Proposition 65 Analytical & Exposure Assessment (Phase II)

For:
Dura Plastic Products, Inc.
533 East Third Street
Beaumont, CA 92223



DRAFT REPORT

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Executive Summary

NSF International ("NSF") conducted wipe and headspace testing and an exposure assessment of Proposition 65 compounds that may be present as impurities on Dura Plastic Products, Inc.'s ("Dura Plastics") PVC fittings (when handled under typical use conditions) to determine warning obligation, if any, under the Safe Drinking Water and Toxic Enforcement Act of 1986 (California Proposition 65) ("Prop 65").

Table 1. Proposition 65 Analytes and Safe Harbor Limits

Chemical	NSRL (μg/day)¹	MADL (μg/day) ¹	Testing Type	Result
Methyl chloride	N/A	1800 (inhalation)		
Vinyl chloride	3	N/A	Headspace &	
1,3-butadiene	0.4	40 (inhalation)	Wipe	
Acrylonitrile	0.7	N/A		
Bisphenol A	N/A	3 (dermal); 0.3 (oral)	Tri se	
Styrene	27	N/A		
Lead	15 (oral)	0.5		
Cadmium	0.05 (inhalation)	4.1 (oral)		
Arsenic	0.06 (inhalation) 10 (except inhalation)	Not determined	Wipe	Not detected
Phthalates	146 - 310	8.7 - 2200 (oral)		
Polyaromatic hydrocarbons	0.033 (oral)- 0.2	N/A		
Ethyl acrylate	5.8	N/A		
Chlorinated paraffins	8	N/A		

¹Values in bold are estimates of derived Safe Harbor limits based on reference to regulatory authority values and should not be considered definitive. See Table 17 in Appendix C for further details.

Table 2. Estimated Total Relevant Intake Referencing Analytical Detection Limits

Analyte	Total Intake (µg/day)
A1	PVC Fitting
Acrylonitrile	< 4.68
Arsenic	< 0.376
Bisphenol A	< 0.109
1,3-Butadiene ¹	< 0.540
Cadmium	< 0.287
Chlorinated paraffins	< 0.939
Methyl chloride ¹	< 12.9
Ethyl acrylate	< 7.48
Lead	< 0.285
Phthalates	< 2.63
Polyaromatic Hydrocarbons ²	< 1.13
Styrene	< 2.19
Vinyl chloride	< 3.04

¹ Inhalation exposure

² Oral exposure

Dura Plastics PVC fittings were evaluated for potential exposure to listed chemicals that may occur by several intake routes, namely dermal absorption of chemicals transferring from the solid surfaces after handling, indirect oral exposure that occurs through direct hand-to-mouth and indirect hand-to-mouth exposures, and inhalation exposures to off-gassing volatile chemicals.

As the analysis of product samples resulted in non-detectable residues of surface and air concentrations of listed chemicals for those exposure scenarios considered as part of this assessment, no warning obligation under Proposition 65 is evident for these products prior to exposure to citizens of the state. To evaluate estimates of exposure relative to analytical detection limits in comparison to Proposition 65 Safe Harbor limits (to ensure sufficiency of the analysis), an exposure assessment was conducted using conservative assumptions to estimate inhalation, dermal, and oral exposures. Specifically, 280 ft of pipe is considered the average run length for drinking water lines in any residential establishment where 140 ft of pipe per day is the assumed installation cadence for any one worker (relevant to PVC Pipe, < 1" pipe). Within this system, an estimated 200 pipe joints, or 100 fittings (50 fittings/day) are assumed with reference to NSF/ANSI 61. Handling assumptions resulting in inhalation, dermal, and oral exposure were considered (as outlined in Table 7) resulting in the total estimated intake levels identified in Table 2. Further refinement and improved sensitivity of analytical detection limits for those analytes bolded in red in Table 2 may be considered, such as may be realized by increasing the wiped surface area, i.e. wiping multiple fitting components. In addition, Dura Plastics marketing data may indicate that far fewer fittings may be applied on a daily basis. In addition, transfer rates of chemicals were considered linear and additive, normalized to account for loading and off-loading of lead that may occur during the day; however, hand wiping of individuals for dermal chemical loading after typical exposure conditions may provide a more accurate representation of maximum chemical loading on the skin.

Introduction

For those manufacturers selling product(s) into the State of California, the Safe Drinking Water and Toxics Enforcement Act of 1986 (otherwise known as Proposition 65) requires that a "clear and reasonable" disclosure of chemicals known to the state to be carcinogens or reproductive toxicants (where at least one chemical per endpoint is named) be indicated on the product, its packaging, or associated marketing materials prior to exposure to the citizens of the state. Such a "warning" allows for a manufacturer to maintain Safe Harbor under the regulation, thus reducing the risk of enforcement through litigation. Exclusion from warning requires a determination that the product(s) does not contain listed chemicals or the resulting exposure from use of the product under typical exposure conditions to a listed chemical is below Safe Harbor limits, where available, thus introducing a second mechanism to maintain Safe Harbor under the regulation

For those exposures to listed chemicals that are not otherwise exempted (i.e. dermal, inhalation, and indirect oral exposure during installation or maintenance of the pipe and fittings), an understanding of the presence of listed chemicals is required. As such, NSF International was contracted by Dura Plastic Products, Inc., to conduct a Proposition 65 exposure assessment for exposure to listed chemicals for the following plumbing products:

Table 3. Dura Plastics Products

Product Type	Tradename	Facility	NSF DCC#
PVC Fittings	Dura Plastic Pipe Fittings (1/8 – 12")		
	Manifold Tee, SPG X S X FPT (1")	All	PM01886
	Manifold Tee, SPG X S X MPT (3/4-1")		

Product Information

Overview

Dura Plastic Products are rigid polyvinyl chloride (PVC) 3/4" manifold tee fittings that are formulated with PVC polymer resin, modifiers, processing additives, stabilizers, pigments, etc. These fittings may be used broadly to plumb drinking water service within commercial and residential locations. Once installed, maintenance is not anticipated, with an expected service lifetime greater than 50 years.

Table 4. Dura Plastic Products, Analytical Sample Characterization

Product	Lot No.	Unit Description	Sample Dimensions ¹ (cm)	Estimated Surface Area ² (cm ²)	Sample Weight (g)
3/4" Tee-Slip	LOC: C-116, 401-007		Short Cylinder D1= 3.3 D2= 2.7 H = 2.5 Long Cylinder D1 = 3.3 D2 = 2.7 H = 8.4	Exterior= 121.5 Interior= 92.5 Total= 214.0	51.0787

¹D1 = total diameter; D2 = inner diameter; H= height of cylinder

Scope of Testing & Anticipated Exposure Scenario

To determine the concentration of dislodgeable chemical residue on the fitting surface and the release of volatiles into air that may result in human exposure (inhalation, dermal, and oral) during installation, wipe testing and headspace analysis were conducted for representative product samples (as described in Table 4). As occupational exposure conditions are considered worst case (i.e. the most extreme volume of sample handling and time of exposure would occur) relative assumptions were applied. After installation, residential exposure to volatile compounds may occur. Estimates of exposure were determined based on 100 fittings installed within 280 ft of drinking water lines in any one residential location that may off-gas over a 24-hour period. Detection limits are included in Tables 3 and 4 and were used within exposure estimations as analytes were not detectable in sample analysis. Pictures of samples as received by NSF and the standard calibrations for the analytical assessment are included in Appendix A.

Test Methods & Results

Wipe Testing & Analysis:

To assess the exposure to surface residues of listed chemicals from normal handling of the product, wipe testing was performed in accordance with NIOSH wipe method 9100. Samples were placed on a clean templated area of lab bench and were wiped with a pre-moist individually wrapped wipe folded in to fourths, with a firm pressure. An overlapping "S" pattern with the moist wipes was

² Total surface area was calculated as the sum of the exterior surface area (exterior cylinder plus the occupied space of the circular ends) and interior surface area

used to cover the entire surface. The interior surface of each sample was wiped in a similar manner. The wipe was folded once more to reveal an unexposed surface and the vertical "S" strokes pattern was repeated. This step was repeated once more. One wipe was used for surface sampling of each sample. Three replicates for each sample were prepared. The wipes were then transferred into glass scintillation vials, extracted, and then analyzed according to the methods in Table 5 below:

Table 5. Analyte Extraction, Methods, and Detection Limits

Analyte(s)	Detection Limit ^a (μg/sample)	Detection Limit (ng/cm²)	Detection Method ^b	Wipe Extraction Solvent
Arsenic	0.2	0.9		10.0 mL of diluent (2% nitric
Cadmium	0.2	0.9	ICP-MS	acid and 2% hydrochloric acid
Lead	0.2	0.9		in DI water)
Acrylonitrile	0.77	3.6		
Ethyl acrylate	1.2	5.7		
Styrene	0.36	1.7	GC-FID	
1,3-Butadiene	4.9	23	30112	
Bisphenol A	0.06	0.28		10.0 mL of diluent
Phthalates ^c	1.6	7.5		(dichloromethane/ methanol)
Methyl chloride	6.5	30	GC-MS	(Signaturality methanol)
Vinyl chloride	2.0	9.3	CC MID	
PAHs ^d	1	4.7	GC-SIM	
Chlorinated paraffins	0.49	2.3	LC-MS	

^a Adjusted for extraction volume

Headspace Analysis:

Approximately 1 g of each sample was weighed accurately and place into a headspace vial (20 cm³) and was sealed. PVC samples were incubated at 82 °C for 15 minutes before analysis. After incubation, 500 μ L for each headspace vial was extracted by syringe and manually injected into the gas chromatogram. Three replicates for each sample were prepared.

Table 6. Headspace Analytes, Methods, and Detection Limits

Analyte	Detection Method	Detection Limit (µg/g sample) ^a	Detection Limit (ng/sample in 20 cm ³) ^b	Detection Limit (ng/cm ³ ·s) ^c
1,3-Butadiene	GC-FID	0.493	20	0.056
Vinyl chloride	GC-MS	0.200	8.0	0.023
Chloromethane	GC-MS	0.650	26	0.074

^a per 1 μL injection volume

^b ICP-MS: Inductively-Coupled Plasma- Mass Spectrometry; GC-FID: Gas chromatography with an Flame Ionization Detector; GC-MS: Gas Chromatography with a Mass Spectrometer using Selected Ion Monitoring; LC-MS: Liquid Chromatography with a Mass Spectrometry Detector

^c Benzylbutylphthalate, bis(2-ethylhexyl)phthalate, di-n-butylphthalate, diethylphthalate, dimethylphthalate, di-n-octyl phthalate

^d Polyaromatic Hydrocarbons: Acenaphthene, acenaphthylene, anthracene, benzo(a)anthracene, benzo(a)pyrene, benzo(b)fluoranthene, benzo(g,h,i)perylene, benzo(k)fluoranthene, chrysene, dibenz(a,h)anthracene, dibenzofuran, fluoranthene, fluorene, indeno(1,2,3-cd)pyrene, naphthalene, phenanthrene, pyrene

^b 500 μL injection volume to instrument

^c 15 min, or 900 second incubation

Test Results:

Replicate samples for both wipe testing and headspace analysis were below detections limits for all analytes at the detection limits indicated in Tables 5 and 6. Chromatograms of the replicate analyses are included in Appendix B.

Proposition 65 Exposure Assessment

A conservative assessment was conducted to determine the worst-case scenario for workers and consumers exposed to dislodgeable and/or volatile listed chemical residues relative to the achievable detection limits for each Dura Plastics PVC fittings (See Tables 8-10). As consumers are expected to support only minor installations that occur infrequently and of limited duration, occupational exposure is considered worst-case for dermal and oral exposures and therefore the focus of this assessment. Inhalation of volatile, listed chemicals for a fully installed system was considered for residential exposure and included in Table 9. As these products are not marketed to children and children are unlikely to handle the product during or after installation, exposure to children was excluded from the present assessment.

Residuals on the surface of the fittings are assumed to be static, i.e. further residual would not be expected to migrate to the fitting surface over time. The concentration of listed chemical residues on the surfaces were calculated on a ng per square centimeter basis with reference to the component surface areas described in Table 4. The amount of dislodgeable residue available for contact was normalized to µg/hour to account for the loading and unloading that continually occurs throughout the exposure period. It is assumed that one worker can install 280 feet of plumbing (tube or piping) over a two-day period, which is the total amount of piping in a residence as set forth under NSF/ANSI Standard 61 (NSF 2017). A conservative estimate of the number of fittings that would occur in a residential system is approximately 100 (representing 200 joints in the system), with reference to NSF/ANSI 61 (2017), Table B11, for 0.5 to 1-inch nominal diameter pipe, or 50 fittings per day. Handling of a fitting was assumed to occur as a one hand (palm) exposure by any individual (i.e. the fitting is collected using one hand, held by the same hand and then the adjoining plumbing component is affixed by the second hand) that over the course of several fittings and plumbing configurations, either hand may be used. As the potential residual is static on the surface, dermal residual would be expected to be distributed across the hands during a palmar exposure. Palmar handling is expected to be the most relevant exposure (as opposed to dorsal hand surfaces) and would incur the highest total residue on the skin due to a higher surface area of total exposure and is thus considered the most conservative scenario for dermal absorption. The resulting estimated exposure values were then compared to Safe Harbor limits established under California Proposition 65 as either a No Significant Risk-Level (NSRL) or Maximum Allowable Dose Level (MADL) (See Tables 1 and 2). For those chemicals lacking an NSRL or MADL value, derived values were estimated using the available regulatory authority values (see Appendix C, Table 17 for further details).

Inhalation:

For those chemicals considered not to be volatile (vapor pressure < 100 mm Hg, and boiling point < 250 °C), any exposure occurring by the inhalation route would be considered negligible as compared to dermal and oral exposure, and thus are not considered within this assessment. Those chemicals considered volatile (including 1,3-butadiene, chloroform, chloromethane, and vinyl chloride), were evaluated to determine the air concentration off-gassing during and after product installation. To provide the most conservative assumption, a 10 m³ room without ventilation was identified as the default space that a plumbing system may be installed. Each chemical was assumed to distribute instantaneously and would be inhaled at a default 50 % absorption, or intake rate. Breathing rates of 1.5 m³/hour for a worker over an 8-hour exposure for 50 fittings per day and 0.78 m³/hour for an adult for a 24-hour exposure for a total 100 fittings installed, were used as defaults (US EPA, 2011; NSF/ANSI, 2017). As off-gassing is anticipated to decrease over time, estimates of exposure are considered conservative. Overall, the calculation applied for the worker scenario is:

(1) Inhalation intake = ng/sample·cm³·hr x 6.25 fittings/hr/ 10^7 dilution (cm³ to 10m³ in m³) x 1.5m³ x 8 hrs/day

And the consumer scenario (24 hours of exposure):

(2) Inhalation intake = ng/sample·cm³·hr x 12.5 fittings/hr/ 10^7 dilution (cm³ to 10 m³ in m³) x 0.78 m³ x 24 hrs/day

Dermal:

Wipe testing was performed, as explained above, to determine the potential for the identified listed chemicals to be released from the Dura Plastics fittings during worker handling of the product. Dermal loading during handling is expected to occur and therefore dermal absorption may be relevant dependent on dermal absorption characteristics of each chemical as indicated or estimated on a chemical specific basis in Table 8 (see Table 18, in Appendix C for associated references).

A 30% transfer rate from the fitting surface to the skin is considered conservative with reference to the US EPA Exposure Factors handbook (2011), Table 7-27, where chemical transfer rates are considered a function of the state of the skin and not of the chemical property of the transferring chemical. Within this assessment, chemical transfer rates ranged from $0.9 (\pm 3.1)\%$ for dry skin to $14 (\pm 18)\%$ for sticky skin. A 30% transfer rate was used as a conservative assumption. Overall the general transfer to the skin may be calculated as follows:

(3) Chemical transfer = (μ g chemical/hr x 30%) = μ g chemical/hr

Therefore, using the estimated or reported dermal absorption rate as a conservative estimate of possible intake following handling of Dura Plastics fittings and assuming that the maximal loading onto the skin will remain entirely on the hands (e.g., not washed off or otherwise exfoliated), a conservative dermal exposure concentration on an hourly basis can be derived as follows:

(4) Dermal intake = Transfer (μ g/hr) x absorption rate (%) = μ g/hr

(5) Loading on skin = Transfer (μ g/hr) – Intake (μ g/hr) = μ g/hr

This resulting value would represent the amount of any chemical remaining on hands that may be available for potential further transfer (such as by direct or indirect oral exposure).

Oral:

Oral exposure is the exposure pathway of greatest concern to the general public for non-volatile chemicals and is also the most relevant pathway for assessing exposure to non-volatile chemicals following occupational use of the Dura Plastics products. The transfer of chemical from the surface of the product to its handler(s) via incidental ingestion may occur as a result of direct mouthing, direct hand-to-mouth activity, or indirect hand-to-mouth activity. In this instance, direct mouthing is not relevant to the assessment as children are not reasonably anticipated to handle Dura Plastics products.

The oral exposure potential for listed chemicals from the surface of Dura Plastics fittings focuses on hand-to-mouth exposure pathways, whereby transfer of chemical after product handling may result from direct touching of the hand to the mouth (i.e., licking, nail biting, finger sucking, etc.) or via indirect transfer from the hands to other objects which are subsequently mouthed (i.e., food, cigarettes, etc.).

OEHHA's Proposition 65 Interpretive Guideline No. 2011-001 provides the necessary steps and assumptions for calculating likely hand-to-mouth transfer of lead from consumer products; however, these algorithms are consistent with any surface residue that may occur for non-volatile chemicals and are thus applied generally for this assessment. The algorithms they employ are as follows (OEHHA, 2011):

Total lead intake for hand-to-mouth activity:

(6) Intakeнм = Intakeнм direct + Intakeнм indirect

where,

• Intakehm direct is the lead intake from directly handling the product containing lead and the touching the mouth. This can be calculated from the following equation:

(7) IntakeHM direct = $L_{hand-D} \times SA_D \times f_{direct} \times \lambda D \times t$ where,

- o Lhand-D represents the lead loading on the part of the hand touching the mouth.
- o SAD represents the surface area of the part of the hand in direct contact with the mouth.
- \circ f_{direct} represents the direct hand-to-mouth transfer factor. A default value for this parameter is 0.5.
- \circ λ_D represents the hourly rate of direct hand-to-mouth contact
- o t represents the average number of hours during the day that a given product is used.

and where,

• Intakehm,indirect is the lead intake from handling the lead-containing product and then handling and depositing lead on an intermediate item and then eating or touching the mouth with that item. This can be calculated from the following equation:

(8) IntakeHM indirect = Lhand-I x SAI x findirect x \(\lambda I \) x t

where.

- L_{hand-I} represents the lead loading on the part of the hand touching the intermediate object(s).
- SA_I represents the surface area of the hand in contact with the part of the intermediate object(s) reaching the mouth.
- \circ f_{indirect} represents the indirect hand-to-mouth transfer factor. A default value for this parameter is 0.25.
- \circ λ_I represents the hourly rate of indirect hand-to-mouthed object contact.
- o t represents the average number of hours during the day that a given consumer product is used.
- o OEHHA indirect Scenarios 1 and 2 are summed and are further described in Table 4.

OEHHA Interpretive Guideline No. 2008-001 considers two indirect exposure scenarios. The first indirect exposure scenario consists of the consumption of a snack food which was assigned a λ_I value of 10 contacts/hour and a SA_D value of 19 cm² (3 fingertips). The second indirect exposure scenario was the consumption of a large food item (e.g. a sandwich or apple) which was assigned a λ_I value of 1 contacts/hour and a SA_D value of 190 cm² (90% of the one-side of the palmar area which is 210 cm²).

Case-by-case assumptions for each unique consumer product assessed must be used in order to choose appropriate parameter values for these equations. This assessment was conducted using conservative exposure assumptions based upon normal use of the fittings. Table 7 lists the assumptions for time and surface area on the hand required when installing Dura Plastics products.

Table 7: Exposure Assumptions for Installation of Dura Plastics Products

Variable	Assumption	Rationale for Selected Assumption
Component surface area	X cm ²	As calculated for submitted samples. See Table 4.
PVC fittings handled	50 fittings/day (or 6.25 fittings/hr)	NSF/ANSI 61 (2017), Table B11: 200 joints are estimated in residential systems (280 ft/ residence @ 140 ft/ worker /day) where each fitting represents 2 joints, or 100 fittings per system handled over 2 days
Work day	8 hours/day	Standard working hours for plumbing contractors
Inhalation rate (worker)	1.5 m ³ / hr	US EPA Exposure Factors handbook (2011)
Inhalation rate (general)	0.78 m ³ / hr	US EPA Exposure Factors handbook (2011)
Minimum room size	10 m ³	Size of small bathroom or utility room
L _{hand-D} L _{hand-1} (fingers)	X μg /cm²	Data obtained from wipe studies as reported in Table 4, then calculated in accordance with equations 1-3 above and provided in Table 8. Installation Exposure Assumptions: - Assumes 1- palmar exposure during individual component installation that is distributed across the hands over the course of a day - From OEHHA guidelines (2008; 2011) 2 palms = 420 cm ²
SA _D	19 cm ²	The OEHHA guidelines (2008; 2011) indicate that 3 fingertips may be used to derive the SAD value, where 3 fingertips = 19 cm2 (males)
SA ₁ Scenario 1	19 cm ²	Based on the OEHHA guidelines (2008), it is assumed that food contact scenario #1 would utilize 3 fingertips for determining SAI (19 cm ²)
SA _I Scenario 2	190 cm ²	Based on the OEHHA guidelines (2008), it is assumed that food contact scenario #2 would utilize 90% of the palmar area of 1 hand (190 cm ²)
f _{direct}	0.5	Default value from OEHHA guidance (2011)
findirect	0.25	Default value from OEHHA guidance (2011)
λ _D	9 contact/hr	Estimated direct hand-to-mouth contact frequency per OEHHA guidance (2008)
λ _I Scenario 1	10 contact/hr	Estimated indirect hand-to-mouth contact frequency per OEHHA guidance (2008) for described food contact scenario 1
λ _I Scenario 2	1 contact/hr	Estimated indirect hand-to-mouth contact frequency per OEHHA guidance (2008) for described food contact scenario 2
t	8 hr/1 hr	Assumptions used: Direct = 8 hours, Indirect food consumption = 1 hour

Applying the above equations, assumptions, and analytical test results (i.e., detection limits for this case), the following inhalation, dermal, oral, and total intakes were estimated for the Dura Plastics products as identified in Table 2 and summarized in Tables 8 - 10 below.

Table 8: Summary Calculations for Oral and Dermal Exposure (per Detection Limits) for Dura Plastics PVC Fittings

Analyte	Detection Limit (µg/sample) ^a	Analyte Surface Residue (µg/cm²)b	6.25 fittings/hr (cm²/hr) ^c	μg/hr	Transfer (30%) (µg/hr) ^d	Dermal Intake Rate (%)°	Dermal Intake (µg/hr)	Dermal Intake (μg/day) ^f	Loading on skin (µg/hr) ^g	Lhand 420 cm ² (µg/cm ²) ^h	Intake HM D	Intake HM I, Scenario 1 (19 cm ²) ^j	Intake HM I, Scenario 2 (190 cm²)	Total Oral Intake ^k (µg/day)
Acrylonitrile	0.77	0.0036	759	2.73	0.819	1.00	0.819	6.55	0.000	0.000	0.000	0.000	0.000	0.000
Arsenic	0.2	0.0009	759	0.710	0.213	0.100	0.021	0.170	0.192	0.000	0.312	0.022	0.022	0.355
Bisphenol A	0.06	0.0003	759	0.21	0.064	0.086	0.005	0.044	0.058	0.000	0.095	0.007	0.007	0.108
1,3-Butadienel	4.9	0.0230	759	17.5	5.25	0.000	0.000	0.000	5.25	0.012	8.55	0.594	0.594	0.000
Cadmium	0.2	0.0009	759	0.71	0.213	0.005	0.001	0.009	0.212	0.001	0.345	0.024	0.024	0.393
Chlorinated Paraffins	0.5	0.0023	759	1.77	0.532	0.100	0.053	0.426	0.479	0.001	0.780	0.054	0.054	0.889
Ethyl acrylate	1.23	0.0057	759	4.37	1.31	1.00	1.31	10.5	0.000	0.000	0.000	0.000	0.000	0.000
Lead	0.2	0.0009	759	0.71	0.213	0.003	0.001	0.005	0.212	0.001	0.346	0.024	0.024	0.394
Methyl chloride	6.5	0.0304	759	23.1	6.92	0.100	0.692	5.54	6.23	0.015	10.1	0.704	0.704	11.6
Phthalates	1.6	0.0075	759	5.68	1.70	0.050	0.085	0.681	1.62	0.004	2.64	0.183	0.183	3.00
Polyaromatic Hydrocarbons	1	0.0047	759	3.55	1.06	0.430	0.458	3.66	0.607	0.001	0.988	0.069	0.069	1.13
Styrene	0.36	0.0017	759	1.28	0.383	1.00	0.383	3.07	0.000	0.000	0.000	0.000	0.000	0.000
Vinyl chloride	2	0.0093	759	7.10	2.13	0.000	0.001	0.005	2.13	0.005	3.47	0.241	0.241	3.95
c Assumes 50 fitted to the second of the sec	Appendix C for), for 8 hour/day) palms, or 420 cm) and Table 4 for) and Table 4 for	y for an 8-ho references 2 assumptions	3	5 fittings	s/ hour									

k See equation (6)

^{1,3-}Butadiene is a gas at room temperature, any dermal residual would be volatilized and inhaled and thus dermal and oral intake are noted as zero.

Table 9: Summary of Calculations for Total Estimated Inhalation Exposure (per Detection Limit) from Dura Plastics PVC Fittings

Analyte	Detection Limit (ug/g·μL)	Detection Limit (ng/sample · cm³·s) ^a	Detection Limit (ng/sample (fitting) · cm³·hr)	6.25 fittings/hr (ng/cm³·hr)	Distribution to 10 m ³ room (ng/m ³ ·hr)	Inhaled concentration 1.5 m³/hr (ng/hr)	Total Intake (50% absorption) (ng/hr)	Total Intake Worker for 8- hour day (µg/day) ^b	Total Intake Adult for 24 hours/day full installation (µg/day) ^c
1,3-Butadiene	0.493	0.056	201	1260	126	189	94.4	0.76	2.36
Methyl chloride	0.650	0.074	266	1660	166	249	124	1.00	3.11
Vinyl chloride	0.200	0.023	81.7	511	51.1	76.6	38.3	0.31	0.96

 $^{^{}a}$ 500 μ L injection volume, Table 4 for sample grams, 20 cm 3 vial volume, 15 min (900 sec) incubation b See equation (1) and Table 6 for assumptions

Table 10: Total Estimated Daily Intake from Dura Plastics PVC Fittings (Worker)

Analyte	Dermal Intake (µg/day)	Oral Intake (µg/day)	Inhalation Intake (µg/day)	Total Intake (µg/day) adjusted for 5 days/ week
Acrylonitrile	6.55	0.000	N/A	4.68
Arsenic	0.170	0.355	N/A	0.376
Bisphenol A	0.044	0.108	N/A	0.109
1,3-Butadiene	0.000	0.000	0.755	0.540
Cadmium	0.009	0.393	N/A	0.287
Chlorinated Paraffins	0.426	0.889	N/A	0.939
Chloromethane	5.54	11.6	0.996	12.9
Ethyl acrylate	10.5	0.000	N/A	7.48
Lead	0.005	0.394	N/A	0.285
Phthalates	0.681	3.00	N/A	2.63
Polyaromatic Hydrocarbons	3.66	1.13	N/A	3.42
Styrene	3.07	0.000	N/A	2.19
Vinyl chloride	0.005	3.95	0.306	3.04

^a 1,3-Butadiene is a gas at room temperature. Any dermal exposure would be rapidly volatilized. Inhalation is the relevant route of exposure.

^c See equation (2) and Table 6 for assumptions

Conclusions

Dura Plastics PVC fittings were analyzed for the presence of Proposition 65 listed chemical compounds conducted as a wipe test on the outer and inner surfaces of the fittings to assess the presence of dislodgeable residues and through headspace analysis to determine air concentration of volatile compounds that may pose a risk to consumers and workers during handling and installation. According to the methods applied within the assessment, no detectable level of listed chemical was found for any replicate analysis for any product. As such, no warning obligation under Proposition 65 exists at this time. Further evaluation of estimates of exposure relative to the detection limits of the analysis were conducted to determine whether the required sensitivity was achieved (i.e., is there risk for future analysis detecting listed chemicals near Safe Harbor limits). Exposure calculations were prepared with reference to OEHHA's Proposition 65 Interpretive Guidelines No. 2008-001 and No. 2011-001 to estimate dermal and oral exposure and standard biological assumptions for inhalation exposures from typical use and handling under occupational conditions based on NSF International use information. Overall, analytical sensitivity for most of the tested compounds were considered sufficient to demonstrate exposure at less than Safe Harbor limits for PVC fittings (which is especially important for heavy metals, bisphenol A, and phthalates that are heavily litigated chemicals). Exposure estimates exceed Safe Harbor limits for 1,3butadiene and ethyl acrylate, however values are only marginally higher than Safe Harbor limits, so are likely to pose little risk of exposure near Safe Harbor limits as conservative estimations were used in this assessment. Estimated exposure at the detection limits for acrylonitrile and polyaromatic hydrocarbons are within an order of magnitude of the Safe Harbor limits. Although risk is low, additional analysis may be conducted with increased surface area for wipe testing to achieve improved analytical sensitivity for these analytes.

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References:

California OEHHA. 2018. Office of Environmental Health Hazard Assessment Proposition 65 No Significant Risk Levels (NSRLs) for Carcinogens and Maximum Allowable Dose Levels (MADLs) for Chemicals Causing Reproductive Toxicity. April 2018. https://oehha.ca.gov/media/downloads/proposition-65/general-info/safeharborlist041218.pdf

California OEHHA.2011. Office of Environmental Health Hazard Assessment. Proposition 65 Interpretive Guideline No. 2011-001: Guideline for Hand-to-Mouth Transfer of Lead through Exposure to Consumer Products. May 2011. Available at https://oehha.ca.gov/media/downloads/crnr/2011handtomouthpb.pdf.

California Division of Drinking Water. 2016. 17 California Code of Regulations. https://www.waterboards.ca.gov/drinking_water/certlic/drinkingwater/documents/lawbook/dwregulations-2016-09-23.pdf

Hazardous Substances Databank (HSDB). 2017. National Institutes of Health, Health & Human Services (NIH). U.S. National Library of Medicine. Toxicology Data Network.. Last updated 4-14-2017. https://toxnet.nlm.nih.gov/.

NIOSH. 1996. LEAD in Surface Wipe Samples. Method 9100, Issue 2.15 May 1996.

NSF/ANSI 61. 2017. <u>Drinking Water System Components-Health Effects</u>. NSF International, Ann Arbor, MI. Available from the NSF bookstore at http://www.techstreet.com/nsfgate.html.

US EPA. Exposure Factors Handbook. 2011. https://cfpub.epa.gov/ncea/risk/recordisplay.cfm?deid=236252

Additional references are cited for relevant sections within this document.

Appendix A- Samples & Analytical Standard Calibration

Dura Plastics Samples (as Received)



Standards Preparation & Calibration

Standard Preparations for Metal Analysis

Standard Stock 1 (1000 ppb STD):

0.1 mL of 1000 µg/mL lead, cadmium and arsenic standard solutions were transferred to a 100.0 mL plastic volumetric flask and diluted to volume with 2% nitric acid in DI water. Mixed well.

Standard Series Preparation:

A standard series of 10 standards were prepared by 2x and 5x serial dilution of the standards. The details of the standard series are given below.

Standard label	Concentration of each analyte (Pb, Cd, As) (ng/mL)
Standard 1/Standard Stock 1	1000
Standard 2	500
Standard 3	100
Standard 4	20
Standard 5	4
Standard 6	0.8
Standard 7	0.16
Standard 8	0.032
Standard 9	0.0064
Standard 10	0.00128

ICP-MS Instrument Parameters:

Analyte(s): Pb (208), Cd (111), As (75)

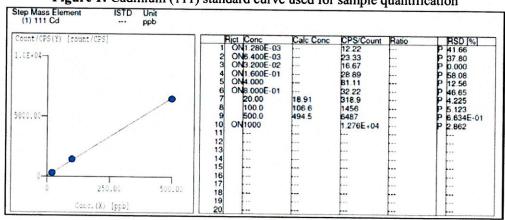
Repetitions: 3

Peak Integration: FullQuant (3 points), 0.3s per integration

Flush Delay: 30 s Stabilization Delay: 30 s

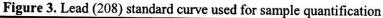
Rinse Time: 30 s

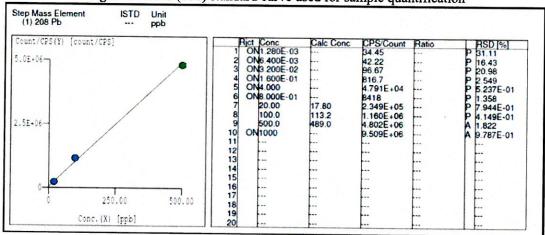
Figure 1: Cadmium (111) standard curve used for sample quantification



Step Mass Eler (1) 75 As CPS/Count Ratio
70.00
65.56
66.67
190.0
3603
745.6
1.701E+04
0.352E+04
3.921E+05
7.458E+05 P 14 29 P 32 69 P 6 662 P 9 283 P 4 747 P 11.39 P 1.353 P 8 136E-01 P 1.493 P 6.403E-01 Count/CPS(Y) [count/CPS] ON1.280E-03 ON6.400E-03 ON3.200E-02 5.0E+05-23 4 5 6 7 8 9 10 11 12 13 14 15 16 17 ON3.200E-02 ON1.600E-01 ON4.000 ON8.000E-01 20.00 100.0 500.0 ON1000 ON---19.34 104.0 496.7 8.136E-01 1.493 6.403E-01 2.5E+05-250.00 500.00 18

Figure 2. Arsenic (75) standard curve used for sample quantification





Standard Preparations for Volatile Analytes for GC-MS/FID Analysis

Conc.(X) [ppb]

Acrylonitrile, ethyl acrylate, styrene, (≥99% Reagent Plus)	Analytical standards, unless otherwise indicated were used to prepared, $100\mu L$ of standard with 9.9mL of Methanol	
1,3-Butadiene	200 μg/mL in Methanol	
Bisphenol A, 97%	501.5mg of Bisphenol A was accurately weighed into a scintillation vial and dissolved in 10mL of Methanol to make 5000ppm Bisphenol A Standard.	
Chloromethane	100 ppm, 50 ppm and 10 ppm chloromethane standard solutions were prepared by diluting the chloromethane stock standard (200 µg/mL in Methanol) in methanol.	
Vinyl chloride	A working standard of 200 μ g/mL of Vinyl Chloride was prepared by diluting 100 μ L of stock solution (Vinyl Chloride, 2000 μ g/mL in Methanol) in 900 μ L of methanol. A standard series of Vinyl Chloride standards (100 μ g/mL, 20 μ g/mL, 4 μ g/mL, 0.8 μ g/mL and 0.16 μ g/mL) was prepared by 5x serial dilution with methanol.	

A 100ppm standard mix Z was prepared by adding 1mL of each of 1000ppm acrylonitrile, ethyl acrylate, and styrene into a scintillation vial, followed by $200\mu L$ of each of 5000ppm bisphenol A, and then mixed with 4.6mL of methanol.

A 50ppm standard mix Y was prepared by adding $50\mu L$ of each of 200ppm chloromethane and 1, 3-butadiene into a glass vial inset in a 2mL GC sampling vial, and then mixed with $90\mu L$ of methanol.

Head space and wipe extracts analyses were performed with the below specified GC/MS and GC/FID method parameters for respective analytes with an injection volume of 0.5 mL performed via manual injection.

Gas Chromatography Flame Ionization Detector (GC/FID) Analysis

Analytes:

Acrylonitrile, ethyl acrylate, styrene, 1,3-butadiene, and bisphenol A

Apparatus:

Agilent 6890N Gas Chromatograph

Agilent 5973 Network Quadrupole Mass Spectrometer

Injection Volume:

 $1.0 \mu L$

Injection Mode: Column:

Splitless Agilent DB-5ms, 30 m \times 0.32 mm ID, 1 μm

Oven:

150 - 300 °C

Gas Chromatography Mass Spectrometry (GC/MS) Analysis

Analytes:

Chloromethane and vinyl chloride screening

Apparatus:

Agilent 6890N Gas Chromatograph

Agilent 5973 Network Quadrupole Mass Spectrometer

Injection Volume:

 $1.0 \mu L$

Injection Mode:

Splitless Agilent DB-5ms, 30 m \times 0.32 mm ID, 1 μm

Column: Oven:

35 - 240 °C

Detector:

Mass 52.00 and 50.00 with dwell time 100 milliseconds for chloromethane mass

64.00 and 62.00 with dwell time 100 milliseconds for vinyl chloride

Figure 4. Chromatogram of Acrylonitrile Standard peak showing retention time at 3.3min

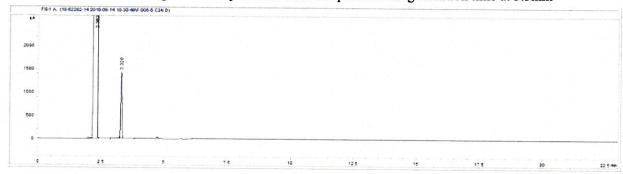


Figure 5. Chromatogram of Chloroform Standard peak showing retention time at 5.5min

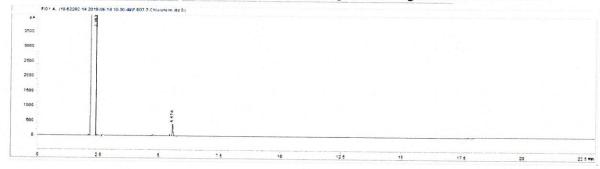


Figure 6. Chromatogram of Ethyl Acrylate Standard peak showing retention time at 7.3min

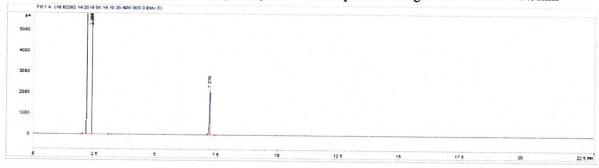


Figure 7. Chromatogram of Styrene Standard peak showing retention time at 10.3min

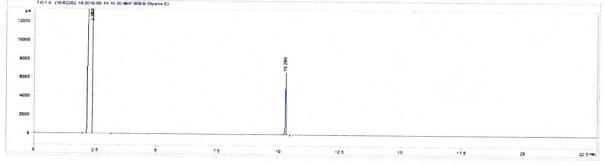


Figure 8. Chromatogram of 1,3-Butadiene Standard peak showing retention time at 15.2min

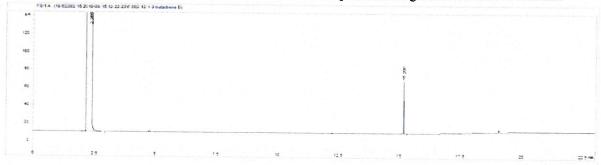


Figure 9. Chromatogram of Bisphenol A Standard peak showing retention time at 19.2min

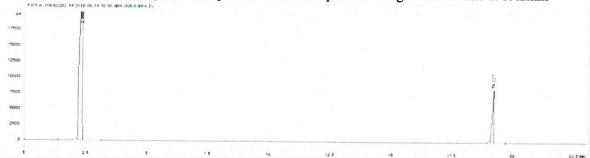


Figure 10. Chromatogram Standard mix Y

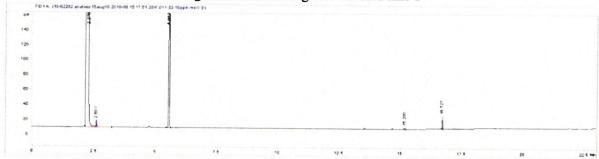


Figure 11. Chromatogram Standard mix Z

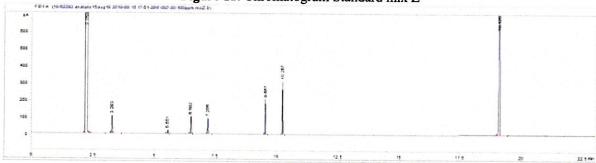
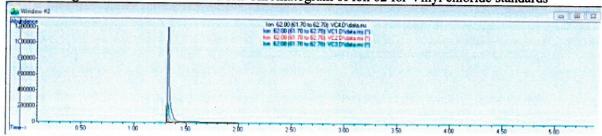


Figure 12. GC-MS extracted Ion Chromatogram of ion 62 for Vinyl chloride standards



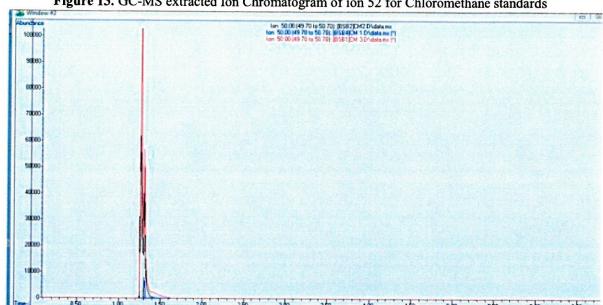


Figure 13. GC-MS extracted Ion Chromatogram of ion 52 for Chloromethane standards

Standard Preparation for Phthalate Analysis

The standard calibration mix of phthalate calibration mix (benzyl butyl phthalate (85-68-7), bis(2 ethylhexyl)phthalate (117-81-7), di-nbutyl phthalate (84-74-2)diethylphthalate dimethylphthalate (131-11-3), di-n-octyl phthalate (117-84-0)) of each 2000 µg/mL was diluted as follows:

Standard Label	Volume of concentrate	Volume of Dichloromethane	Phthalate concentration (ppm) 769.2	
Phthalate Std 1	$500 \mu L$ of the standard mix	800 μL		
Phthalate Std 2	500 μL of the std 1	800 μL	295.9	
Phthalate Std 3	500 μL of the std 2	800 μL	113.8	
Phthalate Std 4	500 μL of the std 3	800 μL	43.8	
Phthalate Std 5	500 μL of the std 4	800 µL	16.8	

Gas Chromatography Mass Spectrometry (GC/MS) Analysis

Analytes:

Phthalate Screening

Apparatus:

Agilent 6890N Gas Chromatograph

Agilent 5973 Network Quadrupole Mass Spectrometer

Injection Volume:

1.0 µL

Injection Mode:

Splitless

Column:

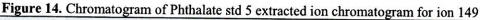
Agilent DB-5ms, 30 m \times 0.32 mm ID, 1 μ m

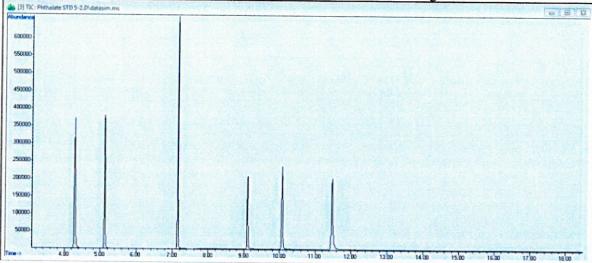
Oven:

150 - 300 °C

Detector

Mass 149.00 and 163.00 with Dwell time 100 milliseconds





Polyaromatic Hydrocarbons (PAHs)

Methods:

EPA 3580 (Wipe); EPA 8270 (analytical method by GC-SIM).

Analytes:

Acenaphthene, acenaphthylene, anthracene, benzo(a)anthracene, benzo(a)pyrene, benzo(b)fluoranthene, benzo(g,h,i)perylene, benzo(k)fluoranthene, chrysene,

dibenz(a,h)anthracene, dibenzofuran, fluoranthene, fluorene, indeno(1,2,3-cd)pyrene,

naphthalene, phenanthrene, pyrene

Chlorinated paraffin Analysis

The presence of chlorinated paraffins in wipe extract was screened with Liquid chromatography Mass spectrometry per method specifications given below.

LC-MS System Components

Pump/Autosampler:

Agilent HPLC 1100 MS

Detector:

API 2000

Integration:

Analyst Software (Version 1.5.1)

HPLC Operation Conditions

Injection Mode:

Flow injection without column

Mobile phase flow:

0.4 mL/min

Mobile phase: Injection volume: Chloroform 20 µL

Column heater Temperature:

Ambient temperature

Sample Tray Temperature:

Ambient temperature

MS Operation Conditions

Polarity: Negative
Mass scan range: 200-1000 Da

Scan time (seconds): 0.64 Acquisition period (Min): 3 Declustering potential (DP): -50 Entrance potential (EP): -7 Focusing potential (FP): -350 Nebulization Gas (NEB): 15 Curtain gas (CUR): 15 IonSpray voltage (IS): -4200 Temperature (TEM): 550 Interface heater: On Scan type: Q1 scan

Ion source: APCI TurboSpray

Resolution Q1: Unit

Appendix B- Sample Chromatograms

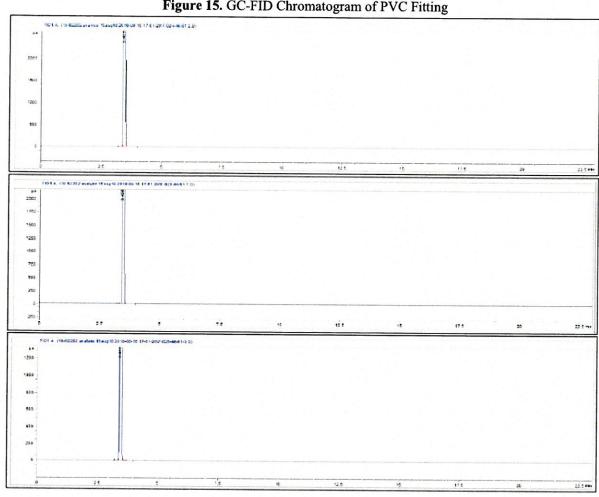


Figure 15. GC-FID Chromatogram of PVC Fitting

Figure 16. GC-MS extracted Ion Chromatogram of ion 62 for Vinyl chloride analysis for PVC fitting repetitions overlapped with Vinyl chloride standard

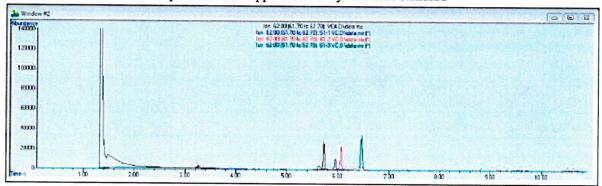


Figure 17. GC-MS extracted Ion Chromatogram of ion 52 for chloromethane analysis for sample PVC fitting, repetitions overlapped with chloromethane standard

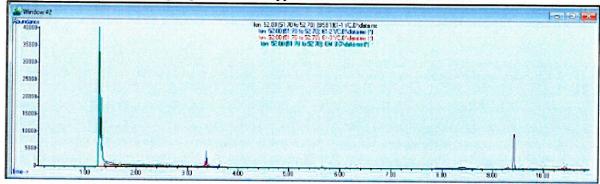
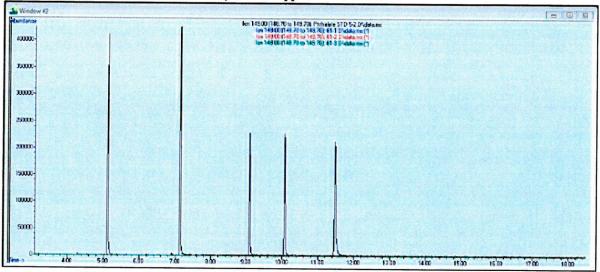
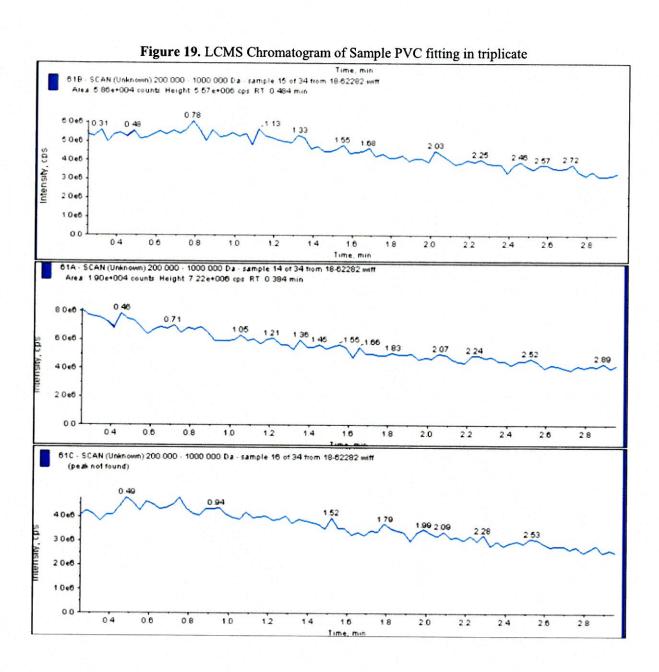


Figure 18. Extracted ion chromatogram for ion 149 of sample PVC fitting, triplicates for Phthalate analysis overlapped with standard 5





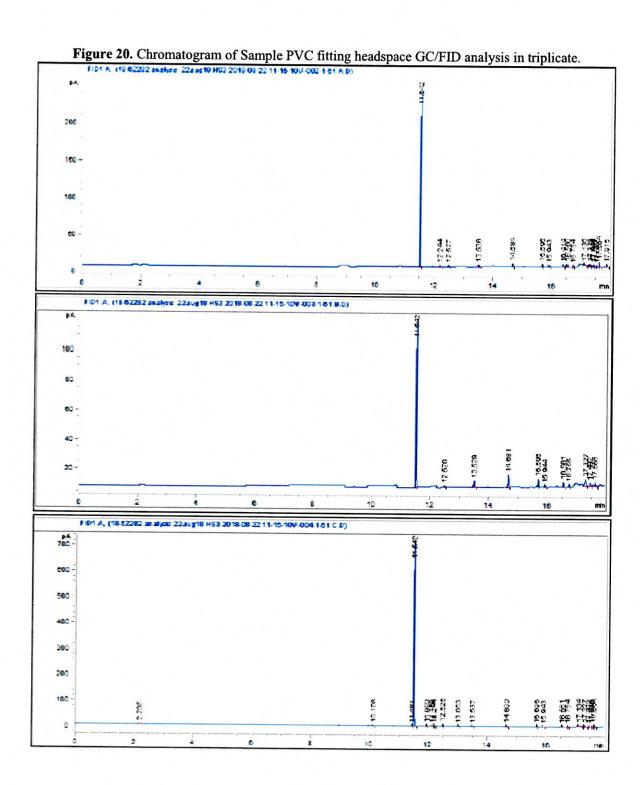
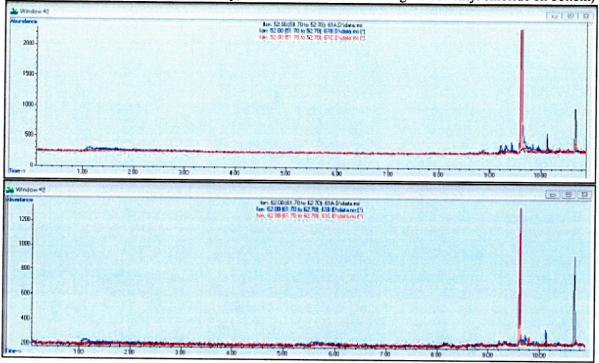


Figure 21. Chromatogram of Sample PVC fitting, headspace GC/MS analysis in triplicate. (Extracted Ion chromatogram for chloromethane on top, and Extracted Ion chromatogram for vinyl chloride on bottom)



Appendix C- Safe Harbor Estimates & Dermal Absorption Rates

Table 17. Safe Harbor Estimates

Chemical	Safe Harbor Type	Value (μg/day)	Basis
Methyl chloride	MADL	1800 (inhalation)	Based on the US EPA RfC of 0.09 mg/m³ and a 20 m³/day inhalation rate, resulting in 1.8 mg/d, or 1800 µg/d threshold exposure for inhalation. See https://oehha.ca.gov/media/downloads/crnr/mectoxrev.pdf
1,3-Butadiene	MADL	40 (inhalation)	Based on the US EPA RfC of 0.002 mg/m³ and an inhalation rate of 20 m³/day, resulting in 0.04 mg/day, or 40 µg/day threshold exposure for inhalation: See https://www.epa.gov/sites/production/files/2016-08/documents/13-butadiene.pdf
Bisphenol A	MADL	0.3 (oral)	Based upon a 10% (rounded from 8.6%) dermal penetration rate that was applied with the 3 μg/day dermal Safe Harbor limit. Assuming 100% absorption for the oral route of exposure results in an estimated Safe Harbor threshold of 0.3 μg/day for oral exposure. See EFSA. Scientific opinion on the risks to public health related to the presence of bisphenol A (BPA) in foodstuffs—executive summary. EFSA J. 2015;13(1):3978.
Ethyl acrylate	NSRL	5.8	Based on the US EPA cancer slope factor of 0.048 (mg/kg/day) ⁻¹ applied against a 10 ⁻⁵ lifetime adjusted risk level, resulting in a 5.8 µg/day estimated Safe Harbor limit value. See https://www.epa.gov/sites/production/files/2016-09/documents/ethyl-acrylate.pdf

Table 18. Dermal Absorption Rates

Chemical	Dermal Uptake Rate (ug/cm2/hr)	Dermal Uptake Rate (%)1	Basis
Acrylonitrile	60.0000	1.0	US EPA; Ambient Water Quality Criteria Doc: Acrylonitrile (Draft) p.C-17 (1980) (up to 67 ug/cm ² /hr within this assessment, 100% assumed to be absorbed)
Arsenic		0.10	Post, G. Dermal Absorption of Inorganic Arsenic from Water. January 2003. https://www.state.nj.us/dep/dsr/research/dermal-arsenic-whitepaper.pdf (Absorption from water considered worst-case and used as a conservative estimate of absorption).
Bisphenol A		0.086	EFSA. Scientific opinion on the risks to public health related to the presence of bisphenol A (BPA) in foodstuffs—executive summary. EFSA J. 2015;13(1):3978.
1,3-Butadiene		0.00	Gas at room temperature. Dermal absorption is unlikely per ATSDR Medical Management Guidelines for 1,3-butadiene: https://www.atsdr.cdc.gov/MMG/MMG.asp?id=455&tid=8 Refer to inhaled dose estimations.
Cadmium		0.005	ATSDR, 1999: https://www.atsdr.cdc.gov/csem/csem.asp?csem=6&po=9
Chlorinated Paraffins		0.10	European Commission. JRC.October 1999. Alkanes, C10-13, chloro (Short Chain Length Chlorinated Paraffins). Summary Risk Assessment Report. https://echa.europa.eu/documents/10162/6b80f785-0a37-4f3c-8f9e-5e88242694fa (Dermal absorption expected to be low. 10% used as a default)
Methyl Chloride		0.00	US EPA Provisional Peer-Reviewed Toxicity Values for Chloromethane. December 4, 2012. Colorless gas at room temperature. See inhalation data. https://cfpub.epa.gov/ncea/pprtv/documents/Chloromethane.pdf
Ethyl acrylate		1.00	No specific data available. Dermal penetration is expected per US EPA Hazard Summary document: https://www.epa.gov/sites/production/files/2016 09/documents/ethyl-acrylate.pdf
Lead		0.003	World Health Organization, International Programme on Chemical Safety (ICPS). Environmental Health Criteria No. 165: Inorganic Lead. Geneva: 1995. Available at http://www.inchem.org/documents/ehc/ehc/ehc/ehc165.htm
Phthalates (BBP)		0.050	NICNAS DEHP July 2010
Polyaromatic Hydrocarbons		0.43	Moody, et. al. In vivo and in vitro dermal absorption of benzo(a) pyrene in rat guinea pig, human, and tissue-cultured skin. Journal of Dermatological Science. (9)1: 48-58. January 1995. https://www.sciencedirect.com/science/article/pii/092318119400356J
Styrene	60.0000	1.00	Sullivan, J.B., Krieger G.R. (eds). Clinical Environmental Health and Toxic Exposures. Second edition. Lippincott Williams and Wilkins, Philadelphia, Pennsylvania 1999., p. 1155 (up to 36 ug/cm ² /hr within this assessment, 100% assumed to be absorbed)
Vinyl chloride		0.0003	https://www.ncbi.nlm.nih.gov/books/NBK304420/; https://www.atsdr.cdc.gov/toxguides/toxguide-20.pdf

¹ Relative to subject dermal loading estimations