Human Health Risk Assessment of Volatile Organic Compound Emissions from Boreal Nature Evolution Spray Polyurethane Foam

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EXECUTIVE SUMMARY

A Human Health Risk Assessment for Genyk Inc.'s Boreal Nature Evolution was conducted by Eric Rosenblum PHD, DABT. Emissions testing of Boreal Nature Evolution, a two-part spray-applied polyurethane thermal insulating foam, was performed by Exova in accordance with the Underwriters Laboratories of Canada, CAN/ULC-S774-09 Testing Standard. Headspace and dynamic chamber analysis were performed on test specimens of the thermal insulation and volatile organic compound (VOC) emissions were characterized by gas chromatography-mass spectroscopy.

The purpose of the risk assessment was two-fold: (1) to determine whether VOC emissions from Boreal Nature Evolution pose a health risk to individuals residing in homes or buildings insulated with this product and (2) to determine an acceptable residential re-occupancy time after application of Boreal Nature Evolution. The risk assessment was undertaken using guidelines, protocols and methodologies proposed and accepted by Health Canada, the Canadian Construction Materials Centre and the United States Environmental Protection Agency (USEPA). These guiding principles of risk assessment were utilized to predict the human health risk associated with potential exposure to VOC emissions from Boreal Nature Evolution.

Potential health risk associated with consumer exposures to volatile organic compounds (VOCs) released from the Boreal Nature Evolution foam was based on consideration of relevant chemical and toxicity data. Human exposure was conservatively based maximum indoor air concentrations of each VOC emission product measured over a 30-day foam curing period. In addition, the magnitude, frequency, and duration of residential human exposure to each VOC product, and their individual decay patterns over a 30-day period of dynamic chamber analysis was considered. Risk conclusions used conservative safety margins to assess potential exposure to maximum possible concentrations relative to established airborne levels considered safe for human exposure.

Review of the dynamic chamber analysis data for Boreal Nature Evolution indicates that peak concentrations of most VOC emission products would likely be reached within 1 to 12 hours post application. In addition, maximum airborne concentrations for most identified VOCs decrease over the testing period, suggesting these levels would not be maintained within the indoor air for extended periods. Therefore, chronic exposure to maximum level of VOC concentrations would not occur.

One compound: ethene, 1,2 dichloro was selected as a Chemical of Potential Concern (COPC) based on the maximum concentration measured at a concentration greater than available health-based safety threshold. However, maximum airborne concentrations of this COPC were not maintained throughout the 30-day time course but decrease from maximum concentrations detected in the first analytical sampling point (1-hour) to below the general population health-based threshold by the 12-hour sampling point. Ethene, 1,2 dichloro concentrations remains below the established safety threshold for all time points >12-hours and were below the quantification limit (BQL) during the final time point (30-day).

This risk assessment of the residential scenario revealed that, 12-hours post-application of the Boreal Nature Evolution product, exposure to COPC concentrations are not anticipated to result in a human

dose that would result in adverse health effects. Additionally, the total VOC (TVOC) concentration reported at the 12-hour time point falls within the TVOC range of 1 mg/m^3 and 5 mg/m^3 proposed by Canada and the US for office environments. *Ambient air concentrations of VOCs 12-hours after application of this construction material are expected to be well within the established safe range for human exposure.*

The conclusion of this assessment is that Boreal Nature Evolution spray-applied rigid polyurethane thermal insulation product sold by Genyk Inc. should not pose a health risk to individuals residing in homes or buildings insulated with this material 12 hours post-application of the product. Therefore, the recommended re-occupancy time for residents of structures insulated with Boreal Nature Evolution is 12 hours.

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1 INTRODUCTION

Spray polyurethane foams (SPF) are thermal insulating products commonly used in commercial, institutional, and residential construction. Polyurethane insulating foams are formed through a chemical reaction between an isocyanate and a polyol compound which, when mixed at the site of application, form the finished foam product. Prior to application these two main ingredients are stored in separate compartments commonly referred to as A-side and B-side components. The physical and chemical character, structure and molecular size of the isocyanate and polyol compounds influence the polymerization reaction, as well as ease of processing and final physical properties of the finished polyurethane foam. Once the spray foam is applied and cured, it is considered relatively inert. "Curing" refers to the reaction of the mixed A-side and B-side components to produce a polyurethane foam. The curing time (complete reaction) varies depending on the type of SPF product, product formulation, applicator technique, foam thickness, temperature, humidity and other factors. Together, these factors will impact re-occupancy time. Some manufacturers recommend 24 hours after application for the two-component high pressure "professional" SPF system for worker re-entry without the use of personal protective equipment (PPE) and for re-occupancy by residents and other building occupants, but the recommended time may vary. (US EPA 2017).

During the curing time, it is possible for consumers to be exposed to VOCs which are emitted from the SPF product into the indoor air. Volatile organic compounds are carbon-based molecules, such as alcohols, phenols, aldehydes, ketones, and hydrocarbons that have a low boiling point (50-250°C) and high vapor pressure at ordinary room temperature. Due to the low boiling point and high vapor pressure, VOCs from the liquid or solid form of the compound can evaporate or sublimate and enter the surrounding air. VOCs are released from a variety of consumer products and are ubiquitously present at low levels in various indoor environments (office, home and workplaces).

Most available toxicity data associated with SPF products evaluates potential risks occurring under occupational scenarios rather than general population exposures to SPF emissions. Thus, the potential short or long-term general population health effects associated with exposures to VOCs released from SPF material are fundamentally unknown. Due to the lack of established general population toxicity thresholds for SPF products, the human health risks associated with non-occupational exposure to SPFs and/or their VOC emissions can only be evaluated using human health risk assessment protocols. Specifically, human risk predictions are made by comparing measured VOC concentrations emitted from SPF products with available and appropriate toxicity thresholds (CEPA 1994; US EPA 1989).

Spray polyurethane foam insulation products manufactured and developed for use in residential or commercial buildings must undergo standardized VOC emissions testing before commercialization and approval by the Canadian Construction Materials Centre (CCMC). For SPF formulations used in residential spaces, VOC emissions are to be tested in accordance with appropriate methods outlined in the Underwriters Laboratories of Canada, CAN/ULC-S774-09, *Standard Laboratory Guide for the Determination of Volatile Organic Compound Emissions from Polyurethane Foam*. VOC analysis included in the CAN/ULC-S774-09 method includes both headspace and dynamic chamber analysis testing.

Measurements of VOCs emitted from SPFs can then be used to conservatively predict indoor air concentrations and consumer inhalation exposures.

Headspace analysis involves an initial screening of VOC emissions from a test specimen of a polyurethane product aged for approximately 24 hours. Dynamic chamber analysis following CAN/ULC-S774-09 identifies VOCs released from SPF insulation and quantifies the VOC emission rates during a 30-day curing period. The results obtained by dynamic chamber analysis are then used to predict potential indoor air concentrations of VOCs emitted into a typical residential or workplace building. Under CAN/ULC-S774-09 the chamber test parameters are intended to simulate a field installation (250 m^2 of material installed in a 500 m^3 house with a ventilation rate of 0.3 air changes per hour).

The results of VOC emissions testing provide data that can then be used to evaluate human health risk by using assessment protocols that provide guidelines for evaluating chemicals with or without known toxicity thresholds. For compounds without toxicity thresholds, this protocol involves using chemical analogs with established toxicity thresholds and similar molecular structures and biochemical characteristics to the compounds in question.

2 ANALYTICAL RESULTS

A test sample of Boreal Nature Evolution was prepared on 13 February 2019 at Gentyk Inc. under supervision of Gabriel LeBlanc of QAI Laboratories. The product was sprayed onto a sheet of aluminum foil to create a panel. The sample piece was sealed in a bag. The bag was secured in a locked transport case and transported via overnight courier to the Element testing facility in Warren, MI.

On 14 February 2019 the sample piece was removed from its packing and cut into three specimens for introduction into the chambers. The specimens were freshly cut on all six sides. The dynamic-chamber specimens were cut into two (2) thicknesses of 25mm and installed into stainless steel specimen holders. The exposed surface area provided a chamber loading ratio of 0.5m^2/m^3 (square meters per cubic meter). Specimen #1 was introduced to the 51.2-liter stainless steel dynamic chamber, specimen #2 was introduced to the headspace chamber.

In accordance with the testing standards, the SPF emissions measurements are to commence 24 hours after the sample's manufacture (CAN/ULC-S774-09; section 6.1.2), introduction of the specimen to the dynamic chamber occurred at 14:00hrs EST; exactly 24 hours and 0 minutes after manufacture. The dynamic test chamber was operated in an environmentally-controlled enclosure with the air sampling apparatus mounted externally. Air samples to determine chamber emission concentrations were taken at the specified time intervals as prescribed in the CAN/ULC-S744-09 standard; air samples were drawn at 1, 12, 24, and 48 hours and on days 4, 7, 14, and 30 (refer to section 7.3). The air samples were then analyzed as described in Section 4 and Appendix A — Analytical Method of Element Report Project Number: EWA099832.

For headspace analysis, a test specimen was cut from the sample piece and installed in the headspace chamber (0.60-liter volume) to occupy greater than 50% of the 0.60-liter volume. The chamber was

then sealed and maintained at 40°C for 24 hours at zero air flow. Twenty-four hours later an air sample was drawn from the headspace chamber for analysis.

To identify and quantify VOC emissions from the sample, Carbotrap TM 400 absorbent tubes, in conjunction with gas chromatograph/mass selective detector (GC/MSD) analysis, were utilized for all air sampling sessions. The CarbotrapTM 400 absorbent tubes were thermally desorbed using a CDS thermal desorption unit at 300°C for three minutes. Any volatilized compounds were directed into the GC/MSD for compound identification and quantification. This assessment only addresses the toxicity of VOCs which are reported with a confidence of identification of ≥ 75%. All VOCs, regardless of confidence of identification, are evaluated for toxicity based on total VOCs (TVOCs) thresholds. Specifically, measurements of TVOCs represent the amount of VOCs without distinguishing different chemicals. Presently there are no regulatory thresholds for human exposures to TVOCs, however, target goals have been proposed by some certifying bodies in both Canada and the United States (Health Canada 1995). The headspace and dynamic chamber conditions for the test period are presented in Exova Report Project Number: 528153.

2.1 Head Space Analysis

The results of the headspace analysis are not included in the subsequent sections of this risk assessment. Specifically, headspace analysis is an initial screening of VOC emissions from the test specimen and often generates higher concentrations of compounds that volatilize quickly, making the analysis useful for assessment of compounds with concentration levels in the 1- and 12-hour tests that are too low for identification by mass spectral library. In most situations, the headspace analysis is not required since the concentrations are of sufficient strength during the subsequent chamber tests. VOC emissions solely detected in the exaggerated conditions of headspace analysis are considered non-typical and are do not allow an estimated indoor air VOC concentration to be accurately modeled. While the results of the headspace analysis are not used in the risk assessment, the following provides a general review of the VOCs detected during headspace analysis:

SIxteen VOC compounds emitted from the Boreal Nature Evolution test specimen were measured and identified with ≥ 75% confidence during headspace analysis. The concentration of the 16 VOCs ranged from 0.017 mg/m^3 (beta myrcene-) to 1.253 mg/m^3 (1,4 dioxane). The following VOC concentrations in were below available occupational exposure concentrations considered safe for occupational duration exposures:

- 1,2 dichloropropane
- 1,4 dioxane, cyclotrisiloxane
- 1,2-dimethylimidazole, hexamethyl
- chlorobenzene
- limonene
- eucalyptol

Established safe occupational exposure concentrations specific to the following VOCs were not available:

- 2-methyl 2-butanal
- 2-ethyl trans 2-butanal
- 3-carene
- 1,4 dioxane, 2,5 dimethyl
- 1-methyl-4-methyethyl benzene
- 1-chloro-2-methyl benzene
- 1-chloro-4-methylbenzene
- beta myrcene

All other VOCs measured in the headspace analysis were also detected in the dynamic chamber analysis and are discussed in greater detail below.

2.2 Dynamic chamber analyses

A total of 5 VOC emission products were identified with >75% confidence through dynamic chamber analysis of Boreal Nature Evolution (Table 1). Four of the 5 total VOCs had maximum airborne concentration during the 1- hour time point. One compounds, cyclotetrasiloxane, octamethyl-; had a maximum emission concentration at ≥ 24 hours. The maximum air concentrations of VOCs emitted from the Boreal Nature Evolution SPF ranged from 1.293 to 0.005 mg/m^3. The maximum concentration of each VOC emission product, and the time in which these levels were detected, are summarized in the Table 1 below.

Table 1 Maximum Indoor Air Concentrations of VOC Emission Products from Boreal Nature Evolution*

VOC Emission Product Identified	Maximum Indoor Air Concentration (mg/m^3)	Time of Maximum Detection (hrs)
Ethene 1,2, dichloro-	1.293	1-hour
1,4 dioxane	0.026	1-hour
1,3 doixolane, 2-ethyl-4-methyl	0.011	1-hour
Cyclotetrasiloxane, octamethyl	0.005	14-day
Propene, 2-chloro-3,3,3 trifluoro	4.44	1-hour

*This table includes only VOCs which are reported with a confidence of identification of ≥ 75%.

Most of the identified VOCs are emitted at maximum concentrations shortly after SPF application and rapidly decrease over the 30-day testing time course. Specifically, analytical test results indicate that measured concentrations of 4 of the 5 identified VOCs decrease from maximum concentration before the 24-hour time point. In addition, the total number of identified VOCs decreases over the 30-day testing time course. Specifically, 5 identified VOCs are present at the 1-hour time point, 2 identified VOCs are present during the 12-hour to the final 30-day measurement.

The Boreal Nature Evolution foam VOC emission profile is used to quantitatively estimate human exposures to VOCs released during the foam curing process. These conservative exposure estimates were then applied within the risk assessment protocol to quantify the human health risk associated with potential exposure to VOCs released from Boreal Nature Evolution foam product.

Review of the dynamic chamber analysis data indicates that peak concentrations of most identified VOCs released for the Boreal Nature Evolution foam would occur within 12 hours of application. In addition, maximum airborne concentrations drop over the testing period (with the exception of cyclotetrasiloxane, octamethyl), suggesting these maximum VOC concentrations would not be maintained within the indoor air for extended periods. Consumer exposure to maximum level of most VOC concentrations would occur in homes occupied less than 12 hours after Boreal Nature Evolution application.

3 RISK ASSESSMENT

Following CAN/ULC-S774-09 methodology for each identified VOC found in Boreal Nature Evolution foam, the maximum measured concentration emitted during the 30-day analytical time course along with its time of detection were utilized to conservatively predict the potential for human health risks associated with the product. The human health risk assessment discussed in the following sections was conducted using conservative “worst case scenario" assumptions that would lead to an overestimation of potential exposure and risk. Specifically, although dynamic chamber analysis reveals that VOC levels and the total number of VOCs emitted from the foam product decline over the 30-day time course, the screening method utilized in this risk assessment evaluated prolonged residential exposure assuming sustained, chronic exposure to the maximum measured VOC concentrations detected by dynamic chamber analysis. The assumption that chronic human exposures are equal to maximum measured airborne concentrations provides an ample margin of safety for human health in order to address the following questions:

1. *Will exposure to maximum indoor air concentrations of VOC emission products from Boreal Nature Evolution (outlined in Table 1) pose a significant human health risk to residents of homes or buildings insulated with this construction material?*
2. *What is the residential re-occupancy time for Boreal Nature Evolution? (i.e. when is it safe for individuals to reside or enter buildings following the application of the insulation material?).*

3.1 Hazard Identification

The hazard identification step is used to screen VOCs released from the Boreal Nature Evolution product to determine if they require further evaluation as Chemicals of Potential Concern (COPCs). This is conducted by comparing established health-based air concentration safety thresholds with the maximum VOC concentrations measured over a 30-day curing time-course. The screening hierarchy used herein prioritized general population health-based air thresholds when available, followed by conservative application of established occupational exposure safety thresholds to evaluate general population exposure hazard, and finally, for compounds where neither general population nor occupational safety thresholds exist, hazard assessment utilized available safety thresholds for compounds with similar chemical characteristics. General population health-based air thresholds were

selected from regulatory agencies such as the Agency for Toxic Substances and Disease Registry (Minimum Risk Levels or MRLs), the United States EPA (Integrated Risk Information System or IRIS), the California EPA (Chronic Reference Exposure Levels or ChRELs) and, the European Chemical Agency (ECHA) Derived No Effect Levels (DNELs) for general population exposures. Regulatory thresholds for the general population exist at concentrations below those that might cause adverse health effects in the people most sensitive to such substance-induced effects.

In cases where established general population safety thresholds were not available, VOC emission concentrations were compared to 1% of established occupational exposure thresholds. Because occupational exposure evaluations are based on exposure durations and frequencies that are different than that experienced by a consumer, it is not generally recommended that occupational exposure limits be used as standards for general population indoor air quality. In addition, occupational exposures do not address exposures to sensitive sub-populations such as young children or the elderly. For this reason, the occupational exposure limits were reduced by a safety factor (1%) to err on the side of caution when using occupational safety thresholds to assess the potential for general population human health risks under the exposure scenario evaluated herein. This approach follows CAN/UCL-S774-09 guidance which considers a safe level of general population exposure to VOC concentrations in indoor air as 1% of an ACGIH TLV –TWA, OSHA-PEL, NIOSH-REL or another available (OEL, TLV, WEEL) occupational exposure threshold. In cases where neither an occupational nor a general population health-based air threshold has been established, a chemical analog was used to assess hazard. Specifically, a health-based air threshold assigned to a compound similar in chemical nature to the identified VOC product, or 1% of a no observed adverse effect level (NOAEL) derived from animal or human toxicity data, was used as an acceptable health-based air concentration (CEPA 1994; US EPA 1989; Klaassen 1991).

If the measured maximum VOC concentration released from the Boreal Nature Evolution was found to be below the acceptable health-based air threshold, then the compound was dropped from further consideration. If the maximum measured VOC concentration exceeded the available health-based air concentration, the compound was considered a COPC and additional review of pertinent toxicity data and the magnitude and duration of potential VOC exposure was conducted to refine the hazard assessment. Table 2 summarizes the maximum measured VOC concentrations and the selected health safety thresholds.

Table 2 Maximum Indoor VOC Air Concentrations and Health Based Air Threshold*

VOC	Maximum Indoor Air Concentration (mg/m^3) [1]	Health Based Air Threshold (mg/m^3) [2]
Ethene 1,2, dichloro-	**1.293**	**0.790** [a]
1,4 dioxane	0.026	0.03 [b]
1,3 dioxolane, 2-ethyl-4-methyl	0.011	0.033 [c]
Cyclotetrasiloxane, octamethyl	0.005	13 [d]
Propene, 2-chloro-3,3,3 trifluoro	4.44	9.5 [e]

VOCs in bold text exceed available safety thresholds

*This table includes only VOCs which are reported with a confidence of identification of ≥ 75%.

[1] Based on measured VOC emissions and CAN/UCL- S774-09 residential exposure parameters

[2] Gas converted from ppm to mg/m^3 as follows: ppm= (mg/m^3 x 24.45)/ (molecular weight)

[a] ATSDR MRL

[b] US EPA IRIS RfC

[c] 1% of the ECHA occupational DNEL for the analog 1,3 dioxolane

[d] ECHA general population DNEL

[e] 1% of the German MAK value for the analog 2,3,3,3-tetrafluoropropene

3.1.1 Selection of Chemical Analogs

No health-based air-threshold values were located specific to the following compounds measured in the Boreal Nature Evolution emissions; thus, these compounds were screened based on the use of chemical analog, with rationale for analog selection and the resulting COPC consideration documented below:

1,3 dioxolane, 2-ethyl-4-methyl

The toxicity of 1,3 dioxolane, 2-ethyl-4-methyl was evaluated using the health-based air threshold published for the chemical analog 1,3 dioxolane. The maximum concentration of 1,3 dioxolane, 2-ethyl-4-methyl (0.011 mg/m^3) was appreciably less than 1% of the ECHA occupational DNEL established for 1,3 dioxolane (3.306 mg/m^3). In addition, the concentration of 1,3 dioxolane, 2-ethyl-4-methyl decreases from the maximum value at 1-hour to below the lower limit of quantification (BLQ) by the 12-hour time point. Therefore, 1,3 dioxolane, 2-ethyl-4-methyl is not considered a COPC and is not considered further in this risk assessment process.

Propene, 2-chloro-3,3,3 trifluoro

The toxicity of Propene, 2-chloro-3,3,3 trifluoro was evaluated using the health-based air threshold published for the chemical analog 2,3,3,3-Tetrafluoropropene which is reported as having a 99.1% structural similarity to Propene, 2-chloro-3,3,3 trifluoro. The maximum concentration of Propene, 2-chloro-3,3,3 trifluoro (0.154 mg/m^3) was appreciably less than 1% of the German MAK value established for ,3,3,3-Tetrafluoropropene (950 mg/m^3). In addition, the concentration of Propene, 2-chloro-3,3,3 trifluoro consistently decreases from the maximum value at 1-hour throughout the 30-day time course. Thus, prolonged exposures to the maximum concentration will not occur and all exposures

concentrations are below the 1% of the German MAK value established for 2,3,3,3-Tetrafluoropropene. Therefore propene, 2-chloro-3,3,3 trifluoro is not considered a COPC and is not considered further in this risk assessment process.

3.1.2 Selection of Contaminants of Potential Concern (COPCs)

The VOC emission products present at concentrations below the health-based screening thresholds were not considered COPCs and were not considered further in this risk assessment process. With the exception of 1 VOC (Ethene 1,2, dichloro), the maximum modeled indoor air concentrations for the identified VOCs were below the available health-based air thresholds published for compounds or their chosen chemical analog. The maximum concentration of Ethene 1,2, dichloro, which was measured at the 1-hour time point, exceeds the ATSDR MRL for the substance. Therefore, Ethene 1,2, dichloro was selected for further consideration as a COPC.

3.1.3 Hazard Assessment for COPCs

The next step in hazard identification includes a review of relevant toxicity data to establish the range of toxic effects attributed to exposures to the identified COPC. The goal of this additional hazard review is to determine if the potential inhalation exposure to COPCs as emitted from Boreal Nature Evolution are considered safe relative to established no-observable-adverse-effect-levels (NOAELs). This step helps to establish if short and/or long-term exposure to predicted maximum indoor air concentrations of COPCs would pose a significant human health risk to exposed individuals and provides insight into the dose response associated with these COPCs. The dose response is the relationship between the potential received dose and the probability of adverse health effects.

3.1.3.1 Ethene 1,2, dichloro -

Ethene 1,2, dichloro (CAS# 156-60-5) commonly called 1,2-dichloroethylene or 1,2-DCE, is an organochloride with the molecular formula C2H2Cl2. It is a highly flammable, colorless liquid with a sharp, harsh odor. It can exist as either of two geometric isomers, cis-1,2-dichloroethene or trans-1,2-dichloroethene, but is often used as a mixture of the two. They have modest solubility in water. These compounds have few industrial applications.

Acute exposures to high concentrations (>1000 ppm) of trans-1,2-dichloroethylene have been reported to cause eye irritation, nausea, vertigo, and narcosis in humans. Due to its narcotic effects, trans-1,2-dichloroethylene has been used as an anesthetic in humans. One human fatality, presumably from depression of the central nervous system, was reported following exposure to an unknown quantity of 1,2- dichloroethylene vapor (isomer composition unreported) in an enclosed area (US EPA 2006). Short-term inhalation experiments were conducted with “relatively” low concentrations of trans-dichloroethene. Two doctoral candidates self-administered the chemical (as a vapor) in a well insulated 10 m^3 room. Using a manual sprayer and later a vaporizer (with attached oxygen tank), the chemical was uniformly distributed through the exposure chamber by means of fan and a ventilator. The concentration of trans-dichloroethene in the exposure chamber was determined analytically by determining the chlorine content in the gas mixture employing the “lime method” from which the dichloroethene content was then calculated. Both individuals were exposed simultaneously in the same room. They appeared to react very similarly. Experiments lasted for 5 to 30 min. Based on

concentrations of trans-dichloroethene in inspired and expired air, the authors estimated that approximately 73% of the chemical was absorbed. Five-minute exposures to 275 ppm 1,2 dichlorethene (1,090 mg/m^3) were reported to cause no effect (NRC 2010).

Inhalation toxicity studies of trans-1,2-dichloroethylene in animals include a subchronic rat study by Freundt et al. (1977) and a developmental rat study by Hurtt et al. (1993). Freundt et al. (1977) exposed groups of six female Wistar rats by inhalation to 0 or 200 ppm (0 or 794 mg/m^3) of trans-1,2-dichloroethylene for 8 hours/day for 1 day only and for 8 hours/day, 5 days/week for prolonged durations of 1, 2, 8 and 16 weeks. Additional studies were done at higher concentrations (1000 and 3000 ppm) for 8 hours/day for a single day. All concentrations were given as mean values with a variability of ±3% (S.E.M.) based on monitoring the chambers using gas chromatography. Subsequent to single and repeated exposures at 200 ppm, the rats were examined for gross pathology and histological pathology of selected organs (brain, sciatic nerve, lung, heart, liver, kidney, spleen, brain, and muscle). No signs of narcosis were observed during exposure, and no mortality was reported. Histopathological effects were observed only in the liver (fatty accumulation in liver lobule and Kupffer cells) and lungs (capillary hyperemia and alveolar septum distension). Repeated exposures of 200 ppm for 1 and 2 weeks produced only slight histopathological changes for liver and lungs in contrast to the studies of 8 and 16 weeks where slight to severe changes were noted. Therefore, these latter studies of longer duration will only be addressed in this report. In the group exposed for 8 weeks, fatty degeneration was observed in the liver lobule of 3/6 treated rats (versus 0/6 controls) and in the Kupffer cells of 3/6 treated rats (versus 1/6 controls). In the group exposed for 16 weeks, fatty degeneration both in the liver lobule and in Kupffer cells was observed in 5/6 treated rats and 2/6 controls. The observed liver lesions were graded as slight changes, except for Kupffer cell fat accumulation in the 8-week exposure group (all 3 treated and 1 control rats showing the lesion) and liver lobule fat accumulation in the 16-week exposure group (3 of the 5 treated rats with the lesion), which were graded as severe changes. Lung lesions were all graded as slight changes. In the 8-week exposure group, pulmonary capillary hyperemia and distension of the alveolar septum were observed in 6/6 treated rats (3 with severe pneumonic infiltration) and 0/6 controls. Identical findings were reported in the16-week exposure group. **This study identified a free-standing LOAEL of 200 ppm (794 mg/m^3) for hepatic and pulmonary lesions in rats subchronically exposed to trans-1,2- dichloroethylene.**

These findings are supported by shorter-term experiments described in the same paper. Freundt et al. (1977) observed the same hepatic and pulmonary effects (hepatic fatty infiltration, pulmonary capillary hyperemia, and alveolar septal distension) in rats exposed to 200 ppm for as short as 8 hours. With the exception of one rat in a single exposure for 8 hours only), the incidence and/or severity was lower. Eight-hour exposure to higher concentrations produced no additional effects, except that histopathology of the cardiac muscle was observed in rats given a single 8-hour exposure to 3000 ppm. Additional studies showed that pulmonary lesions similar to those observed by inhalation exposure were also produced by intraperitoneal exposure. Based on this finding and the absence of histological evidence (transudates or exudates) for irritation of the bronchial epithelium, the investigators suggested that irritation can be discounted as the causal agent for the observed lesions and that the pulmonary lesions may be, at least in part, systemic in origin (US EPA 2006).

An overview of all the brief and prolonged studies demonstrates that both dose (200, 1000 and 3000 ppm for 8 hours) and time (200 ppm for 8 hours, 1, 2, 8 and 16 weeks) do appear to make a difference in the severity of fat accumulation in the liver lobule and of cardiotoxicity. A developmental study by Hurtt et al. (1993) showed that the developing organism is not a sensitive target for trans-1,2-dichloroethylene. Hurtt et al. (1993) exposed groups of 24 presumed pregnant female CRL:CD BR rats by inhalation to concentrations of 0, 2000, 6000, or 12,000 ppm (0, 7940, 23,820, or 47,640 mg/m^3) of trans-1,2-dichloroethylene (99.64% purity) for 6 hours/day on gestational days (GD) 7-16. Rats were observed daily (twice daily on exposure days) for clinical signs. During exposure, the response of the dams to a sound stimulus (rapping on the side of the exposure chamber) was recorded; because of the design of the chamber, not all animals in each group could be observed. Maternal body weight was recorded on GD 1, 7-17, and 22; feed consumption was measured on alternate days from GD 1-19 and on GD 22. Dams were sacrificed on GD 22 and examined for gross pathology; the weights of liver, gravid uterus and empty uterus were recorded. Other endpoints included the number of uterine resorptions (revealed by ammonium sulfide staining in apparently 'nonpregnant' dams), fetal mortality, weight and sex of live fetuses, and the number of stunted live fetuses. All fetuses were examined for external malformations and variations, and subsequently analyzed for either skeletal or visceral changes. Two control females were found to be not pregnant and were excluded from most analyses. No maternal mortality was observed (Hurtt et al., 1993). Significantly reduced body weight gain was observed at 6000 ppm on GD 11-13 and at 12,000 ppm on GD 7-17 (actual loss of weight on GD 7-9). Significantly reduced feed consumption occurred at 2000 ppm on GD 13- 15, and at both higher doses during the exposure period. Body weight and food consumption reverted to normal values during the post-exposure period. Ocular irritation (lacrimation and stained periocular hair) was observed in all exposed groups. Narcotizing effects of treatment and alopecia were observed at 6000 and 12,000 ppm, and lethargy and salivation at 12,000 ppm. Of these clinical signs, only alopecia was observed in exposed rats in the post-exposure period. No other compound-related effects were observed in dams. Significant trends and increases in the mean number of total and early resorptions per litter were found in dams exposed to 6000 or 12,000 ppm. However, the researchers considered this finding to be not biologically significant, but rather an artifact of the unusually low resorption rate in the concurrent control group; rates in exposed groups were within the limits of historical control data from the same laboratory during the previous 2 years. The pregnancy rate, corpora lutea, fetuses per litter, and number of stunted fetuses were unaffected by treatment. At 12,000 ppm, mean fetal weight was significantly reduced and there was a small, statistically nonsignificant increase in the incidence of hydrocephalus. Otherwise, treatment had no significant effect on the incidence of fetal malformations or variations. In this study, fetal effects were found only at high concentrations producing overt maternal toxicity, indicating that the developing organism is not a sensitive target of trans-1,2-dichloroethylene toxicity (US EPA 2006).

In a briefly-described range-finding experiment for the developmental study, Hurtt et al. (1993) exposed groups of pregnant female Crl:CD BR rats by inhalation to 0, 6000, 9000, or 12,000 ppm (0, 23,820, 35,730, or 47,640 mg/m^3) of trans-1,2-dichloroethylene for 6 hours/day on gestational days 7-16. Narcosis [central nervous system (CNS) depression] was observed in all test groups during exposure and was evident as incoordination immediately following exposure. Maternal body weight gain and food

consumption were decreased at the two highest exposure levels, and fetal body weight was decreased at the highest level (US EPA 2006).

Neither trans-, cis-, or cis- and trans-1,2-dichloroethene were mutagenic in salmonella typhimurium strains TA97 (cis- isomer only), TA98, TA100, TA1535, or TA1537, with or without metabolic activation. In CHO cells in vitro, cis-1,2-dichloroethene induced sister chromatid exchanges (SCEs) in the absence of metabolic activation; results were equivocal with S9. The cis- and trans- mixture induced increases in SCE frequency in cultured CHO cells with and without metabolic activation; however, the trans-isomer was negative in this assay. Neither isomer nor the isomeric mixture included chromosomal aberrations in CHO cells with or without metabolic activation. In vivo genotoxicity studies, trans-1,2-dichloroethene was negative in a mouse bone marrow chromosomal aberration assay, in host-mediated gene mutation assays in S. typhimurium and in gene mutation and gene conversion assays in saccharomyces cerevisiae. cis-1,2-dichloroethene was positive in a mouse bone marrow chromosomal aberration assay, and in host-mediated gene mutation assays in S. typhimurium and S. cerevisiae. Results were equivocal for the cis- isomer in a gene conversion assay in S. cerevisiae (NRC 2010).

The acute exposure duration MRL (14 days or less) is based on the LOAEL of 200 ppm for trans-1,2-dichloroethene over an 8-hour period that caused fatty degeneration of the liver (Freundt et al. 1977). Longer periods of exposure at 200 ppm showed increased numbers and severity of response. The intermediate duration inhalation exposure MRL (15-364 days) is based on the same study and effects (Freundt et al. 1977) in which rats were exposed to 200 ppm trans-1,2-dichloroethene for 8 hours per day, 5 days per week for 8 or 16 weeks. An uncertainty factor of 1,000 is used: 10 for using a LOAEL, 10 for extrapolation from animals to humans, and 10 for human variability. The available toxicological data for trans-1,2-dichloroethene suggest that acute to intermediate exposures to air concentrations less than the MRL value of 0.8 mg/m^3 are unlikely to result in any significant toxicological effect.

1,2-Dichloroethene was identified as a COPC associated with the Boreal Nature Evolution foam based on the maximum concentration measured during the 1-hour time point exceeding the intermediate exposure duration MRL. The maximum 1,2-dichloroethene concentrations decreased to below the MRL value by the 12-hour time point and remain below this general population health-based exposure threshold for the remainder of the analytical time course. Following review of the available toxicological data for 1,2-dichloroethene, it has been concluded that this compound, as released from the Boreal Nature Evolution foam, is unlikely to result in toxicological effects.

3.2 Exposure Assessment

A toxic response following exposure to a hazardous substance is not only dependent on the hazard of the agent but is also dependent on the duration of the exposure. Specifically, a chemical substance will not produce adverse effects in biological systems unless the agent (or agent's metabolite) reaches appropriate sites in the body at a concentration and for a length of time sufficient to produce the adverse effect. Therefore, to fully characterize the potential risk associated with VOC emissions from Boreal Nature Evolution, assessment of the exposure situation is also required. In the following section of this risk assessment, the exposure to VOC emission products in general, will be addressed. This step is designed to describe and characterize the likelihood, extent, magnitude, duration, and the route of

exposure to the VOCs identified in Section 2.0. The likelihood and the extent of human exposure to VOC emissions from Boreal Nature Evolution, or insulation material in general, depend on several factors and these include (1) the characteristics of the residential structure (size and air-tightness of the house), (2) the chemical nature of the VOC (3) the activity patterns of the residents or time spent indoors. These factors were considered herein to assess the potential consumer exposure to VOCs emitted from Boreal Nature Evolution.

Generally, VOCs, when released into the indoor environment of a residence, are expected to exist solely as vapors (US EPA 1989; Klaassen 1991). VOC concentrations within the indoor air are reduced by degradation reactions of the compounds with hydroxyl radicals and removal of VOCs from the indoor air through ventilation. Ventilation, as defined here, is the flow rate of clean outdoor air into an occupied space or a building. Ventilation is the primary means of reducing the concentrations of air contaminants that are generated indoors. Therefore, it is expected that VOCs will be both degraded and removed from the indoor air, and their ambient levels will decrease over time; thus, accumulation to a potentially toxic level is not likely. In addition, airborne concentrations of most VOCs emitted from Boreal Nature Evolution decrease over the testing period. Therefore, maximum identified VOC levels would not be maintained in a residence for extended periods. Furthermore, due to regular daily activities of the general population (going to school, work, and playing outside), most individuals in a residential environment would not be exposed continuously.

In the worst-case scenario, the maximum potential level of human exposure to VOCs from Boreal Nature Evolution SPF insulation is established as the maximum indoor air concentrations determined by dynamic chamber analysis (Table 1). The maximum indoor air concentrations of VOC products emitted from Boreal Nature Evolution are predicted based on a 500 m^3 house with a ventilation rate of 0.3 air exchanges/ hour (CAN/UCL- S774-09). It is important to note that this value is very conservative and will result in an indoor air concentration significantly higher than would be encountered under a typical consumer exposure scenario. For example, as outline under the *California Standard Method for The Testing and Evaluation of Volatile Organic Chemical Emissions from Indoor Sources Using Environmental Chambers Version 1.2* air exchange rates of 0.68 exchanges/hour and 0.82 exchanges/hour have been suggested for a private office and standard schoolroom respectively (CDPH 2010). In addition, residential air exchange rates 0.61-0.71 exchanges/hour have been proposed in the US EPA Exposure factor handbook (US EPA 2011; Table 17-11). Inclusion of these ventilation rates within this hazard evaluation for residential indoor air exposure model would result in an appreciably lower maximum VOC concentration than those predicted through dynamic chamber analysis and outlined above in Table 1.

In addition, the maximum concentration of the COPC ethene 1,2, dichloroethene falls below the health based general population air threshold in ≤ 12 hours. Specifically, 1,2, dichloroethene was identified as COPC based on a maximum concentration, which occurs during the 1-hour time point, exceeding the ATSDR inhalation MRL published for this compound. The concentration of 1,2, dichloroethene falls below the health-based air threshold during the 12-hour time point and continues to decrease throughout the 30-day time point. Exposures to concentrations of 1,2, dichloroethene above the ATSDR MRL would only occur if a room was occupied <12-hours after application of the Boreal Nature Evolution. It is therefore concluded that exposure to the COPC, as released from the Boreal Nature

Evolution foam, is unlikely to result in toxicological effects provided that consumer occupation begins 12 hours after Boreal Nature Evolution installation.

Measurements of total VOCs (TVOC) represent the amount of volatile organic compounds (VOCs) without distinguishing different chemicals. Presently there are no regulatory thresholds for human exposures to TVOCs, however, the more conservative literature suggests that <0.3mg/m^3 represents an "acceptable" TVOC level and that >3mg/m^3 represents a "hazardous" TVOC level. Target goals of 1 mg/m^3 and 5 mg/m^3 have been proposed by some certifying bodies in both Canada and the United States, respectively (Health Canada 1995). The American Industrial Hygiene Association (AIHA) recommends a TVOC exposure limit of 1 mg/m^3. The European Community has prepared a target guideline value for TVOC of 0.3 mg/m^3 for office environments.

Dynamic chamber analysis of Boreal Nature Evolution indicates that the TVOC concentration during the 12-hour sampling period is 1.786 mg/m^3. This TVOC falls within the TVOC range of 1 mg/m^3 and 5 mg/m^3 proposed by Canada and the US for office environments. The TVOC concentration at the 4-day time point (0.594 mg/m^3) falls below the target and action limits of 1mg/m^3 proposed by AIHA and proposed within Canada (Health Canada 1995).

Therefore, the potential for consumer exposure to high concentrations of VOCs released from the Boreal Nature Evolution foam product for acute or chronic durations is low. In any scenario, potential VOC exposure is likely to be of short duration to concentrations less than those calculated herein. The low individual VOC concentrations relative to safe levels, the continuous decay of VOC emissions from the foam product, and the low potential for continuous exposures to VOC levels associated with toxicity within the residential environment, suggests a low risk for adverse health effects associated with exposure to any individual VOC released from the Boreal Nature Evolution product.

3.3 Risk Characterization

Risk characterization is the final step in the risk assessment process. It involves integrating all information developed through hazard identification, dose response assessment and exposure assessment for estimating risk to humans. Throughout this assessment, conservative assumptions have been used to err on the side of caution in estimating the potential health risk associated with Boreal Nature Evolution derived VOC emission products.

This analysis has revealed that VOC products emitted from Boreal Nature Evolution foam are unlikely pose a health risk to individuals residing in buildings insulated with this material. Numerous factors support this conclusion:

1. After the 12 hour-time point, airborne concentrations of all VOCs were well below the available safety guidelines.
2. Exposures to concentrations of 1,2 dichloroethene above the ATSDR MRL value would only occur if a room was occupied <12-hours after application of the Boreal Nature Evolution. At the 12-hour time point, 1,2 dichloroethene concentrations are 27% of the general population health-based threshold and decreases to non-detect on the 30th day.

3. Prolonged exposure to the maximum 1,2 dichloroethene associated with Boreal Nature Evolution will not occur due as this VOC decreases from the maximum concentration detected at 1-hour to BQL by the 30-day time point. Following review of the available toxicological data for it has been concluded that exposures to acute exposures to 1,2 dichloroethene concentrations below the ATSDR MRL health-based threshold are unlikely to result in toxicological effects.
4. The decay pattern of the VOC emissions over the 30 day time course indicate that ambient indoor VOC air concentrations post SPF application will decrease rapidly over time.
5. The real-world indoor air VOC concentrations will likely be lower than those developed herein using conservative exposure assumptions; therefore, the level of human exposure is likely to be considerably lower than the maximum predicted indoor air concentrations considered in the analysis above. In addition, human activity patterns are likely to contribute to lower and more intermittent exposures.
6. The TVOC concentration reported at the 12-hour time point falls within the TVOC range of 1 mg/m^3 and 5 mg/m^3 proposed by Canada and the US for office environments.

4 RECOMMENDATIONS

Overall, the concentrations of airborne VOCs and TVOC released from the Boreal Nature Evolution foam will decrease over the product curing time and should not accumulate to a toxic concentration. Therefore, chronic exposures to maximum airborne concentrations of VOC or TVOC associated with installation of the product will not occur. While concentrations of 1,2 dichloroethene exceed the available general population health-based threshold at the 1-hour time point, concentrations measured at all subsequent time points ≥ 12-hours are below the threshold value. Based on the integration of all information presented in the steps of the risk assessment process, a residential re-occupancy time of >12 hours is recommended for Boreal Nature Evolution.

This risk assessment indicated that there is a low human health risk associated with exposure to VOC emissions from Boreal Nature Evolution foam. Specifically, VOC levels decrease rapidly over the analytical time course. Therefore, prolonged exposures to maximum VOCs emitted from the Boreal Nature Evolution are not anticipated. In addition, the two VOCs which remain at the final 30-day sampling period are well below the available health-based thresholds and are not associated with appreciable toxicity. Furthermore, the TVOC concentration (which includes both identified and unidentified VOCs) falls within the acceptable range proposed by Canada and the US for office environments within the 12-hour analytical time point. Therefore, based on the assessment presented herein, it is concluded that, 12 hours after installation, exposure to Boreal Nature Evolution SPF insulation should not pose a health risk to occupants of residential or commercial buildings.

5 REFERENCES

ATSDR 1996. Toxicological Profile For 1,2-Dichloroethene U.S. Department of Health And Human Services Public Health Service Agency for Toxic Substances and Disease Registry. Available at https://www.atsdr.cdc.gov/ToxProfiles/tp87.pdf

CDPH, 2017. California Department of Public Health. CDPH/EHLB/Standard Method V1.2. Standard Method for The Testing and Evaluation of Volatile Organic Chemical Emissions from Indoor Sources Using Environmental Chambers. Version 1.2.

CEPA 1994. Canadian Environmental Protection Act, Human Health Risk Assessment for Priority Substances. ISBN 0-662-22126-5. Cat. No. En40-21S/41E. Available at < http://www.hc-sc.gc.ca/ewh-semt/alt_formats/hecs-sesc/pdf/pubs/contaminants/approach/approach-eng.pdf >.

Freundt KJ, Liebaldt GP, Lieberwirth E. 1977. Toxicity studies on trans-1,2-dichloroethylene. Toxicology 7:141-153. As cited in ATSDR 1996.

Health Canada 1995. Indoor Air Quality in Office Buildings: A Technical Guide. Available at http://publications.gc.ca/collections/Collection/H46-2-93-166Erev.pdf >.

Hurtt ME, Valentine R, Alvarez L. 1993. Developmental toxicity of inhaled trans- 1,2-dichloroethylene in the rat. Fundam Appl Toxicol 20(2):225-230. As cited in ATSDR 1996.

Klaassen, C.D. 1991. Casarett and Doull's Toxicology: The Basic Science of Poisons 4th edition. Pergamon Press New York, New York 1991.

US EPA 1989. Risk Assessment Guidance for Superfund Volume I Human Health Evaluation Manual (Part A). EP A/540/1-89/002.

NRC 2010. National Research Council (US) Committee on Acute Exposure Guideline Levels. Acute Exposure Guideline Levels for Selected Airborne Chemicals: Volume 8. Washington (DC): National Academies Press (US); 2010. 3, 1,2-Dichloroethene cis-1,2-Dichloroethene trans-1,2-Dichloroethene Acute Exposure Guideline Levels. Available from: https://www.ncbi.nlm.nih.gov/books/NBK220016/

US EPA 2006. Provisional Peer Reviewed Toxicity Values for trans-1,2-Dichloroethylene (CASRN 156-60-5) Derivation of a Chronic Inhalation RfC. Available at <https://hhpprtv.ornl.gov/issue_papers/Dichloroethylenetrans12.pdf>

US EPA 2017. United States EPA Design for the Environment, Potential Chemical Exposures From Spray Polyurethane Foam. Available at < https://www.epa.gov/saferchoice/potential-chemical-exposures-spray-polyurethane-foam#curing-rates >

6 CLOSURE

A Human Health Risk Assessment (HHRA) has been completed as authorized. This report has been prepared for the exclusive use of Genyk Inc.and its agents for specific application to the polyurethane product Boreal Nature Evolution. It has been prepared in accordance with generally accepted toxicological practices and no other warranty, express or implied, is made. Any use which a Third Party makes of this report, or any reliance on decisions to be made based on it, are the responsibility of such Third Parties. Dr, E. Rosenblum accepts no responsibility for damages, if any, suffered by any Third Party because of decisions made or actions based on this report.

I trust that this report fulfils your requirements for this project. Should you require additional information, please contact me.

5/3/2019

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