HUMAN HEALTH RISK ASSESSMENT OF VOLATILE ORGANIC COMPOUND EMISSIONS FROM A TWO-PART SPRAY APPLIED POLYURETHANE INSULATING FOAM FOR GENYK

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EXECUTIVE SUMMARY

Lalita Bharadwaj, Ph.D. undertook a Human Health Risk Assessment for a two-part spray-applied polyurethane thermal insulating foam developed by Genyk. Exova Warren Testing Facilities in Warren, Michigan performed emissions testing of a test specimen of the spray-applied foam insulation, identified here in this report as "*Genyk PU-Foam*". Emission testing was conducted in accordance with 'Procedure B' of the Underwriters Laboratories of Canada, CAN/ULC-S774-09 Testing Standard. Headspace and dynamic chamber analyses were performed on a test specimen of "*Genyk PU-Foam*" 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 volatile organic compound (VOC) emissions from the two-part spray-applied polyurethane foam insulation, developed by Genyk, pose a health risk to individuals residing in homes or buildings where this product has been applied under the standards and regulations appropriate to PU-Foam insulation application and 2) to determine an acceptable residential occupancy time for the polyurethane thermal insulating foam. The health risk assessment was undertaken using guidelines, protocols and methodologies proposed and readily accepted by Health Canada and the Canadian Construction Materials Centre. These guiding principles of risk assessment were utilized to predict the human health risk associated with potential exposure to VOC emissions from the Genyk product.

Careful consideration of all relevant chemical and toxicity data was given to the assessment to determine the potential for health risk. The assessment accounted for the potential for human exposure to maximum indoor air concentrations of each VOC emission product identified through dynamic chamber analysis of the spray-applied polyurethane insulating foam. The assessment took into consideration the chemical nature and toxicity information of the VOC emissions, potential for human exposures, the magnitude, frequency and duration of human exposure to each VOC product, and their individual decay patterns over a 30-day period of dynamic chamber analysis. The

assessment also included comparisons (including stringent safety margins) between potential exposure to maximum possible levels and the toxicological profiles of the VOC products emitted.

The conclusion of this assessment is that VOC emissions from "Genyk PU-Foam" will not pose a health risk to individuals residing in homes or buildings where this product is applied under standardized regulatory guidelines.

The decay pattern of the VOC products (up to 30 days), indicate the concentration of individual airborne VOC and the total VOC (TVOC) decrease over time. Maximum airborne emission concentrations of VOC emission products measured within 1 hour of dynamic chamber analysis were found to be below airborne exposure concentrations considered safe for human exposure.

Considering that VOC emission products were classified as having a low order inhalational toxicity following short term low-level exposures and in general the maximum emission concentrations were below the safety standards applied in this risk assessment, it was concluded that airborne concentrations of VOC or TVOC emitted from "*Genyk PU-Foam*" would be considered safe for human exposure. Volatile organic compound emission concentrations, within 1 hour following the application of "*Genyk PU-Foam"* will not pose a significant human health risk to individuals residing in homes where this material is applied under the standards and guidelines associated with PU-Foam application procedures.

Overall data suggest a low risk for adverse inhalational exposures and thus a low potential for health risk. *Ambient VOC concentrations at 1 hour following the application of "Genyk PU-Foam" will be within an acceptable range for human exposure*. *Therefore, the recommended limiting residential occupancy time for "Genyk PU-Foam" is 1 hour and applies to residents of structures insulated with this material*.

1.0 INTRODUCTION

In March 2015, Dr. Lalita Bharadwaj undertook a human health risk assessment to evaluate the potential impacts on human health from exposure to Volatile Organic Compound (VOC) products emitted from a two-part spray-applied polyurethane insulating foam identified as "*Genyk PU-Foam*" and developed by Genyk.

Volatile organic compounds are chemicals that contain carbon and hydrogen. Typically, VOC have high vapour pressures, easily vaporize at normal temperature and pressure and have boiling points that range from 50-250^{o}C. Several thousand compounds both natural and synthetic are classified as VOC. These include carbon-based molecules such as; aldehydes, ketones, alcohols, amines, aliphatic and aromatic hydrocarbons, some of which are halogenated. Many of these volatile organic compounds are ubiquitously present, at low levels in various indoor air environments (office, home and workplaces). Volatile organic compounds (VOCs) can be emitted into indoor air from a variety of sources. These include and are not limited to the following: cigarette smoke, furnishings, vehicle exhaust, and various building materials such as paint, varnish and glues and household products such as air fresheners (1).

Standard approaches of risk assessment were utilized to characterize the potential human health risks associated with exposures to VOC emitted from the two-part spray-applied polyurethane insulating foam. In this case the risk assessment was based on maximum likely exposures to VOC emission products. It was assumed that individuals would be exposed sub-chronically (a period of exposure of 1- 3 month duration) to maximum concentrations of VOC emission products as determined by dynamic chamber analysis of *"Genyk PU-Foam"*.

Spray-applied polyurethane foams are commonly utilized in commercial, institutional and residential construction. Currently, there is an incomplete source of toxicity data evaluating the potential human health effects associated with exposures to PU spray foam or to its volatile organic compound (VOC) emission products under conditions other than those associated with occupational exposures. The potential short or long-term health effects associated with exposure to this material in the general population are fundamentally unknown. Due to the lack of

detailed toxicity information, the human health risks associated with short and/or long-term exposures to PU spray foams and their emission products can only be predicted by the application of human health risk assessment protocols (2,3).

Spray-applied PU foam 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 (4). For polyurethane formulations intended for use 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*. These include both Headspace (HS) and dynamic chamber analysis (DCA [Procedure B]) methods. These are briefly described below. Headspace and dynamic chamber analyses involve the measurements of VOC emissions from test specimens generated from sample panels of polyurethane foam that have been aged for approximately 20 to 24 hours. The test specimen, utilized for headspace and dynamic chamber analyses, is cut from the sample panel. A strict process is followed for the generation of both the sample panel and the test specimens. This process can be reviewed in the client report entitled; *V.O.C Emissions Profiling for Genyk"* and prepared by Exova (5). Within the body of this report, a brief description of the Headspace and Dynamic chamber analyses for the PU foam in this case are outlined below.

The sample panel was produced in accordance with the CAN/ULC-S705.1-01 Standard and was produced using a commercially available, fixed, positive displacement pump. A pump specifically designed for the application of spray-applied polyurethane thermal insulation. The thermal insulation panel is produced by spraying the product onto a sheet of high density polyethylene (HDPE) covered aluminum foil. This is in accordance with Section 6.1.3 of the Testing Standard. Once created it is sealed in air-tight packaging and then transported via overnight courier to the Exova Testing Facility in Warren, Michigan. The sample panel is removed from its air-tight packaging and is subsequently cut into appropriately sized and shaped pieces to create the test specimen. The resulting test specimen is then placed into test chambers

for headspace and dynamic chamber analyses. In this case, a test specimen was produced on January 7th, 2015 and installed into the test chambers (5).

Headspace analysis involves an initial screening of VOC emissions from the test specimen. Headspace analysis is advantageous when concentration levels of VOCs, in the 1 and 12 hour testing intervals, are too low for identification by mass spectral library. The Headspace apparatus is known to generate higher concentrations of compounds that volatize quickly. In situations where emission concentrations are of sufficient strength during subsequent DCA testing of products, headspace analysis is not required in the majority of testing situations. VOC emissions, solely detected in these exaggerated conditions of headspace analysis are considered non-typical and are not considered further in the analyses procedures.

Procedure B of the Underwriters Laboratories of Canada, dynamic chamber analysis, determines polyurethane VOC emission profiles over a 30-day period. In accordance with the testing standard, DCA commences 24 hours after the manufacture of the sample panel (CAN/ULC-S774-09; Section 6.1.2). In general, DCA is a procedure used to identify, quantify, and determine emission rates of VOC(s) released from commercial formulations of spray PU foams once foams have cured over an initial 24 hour period. The results obtained by dynamic chamber analysis of PU foam products are used to predict potential indoor air concentrations of VOC emission products that could occur in a typical residential or workplace building where spray PU insulating foams are applied. These data provide a quantitative estimate of the potential levels of human exposure to PU-derived VOC emission products and are vital for determining the degree of human health risk associated with exposure to these chemicals in the household, workplace or other inhabited structures.

1.1 Headspace and Dynamic Chamber Analysis

Headspace and dynamic chamber analyses were performed to characterize VOC emissions from the test specimen of the spray-applied polyurethane insulating foam developed by Genyk. Analysis was completed by the Exova Building Products Laboratory using procedures outlined in CAN/UCL-S774-09 [Standard Laboratory Guide for the Determination of Volatile Organic

Compound Emissions from Polyurethane Foam] (5). Head Space analysis was performed on the test specimen. Using Carbotrap^{TM} 400 absorbent tubes, in conjunction with gas chromatography-mass selective detector analysis; the number, chemical nature and the relative concentrations of VOC products emitted from the test specimen of the spray-applied PU foam was determined.

1.2 Headspace Analysis

Headspace analysis of test specimen "*Genyk PU-Foam*" revealed that fifteen (15) VOC products were emitted from the "*Genyk PU-Foam*" test specimen. The compounds emitted and their respective concentrations are summarized in Table 8.2 of the Exova emissions report (5).

Emission products identified through the process of headspace analysis were generally classified as hydrocarbon based compounds. In general terms, a mix of compounds was identified and these included compounds such as: halogenated aliphatic hydrocarbons, aromatic hydrocarbons, organosilicon compounds, amines, and a phthalate based compound. Volatile organic compound emission concentrations ranged from the lowest airborne concentration of 0.05 mg/m^3 to the highest airborne concentration of 1.02 mg/m^3.

Appropriate and comparable exposure limits assigned to individual VOCs identified through headspace analysis of the "*Genyx PU-Foam*" specimen were reviewed and utilized as a comparison guideline to gage potential health risks associated with exposures to the airborne concentrations identified by the headspace analysis. Through this review it was found that airborne concentrations detected in the analysis are below exposure limits considered safe for human exposure under occupational conditions. Reported personal exposure levels of polyurethane applicators have been found to range in concentration from 0.120 mg/m^3 to 0.570 mg/m^3 (7-9). There was one VOC emission (Propane, 2,2-difluoro) that was found at airborne concentrations above reported personal exposure levels, however the emission concentrations were found below occupational safety guidelines. The range of VOC concentrations, identified through headspace analysis, was 0.020 mg/m^3 to 1.02 mg/m$^{3.}$ The range of airborne TVOC concentrations of 2.55 mg/m^3 was found to be within proposed TVOC guidelines (refer to Exova Table 8.2 of the Exova emissions report [5]). A TVOC within the range of 1 mg/m^3 to 5 mg/m^3

has been recommended for Canadian and US office environments. The TVOC determined by headspace analysis of the "*Genyk PU-Foam*" specimen was within the range recommended for US and Canada.

1.3 Dynamic Chamber Analysis

Subsequent to headspace analyses, discrete dynamic chamber analysis was performed on the two-part spray-applied polyurethane foam test specimen "*Genyk PU-Foam*" (5). VOC emission products, identified through DCA, were measured in air samples collected at specified time intervals (1, 12, 24, 48 hours and 4, 7, 14, and 30 days) as prescribed by Section 7.3 of the CAN/UCL-S774-09 Standard. Dynamic chamber analysis was utilized to screen for VOCs emission products derived from the "*Genyk PU-Foam*" test specimen. These emissions can be reviewed in Tables 8.4.1-8.4.8 of the Exova emissions report (5). The VOC emissions from "*Genyk PU-Foam*" were determined over a 30-day period of testing.

The results obtained by dynamic chamber analysis are summarized below and were utilized as a quantitative estimate of the potential levels of human exposure to "*Genyk PU-Foam*" -derived VOC emission products. These data were applied to the risk assessment process to determine the degree of human health risk associated with potential exposures to these specific VOC emissions derived from the Genyk two-part spray-applied polyurethane insulating foam (referred to as "*Genyk PU-Foam*").

1.3.1 Unique VOC Emission Products

A total of nine (9) unique VOC emission products were identified through the dynamic chamber analysis of *"Genyk PU-Foam"*. Headspace analysis yielded fifteen (15) VOC emission products. Six (6) of the fifteen (15) VOCs identified through headspace analysis were also identified as emissions in the DCA of *"Genyk PU-Foam"*. Table 1 provides a summary of the unique VOC emission products identified through the process of DCA.

Table 1: Unique VOC Emissions Products Identified Through DCA

	Unique VOC Emission Product
1	Propane, 2,2-difluoro
2	1,4-Dioxane
3	Benzene, Chloro
4	Squalene
5	Tris(3-chloropropyl)phosphate
6	Nitrobenzene, 3-(2-cyano-2-phenylethenyl)
7	Cyclotrisiloxane, hexamethyl-
8	Cyclotetrasiloxane, octamethyl-
9	Bis(2-ethylhexyl)phthalate

Note: Bolded numbers indicate the VOC was also identified in Headspace analysis.

Dynamic chamber analysis demonstrated that nine (9) unique VOCs were emitted from "Genyk PU-Foam*"*. A summary of the DCA analysis is provided on page 21 of 27, Section 9 of the Exova emissions report (5). An outline of the number of compounds identified at each testing interval is provided in Table 9.2 of the Exova publication (5). A brief summary of the DCA results is provided below.

Nine unique VOCs were identified as emission products of "*Genyk PU-Foam"*. Four VOC emission products [propane, 2,2-difluoro-; 1,4-dioxane; benzene, chloro and squalene] were detected at the 1 hour DCA testing interval. Propane, 2,2-difluoro was only detected at the 1, 12 and 24 hour DCA testing intervals suggesting that this VOC compound is transiently emitted from "Genyk PU-Foam". 1,4-Dioxane was also a transient VOC emission product. It was not detected at intervals subsequent to the 12 hour testing period. Additionally, benzene, chloro- and squalene were also noted as very transient VOC emission products of "Genyk PU-Foam". These two VOC emissions were only measured in air samples collected for analysis as the 1 hour testing interval. Benzene, chloro- and squalene were not detected in air samples collected for analysis at intervals subsequent to the 1 hour testing period.

Five VOC emission products [propane, 2,2-difluoro-; 1,4-dioxane; tris(3-chloropropyl)phosphate; nitrobenzene, 3-(2-cyano-2-phenylethenyl and bis(2-ethylhexyl)phthalate] were detected at the 12- hour DCA testing interval. Nitrobenzene, 3-(2-cyano-2-phenylethenyl and bis(2-ethylhexyl)phthalate were not detected in air samples collected subsequent to the 12 hour DCA testing period suggesting that these VOC are transient emission products and are not emitted from "Genyk PU-Foam" over a sustained period of time. Tris(3-chloropropyl)phosphate was not detected at the 1 hour testing interval. However tris(3-chloropropyl)phosphate was detected in air samples collected at 12, 24 and 2-days of DCA testing. Tris(3-chloropropyl)phosphate was not detected in air samples collected for analysis at testing intervals subsequent to the 2 day testing period.

Volatile organic compound emissions were not detected in air samples collected for analysis at days 4,7 and 14. These data suggest that VOC emissions are transient and do not persist. Two VOC emission products (cyclotrisiloxane, hexamethyl and cyclotetrasiloxane, octamethyl) were detected in air samples collected at the 30 day DCA testing period. These VOC emission products were not detected in air samples measured in previous testing periods.

The airborne VOC concentrations measured in air samples collected over the 30 day DCA testing period ranged in concentration from 0.004 mg/m^3 to 0.07 mg/m^3. These data suggest that VOC concentrations emitted are low and are found to be well below the personal exposure levels reported for polyurethane applicators. Personal exposure levels have been found to range in concentration from 0.120 mg/m^3 to 0.570 mg/m^3 (7-9) suggesting the airborne emission concentrations are within a range safe for human exposure.

In summary, nine (9) unique VOC compounds were identified as emission products. The number of VOCs emitted from "*Genyk PU-Foam*" drop rapidly over the DCA testing period. Four (4) and five (5) VOCs were measured at the 1 and 12 hour testing intervals. Two VOC emission products were detected at 24 hours and 1 VOC product was detected at the 2 day testing interval. All emission levels were below personal exposure levels reported for polyurethane applicators and emissions were not detected at the 4,7 and 14 day DCA testing periods. Two VOCs, not previously measured in air samples collected at 1, 12, 24-hours or 2, 4,

7, 14-day DCA intervals were detected at the 30 day testing period. These data suggest that VOCs derived from "*Genyk PU-Foam*" are transiently emitted, at low levels and do not persist over the 30 day DCA testing period.

Table 2 provides a summary of the VOCs identified through DCA of "Genyk PU-Foam", the maximum measured airborne concentration and the time in which the maximum emission levels were detected.

Table 2: Maximum Airborne Concentrations of VOC Emissions from "*Genyk PU-Foam*" and Time of Detection.

VOC Emission Identified	Maximum Airborne Concentration (mg/m^3)	Time of Detection (hours)
Propane, 2,2-difluoro	0.07	1
1,4-Dioxane	0.02	1
Benzene, chloro	0.004	1
Squalene	0.010	1
Tris(3-chloropropyl)phosphate	0.05	12
Nitrobenzene,3-(2-cyano-2-phenylethenyl)	0.01	12
Cyclotrisiloxane, hexamethyl-	0.01	30 days
Cylcotetrasiloxane,octamethyl-	0.01	30 days
Bis(2-ethylhexyl)phthalate	0.01	12
Bis(2-ethylhexyl)phthalate	0.27	30 days

Review of DCA indicates that maximum measured emission concentrations were measured at 1, 12 hours or 30 days of DCA testing. The time in which maximum levels were measured was dependent on the specific VOC emission product identified. Through review of DCA testing, it is evident that 9 VOC compounds are emitted from "Genyk PU-Foam". However the total number of VOCs emitted, the chemical nature of the VOCs and their associated maximum emission

concentrations vary. Additionally there is a decline in the total number and the airborne concentration of VOC emissions from "*Genyk PU-Foam*" over time.

In summary, DCA data suggests that the number of VOCs emitted from "Genyk PU-Foam" decline over the DCA testing period. Maximum measured VOC emission concentrations are not maintained throughout the 30-day period of testing. Emissions fluctuate from detectable to undetectable. Only two (2) VOC products are measured in air samples collected for analysis at the 30 day testing period. Review of the DCA data for "Genyk PU-Foam" also indicates that peak concentrations of VOC emission products would likely be reached within 1 hour following the application of this material to a residential building. An overall maximum emission concentration of 0.07 mg/m^3 was detected at the 1 hour testing interval. Emission concentrations measured in air samples collected at subsequent DCA time intervals did not exceed the overall maximum emission concentration of 0.07 mg/m^3 detected at 1 hour DCA. Emission concentrations of VOCs were detected at levels between 0.01 mg/m^3 and 0.05 mg/m^3 at the 12 hour DCA testing interval. Volatile organic airborne concentrations of 0.01 mg/m^3 were detected for only two VOCs at the testing interval of 30 days.

The maximum indoor air concentrations, summarized above in Table 2, and determined through DCA analysis, represent the highest estimated level of human exposure to VOC products emitted from "*Genyk PU-Foam*". The time in which maximum VOC concentrations were detected specifies the point in time when maximum concentrations would be reached in a residence following the application of this spray-applied PU foam insulation (ie. in general, it is assumed that individuals occupying homes within 1 hour after the application of the PU foam insulation to their residence would be exposed to these levels). The maximum measured concentrations of each VOC emission product along with its time of detection were utilized in the process of a human health risk assessment to evaluate the potential human health risks that may be associated with exposures to maximum airborne VOC emissions derived from the Genyk two-part spray-applied polyurethane insulating foam.

The toxicity of each VOC emission product was addressed in the assessment. The human health risk assessment was conducted using conservative assumptions that would lead to an

overestimation of potential exposure and risk. Thus in this case, a "worst case scenario" was applied to the assessment. In this scenario it was assumed that human exposure levels are equal to the maximum measured airborne VOC concentrations detected by DCA of the "Genyk PU-Foam" test specimen.

Few experimental assessments have been conducted to evaluate exposure levels to VOC emissions during the spraying and application process of spray-applied polyurethane foam insulations. Of the studies conducted to date, personal exposure levels to VOC emissions have been evaluated for spray-gun operators and their helpers during the application of PU foams to houses and office buildings (6). Recorded personal VOC exposures reported in exposure assessment studies were found to be in the range of 0.120 mg/m^3 to 0.570 mg/m^3. These exposure levels are above the range of maximum measured airborne concentrations identified through the process of DCA of the two-part spray-applied PU foam ("Genyk PU-Foam"). In general maximum VOC airborne concentrations derived from "Genyk PU-Foam" ranged in concentration from 0.01 mg/m^3 to 0.07 mg/m^3. Reported personal VOC exposure levels of sprayers have found to be slightly higher than those of helpers and range in concentration form 0.120 mg/m^3 to 0.570 mg/m^3 (7-9). The concentration range of personal VOC exposure levels reported in these studies are above the range of maximum airborne emission concentrations reported through the DCA of the Genyk spray-applied PU foam insulation. In summary, the range of maximum emission concentrations (0.01 mg/m^3 to 0.07 mg/m^3) measured through the DCA of "*Genyk PU-Foam*" fall below the range of personal exposure concentrations reported in previous exposure assessment studies.

The personal exposure data reported in these studies provide an indication of the range of VOC concentrations occupants may typically be exposed to following the application of a spray-applied PU insulating foam to a residential structure. These data also provide an indication of the range of concentrations that are typically experienced by polyurethane applicators and the helpers of those applicators. These exposure levels represent typical occupational exposures and provide guidance towards evaluating health risk in this case. Furthermore, the occupational exposure levels provide some support towards the utilization of maximum measured airborne emissions in the application of the risk assessment process that is aimed primarily at evaluating

health risk. Although, DCA reveal that maximum levels are not maintained in air for extended periods, the assumption that human exposures are equal to maximum measured airborne concentrations provides an ample margin of safety to assess risk to human health. These assumptions were utilized in the assessment of human health risk. The following questions were addressed in this particular risk assessment process.

1) Will exposure to maximum indoor air concentrations of VOC emission products from "*Genyk PU-Foam"* (outlined in Table 2) pose a significant human health risk to residents of homes or buildings where this construction material is applied under the regulatory standards and guidelines for application of PU-Foam products?
2) What is the limiting residential occupancy time for "*Genyk PU-Foam"*? (ie. When is it safe for individuals to reside or enter buildings following the application of "*Genyk PU-Foam*" under the regulatory standards and guidelines for application of PU-Foam products?).

2.0 RISK ASSESSMENT

Risk assessment is a process that involves the characterization of the probability of adverse human health effects that may be associated with exposure to environmental chemicals (2,3,6). This process was used here to predict the potential for human health risk associated with an exposure to VOC products emitted from the polyurethane product "Genyk PU-Foam" developed by Genyk. A risk assessment evaluates a product's potential to produce adverse human health effects. Emission data obtained from environmental chamber testing is used to predict human exposure concentrations of contaminants, and these concentrations are assessed for their potential to produce cancer and non-cancer risks. The data is reviewed according to standards and guidelines available from occupational exposure limits. These limits are available from numerous governmental organizations. The EPA and Health Canada's carcinogenic and non carcinogenic risk levels, and sensory irritation and odorant limits are also considered in the risk assessment process. Risk assessment is an obligation for those manufacturers who want to understand potential health risks associated with use of their products. The risk assessment process is divided into four major steps; hazard identification, dose-response assessment, exposure assessment and risk characterization and each step is briefly outlined below.

The first step, hazard identification, involves the identification of Contaminants of Potential Concern (COPC). In this step of the risk assessment process, VOC emission products are evaluated for their safety through review of available toxicity data. The maximum measured concentration of each VOC emission product is compared to levels of exposure that have been accepted as "safe" for industrial workers. Accepted levels of exposure signify Threshold Limit Values (TLV) and/or Occupational Exposure Limits (OEL). These values of exposure are assigned by governing occupational agencies such as the American Conference of Industrial Hygienists [ACGIH] (10), National Institute for Occupational Safety and Health [NIOSH] (11) and the Occupational Safety and Health Administration [OSHA] (12). However there are cases in which TLV values have not yet been assigned to chemicals that are presently utilized in commercial or industrial processes or are created via chemical reactions and emitted as a result of industrial or commercial processes. For example chemicals emitted from PU-Foam insulation may not have an assigned TLV. Thus in this case where an exposure guideline has not been developed, maximum indoor air concentrations, of the VOC emission product identified, are compared to a no observed adverse effect levels (NOAEL) derived from animal/human toxicity data (2,3,6) or a TLV value assigned to the parent compound or a compound similar in chemical and physical nature to the identified VOC product.

Contaminants of Potential Concern are defined as emission products where an appropriate TLV or Exposure Limit is not available to make a comparison to maximum emission concentrations or where the maximum emission concentrations exceed the regulatory limit. In this case, a thorough review of toxicity data is required to assess and evaluate the health risks associated with a potential repeated exposure to maximum emission concentrations to determine the safe and unsafe levels of exposure. The first step of the risk assessment process thus involves a review of pertinent toxicity data (which may include inhalational, reproductive, developmental, carcinogenic, mutagenic and/or genotoxic information), chemical and physical properties and characteristics of, and occupational exposure limits for each VOC emission product identified.

In the second step of the risk assessment process the dose-response relationship is evaluated for the COPC identified. Generally, adverse health effects will only occur when an agent is absorbed

by a human receptor and distributed to target organs/tissues at concentrations and for durations of exposure sufficient to elicit toxicity. Therefore the nature of the relationship between the received dose and the probability of an adverse biological response is evaluated in the dose-response step of the risk assessment. In this step the relationship between the magnitude of the received dose and the occurrence of an adverse health response is characterized (2,3,6). The dose-response assessment considers whether exposure to maximum measured concentrations of airborne COPC could result in an absorbed dose likely to pose a risk to human health.

The third step in the risk assessment process involves defining the type of human exposure to VOC emission products identified as COPC. This step includes [1] describing the magnitude, frequency and duration of exposure to VOC(s) emissions and [2] identifying the possible exposure routes. In the case of emission products from "Genyk PU-Foam": [1] the magnitude, frequency and duration of exposure were classified as a short term continuous low-level exposure and [2] the main route of exposure was via the respiratory tract. Dermal and oral exposure routes are considered insignificant in this case.

The potential for human health risk is characterized in the fourth and final step of the risk assessment process. The likelihood that humans may experience toxicological effects under the actual conditions of exposure is determined here. In this case, it was determined whether individuals are at risk of experiencing adverse health effects by residing in buildings where the polyurethane foam product is applied under the regulatory standards and guidelines pertaining to PU-Foam treatment.

3.0 HAZARD IDENTIFICATION

This section summarizes the contaminants of potential concern that were selected for this assessment. A review of the DCA analysis of "*Genyk PU-Foam*" indicated that there were nine (9) VOCs emitted from the spray-applied polyurethane insulating foam. The maximum measured concentrations of each VOC emitted, as identified through DCA of "*Genyk PU-Foam*" were summarized above in Table 2.

3.1 Selection of Contaminants of Potential Concern (COPC)

Based on human health considerations, a selection process was performed to identify contaminants of potential concern (COPC) from the list of VOC products emitted from "Genyk PU-Foam". The procedure followed for selection of COPC is described below.

Firstly, contaminants of potential concern were identified by comparing maximum measured concentrations of each VOC to 1% of the American Conference of Government Industrial Hygienists (ACGIH) 2010 Threshold limit values established for these chemicals. The ACGIH TLV-TWA divided by 100 is industry protocol for establishing chronic human exposure levels suitable for residential scenarios (24 hours per day, 7 days per week). Maximum measured concentrations of VOC emission products at concentrations exceeding the above referenced guideline were considered COPC. In other words, these VOC emission products were considered to demonstrate a potential to cause adverse health outcomes under prolonged or repeated exposure. Maximum concentrations of volatile organic compounds emitted at levels at or below referenced guidelines were considered safe for human exposure.

Exposure levels that are considered to be acceptable ("safe") for human exposure such as the TLV-TWA® are usually allocated to various chemicals by the American Conference of Governmental Industrial Hygienists [ACGIH], however other agencies such as the National Institute for Occupational Safety and Health [NIOSH], Occupational Safety and Health Administration [OSHA] and other governing bodies of occupational and industrial hygiene assign exposure limits to chemicals. As a further step in the risk assessment process, maximum measured airborne concentrations of COPC were compared to occupational exposure limits assigned by agencies other than the ACGIH. Occupational exposure limits do not represent a fine line between safe and dangerous concentrations, nor are they a relative index of toxicity (13a-16). For the purposes of this risk assessment occupational exposure limits were used to facilitate the risk assessment process and help to predict the potential for human health risk associated with an exposure to VOC emission products. It is not generally recommended that occupational exposure limits be used as standards for indoor air quality in the home and for this reason the occupational exposure limits were reduced by a suitable safety factor to err on the side

of caution when assessing the potential human health risks associated with this particular case. The magnitude of this safety factor depends primarily on the number, the toxicity and the relative quantity of VOC emission products and other contaminants ordinarily present in the home (2,3,6,10). However, the Canadian Construction Materials Centre proposes a safety of 100. Thus, for the purposes of this risk assessment all exposure limits were divided by 100 in order to assess the human safety to maximum emission levels.

In summary, if no TLV-TWA® guideline is established or available for an individual VOC emission product, then maximum airborne concentrations were compared to either a TLV-TWA® ÷ 100 derived for the parent compound, a chemically similar compound, a guideline value established by another governing agency other than the ACGIH, and/or an inhalational No Observed Effect Levels ÷ 100 [(NOEL)- an airborne concentration that produced no observed adverse effects in exposed animals] derived from animal toxicity studies. If measured concentrations were found to be below the NOEL ÷ 100 value then the VOC emission product was dropped for further consideration. VOC emission products measured at concentrations exceeding the above guidelines or derived levels (NOEL ÷ 100; when no TLV-TWA® guidelines were available) were selected for further consideration and deemed COPC.

Table 3, summarizes the VOC emission products, their maximum measured concentrations and their respective ACGIH TLV-TWA® (or regulatory limits) values divided by 100.

Table 3: Maximum Indoor Airborne Concentrations of VOC Emission Products from "*Genyk PU-Foam*" and ACGIH TLV-TWA® (regulatory limit) ÷ 100.

VOC Emission Product Identified	Maximum Indoor Air Concentration (mg/m^3)	ACGIH TLV-TWA® (regulatory limit) ÷ 100
Propane, 2,2-difluoro-	0.07	[a]41.73
1,4-Dioxane	0.02	[b]0.721
Benzene, chloro-	0.004	[c]0.460
Squalene	0.01	NA
Tris(3-chloropropyl)phosphate	0.05	[d]10.03
Nitrobenzene, 3-(2-cyano-2-phenylethenyl)	0.01	[e]0.10
Cyclotrisiloxane, hexamethyl	0.01	NA
Cyclotetrasiloxane, octamethyl	0.01	NA
Bis(2-ethylhexyl)phthalate	0.01	[f]0.050
TVOC	0.194	^1.0 to 5.0

Note:
NA- Unavailable

Maximum Indoor Air Concentration Exceeds Exposure Limit ÷ 100

Unless specified in the notes below, regulatory limits utilized in the above table have been derived by the ACGIH and are representative of the ACGIH-TLV-TWA® for each specific compound listed in the table.

[a]Exposure limit of 1,000 ppm or 4173 mg/m^3 (8-hour time-weighted average) was recommended by the American Industrial Hygiene Association, Workplace Environmental Exposure Limit (WEEL) Committee. Extensive toxicity analysis of fluorinated hydrocarbons has been undertaken and information is provided at the following website. http://www.nap.edu/catalog.php?record_id=9268 ([12a]- National Research Council. *Toxicity of Alternatives to Chlorofluorocarbons: HFC-134a and HCFC-123.* Washington, DC: The National Academies Press, 1996 http://www.nap.edu/catalog.php?record_id=9268).

[b]ACGIH TLV-TWA® for 1,4-Dioxane
[c]ACGIH TLV-TWA® for Chlorobenzene
[d] OECD Exposure limit established for Tris(3-chloropropyl)phosphate
[e] Canadian Ontario Occupational Exposure Limit for 3-Nitrobenzonitrile
[f] OSHA Exposure limit for Bis(2-ethylhexyl)phthalate
^ Proposed TVOC for US and Canada office environments.

As summarized in Table 3, six of the nine VOC emission products emitted from "Genyk PU-Foam" have available ACGIH TLV-TWA® and/or other suitable exposure limits to be applied as comparative levels for the evaluation and identification of COPC and potential for human health risks. The maximum airborne concentration of six (6) VOC emission products were found to be below the safety limits applied in this risk assessment (refer to Table 3). Three VOC

emission products did not have available safety limits to assess potential risk to maximum emission concentrations. These included the following VOC compounds: Squalene, Cyclotrisiloxane, hexamethyl and Cyclotetrasiloxane, octamethyl. To facilitate the risk assessment process, relevant safety and toxicity information will be reviewed for these three VOC products.

3.2 Hazard Information for VOCs: Considerations for COPC

3.2.1 Squalene

Squalene, is an isoprenoid compound structurally similar to beta-carotene, and is an intermediate metabolite in the synthesis of cholesterol. In humans, about 60 percent of dietary squalene is absorbed. It is transported in serum generally in association with very low density lipoproteins and is distributed ubiquitously in human tissues, with the greatest concentration in the skin, where it is one of the major components of skin surface lipids. Squalene is not very susceptible to peroxidation and appears to function in the skin as a quencher of singlet oxygen, protecting human skin surface from lipid peroxidation due to exposure to UV and other sources of ionizing radiation[Kelly, 1999 (13)]. The World Health Organization (WHO) and the United States Department of Defense have both published extensive reports that emphasize that squalene is a chemical naturally occurring in the human body, and is present even in the oils of human fingerprints. The WHO also explains that squalene has been utilized in over 22 million flu vaccines which have been given to individuals in Europe since the late 1990's without significant vaccine-related adverse events.

In consideration of the above information regarding squalene, the transient nature of its emission and the low airborne concentrations, Squalene is not considered a COPC and will not be considered further through the risk assessment process.

3.2.2 Siloxane Compounds

Two cyclosiloxane compounds were measured at low levels in air samples collected at the 30-day DCA testing interval. Cyclotrisiloxane, hexamethyl and cyclotetrasiloxane, ocatmethyl were

emitted at low levels from "Genyk PU-Foam" test specimen. Siloxane chemicals are compounds composed of the following units R_2SiO where R is either a hydrogen atom or a hydrocarbon group. Siloxane compounds belong to a wider class of organosilicon compounds.

In November 2008, pursuant to Section 74 of the Canadian Environmental Protection Act, 1999 (CEPA, 1999), the Ministers of the Environment and of Health conducted a screening assessment of decamethyl cyclopentasiloxane [refered to as D5 in their documents] and octamethyl cyclotretrasiloxane [refered to in their documents as D4] (Environment Canada and Health Canada. _Screening Assessment for the Challenge Octamethylcyclotetrasiloxane (D4)_. November 2008. http://www.ec.gc.ca/substances/ese/eng/challenge/batch2/batch2_556-67-2.cfm [ii] Environment Canada and Health Canada. *Screening Assessment for the Challenge: Decamethylcyclopentasiloxane (D5)*. November 2008. http://www.ec.gc.ca/substances/ese/eng/challenge/batch2/batch2_541-02-6.cfm

In the review conducted by the Ministries of Environment and Health it was concluded that D5 and D4 are not entering the environment in a quantity or concentration or under conditions that constitute or may constitute a danger in Canada to human life or health. They also concluded that the most significant contribution to daily intake of D5 from environmental media is inhalation of indoor air. This conclusion was based on a study of approximately 130 homes in Syracuse, New York in which D5 was detected in 85% of the homes included in the ambient indoor air analysis. The Ministries reported that the maximum concentration of D5 in indoor air measured in the homes was 1.56 $mg/m^{3.}$ The mean concentration of D5 was reported at 0.136 mg/m^3. Ambient indoor levels as reviewed in the Ministries report are well above emission levels measured within the process of DCA of "Genyk PU-Foam".

As summarized in the Ministries report of 2008, the lung was identified as the primary target organ for repeated inhalational exposures to D5. The lowest concentration at which lung effects were observed in repeated inhalational exposure animal toxicity studies was 450 mg/m^3. The lethal concentration 50 (LC50) of 8670 mg/m^3 derived for D5 was determined through toxicity studies of single 4 hour whole body inhalation exposure in Fisher 344 rats. D5 has not been classified for carcinogenicity, genotoxicity or reproductive/developmental toxicity by any international agency.

The Ministries report indicated that an important toxicological effect of repeated D4 exposure is impaired fertility. However this conclusion was based primarily on assessments performed by the European Commission and the Danish EPA. The Danish EPA also identified the liver as a target organ of repeated D4 exposure. A critical effect level of 85 mg/m^3 for repeated-dose toxicity via inhalation was based not only on increased liver weights, but also on effects observed in other organs (adrenals, thymus, lungs) in a three-month rat inhalation study. The LC50 for D4 of 36 000 mg/m^3 was derived from single 4-hour nose-only inhalation exposure studies in Fischer rats. Taking into account all relevant toxicity information the low potential for acute toxicity and the nature of the hazards associated with siloxane compounds (repeated very high level of exposure) and the potential for cumulative exposures as a result of the presence of siloxane compounds in other relevant domestic/commercial products it is concluded that siloxane emissions of 0.01 mg/m^3, measured at the 30-day DCA testing interval, will not pose significant risk to exposed individuals.

Taking into consideration the comprehensive review performed by the Ministries of Health and Environment, the LC50s and the critical effect levels identified for these compounds it is evident that health impacts to siloxane compounds are associated with continuous repeat high level exposures. The scenario of exposure in this case is not reflective of a continuous high level of exposure. The siloxane emissions are low, compared to the critical effects levels derived for D4 and D5, emissions are only observed at the 30 day period of testing, are at very low levels and at levels not associated with health hazards. Additionally, measured maximum airborne concentrations are well below those typically measured in indoor ambient air. Siloxane compounds are not considered COPC and will not be considered further through the risk assessment process.

4.0 DOSE-RESPONSE ASSESSMENT

The relationship between the potential received dose and the probability of adverse health effects is evaluated in the dose-response step of the risk assessment process. The intention of this risk assessment is to determine the relationship between exposure to maximum indoor air VOC

concentrations and the potential for an adverse human health effect. Possible durations of exposure will be considered below.

4.1 Threshold Limit Values and Dose Response Assessment

In order to determine whether the maximum indoor air concentrations of VOC emission products pose a significant health risk to an individual residing in a home where "Genyk PU-Foam" is applied, a comparison of this value was made with an exposure level that is considered acceptable ("safe") for human exposure. This "safe" level represents the ACGIH-Threshold Limit Value-Time Weighted Average® ÷ 100 (TLV-TWA® ÷ 100), a NOEL ÷ 100 or an exposure limit derived from another regulatory body such as NIOSH, or OSHA. The safe levels for human exposure were determined in the hazard identification step of the risk assessment process. A safety factor of 100, applied to the TLV-TWA® or other derived exposure limits provides an ample margin of safety in this case. Thus, it is assumed here that a chronic lifetime exposure to levels of TLV-TWA®, or other relevant and appropriate exposure limit ÷ 100 would not pose a significant health risk to occupants of a home where "*Genyk PU-Foam*" is applied. Considering the toxicity data, the low emission levels and the transient nature of the maximum airborne VOC emissions; an acute, subacute, subchronic or chronic exposure to these VOC is unlikely to occur and result in any appreciable risk to human health.

There are several factors supporting the use of a relevant exposure limit, such as the TLV-TWA® ÷ 100, as a reasonable comparative value for the current assessment of "*Genyk PU-Foam*". Through the hazard assessment step of the risk assessment it was determined that "*Genyk PU-Foam*" –derived VOC emissions will not pose significant inhalational toxicity under conditions where individuals would be exposed to low airborne concentrations (inhalation being considered the primary route of exposure since the emission products are expected to exist primarily in the vapour phase). The emission concentrations are not likely to produce significant adverse systemic injury, and animal toxicity data indicate the risk of significant adverse effects following acute, subchronic or chronic exposure to low-levels of "Genyk PU-Foam" –derived VOC emissions is insignificant.

A review of relevant human and animal studies indicated that toxicity is associated with repeated exposures to extremely high airborne concentrations. The dynamic chamber analysis demonstrates emission levels are low and maximum levels are not persistent. Therefore, the potential for exposures to concentrations and for durations of exposure that are likely to be associated with adverse effects are improbable in this case. In any scenario, potential exposure is likely to be of a short term duration, to low levels, rapid high levels of absorption into the human body is not likely, the accumulation to acute toxic concentrations in the ambient air, and/or in the body following absorption, is also very low, and exposure should not lead to a chronic or an acute adverse outcome.

Overall, exposure to maximum measured concentrations of VOC emissions derived ''Genyk PU-Foam" are not likely to result in a received human dose that would result in adverse human health effects.

5.0 EXPOSURE ASSESSMENT

A chemical agent 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. Thus, whether a toxic response occurs is not only dependent on dose, but is also dependent on the chemical and physical properties of the agent, the exposure situation and the susceptibility of the subject. Thus to characterize fully the potential hazard associated with exposure to the emission products from "*Genyk PU-Foam*", information on 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 of the risk assessment process is designed to describe and characterize the likelihood, the extent, the magnitude, the duration and the route of exposure to the VOC emission products identified in Section 1.0.

The likelihood and the extent of human exposure to VOC emissions from "*Genyk PU-Foam*" or polyurethane material in general, depend on several factors and these include: [1] the chemical nature of the VOC products, [2] the characteristics of the residential structure (size and air-

tightness of the house) and [3] the activity patterns of the residents, or time spent indoors and [4] the susceptibility of the exposed individuals (6). These factors will be considered here to assess the degree of exposure to VOC products emitted from "*Genyk PU-Foam*".

Generally, VOC products when released into the indoor environment of a residence are expected to exist solely as vapours (3,5). Thus, the respiratory system constitutes the primary route of exposure to each of the VOC emission products identified through emissions testing. VOC vapours within the ambient atmosphere are likely to be degraded quickly (6). For example, many VOC are degraded in the atmosphere by reaction with photochemically produced hydroxyl radicals. Typically, the estimated half-life for VOC vapours range between a few minutes to several hours. Therefore it is expected that in a home, these VOC emissions will be degraded, their ambient levels will decrease over time and accumulation to a potentially toxic level in the ambient air of a residential building is not likely. Therefore, in this case, the duration of exposure to low-level emission products is relatively short and repeated exposure to maximum emission levels would not be maintained and extended for long periods of time. Additionally, acute exposures to low-levels are not associated with adverse health impacts.

In the worst-case scenario, the maximum potential level of human exposure to VOCs emitted from "*Genyk PU-Foam*" could be as high as the maximum indoor air concentrations determined by dynamic chamber analysis and outlined in Tables 1 and 2. The maximum indoor air concentrations of VOC products emitted from "*Genyk PU-Foam*" are predicted based on a 500 m^3 house with a ventilation rate of 0.3 air exchanges/ hour (4). By applying this low estimate for air exchange rate, the dynamic chamber analysis provides a very conservative estimate for maximum indoor air concentrations of the VOC products. Thus, even immediately after application of the polyurethane foam insulation, the actual maximum indoor air concentrations in most structures would likely be lower than those predicted through DCA and outlined above in Tables 1 and 2. Individuals would likely be exposed intermittently, for a short period of time in the case of a residential environment. It can safely be assumed that the actual level of human exposure "*Genyk PU-Foam*"-derived VOC emission products would be considerably lower than the maximum indoor air concentrations applied in the process of this risk assessment. The combined factors of low levels of VOC emission relative to safe levels, short duration of VOC

emissions and the low potential for repeated chronic exposure by occupants, to levels associated with toxicity, suggest a low risk for adverse health effects posed by exposure to airborne emission products of "*Genyk PU-Foam*".

6.0 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 (toxicity, measured air concentrations, exposure pathway information, inhalation route), for the purpose of estimating risk to humans. Throughout this assessment, procedures have been used to err on the side of caution in estimating the potential health risk associated with "*Genyk PU-Foam*" -derived VOC emission products.

This analysis has revealed that VOC products emitted from "Genyk PU-Foam" should not pose a health risk to individuals residing in buildings insulated with this material.

A number of factors support this conclusion:

[1] In general maximum airborne concentrations of VOC emission products were below the safety guidelines. Airborne concentrations were measured at levels well below levels associated with health risk.

[2] In general VOC emission products from "*Genyk PU-Foam*", at concentrations determined through DCA, are of low order toxicity under conditions of low-level human exposures, posses a low inhalational toxicity at low level airborne concentrations and have not been demonstrated to pose a significant carcinogenic risk to the general population at intermittent low levels of exposure. Repeated high levels of exposure have been associated with adverse health effects, a scenario of exposure not likely to occur in this case.

[3] Based on the decay pattern of the VOC emission products (up to 30 days), ambient indoor VOC air concentrations will decrease rapidly over time and should not accumulate to a toxic concentration in the home or in any other residential building. Acute exposures to low-levels are not associated with adverse impacts to human health.

[4] Exposure to maximum potential indoor air concentrations of VOC emission products was demonstrated through the risk assessment process to possess a low potential for human health risk under the conditions of exposure outlined in the Exposure Assessment Section of the document.

[5] Low-level exposures to VOC products emitted from "Genyk PU-Foam" are not associated with acute or chronic adverse health effects.

Presently there are no Canadian or U.S. human exposure standards for total volatile organic compounds (TVOC), however a target of 1 mg/m^3 and 5 mg/m^3 respectively, are being discussed for indoor office environments. The European Community has prepared a target guideline value for TVOC of 0.3 mg/m^3 for office environments. TVOC concentrations (0.194 mg/m^3), based on the maximum emission concentrations measured for each VOC emitted, fall well below the recommended guideline for office environments.

Overall, the concentrations of airborne VOC and TVOC decrease over time and are not likely to accumulate in ambient air to toxic concentrations. Thus in this case, exposure to maximum airborne concentrations of VOC or TVOC, will not pose a significant human health risk. Based on the integration of all information presented in the steps of the risk assessment process, a residential occupancy time of 1 hour has been recommended for "Genyk PU-Foam". The residential occupancy of 1 hour applies to residents of structures insulated with this material.

7.0 RECOMMENDATIONS

Indoor exposures to VOCs from building materials are of obvious concern. Since there are numerous sources of VOC in building material and home furnishings, it is clear that regulatory

improvements to indoor VOC standards in residential buildings will not be achieved by singling out individual products, but rather through an assessment of all potential components of such residences. Significant improvements in the indoor air of individual VOC could be achieved by establishing an overall limit in the amount of total VOC contributed by all housing materials used in the construction of new buildings. This limit could then be maintained through adequate ventilation.

The current risk assessment indicates that there is a low human health risk associated with exposure to VOC emission products from "*Genyk PU-Foam*". Since no significant threat to health can be associated with a short-term exposure to low-levels of these emission products, maximum levels are transient and do not persist at levels exceeding safety limits over the 30-day period of dynamic chamber analysis, it is suggested that a residential occupancy time of 1 hour be considered for "*Genyk PU-Foam*". With a planned assessment of all building materials, the use of "*Genyk PU-Foam*" insulation should not pose an additional health risk to occupants of residential or commercial buildings when applied under the regulatory guidelines and standards established for PU-Foam applications.

8.0 CLOSURE

A Human Health Risk Assessment (HHRA) has been completed as authorized. This report has been prepared for the exclusive use of Genyk and its agents for specific application to the two-part polyurethane spray foam insulation "*Genyk PU-Foam"*. It has been prepared in accordance with generally accepted toxicological practices and no other warranty, expressed 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, is the responsibility of such Third Parties. Dr. L. Bharadwaj accepts no responsibility for damages, if any, suffered by any Third Party as a result 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 Dr. Lalita Bharadwaj.

Yours very truly,

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