	DATA	Variables:	134
Engine:	V6	Indexes:	0
Created:	12:57 Friday, June 22, 2001	Observation Length:	576
Last Modified:	12:57 Friday, June 22, 2001	Deleted Observations:	0
Protection:	_	Compressed:	NO
Data Set Type:		Sorted:	NO
Label:			

-----Engine/Host Dependent Information-----

Data Set Page Size:	16384
Number of Data Set Pages:	19
First Data Page:	2
Max Obs per Page:	28
Obs in First Data Page:	27
Number of Data Set Repairs:	0
File Name:	c:\mag\phth\macro\data\d5time.sd2
Release Created:	6.12.00
Host Created:	OS2

-----Alphabetic List of Variables and Attributes-----

#	Variable	Type	Len	Pos
2	D5T_101	Char	4	8
3	D5T_102	Char	4	12
4	D5T_103	Char	4	16
5	D5T_104	Char	4	20
6	D5T_105	Char	4	24
7	D5T_106	Char	4	28
8	D5T_107	Char	4	32
9	D5T_108	Char	4	36
10	D5T_109	Char	4	40
11	D5T_110	Char	4	44
12	D5T_111	Char	4	48
13	D5T_112	Char	4	52
14	D5T_113	Char	4	56
15	D5T_114	Char	4	60
16	D5T_115	Char	4	64
17	D5T_116	Char	4	68
18	D5T_117	Char	4	72
19	D5T_118	Char	4	76
20	D5T_119	Char	4	80
21	D5T_120	Char	4	84
22	D5T_121	Char	4	88
23	D5T_122	Char	4	92
24	D5T_123	Char	4	96
25	D5T_124	Char	4	100
26	D5T_201	Char	4	104

27	D5T_202	Char	4	108
28	D5T_203	Char	4	112
29	D5T_204	Char	4	116
30	D5T_205	Char	4	120
31	D5T_206	Char	4	124
32	D5T_207	Char	4	128
33	D5T_208	Char	4	132
34	D5T_209	Char	4	136
35	D5T_210	Char	4	140
36	D5T_211	Char	4	144
37	D5T_212	Char	4	148
38	D5T_213	Char	4	152
39	D5T_214	Char	4	156
40	D5T_215	Char	4	160
41	D5T_216	Char	4	164
42	D5T_217	Char	4	168
43	D5T_218	Char	4	172
44	D5T_219	Char	4	176
45	D5T_220	Char	4	180
46	D5T_221	Char	4	184
47	D5T_222	Char	4	188
48	D5T_223	Char	4	192
49	D5T_224	Char	4	196
50	D5T_225	Char	4	200
51	D5T_226	Char	4	204
52	D5T_227	Char	4	208
53	D5T_228	Char	4	212
54	D5T_229	Char	4	216
55	D5T_230	Char	4	220
56	D5T_231	Char	4	224
57	D5T_232	Char	4	228
58	D5T_233	Char	4	232
59	D5T_234	Char	4	236
60	D5T_235	Char	4	240
61	D5T_301	Char	4	244
62	D5T_302	Char	4	248
63	D5T_303	Char	4	252
64	D5T_304	Char	4	256
65	D5T_305	Char	4	260
66	D5T_306	Char	4	264
67	D5T_307	Char	4	268
68	D5T_308	Char	4	272
69	D5T_309	Char	4	276
70	D5T_310	Char	4	280
71	D5T_311	Char	4	284
72	D5T_312	Char	4	288
73	D5T_313	Char	4	292
74	D5T_314	Char	4	296
75	D5T_315	Char	4	300
76	D5T_316	Char	4	304
77	D5T_317	Char	4	308
78	D5T_318	Char	4	312
79	D5T_319	Char	4	316
80	D5T_320	Char	4	320
81	D5T_321	Char	4	324
82	D5T_322	Char	4	328
83	D5T_323	Char	4	332

84	D5T_324	Char	4	336
85	D5T_325	Char	4	340
86	D5T_326	Char	4	344
87	D5T_327	Char	4	348
88	D5T_328	Char	4	352
89	D5T_329	Char	4	356
90	D5T_330	Char	4	360
91	D5T_331	Char	4	364
92	D5T_332	Char	4	368
93	D5T_401	Char	4	372
94	D5T_402	Char	4	376
95	D5T_403	Char	4	380
96	D5T_404	Char	4	384
97	D5T_405	Char	4	388
98	D5T_406	Char	4	392
99	D5T_407	Char	4	396
100	D5T_408	Char	4	400
101	D5T_409	Char	4	404
102	D5T_410	Char	4	408
103	D5T_411	Char	4	412
104	D5T_412	Char	4	416
105	D5T_413	Char	4	420
106	D5T_414	Char	4	424
107	D5T_415	Char	4	428
108	D5T_416	Char	4	432
109	D5T_417	Char	4	436
110	D5T_418	Char	4	440
111	D5T_419	Char	4	444
112	D5T_420	Char	4	448
113	D5T_421	Char	4	452
114	D5T_422	Char	4	456
115	D5T_423	Char	4	460
116	D5T_424	Char	4	464
117	D5T_425	Char	4	468
118	D5T_426	Char	4	472
119	D5T_427	Char	4	476
120	D5T_428	Char	4	480
121	D5T_429	Char	4	484
122	D5T_430	Char	4	488
123	D5T_431	Char	4	492
124	D5T_432	Char	4	496
125	D5T_433	Char	4	500
126	E101	Num	8	504
127	E102	Num	8	512
128	E103	Num	8	520
129	E104	Num	8	528
130	E105	Num	8	536
131	E106	Num	8	544
132	E166	Num	8	552
133	E177	Num	8	560
134	E199	Num	8	568
1	MASTERID	Char	8	0

Appendix B – Mouthing Times Among Young Children From Observational Data

TAB G

UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
WASHINGTON, DC 20207

Memorandum

Date: June 17, 2002

TO : Marilyn G. Wind, Ph. D.
Deputy Associate Executive Director
Directorate for Health Sciences

THROUGH: Susan Ahmed, Ph. D.
Associate Executive Director
Directorate for Epidemiology

Russell H. Roegner, Ph. D.
Division Director
Division of Hazard Analysis

FROM : Michael A. Greene, Ph. D.
Mathematical Statistician
Division of Hazard Analysis

SUBJECT : Mouthing times for children from the observational study

Attached is a report on mouthing times for children up to 36 months old from the observational study.

Mouthing Times Among Young Children From Observational Data

Michael A. Greene
Mathematical Statistician
Division of Hazard Analysis

Executive Summary

This paper reports on mouthing times using data collected in a CPSC study that observed mouthing activities among young children. Demographic and other data were also obtained from telephone interviews. There were 551 children who were recruited in a telephone survey. The purpose of the study is to provide estimates for mouthing times for soft plastic and other objects for a risk assessment associated with oral intake of DINP.

The data. For most of the children, child and family demographics characteristics as well as the typical time these children spent awake, taking naps and in meals were reported in telephone interviews. ITS-RAM (CPSC Contractor) observers recorded the duration of every mouthing activity as well as a detailed description of each object mouthed.

Characteristics of the sample. The 551 children were recruited in the Chicago and Houston metropolitan areas. The sample was 55 percent male and 45 percent female. Age varied between 3 months and six years, 9 months. About two thirds of the children were the only child six years old or younger in the family. About 61 percent of the sample came from the Chicago metropolitan area and the remaining 39 percent came from the Houston metropolitan area. The racial composition was 85 percent White, 9 percent Black, 3 percent Asian and 4 percent Multi-racial. In addition, 19 percent of the children were identified as Hispanic. The sample, while otherwise demographically balanced, had fewer people in the lower income strata than the U.S. in general. This is typically found in telephone based surveys because people in the lowest income strata are less likely to have telephones.

A total of 169 children were included in the observational study where professional observers watched and recorded children's mouthing activities for four hours (two hours on two days). All these children were 36 months old or younger.

Exposure Time. Exposure time was defined as the length of time that a child was awake and not eating. This is the time that a child has available to mouth objects. It was necessary to use exposure time to extrapolate from the four hours of mouthing observations per child to a typical day. Average exposure was about 10 hours for children under 2 and 10.7 hours for children between 2 and 3 years of age.

Exposure time was modeled as related to child's age, number of children under six in the family, sex, adult's and child's racial and ethnic characteristics, marital status and income. Only child's age and number of children under age six were statistically significant. The model for exposure time in hours per day was

Exposure Time = 9.04 + 0.53 One Child + 0.23 Two Children + 0.0375 Age

where age was measured in months.

Observed Mouthing Times for Children under 3 years. Mouthing times were categorized into various groups by the type of object mouthed. Some of the categories were as follows: all objects; pacifiers; non pacifiers; all soft plastic objects; all soft plastic objects not including food contact items; soft plastic toys, teethers and rattles; soft plastic toys, and others. For all the children, average hourly mouthing times calculated from the two hour observation period were as follows: all objects 7.7 minutes per hour, pacifiers 2.6 minutes and non pacifiers 5.1 minutes. Non pacifier mouthing time was further broken down into categories of soft plastic items (0.4 minutes average per hour), and soft plastic toys (0.13 minutes per hour). Mouthing times decreased with age for most categories. Within age groups, the distribution of mouthing times also displayed positive skewness, that is there were only a few children with long mouthing times and many with little or no mouthing activity. In particular, for categories that contained few objects such as all soft plastic items or soft plastic toys, many children did not have any reported mouthing time.

Mouthing times and exposure times for various object categories were jointly analyzed to determine if they were correlated. No correlation coefficients were statistically significant, but there were borderline p values (0.07 and 0.06 respectively) for two object categories, (1) soft plastic toys and (2) soft plastic toys, teethers and rattles. The correlation coefficients were negative in these categories.

Statistical Procedures for Estimating Daily Mouthing Times. Daily mouthing times were estimated by multiplying observed mouthing times by exposure time, using the model for exposure time described above. Means, medians, 95th and 99th percentiles were estimated. Bootstrap procedures were used for confidence intervals.

Results. For the category of all objects except pacifiers, estimated average daily mouthing times were 70 minutes (95% confidence interval 60-80 minutes) for children between 3 months and 1 year of age, 48 minutes (39-57 minutes) for children between 1 year and 2 years, and 37 minutes (27-49 minutes) for children between 2 and 3 years of age. The 95th percentiles for mouthing times for these children was about two hours per day in each age group.

Most of the objects in the non pacifier category were not soft plastic items, in fact the largest single category mouthed was anatomy (fingers, hands and skin). Soft plastic toys represented a small part of these times. For soft plastic toys, the daily average mouthing times were 1.3 minutes (0.7- 2.0 minutes) for children between 3 months and one year, 1.9 minutes (1.2 – 2.6 minutes) for children between 1 and 2 years and 0.8 minutes (0.3 – 1.6 minutes) for children between 2 and 3 years of age. The 95th percentile mouthing times for soft plastic toys were as follows (with 95 percent confidence intervals in parentheses): 7.1 minutes (3.9 – 11.0), 8.9 minutes (5.7 – 11.7) and 3.3 minutes (1.4-16.3) for children under 1 year, 1-2 years and 2-3 years respectively.

1. Introduction

Evaluation of the potential health risks of diisononyl phthalate (DINP) to children from oral ingestion requires three components. These are (1) the health effects of DINP as related to the amount ingested, (2) the migration rates from various objects likely to be mouthed and (3) the amount of mouthing time. Health effects have been reported in a report prepared by the Consumer Product Safety Commission staff (CPSC, 1998) and by CPSC's Chronic Hazard Advisory Panel (CPSC, 2001). Migration rates have been estimated from children's toys in CPSC (1998), Konemann et al (1998), Rijk and Ehlert, (1999) and LGC (1999). There are ongoing migration rate studies in the United States and Europe. Mouthing times were studied in three reports, two in the United States, Smith and Kiss (1998) and Juberg, Alfano, Coughlin and Thompson (2001) and one in the Netherlands, Groot, Leekerkerk and Steenbekkers (1998). This present study is the fourth study.

This study is based on observation of children in the Chicago and Houston metropolitan areas during 2000 and 2001. Data was collected by professional observers. They observed children between 3 months and 36 months of age. This data was collected in connection with the DINP risk assessment.

This study differs from the previous studies in several ways. The sample in this study is geographically diverse, because children were recruited from two large metropolitan areas in the United States. Also, as a result of random digit dialing telephone recruitment for the study, the sample is ethnically and demographically diverse. Also the study contains a wealth of demographic and observational data on the children to permit relating mouthing times to the characteristics of the children.

Section 2 reviews the literature. Section 3 describes the study procedures and the sample demographics. Section 4 describes the procedure for obtaining exposure estimates and presents the estimates. Section 5 analyzes mouthing times for the two-hour observation periods. Section 6 examines the question of whether mouthing times and exposure are related. Section 7 contains a model for daily mouthing times based on the exposure and mouthing time observations. This is proposed for use for estimation of DINP intake for the risk assessment. Finally, section 8 discusses the findings.

2. Literature

There are three empirical studies of children's mouthing activities, one conducted in the Netherlands (Groot, Leekerkerk and Steenbekkers, 1998), and two in the United States, (Smith and Kiss, 1998 and Juberg, Alfano, Coughlin and Thompson, 2001). The Netherlands study was used in the European Union's DINP risk assessment (Konemann,

1998) and the CPSC staff previous DINP risk assessment (CPSC, 1998). Juberg et al provided the basis for the exposure estimates used by CPSC's Chronic Hazard Advisory Panel (CPSC, 2001). Brief summaries of these studies are below.

The Netherlands study involved 42 children, 21 boys and 21 girls aged between 3 and 36 months. Children were recruited in the area around Wageningen Agricultural University, where the study authors were employed. Posters in day care centers and supermarkets, a mail campaign in neighborhoods with young families and ads in local newspapers were used to recruit participants. Parents were asked to time their children's mouthing activities during twenty 15-minute periods spread over two days. This provided a total of five hours of observations. Parents were given stopwatches for measuring mouthing times and asked to write down the object that was mouthed. Researchers later grouped the objects that were mouthed as pacifiers (dummy in the study's terminology), fingers, non toys, toys meant for mouthing and toys not meant for mouthing. Parents also were asked to provide demographic information and also the length of time the child was awake, but not eating during the day (i.e. exposure time). Mouthing times were extrapolated to a full day from the reported mouthing times and the exposure time.

Data from this study is shown in Table 1 below:

Table 1
Exposure and Mouthing Times in Groot et al (1998)

Age Group	Number of Children	Average Exposure Time (Hours)	Average Mouthing Times (minutes): Non Pacifiers	Toys for Mouthing and Other Toys	Toys for Mouthing Only
3-6 months	5	7.8	36.9	14.7	3.4
6-12 months	14	8.3	44.0	27.9	5.8
12-18 months	12	8.6	16.4	3.6	0.0
18-36 months	11	8.7	9.3	1.1	0.0

Notes: Number of Children from Groot et al (1998) table 5-1, page 15. Exposure times, table 5-8 page 20, Mouthing times from table 5-12 pages 26-27. Non pacifiers include toys for mouthing, other toys, non toys, and fingers. Toys for mouthing and other toys include toys for mouthing only. Examples of toys for mouthing were teethers, plastic keys, plastic building blocks; other toys were cloth books, plastic books, etc. (Groot et al, page 35).

The Netherlands study showed that mouthing time for toys was highest for children 6-12 months old, representing about 13 percent of the non pacifier mouthing time (Groot et all, 1998, page 24). For both younger and older children, toys for mouthing played a small role in total mouthing time.

CPSC staff reanalyzed these data as part of the 1998 DINP risk assessment (CPSC, 1998). This study used mouthing times from toys for mouthing and other toys

215

(the second from right column in table 1) for each child provided by the study authors. In analyzing the distribution of mouthing times for children 3-12 months and 13-36 months, considerable positive skewness was found. This represented a situation where most children had relatively short mouthing times, but a few had long mouthing times. Transforming the data to logs provided more symmetry to the distributions. The geometric mean mouthing time (toys for mouthing and other toys) was 12 minutes for children 3-12 months old and 2 minutes for the older children (CPSC, 1998, page B-8).

In another study, Smith and Kiss (1998) observed the mouthing activities of 80 children between 1 and 8 years of age in day care centers and schools in the Washington, DC metropolitan area. Data was reported for all toys, including toys intended for mouthing and other toys. Average toy mouthing times for each age group (i.e., 1-year-olds, 2-year-olds, etc.) varied from less than a half minute per day to almost 7.5 minutes per day, with the youngest age group exhibiting the greatest total mouthing time. This study was not used in the risk assessment because the researchers did not observe children under one year of age, which is the age when the most mouthing activities occur.

The other American study was conducted in the United States by researchers associated with Fisher-Price. The analysis was used for exposure estimates by CPSC's Chronic Hazard Advisory Panel (CPSC, 2001). Participants in this study were recruited from the Fisher-Price Child Research Center Play Laboratory database from children in Western New York (Juberg, et al, 2001, page 136). Children were recruited either for a single day of parental observations (Phase I and Phase II) or a week of observation (Phase III) of their mouthing activities. Phase I and Phase II had 217 children between them, almost evenly divided between under 18 months and 18-36 months. Phase III had 168 children up to 21 months of age.

In this study, parents were asked to record mouthing durations to the nearest minute. Results were reported only for two categories of objects, pacifiers and everything else, denoted as "non-pacifiers" in the report. Non pacifiers included teethers, plastic toys, fingers and a wide range of objects (see Juberg, et al, table 1, page 139 for some examples). Separate analyses were presented for children 18 months and younger, and children between 19 and 36 months. For children up to 18 months, average daily nonpacifier mouthing time was 33 minutes for (Phase I and Phase II) and 36 minutes (Phase III). For children 19-36 months average non pacifier mouthing time was 5 minutes per day. Like the Netherlands data, all mouthing histograms showed long right tails. Mouthing time was also shown to decrease with age (Juberg et al, page 141).

3. Study Procedures and Study Sample

3.1 Procedures

In this present study, children were recruited by random digit dialing of families in Chicago and Houston metropolitan areas. Children for the observational study were selected to meet age quotas of 40 children between 3 months and 1 year of age, 30 children between 1 and 2 years of age and 30 children between 2 and 3 years of age in each metropolitan area. These quotas of 200 children were not completely filled. Children over 36 months of age were recruited for participation in a parental observation study, where parents, rather than professional observers, recorded mouthing times. Some of the parents of the younger children were also asked to observe and record their children's mouthing behavior.

Aside from callbacks, there were two telephone contacts with the families. During the first contact, the telephone interviewer determined if there was a child 6 years old or younger in the family, recruited the child (selected probabilistically if there was more than one eligible child), and collected demographic information. Between the first and second contact, the parent or guardian was mailed instructions and a form to be used to record the child's mouthing activities. The parent was asked to conduct the mouthing study by observing the child for four 15-minute periods. In the second contact, the parent was asked to read the recorded mouthing observations and times to the telephone interviewer. The parent was also asked for information on the child's waking and sleeping hours and the duration of meals and snack times. Also in the second contact children 36 months old or younger were recruited for participation in the professional observation study.

This protocol was revised about two thirds of the way through the study. While monitoring the number of children recruited for professional observations, staff became concerned that the parental observation and the long second contact questionnaire might have increased the chance of dropouts. As a result, the second contact was eliminated. In this phase of the study, 60 children were recruited for the observational study without either exposure time information or parentally observed mouthing times.

There were 551 children at various levels of participation in the study. All subjects provided demographic information. There were 269 children 36 months old or younger and 282 children over 36 months of age. Of the 269 children 36 months old or younger:

60 had only professional observations of mouthing time[1]
109 had both professional observations and parental observations[2]
100 had only parental observations only

The 282 children over 36 months had parental observations only.

The final sample was 169 children with professionally observed mouthing (all 36 months old or younger) and 491 children with parental observations on mouthing times.

---

[1] The term "professional observers" is used as shorthand in this document to refer to the trained contractor staff who visited the families and observed the children. They are to be distinguished from parents who observed their children in this study and in other studies in the literature.

[2] Actually 111 children had both professional and parental observations and 98 had parental observations only. Data from the professional observations for two children were not usable because of recording errors. These two children were considered in the category of parental observations only.

The observers were trained by CPSC and contractor staff. A training film was made using four children under two years of age. The camera remained in front of each child following the child's movements. Timing and recording mouthing activities was demonstrated with two children, while the remaining two were used to test the observer's capability to record the information after completion of the training.

Observations by the staff took place during a three hour period on two different days. Observations were almost always at the child's home. Each three hour period consisted of alternating cycles of twenty minutes of observation followed by ten minutes of rest for the observer. This produced a total of two hours of observations per day, for a total of four hours per child. The observation periods were during the day or early evening. Meals and periods when the child was sleeping were excluded. During the observation of the children, the observers wrote down the duration of every mouthing activity. Observers timed these activities using stopwatches. The observer also recorded a description of the object that was mouthed and the type of mouthing activity such as chewing, sucking, or biting. Data was transcribed into Excel spread sheets and then converted from the spread sheets to SAS datasets.

This study and the study by Smith and Kiss used professional observers, in contrast to Juberg et al and Groot et al who used parents as observers. The advantage of using professional observers is consistency, in that they are trained to use a standardized approach with all the subjects. On the other hand, the parent observers are part of the child's environment and are less likely to change the child's behavior while recording mouthing times. To overcome this potential disadvantage, the observers were asked to arrive early at the child's home, to spend some time with the child so as to become familiar with him/her and to be unobtrusive while recording the observations.

3.2 Demographics

This section describes the demographics of the sample, and, where possible, compares these demographics with the United States as a whole.

For the entire sample 55 percent were boys and 45 percent girls. With respect to household size, 68 percent of children lived in households where they were the only child who was six years old or younger, 27 percent had a sibling six or younger and 4 percent of the children had two or more siblings six or younger. With respect to marital status, 83 percent of adult parents or guardians identified themselves as married, while 17 percent were divorced, widowed, unmarried, separated, etc. Sixty one percent of the children were from the Chicago area and 39 percent from Houston. Racial composition of children and adults in the sample are shown in table 2 below.

Table 2
Percent of Children and Adults by Race

Race	Children	Adults
White	85	88
Black	9	9
Asian	3	1
Multi-Racial	4	1
Total	100	100

Notes: Asian includes Filipino, Indian, Arabic. Multi-Racial includes all categories where more than one race was mentioned. Respondents could mention up to three racial groups. Don't Know, Refused and Other allocated proportionately among White, Black, Asian and Multi Racial. Individuals who chose Hispanic as a race were allocated to White and Black in proportion to the 2000 Census proportions of 97 percent white and 3 percent Black. Based on 551 responses. Totals may not add due to rounding.

In responding to a question as to whether they were of Hispanic origin (in addition to the race question above), 19 percent of adults in the sample said they were Hispanic. The respondents reported that 17 percent of the children were Hispanic.

The racial composition of family households with children under six years old in the U. S. is 83 percent White, 14 percent Black and 4 percent Asian/Pacific or other categories (U. S. Census Bureau, 2000a). Also, according to the Census Bureau, 16 percent of the population with children under six years identify themselves as Hispanic. This latter statistic is in close agreement with the sample. However the sample has disproportionately fewer Blacks than the U. S. population.

Table 3 shows the income distribution in the sample.

Table 3
Distribution of Income

Income Range	Percent of Families in the Sample	Percent of Families in the Sample (Other category Allocated)	Percent of Families in the U. S. with at least one child under six
0 - 20,000	8	9	21
20,000 - 39,999	21	23	24
40,000 - 49,999	16	18	10
50,000 - 74,999	27	30	21
75,000-	20	22	23
Other	9		
Total	100	100	100

Notes: Sample data in the "Other" category includes responses of refused and don't know. Table based on 551 responses. Percent of Families in the U. S. with at least one child under six from U. S. Census Bureau (2000b). Totals may not add due to rounding.

Table 3 shows that the sample's income distribution is generally higher than the income distribution of the U. S. population. This is to be expected with a telephone survey, where families in the lower income strata are less likely to have telephones.[3] As a result, the income profile of participating families omits some families in the lowest income strata. This may also explain the smaller number of Black children in the sample.

Educational attainment is shown in table 4 below.

Table 4
Educational Attainment

Highest Grade Completed	Sample Respondent	Sample Spouse	Household Heads in the U. S.
None			
Grades 1-8	2	2	6
Grades 9-11	7	7	9
Grade 12 or GED	23	22	32
College 1 to 3 year	32	28	27
College 4 years	36	40	26
Refused	0	1	
Total	100	100	100

Notes: The question was "What is the highest grade or year of school you completed.? Answering a particular category means that the highest grade completed was in that category. Based on 551 responses. Household members in the U. S. from U. S. Census Bureau (2000c).

The relationship between education and income suggests that the sample will be biased toward people with higher educational levels, because of the lower phone ownership in the lowest income stratum. It is well known that income and education are correlated.

Table 5 contains the age distribution for the children in the study.

[3] While 6 percent of the total U. S. population does not have a telephone, about 25 percent of households with incomes under $5,000 annually do not have phones (Giesbrecht, Kulp and Starer, 1999).

Table 5
Ages of Study Children

Age (months)	All Study Children at the Initial Telephone Contact	Children with Professionally Observed Mouthing Times: Age at the Initial Telephone Contact	Children with Professionally Observed Mouthing Times: Age During the Observational Study
3-12	88	64	54
12-24	91	60	66
24-36	90	45	49
36-48	111	-	-
48-60	82	-	-
60-72	80	-	-
72-84	9	-	-
Total	551	169	169

Notes: Right endpoint not included in age category. Generally several months elapsed between the initial telephone contact and the observational study. Ages were averaged over the two days of observations. The actual age ranges during the observational study were 3-12 months was 96.5 –359 days, 12-24 months was 373.5-729 days and 24-36 months was 738-1122.5 days.

4. Exposure

4.1 Analysis of Exposure Times

As mentioned above, in order to estimate daily mouthing time from the four hours of observations, it is necessary to know how much time children were awake and not otherwise eating. During the second telephone contact, parents were asked to list the times that the child usually woke up on a weekday and went to sleep at night. They were also asked to list the duration of naps, meals and snacks. From this information, exposure time can be calculated as

$$\text{Exposure Time} = \text{Time Child went to sleep} - \text{Time Child Woke Up} - \text{Meal Durations} - \text{Nap Durations}$$

Meal durations includes snacks. One can then estimate daily mouthing time by multiplying the time awake (in hours) by the average hourly mouthing time.

Groot et al (1988) used this procedure to estimate daily mouthing time. The Fisher-Price study (Juberg, et al, 2001) did not need to do this because parents were asked to watch the child for the entire time that they were awake. This study departs slightly from the Groot study because we collected exposure information on a subset of children (those participating in the second telephone contact) rather than all the children. Since there were 60 children 36 months old or younger who did not have the second telephone contact, it is not possible to estimate every child's daily mouthing time by multiplying by exposure time. Instead, the approach in this section is to model exposure time as related to the demographic variables described in the previous section and then to estimate exposure for all children using the model.

Total exposure time was related to the child's age and sex, parent or guardian's marital status, state, child and parent races, income, and the number of children under 6 in the family. The following variables were dichotomous: sex, child Hispanic, adult Hispanic, state (Illinois or Texas) and parent or guardian marital status (i.e. married, not married). Number of children in the household under six was discrete with values of one child (the subject), two children and three or more children. Income and race used the categories in table 2 and table 3 respectively. Child's age was measured in months and was continuous.

There were occasional missing values in the data. When missing, snack times were imputed as 10 minutes which was the most frequently occurring value for the non missing observations. Meal and nap durations were estimated using the value for the child closest in age to the child with missing values. There were eight observations that did not have either the time that the child awoke in the morning or went to sleep at night. These observations were not used in the analysis because there was much variability in waking or sleeping hours.

4.2 Results

Analysis of variance showed only number of children (p=0.0203) and age ($p <$ 0.0001) were significant predictors of exposure time. Controlling for other variables, each month of age added 0.0375 hours or 2.2 minutes of exposure (standard error 0.17 minutes). The model predicts that a child one year older than another child would have about 27 minutes more exposure, everything else being constant. Children in families with 1 child under six had 18 minutes more exposure than families with 2 children under six and 29 minutes more exposure than families with 3 or more children under six. The difference between 1 and 2 children was not statistically significant, but the difference between 1 and 3 children was significant. Race, sex, state (Illinois or Texas), and marital status were not significant. Income was also not significant. The overall statistics for the model were F=10.66 (19 and 463 df), $p < 0.0001$, $R^2 = 0.27$. Analysis of the residuals showed a normal looking distribution. The Shapiro-Wilk Statistic was 0.99 (p=0.6191).

In a second analysis all the non significant variables were dropped from the model. The regression coefficients had similar values to the full model. The estimated age effect was 2.3 minutes per month (standard error 0.17 minutes). The overall statistics for the model were F=58.82 (3 and 479 df), $p < 0.0001$, $R^2 = 0.27$. The standard error of the estimate was 1.25 hours. Analysis of the residuals showed a symmetric pattern (Shapiro-Wilk Statistic = 0.99, p=0.8662). The model was

$$\textit{Exposure Time} = 9.04 + 0.53\ \textit{One Child} + 0.23\ \textit{Two Children} + 0.0375\ \textit{Age}$$

where Exposure Time is measured in hours, One Child and Two Children are dummy variables indicating the number of children under 6 in the family, and Age is measured in months.

5. Mouthing Time of Children 36 months old and younger

5.1 Data preparation

Before beginning the session, the observers recorded where the child was playing and if anyone else was in the room. Each hour consisted of alternating cycles of 20 minutes of observation and 10 minutes of rest for the observer. This produced two hours of observations per day for a total of four hours total per child. During the session, the observers wrote down the object and the type of mouthing activity. Mouthing activities were recorded as biting, chewing, sucking, lips (touching the object to the lips), sucking, tongue (touching the tongue to the object) or unknown. Combinations of activities were permitted, i.e. biting and sucking. Observers timed the mouthing activities using stopwatches. They were asked to report the activities as accurately as possible. A complete record for a single mouthing activity from the database looked like the following:

Subject:	ILK44904
Activity:	Sucking
Object:	TEETHER
Mouth Time:	2.17
Description:	FROZEN TEETHING RING IN THE SHAPE OF A HAND. FLEXIBLE PLASTIC
Category:	Teether/Rattle, soft plastic

There were 20,807 records of mouthing observations for these children, for an average of 123 per child (standard deviation = 73, median =115). The smallest number of observations was 11 while the maximum was 342.

Among the 20,807 observations, there were 3,952 distinct combinations of objects and descriptions of objects in the database. Staff reviewed every combination to create usable classifications. Classifications were constructed from 51 primitive categories. The primitive categories could appear alone as a category (as in the record above) or in combination with other categories. All the primitive categories are shown below in table 6.

Table 6
Primitive Object Categories

Animal fur	Eating Utensil, other/unkn	Pacifier, fabric/cloth
Book, fabric/cloth	Eating Utensil, soft plastic	Pacifier, hard plastic
Book, other/unkn	Food	Pacifier, nipple
Book, soft plastic	Furniture, hard plastic	Skin, fingers/hands
Bottle, hard plastic	Furniture, metal	Skin, other
Bottle, nipple	Furniture, other/unkn	Teether/Rattle, fabric/cloth/plush
Bottle, soft plastic	Furniture, soft plastic	Teether/Rattle, hard plastic
Carpet	Furniture, uphol	Teether/Rattle, other/unkn
Clothing, fabric/cloth	Furniture, wood	Teether/Rattle, soft plastic
Clothing, hard plastic	Hair	Teether/Rattle, wood
Clothing, other/unkn	Other/Unkn, fabric/cloth	Toy hard plastic
Clothing, soft plastic	Other/Unkn, hard pl	Toy, fabric/cloth/plush
Drinking Cup/Straw, hard plastic	Other/Unkn, hard plastic	Toy, hard plastic
Drinking Cup/Straw, other/unkn	Other/Unkn, metal	Toy, metal
Drinking Cup/Straw, soft plastic	Other/Unkn, other/unkn	Toy, other/unkn
Eating Utensil, hard plastic	Other/Unkn, soft plastic	Toy, soft plastic
Eating Utensil, metal	Other/Unkn, wood	Toy, wood

These primitive categories were combined into 110 unique combinations of primitive categories. Primitive categories were separated by semicolons. Some examples are shown below:

Table 7
Examples of Objects, Descriptions and Categories

Object	Description	Category
BOTTLE	SOFT RUBBER NIPPLE ON BOTTLE	Bottle, nipple; Food
CAR	BAND AID RACING; RACING CHAMPIONS	Toy, metal; Toy, hard plastic
COW	BLUE W/WHITE TRIM TERRY CLOTH COW THAT HAS A RATTLE/SHAKER INSIDE (TAG ON COW SAYS JERRY ELSNER)	Teether/Rattle, fabric/cloth/plush
FINGER & FISH		Toy, hard plastic; Skin, fingers/hands
HAND/PACIFIER	SOFT PLASTIC; NUK; WITH HARD PLASTIC RIM	Pacifier, nipple; Skin, fingers/hands

These were then combined into 13 different groupings of objects. Groupings are shown below. Indenting is meant to suggest that the higher level grouping contains the lower level grouping. As follows:

All Objects

- Non Pacifiers
  - Soft Plastic Objects
    - Soft Plastic Food Contact Items[4]
    - Soft Plastic Non Food Contact Items
      - Soft Plastic Toys, Teethers and Rattles
        - Soft Plastic Toys
        - Soft Plastic Teethers and Rattles
      - Other Soft Plastic[5]
  - Anatomy[6]
  - Toys, Teethers and Rattles, not soft plastic
  - Other Objects[7]
- Pacifiers

The rules for grouping objects were as follows:

1. Every item must fall into exactly one grouping at a particular level of the hierarchy.
2. Items falling into a particular grouping, must also be in the next higher grouping (the grouping above it that is indented to the left)
3. When there are conflicts about where an item will be counted because it appears to be classifiable in two or more groupings at the same level, the higher level will dominate.

Examples of rule 1 are as follows: every item must be either in non pacifiers or pacifiers, and every soft plastic item must be in non-food contact or food contact items. As an example of rule 2, every soft plastic toy is also counted in soft plastic non food contact items. As an example of rule 3, suppose an item in the data would be classified as both soft plastic and anatomy. This could occur for example, if a child was mouthing a pacifier and his fingers at the same time (see the last row in Table 7). Rule 3 allocates this time only to the Pacifier and not to Anatomy.

The items in the partition, All Soft Plastic Toys, are those that are likely to contain a plasticiser such as DINP. Mouthing times related to these objects are the closest to estimating the amount of time children are at risk from DINP oral ingestion. DINP is not presently found in Teethers and Rattles. Estimates based on All Soft Plastic Items represent the amount of DINP ingestion that might occur if DINP was used in Teethers and Rattles and other soft plastic items.

Table 8 below contains the average hourly mouthing time by age and data partition. The data are not corrected for the length of time that the child was able to mouth items, i.e. the exposure time from the last section.

---

[4] Bottle, Drinking Cup/Straw, Fork.
[5] Clothing, Furniture, Other, unknown
[6] Hair, skin, fingers, hands
[7] Books, clothing, carpet and furniture, non soft plastic food contact items such as spoons and cups.

Table 8
Average Mouthing Time in Minutes Per Hour
By Object Category and Age

Object Category	All Ages	Age 3-12 months	Age 12-24 months	Age 24-36 months
All Objects	7.74	10.50	7.33	5.25
Non Pacifiers	5.13	7.14	4.69	3.49
All Soft Plastic Items	0.40	0.45	0.38	0.39
Soft Plastic Items Not Food Contact	0.29	0.41	0.27	0.20
Soft Plastic Toys, Teethers and Rattles	0.21	0.32	0.20	0.09
Soft Plastic Toys	0.13	0.13	0.18	0.07
Soft Plastic Teethers and Rattles	0.07	0.19	0.02	0.02
Other Soft Plastic Items	0.09	0.10	0.07	0.11
Soft Plastic Food Contact Items	0.11	0.04	0.11	0.19
Anatomy	1.78	2.39	1.69	1.21
Non-Soft Plastic Toys, Teethers, Rattles	0.85	1.77	0.56	0.21
Other Items	2.10	2.53	2.06	1.68
Pacifiers	2.61	3.36	2.64	1.76

Notes: Based on 169 children. See the notes for table 5 for a description of the age categories. 54 children up to 12 months old, 66 between 12 and 24 months and 49 children 24-36 months. Object categories follow the hierarchical classifications in the text following table 7. Some categories include other categories: for example soft plastic toys, teethers and rattles includes (1) soft plastic toys and (2) soft plastic teethers and rattles. Other items includes non-soft plastic food contact items (tableware, drinking cups, bottle nipples) furniture, clothing and miscellaneous items.

Table 8 shows that average hourly mouthing times decrease with increasing age. For example, children under 3-12 months mouth objects an average of 10.5 minutes per hour, which drops to 5.25 minutes per hour for children between 24 and 36 months. Among objects mouthed, pacifiers represent about one third of the total mouthing time, with 3.36 minutes per hour for the youngest children, 2.64 minutes per hour for children between 12 and 24 months and 1.76 minutes for children over 24 months. The next largest single item category is anatomy, representing children sucking fingers and thumbs. This is 2.39 minutes for the youngest children and declines to 1.21 minutes for the oldest children.

All soft plastic items, which are items that could contain DINP, represent less than half a minute of mouthing time per hour for each age group. With respect to the soft plastic toys, the youngest children averaged 0.13 minutes (7.8 seconds), the 1-2 year olds averaged 0.18 minutes (10.8 seconds), while the oldest averaged 0.07 minutes (4.2 seconds) per hour.

The data used to construct table 8 includes children who did not have any object mouthing time during the four hour observation period for some object categories. In table 9 the percent of children who were observed mouthing objects by the category of object is shown.

Table 9
Percent of Children Mouthing Objects by Category

Object Category	All Ages	Age 3-12 months	12-24 months	24-36 months
All Objects	100	100	100	100
Non Pacifiers	100	100	100	100
All Soft Plastic Items	80	78	88	73
Soft Plastic Items Not Food Contact	72	76	76	61
Soft Plastic Toys, Teethers and Rattles	57	61	61	47
Soft Plastic Toys	50	43	58	47
Soft Plastic Teethers and Rattles	14	30	9	2
Other Soft Plastic Items	43	46	47	35
Soft Plastic Food Contact Items	28	13	30	41
Anatomy	99	100	97	100
Non Soft Plastic Toys, Teethers and Rattles	91	94	91	86
Other Items	98	98	97	98
Pacifiers	27	43	27	10

Notes: See table 8.

Table 9 shows that during the observation period, every child was observed mouthing some object. Almost all the children mouthed fingers and skin as shown in the values close to 100 percent for anatomy. Between 73 and 88 percent of children (depending on age), mouthed some soft plastic item. Overall about 50 percent mouthed toys, varying between 43 and 58 percent again depending on age. Pacifier use was 43 percent for children under a year, 27 percent for children between one and two years and 10 percent for children over two years.[8]

Mouthing times by category were modeled with the same variables used in the exposure analysis. The models did not fit the data well. Details of that analysis are found in the Appendix.

Table 10 contains other statistics including medians, standard deviations, 95th and 99th percentiles as well as means. Recall that these times are not adjusted for exposure, rather they represent mouthing times for the four hours of observations.

[8] A series of logistic regressions were estimated relating the proportion of children mouthing objects in some of these different categories as a function of the child's age. For most categories age had the right sign, indicating decreasing proportions mouthing as children aged, but the age coefficients were not statistically significant, except for teethers and rattles (p=0.0004). Apparently, the models did not fit well because the proportions did not always decrease with increasing age. As can be seen in table 10 the proportion of children mouthing all soft plastic items and soft plastic toys is higher for 1-2 year olds than either younger or older children.

Table 10
Mouthing Times Statistics for All Soft Plastic Items and Soft Plastic Toys
(Minutes per hour)

Age Group	Mean	Median	Standard Deviation	95th Percentile	99th Percentile
			All Items		
3-12 months	10.50	9.55	7.30	26.17	39.81
12-24 months	7.33	5.49	6.76	22.00	28.75
24-36 months	5.25	2.44	8.19	15.59	47.83
			Non Pacifiers		
3-12 months	7.14	6.88	3.56	13.09	14.36
12-24 months	4.69	3.56	3.65	12.77	18.66
24-36 months	3.49	2.26	3.62	12.83	15.59
			All Soft Plastic Items		
3-12 months	0.45	0.12	0.61	1.83	2.46
12-24 months	0.38	0.23	0.44	1.30	1.90
24-36 months	0.39	0.13	0.61	1.63	2.86
			Soft Plastic Items Not Food Contact		
3-12 months	0.41	0.09	0.55	1.79	2.02
12-24 months	0.27	0.07	0.37	1.09	1.52
24-36 months	0.20	0.02	0.40	1.27	1.81
			Soft Plastic Toys, Teethers and Rattles		
3-12 months	0.32	0.06	0.50	1.79	2.02
12-24 months	0.20	0.01	0.33	0.92	1.27
24-36 months	0.09	0.00	0.28	0.22	1.60
			Soft Plastic Toys		
3-12 months	0.13	0.00	0.25	0.69	1.11
12-24 months	0.18	0.01	0.31	0.88	1.27
24-36 months	0.07	0.00	0.23	0.21	1.60
			Soft Plastic Teethers and Rattles		
3-12 months	0.19	0.00	0.44	1.04	2.02
12-24 months	0.02	0.00	0.07	0.10	0.56
24-36 months	0.02	0.00	0.14	0.00	0.96
			Other Soft Plastic Items		
3-12 months	0.10	0.00	0.21	0.75	0.95
12-24 months	0.07	0.00	0.14	0.35	0.64
24-36 months	0.11	0.00	0.27	0.53	1.44

			Soft Plastic Food Contact Items		
3-12 months	0.04	0.00	0.15	0.28	0.94
12-24 months	0.11	0.00	0.24	0.66	1.20
24-36 months	0.19	0.00	0.39	1.19	1.87
			Anatomy		
3-12 months	2.39	1.52	2.82	10.11	12.17
12-24 months	1.69	0.83	2.73	8.31	14.83
24-36 months	1.21	0.41	2.27	5.11	13.60
			Non Soft Plastic Toys, Teethers and Rattles		
3-12 months	1.77	1.28	1.80	6.53	7.72
12-24 months	0.56	0.31	0.75	1.76	4.64
24-36 months	0.21	0.06	0.40	0.94	2.27
			Other Items		
3-12 months	2.53	2.14	2.13	7.83	8.08
12-24 months	2.06	1.36	2.02	6.59	8.99
24-36 months	1.68	0.70	2.59	7.14	14.31
			Pacifiers		
3-12 months	3.36	0.00	6.93	19.50	37.32
12-24 months	2.64	0.00	6.52	19.86	28.58
24-36 months	1.76	0.00	7.89	4.79	46.34

Notes: See table 8

As noted above, non pacifier objects contain many different categories of objects. Most of the non pacifier mouthing time is contained in the categories of anatomy, non soft plastic toys, teethers and rattles and other items. Very little is in soft plastic items, less in soft plastic toys.

6. Independence of Exposure and Mouthing Times

To convert mouthing times in minutes per hour of exposure to average daily mouthing times, it is necessary to multiply the amount of mouthing time by the time that the child was awake during the day and available to mouth these items, i.e. the exposure time. But, in order to get valid estimates by multiplying mouthing time by exposure, exposure time and mouthing times have to be independent. Consider, for example, the case when they are not independent. Suppose children who have long mouthing times also tend to have shorter exposure times while children with short mouthing times tend to have longer exposure times. Multiplying average exposure time by hourly mouthing time will then overestimate total mouthing time.[9] This situation reflects a negative correlation between mouthing and exposure. On the other hand, if children with longer exposure times tend to have longer mouthing times, then multiplying by exposure time will overestimate mouthing times.

The correlation coefficient between mouthing times and exposure time was estimated for children three years old and under. The sample size was 105 children containing the children with both useful exposure and mouthing time estimates. Partial correlation coefficients were computed that took into account the child's age. Age was used in the analysis because the dependence of exposure on age was shown above in section 4.

Examination of the data showed a non-normal distribution of mouthing times. Spearman correlation coefficients were used rather than Pearson correlation coefficients, because the latter require the normally distributed data for valid hypothesis tests. Spearman correlations are shown in table 11.

Table 11
Spearman Partial Correlation Coefficients of Exposure with Mouthing Times

Response Variable	Spearman Partial Correlation Coefficient	P-value
All Items	0.04	0.69
Non Pacifiers	0.06	0.54
All Soft Plastic Items	-0.05	0.65
Soft Plastic Items Not Food Contact	-0.03	0.75
Soft Plastic Toys, Teethers and Rattles	-0.18	0.07
Soft Plastic Toys	-0.18	0.06
Soft Plastic Teethers and Rattles	-0.09	0.34
Other Soft Plastic Items	0.14	0.15

Table 11 shows none of the partial coefficients were statistically significant. For those that were borderline, namely Soft Plastic Toys, Teethers and Rattles and Soft Plastic Toys, the partial correlation coefficients were negative. This means that longer mouthing times were associated with shorter exposure time and shorter mouthing times were associated with longer exposure time. Treating exposure and mouthing times as independent for these categories has the potential to overestimate daily mouthing times. This is conservative. For the other categories, multiplying estimated exposure time and mouthing times produces valid estimates.

[9] Suppose there are two children with the same age, one with 15 minutes of mouthing time and the second with 1 minute. Suppose in reality one has 10 hours of exposure while the other has 8 hours and the model predicts 9 hours of exposure. The negative correlation implies that the 10 hour exposure would go with the 1 minute of mouthing while the 8 hours of exposure would go with 15 minutes of mouthing. This would result in 10 * 1 + 15 * 8 = 130 minutes of estimated mouthing time for the day. Using the model with 9 hours of exposure for both would result in (15+1)*9=144 minutes, which is an overestimate of the mouthing time.

7. Daily Mouthing Times

Estimates for various statistics and associated confidence intervals were developed using the bootstrap procedure. Ordinary confidence intervals rely on the normal distribution (or some other distribution), but with these particular data, the data did not seem to follow the normal distribution nor any known distribution. The bootstrap procedure uses the actual distribution of the data, i.e. the empirical distribution, to calculate statistics and confidence intervals. Details are in Efron and Tibshirani (1993).

The bootstrap procedure used for this analysis was as follows:

1. Start with the first child in the dataset.
2. Using the child's actual age and the number of children in the family under 6, compute the exposure time as a normally distributed random variable using the model at the end of section 4 for the mean and 1.25 as the standard error.
3. Select at random a mouthing time for a child in the age group. Since there is a weak relationship between age and mouthing times, we define the age groups as the year of age. This means for a child who is between 3 months and a year old, we would select a mouthing time from any child who is in that age group. The selections are done at random.
4. If the last child, then compute statistics. Otherwise get the next child in the dataset and go to back to step 2.

At the end of the process, there is a single bootstrap sample, containing mouthing times for all 169 children in the dataset. Different from the actual data, however, these mouthing times were randomly selected from values in the relevant age group. Each of the 169 bootstrap observations has a mouthing time and an exposure time. The exposure time comes from an actual child's age and number of children in the family. Mouthing times is selected from the age group independently of exposure time. Since the sampling is with replacement, a mouthing time from a given child may have been selected once, twice, three times or more in the bootstrap sample. Other mouthing times may not have been selected at all.

Once the bootstrap sample has been collected, statistics such as the mean, median, 95th percentile can be estimated using conventional statistical procedures. The basic idea of the bootstrap, however, is to repeat the sampling process under the same conditions many times to collect many bootstrap samples. The result is many means, many medians, many 95th percentiles, etc. The analysis in this paper repeated the sampling process 5000 times because large numbers of bootstrap samples are required for estimating percentiles.[10] Confidence intervals can then be computed from the distribution of each

[10] There are a number of different types of bootstrap confidence intervals. This is the percentile interval as described by Efron and Tibshirani (1993, page 170). In an example for estimating percentiles they used 2000 bootstrap replications. Bootstrap confidence intervals based on the normal distribution for the upper percentiles such as the 95th and 99th percentile would be likely to have incorrect coverage because of the skewed distributions.

statistic; for example the 95 percent confidence interval for a given statistic is taken from the 2.5th and 97.5th percentile of the distribution of that statistic. Consider the median, for example. At the end of the bootstrap procedure, there are 5000 medians, each one computed from a bootstrap sample. These are then sorted in ascending order. The bootstrap estimate for the 95 percent confidence interval for the median uses the the 2.5th percentile (the 125th observation from the smallest) as the lower confidence limit and the 97.5th percentile (the 4875th observation from the smallest) as the upper confidence limit.

Statistics for non pacifier objects are shown in table 12a below.

Table 12a
Estimated Daily Mouthing Times for Non Pacifiers
(Time in Minutes)

Age	Mean	Median	95th Percentile	99th Percentile
3-12 months	70.1 (60.6 - 79.8)	65.6 (52.3 - 78.2)	134.4 (117.1 – 153.2)	153.1 (129.6 – 180.6)
12-24 months	47.4 (38.9 – 57.1)	37.0 (28.7 - 49.9)	121.5 (85.2 – 166.0)	180.3 (123.6 – 235.5)
24-36 months	37.0 (27.0 – 48.5)	23.8 (18.4 - 29.3)	124.3 (70.9 - 173.3)	167.9 (104.0 - 208.0)

Notes: Based on 5000 bootstrap samples.

Table 12a shows the average daily mouthing time for non pacifiers was 70.1 minutes (95% confidence interval 60.6 – 79.8 minutes) for children between 3 months and 1 year of age, 47.4 minutes (38.9 - 57.1 minutes) for children between 1 and 2 years and 37.0 minutes (27.0 – 48.5 minutes) for children between 2 and 3 years of age. The medians were less than the means, suggesting that the distributions were skewed to the right. The 95th percentile was over two hours per day in all three age groups.

Table 12b contains average daily mouthing estimates for all soft plastic items and table 12c shows soft plastic toys. Soft plastic items are a subset of non pacifiers and soft plastic toys are a subset of soft plastic items.

Table 12b
Estimated Daily Mouthing Times for Soft Plastic Items
(Time in Minutes)

Age	Mean	Median	95th Percentile	99th Percentile
3-12 months	4.4 (3.0 - 6.1)	1.5 (0.3 - 3.7)	17.5 (12.2 – 23.3)	23.0 (16.2 - 30.1)
12-24 months	3.8 (2.8 - 4.9)	2.2 (1.0 - 3.8)	13.0 (9.6 - 17.8)	18.9 (12.8 - 23.8)
24-36 months	4.2 (2.5 - 6.1)	1.5 (0.2 - 3.0)	18.5 (9.6 - 29.4)	28.0 (15.9 - 37.6)

Notes: Based on 5000 bootstrap samples.

Table 12c
Estimated Daily Mouthing Times for Soft Plastic Toys
(Time in Minutes)

Age	Mean	Median	95th Percentile	99th Percentile
3-12 months	1.3 (0.7 - 2.0)	0.0 (0.0 - 0.3)	7.1 (3.9 - 11.0)	10.5 (5.8 - 13.7)
12-24 months	1.9 (1.2 - 2.6)	0.1 (0.0 - 0.6)	8.8 (5.6 - 11.7)	12.6 (9.0 - 16.0)
24-36 months	0.8 (0.3 - 1.6)	0.0 (0.0 - 0.2)	3.3 (1.4 - 16.3)	12.1 (2.0 - 21.0)

Notes: Based on 5000 bootstrap samples.

8. Discussion and Conclusion

This study contains data from a demographically balanced probability sample. Data was collected on 551 children between 3 months and 6 years of age in the Chicago and Houston metropolitan areas. Recruitment was by random digit dialing. The sample was 85 percent white and 9 percent black, possibly underrepresenting children from the lower income strata as a result of telephone recruitment. Of these 551 children, 169 children were 36 months old or younger and were involved in the professional observational study. The age breakdown for children at the time of the observational study was 54 children up to 12 months old, 66 between 12 and 24 months and 49 between 24 and 36 months. Professional observers watched each of these children for four hours, recording all mouthing activities. These data contained information on the object that was mouthed, the duration of the mouthing and the type of mouthing activity.

Objects were classified into 51 primitive categories. These were then aggregated up to 13 categories such as non pacifiers, soft plastic items and soft plastic toys. Soft plastic items were a subset of non pacifiers and soft plastic toys were a subset of soft plastic items. The last category contains items that would possibly contain diisononyl phthalate (DINP). Average hourly mouthing time was calculated for the children by category and by age of child. Average hourly mouthing times for non pacifiers ranged between 3.5 and 7 minutes depending on the age of the child. Most of the mouthing time for non pacifier items was from mouthing fingers and other parts of the anatomy (1.2 to 2.4 minutes), toys made from materials other than soft plastic (0.2 to 1.8 minutes) and miscellaneous items (1.7 to 2.5 minutes).

While every child put some non pacifier object in his/her mouth during the observation, only about half the children mouthed soft plastic toys. Hourly averages for soft plastic toys varied between 0.1 minutes per hour and 0.2 minutes per hour again depending on the child's age.

To make estimates of daily mouthing times it was necessary to scale the hourly estimates by the time the child is awake and not eating. Estimates for exposure time were made from 491 children. A bootstrap procedure was used to estimate daily mouthing times from estimated exposure and the empirical distribution of mouthing times. This not only provided point estimates but also confidence intervals. Estimates were made for three categories of objects: non pacifiers, soft plastic items and soft plastic toys. There are no practical difficulties in making estimates for other categories of objects mouthed in the data.

Estimates for average daily non pacifier mouthing time were 70 minutes (95% confidence interval 61-80 minutes) for children between 3 months and 1 year of age, 47 minutes (39-57 minutes) for children between 1 year and 2 years and 37 minutes (27-49 minutes) for children between 2 and 3 years of age. The 95th percentiles for these children were about two hours per day. The mean mouthing times for non pacifier objects were somewhat greater than those reported in the literature (see Groot et al, 1998, Juberg et al, 2001).

As suggested by the estimates for hourly mouthing times, very little of the non pacifier object mouthing time came from soft plastic items or soft plastic toys. For soft plastic toys, the daily average mouthing times were 1.3 minutes (0.7- 2.0 minutes) for children between 3 months and one year, 1.9 minutes (1.2 – 2.6 minutes) for children between 1 and 2 years and 0.8 minutes (0.3 – 1.6 minutes) for children between 2 and 3 years of age. The 95th percentiles for soft plastic toys were as follows (with 95 percent confidence intervals in parentheses): 7.1 minutes (3.9 – 11.0), 8.8 minutes (5.7 – 11.7) and 3.3 minutes (1.4 - 16.3) for children under 1 year, 1-2 years and 2-3 years respectively. These estimates are lower than have been used in previous analyses, but they represent a more detailed characterization of objects mouthed than earlier analyses.

References

CPSC (1998), *The Risk of Chronic Toxicity Associated with Exposure to Diisononyl Phthalate(DINP) in Children's Products.* U. S. Consumer Product Safety Commission. Bethesda, MD.

CPSC (2001), *Report to the U. S. Consumer Product Safety Commission by the Chronic Hazard Advisory Panel on Diisononyl Phthalate (DINP).* U. S. Consumer Product Safety Commission.Bethesda, MD.

Efron B and Tibshirani RJ (1993), *An Introduction to the Bootstrap.* Chapman and Hall, New York.

Fields J and Casper L (2001), *America's Families and Living Arrangements: Population Characteristics.* U. S. Department of Commerce, Economics and Statistics Administration, U. S. Census Bureau. Reprot P20-537 Washington, DC.

Giesbrecht LH, Kulp DW and Starer AW (1999), *Telephone Survey Design.* Joint Program in Survey Management Course Manual. University of Maryland, College Park, MD.

Groot ME, Lekkerkerg MC and Steenbekkers LPA (1998), *Mouthing Behaviour of Young Children: An Observational Study.* Wageningen Agricultural University, Household and Consumer Studies. Wageningen, The Netherlands.

Juberg DR, Alfano K, Coughlin RJ and Thompson KM (2001), "An Observational Study of Object Mouthing Behavior by Young Children," *Pediatrics* 107, 1, pp 135-141.

Konemann WH, ed. (1998), *Phthalate release from soft PVC Baby Toys. Report from the Dutch Consensus Group.* Eurpoean Union Scientific Committee on Toxicity, Ecotoxicity and the Environment. RIVM, Bilthoven, The Netherlands.

LGC (1999), "Interlaboratory Validation of Laboratory based Agitation Methods for Determining Phthalate Plasticiser Migration from PVC Toys and Childcare Articles." Laboratory of the Government Chemist, LGC Technical Report Number: LGC/1999/DTI/004. Middlesex, England.

Rijk MAH, Ehlert K (1999), "Validation of the method 'Determination of Diisononylphthalate in saliva simulant,'" Report V99.598, The Netherlands Institute for Applied Scientific Research (TNO), Nutrition and Food Research Institute, Zeist, The Netherlands.

Smith, TP and Kiss CT (1998), "Empirical Observations of Children's Mouthing Behaviors: Frequencies and Durations," U.S. Consumer Product Safety Commission. Washington, DC.

U. S. Census Bureau (2000a), *Current Population Survey (CPS) Reports, America's Family and Living Arrangements, Detailed Tables, Table F1.* Washington, DC, U. S. Census Bureau.

U. S. Census Bureau (2000b), *Current Population Survey, Annual Demographic Survey, March 2000 Supplement, Table FINC-03. Presence of Related children Under 18 Years Old – All Families by Total Money Income in 1999, Type of Family Experience in 1999, Race and Hispanic Origin of Reference Person.* Washington , DC, U. S. Census Bureau.

U. S. Census Bureau (2000c), *Educational Attainment in the United States, March 2000 Detailed Tables, Table 4, Educational Attainment of the Population 15 Years and Over by Household Ratlationship, Age, Sex, Race and Hispanic Origin.* Washington , DC, U. S. Census Bureau.

Appendix
Mathematical Models for Mouthing Times

The patterns were generally similar for all the different categories shown above. The most striking feature was that mouthing times showed a gradual decrease with increasing age where the rate of decrease was slower than linear. This pattern was less obvious in categories where a substantial proportion of children did not mouth these objects at all such as soft plastic toys, teethers and rattles. Many of the observations in these categories were zeroes.

A number of different mathematical forms for mouthing times were considered, including logs of mouthing times which had been fit in Juberg, et al (2001). Neither logs nor the inverse of mouthing times, both consistent with a slower than linear decrease with age could be used because there were zero mouthing times in the data. After exploring various power transformations, the square root transformation seemed to provide the best choice, both in terms of the overall fit and the symmetry of the residuals. However, in all cases, the residuals failed the Shapiro-Wilk test for normality although improved somewhat with the square root transformation as compared with linear and cube root alternatives.

Table A-1 contains results from the full models. The square root of mouthing time was used as the response variable.

Table A-1
Summary of Models for Mouthing Times

Response Variable	R^2	F	Significant Predictors
All Items	0.21	2.24	Age
Non Pacifiers	0.21	2.17	Age
All Soft Plastic Items	0.13	1.28	None
Soft Plastic Items Not Food Contact	0.17	1.66	Age
Soft Plastic Toys, Teethers and Rattles	0.21	2.16	State, Age
Soft Plastic Toys	0.14	1.38	Age
Soft Plastic Teethers and Rattles	0.26	2.83	State, Age
Other Soft Plastic Items	0.19	1.91	Income

Notes: All models had 18 and 150 degrees of freedom. The response variable was the square root of mouthing time. Explanatory variables were as follows: child sex, family marital status, state, child race, adult race, income, number of children under 6 in the family and child's age in months. Sex, two variables indicating if child or adult was hispanic, state (Illinois or Texas) and marital status were dichotomous. Race was expressed in four categories, Black, Unknown Hispanic, White and Other. Number of children under 6 was discrete as one child (the subject), two children and three or more children. Income and race used the categories in table 2 and table 3 respectively. Both F-values and significant predictors have to be interpreted cautiously because residuals in all models did not follow a normal distribution.

As shown in table A-1 only a few variables predicted mouthing time. State (Illinois or Texas) significantly predicted mouthing times for soft plastic toys, teethers and rattles, and soft plastic teethers and rattles. However, both F-values and significant predictors listed have to be interpreted cautiously because residuals in all models did not follow a normal distribution.

TAB H

UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
WASHINGTON, DC 20207

Memorandum

Date: June 18, 2002

TO : Marilyn G. Wind, Ph. D.
Deputy Associate Executive Director
Directorate for Health Sciences

THROUGH: Susan Ahmed, Ph. D.
Associate Executive Director
Directorate for Epidemiology

Russell H. Roegner, Ph. D.
Division Director
Division of Hazard Analysis

FROM : Michael A. Greene, Ph. D.
Mathematical Statistician
Division of Hazard Analysis

SUBJECT : Mouthing times and DINP risk for children over three years of age

Attached is a report on mouthing times for children over three years of age.

Mouthing Times and DINP Risk for Children Over Three Years of Age

Michael A. Greene
Division of Hazard Analysis
Directorate for Epidemiology
U. S. Consumer Product Safety Commission

The risk assessment associated with children's oral exposure to diisononyl phthalate (DINP) from toys does not include an analysis for children more than 3 years of age and older.[1] This is because the data in the telephone survey of mouthing times do not appear to be correct. A substantial number of parents reported more than fifteen minutes of mouthing times during a fifteen minute observation period. This calls into question how long *all* parents actually observed their children during the fifteen minute period, not just those who reported more than fifteen minutes.

Despite the absence of the parental observation data, it seems safe to conclude that children more than 3 years of age are at less risk from DINP exposure than younger children. Evidence from the literature and CPSC's observational study of children under three years of age shows that mouthing times decline as children age. Also since older children tend to weigh more than younger children, DINP intake relative to body weight would decrease even if mouthing times were the same.

This document begins with a discussion of the problems with the survey data and is followed by a discussion of the evidence from CPSC's observational study and other studies.

The Parents Observation Survey Data

There were 491 observations on children completed by parents in the telephone survey, including 109 observations on children 36 months old and younger who were also in the professional observer study. Parents were requested to report mouthing times for four fifteen minute sessions, resulting in a total of (491 x 4 =) 1964 separate observations. Of these 4.2 percent (82 observations) had mouthing times exceeding fifteen minutes in a 15-minute period. Also, there was at least one of the four observations exceeding fifteen minutes for 8.8 percent of the children (43 children).

The age and session breakdown is shown in Table 1 below.

[1] The risk assessment is in Greene, MA (2002b), "Oral DINP Intake Among Young Children."

Available Evidence on Mouthing Among Children 3-6 years of Age

Of the three previous studies of mouthing times, Smith and Kiss (1998), Groot, Lekkerkerk and Steenbekkers (1998) and Juberg, Alfano, Coughlin and Thompson (2001), only Smith and Kiss collected data on children over 3 years of age. These authors observed the mouthing activities of 80 children between 1 and 8 years of age in day care centers and schools in the Washington, DC metropolitan area. Data from Smith and Kiss is shown in Table 2 below.

Table 2
Mouthing Times for Non-Pacifier Objects
In Minutes in a Two Hours Observation Period

Age Group	Mean	Standard Deviation	Minimum	Maximum
1-Year-Olds	10.7	9.2	3.1	35.2
2-Year-Olds	6.4	6.2	1.2	17.6
3-Year-Olds	4.9	5.5	0.5	14.1
4-Year-Olds	2.1	1.3	0.5	4.8
5-Year-Olds	4.6	2.9	1.4	9.0
6-Year-Olds	3.9	4.4	0.3	14.4
7-Year-Olds	5.6	5.5	0.3	17.0
8-Year-Olds	5.4	4.1	0.1	13.1

Notes: Mouthing times in minutes per two hour observation period. Source Smith and Kiss (1998). According to the authors, none of the children in each age group were mouthing pacifiers. The sample size was 10 children in each age group.

Table 2 shows that average mouthing times decrease with increasing age between 1 and 4 years of age, then stabilizes at 4-6 minutes per two hour observation period for the older children. These mouthing times are comparable to CPSC's observational study where one year old children had an average *hourly* non-pacifier mouthing time of 4.7 minutes and two year old children averaged 3.5 minutes (Greene, 2002a, table 10). Scaled to two hours this would be 9.4 and 7 minutes respectively, comparable to means of 10.7 and 6.4 minutes in Smith and Kiss.

Additional evidence is available from the other research on mouthing for children up to 36 months old. Table 3 shows results from Juberg, et al (2001), Groot et al (1998) and from CPSC's most recent observational study (Greene, 2002a). Note that Table 3 shows mouthing time in minutes per day, rather than minutes per two hour observation period.

Table 3
Daily Average Non-Pacifier Mouthing Times From Various Studies
In Minutes Per Day

Age Group (months)	Groot et al (1998)	Juberg et al (2000)	CPSC
0-18	32.4	36.0	61.0
19-36	9.3	5.0	39.5

Note: 0-18 month times for Groot et al (1998) averaged from reported values for 3-6 months, 6-12 months and 12-18 months. Juberg et al (2000) from figure 2 and figure 3 (pages 139 and 140). CPSC data from the professional observer study, Greene (2002a).

Table 3 shows mouthing time for all objects except pacifiers (i.e. non-pacifier mouthing times) because that is the smallest category of objects mouthed that is the same in all three studies.[2] Table 3 shows that in each of the three studies, non-pacifier mouthing time is less for 19-36 month old children than children 18 months and younger.[3] It would be expected that mouthing of soft plastic toys would follow a similar trend.

To further examine the relationship between age and mouthing time, Juberg et al (2001, figure 4, page 141) and Greene (2002a, Appendix) reported fitting regression lines to mouthing time data. Age was a significant predictor in both analyses, entering the models with a negative sign, indicating that mouthing times decreased as age increased for children up to 36 months. There is no reason to believe that this pattern would change for children over 36 months.

Discussion

After a review of the parent observations data, it appears that the data cannot be used for risk analysis. While mouthing times that exceed fifteen minutes in length clearly show erroneous reporting, it is not safe to assume that mouthing times less than

[2] Juberg et al (2001) reported only pacifiers and non-pacifiers. Groot et al (1998) used a more detailed breakdown as toys meant for mouthing, in addition to reporting on pacifier and non pacifier mouthing times. CPSC's observational study (Greene, 2002a) separated toys meant for mouthing into soft plastic toys and non soft plastic toys.

[3] Non-pacifiers included teethers, eating utensils, cloth toys, children's thumbs and fingers and clothing and many other objects, few made of PVC and even fewer containing DINP. For example, Groot et al (1998) found toys meant for mouthing constituted 9 percent of the non-pacifier mouthing time for children 3-6 months old and 13 percent of the mouthing time for children 6-12 months old. In the CPSC professional observer study (Greene, 2002a), which contained a very detailed characterization of objects, soft plastic toy mouthing time averaged 2-4% of the non-pacifier mouthing time.

fifteen minutes in length were from fifteen minute observation periods. They may have been from longer or shorter periods.

Despite the absence of data on mouthing times, it seems unlikely that older children are more at risk from DINP than younger children are. Smith and Kiss' (1998) study of older children mouthing objects shows that average mouthing time for children over 3 is less than for children 1-2 years of age. Also, all studies on children 36 months and under show non-pacifier mouthing times decreasing as children age.

It should also be noted that even if older children had the same mouthing times as younger children, the risk from oral intake of DINP risk would be lower than for younger children. This is because DINP risk is measured in intake per unit body weight. On average, older children weigh more than younger children (see USEPA, 1997, pages 7-1 to 7-11 for children's weights), which would put their risk levels below younger children.

References

Greene, MA (2002a), "Mouthing Times Among Young Children From Observational Data," U. S. Consumer Product Safety Commission, Washington, DC.

Greene, MA (2002b), "Oral DINP Intake Among Young Children," U. S. Consumer Product Safety Commission, Washington, DC.

Groot ME, Lekkerkerk MC and Steenbekkers LPA (1998), *Mouthing Behavior of Young Children" An Observational Study.* Wageningen Agricultural University, Household and Consumer Studies. Wageningen, The Netherlands.

Juberg DR, Alfano K, Coughlin RJ and Thompson KM (2001), "An Observational Study of Object Mouthing Behavior by Young Children," *Pediatrics* 107, 1 pp. 135-141.

Smith, TP and Kiss CT (1998),"Empirical Observations of Children's Mouthing Behaviors: Frequencies and Durations," U. S. Consumer Product Safety Commission, Washington, DC.

USEPA (1997), "Exposure Factors Handbook Volume I: General Factors." EPA/600/P-95/002Fa, U.S. Environmental Protection Agency, Washington, DC.

TAB I

United States
CONSUMER PRODUCT SAFETY COMMISSION
Washington, D.C. 20207

MEMORANDUM

DATE: June 20, 2002

TO : Marilyn L. Wind, Ph.D.
Deputy Associate Executive Director
Directorate for Health Sciences

THROUGH : Andrew Stadnik *Andrew G Stadnik, P.E.*
Associate Executive Director
Directorate for Laboratory Sciences

Warren K. Porter *WKP*
Director
Division of Chemistry

FROM : Shing-Bong Chen, Chemist *SBC*

SUBJECT : Screening of Toys for PVC and Phthalates Migration

Introduction

The concern about potential health effects due to the presence of various phthalates in children's toys resulted in a voluntary action on the part of manufacturers. The action consisted of discontinuing the use of phthalate plasticizers in children's articles intended to be mouthed or sucked, such as teethers, pacifiers, and rattles. The action did not address the use of phthalates in various soft squeeze toys.

As a follow-up to this action the Chemistry Division of the Directorate for Laboratory Sciences, after consultation with the Directorate for Health Sciences, purchased 41 children's products from retail stores. These consisted of teethers, and other toys. The "other toys" were selected based on labeling that indicated they could be mouthed, sucked or chewed. LS staff tested 133 components of the toys (called "specimens") for the presence of polyvinyl chloride (PVC) and phthalates. Eighty-five specimens were soft plastic. Fifty-one specimens tested contained PVC. Of the 51 plastic specimens, 36 contained di-isononyl phthalate (DINP) and 4 contained di-2-ethylhexyl phthalate (DEHP).

The rate of phthalate migration from the specimens containing PVC plasticized with DINP or DEHP was determined by the head over heels (HoH) method originally developed by the Nutrition Research Institute, TNO, The Netherlands and modified as described in the report of a validation program conducted by the European Commission's Joint Research Centre (JRC)[1].

Methods

1. Screening

   The various specimens from the toys were screened for PVC by use of the Beilstein flame test for chlorine. Based on the results of the flame test, those toys made of, or containing PVC, were further analyzed for the presence of phthalates. Gas chromatography/mass spectrometry (GC/MS) provided identification of the phthalates or other plasticizers present. All plastics were subjected to infrared analysis to determine the class of polymers they belonged to.

2. Percent phthalates (DINP and DEHP) determination

   Only those specimens consisting of PVC plasticized with DINP or DEHP were quantitatively analyzed for the amount of plasticizer present. Approximately 0.05 g of PVC was dissolved in 5 ml of tetrahydrofurn (THF) at room temperature. The PVC polymer was then precipitated with 10 ml of hexane and filtered through a Pall Gelman GHP Acrodisc 0.45 μm filter. A 50 μl aliquot of the THF/hexane solution and 20 μg (80 μl of 250 μg /ml) of the internal standard (benzyl butyl phthalate, BBP) were diluted to 20 ml of cyclohexane for quantitative determination by GC/MS.

3. Phthalate migration by JRC HoH Method

   The phthalate migration determination followed the protocol described in the report of a validation program conducted by JRC[1]. The JRC method is modified from the TNO method, which was originally developed at TNO Nutrition and Food Research Institute, The Netherlands. Although the two methods are similar, instead of using 25 ml of artificial saliva and 15 ml of isooctane for extractions, as does the TNO method, the JRC method uses a total of 100ml artificial saliva and 50 ml of cyclohexane.

   Three test disks, when sufficient product was available, were prepared from each PVC specimen using a punch press. The surface area of the disks, including cut edge surfaces, was approximately 9 to 15 cm^2 depending on the thickness of the plastic (0.2 to 7 mm). Each disk was extracted twice, each time with 50 ml of artificial saliva in a 250 ml Schott Duran bottle for 30 minutes. The combined portions of the extraction media were then extracted with 50 ml of cyclohexane containing BBP as an internal standard. Although the JRC protocol calls for concentration of the

245

cyclohexane extract, this was not done since the sensitivity of the GC/MS precluded the need for concentration.

4. Analytical determination

Infrared (IR) - the IR spectrum was obtained using a Nicolet Magna-IR 560 spectrophotometer fitted with an ASI DuraSamplIR ATR cell. A comparison of the spectra of the plastic specimens against the reference spectra in the Aldrich FT-IR Collection Edition II Library and Hummel Polymer and Additives library database provided the polymer identification.

Gas Chromatograph/Mass Spectrometer (GC/MS) – An Agilent 5973N GC-MSD system with an automatic injector was used in the analysis. SCAN mode was used in the identification of plasticizers in cyclohexane extracts. The mass spectra were searched against the CPSC Library and NIST98 Library database for identification. Use of the instrument in the selected ion mode (SIM) at an ion mass of 149 provided a quantitative analysis of the phthalate(s) present. The small amount of diisodecyl phthalate (DIDP), normally present in commercial DINP, was included in the reported amount of DINP.

GC conditions:

Column	30m x 0.25 mm I.D. x 0.25 μm HP-5MS,
Injection	1 μl Pulsed splitless, injector 290 ° C, pulse pressure 35.0 psi, Pulse time 0.5 min, Purge flow 20.0 ml/min, Purge time 2.0 min,
Oven	50 ° C, 1 min, 30 ° C/min to 280 ° C, 15 ° C/min to 325 ° C,
Carrier gas	Helium, 1 ml/min, constant flow.

5. Calibration - of phthalates (DINP or DEHP) for GC/MS analysis in cyclohexane

A set of solutions were prepared containing approximately 1.0, 2.5, 5.0, 7.5 and 10.0 μg /ml of DINP (Jayflex, EXXON) or DEHP (Chem Service Inc., standard grade) and 1.0 μg /ml of BBP (Chem Service Inc., standard grade). The actual ratio of DINP (or DEHP)/BBP was calculated and used in construction of calibration curves.

6. Calculation of % phthalates in PVC specimen

$$\%phthalate = 100 \times C_{phthalate}(\mu g/ml) \times \frac{20ml \times 15ml}{50\mu l} \times \frac{1}{wt.(g)} = \frac{C_{phthalate}(\mu g/ml)}{wt.(g)} \times 0.6ml$$

246

7. Calculation of the phthalate migration from PVC specimen

$$\text{Release}(\mu g/ml) = \frac{C_{phthalate}(\mu g/ml) \times 50ml \times 10cm^2}{60\,\text{min} \times Acm^2}$$

Results

Some of the toys purchased from a local retail store appeared to contain more than one type of plastic. Thus all distinctly different plastics were screened for the presence of polyvinyl chloride (PVC). This resulted in a total of 133 specimens from the 41 toys being screened for PVC. Eighty-five of the specimens were soft plastic. Fifty-one of the 133 specimens were found to contain PVC by chlorine flame test (Beilstein flame test). Fourier Transform Infrared (FTIR) also identified the polymers of those non-PVC products. PVC and phthalates were not found in the nine teethers collected for this study. The results from this screening are presented in Table 1.

Thirty-six specimens (16 toys) contained DINP and four specimens (2 toys) contained DEHP. Seven specimens (5 toys) contained acetyl tri-butyl citrate (ATBC). One toy contained bis(2-ethylhexyl) adipate (DEHA), and three specimens (3 toys) contained no phthalates or other common plasticizers. The results of the identification of plasticizer in PVC are also shown in Table 1.

In summary the screening showed:

133 specimens of plastic from 41 toys –
- 85 of the 133 specimens from 35 toys were soft or flexible plastics.
- 51 of the 133 specimens from 24 toys were PVC –
  - Plasticizers found in the 51 specimens of PVC:
    - 36 DINP from 16 toys
    - 4 DEHP from 2 toys
    - 7 ATBC from 5 toys
    - 1 DEHA
    - 3 not detectable

Labels on the packages were inspected for statements addressing the presence or absence of PVC or phthalates.

1. Four plastic toys from Company #1 (Sample # 01-420-8472, 8481, 8485 and 8486) were labeled "PVC Free" and found to contain polyethylene (PE) or poly(ethylene-co-vinyl acetate) (PEVA) polymer.
2. One toy (01-420-8473) was labeled "no DINP" and found to contain ATBC as plasticizer.
3. One toy (01-420-8483) was labeled "nontoxic", and contained DINP.

247

Table 2. shows the release of DINP or DEHP by the JRC HoH method. Twelve specimens were not tested for DINP release since the specimens were either too small or they were of a shape that precluded cutting a disk. The release of DINP was found to range from 1.05 to 11.09 $\mu g/min/10cm^2$ (average of three disks from the same specimen). The percent by weight of DINP in PVC specimens ranged from 12.86% to 39.38%. The correlation between the phthalate release and percentage of phthalate in the PVC specimen was poor to non-existent. The PVC specimen from a toy yellow duck, previously used in CPSC *in vivo* migration studies, was also tested by the JRC HoH method for comparison purposes. The analytical data and the calculation of GC/MS analysis are shown in the attached appendix.

Conclusions

This memorandum reports on the screening of 133 specimens for PVC used in toys that are intended to be mouthed. The memorandum also reports on the identification of phthalates and other plasticizers used in polyvinyl chloride (PVC). The Health Sciences Directorate will use the data on phthalate migration in the exposure calculation of the risk assessment.

Based on a limited number of toys (41), representing twenty manufacturers, collected from two retail establishments the following observations were made:

1. Thirty-five toys contained soft or flexible plastics.
2. Twenty-four toys were either partially or totally made of PVC.
3. Three manufacturers did not have products containing PVC.
4. Four manufacturers used ATBC or DEHA as the plasticizer in PVC products.
5. None of the nine teethers contained PVC or phthalates.
6. There was no correlation between the % phthalate and phthalate migration from PVC plastic. This confirms previous studies.

Reference

1. Catherine Simoneau, Standard Operation Procedure, "Determination of release of di-isononylphthalate (DINP) in saliva simulant from toys and childcare articles", JRC, European Commission, Nov 11, 2000.

Table1. Identification of Toys, Page 1

CPSC #	Company ID	item descriptions	Chlorine Flame Test(Beilstein)	plastic type by IR	plasticizer type by GC/MS	Soft Toy
01-420-8412	1	purple tub		ABS		
01-420-8412	1	body	x	PVC	ATBC	x
01-420-8412	1	clear edge	x	PVC	ATBC	x
01-420-8413	2	boat,orange		ABS		
01-420-8413	2	blue hippo		BS		
01-420-8413	2	boat,yellow		PP		x
01-420-8414	3	yellow nipple		BS		
01-420-8414	3	pink holder		PP		x
01-420-8414	3	clear bottle		PS		
01-420-8415	2	mirrow		polycarbonate		
01-420-8415	2	face,yellow		polymethacrylate		
01-420-8415	2	edge,ring		PP		
01-420-8415	2	face,white		PP		
01-420-8415	2	circle,black		PP		
01-420-8416	4	rail teether, clear	x	PVC	DEHA	
01-420-8417	5	face	x	PVC	DINP	
01-420-8418	6	purple soother		PEVA		x
01-420-8419	6	green handle		ABS		x
01-420-8419	6	blue handle		PEVA		
01-420-8419	6	pink teether		PEVA		
01-420-8420	7	orang ring		PP		x
01-420-6420	7	blue holder		PP		
01-420-8467	8	cushion, clear	x	PVC	DINP	
01-420-8468	2	purple face		ABS		x
01-420-8468	2	blue hand		BS		
01-420-8469	9	blue seat				x
01-420-8469	9	yellow body	x	PVC	DINP	x
01-420-8470	2	clear color	x	PVC	DINP	x
01-420-8470	2	orange		polycarbonate		
01-420-8470	2	black color		PP		
01-420-8470	2	white color		PP		
01-420-8471	10	blue body		PP		
01-420-8471	10	Suction cup	x	PVC	DINP	x
01-420-8472	9	purple body	x	PVC	DINP	x
01-420-8472	9	red wing		ABS		
01-420-8472	9	green wing		PEVA		x
01-420-8472	9	blue strip		PEVA		x
01-420-8472	9	mirror		PEVA		x
01-420-8473	11	yellow duck		polycarbonate		
01-420-8474	5	teether	x	PVC	ATBC	x
01-420-8474	5	ring		BS		x
01-420-8474	5	holder		PE		
01-420-8475	7	ring	x	ABS(PVC)	ND	
01-420-8475	7	teether		ABS		
01-420-8476	7	body		PE		x
01-420-8477	7	body	x	PVC	DINP	x
01-420-8478	7	green tree	x	PVC	DINP	x
01-420-8479	2	sheet		PE		x
01-420-8480	7	clear ball	x	PVC	DINP	x
01-420-8480	7	hook		PEVA		
				PP		

Table1. Identification of Toys, Page 2

01-420-8480	7	ring		PP		
01-420-8480	7	holder		PS		
01-420-8481	9	holder		ABS		
01-420-8481	9	ring		PE		
01-420-8481	9	teether		PEVA		
01-420-8482	12	yellow turtle	x	PVC	DEHP	x
01-420-8482	12	purple hippo	x	PVC	DEHP	x
01-420-8483	5	blue hook		ABS		
01-420-8483	5	net		polyester		x
01-420-8483	5	green whale	x	PVC	DINP	x
01-420-8483	5	yellow fish	x	PVC	DINP	x
01-420-8484	5	teether, feet		PEVA		x
01-420-8484	5	teether, hand		PEVA		x
01-420-8485	9	cooling teether		PE		x
01-420-8486	9	cool teether		PE		x
01-420-8487	13	hot dog		PE		x
01-420-8487	13	hot dog bun		PE		x
01-420-8487	13	kettchup bottle		PE		x
01-420-8487	13	hamburger bun		PE		x
01-420-8487	13	hamburger		PE		x
01-420-8487	13	chocolate cake		PE		x
01-420-8487	13	orange bottle		PE		x
01-420-8487	13	wafer		PE		x
01-420-8487	13	ice cream cone		PE		x
01-420-8487	13	blue plate		PP		
01-420-8487	13	purple utensil		PP		x
01-420-8487	13	gray can opener		PP		x
01-420-8487	13	pizza cutter,disc		PP		
01-420-8487	13	pink tray		PS		
01-420-8487	13	pizza cutter,handle		PS		
01-420-8487	13	spaghetti	x	PVC	DINP	x
01-420-8487	13	bacon	x	PVC	DINP	x
01-420-8487	13	egg	x	PVC	DINP	x
01-420-8487	13	french fries	x	PVC	DINP	x
01-420-8487	13	donut	x	PVC	DINP	x
01-420-8487	13	lettuce	x	PVC	DINP	x
01-420-8487	13	tomato	x	PVC	DINP	x
01-420-8487	13	ice cream	x	PVC	DINP	x
01-420-8487	13	pizza	x	PVC	DINP	x
01-420-8488	14	hand,feet	x	PVC	DINP	x
01-420-8488	14	face	x	PVC	DINP	x
01-420-8489	15	hand	x	PVC	ATBC	x
01-420-8489	15	face	x	PVC	ATBC	x
01-420-8491	16	body		ABS		
01-420-8491	16	fabric		Nylon		x
01-420-8491	16	hand		PEVA		x
01-420-8491	16	face	x	PVC	DINP	x
01-420-8491	16	leg	x	PVC	DINP	x
01-420-8491	16	hair	x	PVC	ND	x
01-420-8492	17	cape	x	PVC	DINP	x
01-420-8492	17	body	x	PVC	DINP	x
01-420-8492	17	shoe	x	PVC	DINP	x

01-420-8492	17	hat	x	PVC	DINP	x
01-420-8493	18	blue ball		poly silcone		x
01-420-8494	15	green tube		PE		x
01-420-8494	15	white bottle		PE		x
01-420-8494	15	cup white top		PE		
01-420-8494	15	clear pink		polymethacrylate		
01-420-8494	15	bag, strip		PP		x
01-420-8494	15	clear blue		PP		
01-420-8494	15	bag, clear	x	PVC	DEHP	x
01-420-8494	15	bag, green	x	PVC	DEHP	x
01-420-8494	15	beach ball	x	PVC	ATBC	x
01-420-8495	19	yellow ball		ABS		
01-420-8495	19	green protrusion	x	PVC	DINP	x
01-420-8496	16	yellow teether		ABS		
01-420-8496	16	purple CPK		PE		x
01-420-8496	16	pacifier		polycarbonate		
01-420-8496	16	pacifier holder		polycarbonate		
01-420-8496	16	face	x	PVC	ATBC	x
01-420-8497	20	face	x	PVC	DINP	x
01-420-8497	20	hand	x	PVC	DINP	x
01-420-8498	15	green tree		PE		x
01-420-8498	15	gray stone		PP		
01-420-8498	15	green box		PP		
01-420-8498	15	large reptile	x	PVC	DINP	x
01-420-8498	15	small reptile	x	PVC	DINP	x
01-420-8498	15	medium reptile	x	PVC	DINP	x
01-420-8499	16	body		ABS		
01-420-8499	16	hand		PEVA		x
01-420-8499	16	face	x	PVC	DINP	x
01-420-8499	16	leg	x	PVC	DINP	x
01-420-8499	16	hair	x	PVC	ND	x

ABS = poly(styrene:acrylonitrile:butadiene)
BS = poly(styrene:butadiene)
PEVA = poly(ethylene-co-vinyl acetate)
PE = polyethylene
PP = polypropylene
PS = polystyrene
PVC = polyvinyl chloride

DINP = di-isonony phthalatel
DEHP = di-2-ethylhexyl phthalate
ATBC = acetyl tri-butyl citrate
DEHA = bis(2-ethylhexyl) adipate
ND = not detectable

Table 2. DINP and DEHP Release from PVC disk by JRC HoH method

Part 1, DINP

CPSC #	item description	% DINP in PVC disk	Corrected release µg/min/10cm^2
01-420-8417	face	35.50	3.22
01-420-8467	cushion, clear	39.38	4.20
01-420-8469	seat	29.43	2.88
01-420-8471	blue body	25.31	2.73
01-420-8476	body	29.25	6.14
01-420-8477	body	35.90	1.08
01-420-8479	sheet	22.20	1.50
01-420-8483	green whale	39.32	4.02
01-420-8487	spaghetti	35.68	4.32
01-420-8487	bacon	34.23	1.83
01-420-8487	egg	36.44	3.71
01-420-8487	french fries	28.90	10.78
01-420-8487	dount	28.97	6.78
01-420-8487	lettuce	27.36	4.64
01-420-8487	tomato	31.75	6.55
01-420-8487	ice cream	27.52	2.05
01-420-8487	pizza	32.29	11.09
01-420-8488	leg	32.82	6.52
01-420-8491	face	26.57	2.19
01-420-8492	cape	19.51	1.05
01-420-8495	green protrusion	26.82	3.23
01-420-8497	face	32.17	3.52
01-420-8498	large reptile	12.86	2.03
01-420-8499	face	29.95	1.63
yellow duck	body	29.55	7.52

Part 2. DEHP

CPSC #	item description	% DEHP in PVC	Corrected release µg/min/10cm^2
01-420-8482	tub squirt	37.34	2.03
01-420-8494	bag-green	22.11	0.92
01-420-8494	bag-clear	22.86	1.06

Appendix

Table A. DINP migration by HOH - 1.

HOH method

CPSC #	Sample code	specimen code	Sample thickness (mm)	Sample area (cm^2)	Solution conc. (µg/ml)	Conc. factor	Uncorrected release (µg/min/disk)	Corrected release (µg/min/10cm^2)	Corrected release (µg/min/10cm^2),recovery adj	average Corrected release (µg/min/10cm^2),recovery adj
01-420-8417	face	A	2.5	10.93	3.11	1.00	2.59	2.37	2.74	3.22
01-420-8417	face	B	2.5	10.93	4.20	1.00	3.50	3.20	3.70	
01-420-8467	cush	A	2.0	10.56	4.38	1.00	3.65	3.46	3.99	4.20
01-420-8467	cush	B	2.0	10.56	5.06	1.00	4.22	4.00	4.62	
01-420-8467	cush	C	2.0	10.56	4.38	1.00	3.65	3.46	4.00	
01-420-8469	blue seat	A	3.0	11.31	3.63	1.00	3.03	2.68	3.09	2.88
01-420-8469	blue seat	B	3.0	11.31	3.17	1.00	2.64	2.34	2.70	
01-420-8469	blue seat	C	3.0	11.31	3.00	1.00	2.50	2.21	2.55	
01-420-8469	painted	D	3.0	11.31	2.57	1.00	2.14	1.89	2.19	
01-420-8469	painted	E	3.0	11.31	2.82	1.00	2.35	2.08	2.40	
01-420-8469	painted	F	3.0	11.31	5.06	1.00	4.22	3.73	4.31	
01-420-8471	blue body	A	2.2	10.71	2.72	1.00	2.27	2.12	2.45	2.73
01-420-8471	blue body	B	2.2	10.71	3.32	1.00	2.77	2.59	2.99	
01-420-8471	blue body	C	2.2	10.71	3.07	1.00	2.56	2.39	2.76	
01-420-8476	yellow duck	A	2.8	11.16	6.89	1.00	5.74	5.15	5.95	6.14
01-420-8476	yellow duck	B	2.8	11.16	6.29	1.00	5.24	4.70	5.43	
01-420-8476	yellow duck	C	2.8	11.16	8.15	1.00	6.79	6.09	7.03	
01-420-8477	tub toy	A	3.2	11.46	1.32	1.00	1.10	0.96	1.11	1.08
01-420-8477	tub toy	B	3.2	11.46	1.35	1.00	1.13	0.99	1.14	
01-420-8477	tub toy	C	3.2	11.46	1.16	1.00	0.97	0.84	0.98	
ck-1	5ug/ml dinp				4.33					
ck-2	5ug/ml dinp				4.33					
				recovery	0.87					

Table B. DINP migration by HOH - 2.

HOH method

CPSC #	Sample code	specimen code	Sample thickness (mm)	Sample area (cm^2)	Solution conc. (µg/ml)	Conc. factor	Uncorrected release (µg/min/disk)	Corrected release (µg/min/10cm^2)	Corrected release (µg/min/10cm^2),recovery adj	average Corrected release (µg/min/10cm^2),recovery adj
01-420-8479	sheet	A	0.2	9.20	1.38	1	1.15	1.25	1.37	1.50
01-420-8479	sheet	B	0.2	9.20	1.50	1	1.25	1.36	1.49	
01-420-8479	sheet	C	0.2	9.20	1.64	1	1.37	1.49	1.63	
01-420-8483	green whale	A	2.0	10.56	3.48	1	2.90	2.75	3.02	4.02
01-420-8483	green whale	B	2.0	10.56	5.54	1	4.61	4.37	4.80	
01-420-8483	green whale	C	2.0	10.56	4.89	1	4.08	3.86	4.24	
01-420-8487	tomato	A	7.0	14.33	11.32	1	9.43	6.58	7.23	6.55
01-420-8487	tomato	B	7.0	14.33	9.18	1	7.65	5.34	5.86	
01-420-8487	lettuce	C	5.0	12.82	5.92	1	4.93	3.85	4.22	4.64
01-420-8487	lettuce	D	5.0	12.82	6.86	1	5.72	4.46	4.90	
01-420-8487	lettuce	E	5.0	12.82	6.74	1	5.61	4.38	4.81	
01-420-8487	egg	F	3.0	11.31	5.22	1	4.35	3.84	4.22	3.71
01-420-8487	egg	G	3.0	11.31	3.43	1	2.86	2.53	2.78	
01-420-8487	egg	H	3.0	11.31	5.11	1	4.25	3.76	4.13	
01-420-8487	bacon	I	1.5	10.18	2.23	1	1.86	1.83	2.01	1.83
01-420-8487	bacon	J	1.5	10.18	2.16	1	1.80	1.77	1.94	
01-420-8487	bacon	K	1.5	10.18	1.72	1	1.43	1.40	1.54	
01-420-8487	dount	L	1.5	10.18	9.08	1	7.56	7.43	8.16	6.78
01-420-8487	dount	M	1.5	10.18	5.69	1	4.74	4.66	5.12	
01-420-8487	dount	N	1.5	10.18	7.86	1	6.55	6.43	7.06	
ck-3	5ug/ml dinp				4.60					
ch-4	5ug/ml dinp				4.50					
				recovery	0.91					

Table C. DINP migration by HOH - 3.

HOH method

CPSC #	Sample code	specimen code	Sample thickness (mm)	Sample area (cm^2)	Solution conc. (µg/ml)	Conc. factor	Uncorrected release (µg/min/disk)	Corrected release (µg/min/10cm^2)	Corrected release (µg/min/10cm^2),recovery adj	average Corrected release (µg/min/10cm^2),recovery adj
01-420-8487	french fries	O	2.0	10.56	5.85	2	9.75	9.24	10.50	10.78
01-420-8487	french fries	P	2.0	10.56	5.32	2	8.87	8.40	9.55	
01-420-8487	french fries	Q	2.0	10.56	6.85	2	11.42	10.82	12.29	
01-420-8487	pizza	R	2.0	10.56	5.50	2	9.16	8.68	9.86	11.09
01-420-8487	pizza	S	2.0	10.56	6.68	2	11.14	10.55	12.00	
01-420-8487	pizza	T	2.0	10.56	6.36	2	10.60	10.04	11.41	
01-420-8487	ice cream	U	4.0	12.06	2.65	1	2.21	1.83	2.08	2.05
01-420-8487	ice cream	V	4.0	12.06	2.71	1	2.26	1.87	2.13	
01-420-8487	ice cream	W	4.0	12.06	2.48	1	2.07	1.71	1.95	
01-420-8487	spaghetti	X	2.0	10.56	4.84	1	4.04	3.82	4.35	4.32
01-420-8487	spaghetti	Y	2.0	10.56	5.51	1	4.59	4.35	4.94	
01-420-8487	spaghetti	Z	2.0	10.56	4.09	1	3.41	3.23	3.67	
01-420-8488	leg	A	2.5	10.93	7.24	1	6.03	5.52	6.27	6.52
01-420-8488	leg	B	2.5	10.93	8.23	1	6.86	6.27	7.13	
01-420-8488	leg	C	2.5	10.93	7.12	1	5.93	5.43	6.17	
01-420-8491	face	A	2.0	10.56	2.44	1	2.04	1.93	2.19	2.19
01-420-8492	cape	A	1.5	10.18	1.14	1	0.95	0.93	1.06	1.05
01-420-8492	cape	B	1.5	10.18	1.15	1	0.96	0.94	1.07	
01-420-8492	cape	C	1.5	10.18	1.10	1	0.92	0.90	1.02	
ch-5	5ug/ml dinp				4.35					
ck-6	5ug/ml dinp				4.44					
				recovery	0.88					

Table D. DINP migration by HOH - 4.

HOH method										average
CPSC #	Sample code	specimen code	Sample thickness (mm)	Sample area (cm^2)	Solution conc. (µg/ml)	Conc. factor	Uncorrected release (µg/min/disk)	Corrected release (µg/min/10cm^2)	Corrected release (µg/min/10cm^2),recovery adj	Corrected release (µg/min/10cm^2),recovery adj
01-420-8495	green pro	A	2.8	11.16	4.61	1	3.84	3.44	3.82	3.23
01-420-8495	green pro	B	2.8	11.16	3.33	1	2.77	2.49	2.76	
01-420-8495	green pro	C	2.8	11.16	3.75	1	3.13	2.80	3.11	
01-420-8497	face	A	2.5	10.93	3.72	1	3.10	2.84	3.15	3.52
01-420-8497	face	B	2.5	10.93	3.79	1	3.16	2.89	3.20	
01-420-8497	face	C	2.5	10.93	4.99	1	4.16	3.80	4.22	
01-420-8498	L reptile	A	2.8	11.16	2.45	1	2.04	1.83	2.03	2.03
01-420-8499	face	A	2.0	10.56	1.86	1	1.55	1.47	1.63	1.63
ck-7	5ug/ml dinp				4.68					
ck-8	5ug/ml dinp				4.33					
				recovery	0.90					

Table E. DINP migration by HOH - 5.

HOH method

CPSC #	Sample code	specimen code	Sample thickness (mm)	Sample area (cm^2)	Solution conc. (µg/ml)	Conc. factor	Uncorrected release (µg/min/disk)	Corrected release (µg/min/10cm^2)	Corrected release (µg/min/10cm^2),recovery adj	average Corrected release (µg/min/10cm^2),recovery adj
yellow duck		A	2.5	10.93	7.57	1	6.31	5.77	6.48	7.60
yellow duck		B	2.5	10.93	7.89	1	6.58	6.02	6.76	
yellow duck		C	2.2	10.71	9.34	1	7.78	7.27	8.16	
yellow duck		D	2.2	10.71	8.95	1	7.46	6.97	7.83	
yellow duck		E	2.5	10.93	10.25	1	8.55	7.82	8.78	
				recovery	0.89					

Table F. DEHP migration by HOH.

HOH method										average
CPSC #	Sample code	specimen code	Sample thickness (mm)	Sample area (cm^2)	Solution conc. (µg/ml)	Conc. factor	Uncorrected release (µg/min/disk)	Corrected release (µg/min/10cm^2)	Corrected release (µg/min/10cm^2),recovery adj	Corrected release (µg/min/10cm^2),recovery adj
01-420-8482	tub squirt	A	2.0	10.56	2.82	1	2.35	2.22	2.28	2.03
01-420-8482	tub squirt	B	2.0	10.56	2.58	1	2.15	2.04	2.08	
01-420-8482	tub squirt	C	2.0	10.56	2.12	1	1.77	1.68	1.72	
01-420-8494	bag-green	A	0.2	9.20	1.01	1	0.84	0.92	0.94	0.92
01-420-8494	bag-green	B	0.2	9.20	1.02	1	0.85	0.93	0.95	
01-420-8494	bag-green	C	0.2	9.20	0.95	1	0.79	0.86	0.88	
01-420-8494	bag-clear	A	0.1	9.12	1.05	1	0.88	0.96	0.98	1.06
01-420-8494	bag-clear	B	0.1	9.12	1.31	1	1.09	1.19	1.22	
01-420-8494	bag-clear	C	0.1	9.12	1.04	1	0.87	0.95	0.97	
ck-1	5ug/ml dehp				4.82					
ck-2	5ug/ml dehp				4.94					
				recovery	0.98					

Table G. % DINP in PVC

CPSC #	Sample code	Solution conc. (µg/ml)	Conc. factor	% DINP in PVC	Corrected release (µg/min/10cm^2),recovery adj
01-420-8417	face	3.5030	1.00	35.50	3.22
01-420-8467	cush	3.6162	1.00	39.38	4.20
01-420-8469	seat	2.9720	1.00	29.43	2.88
01-420-8471	blue body	2.4386	1.00	25.31	2.73
01-420-8476	body	2.8907	1.00	29.25	6.14
01-420-8477	body	3.1775	1.00	35.90	1.08
01-420-8479	sheet	2.2533	1.00	22.20	1.50
01-420-8483	green whale	3.8598	1.00	39.32	4.02
01-420-8487	spaghetti	3.5082	1.00	35.68	4.32
01-420-8487	bacon	3.0750	1.00	34.23	1.83
01-420-8487	egg	3.7172	1.00	36.44	3.71
01-420-8487	french fries	2.5243	1.00	28.90	10.78
01-420-8487	dount	2.8249	1.00	28.97	6.78
01-420-8487	lettuce	2.8366	1.00	27.36	4.64
01-420-8487	tomato	3.0215	1.00	31.75	6.55
01-420-8487	ice cream	2.6644	1.00	27.52	2.05
01-420-8487	pizza	3.1916	1.00	32.29	11.09
01-420-8488	feet	3.2108	1.00	32.82	6.52
01-420-8491	face	3.1179	1.00	26.57	2.19
01-420-8492	cape	2.1429	1.00	19.51	1.05
01-420-8495	green protrusion	2.4314	1.00	26.82	3.23
01-420-8497	face	2.9547	1.00	32.17	3.52
01-420-8498	large reptile	2.3392	1.00	12.86	2.03
01-420-8499	face	2.8854	1.00	29.95	1.63
yellow duck		2.7036	1.00	29.55	7.60

Table H. % DEHP in PVC

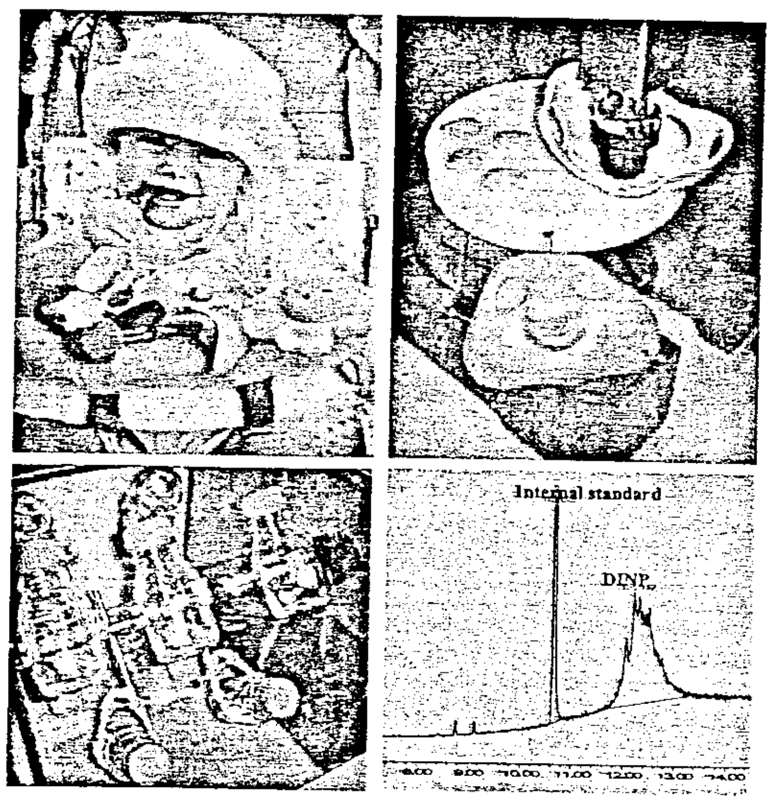
CPSC #	Sample code	Solution conc. (µg/ml)	Conc. factor	% DEHP in PVC	Corrected release (µg/min/10cm^2),recovery adj
01-420-8482	tub squirt	3.87113874	1.0000	37.34	2.03
01-420-8494	bag-green	2.12272607	1.0000	22.11	0.92
01-420-8494	bag-clear	2.50312794	1.0000	22.86	1.06

TAB J

ihcp

JOINT RESEARCH CENTRE
EUROPEAN COMMISSION

Validation of methodologies for the release of di-isononylphthalate (DINP) in saliva simulant from toys



C. Simoneau, H. Geiss, A. Roncari, P. Zocchi, P. Hannaert.

European Commission
DG- Joint Research Centre
Food Products Unit
Institute for Health and Consumer Protection
I-21020 Ispra - Italy

20001 EUR 19826 EN

Executive summary

The European Commission's Joint Research Centre (JRC) co-ordinated the validation of 2 methodologies developed in 2 Member States to test the migration of certain plasticisers from toys. The validation exercise included more than 15 laboratories for both EU and USA, and was sponsored by JRC for consumables and the industry platform for the migration devices, toy samples and reference materials.

The candidate methods were based on dynamic migration of the substances of interest into artificial saliva via mechanical agitation either using a head over heels device (developed by the Nutrition Research Institute, TNO, The Netherlands) or a horizontal shaking device under mild or stringent conditions (developed by the Laboratory of Government Chemist, LGC, United Kingdom).

After harmonization of the standard operating procedure by JRC, the methods were tested for the release of di-isononylphthalate (DINP), the phthalate the most commonly used in toys. The testing was applied both to a standard PVC material and to a variety of toys of different manufacturing processes and levels of DINP.

The data were collected and subjected to statistical evaluation by JRC. The procedure followed the guidelines ISO 5725 (part 2, 1994) and IUPAC harmonized protocol (1995). The collaborative trial results were examined for evidence of individual systematic error ($p < 0.025$) using Cochran's and Grubb's tests successively. The valid results were then subjected to one-way analysis of variance (ANOVA). The parameter used as a measurement of dispersion of the distribution of test results between laboratories was the reproducibility relative standard deviation RSD_R (also called coefficient of variation, or reproducibility variance).

The results showed that the head over heels method exhibited better reproducibility than the other candidate method based on horizontal shaking (mild and stringent). The reproducibility was not affected consistently by the final analytical measurement technique (liquid or gas chromatography). For the head over heels method, the RSD_R was around 30% on the disk reference materials and ranged from 35 to 65% for the range of toys tested in this study.

Laboratories experienced mechanical problems with the horizontal shaking device both under mild and stringent conditions, and thus the number of valid sets did not always reach the required 8 sets. Based on only the valid results obtained, the RSD_R of the mild horizontal shaking method averaged 90% for the disks spread from 62 to 110% for the toys tested. Valid results from the stringent horizontal shaking method gave an RSD_R of 140% for the disks and ranged from 65 to 115% on toys.

In conclusion, the head over heels method could be validated with the appropriate number of laboratories. Considering that in the field of <u>migration</u> of organic contaminants from polymeric food contact materials, validated methods standardised by CEN have shown on average a RSD_R of 38% (solely using standard reference materials such as the reference PVC disks used in this validation) the RSD_R of 30% on disks observed in the case of the method head over heels can be considered acceptable. The extent of spread of on toys depended for a large part in the inherent features of the actual toys tested.