Supporting Materials for a Safe Use Determination for Exposures to Crystalline Silica in Four WOODWISE® Wood Filler Products

Office of Environmental Health Hazard Assessment
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Summary

This document presents an evaluation of a Safe Use Determination (SUD) request from Design Hardwood Products, Inc. (DHPI) for potential exposures to respirable crystalline silica in four WOODWISE® wood filler products: Full-Trowel Filler, Wood Patch, Pre-Finish Filler, and No Shrink Patch-Quick. The evaluation is specific to the information provided to the Office of Environmental Health Hazard Assessment (OEHHA) and is not directly applicable to any other product or exposure scenario.

OEHHA utilized a screening level approach to evaluate this request. In this approach, an upper-end estimate of the concentration of respirable particles of crystalline silica in air from use of the WOODWISE® wood filler products was determined, based on air sampling data from simulation of product use, additional product information, and several assumptions. This estimate was then compared to an air concentration range associated with a cancer risk of one in 100,000 derived from occupational epidemiology studies. Based on this analysis, OEHHA found that exposures to the estimated air concentration of respirable crystalline silica from WOODWISE® wood filler products correspond to a calculated cancer risk of less than one in 100,000. Thus, OEHHA determined that no warning is required for exposures to respirable crystalline silica from use of the four WOODWISE® wood filler products, when the crystalline silica content of those products is as follows:

- **Full-Trowel Filler**: No more than 0.6% total crystalline silica, and 0.2% respirable crystalline silica by weight.
- **Wood Patch**: No more than 0.6% total crystalline silica and 0.2% respirable crystalline silica by weight.
- **Pre-Finish Filler**: No more than 2.0% total crystalline silica and 0.2% respirable crystalline silica by weight.
- **No Shrink Patch-Quick**: No more than 0.6% total crystalline silica and 0.2% respirable crystalline silica by weight.

Provided that these four products meet the above-stated crystalline silica limits, a warning would not be required either for those using the products (e.g., to install or

refinish hardwood flooring) or for occupants of homes or other buildings in which these wood filler products have been used.

This evaluation performed in response to the SUD request was limited to exposure to respirable crystalline silica resulting from use of the four specific WOODWISE® wood filler products identified in the request. Exposures to other listed substances, if any, that may result from the use of these wood filler products were not reviewed by OEHHA in the context of this request. This evaluation does not address exposures to respirable crystalline silica from use of WOODWISE® wood filler products other than application to hardwood floors, as specified in the request.

1. Introduction

The California Environmental Protection Agency's Office of Environmental Health Hazard Assessment (OEHHA) is the lead agency for the implementation of Proposition 65 [1]. On March 8, 2018, OEHHA announced that it had received a request from Design Hardwood Products, Inc. (DHPI) for a Safe Use Determination (SUD) for exposures to crystalline silica in four WOODWISE® wood filler products:

- Full-Trowel Filler,
- Wood Patch,
- Pre-Finish Filler, and
- No Shrink Patch-Quick.

The SUD request was made by DHPI pursuant to Title 27 of the California Code of Regulations, section 25204 [2]. A public comment period on this SUD request was held from March 8 to April 9, 2019. No public hearing was requested and no public comments were received.

Crystalline silica (airborne particles of respirable size) is on the Proposition 65 list of chemicals known to the state to cause cancer. For chemicals that are listed as causing cancer, the "No Significant Risk Level (NSRL)" is defined as the level of exposure that would result in no more than one excess case of cancer in 100,000 individuals exposed to the chemical over a 70-year lifetime. Although an NSRL has not yet been adopted for crystalline silica, OEHHA has previously identified an air concentration range, derived from occupational epidemiology studies using conservative default potency values reviewed by OEHHA, at which exposure is associated with an upper-bound

[1] The Safe Drinking Water and Toxic Enforcement Act of 1986, codified at Health and Safety Code section 25249.5 *et seq*, is commonly known as Proposition 65 and is hereafter referred to as Proposition 65.
[2] All further references are to sections of Title 27 of the Cal. Code of Regulations.

cancer risk of one in 100,000. This air concentration range of 0.54 to 15 micrograms per cubic meter air (µg/m^3) from Goldsmith *et al.* (1995) has been utilized in prior SUDs for crystalline silica[3,4].

OEHHA has identified professional hardwood flooring installers and refinishers using WOODWISE® wood filler products as the user group with the highest exposure to respirable crystalline silica. Exposures to occupants of homes or other buildings in which these wood filler products have been used are expected to be much lower, as are exposures to the "do-it-yourself" members of the public that may on an infrequent basis use these products.

This document first provides a brief description of WOODWISE® wood filler products covered by the SUD request, followed by a brief summary of the empirical data and exposure analysis that accompanied the SUD request. This is followed by a brief discussion of the derivation of the concentrations associated with no significant risk of cancer for crystalline silica. Then OEHHA's analysis of the upper-bound respirable crystalline silica air concentration resulting from occupational use of WOODWISE® wood filler products is presented, and compared to concentrations posing no significant risk of cancer.

1.1 Product Description and Use

The following is based on information provided in the SUD request and additional communications with DHPI and their consultants, SafeBridge Consultants, Inc.

The SUD request covers the four WOODWISE® wood filler products described briefly below.

- **Full-Trowel Filler** is designed to spread across the surface of a wood floor and fill any cracks, gaps, or voids in the surface. This product contains 0.1 to 0.6% total crystalline silica and 0.1 to 0.2% respirable crystalline silica by weight.
- **Wood Patch** is designed for spot-filling of a wood floor surface, but can be diluted with water and used similarly to full-trowel filler. This product contains 0.1 to 0.6% total crystalline silica and 0.1 to 0.2% respirable crystalline silica by weight.

[3] Supporting Materials for a Safe Use Determination for Crystalline Silica in Sorptive Mineral-based Pet Litter. 1999. California Environmental Protection Agency, OEHHA. Available from https://oehha.ca.gov/media/downloads/crnr/sud20final20letter20and20supporting20materials20pet20litter.pdf .

[4] Supporting Materials for a Safe Use Determination for Crystalline Silica in Interior Flat Latex Paint. 2003. California Environmental Protection Agency, OEHHA. Available from: https://oehha.ca.gov/media/downloads/crnr/sud20final20letter20and20supporting20materials20latex20paint.pdf.

- **Pre-Finish Filler** is designed to fill cracks, nail holes, gouges, and broken edges on pre-finished floors, but can be applied to any wood floor. This product contains 0.1 to 2.0% total crystalline silica and 0.1 to 0.2% respirable crystalline silica by weight.
- **No Shrink Patch-Quick** is designed to fill large voids in the surface of a wood floor (e.g., knot holes). This product contains 0.1 to 0.6% total crystalline silica and 0.1 to 0.2% respirable crystalline silica by weight.

Thus the maximum respirable crystalline silica content provided in the SUD request for these wood filler products is 0.2% by weight, and the maximum amount of total crystalline silica is 0.6%, with the exception of Pre-Finish Filler, for which the maximum is 2.0%.

The crystalline silica ("quartz" in the submitted materials) present in each of these products is the result of the use of one product ingredient, MICRONA™ limestone powder, which comes from a single supplier. MICRONA™ limestone powder accounts for 25 to 75% by weight of each WOODWISE® wood filler product (Attachment 1 of the request).

X-ray diffraction analyses (National Institute for Occupational Safety and Health [NIOSH] method 7500 / Occupational Safety and Health Administration [OSHA] method ID-142) of WOODWISE® wood filler product samples provided in Attachment 2 of the request confirm that crystalline silica is present at detectable levels in the form of α-quartz, the most abundant form of crystalline silica. Other forms of crystalline silica, such as cristobalite and tridymite, were not detected.

These wood filler products are used in either the finishing stage of new hardwood flooring installation or in refurbishment of existing hardwood floors. As specified in the request submitted by DHPI, finishing work typically only occurs one or two times per week during hardwood floor installation. Some large contractors may dedicate workers to different aspects of installation and finishing work. Finishing crews may sand up to 4 hours per day, 5 days per week. For the three products that are semi-solid or solid materials (Full-Trowel Filler, Wood Patch, and Pre-Finish Filler), each product is typically applied directly to a hardwood floor surface and then followed by additional treatments (e.g., sanding, staining) as needed. The fourth product, No Shrink Patch-Quick, is a powder that must be mixed with water prior to application to a hardwood floor surface and subsequent treatments (e.g., sanding, staining) as needed.

The WOODWISE® wood filler products are intended for use by professional hardwood flooring installers and are sold by the manufacturer, DHPI, directly to flooring wholesalers. However, wholesalers and subsequent distributers, including online retailers, may sell these wood filler products to the public.

1.2 Exposure Analysis Provided by Design Hardwood Products, Inc.

In the analysis provided by DHPI, a “worst-case” respirable crystalline silica exposure concentration resulting from use of WOODWISE® wood filler products was assessed for professional hardwood flooring installers. Inhalation was the sole exposure pathway included in the analysis.

DHPI submitted empirical data of personal and area air samples from an exposure study in which professional installers applied WOODWISE® Full-Trowel Filler to hardwood floors in a California home without mechanical ventilation and sanded the applied product. The Full-Trowel Filler was selected as it is typically used in greater amounts than the other three products within the scope of the SUD request (i.e., applied across the entire surface of a hardwood floor) and then sanded. Work activities during the air sampling period consisted of preparation work (including an initial, rough sanding of the hardwood floor itself), application of the WOODWISE® Full-Trowel Filler, sanding (rough sanding and finish sanding), and vacuuming of residual dust.

Personal air samples were collected by active sampling for three individuals: a sanding operator, an observer present in each room during the sanding process, and a professional contractor working in the home on tasks other than application or sanding of WOODWISE® Full-Trowel Filler. Area air samples were collected in duplicate by active sampling at breathing zone height in one of the rooms (Room 3) in which WOODWISE® Full-Trowel Filler was applied and sanded; one area air sample was also collected in an adjacent hallway. An additional composite area sample was collected during sanding activities in all three rooms. All samples were collected on 37 millimeter (mm) polyvinyl chloride filters using SKC aluminum cyclones operated at 2.5 liter per minute flow rate in accordance with standardized methods, including the International Organization for Standardization 7708 criteria specified in the OSHA final rule on crystalline silica.

Crystalline silica was measured by X-ray diffraction in accordance with NIOSH Method 7500. No crystalline silica, including respirable crystalline silica, was quantified in any of these personal and area samples. The limit of quantification (LOQ) ranged from 0.0064 and 0.0076 milligrams per cubic meter air (mg/m^3), equivalent to 6.4 and 7.6 $\mu g/m^3$.

Because crystalline silica was not measurable, the analysis provided by DHPI calculated levels from respirable dust particles, or “respirable particulates”, which were quantified gravimetrically in accordance with a modified OSHA Method 600 for samples collected over durations ranging from 259 to 306 minutes (about 5 hours). Respirable particle concentrations ranged from 0.079 mg/m^3 to 0.26 mg/m^3, the highest value being for the personal breathing zone of an observer in the room during first-pass sanding. A worst-case respirable crystalline silica concentration was calculated by multiplying these

respirable dust measurements by 0.6%, the highest concentration of crystalline silica in the product. This resulted in upper bound estimates of respirable crystalline silica concentrations during use ranging from 0.5 – 1.6 μg/m^3.

There was no mechanical ventilation to the outdoors during the study, and windows were kept closed. The natural air exchange rate for the home was calculated from the decay of carbon dioxide in the room after all occupants left, as the only source of carbon dioxide was from exhaled breath. The rate was calculated to be 2.1 air changes per hour. A respirable crystalline silica generation rate of 1.4 μg/minute was estimated from personal sampling data of respirable particles (0.26 mg/m^3) and using an air exchange rate of 2.1 times per hour for a room of volume of 25 m^3 in the home.

The lifetime average exposure concentration was calculated by DHPI by using the estimated respirable crystalline silica generation rate (1.4 μg/minute). DHPI assumed exposure occurs in a small room (volume of 25 m^3) with an air exchange rate of 0.85 per hour, which is an average of the summer and winter median air exchange rate, and takes into account duration and frequency of occupational exposure. Specifically, occupational product use was assumed by DHPI to be four hours of occupational use per day, five days per week, 50 weeks per year for 40 years, averaged over a 70-year lifespan. DHPI calculated the lifetime average exposure concentration to be 0.26 μg/m^3 for professional flooring installers. Table 1 lists the parameters used to derive this estimate.

Table 1. Estimated lifetime average respirable crystalline silica exposure concentration by Design Hardwood Products, Inc.

Parameter	Unit	Value	Basis
Generation rate of respirable crystalline silica (**G**)	µg/minute (min)	1.4	Estimated by measured air concentration of respirable particulates (= 0.26 mg/m^3), room size (= 25 m^3), air change rate (ACH) (= 2.1/hr) and 0.6% respirable crystalline silica content in the product; = [(0.26 × 2.1 × 25 × 0.6% × 1000) / 60]
Room Volume (**V**)	m^3	25	Volume of a small room adapted from US EPA (2011)
Air change rate (**ACH**)	/hour (hr)	0.85	Average of median summer (= 0.6 /hr) and winter (=1.1 /hr) air change rates in California homes from Yamamoto *et al.* (2010)
Room ventilation rate (**Q**)	m^3/min	0.35	= [**ACH** / (60 min / hr)] × (**V**)
Indoor respirable crystalline silica air concentration (**C**)	µg/m^3	4.0	= **G** / **Q**
Exposure hours (**EH**)	hr	40,000	= (4 hr/d × 5 d/wk × 50 wk/yr × 40 yrs), assumed
Lifetime hours (**LH**)	hr	611,520	= (70 yrs × 52 wk/yr × 7 d/wk × 24 hr/d)
Lifetime average exposure concentration	µg/m^3	0.26	= **(C × EH) / LH**

2. OEHHA Analysis of Respirable Crystalline Silica Exposure Concentrations Resulting from Use of WOODWISE® Wood Filler Products

2.1 Existing Cancer Potency Estimates for Crystalline Silica

As discussed in the previous SUDs for crystalline silica (airborne particles of respirable size) referenced above, numerous reviews exist concerning the carcinogenicity of respirable crystalline silica, with evidence of effect in humans coming primarily from occupational studies. The most recent authoritative review was published by the International Agency for Research on Cancer (IARC) in 2018, which concluded, "Crystalline silica in the form of quartz or cristobalite dust is carcinogenic to humans (Group 1). IARC reviewed several meta-analyses and found that "all analyses except

for those devoted to categories without silicosis found an elevated lung cancer risk, whether occurring among those with silicosis or among crystalline-silica-exposed workers, or arising from cohort or case–control studies" (IARC, 2018).

IARC also reviewed the mechanistic evidence and noted that "alveolar macrophages and neutrophils play a central role in diseases associated with exposure to crystalline silica" and that "(a)n inflammation-based mechanism as described in IARC (1997) is a likely mechanism responsible for the induction of lung cancer associated with exposure to crystalline silica, although reactive oxygen species can be directly generated by crystalline silica polymorphs themselves, and can be taken up by epithelial cells. For this reason, a direct effect on lung epithelial cells cannot be excluded." Based on the above, we expect that the screening potency estimates represent upper-end estimates of the true potency when evaluating exposures that are at levels considerably below the occupational permissible exposure level of 50 $\mu g/m^3$ established by the California Division of Occupational Safety and Health (Cal/OSHA)[5].

For this analysis, OEHHA is using the potency value relied on for previous SUDs for crystalline silica. It is based on the analyses reported in Goldsmith et al. (1995): Cancer slope factors ranged from 6.8×10^{-7} to 1.85×10^{-5} $(\mu g/m^3)^{-1}$ for continuous (24-hr, lifetime) exposure to silica dust. Based on these estimates, concentrations associated with a cancer risk of one in 100,000 would range from 0.54 to 15 $\mu g/m^3$ crystalline silica.

2.2 Screening-level Assessment of Respirable Crystalline Silica Exposure Concentrations from Use of WOODWISE® Wood Filler Products

OEHHA conducted a screening-level analysis to derive the upper-end estimate of respirable crystalline silica exposure concentrations for professional hardwood flooring installers using WOODWISE® wood filler products. OEHHA's upper-end estimate of a lifetime average respirable crystalline silica air concentration resulting from occupational use of WOODWISE® wood filler products is 0.2 $\mu g/m^3$. The parameters used are shown in Table 2, and a discussion of the assumptions used follows the table. OEHHA utilized an approach consistent with prior SUDs for evaluation of respirable crystalline silica air concentrations to which exposure could occur in conjunction with a conservative exposure scenario. The identified scenario is use of the WOODWISE® Full-Trowel Filler product in a single-family home, in which respirable crystalline silica is released into indoor air during the application and sanding of the wood filler product.

OEHHA determined that respirable crystalline silica exposures for occupants of homes or other buildings in which WOODWISE® wood filler products are used will be much

[5] Title 8 of the California Code of Regulations, Section 1532.3. Available from the Department of Industrial Relations at https://www.dir.ca.gov/title8/1532_3.html

lower than those for occupational workers. Exposures for occupants will be far less frequent and are expected to be of shorter duration overall.

Table 2. Parameters used in and results of the OEHHA screening-level analysis of the respirable crystalline silica air concentration resulting from occupational use of WOODWISE® Full-Trowel Filler

Parameter	Unit	Value	Basis
A. Maximum concentration of respirable particles measured in personal samples[a]	mg/m^3	0.26	Maximum concentration reported from personal air samples in the exposure study provided by DHPI (Table 4 of the request; data: 0.12, 0.18, 0.26 mg/m^3).
B. Maximum total crystalline silica content of WOODWISE® Full-Trowel Filler	unitless	0.6%	Provided by DHPI (Table 1 of the request).
C. Theoretical maximum respirable crystalline silica air concentration	$\mu g/m^3$	1.56	= **A** × **B** × (1000 µg/mg**)**
D. Lifetime adjustment factor	unitless	13.1%	= (8 hr/24 hr) × (5 d/7 d) × (50 wk/52 wk) × (40 yr/70 yr)
E. Lifetime-adjusted respirable crystalline silica air concentration	$\mu g/m^3$	0.2	= **C** × **D**

[a] From a personal air sample of the worker-observer present for first-pass sanding of floors in each room of the exposure study.

OEHHA's screening-level (i.e., upper-end) estimate of a lifetime average occupational respirable crystalline silica air concentration of 0.2 $\mu g/m^3$ (Line E, Table 2) is based on the assumptions listed below:

1. OEHHA assumes that the maximum concentration of respirable particles from three personal air samples (0.26 mg/m^3, sampling duration: 291 minutes) from the exposure study submitted by DHPI is a conservative estimate of personal exposure for professional hardwood floor installers during use of WOODWISE® Full-Trowel Filler. This selected value is also higher than the four area air samples, including the composite sample that captured all first-pass sanding activity. OEHHA also assumes that all measured respirable particles result from use of the Full-Trowel Filler, which is an overestimate as there could be other sources of respirable particles in the house, such as initial preparation sanding prior to product application.

2. As no crystalline silica was quantified in the personal air samples, OEHHA uses the maximum total crystalline silica content reported for the WOODWISE® Full-

Trowel Filler product (0.6%) and the maximum respirable particle concentration from the personal air sample data in the exposure study (0.26 mg/m^3) to estimate the theoretical maximum respirable crystalline silica, 1.56 µg/m^3. This assumes all crystalline silica in the filler materials will, upon product use, be in the form of respirable crystalline silica, a very conservative assumption. Although some respirable crystalline silica may be generated by sanding, the maximum respirable crystalline silica content in the Full-Trowel Filler product is only 0.2%. OEHHA also assumes that professional floor installers would be exposed to crystalline silica on a full-time occupational basis, i.e., 8 hours per day, 5 days per week, 50 weeks per year, for 40 years. OEHHA assumes that the maximum respirable crystalline silica air concentration derived from a 5-hour sampling duration would be constant throughout the 8-hour workday, every work day, for 40 years. This is also a very conservative assumption.

3. OEHHA anticipates that occupational exposure to crystalline silica from use of the Full-Trowel Filler would be higher than occupational exposure resulting from use of any of the other three wood filler products covered by this SUD request, due to relatively higher amounts of material used in typical Full-Trowel Filler applications, and the requisite sanding activities involved with this use.

In this screening assessment, OEHHA made several conservative assumptions, as noted above, and the upper-end estimate of a lifetime average respirable crystalline silica air concentration to which occupational users would be exposed is 0.2 µg/m^3 (Line E, Table 2). This concentration falls below the lower end of the air concentration range of 0.54 to 15 µg/m^3 associated with a cancer risk of one in 100,000 persons discussed above. Therefore, occupational exposure to crystalline silica from these specific WOODWISE® wood filler products falls below the level posing significant cancer risk.

2.2.1 Uncertainties associated with screening assessment of respirable crystalline silica exposure concentrations from use of WOODWISE® wood filler products

There are uncertainties associated with the models and parameters utilized in the screening assessment of respirable crystalline silica exposure concentrations resulting from use of WOODWISE® wood filler products. The assumptions utilized in this assessment to address the uncertainties likely result in overestimates of exposure:

- OEHHA assumes that the empirical data (personal and area air samples) submitted by DHPI reflect the respirable particle exposure of the average user of WOODWISE® wood filler products in a typical workday. In this study, personal samples of three subjects with different work assignments were measured during a typical product use scenario. However, workers may have different activity patterns (e.g., sanding frequency and patterns) or experience different conditions

(e.g., various types of ventilation in the building; size of the floor area) and thus the occupational scenario employed in the DPHI study may not be representative of all occupational users of WOODWISE® wood filler products. OEHHA selected the highest concentration of personal air sample results to estimate the lifetime exposure.

Measurements were made in a house without mechanical ventilation, and with the windows kept closed. It is likely that open windows or use of mechanical ventilation during sanding of wood filler products applied to flooring would reduce the airborne particle concentrations.

- OEHHA uses the maximum respirable particle concentration measured in the DHPI study to estimate the respirable crystalline silica concentration from use of WOODWISE® Full-Trowel Filler. This assumes that all respirable particles are generated from the Full-Trowel Filler itself, and that other activities performed during product use such as an initial, rough sanding of the hardwood floor itself do not contribute. The use of the maximum respirable particle concentration in calculating the maximum theoretical respirable crystalline silica concentration of 1.56 $\mu g/m^3$ is expected to overestimate respirable crystalline silica concentrations typically experienced by professional hardwood flooring installers.

- OEHHA uses the maximum concentration of crystalline silica in WOODWISE® Full-Trowel Filler, 0.6%, to estimate the respirable crystalline silica concentration from use of the product. The amount of total crystalline silica in the product ranges from 0.1 to 0.6% by weight as reported in the safety data sheet (See Attachment 1 of the request). Additional data was submitted by DPHI for one sample of the product (See Attachment 2 of the request); total crystalline silica content in that sample was 0.36%.

- OEHHA assumes occupational exposure to respirable crystalline silica for 8 hours per day, 5 days per week, 50 weeks per year, for 40 years.

Conclusions

This screening level analysis, which relied on relatively conservative assumptions, only applies to the exposure scenarios discussed in this document. OEHHA is not drawing conclusions for other exposure scenarios or other products.

Based on this screening level analysis of the information and data provided by DHPI, the upper-end estimate of a lifetime average respirable crystalline silica exposure concentration for occupational users of the WOODWISE® Full-Trowel Filler product is 0.2 $\mu g/m^3$. This exposure concentration falls below the low end of the air concentration

range of 0.54 to 15 µg/m^3 associated with an extra cancer risk of one in 100,000 derived from occupational epidemiological studies. Given the above, OEHHA has determined that respirable crystalline silica exposures arising from use of the four WOODWISE® wood filler products that are the subject of this SUD request fall below the level posing a significant cancer risk for professional hardwood flooring installers, "do-it-yourself" users of the products, and occupants of homes and other buildings in which these wood filler products have been used.

Thus, exposures to respirable crystalline silica from use of the four WOODWISE® wood filler products within the scope of the request would not require a Proposition 65 warning. This determination is specific to these four WOODWISE® wood filler products:

- **Full-Trowel Filler**: No more than 0.6% total crystalline silica, and 0.2% respirable crystalline silica by weight.
- **Wood Patch**: No more than 0.6% total crystalline silica and 0.2% respirable crystalline silica by weight.
- **Pre-Finish Filler**: No more than 2.0% total crystalline silica and 0.2% respirable crystalline silica by weight.
- **No Shrink Patch-Quick**: No more than 0.6% total crystalline silica and 0.2% respirable crystalline silica by weight.

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