Assessment Report

No.: T31820301590SC Date: DEC 20, 2018

SHEDRAIN CORP.
8303 NE KILLINGSWORTH,PORTLAND,CLACKAMAS,OR,97220,UNITED STATES

The following samples were submitted and identified on behalf of the client as:
AOAC 46" UNBELIEVABRELLA COMPACT

SGS Case No.	:	CA318202927599
Style / Item No.	:	#2299 (COLOR: OCEAN BLUE)
Manufacturer	:	#32
Buyer	:	SHEDRAIN CORP.
Country of Origin	:	CHINA
Country of Destination	:	UNITED STATES
Sample Receiving Date	:	DEC 07, 2018
Test Performing Date	:	DEC 07 – 20, 2018

Test Requested : Please refer to the result summary.

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

Result Summary :

Test Requested	Conclusion
California Proposition 65 Toxicological Risk Assessment	**The assessed product is not subjected to warning label requirement and exposure will not result in increased risk of adverse health effects**

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 Ltd.

Che Wai Leuk, Jerry
Technical Manager

FINAL

CALIFORNIA PROPOSITION 65 TOXICOLOGICAL RISK ASSESSMENT OF SHEDRAIN CORPORATION'S AOAC 46" UNBELIEVABRELLA™ COMPACT REVERSE UMBRELLA

Prepared by:

ToxServices LLC

19 December 2018

TOXSERVICES TOXICOLOGY RISK ASSESSMENT CONSULTING

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

CONTAINS CONFIDENTIAL BUSINESS INFORMATION

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INTRODUCTION

Analytical testing of ShedRain Corporation's AOAC 46" UnbelievaBrella™ Compact Reverse Umbrella identified several chemicals 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 listed chemicals, specifically heavy metals, plasticizers, and other organic substances measured in the UnbelievaBrella™ to determine if estimated exposure exceeds established Proposition 65 safe harbor levels. Exposure calculations followed risk assessment guidelines established in the California Code of Regulations, 27 CCR §25721[1] and §25821.[2]

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 and anticipated duration of exposure to calculate daily exposure to the detected Proposition 65-listed chemicals to determine Proposition 65 compliance status of the UnbelievaBrella™ .

BASIS OF CALIFORNIA'S PROPOSITION 65 SAFE HARBOR LEVELS

As defined by California's Office of Environmental Health 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[1]). 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[2]).

For any listed chemical, exposures that are less than the applicable safe harbor values (OEHHA 2018b) exempt responsible parties from Proposition 65 warning requirements. The OEHHA-established safe harbor values for the detected Proposition 65-listed chemicals in ShedRain Corporation's AOAC 46" UnbelievaBrella™ Compact Reverse Umbrella are:

Table 1: Safe Harbor Levels for Proposition 65 Chemicals Detected in AOAC 46" UnbelievaBrella™ Compact Reverse Umbrella (SGS 2018)

Chemical (CAS No.)	Safe Harbor Level	Reference
Acrylonitrile (107-13-1)	NSRL: 0.7 µg/day	OEHHA 2018b
Antimony oxide (antimony trioxide)* (1309-64-4)	NSRL: 0.28 µg/day	Appendix A
Benzene (71-43-2)	NSRL: 6.4 µg/day (oral) and 13 µg/day	OEHHA 2018b

[1] https://oehha.ca.gov/media/downloads/proposition-65/general-info/regsart7.pdf
[2] https://oehha.ca.gov/media/downloads/proposition-65/general-info/regsart8.pdf

Table 1: Safe Harbor Levels for Proposition 65 Chemicals Detected in AOAC 46" UnbelievaBrella™ Compact Reverse Umbrella (SGS 2018)		
Chemical (CAS No.)	**Safe Harbor Level**	**Reference**
	(inhalation)	
Bisphenol A (BPA) (80-05-7)	MADL: 3 µg/day (dermal) and 52 (oral) (female reproductive toxicity)	OEHHA 2018b; Appendix B
1,3-Butadiene (106-99-0)	NSRL: 0.4 µg/day	OEHHA 2018b
Di-n-butyl phthalate (DBP) (84-74-2)	MADL: 8.7 µg/day (developmental toxicity, male and female reproductive toxicity)	OEHHA 2018b
Di(2-ethylhexyl)phthalate (DEHP) (117-81-7)	NSRL: 310 µg/day MADL: 410 µg/day (adult oral exposures, developmental toxicity, male reproductive toxicity)	OEHHA 2018b
Ethylbenzene (100-41-4)	NSRL: 41 µg/day	OEHHA 2018b
Formaldehyde (gas) (50-00-0)	NSRL: 40 µg/day	OEHHA 2018b
Naphthalene (91-20-3)	NSRL: 5.8 µg/day	OEHHA 2018b
Nickel (metallic) (7440-02-0) and nickel compounds	NSRL: 1.18 µg/day	Appendix C
Styrene (100-42-5)	NSRL: 27 µg/day	OEHHA 2018b
Toluene (108-88-3)	MADL: 7,000 µg/day; developmental toxicity	OEHHA 2018b

Since not all listed chemicals have established safe harbor NSRLs or MADLs (e.g., antimony and nickel), ToxServices utilized published cancer slope factors, inhalation unit risk values, or other peer-reviewed data, as available, to derive screening-level NSRLs or MADLs that served as the basis for safe harbor determinations. The methods used to derive NSRLs/MADLs for antimony, BPA, and nickel are summarized in Appendices A,B, and C, respectively. Additionally, as some listed chemicals have more than one safe harbor value, ToxServices selected either the lowest (i.e., most conservative) value or the safe harbor value associated with the most relevant exposed population and route of exposure as the comparator in this assessment.

As no direct oral exposures to these chemicals are expected following the anticipated consumer uses of the UnbelievaBrella™, ToxServices evaluated the dermal, indirect oral, and, for volatile chemicals, inhalation exposures to the detected chemicals present in the UnbelievaBrella™ and compared the combined dermal, indirect oral, and inhalation exposure levels, as appropriate for each chemical, to the applicable safe harbor level for each detected chemical.

DESCRIPTION OF TESTED SAMPLES AND TEST RESULTS

ShedRain Corporation's AOAC 46" UnbelievaBrella™ Compact Reverse Umbrella is a retractable umbrella. A total of 27 components were analyzed for Proposition 65-listed chemicals. Pictures of the finished product and its tested components are provided in Figures 1-11, below.

Figure 1: Finished Product (SGS 2018)

Figure 2: Blue Fabric Jacket (SGS 2018)

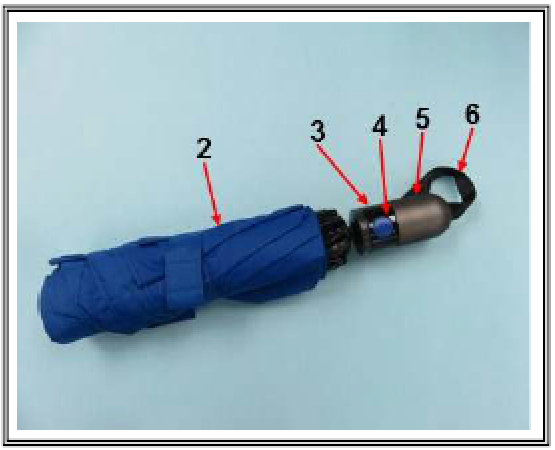

Figure 3: Blue Fabric Canopy, Handle Outer Case, Blue Plastic Button, Dark Gray Handle Cap, and Blue Fabric Loop (SGS 2018)

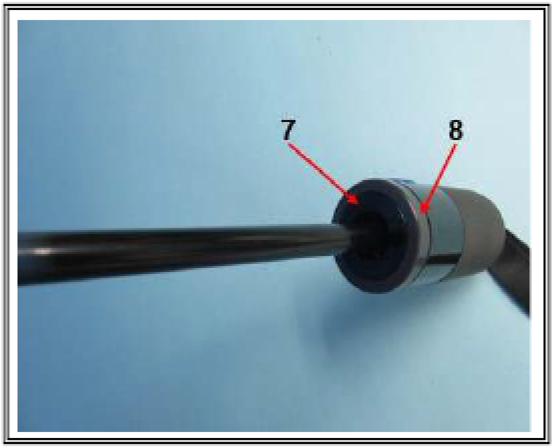

Figure 4: Black Plastic Handle Inner Case, and Gray Plastic Ring (SGS 2018)

Figure 5: Plastic End Cap (SGS 2018)

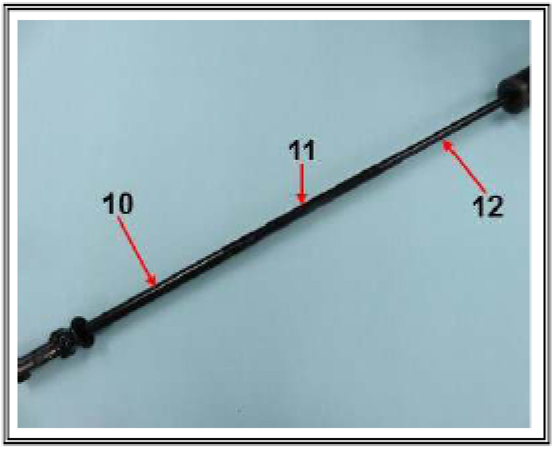

Figure 6: Large, Middle, and Small Shaft (SGS 2018)

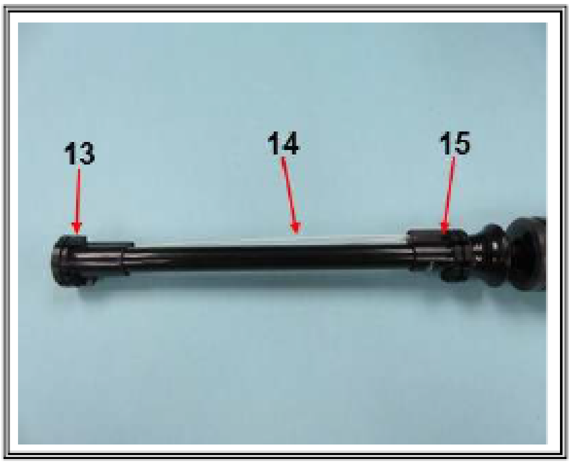

Figure 7: Shaft End, White Fabric Thread, and Black Plastic Runner (SGS 2018)

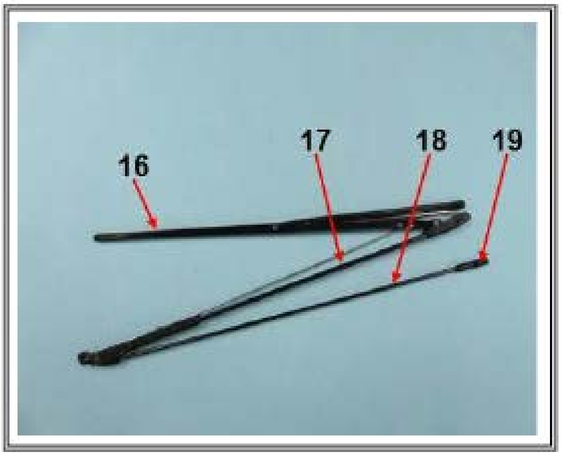

Figure 8: Black Plastic Frame, Joints, and End (SGS 2018)

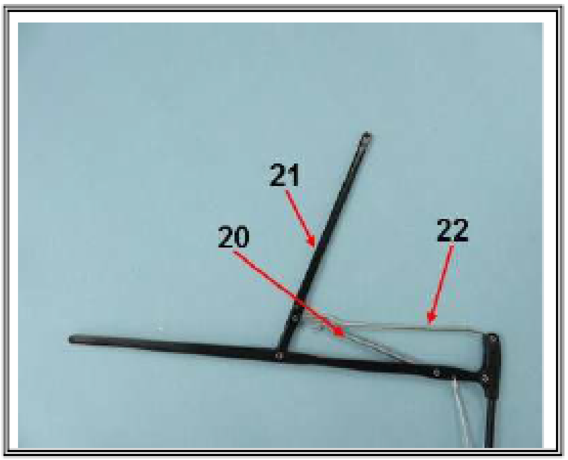

Figure 9: Frame, Spring, Hook (SGS 2018)

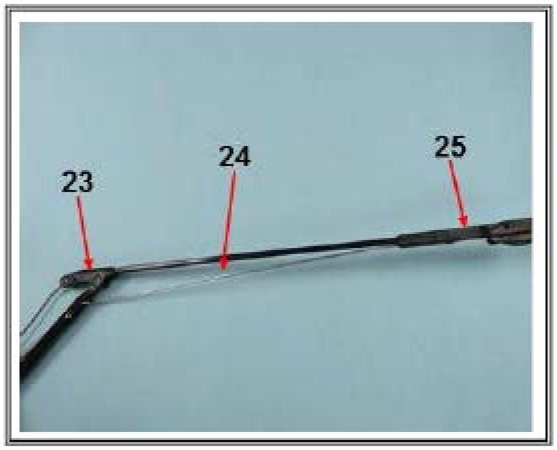

Figure 10: Spring between two Joints (SGS 2018)

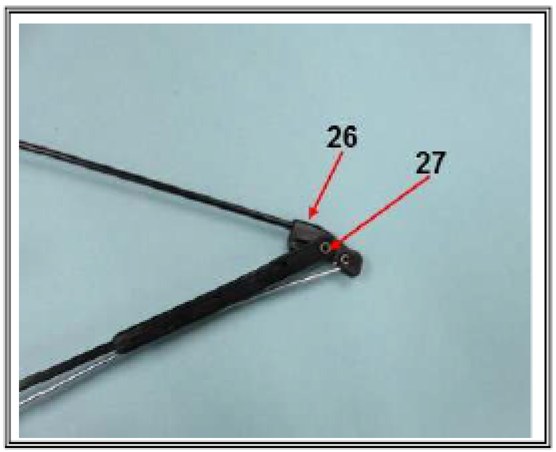

Figure 11: Joint and Rivet (SGS 2018)

SGS Hong Kong Limited performed analytical testing using standard methods and/or SGS in-house methods with analysis by ICP-OES, GC-MS, UV-VIS, HPLC-DAD, and/or HPLC-MS. Analytical test results are summarized below in Table 2. Results are provided for each tested group of components and include the name of each part within the component group, its mass, the identity of each Proposition 65 chemical detected in the component group, the method detection limit, and the test result. These test results are provided in units of mg/kg, equivalent to µg/g. Test results are multiplied by the mass of each part to obtain the total mass of each listed chemical in each component group.

Table 2: Chemicals Measured in Components of the AOAC 46” UnbelievaBrella™ Compact Reverse Umbrella (SGS 2018)						
Part No.	**Part Description**	**Component Weight (g)**	**Chemical (CAS No.)**	**Method Detection Limit (µg/g)**	**Result (µg/g)**	**Total Chemical Mass (µg)**
1	Silvery metal parts: Spring (HKG18-008799.020) + Hook (HKG18-008799.022) + Spring (HKG18-008799.024) + Rivet (HKG18-008799.027)	020: 0.46 022: 1.24 024: 1.50 027: 0.16	Nickel (metallic) (7440-02-0) and nickel compounds	20	5,478	18,406.1
2	Silvery metal parts w/black coating: Large shaft (HKG18-008799.010) + Middle shaft (HKG008799.011) + Small shaft (HKG18-008799.012) + Frame (HKG18-008799.016) + Frame (HKG18-008799.021)	010: 25.81 011: 19.79 012: 14.93 016: 6.12 021: 2.78	Bisphenol A (BPA) (80-05-7)	0.1	8.4	583.2
			Nickel (metallic) (7440-02-0) and nickel compounds	20	53	3,679.8
3	Blue fabric w/blue thread: Jacket (HKG18-008799.001) + Canopy (HKG18-008799.002) + Loop (HKG18-008799.006, + White fabric thread (HKG18-008799.014)	001: 4.98 002: 69.58 006: 3.30 014: 0.68	Formaldehyde (gas) (50-00-0)	5	12	942.5
			Antimony oxide (Antimony trioxide) (1309-64-4)*	20	445	34,950.3
			Naphthalene (91-20-3)	0.1	0.2	15.708
			Styrene (100-42-5)	1.0	1.4	109.956
4	Black plastic handle outer case (HKG18-008799.003) + Blue plastic button (KHG18-008799.004) + Black plastic w/ dark gray coating handle cap (HKG18-008799.005) + Black plastic handle inner case (HKG18-008799.007)	003: 14.07 004: 0.74 005: 10.75 007: 7.78	Bisphenol A (BPA) (80-05-7)	0.1	241.5	8,051.6
			Acrylonitrile (107-13-1)	0.5	4.1	136.7
			1,3-Butadiene (106-99-0)	0.1	0.1	3.3
			Antimony oxide (antimony trioxide) (1309-64-4)*	20	636	21,204.2
			Naphthalene (91-20-3)	0.1	1.6	53.3
			Styrene (100-42-5)	1.0	424.0	14,136.2
			Benzene (71-43-2)	0.5	1.1	36.7
			Toluene (108-88-3)	1.0	15.6	520.1
			Ethylbenzene (100-41-4)	1.0	40.2	1,340.3
			Di(2-ethylhexyl)phthalate	30	30	1,000.2

Table 2: Chemicals Measured in Components of the AOAC 46" UnbelievaBrella™ Compact Reverse Umbrella (SGS 2018)						
Part No.	**Part Description**	**Component Weight (g)**	**Chemical (CAS No.)**	**Method Detection Limit (µg/g)**	**Result (µg/g)**	**Total Chemical Mass (µg)**
			(DEHP) (117-81-7)			
5	Gray plastic ring (HKG18-008799.008) + Black plastic w/silvery printing end cap (HKG18-008799.009) + Black plastic shaft end (HKG18-008799.013) + Black plastic Runner (HKG18-008799.015) + Black plastic frame (HKG18-008799.017)	008: 3.16 009: 1.18 013: 5.21 015: 6.13 017: 2.42	Bisphenol A (BPA) (80-05-7)	0.1	22.5	407.3
			Acrylonitrile (107-13-1)	0.5	2.4	43.4
			Formaldehyde (gas) (50-00-0)	5	9	162.9
			Antimony oxide (antimony trioxide) (1309-64-4)*	20	130	2,353
			Naphthalene (91-20-3)	0.1	0.1	1.8
			Styrene (100-42-5)	1.0	235.0	4,253.5
			Benzene (71-43-2)	0.5	15.6	282.4
			Toluene (108-88-3)	1.0	2.8	50.7
			Ethylbenzene (100-41-4)	1.0	17.5	316.8
6	Black plastic frame (HKG18-008799.018) + frame end (HKG18-008799.019) + Black plastic Joints (HKG18-008799.023, HKG18-008799.025, + HKG18-008799.026)	018: 1.29 019: 0.20 023: 0.71 025: 1.46 026: 0.51	Bisphenol A (BPA) (80-05-7)	0.1	9.2	38.4
			Formaldehyde (gas) (50-00-0)	5	6	25.0
			Naphthalene (91-20-3)	0.1	0.1	0.4
			Styrene (100-42-5)	1.0	92.0	383.6
			Benzene (71-43-2)	0.5	9.8	40.9
			Ethylbenzene (100-41-4)	1.0	2.8	11.7
			Di-n-butyl phthalate (DBP) (84-74-2)	30	260	1,084.2

* Calculated concentration of antimony trioxide is based on the identified antimony.

Table 3 provides the cumulative mass of each detected chemical in all parts of the UnbelievaBrella™.

Table 3: Cumulative Mass for each Chemical Detected in the AOAC 46" UnbelievaBrella™ Compact Reverse Umbrella	
Chemical (CAS No.)	**Total Chemical Mass (µg)**
Acrylonitrile (107-13-1)	180.1
Antimony oxide (antimony trioxide)* (1309-64-4)	58,507.5
Benzene (71-43-2)	359.9
Bisphenol A (BPA) (80-05-7)	9,080.4
1,3-Butadiene (106-99-0)	3.3
Di-n-butyl phthalate (DBP) (84-74-2)	1,084.2
Di(2-ethylhexyl)phthalate (DEHP) (117-81-7)	1,000.2
Ethylbenzene (100-41-4)	1,668.7
Formaldehyde (50-00-0)	1,130.4
Naphthalene	71.3

(91-20-3)	
Nickel (metallic) (7440-02-0) and nickel compounds	22,085.9
Styrene (100-42-5)	18,883.3
Toluene (108-88-3)	570.8

* Calculated concentration of antimony trioxide is based on the identified antimony.

EXPOSURE ASSESSMENT

Consumers may be exposed to the Proposition 65-listed chemicals present in the AOAC 46” UnbelievaBrella™ Compact Reverse Umbrella via direct dermal contact when unpackaging, using, or storing the product. Inhalation of some substances may occur in the case of certain chemicals volatilizing from the product over time. However, inhalation of chemicals emitting from the UnbelievaBrella™ while the consumer is using it outdoors is likely to be extremely limited due to dilution in an infinite volume of outdoor air and is therefore not assessed. Additionally, hand-to-mouth transfer of chemicals may occur as a result of, for example, eating during or after handling the UnbelievaBrella™ or touching the mouth area after contacting the UnbelievaBrella™ . Direct oral exposure is not a reasonably anticipated route of exposure. This evaluation therefore assesses dermal and indirect oral exposures to chemicals in the UnbelievaBrella™, and also assesses inhalation of volatile chemicals measured in or potentially emitting from the UnbelievaBrella™ when brought indoors or stored in a small spaces, such as a vehicle. For each evaluated chemical, ToxServices summed route-specific exposure calculations to obtain total daily exposure.

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, typical 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 is based on the nature of the specific adverse effect(s) that served as the basis for the chemical’s listing on Proposition 65 (27 CCR §25821). That is, the assumption of a 9-month exposure duration is appropriate for chemicals that affect the conceptus (i.e., embryo or fetus), while a longer exposure duration may be more appropriate for a chemical that affects pre-conception maternal or paternal parameters or post-natal growth or development. Exposure to carcinogens is calculated as the concentration of the chemical in the product (or other applicable medium) times the typical average daily exposure/intake rate over a 70-year lifetime (27 CCR §25721) in order to obtain the lifetime average daily dose (LADD).

Dermal Exposure

Exposure via direct dermal contact is the net result of multiple factors, including the mass of the chemical in the material, the mobility of the chemical within the material, the release or transfer rate of the chemical from the material to the skin surface, the surface area of the skin that is in direct contact with the material, contact frequency and duration, transfer efficiency, and dermal retention (i.e., the likelihood that a chemical on the skin will remain on the skin). Collectively, these factors produce a dermal loading dose – i.e., the amount of the chemical present on the skin's surface.

According to OEHHA (2016, 2018a,b), bisphenol A's safe harbor MADL of 3 µg/day applies to dermal exposure from solid materials, which is an external dose, or the amount of BPA present on the surface of the skin. Accordingly, ToxServices calculated the lifetime dermal exposure to BPA using the measured mass of BPA in the UnbelievaBrella™ and the assumption that BPA would migrate at a constant rate over the lifetime of the product.

ToxServices used the following equations to calculate dermal exposure to each chemical measured in the UnbelievaBrella™ . These approaches are based upon United States Environmental Protection Agency (U.S. EPA) methodologies for dermal risk assessment (U.S. EPA 2007). A description of each variable and the value selected for each variable is provided below.

Dermal Exposure (µg/day) = **M** (µg) * **DA** / **PL** (days) * **DE** * **AT**

Equation 1

Dermal Exposure$_{\mathbf{BPA}}$ = **M** (µg) * **DE** / **PL** (days) * **AT**

Equation 2

Chemical Mass (**M**)

The total mass of each evaluated chemical in the UnbelievaBrella™ is provided above in Table 3. As a conservative approach, ToxServices used the total mass from all components for this calculation.

Dermal Absorption (**DA**)

For all compounds except nickel and antimony trioxide, ToxServices assumed 100% dermal absorption as a worst case scenario. Some compounds such as solvents (e.g. toluene and styrene) tend to have significant dermal penetration, so 100% is not unreasonable. For compounds where dermal absorption data are not available, it is conservative to assume 100% absorption.

Although data are available for the dermal absorption of nickel salts, as reviewed in ATSDR (2005), limited data are available for the dermal absorption of elemental or metallic nickel. One study was identified that examined the dermal absorption of 25 mg nickel powder (99.7% purity, particle size of 3 µm) applied as a concentration of 21.7 mg/cm^2 to the skin of three healthy volunteers (Hostýnek et al. 2001). After 96 hours, the majority of the nickel remained at the surface of the skin, and only 0.2% of the dose was absorbed to the stratum corneum. In the EU's nickel risk assessment (EC 2008), the value of 0.2% was used as the fraction of nickel absorbed following dermal contact to nickel metal for risk characterization. Therefore, ToxServices used a dermal absorption factor of 0.2% (0.002 when expressed as a decimal) for nickel.

Similarly, dermal absorption of antimony trioxide is very low in human skin based on in vitro analysis. The total absorbed dose was 0.01% at 100 µg/cm^2 application rate, and 0.02% at 1,000 µg/cm^2, respectively. ToxServices conservatively used the higher value of 0.02%, or 0.0002 as a decimal (ECHA 2018).

Product Lifespan (**PL**)

The manufacturer-provided lifetime of the product is 300 uses (Tam 2018). Therefore, the product lifetime in terms of years will depend on how frequently the umbrella is used. Precipitation data from 1981-2010 suggest the rainiest city in California is Redding, which experiences an average of 82 rainy days per year.[3] ToxServices further assumed on rainy days the umbrella would be used twice per day, going to and from work or school, for example. This is equivalent to 667 days as follows: 300 uses * rainy day / 2 uses * year/82 rainy days * 365 days/year = 667 days. This assumption is conservative because the product would last much longer in drier areas.

Duration of Exposure (**DE**)

The duration of exposure for each use of the umbrella can be estimated based on the amount of time people walk outside on rainy days. As no publicly-available information was identified for this parameter, ToxServices conservatively assumed most people do not walk much in the rain. Those people that take public transportation to school or work would have the greatest amount of time outside on rainy days. ToxServices estimated that an average of 1 hour per day would be spent using the umbrella. As a daily fraction this equals 1 hour * day/24 hrs = 0.042 days. This assumption is conservative because not all parts of the umbrella would be touched with every use; meaningful dermal contact would occur only with the handle and there would be little to no contact with other parts of the product.

Averaging Time (**AT**)

Proposition 65 assumes by default that exposures will occur every day for an individual's entire lifetime, defined as 70 years. However, use of a consumer product such as the UnbelievaBrella™ will not likely occur for this length of time. An "averaging time", which normalizes a shorter exposure duration to a 70-year lifetime exposure equivalent, is therefore needed.

As a conservative exposure estimate for chemicals that are carcinogens or reproductive toxicants, ToxServices assumed a 40-year duration of exposure as the typical length of time that a person could use the same model [insert product type description]. The corresponding averaging time is 40 years/70 years or 0.57.

For developmental toxicants, the anticipated exposure during a shorter duration of 9 months, or 270 days[4], which is the duration of human gestation, is relevant as noted in the California Code of Regulations, 25821, subsection 3.[5] Therefore, an averaging time of

[3] https://www.currentresults.com/Weather/California/average-yearly-city-precipitation.php
[4] 9 months * 30 days/1 month = 270 days
[5] https://oehha.ca.gov/media/downloads/proposition-65/general-info/regsart8.pdf

270 days/270 days or 1.0 is used for Proposition 65 developmental toxicants.

For those chemicals identified as both carcinogens and/or reproductive and developmental toxicants, ToxServices uses the more conservative averaging time of 1.0 in exposure calculations.

Dermal Exposure Calculations

Dermal exposures for each of the evaluated chemicals in the components of the AOAC 46” UnbelievaBrella™ Compact were calculated using Equations 1 and 2 above, and are summarized below in Tables 4 and 5.

Table 4: Dermal Exposure to Evaluated Chemicals in the AOAC 46” UnbelievaBrella™ Compact Reverse Umbrella

Chemical (CAS No.)	M (µg)	DA	PL (days)	DE	AT	Dermal Exposure (µg/day)
Acrylonitrile (107-13-1)	180.1	1	667	0.042	0.57	6.5E-03
Antimony oxide (antimony trioxide)* (1309-64-4)	58,507.5	0.0002	667	0.042	0.57	4.2E-04
Benzene (71-43-2)	359.9	1	667	0.042	0.57	1.3E-02
1,3-Butadiene (106-99-0)	3.3	1	667	0.042	0.57	1.2E-04
Di-n-butyl phthalate (DBP) (84-74-2)	1,084.2	1	667	0.042	1	6.8E-02
Di(2-ethylhexyl)phthalate (DEHP) (117-81-7)	1,000.2	1	667	0.042	1	6.3E-02
Ethylbenzene (100-41-4)	1,668.7	1	667	0.042	0.57	6.0E-02
Formaldehyde (50-00-0)	1,130.4	1	667	0.042	0.57	4.1E-02
Naphthalene (91-20-3)	71.3	1	667	0.042	0.57	2.6E-03
Nickel (metallic) (7440-02-0) and nickel compounds	22,085.9	0.002	667	0.042	0.57	1.6E-03
Styrene (100-42-5)	18,883.3	1	667	0.042	0.57	6.8E-01
Toluene (108-88-3)	570.8	1	667	0.042	1	3.6E-02

* Calculated concentration of antimony trioxide is based on the identified antimony.

Table 5: Dermal Exposure to BPA as Detected in the AOAC 46” UnbelievaBrella™ Compact Reverse Umbrella

Chemical (CAS No.)	M (µg)	DE	PL (days)	AT	Dermal Exposure (µg/day)
BPA (80-05-7)	9,080.4	0.042	667	0.57	0.33

Indirect Oral Exposure

Indirect oral exposure to substances present in the UnbelievaBrella™ may arise from direct hand-to-mouth transfer after contact with the product. Indirect oral exposure resulting from hand-to-mouth contact (**$IOE_{H\rightarrow M}$**) is a function of the concentration of chemicals on the skin (**C_{Skin}**), surface area of the fingertips in direct contact with the mouth (**SA_F**), product lifetime (**PL**), duration of exposure (**DE**), averaging time (**AT**), the hand-to-mouth transfer efficiency (**TE_{HM}**), and its oral bioavailability (**B**). Additionally, indirect oral exposure may result from hand-to-food-to-mouth contact (**$IOE_{H\rightarrow F\rightarrow M}$**), which is a function of the palm surface area (**SA_P**) and the hand-to-food-to-mouth transfer efficiency (**TE_{HFM}**), as explained in detail below. Therefore, two indirect oral exposure scenarios are summed to estimate total indirect oral exposure:

$$\mathbf{IOE_{H\rightarrow M}}\ (\mu g/day) = [\mathbf{C_{Skin}}\ (\mu g/cm^2) * \mathbf{SA_F}\ (cm^2) / \mathbf{PL}\ (days)] * \mathbf{DE} * \mathbf{AT} * \mathbf{TE_{HM}} * \mathbf{B}$$

Equation 3

and

$$\mathbf{IOE_{H\rightarrow F\rightarrow M}}\ (\mu g/day) = [\mathbf{C_{Skin}}\ (\mu g/cm^2) * \mathbf{SA_P}\ (cm^2) / \mathbf{PL}\ (days)] * \mathbf{DE} * \mathbf{AT} * \mathbf{TE_{HFM}} * \mathbf{B}$$

Equation 4

The exposure scenarios are detailed below.

Indirect Oral Exposure Assessment Scenario #1 –Hand-to-Mouth Transfer

Concentration of Chemicals on the Skin (**C**)

The concentration of a listed chemical on the skin (i.e., the dermal loading dose) is estimated using the mass of each chemical in the product and the components' surface area and the assumption of 1:1 ratio between the concentration on the components and the concentration on the skin. This approach is conservative because it assumes that the entire chemical mass, distributed throughout the component, will be available on the surface of the components and can be transferred to the skin.

As dimensions were not available for the UnbelievaBrella™ , ToxServices estimated the surface area of the skin likely to be in direct contact with the UnbelievaBrella™ during use. The concentration of chemical on the skin is then obtained by dividing the chemical mass by the skin surface area. This approach is conservative because it assumes that the entire chemical mass, distributed throughout the components, will be available on the surface of the components and can be transferred to the skin.

This evaluation assumes that the palm of one hand would contact the handle of the UnbelievaBrella™ during use. The U.S. EPA reports 95th percentile values for the surface area of the hands of 0.131 m^2 for adult males and 0.106 m^2 for adult females. Since this is the surface area of both sides of both hands, ToxServices divided the value of 0.131 m^2 for adult males by a factor of 4 to account for the likelihood that only one side/surface of one hand at a time would contact the UnbelievaBrella™ handle, resulting in a surface area of 0.033 m^2 for the adult male hand. Using a conversion factor of 100 cm^2 per 1 m^2, this is equivalent to 330 cm^2.

The concentration of each assessed chemical on the skin is provided below in Table 6.

Table 6: Concentrations of Chemicals on Skin			
Chemical (CAS No.)	**M (µg)**	**SA (cm^2)**	**C_{Skin} (µg/cm^2)**
Acrylonitrile (107-13-1)	180.1	330	0.55

Table 6: Concentrations of Chemicals on Skin			
Chemical (CAS No.)	**M (µg)**	**SA (cm^2)**	**C_{Skin} (µg/cm^2)**
Antimony oxide (antimony trioxide)* (1309-64-4)	58,507.5	330	177.30
Benzene (71-43-2)	359.9	330	1.09
Bisphenol A (BPA) (80-05-7)	9,080.4	330	27.52
1,3-Butadiene (106-99-0)	3.3	330	0.010
Di-n-butyl phthalate (DBP) (84-74-2)	1,084.2	330	3.29
Di(2-ethylhexyl)phthalate (DEHP) (117-81-7)	1,000.2	330	3.03
Ethylbenzene (100-41-4)	1,668.7	330	5.06
Formaldehyde (50-00-0)	1,130.4	330	3.43
Naphthalene (91-20-3)	71.3	330	0.22
Nickel (metallic) (7440-02-0) and nickel compounds	22,085.9	330	66.93
Styrene (100-42-5)	18,883.3	330	57.22
Toluene (108-88-3)	570.8	330	1.73

* Calculated concentration of antimony trioxide is based on the identified antimony.

Surface Area of Fingertips (**SA_F**)

To obtain the total surface area of the hand(s) from which chemicals may be transferred to the mouth, ToxServices assumed that direct contact would only occur between three fingertips and the mouth. This assumption has been included in previous Proposition 65 exposure assessments (OEHHA 2008, 2016). Specifically, OEHHA adjusted U.S. EPA's values for total hands surface area for adult men and women by 50% (to account for palmar surface area of both hands), then by 10% (the surface area of the palmar side of each finger), and then by 30% (the surface area of each fingertip) to obtain the surface area of each fingertip. OEHHA further assumed that direct hand-to-mouth contact would occur for the thumb and two fingertips of one hand, which is a total skin surface are of 19 cm^2 for men and 17 cm^2 for women (OEHHA 2008). Thus, for estimation of indirect oral exposure resulting from hand-to-mouth transfer, ToxServices included the slightly larger surface area of 19 cm^2 (OEHHA 2008, 2016).

Product Lifetime (**PL**)

As noted above, the product lifetime is 667 days.

Duration of Exposure (**DE**)

As noted above, the duration of exposure is 0.042 as a fraction of a day.

Averaging Time (**AT**)

As noted above, the averaging time is 0.57 for carcinogens and reproductive toxicants and 1 for developmental toxicants.

Transfer Efficiency (**TE_{HM}**)

Recent safe use determinations (SUDs) by OEHHA have included a 50% direct hand-to-mouth transfer efficiency rate (OEHHA 2008, 2016). That is, for each contact, 50% of a substance present on the relevant portion of the hands (assumed, as described above, to be 3 fingertips on one hand) is transferred to the mouth area and is available for oral exposure. Based upon the SUD approach, ToxServices assumed that 50% of chemicals present on this skin surface area could be transferred to the mouth and ingested.

Oral Bioavailability (**B**)

ToxServices used substance-specific oral bioavailability values for some of the chemicals detected in the UnbelievaBrella™ in the exposure calculations, as identified below.

In the EU's nickel risk assessment (EC 2008), the oral absorption values for nickel metal used in risk characterization were 0.05-0.3%, where the upper end of the range represented absorption of nickel from the gastrointestinal tract of fasting individuals. Therefore, ToxServices conservatively used an oral bioavailability of 0.3% (0.003 when expressed as a decimal) for nickel.

Studies conducted on organic and inorganic antimony compounds indicate a 1% absorption rate from the gastrointestinal tract (NRC 2000). Antimony compounds used for the treatment of parasitic infections have demonstrated low oral bioavailability in humans (U.S. EPA 2014). Gastric absorption of 5% was reported in four humans following antimony intoxication (Marinovich et al. 2014). Based on available data, ToxServices selected an oral bioavailability of 5% (0.05 when expressed as a decimal) for this assessment.

For all other compounds, ToxServices conservatively assumed 100% bioavailability (1 when expressed as a decimal).

Indirect Oral Exposure Calculations (Scenario #1: Hand-to-Mouth)

Indirect oral exposure arising from hand-to-mouth contact was calculated using Equation 3 above, and is shown below in Table 7.

Table 7: Indirect Oral Exposure: Hand-to-Mouth Transfer ($IOE_{H\rightarrow M}$)

Chemical (CAS No.)	C_{Skin} (µg/cm^2)	SA_F (cm^2)	PL (days)	DE	AT	TE_{HM}	B	$IOE_{H\rightarrow M}$ (µg/day)
Acrylonitrile (107-13-1)	0.55	19	667	0.042	0.57	0.5	1	1.9E-04
Antimony oxide (antimony trioxide)* (1309-64-4)	177.30	19	667	0.042	0.57	0.5	0.05	3.0E-03
Benzene (71-43-2)	1.09	19	667	0.042	0.57	0.5	1	3.7E-04
Bisphenol A (BPA) (80-05-7)	27.52	19	667	0.042	0.57	0.5	1	9.4E-03
1,3-Butadiene (106-99-0)	0.010	19	667	0.042	0.57	0.5	1	3.4E-06
Di-n-butyl phthalate (DBP) (84-74-2)	3.29	19	667	0.042	1	0.5	1	2.0E-03
Di(2-ethylhexyl)phthalate (DEHP) (117-81-7)	3.03	19	667	0.042	1	0.5	1	1.8E-03
Ethylbenzene (100-41-4)	5.06	19	667	0.042	0.57	0.5	1	1.7E-03

Table 7: Indirect Oral Exposure: Hand-to-Mouth Transfer ($IOE_{H \rightarrow M}$)								
Chemical (CAS No.)	**C_{Skin} (µg/cm²)**	**SA_F (cm²)**	**PL (days)**	**DE**	**AT**	**TE_{HM}**	**B**	**$IOE_{H \rightarrow M}$ (µg/day)**
Formaldehyde (50-00-0)	3.43	19	667	0.042	0.57	0.5	1	1.2E-03
Naphthalene (91-20-3)	0.22	19	667	0.042	0.57	0.5	1	7.4E-05
Nickel (metallic) (7440-02-0) and nickel compounds	66.93	19	667	0.042	0.57	0.5	0.003	6.8E-05
Styrene (100-42-5)	57.22	19	667	0.042	0.57	0.5	1	2.0E-02
Toluene (108-88-3)	1.73	19	667	0.042	1	0.5	1	1.0E-03

* Calculated concentration of antimony trioxide is based on the identified antimony.

Indirect Oral Exposure Assessment Scenario #2 – Hand-to-Food-to-Mouth Transfer

Indirect hand-to-object, object-to-mouth contact may also occur. For example, a person may eat a food item while driving or eat a meal after contacting the UnbelievaBrella™ without first washing their hands. A proportion of substances present on the hands may be transferred to food items (e.g., piece of fruit, sandwich, chips) that are consumed without the use of utensils, resulting in oral exposure. Indirect oral exposure resulting from hand-to-food-to-mouth (**$IOE_{H \rightarrow F \rightarrow M}$**) contact is a function of the concentration of the chemical on the palms and transfer efficiency (**TE_{HFM}**) from hands to the item that is then consumed.

In contrast to the above assumption that only 3 fingertips would directly contact the mouth during hand-to-mouth transfer, for assessment of hand-to-food-to-mouth transfer, OEHHA (2008) assumes that 90% of the palmar surface area on one hand (190 cm^2 for men) could transfer a substance onto objects that are subsequently eaten, at a rate of 1/hour, or that the skin surface area contributed by 3 fingertips (19 cm^2) could transfer a substance onto objects that are eaten at a rate of 10/hour. The overall transfer amount is the same for both scenarios. ToxServices used the surface area of 190 cm^2 and frequency of 1/hour for the current exposure assessment.

For transfer efficiency for this scenario, recent SUDs included application of a 25% indirect hand-to-object, object-to-mouth transfer efficiency (OEHHA 2008, 2016). That is, 25% of a chemical present on the palms is transferred first to an intermediate object, in this case, a sandwich or apple, and then to the mouth. Based upon the SUD approach, ToxServices assumed that 25% of all chemicals present on the palms of the hands could be transferred to an object that is then placed in the mouth and ingested.

Indirect Oral Exposure Calculations (Scenario #2: Hand-to-Food-to-Mouth)

Indirect oral exposure arising from hand-to-food-to-mouth contact is calculated using Equation 4 above, and is shown in Table 8.

Table 8: Indirect Oral Exposure: Hand-to-Food-to-Mouth Transfer ($IOE_{H \rightarrow F \rightarrow M}$)								
Chemical (CAS No.)	**C_{Skin} (µg/cm²)**	**SA_P (cm²)**	**PL (days)**	**DE**	**AT**	**TE_{HFM}**	**B**	**$IOE_{H \rightarrow F \rightarrow M}$ (µg/day)**
Acrylonitrile (107-13-1)	0.55	190	667	0.042	0.57	0.25	1	9.3E-04
Antimony oxide (antimony trioxide)* (1309-64-4)	177.30	190	667	0.042	0.57	0.25	0.05	1.5E-02

Table 8: Indirect Oral Exposure: Hand-to-Food-to-Mouth Transfer ($IOE_{H\rightarrow F\rightarrow M}$)								
Chemical (CAS No.)	**C_{Skin} (µg/cm^2)**	**SA_P (cm^2)**	**PL (days)**	**DE**	**AT**	**TE_{HFM}**	**B**	**$IOE_{H\rightarrow F\rightarrow M}$ (µg/day)**
Benzene (71-43-2)	1.09	190	667	0.042	0.57	0.25	1	1.9E-03
Bisphenol A (BPA) (80-05-7)	27.52	190	667	0.042	0.57	0.25	1	4.7E-02
1,3-Butadiene (106-99-0)	0.010	190	667	0.042	0.57	0.25	1	1.7E-05
Di-n-butyl phthalate (DBP) (84-74-2)	3.29	190	667	0.042	1	0.25	1	9.8E-03
Di(2-ethylhexyl)phthalate (DEHP) (117-81-7)	3.03	190	667	0.042	1	0.25	1	9.1E-03
Ethylbenzene (100-41-4)	5.06	190	667	0.042	0.57	0.25	1	8.6E-03
Formaldehyde (50-00-0)	3.43	190	667	0.042	0.57	0.25	1	5.8E-03
Naphthalene (91-20-3)	0.22	190	667	0.042	0.57	0.25	1	3.7E-04
Nickel (metallic) (7440-02-0) and nickel compounds	66.93	190	667	0.042	0.57	0.25	0.003	3.4E-04
Styrene (100-42-5)	57.22	190	667	0.042	0.57	0.25	1	9.8E-02
Toluene (108-88-3)	1.73	190	667	0.042	1	0.25	1	5.2E-03

* Calculated concentration of antimony trioxide is based on the identified antimony.

Inhalation Exposure

Consumers using the UnbelievaBrella™ may inhale volatile chemicals present in or emitting from the product. Human exposure by inhalation is a function of many variables, such as a chemical'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 inhalation 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.

For this evaluation, acrylonitrile, benzene, 1,3-butadiene, ethylbenzene, formaldehyde, naphthalene, styrene, and toluene are considered VOCs. . The remaining detected substances are nonvolatile or semi-volatile and therefore were not assessed for inhalation exposure. ToxServices calculated VOC exposure according to the following equation:

Inhalation Exposure (µg/day) = **M** (µg) / **AV** (m^3) / **PL** (days) * **IR** (m^3/day) * **DE * AT**

Equation 5

The evaluation of inhalation exposure assumes that the UnbelievaBrella™ will be stored in a vehicle while not in use. Although an umbrella may also be stored in an area of the house such as a closet or foyer, individuals typically do not spend significant periods of time in these household locations. Each variable used to calculate inhalation exposure to VOCs is explained in detail below.

Mass (**M**)

The mass of each chemical measured in the UnbelievaBrella™ is provided above in Table 3.

Air Volume (**AV**)

To calculate maximum potential air concentration, the air volume into which the chemicals are emitted is needed. As a conservative approach, ToxServices assumed that the mass of each VOC would be released from the UnbelievaBrella™ into the surrounding air at a constant rate over the lifespan of the product (667 days, as explained above).

ToxServices further assumed that exposure to emitted components could take place in a variety of rooms, buses, cars, etc. As the interior of a car is likely the smallest of these locations, ToxServices used the interior volume of the most common car in California, the Honda Civic[6], which has a passenger volume of 97.8 cubic feet[7], which is equivalent to 2.8 m^3 using a conversion factor of 1 m^3/35.3 ft^3. This is a conservative estimate of the air volume into which the chemicals are emitted, as the air concentration (C) of a given mass (M) of a chemical is inversely related to air volume (V): C = M / V.

Although air change rate is also an important variable in inhalation exposure assessments, to obtain worst-case exposure estimates, this evaluation conservatively assumes that the car in which the UnbelievaBrella™ is stored will not have the ventilation system operating, or that the ventilation system will be on "recirculate".

Product Lifetime (**PL**)

As noted above, the product lifetime is 667 days.

Inhalation Rate (**IR**)

OEHHA (2015) recommends age-specific exposure calculations for residential cancer risk assessments; however, 27 CCR §25721 also specifies inhalation rates for calculation of exposure under Proposition 65. These latter values are provided below in Table 9 for consistency with NSRL/MADL development processes. ToxServices selected the highest inhalation rate of 20 m^3/day as a conservative approach, as this results in highest estimates of exposure.

Table 9: Default Inhalation Rates (27 CCR §25721)

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

[6] https://www.sacbee.com/site-services/databases/article168523142.html
https://www.usatoday.com/story/news/nation-now/2017/08/30/these-most-popular-cars-and-trucks-every-state/478537001/
[7] http://owners.honda.com/vehicles/information/2017/Civic-Sedan/specs#mid^FC2E5HEW

Duration of Exposure (**DE**)

Americans spend an average of 17,600 minutes driving each year.[8] However, divers in California may spend longer than this driving. One source asserts that people in California drive 1.5 times longer than other Americans.[9] For the purpose of obtaining worst-case exposure estimates, this evaluation assumes an average driving time of 26,400 minutes/year. As there are 1,440 minutes per day and 365 days/year, this equates to 0.05 as a fraction of a day (26,400 minutes / year * day/1,440 minutes * year/365 days = 0.05).

Averaging Time (**AT**)

As noted above, the averaging time is 0.57 for carcinogens and reproductive toxicants and 1 for developmental toxicants.

Inhalation Exposure Calculations

Exposure to VOCs present in the UnbelievaBrella™ was calculated using Equation 5 above and is provided below in Table 10.

Table 10: Inhalation Exposure Calculations for Evaluated Substances

Chemical (CAS No.)	M (µg)	AV (m^3)	IR (m^3/day)	PL (days)	DE	AT	Inhalation Exposure (µg/day)
Acrylonitrile (107-13-1)	180.1	2.8	20	667	0.05	0.57	5.5E-02
Benzene (71-43-2)	359.9	2.8	20	667	0.05	0.57	1.1E-01
1,3-Butadiene (106-99-0)	3.3	2.8	20	667	0.05	0.57	1.0E-03
Ethylbenzene (100-41-4)	1,668.7	2.8	20	667	0.05	0.57	5.1E-01
Formaldehyde (50-00-0)	1,130.4	2.8	20	667	0.05	0.57	3.5E-01
Naphthalene (91-20-3)	71.3	2.8	20	667	0.05	0.57	2.2E-02
Styrene (100-42-5)	18,883.3	2.8	20	667	0.05	0.57	5.8
Toluene (108-88-3)	570.8	2.8	20	667	0.05	0.57	3.1E-01

SAFE HARBOR DETERMINATION AND RISK ASSESSMENT

ToxServices compared the exposure estimates calculated herein to established Proposition 65 safe harbor NSRLs and MADLs (OEHHA 2018b) or ToxServices's screening-level values to determine whether or not the UnbelievaBrella™ has safe harbor from Proposition 65 requirements. Exposures arising from dermal exposure, indirect oral exposure, and, for volatile chemicals, from inhalation exposure were summed to obtain total daily exposure for each chemical. Additionally, as some listed chemicals have more than one safe harbor value, ToxServices selected either the lowest (i.e., most conservative) value or the safe harbor value associated with the most relevant route of exposure as the comparator in this assessment. Since nickel (elemental/metallic) and antimony do not have established safe harbor values, ToxServices utilized published

[8] https://newsroom.aaa.com/2016/09/americans-spend-average-17600-minutes-driving-year/
[9] https://alankandel.scienceblog.com/2014/02/07/annual-per-capita-california-driving-1-5-times-the-national-average/

cancer risk assessments to derive screening-level NSRLs that served as the basis for health risk assessment.

Total exposures to the evaluated chemicals measured in the UnbelievaBrella™ are presented in Table 11.

Table 11: Total Exposure to Proposition 65 Listed Chemicals Measured in ShedRain Corporation's AOAC 46" UnbelievaBrella™ Compact Reverse Umbrella

Chemical (CAS No.)	Dermal Exposure (µg/day)	$IOE_{H\rightarrow M}$ (µg/day)	$IOE_{H\rightarrow F\rightarrow M}$ (µg/day)	Inhalation Exposure (µg/day)	Total Exposure (µg/day)
Acrylonitrile (107-13-1)	6.5E-03	1.9E-04	9.3E-04	5.5E-02	6.3E-02
Antimony oxide (antimony trioxide)* (1309-64-4)	4.2E-04	3.0E-03	1.5E-02	N/A	1.9E-02
Benzene (71-43-2)	1.3E-02	3.7E-04	1.9E-03	1.1E-01	1.2E-01
BPA	3.3E-01	9.4E-03	4.7E-02	N/A	0.38
1,3-Butadiene (106-99-0)	1.2E-04	3.4E-06	1.7E-05	1.0E-03	1.2E-03
Di-n-butyl phthalate (DBP) (84-74-2)	6.8E-02	2.0E-03	9.8E-03	N/A	8.0E-02
Di(2-ethylhexyl)phthalate (DEHP) (117-81-7)	6.3E-02	1.8E-03	9.1E-03	N/A	7.4E-02
Ethylbenzene (100-41-4)	6.0E-02	1.7E-03	8.6E-03	5.1E-01	5.8E-01
Formaldehyde (50-00-0)	4.1E-02	1.2E-03	5.8E-03	3.5E-01	3.9E-01
Naphthalene (91-20-3)	2.6E-03	7.4E-05	3.7E-04	2.2E-02	2.5E-02
Nickel (metallic) (7440-02-0) and nickel compounds	1.6E-03	6.8E-05	3.4E-04	N/A	2.0E-03
Styrene (100-42-5)	6.8E-01	2.0E-02	9.8E-02	5.8	6.6
Toluene (108-88-3)	3.6E-02	1.0E-03	5.2E-03	3.1E-01	3.5E-01

* Calculated concentration of antimony trioxide is based on the identified antimony

The results of the Proposition 65 safe harbor determination for all detected substances are provided below in Table 12.

Table 12: Safe Harbor Determination for Evaluated Chemicals Measured in ShedRain Corporation's AOAC 46" UnbelievaBrella™ Compact Reverse Umbrella

Chemical (CAS No.)	Total Exposure (µg/day)	Proposition 65 Safe Harbor Level (µg/day)	Safe Harbor Demonstrated?
Acrylonitrile (107-13-1)	6.3E-02	0.7	Yes
Antimony oxide (antimony trioxide)* (1309-64-4)	1.9E-02	0.28	Yes
BPA (80-05-7)	Dermal: 0.33 Oral: 5.6E-02	Dermal: 3 Oral: 52	Yes
Benzene (71-43-2)	0.38	6.4	Yes
1,3-Butadiene (106-99-0)	1.2E-03	0.4	Yes
Di-n-butyl phthalate (DBP) (84-74-2)	8.0E-02	8.7	Yes
Di(2-ethylhexyl)phthalate (DEHP) (117-81-7)	7.4E-02	NSRL: 310 MADL: 410	Yes
Ethylbenzene (100-41-4)	5.8E-01	41	Yes

Table 12: Safe Harbor Determination for Evaluated Chemicals Measured in ShedRain Corporation's AOAC 46" UnbelievaBrella™ Compact Reverse Umbrella			
Chemical (CAS No.)	**Total Exposure (µg/day)**	**Proposition 65 Safe Harbor Level (µg/day)**	**Safe Harbor Demonstrated?**
Formaldehyde (50-00-0)	3.9E-01	40	Yes
Naphthalene (91-20-3)	2.5E-02	5.8	Yes
Nickel (metallic) (7440-02-0) and nickel compounds	2.0E-03	1.18	Yes
Styrene (100-42-5)	6.6E	27	Yes
Toluene (108-88-3)	3.5E-01	7,000	Yes

SUMMARY

The above calculations demonstrate that total exposure to the Proposition 65-listed substances measured in ShedRain Corporation's AOAC 46" UnbelievaBrella™ Compact Reverse Umbrella do not exceed their respective Proposition 65 safe harbor values.

DISCUSSION

Human exposure to a chemical 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. It is imperative to identify and characterize the potential for dermal, indirect oral, and/or inhalation exposure in order to accurately characterize human health risks.

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 the entire mass of chemicals detected in all components of the AOAC 46" UnbelievaBrella™ Compact Reverse Umbrella – even those components with limited dermal contact potential - would be released at a constant, linear rate over the anticipated life-span of the components, and that the release rate would be the same for all materials composing AOAC 46" UnbelievaBrella™ Compact Reverse Umbrella. Additionally, conservative over-estimates were made regarding the amount of dermal contact with AOAC 46" UnbelievaBrella™ Compact to reflect potential worst-case exposure scenarios.

Collectively, the conservative assumptions used in this report indicate that the exposure values calculated herein are over-estimates. For all listed substances in ShedRain Corporation's AOAC 46" UnbelievaBrella™ Compact Reverse Umbrella, this provides additional assurance that applicable safe harbor values are not likely to be exceeded when AOAC 46" UnbelievaBrella™ Compact Reverse Umbrella is used according to the parameters included in the exposure calculations presented herein.

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APPENDIX A: DERIVATION OF A SCREENING-LEVEL NSRL FOR ANTIMONY OXIDE

Antimony oxide is included on Proposition 65 due to its carcinogenicity, but no NSRL has been established (OEHHA 2018b). Chronic inhalation studies were conducted in rats and swine for antimony trioxide (Watt 1983). Based on these studies, the National Research Council established an inhalation unit cancer risk of 7.1 $x10^{-4}$ $(\mu g/m^3)^{-1}$ (NRC 2000). As a screening-level approach to assess Proposition 65 regulatory compliance and to assess health risks, ToxServices used the risk value of 7.1 $x10^{-4}$ $(\mu g/m^3)^{-1}$ as the basis for a screening-level NSRL for this chemical. OEHHA (2009) defines the cancer unit risk as the excess cancer risk associated with an inhalation exposure to a concentration of 1 $\mu g/m^3$ of a given chemical.

As a first step to derive a NSRL, the inhalation unit cancer risk is divided by 20 m^3/day, which is the reference human inhalation rate as follows to derive the cancer slope factor (OEHHA 2009):

$$\mathbf{CSF = IUR / 20\ m^3/day}$$

where CSF is the cancer slope factor, IUR is the inhalation unit cancer risk, and 20 m^3/day is the reference human inhalation rate. Thus:

$$CSF = 7.1\times10^{-4}\ (\mu g/m^3)^{-1}\ /\ 20\ m^3/day$$

$$CSF = 0.0000355\ (\mu g/day)^{-1}$$

Next, the following equation is used to obtain the dose associated with 1 in 100,000 cancer risk by using the cancer slope factor (OEHHA 2009). As OEHHA defines the NSRL as 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), the acceptable level of risk is 1 in 100,000, or 10^{-5}. Thus:

$$\mathbf{CSF\ (\mu g/kg/day)^{-1} = Risk\ at\ NSRL\ /\ Dose}$$

$$0.0000355\ (\mu g/day)^{-1} = 10^{-5}\ /\ Dose$$

$$Dose = 10^{-5}\ /\ 0.0000355\ (\mu g/day)^{-1}$$

$$Dose = 0.28\ \mu g/day$$

The screening-level NSRL of 0.28 µg/day therefore serves as the basis for antimony oxide Proposition 65 compliance determination and evaluation of health risks for the purpose of this assessment.

APPENDIX B: DERIVATION OF A SCREENING-LEVEL MADL FOR BISPHENOL A

Bisphenol A (BPA, CAS #80-05-7) is included on the State of California's Proposition 65 list as a female reproductive toxicant (OEHHA 2018a). In 2016, OEHHA established a dermal MADL of 3 µg/day for BPA (OEHHA 2018b). OEHHA has not yet established an MADL for oral exposure to BPA, as they are awaiting results from unspecified federal research.[10] However, since Proposition 65 listings apply in general to all relevant routes of exposure, and OEHHA is clearly concerned about oral exposure to BPA through use of food contact materials, ToxServices utilized a peer-reviewed publication to establish a screening-level MADL for oral exposure to BPA through use of consumer products where oral exposure is expected to be indirect, minimal, and/or incidental.

Under Title 27 of the California Code of Regulations, §25801, the MADL is defined as "the level of exposure to a listed chemical which will have no observable effect, assuming the exposure at one thousand times the level in question." In mathematical terms:

MADL = NOEL * BW/1,000

The NOEL is defined as "the highest exposure level which results in no observable reproductive effect…" and may be obtained directly from a scientific study or "may be calculated by means of a generally-accepted scientific methodology such as the benchmark dose methodology" (27 CCR §25801). The basis for the thousand-fold extrapolation factor in the above equation is not described.

Goodman et al. (2017) performed a literature search to identify a NOEL from the most sensitive study of sufficient quality to serve as the basis for oral MADL development. These authors identified a 90-day study in pregnant female rats (Delclos et al. 2014) as the most appropriate basis for the MADL. In this study, dams were exposed beginning on GD 6 and offspring dosed directly beginning the day after birth. The most sensitive effect was a significant increase in serum estradiol in PND 80 female offspring, and was associated with a NOEL of 2,700 µg/kg/day. Goodman et al. (2017) used this NOEL in calculation of their MADL.

However, in risk assessment, it is standard procedure to apply modifying factors to an experimental NOEL to account for uncertainties in the application of laboratory animal data to human exposure conditions and/or to account for lack of data. The adjusted NOEL is then used in risk criterion calculations. In the case of the Goodman et al. (2017) MADL derivation, the authors note that one limitation of their approach was the use of a NOEL from a subchronic study, even though an MADL is intended to reflect chronic exposure conditions. It is therefore logical to apply an uncertainty factor (UF) to the

[10] https://oehha.ca.gov/proposition-65/crnr/notice-emergency-action-amend-section-256033-title-27-california-code

NOEL from the Delclos et al. (2014) study to account for less-than-chronic exposure. This practice is based on the assumption that adverse effects seen in subchronic studies will be observable at lower doses in longer-term studies (Dourson et al. 1996). Although the default subchronic-to-chronic UF is 10, available data suggest that the actual difference between subchronic N(L)OAELs and chronic N(L)OAELS is only 2-3 (Dourson et al. 1996). The use of a 10-fold subchronic-to-chronic uncertainty factor may therefore be overly conservative. More recently, OEHHA identified an appropriate subchronic-to-chronic factor of √10 (i.e., 3.2, rounded to 3) for development of chronic, non-cancer reference exposure levels (RELs) in cases where the subchronic study is 8-12% of the estimated lifetime (OEHHA 2008). A 90-day study is roughly 8-12% of the reported Sprague-Dawley lifespan of 24-36 months.[11]

ToxServices therefore applied a subchronic-to-chronic UF of 3 to the most sensitive NOEL of 2,700 µg/kg/day identified by Goodman et al. (2017) to obtain an adjusted NOEL of 900 µg/kg/day. The oral MADL is then calculated as:

MADL = ($NOEL_{Adj}$ * BW)/1,000 = (900 µg/kg/day * 58 kg)/1,000 = 52 µg/kg/day

Limitations associated with the use of the NOEL identified by Goodman et al. (2017) as the basis for a screening-level oral MADL for BPA include their relatively stringent literature search criteria, potential conflict of interest due to funding source[12], and differences in the metabolism of BPA by rats vs. humans. With respect to literature search criteria, Goodman et al. (2017) specifically exclude studies that assessed biochemical effects or gene expression; they limited their analysis to studies that included "morphologically-evident effects pertinent to reproduction or reproductive endpoints themselves." Interestingly, the effect these authors identify as the most sensitive and choose as their overall NOEL is a biochemical/endocrine activity effect: serum estradiol levels. It is therefore possible that the authors may have missed studies that only evaluated hormone levels without tissue histopathology or functional evaluations. Moreover, in their evaluation of BPA's reproductive toxicity potential, the Developmental and Reproductive Toxicant Identification Committee (DRTIC) determined that BPA adversely affects ovarian development, particularly oocyte/follicle maturation, as evidenced by altered ovarian gene expression, disrupted follicle development trajectory (i.e., developmental pathway), inhibited follicle growth, follicular atresia, and reduced corpora lutea.[13] This suggests that OEHHA could consider gene expression and/or biochemical data as relevant in BPA risk assessment and oral MADL development.

[11] https://www.taconic.com/pdfs/sprague-dawley-rat.pdf
[12] The study was funded by the Can Manufacturers Institute, and the lead author has represented the American Chemistry Council in OEHHA's evaluations of BPA.
[13] https://oehha.ca.gov/media/downloads/crnr/03172016dermalbpamadlisor.pdf

APPENDIX C: DERIVATION OF A SCREENING-LEVEL NSRL FOR NICKEL (ELEMENTAL/METALLIC)

Elemental nickel (CAS #7440-02-0) is included on Proposition 65 due to its carcinogenicity (OEHHA 2018a)[14]. In 1991, OEHHA established a unit risk factor of 2.6 $\times 10^{-4}$ $(\mu g/m^3)^{-1}$ and an inhalation cancer potency factor of 0.91 $(mg/kg/day)^{-1}$ for nickel based on epidemiological data[15]. More recently, the Texas Commission on Environmental Quality (TCEQ) established an inhalation unit risk factor (URF), also known as an inhalation unit risk (IUR), of 1.7 x10^{-4} $(\mu g/m^3)^{-1}$ for nickel (TCEQ 2017) based on epidemiological studies published more recently than those evaluated by OEHHA. As a screening-level approach to assess Proposition 65 regulatory compliance and to assess health risks, ToxServices used the more recently-derived TCEQ value of $(\mu g/m^3)^{-1}$ as the basis for a screening-level NSRL for this chemical. OEHHA (2009) defines the cancer unit risk as the excess cancer risk associated with an inhalation exposure to a concentration of 1 $\mu g/m^3$ of a given chemical.

As a first step to derive a NSRL, a unit risk value (UR) is transformed to a CPF as follows (OEHHA 2009):

$$\mathbf{UR = \frac{CPF * 20\ m^3/day}{70\ kg * CF}}$$

where UR is the cancer unit risk (oral or inhalation), CPF is the cancer potency factor, 70 kg is the reference human body weight, 20 m^3/day is the reference human inspiration rate/day, and CF is the conversion factor from mg to µg (= 1,000 µg/mg). Thus:

$$1.7\times10^{-4}\ (\mu g/m^3)^{-1} = \frac{CPF * 20\ m^3/day}{70\ kg * 1{,}000\ \mu g/mg}$$

$$CPF = 0.595\ (mg/kg/day)^{-1}$$

Next, the following equation is used to obtain the dose associated with 1 in 100,000 cancer risk (OEHHA 2009):

$$\mathbf{CPF\ (mg/kg/day)^{-1} = Risk\ /\ Dose}$$

As OEHHA defines the NSRL as 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), the acceptable level of risk is 1 in 100,000, or 10^{-5}. Thus:

$$0.595\ (mg/kg/day)^{-1} = 10^{-5}\ /\ Dose * 1{,}000\ \mu g/mg$$

[14] https://oehha.ca.gov/chemicals/nickel-and-nickel-compounds
[15] https://oehha.ca.gov/media/downloads/crnr/appendixb.pdf

$$\text{Dose} = 10^{-5} / 0.595\ (\text{mg/kg/day})^{-1} * 1{,}000\ \mu\text{g/mg}$$

$$\text{Dose} = 1.68 \times 10^{-5}\ \text{mg/kg/day} * 1{,}000\ \mu\text{g/mg} = 0.017\ \mu\text{g/kg/day}$$

As a final step, the dose is multiplied by the default human body weight of 70 kg to obtain a screening-level NSRL in units of µg/day:

$$\text{NSRL} = 0.017\ \mu\text{g/kg/day} * 70\ \text{kg} = 1.18\ \mu\text{g/day}$$

The screening-level NSRL of 1.18 µg/day therefore serves as the basis for nickel Proposition 65 compliance determination and evaluation of health risks for the purpose of this assessment.

REPORT APPROVALS

AUTHORS/REVIEWER		
	AUTHORS	Nancy Linde, M.S. Senior Toxicologist ToxServices LLC
	SENIOR REVIEWER	Jennifer Fleischer, Ph.D., M.H.S., D.A.B.T. 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