Proposition-65 Risk Assessment for Mulch and Soil Products

A Special Report of the
Mulch & Soil Research Foundation

California Proposition-65 Requires:

…. any person in the course of doing business (in California) must provide a clear and reasonable warning prior to exposing any person to a chemical known to the State to cause cancer or reproductive harm [California Health and Safety Code (HSC) § 25249.6].

- **Doesn't matter how your product got to CA.**
- **Doesn't matter if you were NOT aware your product was being sold in CA.**
- **ONLY matters that it is being sold in CA.**

Proposition-65 Labeling

⚠ WARNING

This product can expose you to chemicals including arsenic, which is known to the State of California to cause cancer. For more information go to www.P65Warnings.ca.gov

Vs

OMRI LISTED® For Organic Use

A confusing mixed message to consumers for organic based mulch & soil products!

Enforcement

- First right is State Attorney General.
- If AG declines, a “citizen” suit may be submitted to the AG for approval and 60-day notice.
- If the “citizen” (usually a litigation mill) cannot demonstrate a valid case, the AG can prohibit further action.
- If approved, the “citizen” can proceed.
- A dozen law firms generate 80% of Proposition-65 litigation in CA.
- Compliance under litigation is extremely expensive (6 figures on average)
- Once one product is identified in violation, litigators seek every similar industry company to target.
- Most small businesses don’t have the financial resources to prove they are under the safe harbor limits for their products; so, litigators pocket the settlements and fees.

Naturally Occurring Metals

The following table presents the typical concentrations of metals listed as regulated by Proposition 65 in normal soil.

These metals may be taken up by plants during their growth, hence, it is possible that trace metals may be found in plant material such as wood, bark and other vegetative materials that are incorporated into garden mulch, potting mixes, landscape soils and soil amendments/compost.

Element/Compound	Presence of Proposition 65-Listed Metals in Earth's Crust
Arsenic (Inorganic Compounds)	7.2
Beryllium	2.8
Cadmium	0.15
Chromium (Hexavalent Only)	NA
Cobalt	25
Lead	19
Nickel	75

Exception to the Rule

"An exposure for which the person responsible can show that the exposure poses no significant risk assuming lifetime exposure at the level in question for substances known to the state to cause cancer, and that the exposure will have no observable effect assuming exposure to one thousand (1000) times the level in question for substances known to the state to cause reproductive toxicity…" [non-relevant text omitted] [HSC § 25249.10(c)].

Translation:
Your product is exempt from P-65 labeling if you can PROVE user exposure to your product is 1/1000 th of the "Safe Harbor" limit set by CA.

NSRLs & MADLs

The numerical thresholds for exemptions called No Significant Risk Levels (NSRLs) and Maximum Acceptable Daily Limits (MADLs) set forth as dose levels [27 CCR § 25705 (cancer hazards) and § 25805 (reproductive hazards). The NSRLs and MADLs (exposure limits) relevant to the Proposition 65-regulated chemicals in mulch and soil products include the following:

Element/Compound	Hazard	NSRL (µg/Day)	MADL (µg/Day)
Arsenic (Inorganic Compounds)	•Cancer •Developmental toxicity	**< 0.06 (inhaled)**	**< 10 (other)**
Beryllium	•Cancer	**0.1**	**0.0002 (sulfate)**
Cadmium	•Male reproductive •Cancer	**4.1 (oral)**	**0.05 (inhalation)**
Chromium (Hexavalent Only)	•Cancer •Reproductive toxicity	**0.001 (inhalation)**	**8.2 (oral)**
Cobalt	•Cancer	**None Established**	**None Established**
Lead	•Cancer •Reproductive toxicity	**15 (oral)**	**0.5**
Nickel	•Cancer •Reproductive toxicity	**None Established**	**None Established**

MSRF Researched Exposure

Workers conducted specific work tasks using the following mulch and soil materials for a 75 to 80-minute period while wearing air monitoring devices:

- **Potting plants using a potting mix;**
- **Preparing plots for planting using landscape soils / soil amendments/compost;**
- **Spreading mulch using Medium Nuggets;**
- **Spreading mulch using Premium Red Mulch; and**
- **Spreading mulch using Shredded Mulch.**

These products and the tasks performed while using them were deemed to be representative of products made and sold to consumers and employers engaged in gardening and landscape activities.

MSRF Assessing Exposure

- During the designated tasks, workers wore calibrated personal sampling pumps that drew a precise amount of air through a filter, which was subsequently analyzed gravimetrically by a certified industrial hygiene laboratory.

- The mass of dust when divided by the amount of air sampled yields a calibrated exposure expressed in micrograms per cubic meter, or $\mu g/m^3$, which can be converted to μg/hour.

- The results indicate exposures to total dust during the various tasks ranged from 287.5 to 587.5 μg/hour.

Calculating Exposure Risk

- Once the total dust exposure over a one-hour period for a particular task with a certain product is determined, we next convert total dust exposure into an exposure to the specific Proposition 65 chemical of concern.

- This calculation is expressed as the amount of total dust exposure per hour (μg/hour) times the number of hours the task hypothetically requires, which yields total dust exposure.

- This value is then multiplied by the concentration of Proposition 65 chemical (converted from mg/kg to μg/μg) to yield the exposure to the subject chemical, which is then compared to the NSRL or MADL.

Calculating Exposure Risk

The Formula:

[(Number of hours of exposure in a day) *x* (Dust Exposure for Product and Task in µg/hour†)] *x* [(P65 Chemical Presence in Product in mg/kg†† *x* 1,000)††† 1,000,000,000††††] = Exposure in µg/day

†See Step 2 for values.
†† Results from testing lab
††† Converts mg/kg to µg/kg
†††† Converts µg/kg to µg/µg

See Excel spreadsheet for auto calculations

Step-By-Step

<u>Step 1</u>: Select product and task most representative of the product used and the activity:

1. **Potting plants using a potting mix;**
2. **Preparing plots for planting using landscape soils or soil amendments/compost;**
3. **Spreading medium-sized mulch;**
4. **Spreading fine mulch; or**
5. **Spreading shredded mulch.**

Step-By-Step

Step 2: Select the hourly total dust exposure for the selected product and task combination (micrograms/hour):

	Total Dust Exposure per hour	
	Activity	µg/hour
1	Potting plants using a potting mix	441.7
2	Preparing plots for planting using landscape soils or soil amendments/compost;	341.7
3	Spreading medium-sized mulch	387.5
4	Spreading fine mulch	458.3
5	Spreading shredded mulch	395.7

Step-By-Step

Step 3: Estimate the number of hours a person (consumer or employee) will engage in the product and task activity in *any day*. Once an estimate of hours is determined, Step 2 (*hourly total dust exposure*) is multiplied by this value.

NOTE:

- **This value can only be an estimate because there will be large variation in terms of customer project size or use pattern.**
- **This value can be obtained by further analysis and studies based on number of bags of product used or by average number of bags purchased, for example.**
- **However, the number of hours largely addresses this issue of variability, and estimates devised by each manufacturer will be the best estimates available.**

Step-By-Step

Step 4: Enter the concentration of Proposition 65 chemical resulting from laboratory analysis* of the product (expressed in mg/kg, or ppm).

Step 5: Convert mg/kg to μg/kg by multiplying by 1,000.

Step 6: Convert μg/kg to μg/μg by dividing by 1,000,000,000

Step 7: Multiply the value from Step 3 (exposure) by the value from Step 6 (dose) to determine the total dust value in μg per day (risk assessment).

*Product tests should be run by a California Certified Laboratory qualified for Proposition-65 testing.

Step-By-Step

Step 8:

- Proposition 65 warning applicability is determined by comparison of the daily exposure in μg/day (from Step 7) with the regulatory safe harbor levels (Table 1).
- If an applicable NSRL for a cancer-causing chemical is exceeded, an additional question that must be asked is the frequency of a daily exposure at the value estimated because NSRLs apply to an average daily exposure over a lifetime.
- Therefore, a landscape employee who may work as long as 50 years is more likely to be exposed over a lifetime in excess of an NSRL if the calculated daily exposure exceeds the NSRL compared to a consumer gardener or mulch user who would only work with materials a few days per year.
- If a MADL is exceeded based on the above exposure/analysis in any single day, a Proposition 65 warning is required. This is the reason why most Proposition 65 enforcement actions are related to reproductive toxicity—especially lead—compared to carcinogenic chemicals.

Table 1: CA Proposition-65 Safe Harbor Limits

Element/Compound	Hazard	NSRL (µg/Day)	MADL (µg/Day)
Arsenic (Inorganic Compounds)	•Cancer •Developmental toxicity	**< 0.06 (inhaled)**	**< 10 (other)**
Beryllium	•Cancer	**0.1**	**0.0002 (sulfate)**
Cadmium	•Male reproductive •Cancer	**4.1 (oral)**	**0.05 (inhalation)**
Chromium (Hexavalent Only)	•Cancer •Reproductive toxicity	**0.001 (inhalation)**	**8.2 (oral)**
Cobalt	•Cancer	**None Established**	**None Established**
Lead	•Cancer •Reproductive toxicity	**15 (oral)**	**0.5**
Nickel	•Cancer •Reproductive toxicity	**None Established**	**None Established**

Step-By-Step

Step 9: After determination of whether or not Proposition 65 warnings are required, the calculations should be maintained in order to defend against allegations not based on a comparable scientific exposure analysis, or on the basis that the allegation of a violation cannot be shown because there was no knowing or intentional exposure due to reasonable application of the regulatory exposure assessment consistent with the safe harbor regulations.

Translation: Keep a copy to CYA.

Or Use Excel Calculator

Prop 65 Exposure Assessment						
This is a BLUE number calculator. ONLY change BLUE numbers or BLUE Text						
Product Name:	USER ENTRY					
Activity:	Potting plants using potting mix					
Date:	USER ENTRY					
Assessor's Name:	USER ENTRY					
Lab ID#:	USER ENTRY					
Select Element/Compound for Evaluation	Arsenic (Inorganic)					
Step 1. Select product type	Potting plants using potting mix					
Step 2. Select Total Dust Exposure per hour from Table to the Right	441.7	µg/hour				
Step 3. Enter number of hours exposed in a day	8.0	hours/day		**Exposure To Total Dust Per Hour**		
Equals the total Exposure per Day	3,533.6	µg/day		**Activity**	**µg/hour**	
				Potting plants using potting mix	441.7	
Step 4. Enter your test data as mg/kg (or ppm)	2.0	mg/kg		Preparing plots for planting using landscape soils/soil amendments/compost	341.7	
Step 5. Convert mg/kg to µg/kg (multiply by 1,000)	2,000.0	µg/kg		Spreading mulch - medium nuggets	387.5	
Step 6. Convert µg/kg to µg/µg by dividing by 1,000,000,000	0.000002	µg/µg		Spreading mulch – premium red mulch	458.3	
Step 7. Calculate Total Exposure value (Row 14 times Row 18)	0.007067	µg/day		Spreading mulch - shredded	395.8	
	If Step 7 is Red = Fail, Black = Pass					
				Element/Compound	**NSRL µg/day**	**MADL µg/day**
Prop 65 NSRL	0.06	µg/day		Arsenic (Inorganic Compounds)	< 0.06 (inhaled)	< 10 (other)
Prop 65 MADL	10	µg/day		Beryllium	0.1	0.0002 (sulfate)
				Cadmium	4.1 (oral)	0.05 inhalation
Step 8. If value from Step 7 is black, Prop 65 labeling is not needed.				Chromium (Hexavalent Only)	0.001 (inhalation)	8.2 (oral)
				Cobalt	None Established	None Established
If value from Step 7 is Red, review MSRF report, page 9 for options regarding further evaluation				Lead	15 (oral)	0.5
				Nickel	None Established	None Established
FINAL date: 4/25/19						

Wood Dust

- **Although CA lists wood dust as a Proposition-65 known health hazard, it presently has no NSRL or MADL on Wood Dust even though OSHA and all other states have published limits on exposure.**

- **Based on this research, MSC has requested CA issue an NSRL or Letter of Exemption for Mulch & Soil Products.**

- **The CA Office of Environmental Health Hazard Assessment (OEHHA) has not responded.**

Donor Thank You

This research was made possible by the generous donations of the following companies:

- **Gro-Well Brands, Tempe, AZ**
- **Harvest Consumer Products, Mooresville, NC**
- **Kellogg Garden Products, Carson, CA**
- **Mountain West Bark, Rexburg, ID**
- **Oldcastle Lawn & Garden, Atlanta, GA**
- **Sun Gro Horticulture, Agawam, MA**
- **Swanson Bark & Wood Products, Longview, WA**

About MSRF

The MSRF was founded in 2005 as a not-for-profit, tax exempt, charitable and scientific organization under Section 501(c)(3) of the IRS Code (1976):

- **to promote public education and safety;**
- **to develop and implement scientific testing methods; and**
- **to conduct scientific research on the use of mulch and soil products for consumer gardening, commercial greenhouse, and professional landscape applications.**

The Foundation is an independent but supporting organization to the Mulch & Soil Council which represents the common business interests of producers of mulch and soil products in North America.