



*Protocol for Proposition 65 Chemical
Exposure & Regulatory Risk Assessment
for Use of Garden Mulches,
Potting Mixes, Landscape Soils &
Soil Amendments/Composts*

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About the Mulch & Soil Research Foundation (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.

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California’s Proposition 65 law requires any person in the course of doing business to 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].

Products manufactured or formulated and packaged by businesses in the mulch and soil industry are expected to contain such chemicals at low concentrations because of the natural presence of metals in native mineral 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. The following table presents the typical concentrations of metals listed as regulated by Proposition 65 in normal soil:

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

Due to the fact that the threshold for warning is defined as any detectable level of exposure [HSC § 25249.11(c)], it is essential that purveyors of mulch and soil products review and, to the extent necessary, have products tested to determine whether a detectable exposure may occur, which potentially requires a warning. However, despite this extraordinary low applicability threshold, the statute provides for an exemption from warning if:

“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)].

This statutory exemption is implemented through regulations of the Office of Environmental Health Hazard Assessment (OEHHA), which includes procedures to conduct exposure and regulatory risk assessments, and 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 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)	<ul style="list-style-type: none"> • Cancer • Developmental toxicity 	< 0.06 (inhaled)	< 10 (other)
Beryllium	<ul style="list-style-type: none"> • Cancer 	0.1	0.0002 (sulfate)
Cadmium	<ul style="list-style-type: none"> • Male reproductive • Cancer 	4.1 (oral)	0.05 (inhalation)
Chromium (Hexavalent Only)	<ul style="list-style-type: none"> • Cancer • Reproductive toxicity 	0.001 (inhalation)	8.2 (oral)
Cobalt	<ul style="list-style-type: none"> • Cancer 	None Established	None Established
Lead	<ul style="list-style-type: none"> • Cancer • Reproductive toxicity 	15 (oral)	0.5
Nickel	<ul style="list-style-type: none"> • Cancer • Reproductive toxicity 	None Established	None Established

Therefore, in order to apply these exempt levels of exposures, the producer of the garden mulch, potting soil, landscape soil or soil amendment/compost must compare these values to the results of an Exposure Assessment—this process is known as the Regulatory Risk Assessment.

Exposure Assessment

An Exposure Assessment to determine the amount of total dust to which workers representing gardeners, landscaping or nursery employees would be exposed to while performing simulated tasks using mulch and soil products was performed. This study was conducted on July 10, 2018 at a residential location in Stockton, San Joaquin County, California.

The full report of the study conducted by California Industrial Hygiene Services, Inc. is found in Appendix A. To briefly summarize, workers conducted specific work tasks using the following mulch and soil materials for a 75 to 80-minute period while being monitored (as described in Appendix A):

- 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.

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. As the report indicates, the mass of dust when divided by the amount of air sampled yields a calibrated exposure expressed in micrograms per cubic meter, or $\mu\text{g}/\text{m}^3$, which can be converted to $\mu\text{g}/\text{hour}$. The results indicate exposures to total dust during the various tasks ranged from 287.5 to 587.5 $\mu\text{g}/\text{hour}$.

Table 1 of Appendix A presents the data generated by the study in both $\mu\text{g}/\text{m}^3$ and $\mu\text{g}/\text{hour}$. (The latter expression in $\mu\text{g}/\text{hour}$ facilitates extrapolation for Proposition 65 regulatory risk assessment purposes.)

Regulatory/Risk Calculations

Once the total dust exposure over a one-hour period for a particular task with a certain product is determined as shown in the previous discussion, the next step is to 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 ($\mu\text{g}/\text{hour}$) 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 $\mu\text{g}/\mu\text{g}$) to yield the exposure to the subject chemical, which is then compared to the NSRL or MADL.

This narrative explanation can be described as a step-by-step approach as follows:

Step 1: 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 2: Select the hourly total dust exposure for the selected product and task combination (micrograms/hour):

Total Dust Exposure per hour from Table 1, Appendix A.		
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 3: Estimate number of hours a person (consumer or employee) will engage in the product and task activity in any day. 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. Once an estimate of hours is determined, Step 2 hourly total dust exposure is multiplied by this value.

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 by the value from Step 6 to determine the total dust value in µg per day.

The Formula:

$$[(\text{Number of hours of exposure in a day}) \times (\text{Dust Exposure for Product and Task in } \mu\text{g/hour}^\dagger)] \times [(\text{P65 Chemical Presence in Product in mg/kg}^{\dagger\dagger} \times 1,000)^{\dagger\dagger\dagger} \div 1,000,000,000^{\dagger\dagger\dagger}] = \text{Exposure in } \mu\text{g/day}$$

[†]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

The µg/day exposure level determined in Step 7 is compared to the Proposition 65 regulatory safe harbor levels in the following table:

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

Step 8: Proposition 65 warning applicability is determined by comparison of the daily exposure in µg/day with the regulatory safe harbor levels. 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.

Alternatively, 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.

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.

Example Calculation #1: Consumer using **POTTING SOIL** for two (2) hours to re-pot plants

Part A. Calculating the Total Exposure per Day in $\mu\text{g}/\text{day}$

Step 1: Potting plants using a potting mix.

Step 2: Total dust exposure from MSRF Study (Appendix A, Table 1): 441.7 $\mu\text{g}/\text{hour}$

Step 3: Hours engaged in task: 2 hours/day. Multiply 2 hours/day by the total dust exposure per day 441.7 $\mu\text{g}/\text{day}$ to equal 883.4 $\mu\text{g}/\text{day}$

Part B: Converting mg/kg to $\mu\text{g}/\mu\text{g}$:

Step 4: Consult testing data for Proposition 65 chemical(s) of concern. For this example, 5 mg/kg will be used.

Step 5: The 5 mg/kg is converted to $\mu\text{g}/\text{kg}$ by multiplying by 1,000) to equal 5,000 $\mu\text{g}/\text{kg}$

Step 6. The 5,000 $\mu\text{g}/\text{kg}$ is converted $\mu\text{g}/\mu\text{g}$ by dividing by 1,000,000,000 to equal 0.000005 $\mu\text{g}/\mu\text{g}$.

Part C: Calculating Total Exposure per day:

Step 7. Multiply the value from Step 3 by the value from Step 6.

$$883.4 \mu\text{g}/\text{day} \times 0.000005 \mu\text{g}/\mu\text{g} = 0.004417 \mu\text{g}/\text{day} \text{ for lead}$$

Part D: Determining if Prop 65 labeling is required.

The value 0.004417 $\mu\text{g}/\text{day}$ is compared to lead's NSRL for cancer: 15 $\mu\text{g}/\text{day}$ and 0.5 $\mu\text{g}/\text{day}$ for reproductive harm—neither of which is exceeded; therefore, no Proposition 65 warning is applicable.

Example Calculation #2: Landscaper using SOIL AMENDMENT/COMPOST for an 8-hour workday:

Part A. Calculating the Total Exposure per Day in µg/day

Step 1: Landscaper using soil amendment/compost.

Step 2: Total dust exposure from MSRF Study (Appendix A, Table 1): 341.7 µg/hour

Step 3: Hours engaged in task: 8 hours/day. Multiply 8 hours/day by the total dust exposure per day 341.7 µg/day to equal 2,733.6 µg/day

Part B: Converting mg/kg to µg/µg:

Step 4: Consult testing data for Proposition 65 chemical(s) of concern. For this example, 5 mg/kg will be used.

Step 5: The 5 mg/kg is converted to µg/kg by multiplying by 1,000) to equal 5,000 µg/kg

Step 6. The 5,000 µg/kg is converted µg/µg by dividing by 1,000,000,000 to equal 0.000005 µg/µg.

Part C: Calculating Total Exposure per day:

Step 7. Multiply the value from Step 3 by the value from Step 6.

$$2,733.6 \mu\text{g/day} \times 0.000005 \mu\text{g}/\mu\text{g} = 0.013668 \mu\text{g/day for lead}$$

Part D: Determining if Prop 65 labeling is required.

The value 0.013668 µg/day is compared to lead's NSRL for cancer: 15 µg/day and 0.5 µg/day for reproductive harm—neither of which is exceeded; therefore, no Proposition 65 warning is applicable.

Refinement of Risk Assessment Calculations

In the event the methodology described above exceeds or is close to regulatory safe harbor levels, there are means to refine the analysis based on risk assessment principles.

- (1) Averaging exposure time for carcinogenic chemicals. As discussed above, the NSRL is based on a lifetime exposure (70 years for a consumer; 50 years for a person occupationally exposed). This distinction between NSRLs and MADLs should be recognized during any Proposition 65 analysis.
- (2) Total dust exposure refinement: The measurement of total dust in the study included all airborne dust an exposed person would encounter and is assumed as the exposure. In fact, there are different sub-types of exposure with distinct routes

and efficiencies of uptake; for example, very fine particulate matter called “respirable dust” less than 10 microns, or micrometers (μm) in diameter reach deep into the lungs are readily-absorbed by the body, while “inhalable dust” 100 μm s or less enter the lungs but are slightly less efficiently absorbed. However, the larger particles, which are to a larger extent captured by the upper respiratory tract and swallowed are much less efficiently absorbed into the body. It would not be unreasonable to estimate that less than half of the ingested lead is not absorbed into the body of an adult.

- (3) Background dust: Technically, background dust should be subtracted from the total dust exposure estimates, which would reduce the total dust exposure determinations for each product, activity and exposure estimate. However, due to unusually high background dust in the open area in a high-particulate San Joaquin Valley and during fire season, as well, which may not be representative of background dust at the point of product use, background has not been subtracted from the total dust values obtained and used for the calculations¹. The result is that any Proposition 65 exposure assessment using this protocol is very conservative.

¹ July 10, 2018 airborne particulate matter (PM) measured by the San Joaquin Air Pollution Control District nearest to the subject assessment site indicated the following PM2.5 and PM10 concentrations, which are compared to California Ambient Air Quality Standards showing values approaching regulatory limits in local ambient air.

	Results	State Standard
PM2.5	7.5	12 $\mu\text{g}/\text{m}^3$ (annual average)
PM10	33.27	50 $\mu\text{g}/\text{m}^3$ (24-hour average)

Note: Total Dust is not monitored by the District and no standard is established but is expected to be a significant contributor to total dust volume.