



**Industrial Hygiene Study:
Diisocyanates Exposure
Noble House, Inc., Victoria, CA**

Client: Dirk Straun, Facilities Director
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Industrial Hygiene Report Reliance Statement and Warranty

Gold Health and Safety Consulting, Inc. (“GSC”) was engaged by Dirk Straun, Facilities Director of Noble House, Inc. (“Client”) to conduct an industrial hygiene study of employee exposure to airborne diisocyanates at the Navien production line of the Client’s facilities in Victoria, California. GSC performed the study on April 23, 2013 in accordance with generally accepted professional industrial hygiene practices.

GSC’s services consist of professional opinions and recommendations made in accordance with generally accepted industrial hygiene principles and practices and are designed to provide a tool to assist the Client. GSC or those representing GSC bear no responsibility for the actual conditions or safety of the Client’s operations or facilities.

Upon acceptance of the report, the Client agrees that GSC’s investigation shall be limited by the terms and conditions stated in GSC’s report, and that the actual health and safety conditions at the facility may change with time or operational changes; that hidden conditions (not discoverable within the scope of this assessment) may exist at the site; and that the scope of this investigation was limited by time, budget and other constraints imposed by the Client.

Regardless of the findings of GSC, GSC makes no warranty that the site is free from existing safety hazards, contaminants, or other non-compliance situations. GSC is not responsible for consequences or conditions arising from facts that were concealed, withheld, or not fully disclosed at the time the Survey was conducted.

GSC represents to the Client that it has used the degree of care and skill ordinarily exercised by health and safety consultants in the performance of the services and in the assembling of data and information related thereto, in accordance with generally accepted professional practices. No other warranties are made either expressed or implied.

GSC is not licensed as medical professionals; therefore the conclusions and recommendations contained within this report do not constitute medical opinions, human health risk analysis, or public health alerts. A licensed physician should be consulted for such opinions.

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I. LABORATORY ANALYTICAL RESULTS

Section 1.0 - GENERAL BACKGROUND

1.1 Introduction and Purpose

Gold Health and Safety Consulting, Inc. (“GSC”) was engaged by Dirk Straun, Facilities Director of Noble House, Inc. (“Noble House” or the “Client”) to conduct an industrial hygiene study of airborne diisocyanates at the Navien production line. The study was conducted at Noble House’s manufacturing facility located in Victoria, California. The sole purpose of the study and this report is to provide the Client with information regarding potential diisocyanate exposure issues at the Navien production line, at the time of the study.

1.2 Site Background and History

Noble House, Inc. (“Noble House”) is a medical device manufacturer. The facility manufactures microsurgery catheters and stents. Workplace activities include assembly, coating, and cleaning. Much of the operations occur within large clean rooms. There are also Administrative, Sales, and Engineering offices at the facility.

Dirk Straun, Noble House’s Facilities Director, requested that GSC collect industrial hygiene samples at the Navien production line during coating of parts. The coating product used was Bacon Industries, Inc.’s Flexobond 431 urethane resin which uses a mixture of Diisocyanate catalysts. Employees applying this product were concerned about airborne chemical exposure.

GSC has previously conducted a similar study for Noble House at the same operation on August 22, 2012. At that time, monitoring results showed that airborne exposure to diisocyanates was well below applicable Cal-OSHA permissible exposure limits. However, as the activity level at the Navien production line has increased, Mr. Straun wished to get an updated study performed to assure that airborne exposure was still within acceptable limits.

1.3 Diisocyanate Hazards and Permissible Exposure Limits

As discussed above, the catalyst component to the Flexobond 431 used at the Navien production line contains a mix of diisocyanates, including Methylene bisphenyl isocyanate and Diphenylmethane diisocyanate (“MDI”). Diisocyanates are frequently found in two-part polyurethane systems as the catalyst component.

Diisocyanate compounds have similar health effects. According to the National Institute of Occupational Safety and Health (“NIOSH”), diisocyanates may enter the body via inhalation, ingestion, skin and/or eye contact. Diisocyanate exposure targets the eyes, skin, and respiratory system. Overexposure to diisocyanates can cause irritation to the eyes, skin, nose, throat; choking, coughing and chest pain; nausea, vomiting, and abdominal pain; bronchitis, bronchospasm, pulmonary edema, breathing difficulty, asthma; as well as conjunctivitis and lacrimation (discharge of tears). In addition, diisocyanates are regarded as a potential occupational carcinogen.

Diisocyanates are known as sensitizers. Some individuals exposed to diisocyanates may develop a reaction similar to allergies or asthma that worsens with subsequent exposure. Over time, it may be necessary for these individuals to avoid any and all exposure to diisocyanates. Fortunately, diisocyanates have low volatility and thus do not become readily airborne. However, during some operations, such as in paint spray booths, mists containing diisocyanates may become inhaled if exhaust ventilation is not adequate.

The California Division of Industrial Relations (commonly known as “Cal-OSHA”) regulations set airborne exposure standards for numerous hazardous chemicals in the workplace. These standards are known as “Permissible Exposure Limits” or PELs. The PELs are intended to maintain a safe working environment for full-time employees. Not all diisocyanate compounds have a PEL; however, for those that do (such as MDI) the PEL is uniformly set to an amount of no more than 0.005 parts per million in air (“ppm”). This is the maximum allowable time-weighted average concentration for an employee work shift of 8 hours.

Section 2.0 – SAMPLING METHODOLOGY

2.1 Diisocyanate Sampling Methodology

GSC’s used Galson Laboratory’s Diisocyanate Profile method was to collect and analyze the samples for Diisocyanates at the Navien production line, as we did during the August 2012 study. The method is somewhat similar to OSHA’s method 42 for diisocyanates. The Diisocyanate Profile captures all diisocyanates for which Cal-OSHA has a PEL, and thus was chosen since the MSDS does not disclose the specific names of all the diisocyanates used in the catalyst component of Flexobond 431.

The method requires that a known volume of air be drawn through a glass fiber filter that has been treated with 1-(2-pyridyl) piperazine. At the laboratory, the filter is desorbed with a solution of acetonitrile/dimethyl sulfoxide. The resulting solution is then injected into a high pressure liquid chromatograph using an ultraviolet or fluorescence detector. By knowing the volume of air collected and the amount of material collected onto the media, the concentration can be calculated.

2.3 General Sampling Strategy

The sampling was conducted by GSC on April 23, 2013. Four personal samples were collected from employees assigned to the Navien production line. Personal samples provide a good representation of actual employee exposure. In addition, one area sample was collected. The area sample was positioned close to the Flexobond 431 use area to approximate a worst-case scenario exposure.

The samples were collected during the first shift. GSC understands that on the dates of the sampling, the workload was typical of that normally found at Noble House. The samples were collected for a period of about an hour and a half, which is typical of the daily workload involving Flexobond 431.

All samples were collected using SKC brand universal sampling pumps model 224-PCXR8 owned by GSC. A sample flow rate of approximately 1.0 liters per minute (“LPM”) was used to collect the samples, per the sampling method’s recommendations.

Each sample train was pre-calibrated to the desired flow rate by GSC using a BIOS Dry Cal primary pump calibrator. The BIOS Dry Cell calibrator last received a calibration check and certification on May 23, 2012 by CIH Equipment Company of Clearwater, Florida. The average of ten sample train flow rate readings were used for both pre- and post-calibration checks. All sample media was provided by Galson Labs.

For each sample, once the sampling train was completely assembled and pre-calibrated, the pump with tubing, sample holder, and sample was placed on the employee to be monitored. At the end of the sampling period, GSC collected the sampling trains, post-calibrated them, and labeled the samples.

Following field services, the samples were transported in a small insulated cooler with an ice pack and were stored in a freezer at GSC’s office while awaiting shipment. They were packaged and shipped the same day inside a small insulated cooler with an ice pack. The samples were shipped via Federal Express overnight shipping to the analytical laboratory.

2.4 Analytical Laboratory Services

Following field sampling activities, the samples were shipped to Galson Laboratories (“Galson”), of East Syracuse, New York for analysis. Galson is certified by the American Industrial Hygiene Association Laboratory Accreditation Program for industrial hygiene analysis. Standard turnaround time (five business days) for the analytical results was requested by Noble House. Appropriate chain-of-custody procedures were used for both shipment to and receipt by Galson.

Section 3.0 – SAMPLING RESULTS

3.1 Diisocyanate Sampling Results

The analytical results of the sampling for airborne diisocyanate are contained in Table I below:

Table I: Diisocyanate Sampling Results

In parts per million (“ppm”)

Employee Name	2,4 Toluene Diisocyanate	2,6 Toluene Diisocyanate	HDI Monomer	HMDI	Isophorone Diisocyanate	MDI Monomer
Pam McFarlane	<0.0002	<0.0002	<0.0002	<0.0001	<0.0001	<0.0001
Martha Ocugueda	<0.0002	<0.0002	<0.0002	<0.0001	<0.0001	<0.0001
Harmilla Mondragon	<0.0002	<0.0002	<0.0002	<0.0001	<0.0001	<0.0001
Natalie Nolasco	<0.0002	<0.0002	<0.0002	<0.0001	<0.0001	0.0001
Area Sample	<0.0002	<0.0002	<0.0002	<0.0001	<0.0001	<0.0001
Blank	ND	ND	ND	ND	ND	ND
Cal-OSHA PEL	0.005	NA	0.005	0.005	0.005	0.005

ND = Not detected
NA = Not applicable

The sample analysis results showed that on the date of the sampling, exposure to diisocyanates were well below the corresponding Cal-OSHA PELs for each diisocyanate monitored. For additional discussion of these results, please refer to Section 4.0, Discussion and Conclusions.

For further information, please see Galson’s full laboratory report, which has been included in Appendix I of this report.

Section 4.0 – DISCUSSION and CONCLUSIONS

GSC’s conclusions are based upon the conditions observed at the date and time of the sampling, as well as the available information and data, including that provided by the Client. Topics not explicitly discussed within this document should not be assumed to have been investigated.

Four personal and one area air sample were collected at the Navien production line for exposure to diisocyanates (the catalyst for the Flexobond 431). Diisocyanates were identified by GSC as being potential exposure hazards during our review of the MSDS provided by the Client. The sampling was to assure that exposure to these chemicals at the Navien production line is safe and in compliance with Cal-OSHA limits. A prior study conducted by GSC during August 2012 showed that exposure levels were acceptable, but Noble House wished to have an additional study performed due to the increase of production activity at the Navien line.

The diisocyanate samples were collected on April 23, 2013. All samples were collected according to appropriate industrial hygiene methodologies. One sample blank was also analyzed. All samples were analyzed by an AIHA certified analytical laboratory. The conditions on the date of the sampling are believed to be representative of normal work conditions at the facility.

All sample results were well below their corresponding Cal-OSHA Permissible Exposure Limit. These results indicate that the employees at the Navien production line are not being overexposed to diisocyanates under similar work conditions.

Section 5.0 – RECOMMENDATIONS

5.1 Specific Recommendations

GSC has no specific recommendations at this time.

5.2 General Recommendations

1. Maintain the general room ventilation at the Navien production area in proper operation and continue its use when production is occurring.
2. Assure that employees are aware of the hazards of the materials that they work with, and their rights to access and obtain copies of material safety data sheets per Cal-OSHA regulations and the Noble House's Hazard Communication Program Plan.
3. Employees have the right to review the content of this report and should be explained the results of the sampling discussed herein.
4. Pursuant to the client's request the samples collected for the purpose of this report were collected solely on one day. Although it is believed that on the date the sampling occurred each employee's work conditions were similar to those typically found at Noble House, normal variations in sampling and work flow can occur during any industrial hygiene sampling project, thereby affecting the results. For this reason, GSC always recommends that multiple days of sampling be performed to improve the statistical reliability of the results. In addition, should production rates substantially increase, GSC recommends additional sampling. Finally, should chemical usage change, a qualified industrial hygienist should review the new usages and amounts and determine if sampling is required or advisable.

APPENDIX I

LABORATORY ANALYTICAL RESULTS