



## Assessment Report

No. HKGEC1800499202

Date : 03 Oct 2018

AN DIANN ENTERPRISE CO., LTD. / HON MON ENTERPRISE CO., LTD.  
NO. 71, CHNEG CONG ST., GUAN TIAN INDUSTRIAL PARK  
TAINAN CITY 72046, TAIWAN (R.O.C)

The following sample was submitted and identified on behalf of the client as: EVA

SGS Job No. : 4114114 – HK  
SGS Reference No. : KA/2018/80705  
Colour : WHITE  
Assessment Period : 06 Jul 2018 – 07 Sep 2018

Test Requested : Please refer to the result summary.

Test Method & Results : Please refer to next page(s).

Result Summary :

Test Requested	Conclusion
<b>California Proposition 65 Toxicological Risk Assessment</b>	The assessed product is not likely to be at increased risk of adverse health effects and is not subject to the warning label requirement

Comments: The California Proposition 65 Toxicological Risk Assessment was conducted by ToxServices LLC on behalf of SGS.

Signed for and on behalf of  
SGS Hong Kong Limited

Chan Chun Kit, Dickson  
Operation Manager

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Unless otherwise stated the results shown in this test report refer only to the sample(s) tested and such sample(s) are retained for 30 days only.

**CALIFORNIA PROPOSITION 65 TOXICOLOGICAL RISK ASSESSMENT OF  
FOAM INSERT**

**Prepared by:**

**ToxServices LLC**

**September 7, 2018**



1367 Connecticut Ave., N.W., Suite 300  
Washington, D.C. 20036

## TABLE OF CONTENTS

INTRODUCTION .....	1
BASIS OF CALIFORNIA’S PROPOSITION 65 SAFE HARBOR LEVELS .....	1
DESCRIPTION OF TESTED SAMPLES AND TEST RESULTS .....	2
PHYSICAL AND CHEMICAL PROPERTIES OF STYRENE .....	3
PHYSICAL AND CHEMICAL PROPERTIES OF NAPHTHALENE.....	3
EXPOSURE ASSESSMENT .....	4
<i>Exposure by Dermal Contact</i> .....	4
<i>Exposure by Inhalation</i> .....	7
<i>Total Daily Exposure</i> .....	10
SAFE HARBOR DETERMINATION AND RISK ASSESSMENT.....	10
SUMMARY .....	10
DISCUSSION.....	10
REFERENCES .....	12
REPORT APPROVALS.....	14

## TABLE OF FIGURES

Figure 1: Foam Insert.....	2
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## TABLE OF TABLES

Table 1: Chemicals Measured in the Foam Insert .....	2
Table 2: Physical and Chemical Properties of Styrene.....	3
Table 3: Physical and Chemical Properties of Naphthalene.....	3
Table 4: Total Chemical Masses in Foam Insert .....	6
Table 5: Dermal Exposure Calculations for Detected Substances.....	6
Table 6: U.S. EPA Residential Air Volume Values .....	8
Table 7: Default Inhalation Rates .....	9
Table 8: Inhalation Exposure Calculations for Detected Substances .....	9
Table 9: Total Daily Exposure Calculations.....	10
Table 10: Safe Harbor Determination for Detected Substances .....	10

## INTRODUCTION

Analytical testing of a foam shoe insert identified the presence of styrene (CAS #100-42-5) and naphthalene (CAS #91-20-3), chemicals that are included on California's Proposition 65 list of chemicals known to the State to cause cancer or reproductive toxicity (OEHHA 2018a). ToxServices evaluated potential consumer exposure to styrene and naphthalene emitting from the foam insert or measured in its accessible components to determine if estimated exposure levels exceed established Proposition 65 safe harbor levels. Exposure calculations followed risk assessment guidelines established in the California Code of Regulations, 27 CCR §25721<sup>1</sup> and §25821.<sup>2</sup>

Proposition 65 details label warning requirements and drinking water discharge prohibitions for consumer products containing listed substances. However, if an exposure subject to Proposition 65 can be shown to be less than a substance-specific acceptable exposure level, the responsible party has "safe harbor" from the Proposition 65 warning requirement and drinking water discharge prohibition.

In this toxicological risk assessment (TRA), ToxServices puts analytical testing results into context with exposure factors such as dermal absorption, inhalation rate, and anticipated duration of exposure to calculate daily exposure to styrene and naphthalene to determine Proposition 65 compliance status of the foam shoe insert.

## BASIS OF CALIFORNIA'S PROPOSITION 65 SAFE HARBOR LEVELS

As defined by California's Office of Environmental Health and Hazard Assessment (OEHHA), carcinogen safe harbor levels are termed No Significant Risk Levels (NSRLs), while reproductive/developmental toxicant safe harbor levels are termed Maximum Allowable Dose Levels (MADLs). For carcinogens or potential carcinogens, a NSRL is equivalent to an exposure level that results in 1 excess cancer in an exposed human population of 100,000, assuming lifetime exposure at the level in question (27 CCR §25703<sup>1</sup>). The MADL is defined as the maximum no-observable-effect dose level for reproductive/developmental toxicity endpoints in laboratory animals or humans divided by 1,000 (OEHHA 2001, 27 CCR §25803<sup>2</sup>).

For any listed chemical, exposures that are less than the applicable safe harbor values (OEHHA 2018b) exempt responsible parties from Proposition 65 warning requirements. OEHHA has established the following safe harbor levels for styrene and naphthalene:

- Styrene<sup>3</sup>
  - NSRL of 27 µg/day
- Naphthalene<sup>4</sup>
  - NSRL of 5.8 µg/day

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<sup>1</sup> <https://oehha.ca.gov/media/downloads/proposition-65/general-info/regsart7.pdf>

<sup>2</sup> <https://oehha.ca.gov/media/downloads/proposition-65/general-info/regsart8.pdf>

<sup>3</sup> <https://oehha.ca.gov/proposition-65/chemicals/styrene>

<sup>4</sup> <https://oehha.ca.gov/proposition-65/chemicals/naphthalene>

## DESCRIPTION OF TESTED SAMPLES AND TEST RESULTS

The foam insert is used as a therapeutic shoe pad composed of ethylene-vinyl acetate (EVA) (Tsui 2018). The pad is inserted into the shoe(s) to provide the wearer with additional support and comfort. The foam insert has a density of 115-119 kg/m<sup>3</sup> and has a maximum thickness of 7 mm.

Test data were generated by SGS according to their in-house method (RSTS-E&E-CP65-001). Briefly, SGS screened the foam insert for substances listed on California's Proposition 65. Additional details on test conditions are available in SGS report number HKGEC1800499201, Dated July 19, 2018. The tested foam insert is depicted below in Figure 1.



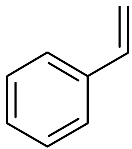
**Figure 1: Foam Insert**

Test results are summarized below in Table 1. Results are provided for each tested component, and include the name of the tested component, its mass, the identity of each Proposition 65 chemical detected in each component, the chemical-specific method detection limit (MDL), and the test result. These test results are presented in units of mg chemical per kg component (mg/kg).

<b>Table 1: Chemicals Measured in the Foam Insert</b>					
<b>Part No.</b>	<b>Part Description</b>	<b>Sample Weight (g)</b>	<b>Detected Prop 65 Listed Substance (CAS No.)</b>	<b>Method Detection Limit (mg/kg)</b>	<b>Result (mg/kg)</b>
1	White Foam	322	Styrene (100-42-5)	0.5	1.7
			Naphthalene (91-20-3)	0.1	0.2

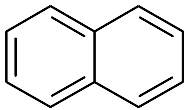
## PHYSICAL AND CHEMICAL PROPERTIES OF STYRENE

Table 2 summarizes selected physical and chemical properties of styrene. The Henry's Law constant of  $2.75 \times 10^{-3}$  atm-m<sup>3</sup>/mole indicates that styrene is volatile from water surfaces and the vapor pressure of 6.4 mm Hg indicates that styrene may volatilize from dry surfaces.

Property	Value	Reference
Molecular formula	C <sub>8</sub> -H <sub>8</sub>	ChemIDplus 2018a
CAS number	100-42-5	ChemIDplus 2018a
Chemical structure		ChemIDplus 2018a
Molecular weight	104 g/mol	ChemIDplus 2018a
Boiling point	145°C	ChemIDplus 2018a
Vapor pressure	6.4 mm Hg at 25°C	ChemIDplus 2018a
Water solubility	310 mg/L at 25°C	ChemIDplus 2018a
Density/specific gravity	0.9016 g/cm <sup>3</sup> at 25°C	HSDB 2014a
log P <sub>ow</sub>	2.95	ChemIDplus 2018a
Henry's law constant	$2.75 \times 10^{-3}$ atm-m <sup>3</sup> /mole at 25°C	ChemIDplus 2018a

## PHYSICAL AND CHEMICAL PROPERTIES OF NAPHTHALENE

Table 3 summarizes selected physical and chemical properties of naphthalene. The Henry's Law constant of  $4.4 \times 10^{-4}$  atm-m<sup>3</sup>/mole indicates that naphthalene is moderately volatile from water surfaces and the vapor pressure of 0.085 mm Hg indicates that naphthalene may volatilize from dry surfaces.

Property	Value	Reference
Molecular formula	C <sub>10</sub> -H <sub>8</sub>	ChemIDplus 2018b
CAS number	91-20-3	ChemIDplus 2018b
Chemical structure		ChemIDplus 2018b
Molecular weight	128 g/mol	ChemIDplus 2018b
Boiling point	217.9°C	ChemIDplus 2018b
Vapor pressure	0.085 mm Hg at 25°C	ChemIDplus 2018b

<b>Property</b>	<b>Value</b>	<b>Reference</b>
Water solubility	31 mg/L at 25°C	ChemIDplus 2018b
Density/specific gravity	1.162 at 20°C	HSDB 2014b
log P <sub>ow</sub>	3.3	ChemIDplus 2018b
Henry's law constant	4.4 x 10 <sup>-4</sup> atm-m <sup>3</sup> /mole at 25°C	ChemIDplus 2018b

## EXPOSURE ASSESSMENT

The consumer will place the foam insert into the shoe(s) prior their being worn and the bottom of the feet will be in contact with the foam insert while the shoes are being used. Additionally, inhalation exposure will occur to chemicals emitted from the foam during use of the shoe and while they are not worn but are stored in proximity to the user. Therefore, ToxServices evaluated dermal and inhalation exposures to styrene and naphthalene present in and emitted from the foam insert. Direct and indirect ingestion of chemicals emitted from or present in the foam insert is unlikely due to the anticipated use of the foam insert and the limited hand dermal contact with the foam insert while placing it into the shoe(s).

The California Code of Regulations (CCR) specifies the methodologies that are to be used to evaluate exposure to chemicals causing cancer or reproductive toxicity. Specifically, exposure to a reproductive toxicant is calculated as the concentration of the chemical in the product (or other applicable medium, such as air or water) times the relevant rate (i.e., pattern and duration) of exposure to that medium (maternal exposure rate for pre-natal toxicities, infant/child exposure rate for post-natal effects). The relevant exposure rate must consider the nature of the chemical's specific adverse effect(s) (27 CCR §25821). That is, the assumption of a short exposure duration is likely appropriate for teratogens, while a longer exposure duration would be more appropriate for a chemical that affects growth rate. Exposure to carcinogens is calculated as the concentration of the chemical in the product (or other applicable medium) times the average daily exposure/intake rate over a 70-year lifetime (27 CCR §25721).

### *Exposure by Dermal Contact*

Exposure via direct dermal contact is the net result of multiple factors, including the initial concentration of the chemical in the material, the amount of the chemical that may realistically be released from the material every day, contact frequency and duration, dermal absorption, and the anticipated durability of the product. ToxServices used the following equation to calculate dermal exposure to styrene and naphthalene:

$$\text{Dermal Exposure} = \text{Total Chemical Mass } (\mu\text{g}) / \text{Product Lifespan (days)} * \text{Averaging Time}$$

*Equation One*

This approach is based upon United States Environmental Protection Agency (U.S. EPA) methodologies for dermal risk assessment (U.S. EPA 2007). Values selected for each variable are explained individually below. ToxServices conservatively assumed 100% dermal absorption for styrene and naphthalene and that the foam inserts are used continually (24 hours/day). These conservative assumptions result in over-estimates for the anticipated dermal exposures to styrene and naphthalene from the foam insert.

### Total Chemical Mass

The total chemical mass can be derived using the following formula:

**Total Chemical Mass** = Chemical Concentration ( $\mu\text{g/g}$ ) \* Foam Density ( $\text{g/cm}^3$ ) \* Foam Thickness (cm) \* Foam Area ( $\text{cm}^2$ )

*Equation Two*

Each of these parameters is discussed below.

### *Chemical Concentration*

As discussed above, the foam insert contains 1.7 mg styrene/kg foam and 0.2 mg naphthalene /kg. These values are equivalent to 1.7  $\mu\text{g/g}$  and 0.2  $\mu\text{g/g}$ , respectively.

### *Foam Density*

As identified previously, the density of the foam is specified as 115-119  $\text{kg/m}^3$  (Tsui 2018). For the exposure calculations, ToxServices used the value of 119  $\text{kg/m}^3$  as a worst-case scenario. This is equivalent to 0.119  $\text{g/cm}^3$  as derived below:

$$119 \text{ kg/m}^3 * 1,000 \text{ g/kg} * (1 \text{ m} / 100 \text{ cm})^3 = 0.119 \text{ g/cm}^3$$

### *Foam Thickness*

The foam thickness has been identified as 7 mm (Tsui 2018). This is equivalent to 0.7 cm (7 mm \* 1 cm/10 mm = 0.7 cm).

### *Foam Surface Area (SA)*

The area of the foam insert used will be dependent on the size of the shoe to which it is inserted. ToxServices conservatively assumed the consumer is an adult that wears an extra wide (4E) American size 13 shoe. Such a shoe has a length of 29.5 cm and width of 12.1 cm.<sup>5</sup> Although the foam insert is not likely to be perfectly rectangular, ToxServices conservatively calculated the area of the shoe as 387.2  $\text{cm}^2$  (32 cm \* 12.1 cm = 387.2  $\text{cm}^2$ ). ToxServices assumed that the area of the foam insert is the same as the area of the shoe and used the value of 387.2  $\text{cm}^2$  as the area of the foam insert.

<sup>5</sup> <http://www.sizecharter.com/clothing-fit-and-measurement/understanding-shoe-sizing>



The total masses of styrene and naphthalene present in a foam insert with the above characteristics is presented in Table 4, below

<b>Detected Prop 65 Listed Substance (CAS No.)</b>	<b>Detected Concentration (µg/g)</b>	<b>Foam Density (g/cm<sup>3</sup>)</b>	<b>Foam Thickness (cm)</b>	<b>Foam SA (cm<sup>2</sup>)</b>	<b>Total Chemical Mass (µg)</b>
Styrene (100-42-5)	1.7	0.119	0.7	387.2	54.8
Naphthalene (91-20-3)	0.2	0.119	0.7	387.2	6.5

### Product Lifespan

Chemicals present in footwear inserts, including styrene and naphthalene, will be continuously released over a period of time, which can be no greater than the estimated lifetime of the article. The lifespan of shoe inserts depends on several factors, including insert quality, insert material, body weight, frequency of use, and intensity of activities performed while using the inserts.<sup>6</sup> For typical use, inserts should last 6-9 months, while intense or frequent use may require that inserts be replaced every 3-6 months. ToxServices assumed that the inserts will last for 3 months. Thus, styrene and naphthalene would migrate from the foam insert over 90 days (30 days/month \* 3 months).

### Averaging Time

For carcinogens, Proposition 65 assumes by default that exposures will occur for an individual's entire lifetime, defined as 70 years. As it is unlikely that an individual will use the same style of insert for their entire lifetime, an "averaging time", which normalizes a shorter exposure duration to a 70-year lifetime exposure equivalent, of 10 years/70 years (0.14) is included in the exposure calculations.

### Dermal Exposure Calculations

Dermal exposures for each of the detected chemicals were calculated using Equation 1 above and are summarized below in Table 5.

<b>Detected Prop 65 Listed Substance (CAS No.)</b>	<b>Total Chemical Mass (µg)</b>	<b>Product Lifespan (days)</b>	<b>Avging Time</b>	<b>Dermal Exposure (µg/day)</b>
Styrene (100-42-5)	54.8	90	0.14	0.085
Naphthalene (91-20-3)	6.5	90	0.14	0.010

<sup>6</sup> <https://www.theinsolestore.com/blog/how-often-should-i-replace-my-insoles-arch-supports/>; <https://www.drscholls.com/faqs/>

### ***Exposure by Inhalation***

Human exposure to a substance by inhalation is a function of the net effect of multiple environmental, physicochemical, and physiological variables. In the absence of sufficient exposure to a substance, there will be no adverse health effect. Hence, the toxicity potential is directly related to the magnitude, duration, and route of exposure. This is the fundamental toxicological concept that underlies the establishment of “safe harbor” levels for substances listed on Proposition 65, and also underlies risk values such as the reference dose/concentration. For substances that may be inhaled, it is imperative to identify and characterize the potential for inhalation exposure in order to accurately characterize human health risks.

Airborne chemicals travel through the air at a certain rate, for a finite period of time, and for a certain distance, all of which are determined by physicochemical properties (which govern transport through various media) and by environmental conditions, such as air flow. Humans may inhale airborne substances of various physical states, such as gases, vapors, and aerosols, the aerodynamic behavior and toxicological properties of which are all different. A vapor is a substance in the gas phase, and vapors can be emitted from solids or liquids under the right temperature and pressure. Once in the respiratory tract, gases, vapors, and soluble particles may be absorbed into the local lymph nodes and/or into the systemic circulation. Highly water soluble and reactive vapors dissolve in the upper respiratory tract and can be absorbed systemically, while less water soluble/reactive vapors can reach the lower airways to exert local (e.g., irritation) and systemic effects (Gad 2006, Inchiosa 2006).

Human exposure by inhalation is a function of many variables, such as a substance’s volatility, the properties of the matrix/material in which it is present, the likelihood that it will migrate from the matrix/material to the air, the duration of exposure, and breathing rate. Many of these exposure determinants can be measured or estimated. In the absence of product-specific data, published data, default values, and/or conservative assumptions may be used to obtain conservative, health-protective estimates of exposure. Whenever available and plausible, higher-than-likely values for exposure determinants are included in the chemical exposure calculations as a conservative approach.

**Inhalation Exposure ( $\mu\text{g}/\text{day}$ )** = Total Chemical Mass ( $\mu\text{g}$ ) / Air Volume ( $\text{m}^3$ ) / Product Lifetime (days) \* Inhalation Rate ( $\text{m}^3/\text{day}$ ) \* Duration of Exposure (days) \* Averaging Time

***Equation Three***

Each variable used to calculate exposure via inhalation is explained in detail below. Although body weight is typically included as a variable in exposure assessments, since Proposition 65 safe harbor values are expressed in terms of “mass per day”, it was not necessary to include body weight. ToxServices conservatively assumed 100% of the inhalation exposure for styrene and naphthalene would be absorbed for the inhalation exposure calculations.

### Total Chemical Mass

As discussed above, ToxServices calculated the total mass of styrene and naphthalene in a foam insert designed to fit an extra wide (4E) American size 13 shoe as 54.8 µg and 6.5 µg, respectively.

### Air Volume

Published estimates for the average air volumes for residential spaces with the indicated dimensions are tabulated below in Table 6.

<b>Room Dimension</b>	<b>Static Air Volume</b>
12 x 15 foot room – 8 foot ceiling	41 m <sup>3</sup>
4 x 12 foot room – 8 foot ceiling	11 m <sup>3</sup>
Adapted from U.S. EPA (2011), Table 19-11	

As room dimensions vary, ToxServices included the smaller value of 11 m<sup>3</sup> for the 4 x 12 foot room as a conservative estimate, as the air concentration (C) of a given mass (M) of a chemical is inversely related to air volume (V):  $C = M / V$ . Since the foam insert may be used in small rooms in the home or office, the use of a small air volume is an additional conservative assumption, as these spaces are not likely to be smaller than a 4 x 12 foot room.

Air change rate is also an important variable, as air flow (i.e., the continuous influx and efflux of air in a space) essentially increases the effective volume of air into which a substance may be emitted, which serves to decrease the air concentration available for inhalation: over a given time period, a proportion of a space's air volume is removed (assumed to be primarily through residential ventilation systems) and is replaced by influx of an equal volume of air. The rate of new air influx equals the rate of existing air efflux such that the overall volume of air in the space remains relatively constant, but the composition of the air is continuously mixing.

The U.S. EPA (2011) provides estimates for the air change rate, which represents the rate at which air is removed from a space and is replaced by fresh air in that space, of various building types. For homes and offices, the U.S. EPA's default value for air change rates are 0.45/hr and 1.5/hr, respectively. However, the California Department of Public Health (CDPH) identifies an effective outdoor air change rate of 0.23/hr for new single-family residences and 0.68/hr for private offices (CDPH 2017). Since the CDPH values are more conservative than the U.S. EPA's values, ToxServices included the lower air change rates reported by CDPH as a conservative approach. Thus, the actual air volume into which a substance emits is increased by a factor of 0.23, essentially increasing the air volume into which a chemical may emit. To account for this, ToxServices adjusted the above air volume of 11 m<sup>3</sup> by a factor of 0.23/hour, the lower of the two air change rates identified by CDPH, for an effective air volume of 13.53 m<sup>3</sup> ( $11 \text{ m}^3 * 1.23 = 13.53 \text{ m}^3$ ).

### Product Lifespan

As discussed above, ToxServices used a lifespan of 90 days (30 days/month \* 3 months) for the foam insert.

### Inhalation Rate

OEHHA (2015) recommends age-specific exposure calculations for cancer risk assessments; however, 27 CCR §25721 specifies inhalation rates for calculation of exposure under Proposition 65. These latter values are provided below in Table 7, for consistency with NSRL/MADL development processes. ToxServices selected the inhalation rate of 20 m<sup>3</sup>/day as a conservative approach, as this results in highest estimates of exposure.

<b>Age</b>	<b>Inhalation Rate</b>
0 – 2 years	4 m <sup>3</sup> /day
2 – 10 years	15 m <sup>3</sup> /day
10 – 18 years	20 m <sup>3</sup> /day
> 18 years	20 m <sup>3</sup> /day
Pregnant women	20 m <sup>3</sup> /day

### Duration of Exposure

No data on footwear use was identified aside from physical activity and exercise (U.S. EPA 2011). Therefore, ToxServices conservatively assumed that the shoes + inserts could be worn during a full work shift of 8 hours, equivalent to 0.33 days (8 hours \* 1 day/24 hours = 0.33 days).

### Averaging Time

As discussed above, ToxServices used an averaging time of 10 years/70 years (0.14) is included in the exposure calculations for the foam insert.

### Inhalation Exposure Calculations

Exposure estimates for the four measured volatile chemicals were calculated using Equation Three above and are provided below in Table 8.

<b>Detected Prop 65 Listed Substance (CAS No.)</b>	<b>Total Mass (µg)</b>	<b>Air Volume (m<sup>3</sup>)</b>	<b>Product Lifespan (days)</b>	<b>Inhalation rate (m<sup>3</sup>/day)</b>	<b>Duration of Exposure (days)</b>	<b>Avging Time</b>	<b>Inhalation Exposure (µg/day)</b>
Styrene (100-42-5)	54.8	13.53	90	20	0.33	0.14	0.042
Naphthalene (91-20-3)	6.5	13.53	90	20	0.33	0.14	0.005

### ***Total Daily Exposure***

The total daily exposure to styrene and naphthalene emitting from or present in the foam inserts is the sum of the dermal and inhalation exposures. The total daily exposure calculation is presented in Table 9, below.

<b>Table 9: Total Daily Exposure Calculations</b>			
<b>Detected Prop 65 Listed Substance (CAS No.)</b>	<b>Dermal Exposure (µg/day)</b>	<b>Inhalation Exposure (µg/day)</b>	<b>Total Exposure (µg/day)</b>
Styrene	0.085	0.042	0.127
Naphthalene	0.010	0.005	0.015

### **SAFE HARBOR DETERMINATION AND RISK ASSESSMENT**

ToxServices compared the exposure estimates calculated herein to established Proposition 65 safe harbor NSRLs and MADLs (OEHHA 2018b) to determine whether or not the foam insert has safe harbor from Proposition 65 requirements and to assess health risks. For styrene and naphthalene, exposures arising from dermal exposure and from inhalation exposure were summed to obtain total daily exposures.

The results of the Proposition 65 safe harbor determination for all detected substances are provided below in Table 10.

<b>Table 10: Safe Harbor Determination for Detected Substances</b>		
<b>Detected Prop 65 Listed Substance (CAS No.)</b>	<b>Exposure (µg/day)</b>	<b>Applicable Safe Harbor Level (µg/day)</b>
Styrene (100-42-5)	0.127	NSRL: 27
Naphthalene (91-20-3)	0.015	NSRL: 5.8

The results of the safe harbor determination show that exposure to the detected substances emitted from or present in the foam insert does not exceed available, applicable Proposition 65 safe harbor levels.

### **SUMMARY**

The above calculations demonstrate that total exposure to the two Proposition 65-listed substances detected in or emitting from the foam insert do not exceed their respective Proposition 65 safe harbor values.

### **DISCUSSION**

As demonstrated through this report, exposure is the net effect of multiple variables. Wherever possible, ToxServices included conservative assumptions and default values for these variables as a health-protective approach. For example, ToxServices assumed that styrene and naphthalene would be released at a constant, linear rate over the anticipated life-span of the foam insert. An additional conservative assumption is that the

consumer would not wear socks and would be in direct dermal contact with the foam insert during its use. It is unlikely that an individual would use the foam insert in this way without socks while at work or in the home; therefore, the dermal exposure calculation represents a conservative estimate of consumer dermal exposure. With respect to inhalation, this assessment assumed that styrene and naphthalene would be emitted into a small air volume. In reality, the consumer is likely to occupy indoor spaces with larger air volume or be outdoors where the concentration of emitted styrene and naphthalene is likely to be significantly less than those calculated herein.

Collectively, the conservative assumptions used in this report indicate that the exposure values calculated herein are over-estimates. For styrene and naphthalene in the foam insert, this provides additional assurance that applicable safe harbor values are not likely to be exceeded and that consumers using the foam insert are not at increased risk of carcinogenicity from styrene and naphthalene following use of the foam insert.

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REPORT APPROVALS

<u>AUTHORS/REVIEWER</u>	<b>AUTHORS</b>	Zachariah Guerrette, Ph.D., D.A.B.T. Toxicologist ToxServices LLC
	<b>SENIOR REVIEWER</b>	Margaret H. Whittaker, Ph.D., M.P.H., CBiol., F.R.S.B., E.R.T., D.A.B.T. Managing Director and Chief Toxicologist ToxServices LLC

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This report has been finalized and authorized for release to the client.



Margaret H. Whittaker, Ph.D., M.P.H., CBiol., F.R.S.B., E.R.T., D.A.B.T.  
Managing Director and Chief Toxicologist  
ToxServices LLC