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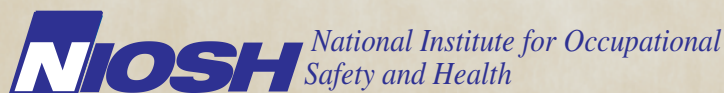


Evaluation of Contact Dermatitis Among Ink Ribbon Manufacturing Employees – New York

Loren C. Tapp, MD, MS
Srinivas Durgam, MSPH, MSChE, CIH
Charles Mueller, MS

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ABBREVIATIONS

ACGIH®	American Conference of Governmental Industrial Hygienists
AIHA	American Industrial Hygiene Association
CFR	Code of Federal Regulations
CP1	Coating area Plant 1
CP2	Coating area Plant 2
CT	Charcoal tube
ftpm	Feet per minute
GA	General area
GC-MS	Gas chromatography-mass spectrometry
HHE	Health hazard evaluation
HVAC	Heating, ventilating, and air-conditioning
LEV	Local exhaust ventilation
LLNA	Local lymph node assay
MDC	Minimum detectable concentration
MEK	Methyl ethyl ketone
mL	Milliliter
MQC	Minimum quantifiable concentration
MSDS	Material safety data sheet
NAICS	North American Industry Classification System
NIOSH	National Institute for Occupational Safety and Health
OEL	Occupational exposure limit
OSHA	Occupational Safety and Health Administration
PEL	Permissible exposure limit
PGMEA	Propylene glycol methyl ethyl ether acetate
PPE	Personal protective equipment
ppm	Parts per million
PR	Prevalence ratio
REL	Recommended exposure limit
SMM	Solvent mixture making
STEL	Short-term exposure limit
TD	Thermal desorption
TLV®	Threshold limit value
TWA	Time-weighted average
WEEL	Workplace environmental exposure level
VOC	Volatile organic compound

HIGHLIGHTS OF THE NIOSH HEALTH HAZARD EVALUATION

The National Institute for Occupational Safety and Health (NIOSH) received a request for a health hazard evaluation at an ink ribbon manufacturing plant in New York. The employer submitted the request because several production employees had dermatitis possibly from exposure to ink ingredients or ink mixtures.

What NIOSH Did

- We evaluated the facility in August 2007, March 2008, and September 2009.
- We looked at work practices and personal protective equipment use.
- We took air samples for volatile organic compounds in production areas.
- We spoke privately to employees about skin symptoms.
- We reviewed material safety data sheets, training programs, and medical records.
- We tested ink ingredient and ink mixture samples to see if they could cause an allergic skin reaction.
- We gave the entire workforce a written health survey.
- We noted workplace changes made by the company on the basis of our recommendations.
- We tested employees who had a history of dermatitis for skin allergies. Common skin allergens and workplace agents were used for testing.

What NIOSH Found

- Employees in the production areas had skin exposures to chemicals.
- Chemicals and ink dust were seen on work surfaces.
- Some employees were using gloves that did not protect them from certain solvents.
- Air sampling found very low levels of chemicals in the air.
- One ink ingredient, one ink mixture, and one brand of hand wipes were found to be skin allergens.
- Eighteen of 22 interviewed employees had dermatitis during the August 2007 site visit.
- Employees who worked in the production areas had more dermatitis than employees who worked in nonproduction areas.
- None of the employees who were tested had allergic skin reactions to workplace substances.

HIGHLIGHTS OF THE NIOSH HEALTH HAZARD EVALUATION (CONTINUED)

What Managers Can Do

- Replace work chemicals found to cause skin allergy with ones that do not.
- Require good housekeeping practices and continue Best Practices training to reduce skin exposure to inks.
- Continue to provide soaps and skin moisturizers that are less irritating.
- Continue to provide annual training on how to maintain healthy skin.
- Provide employees who are allergic to gloves with gloves that do not contain allergens.
- Refer employees with continual dermatitis to a dermatologist.

What Employees Can Do

- Avoid getting chemicals on your skin.
- Promptly clean up chemicals that spill onto work surfaces.
- Use work practices shown in the Best Practices training video.
- Use the correct gloves for the work you are doing and wear them as directed.
- Use good skin cleaning and moisturizing practices to keep skin healthy.
- Promptly report skin problems to your supervisor.

NIOSH evaluated skin exposures to workplace chemicals and contact dermatitis among ink ribbon manufacturing employees. We found that work-related contact dermatitis was associated with being exposed to ink production work and with having a history of allergic disease. We found that some workplace chemicals were skin sensitizers. Skin patch testing results indicated an irritant cause for the dermatitis. We recommended substitutions, improvements in ventilation and work practices, better hand hygiene to control skin exposure to chemicals, and early dermatologic referral for employees with persistent contact dermatitis.

In May 2007, NIOSH received a management request for an HHE to look at dermatitis in production employees. In August 2007, we toured the plant, interviewed employees, and examined their skin for irritation. We took air samples for volatile organic compounds, reviewed MSDSs and medical records, and tested workplace substances to see if they could cause skin allergy. Our evaluation found that airborne solvent exposures were low; however, production employees had the potential for skin contact with chemicals. The predominant location of dermatitis in employees was the hands and fingers, suggesting that the most likely cause of dermatitis was direct skin exposure to chemicals. Some ingredients in workplace inks, hand wipes, and hand cleaners were known sensitizers or were found to be sensitizers by our testing.

In March 2008, we asked employees to fill out health questionnaires and observed workplace improvements made by the company. The analysis of questionnaire data revealed that reporting work-related dermatitis was related to being exposed to ink production work and having a predisposition to allergic disease (defined as asthma, atopic eczema, or allergic rhinitis/hay fever).

Our initial findings suggested that the cause of the employees' dermatitis was skin allergies, so we returned to do skin patch testing in September 2009. We tested 13 employees with a history of dermatitis to newly identified workplace allergens and to common allergens. No skin patch test participants reacted to any of the workplace substances; seven reacted to common allergens. A dermatologist under contract to NIOSH diagnosed eight participants with irritant contact dermatitis. Employees were exposed to several irritants at work including solvents, dusts, and irritating soaps and/or hand wipes. In addition, employees with dermatitis reported worsening of symptoms when exposed to cold, dry weather. Because the company made improvements in ventilation, work practices, and housekeeping; introduced appropriately protective gloves; introduced less irritating hand products; and began healthy skin program training, the dermatitis of most skin patch test study participants improved or resolved.

Although no participants reacted to workplace materials, we recommended taking precautions in handling sensitizing substances, because prolonged and/or large exposures to those substances may cause a skin sensitizing reaction in allergy-prone employees.

SUMMARY

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Keywords: NAICS 339944 (Carbon Paper and Inked Ribbon Manufacturing), skin exposure, inks, PPE, gloves, chemicals, solvents, contact dermatitis, skin patch testing

In May 2007, NIOSH received a request for an HHE from the management of an ink ribbon manufacturing plant in New York. The request indicated that several production employees had reported dermatitis over the few years prior to the request, possibly caused by working with ink and solvent mixtures. We visited the plant in August 2007 to meet with management and employee representatives, learn more about the manufacturing process, observe work practices, evaluate PPE use, interview employees, conduct an environmental evaluation, and review pertinent records. We returned in March 2008 to administer health questionnaires and document process and work practice changes. In September 2008, we sent an interim report and then met with managers and employees to explain the results of our evaluation. In September 2009, we performed skin patch testing to assess whether employees with dermatitis had skin allergy to the workplace skin allergens we identified or to common allergens. We sent letters summarizing the patch testing results to managers and personal results to patch test study participants in November 2009. This report includes the final results and conclusions of our evaluation, and recommends ways to prevent work-related dermatitis using the hierarchy of controls as a guide.

Background and Process Description

This company manufactured wax, wax resin, and resin-based ink ribbons, which were packaged and shipped throughout the world. The ink ribbons consisted of a sturdy plastic film on which single or multiple coatings of ink mixtures were applied to one or both sides of the film. Company managers requested our assistance to evaluate dermatitis in employees exposed to inks and solvents used to make ink ribbon products and to the dust created when ribbons were cut. According to managers, production employees began reporting dermatitis in 2005. Inkmakers and coaters had reported most of the rashes. Twenty-seven employees reported having a rash at some time between the summer of 2005 and our first site visit in August of 2007; some employees had seen a dermatologist, and a few had undergone skin patch testing. A new product, “Ink Ribbon A,” was introduced into production in a limited amount in late 2003 and into full production in 2004. Some managers and production employees felt that exposure to this product might have been responsible for the new cases of dermatitis.

INTRODUCTION

(CONTINUED)

The production process occurred in two plants. Plant 1 contained the kitting room, wax ink area, solvent ink area (which included the solvent ink room, SMM center, and backing room), coating area, and slitting area. Plant 2 contained an additional coating area and the parts washing room. The CP1 used a different coating technology than CP2. The main solvents used at this facility were toluene, MEK, and isopropyl alcohol.

Dry chemical ingredients were weighed and placed into bags in a batch process in the kitting room. In the solvent ink area, solvent was weighed and added to large heated stainless steel vessels along with the dry ingredients from the kitting room. Some coating mixtures that needed agitation and mixing were created in mixing vessels in the solvent ink area. The wax ink area contained mixing vessels to which waxes were added along with dispersing agents and color pigments. These coating mixtures were used in the coating machines in CP1 and CP2 where they were then coated onto the plastic film.

On the basis of the product configuration, the coating machines in CP1 and CP2 could coat the plastic film with coating mixtures on one or both sides and, if needed, apply multiple coats on the same side. The coated film passed by a drying lamp and was then wound onto wide rolls called “jumbo rolls” as the finished product. Slitting machines cut these rolls to the required width. The finished ribbon product was wound on cores and packaged with shrink wrap.

The plant operated 24 hours a day, 7 days a week. Hourly production employees worked seven 12-hour shifts in a 2-week period. Shift changeover occurred at 7 a.m. and 7 p.m. About 30 hourly employees in the distribution center a few blocks away worked five 8-hour shifts per week. At the time of our initial evaluation, approximately 400 employees worked at the plant. During our second and third site visits, employees numbered between 300 and 350.

First Site Visit – August 2007

In August 2007, we held an opening conference with management and employee representatives and toured the facility to observe work processes and practices.

We observed the weighing of dry raw materials in the kitting room and wax ink area and the dust bagging and disposal methods for dust collectors in the kitting room and slitting area. We collected spot slot air velocity measurements with a thermal anemometer (TSI Velocicalc® Model 8345, TSI, Shoreview, Minnesota) to determine whether the local exhaust hoods in the kitting room, wax ink area, solvent ink area, and parts washing room were functional. We used TD tubes to collect seven GA air samples to screen for VOCs in different areas of the plant. We also collected seven CT samples (side-by-side samples) to quantify VOCs identified from the screening. We confidentially interviewed production employees who had reported skin problems to management or who were chosen by job title and availability. Preliminary recommendations were given in a closing conference.

We requested bulk samples of certain workplace materials to test for potential skin sensitization using LLNA and chemical analysis. We reviewed documents including ink MSDSs and contents of hand products and gloves used by employees. We also reviewed medical records of employees with rash whom we had interviewed.

Details on our methods for measuring VOCs in air and to test workplace substances for the potential to cause skin sensitization are explained in Appendix A. The OELs and potential health effects for VOCs are discussed in Appendix B.

Second Site Visit – March 2008

In March 2008, we administered health questionnaires to employees to evaluate possible associations between dermatitis and employee exposures, work practices, and PPE use. We asked about these topics in addition to demographic information, pertinent medical history, and nonwork exposures. Because the company had made changes in the workplace on the basis of our preliminary recommendations, we asked about PPE use, hygiene practices, work exposures, and dermatitis for two time periods: August 2007 (time of the first NIOSH site visit) and March 2008 (time of the

second NIOSH site visit and questionnaire). Questionnaire data were analyzed with SAS Version 9.2. (SAS Institute Inc., Cary, North Carolina). Details of the questionnaire analysis are described in Appendix A.

We classified our exposure groups on the basis of the reported current job title of the participant (i.e., our best indicator of ink exposure). All supervisors and managers of nonproduction staff and all administrative and office staff (with minimal or no ink production exposures) were classified as the “ink-unexposed” group, and all other reported current job titles were classified as the “ink-exposed” group (i.e., exposed to ink production work).

We defined work-related dermatitis by positive responses to both having dermatitis on hands, wrists, or forearms since being hired; and dermatitis improving away from work sometimes, usually, or always. A personal history of allergic disease, or atopy, was defined as ever having one of the following: asthma, a persistent itchy rash that affected skin creases (atopic dermatitis), or symptoms of allergy or hay fever. A family history of atopy was defined as having a blood relative (parents, brothers, or sisters) ever having one of the following: asthma, persistent rash, or allergy or hay fever.

During our second site visit, we documented substitutions of ink ingredients and hand products; changes in work processes and employee work practices; and improvements that had been put in place since our first site visit in engineering controls, housekeeping, employee training, and glove type provided for employees. We returned in September 2008 to present our preliminary findings to employees and managers and to answer questions.

Third Site Visit - September 2009

In September 2009, we returned to conduct skin patch testing on employees with a history of dermatitis (study group) and employees without a dermatitis history (comparison group). We tested participants to specific workplace substances that were found to be skin allergens in mice and to other possible workplace skin allergens. Eligibility and procedures for participants in skin patch testing are explained in Appendix C. Because the preparations we used had not been used in skin patch testing on people before, employees with no dermatitis history were needed to make sure nonstandard preparations of workplace substances would not

produce skin reactions due to irritation nor cause false positive reactions.

During our visit, we observed new engineering controls that we had recommended in our interim letter. These changes are discussed in the Results section.

RESULTS

First Site Visit – August 2007

Environmental Evaluation

Our observations and the spot air velocity measurements identified a nonfunctioning local exhaust hood for the solvent ink area scale. The dust generated during the weighing of dry materials in the wax ink area was not fully captured by the LEV. Other local exhaust hoods we tested in the kitting room, wax ink area, and solvent ink area were functional. After our first site visit, we recommended improving general housekeeping within the plants and conducting a baseline survey to evaluate the LEV systems.

Analysis of the seven GA air samples collected with TD tubes indicated the presence of a multitude of chemicals. On the basis of their relative abundance in the screening samples, potential skin irritancy, and our review of MSDSs, we quantitatively analyzed the CTs for MEK, methyl isobutyl ketone, xylene, toluene, methyl vinyl ketone, PGMEA, trichloroethylene, limonene, and chemical constituents of “Chemical X,” an acrylic plastic powder. These results, the MDC and MQC for each analyte, and the applicable OELs are presented in Table D1 (Appendix D). Methyl isobutyl ketone, methyl vinyl ketone, trichloroethylene, and Chemical X constituents were not detected in our air samples. Toluene concentrations ranged from 0.34–11 ppm. All the air samples were analyzed for different isomers of xylene, and the highest air concentration of 0.11 ppm was observed in an air sample collected in the wax ink area. PGMEA concentrations ranged up to 0.55 ppm. All the air sample concentrations were very low.

Document and Glove Review

We reviewed the MSDSs of the four different types of hand hygiene products (two gritty-type hand cleaners, one lotion soap, and one hand lotion) and two types of hand wipes that were available to employees. In addition, the complete lists of ingredients for the blue and green hand wipes and one of the hand cleaners were obtained from their containers. At least two of the ingredients listed on the blue hand-wipes container were known sensitizers – d-limonene and triazine. The potentially irritating and sensitizing ingredients of each hand-wipe product are listed in Table D2 (Appendix D), along with the MSDS statement concerning the products' skin hazard potential. Both hand-wipe products contain a variety of sensitizing ingredients, however, only the green hand-wipe product states that use may cause sensitization by prolonged skin contact. Hand cleaners often contain compounds irritating to skin.

We reviewed the MSDSs for the chemicals used in formulating coating mixtures for Ink Ribbon A, which managers and employees identified as a potential cause of dermatitis. The MSDS for Chemical X, one component of Ink Ribbon A, indicated it is a resin copolymer. Upon our request, the manufacturer of Chemical X identified the proprietary chemical ingredients that make up the polymer; these ingredients are known skin sensitizers.

We also evaluated the gloves provided to employees: disposable nitrile gloves (Touch N Tuff, N Dex Nitehawk), arm-length nitrile gloves of two kinds (lined green Solvex, MAPA blue and yellow), Ansell Barrier® gloves, gloves for heat protection (yellow fuzzy duck), and cotton lining gloves (various types – thin, thick with rubber grip) for absorbing sweat. The nitrile gloves used at the facility were appropriate for working with isopropyl alcohol but not with toluene or MEK. We were informed that Ansell Barrier gloves were provided to employees working in the solvent ink area. However, we did not observe employees wearing these gloves.

Laboratory Evaluation

Results of the LLNA testing of the blue hand wipes were positive for sensitization in both intact (without a pre-existing condition) and breached (slightly abraded) skin. The testing also evaluated the product for irritancy; results were negative for irritation.

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The LLNA testing of the three coating mixtures of Ink Ribbon A revealed that the “Coating C” mixture was positive for skin irritancy and sensitization. Two potentially sensitizing ingredients in this coating mixture, “Chemical Y,” a polyvinyl butyral compound, and Chemical X, were further evaluated. Chemical Y tested positive for skin sensitization by LLNA. The suspect ingredient in Chemical Y, polyvinyl butyral, was tested and also found to be sensitizing. On the basis of an extensive literature search, we identified one study that found polyvinyl butyral to be nonirritating to the skin of rabbits [Knapczyk 1997]. No sensitization studies were located. The MSDS for Chemical Y does not list skin sensitization as a potential health hazard.

The second ingredient of the ink coating mixture, the resin copolymer Chemical X, was found to contain very small amounts of residual monomers known to be skin sensitizers. If the resin is in a 100% polymer form, it is not sensitizing. However, studies have shown that polymers often contain residual monomer [Bjorkner 1999; Pfeiffer and Rosenbauer 2004]. The results of our chemical analyses indicated that Chemical X contains residual “Monomers A and B” at estimated average concentrations of 0.033% and 0.0035% by weight, respectively. The MSDS for Chemical X does not list skin sensitization as a potential health hazard.

Employee Interviews

Twenty-two production employees were interviewed; 19 were from a list of 27 who had reported skin problems to management (the other eight were unavailable) and three others were chosen by job title (i.e., high ink exposure potential) and availability. Among the 22 employees interviewed, 18 reported a history of rash (one of the 19 from the list reported no history of rash).

The eighteen employees with a history of rash included six inkmakers, three CP2 coaters, two slitters, and one each from the following areas: kitting room, CP1 coating, maintenance, utility operation, quality assurance, warehouse, and supervision. Seventeen reported that their rash began during or after 2004. Thirteen consulted a physician because of their rash. Seven employees with rash reported that they thought Ink Ribbon A was responsible; three of these specified Coating C, a coating from Ink Ribbon A, as the problem. Six employees reported that use of

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the blue hand wipes, but not the green hand wipes, irritated their skin and/or caused a rash. One reported Rasol5000, and another reported 25B pigment (both are ink ingredients) as the cause of their rash. Some employees with rash stopped using the blue hand wipes and reported that the rash resolved. On examination, 17 employees had dermatitis on their hands, wrists, and/or forearms with two of the 17 also having dermatitis on the face and/or lower extremities. One employee had dermatitis on the legs only. Characteristics of employee dermatitis included red, slightly raised, dry patches, some with flaking and/or cracking of the skin, some with tiny red papules and/or vesicles.

Medical Record Review

We obtained medical records of ten employees who had experienced rash while working at this company and had seen a medical provider for the rash. Of these ten employees, six were diagnosed with work-related contact dermatitis; these six included two with work-related allergic contact dermatitis and four for whom the type (allergic vs. irritant) was not identified. The two employees diagnosed with allergic contact dermatitis were skin patch tested by their personal physicians but were not patch tested to specific products used in the workplace. One had also been diagnosed with work-related occupational asthma. Both had improvement of symptoms after being transferred to work areas without wet process exposure. Of the remaining four employees, three were diagnosed with dyshidrotic eczema (i.e., recurrent, small itchy blisters on hands and feet), and one had not been given a clear diagnosis.

Second Site Visit – March 2008

Health Questionnaire

Description of Participants and Exposure Groups

On the day scheduled for administering the health questionnaire in March 2008, 291 of 349 (83%) available employees completed the questionnaire. Information obtained from employee rosters and employee sign-in sheets at the time of the questionnaire was used to calculate participation rates. Of 207 employees working A, B, C, and D shifts, 203 (98%) participated; of 113 office employees, 63 (56%) participated; and of 29 distribution

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center employees, 25 (86%) participated. On the basis of the questionnaire responses, we found 10 of the respondents in March 2008 were not employed by the company in August 2007.

From August 2007 to March 2008, one employee changed from an ink-unexposed to an ink-exposed job, and another employee changed from an ink-exposed to an ink-unexposed job. Because the movement of employees between exposed and unexposed jobs was rare, we used the job exposure classifications from March 2008 as representative of both time periods when looking at demographic data (Table 1.)

Table 1. Demographic characteristics among ink-exposed and ink-unexposed employees

Characteristic	Ink-exposed (N = 251–254)* Number (%)	Ink-unexposed (N = 37) Number (%)
Male	203 (80)	16 (43)
Personal history of atopy	143 (56)	28 (76)
Family atopy	119 (47)	25 (68)
Age in years – Average	44.9	43.5
Total years at company – Average	12.2	10.6

*Range of denominators (i.e., the number of employees answering each question differed)

Dermatitis Among Employees

Of 291 participants, 60 (21%) reported having dermatitis on their hands, wrists, or forearms since they began working at the company; none of the 10 employees hired since August 2007 reported dermatitis. Among these 60 employees, 44 reported that the dermatitis improved away from work sometimes, usually, or always, and 27 reported that they had seen a doctor for their dermatitis. Twenty-four of 60 employees reported that their dermatitis was worse in winter; 29 reported that season made no difference, and 3 reported worsening dermatitis in summer. Fifty-three of the 60 employees with dermatitis since hire reported the year in which their dermatitis began; 35 (66%) reported that their dermatitis began in 2005 or later; 7 reported that their dermatitis began in 2005; 16 in 2006; and 11 in 2007. The year of dermatitis onset was of interest because Ink Ribbon A had been suggested as a possible cause and was introduced into production in early 2004.

RESULTS

(CONTINUED)

Employees reporting dermatitis since hire also reported the jobs they held when their dermatitis began. The most common jobs were slitting (20), coater (8), and inkmaker (6). When asked what they thought caused their rash, the most commonly reported causes were blue hand wipes (12), cold or dry weather (7), and Ink Ribbon A or a component of Ink Ribbon A (6). Among employees with dermatitis since hire, dermatitis reported in August 2007 and March 2008 most often occurred on the back of the hands (60%–63%) and the back of the fingers (51%).

We looked at the prevalence (%) of dermatitis and work-related dermatitis since hire. As measured by the prevalence ratio, the ink-exposed group was nearly three times as likely to report dermatitis of the hands, wrists, and forearms since hire as the unexposed group. When work-relatedness was taken into account, they were six times as likely to report work-related dermatitis since hire. Both of these relationships were statistically significant (Table 2). Because our survey did not include questions about the work-relatedness of dermatitis reported for August 2007 and March 2008, we were unable to estimate the prevalence of work-related dermatitis for those periods. Among ink-exposed employees, the prevalence of dermatitis was slightly lower (3%) in March 2008 than in August 2007.

Table 2. Self-reported dermatitis among ink-exposed and ink-unexposed employees

	Ink-exposed (N = 244–254)* Number (%)	Ink-unexposed (N = 37) Number (%)	Prevalence Ratio† (P value)
Dermatitis of hands, wrists, or forearms since being hired	57 (22)	3 (8)	2.8 (0.04)‡
Work-related dermatitis of hands, wrists, or forearms since being hired§	43 (17)	1 (3)	6.3 (0.02)‡
Dermatitis in March 2008 (“current”)	32 (13)	3 (8)	1.6 (0.59)
Dermatitis in August 2007¶	40 (16)	3 (8)	2.0 (0.19)

*Range of denominators (i.e., the number of employees answering each question differed)

†The percent in the exposed group divided by the percent in the unexposed group

‡Statistically significant

§Work-related dermatitis defined by positive responses to both having dermatitis on hands, wrists, or forearms since being hired, and dermatitis improving off work sometimes, usually, or always

¶Exposure groups based on reported job in August 2007

Differences Between Ink-exposed Employees With and Without Dermatitis in August 2007

To determine factors that may be associated with dermatitis, we looked at ink-exposed employees working in August 2007 and compared characteristics, behaviors, and PPE use among those with and without dermatitis in August 2007 (Table 3). We used the August 2007 period because this is when the concern was greatest, and no changes or interventions had been implemented at that point.

Table 3. Characteristics, behaviors, and PPE use among ink-exposed employees with and without dermatitis in August 2007

Characteristics	Ink-exposed employees*		P value
	With dermatitis in August 2007 (N = 36–40)†	Without dermatitis in August 2007 (N = 180–204)†	
	Average	Average	
Age	46.6	45.2	0.31
Total years at the company	13.3	12.6	0.43
# times applied lotion	1.5	1.3	0.49
# times wash hands in 24 hours	6.2	6.8	0.47
	Number (%)	Number (%)	
Males	32 (80)	163 (80)	0.99
Atopic history	34 (85)	102 (50)	<0.01‡
Family history of atopy	19 (48)	94 (46)	0.89
Worked with wet hands ≥ 2hrs a day	3 (8)	15 (7)	>0.99
Used gloves	28 (70)	108 (53)	0.051
Usually reused gloves (among glove users)	10 of 27 (37)	64 of 105 (61)	0.03‡
Used Tyvek® sleeves	10 (26)	41 (21)	0.53
Used cotton sleeves	12 (31)	67 (35)	0.65
Used blue hand wipes	28 (78)	121 (65)	0.15
Used green hand wipes	12 (32)	99 (52)	0.02‡

*Exposure groups based on reported August 2007 job

†Range of denominators (i.e., the number of employees answering each question differed)

‡Statistically significant

RESULTS

(CONTINUED)

Dermatitis among exposed workers was significantly associated with a personal history of atopy ($P < 0.01$). The use of gloves was greater in those employees with dermatitis, but was not statistically significant ($P = 0.051$). Among glove users, reusing gloves was more common in employees without dermatitis ($P = 0.03$). The use of green hand wipes was statistically greater among exposed workers without dermatitis than among those with dermatitis ($P = 0.02$). We compared exposures that were not work related for the two groups (e.g., preparing food, cleaning the household or car, caring for children under the age of 4 years, handling soil or plants, handling oil, handling solvents or paints, handling glue, and handling cement or drywall). The comparison showed no meaningful differences in these exposures between workers with dermatitis and those without dermatitis.

The Use of Hand Wipes and Dermatitis

Our LLNA testing showed that the blue hand wipes can produce skin sensitization. For this reason, we recommended that the company eliminate these hand wipes from the workplace. The company removed the blue hand wipes from the workplace prior to January 2008. Among the 40 ink-exposed employees with dermatitis in August 2007, 33 (83%) reported that they were using blue hand wipes when their dermatitis began. Twenty (61%) of the 33 reported that their dermatitis improved or resolved after they stopped using these wipes. Of ink-exposed employees working in August 2007, 59 (24%) reported they did not use hand wipes, and 36 (15%) had missing information. Of those reporting complete information on blue and green hand-wipe use, 81 (33%) used both, 55 (23%) used only blue, and 13 (5%) used only green hand wipes. Ink-exposed employees who used green hand wipes were half as likely to report dermatitis as those not using green hand wipes ($PR = 0.48$; $P = 0.02$). Those using blue hand wipes were more likely to report dermatitis, but this relationship was not statistically significant ($PR = 1.69$; $P = 0.15$). Employees in the ink-exposed group who used blue hand wipes exclusively were nearly three times as likely to report dermatitis in August 2007 ($PR = 2.93$; $P < 0.01$) compared to those who did not use hand wipes or used green hand wipes at least some of the time.

Use of Personal Protective Equipment and Hygiene Practices in August 2007 and March 2008

We looked at hygiene practices and PPE use for ink-exposed employees in August 2007 and March 2008 (Table 4). From August 2007 to March 2008, we found small increases in glove use, number of hours gloves were worn per day, and number of times gloves were changed per day. The practice of reusing gloves among glove wearers and the use of cotton and Tyvek® sleeves stayed about the same. The number of times moisturizing hand lotion was applied on a typical workday increased between August 2007 and March 2008. Of the 60 employees with dermatitis since hire at the company, 26 reported that their dermatitis had improved since the company management had made changes in gloves, soaps, and training programs; 20 reported their dermatitis did not improve; and 11 had improved before the workplace changes.

Table 4. Reported PPE use and hygiene practices among ink-exposed employees in August 2007 and March 2008

Reported PPE use and hygiene practices	August 2007 (N = 227–244)*	March 2008 (N = 247–254)*
	Average	Average
# times lotion applied over 24 hours	1.3	2.1
# times hands washed in 24 hours	6.7	6.7
# hours per day gloves used (among glove users)	4.9 (N = 126)	5.4 (N = 154)
# times per day gloves changed to new pair (among glove users)	4.1 (N = 122)	4.7 (N = 146)
	Number (%)	Number (%)
Green hand-wipe use	111 (49)	173 (70)
Used Tyvek sleeves	51 (22)	51 (20)
Used cotton sleeves	79 (34)	81 (33)
Used gloves at work	136 (56)	156 (61)
Reused gloves (among glove users)	74 (56) (N = 132)	78 (51) (N = 152)

*Range of denominators (i.e., the number of employees answering each question differed)

Hygiene and Personal Protective Equipment Practices Among Higher Risk Employees in March 2008

To see how well employees in the ink-exposed jobs with higher potential for exposure were using PPE and practicing good hygiene, we looked at the same hygiene and PPE practices as Table 4 for specific job groups. We combined kitters, inkmakers, coaters, solvent recovery, and utility operators into the wet ink mixture-exposed group and all slitters into the finished product dust-exposed group. Employees of both groups reported applying moisturizing lotion about twice a day. Of wet ink mixture-exposed employees, 94% reported using gloves during work, using gloves an average of about 6 hours per day, and changing to a clean pair of gloves over six times per day. Of dust-exposed employees, 34% reported using gloves during work, using gloves an average of 4 hours a day, and changing to a clean pair of gloves fewer than two times per day. Results are presented in Table D3, Appendix D.

Documentation of Workplace Changes Occurring Between August 2007 and March 2008

Between our August 2007 and March 2008 site visits, we sent company managers information on educational programs targeting skin health and methods to prevent dermatitis. We recommended additional employee education, evaluation of hand cleaners for sensitizing agents, use of moisturizing lotion, and elimination of the blue hand wipes while our lab evaluated the blue hand wipes, ink ingredients, and mixtures. We recommended use of the Ansell Barrier gloves as they are protective against all three major solvents that the company uses [Forsberg and Mansdorf 2007]. We also suggested the use of a better fitting glove over these gloves to improve dexterity.

During our second site visit in March 2008, we found that the company had implemented our initial recommendations and made a variety of modifications to work processes and practices. These changes are described below, grouped according to the occupational safety and health hierarchy of controls for controlling exposure:

Substitution

- Hyperdispersants, used in the manufacturing process in a fine dry powder form, were mentioned by employees as a concern because these materials got on their skin and clothes and were hard to clean up. We observed that the material became airborne when dispensed in the powder form. This material was found on the floors of the wax ink area and near the scale. During our second site visit, we found that the powder form had been replaced with a waxy solid kept in liquid phase by heating the material to around 95°F. Employees used a hand pump to dispense the required quantity of material as needed (Figure 1). Review of the MSDS of this material indicated that the melting point was 95°F, and hence would be nonvolatile at typical storage temperatures.



Figure 1. Hand pump used to dispense the waxy solid.

RESULTS

(CONTINUED)

- The company removed several of the original hand hygiene products and the blue hand wipes and introduced less irritating hand care products for employees. One of the original hand cleaners and the green hand wipes were still used.

Engineering Controls

- In the kitting room, the seal on the dust collector drum was modified to ensure complete enclosure.
- A ventilation survey of each area was being conducted to establish a baseline for performance of the system.
- Automated slitting machines were modified to handle a variety of different products. These machines have built-in dust collection systems that help capture dust generated during the slitting process.

Administrative Controls

- Cleaning of the supply air diffusers throughout Plant 1, the dust collector, and HVAC system serving the wax ink area had begun.
- Simple ventilation checks using a streamer attached to a pole were being done by employees to ensure the local exhaust hoods were functioning and drawing air inwards.
- A housekeeping checklist was generated for locations in the ink making area (i.e., kitting room, solvent ink area, and wax ink area). The checklist was to be completed at the end of each shift and made available to employees on the next shift. The supervisor conducted housekeeping audits before the start of each shift.
- Videos were developed showcasing the best practices when conducting specific tasks such as transferring materials to drums or totes, and weighing materials. The training videos were used to educate employees performing these operations (e.g., kitters and inkmakers). The videos were also being integrated into the training of new employees hired for these jobs or when employees are cross-trained.
- The final product was shrink-wrapped before sending to the distribution center.

RESULTS

(CONTINUED)

- The “Healthy Skin Program,” initiated in January 2008, explained the importance of good skin care and dermatitis prevention methods.

Personal Protective Equipment

- Between our August 2007 visit and March 2008 visit, the company discontinued use of the synthetic gloves and introduced the following gloves into the workplace: blue Stanzoil®/NK-22, yellow and black Kevlar® K1450, purple Trilites®/994, and blue and black Temp-Tec® NL-56 Neoprene. The Stanzoil/NK-22 and Temp-Tec NL-56 gloves are made of neoprene, and Trilites/994 is made from a blend of neoprene, nitrile, and natural rubber. We reviewed the manufacturers’ product specification sheets, which indicated that these gloves are designed for brief use when working with solvents such as MEK and toluene, but not for extended use.
- Employees had been provided with personal PPE totes (Figure 2). This ensures that they have a clean and safe location for storage of their PPE such as unused gloves and filtering-facepiece respirators.



Figure 2. Personal PPE tote.

RESULTS

(CONTINUED)

- Charts containing information on the appropriate glove for the jobs being conducted in a given area were posted throughout the plant (Figure 3). Employees were provided the appropriate type of gloves and educated on donning and doffing procedures.



Figure 3. Glove use chart posted at locations throughout the production areas.

Third Site Visit – September 2009

Skin Patch Testing

Skin patch testing was performed on 13 of the 40 eligible study participants (the “study group”). Of the remaining 27 who did not participate, 10 did not return phone messages, eight refused, eight were unable to be contacted (wrong or missing phone number, no answering machine/service), and one was no longer employed at the company. Seven of 230 comparison employees (the “comparison group”) were chosen by convenience and skin patch tested to only the workplace substances. Of the 13 with dermatitis history, nine had active skin irritation on their hands, wrists, and/or forearms; the remaining four did not have active skin problems. None of the comparison employees had active skin problems.

RESULTS

(CONTINUED)

Eight of the nine study participants with active skin rash were diagnosed with irritant contact dermatitis by the dermatologist contracted by NIOSH; five of the eight also had additional skin diagnoses (i.e., dyshidrotic dermatitis, lichen simplex chronicus, seborrheic dermatitis, and psoriasiform dermatitis). One of these nine study participants was unable to continue the testing because of skin discomfort and could not be evaluated. In addition, three of the 13 study participants had irregular skin lesions that were not related to work; we recommended further evaluation by their dermatologist.

No study group (13) or comparison group (7) participants had a skin reaction to the workplace-specific materials. Seven study participants had positive skin patch test reactions to one or more of the 50 common North American allergens, including:

- Thiuram mix and mixed dialkyl thiourea (additives used to make protective gloves)
- 4-tert-butylphenolformaldehyde resin (glue used in leather products)
- Potassium dichromate (chemical used in leather tanning and also an ingredient in cement)
- Nickel (most common allergen found in North America – used to make costume jewelry, belt buckles, metal wrist bands, etc.)
- Amerchol L101 (also known as lanolin, or sheep oil, used in many emollients)
- Bacitracin and neomycin sulfate (topical antibiotics)
- 4-phenylenediamine base (chemical used in hair dyes)
- Cinnamic aldehyde
- Balsam of Peru
- Fragrance mix (found in many personal hygiene products such as lotions, shampoos, shower gels)
- Disperse blue mix 106/124 (chemical used to dye poly-blend clothing)
- Composite mix (mixture of Tanacetum vulgare [ragweed], Arnica montana [arnica], Parthenolide [feverfew], Chamomilla romana [chamomile], and Achillea millefolium [yarrow])

RESULTS

(CONTINUED)

Employees with positive skin reactions were counseled to avoid allergens they reacted to in order to prevent allergic contact dermatitis. Employees with a dermatitis history (past or current) were advised to protect their skin from irritants by using appropriate gloves, cleaning the skin appropriately with gentle skin cleansers, and using skin moisturizing products frequently.

Study participants received a letter informing them of their individual skin patch test results, what the results mean, and, in the case of positive reactions, which chemicals, materials, or items they should avoid. They were also given information on ways to prevent or alleviate irritant contact dermatitis symptoms. Participants were asked to share this information with their personal healthcare providers.

Documentation of Workplace Changes Occurring Between September 2008 and September 2009

During our last site visit, we observed a few additional engineering controls that had been instituted based on recommendations we made in our interim letter. These changes were:

- In August 2007, the company was using an enclosed hood in the kitting room to weigh dry and powdery ink ingredients (Figure 4). As can be seen in Figure 4, ink ingredient materials spilled when transferred from larger 55-gallon containers to smaller drums. This was a possible source of employee exposure to sensitizing ink ingredients. We recommended installing semi-downdraft ventilation booths as described in an earlier NIOSH publication titled “Control of Dust from Powder Dye Handling Operations” [NIOSH 1997]. This was implemented as shown in Figure 5.

RESULTS

(CONTINUED)



Figure 4. Enclosed hood to weigh dry powders in the kitting room – August 2007.



Figure 5. Semiventilated downdraft booth installed in the kitting room – September 2009.

RESULTS

(CONTINUED)

- In August 2007, we recommended keeping the empty drums close to the LEV hood slots when transferring solids or liquids (Figure 6). The solvent weighing booth in the SMM center was modified by adding an additional slotted hood to increase exhaust ventilation (Figure 7). We did not evaluate the modified exhaust hood.



Figure 6. Ventilated solvent weighing booth in the SMM center – August 2007.



Figure 7. Modified solvent weight booth in the SMM center – September 2009.

Our evaluation found that airborne solvent exposures were low; however, production employees had the potential for chemicals to contact their skin. Because the predominant location of dermatitis in employees was the hands and fingers, the most likely cause of dermatitis is direct skin exposure to chemicals. Many workplace substances are skin irritants, and some are known skin sensitizers. We found some ink ingredients and one brand of hand wipes to be skin sensitizers by LLNA testing.

Health questionnaire data revealed that exposure to ink production work and a personal history of atopy were associated with work-related dermatitis. Exposure to inks is a well-known cause of dermatitis [Nethercott and Holness 1999]. The association between a history of atopy and work-related dermatitis is consistent with other studies that found individuals with a predisposition to developing allergies appear to have a greater likelihood of developing work-related dermatitis under certain conditions [Klas et al. 1996; Belsito 2005]. Production employees with dermatitis wore gloves more often and reused gloves less often than those without dermatitis. Because we collected information at one point in time (i.e., cross-sectional study), we cannot determine if those with dermatitis tend to wear gloves more often or if those who wear gloves more often tend to develop dermatitis. We did see a small increase in the use of gloves and skin moisturizer, and a small decrease in the prevalence of dermatitis among ink-exposed employees, from August 2007 to March 2008, suggesting that the employee training has had a positive impact.

The results from exposure assessments, laboratory analyses of workplace chemicals, record reviews, and questionnaire responses led us to assess whether employee dermatitis had an allergic component. Because no skin patch test participants reacted to any of the workplace substances on patch testing, and eight of nine were diagnosed with irritant contact dermatitis by the NIOSH-contracted dermatologist, we believe the majority of cases of dermatitis were from irritant causes. Irritants that employees are potentially exposed to at work include solvents, dusts, soaps, and/or hand wipes. In addition, several employees reported worse skin symptoms during winter, which is consistent with skin irritation from cold, dry weather. Information on contact dermatitis found in Appendix B may be helpful in recognizing, understanding, and preventing the disease.

DISCUSSION (CONTINUED)

No participants reacted to the workplace-specific ingredients that were skin sensitizers in mice studies. It is unclear if this was due to lack of sufficient numbers of study participants, the specific concentrations of the workplace ingredients used for patch testing, the mouse model not being a good surrogate for sensitization in humans, or other factors not yet understood. It is possible that some current or former employees with dermatitis who did not participate may have reacted to these allergens.

Despite the negative skin patch test results for workplace substances, the results of the LLNA animal study should not be disregarded. The LLNA has been supported in the international scientific literature as a good predictor of human skin sensitization [Kimber et al. 2001; EPA 2003]. The positive animal test results provide further reason for taking precautions in handling those substances because prolonged and/or heavy exposures could result in future skin sensitization in employees who are prone to allergies.

Since the company instituted improvements in ventilation, work practices, and housekeeping, and began its healthy skin training program, the occurrence of dermatitis among ink-exposed employees has decreased modestly, on the basis of questionnaire responses. In addition, the skin patch testing found that the dermatitis of most study participants has improved or resolved. It is important to note, however, that one fourth to one third of persons diagnosed with hand dermatitis will have chronic and persistent dermatitis symptoms, and this is not affected by whether the dermatitis is irritant or allergic [Jungbauer et al. 2004; Cvetkovski et al. 2006]. Studies on the prognosis of occupational contact dermatitis stress the importance of primary prevention. The company management has made important workplace changes to date. Following the additional recommendations in this report will further protect employees from potentially hazardous workplace exposures.

CONCLUSIONS

We found that production employees had the potential for skin exposure to chemicals, that some workplace chemicals were skin sensitizers, and that work-related dermatitis was associated with exposure to inks and to having an allergic predisposition. Skin patch testing found that no employees had skin allergy to workplace chemicals, and that all skin patch test participants with active dermatitis were diagnosed with irritant contact dermatitis. The company has made several improvements in the workplace to reduce ink exposures among employees and to provide appropriate PPE and training to employees. It appears that these improvements have contributed to the decrease in employee cases of dermatitis.

RECOMMENDATIONS

On the basis of our findings, we recommend the actions listed below to create a more healthful workplace. We encourage the company to continue to use the labor-management health and safety committee or working group to discuss the recommendations in this report and develop an action plan. Those involved in the work can best set priorities and assess the feasibility of our recommendations for the specific situation at the company. Our recommendations are based on the hierarchy of controls approach (refer to Appendix B: Occupational Exposure Limits and Health Effects). This approach groups actions by their likely effectiveness in reducing or removing hazards. In most cases, the preferred approach is to eliminate hazardous materials or processes and install engineering controls to reduce exposure or shield employees. Until such controls are in place, or if they are not effective or feasible, administrative measures and/or personal protective equipment may be needed.

Elimination and Substitution

Elimination or substitution of a toxic/hazardous process material is a highly effective means for reducing hazards. Incorporating this strategy into the design or development phase of a project, commonly referred to, as “prevention through design,” is most effective because it reduces the need for additional controls in the future.

- Investigate options for substituting nonsensitizing ink ingredients for those ingredients we found to be sensitizing.

Engineering Controls

Engineering controls reduce exposures to employees by removing the hazard from the process or placing a barrier between the hazard and the employee. Engineering controls are very effective at protecting employees without placing primary responsibility of implementation on the employee.

- Maintain the exhaust ventilation in the wax ink area and solvent ink area according to the manufacturer's recommendation. For drum filling operations, we recommend following the guidelines in "Industrial Ventilation – A Manual of Recommended Practice for Design," which requires a minimum duct velocity of 3500 fpm and an air flow rate of 100 cubic feet per minute per square foot of drum surface area [ACGIH 2007].

Administrative Controls

Administrative controls are management-dictated work practices and policies to reduce or prevent exposures to workplace hazards. The effectiveness of administrative changes in work practices for controlling workplace hazards is dependent on management commitment and employee acceptance. Regular monitoring and reinforcement are necessary to ensure that control policies and procedures are not circumvented in the name of convenience or production.

- Refer employees with recurrent or persistent skin symptoms in a timely manner to a dermatologist knowledgeable about occupational diseases and skin patch testing. Allergic contact dermatitis can be diagnosed definitively only with skin patch allergy testing. Skin patch testing allows these employees to know if they have skin allergy to certain workplace substances, as well as to other common skin allergens. The results can be used to counsel employees individually on what substances to avoid to prevent dermatitis recurrence. If employees are allergic to ink ingredients that they are unlikely to have contact with outside of work, it may be possible to avoid the ink ingredients by additional or more protective PPE and careful work practices. If these protective methods fail to relieve the dermatitis symptoms, then removal from exposure may be necessary. In some cases of allergic skin

RECOMMENDATIONS (CONTINUED)

disease, employees may have to be reassigned with retention of pay and employment status to areas where exposure is minimal or nonexistent.

- Provide annual healthy skin program training in the fall to help employees remember preventive measures they can take to protect their skin from drying out in winter. Employees with a history of allergic disease should be informed that they are at increased risk for developing contact dermatitis and need to take extra precautions to keep their skin healthy. See Appendix B, Occupational Exposure Limits and Health Effects, Contact Dermatitis, for tips on preventing dermatitis. A healthy skin barrier is one of the best protections against irritant and allergic contact dermatitis.

Personal Protective Equipment

PPE is the least effective means for controlling employee exposures. Proper use of PPE requires a comprehensive program and calls for a high level of employee involvement and commitment to be effective. The use of PPE requires the choice of the appropriate equipment to reduce the hazard and the development of supporting programs such as training, change-out schedules, and medical assessment if needed. PPE should not be relied upon as the sole method for limiting employee exposures. Rather, PPE should be used until engineering and administrative controls can be demonstrated to be effective in limiting exposures to acceptable levels.

- Provide the appropriate gloves for the nature of the exposure. Neoprene gloves are protective against MEK and toluene splashes and are recommended for short duration use. Chemical resistant gloves made of materials such as butyl rubber are protective against MEK for longer time periods. Gloves made of polyvinyl alcohol are protective against toluene, but may degrade if in direct contact with water or water-containing mixtures. These gloves are recommended for extended use and should be made available to the employees working in the solvent ink area.
- Provide gloves without sensitizing additives (i.e., thiurams and thioureas) to employees who continue to have hand dermatitis after using currently provided gloves.

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Volatile Organic Compounds

SKC Pocket Pump® air sampling pumps calibrated at a flow rate of 50 cubic centimeters per minute were used for sampling airborne VOCs. All air sampling pumps were calibrated before and after use. We collected 14 GA air samples to evaluate airborne VOC concentrations using both thermal TD tubes and CTs. TD tubes were used to screen for various VOCs, and CTs were used to quantify chemicals identified from the chromatogram. Five samples each of TD tubes and CTs were collected from the wax ink area, the solvent ink area, and CP1 of Plant 1. Two samples each of TD tubes and CTs were collected from CP2 and the parts washing room of Plant 2. The GA air samples were placed near an employee's work station or location. The TD tubes were analyzed by a GC-MS per NIOSH Method 2549 [NIOSH 2010]. The CTs were also analyzed by GC-MS per modified NIOSH Method 1501 [NIOSH 2010].

Local Lymph Node Assay

Bulk samples of Chemical Y, three ink coatings used to make Ink Ribbon A, and blue hand wipes were analyzed by LLNA to test their potential to cause skin sensitization.

The LLNA evaluates the ability of a substance to induce lymphocyte proliferation as a result of chemical sensitization in mice. LLNA has been accepted as a stand-alone alternative to the Guinea Pig Maximization Test and the Buehler Assay by regulatory authorities for assessing the allergic contact dermatitis potential of chemicals [Kimber et al. 2001; EPA 2003]. The basic principle underlying the LLNA is that sensitizers induce proliferation of lymphocytes in the lymph nodes, draining the site of chemical application. This proliferation is generally proportional to the dose applied, and provides a means of obtaining a quantitative measurement of sensitization potential.

Chemical Analysis of Chemical X

We evaluated Chemical X for residual monomer compounds. A 1 gram portion of the bulk material was weighed into a 10 mL headspace vial. Six separate aliquots of the sample were weighed for analysis, and each sample was capped and allowed to sit at ambient temperature for 16 hours to equilibrate before analysis. The headspace was analyzed by GC-flame ionization detector. A working standard was prepared by placing 5 microliter of Monomer A and 5 microliter of Monomer B into 10 mL of hexadecane. A six-point calibration curve was prepared from the working standard. Two assumptions were made during the analysis:

- Hexadecane solvent and the bulk material will yield equivalent amount of Monomer A and Monomer B in the headspace.
- Equilibrium was reached between headspace and the sample after 16 hours at ambient temperatures.

The values are reported as an estimate because of the nonstandard analytical procedure.

Statistical Analyses

Descriptive statistics including means, frequencies, and percents were provided to summarize the data from the questionnaires. To compare prevalence of dermatitis for those in the ink-exposed and ink-unexposed job categories, either the chi-square test or the Fisher's exact test was used, and the PR was reported. The PR is defined as the prevalence of dermatitis reported by ink-exposed employees divided by the prevalence of dermatitis reported by ink-unexposed employees. Therefore, a PR > 1 would indicate that an ink-exposed employee was more likely to report dermatitis. Similarly, we compared the prevalence of dermatitis for those using and not using certain types of hand wipes. To compare characteristics, behaviors, and PPE use among ink-exposed employees with and without dermatitis in August 2007, we used t-tests, chi-square tests, or Fishers exact tests, as appropriate. Results with *P* values ≤ 0.05 were considered statistically significant.

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APPENDIX B: OCCUPATIONAL EXPOSURE LIMITS AND HEALTH EFFECTS

In evaluating the hazards posed by workplace exposures, NIOSH investigators use both mandatory (legally enforceable) and recommended OELs for chemical, physical, and biological agents as a guide for making recommendations. OELs have been developed by Federal agencies and safety and health organizations to prevent the occurrence of adverse health effects from workplace exposures. Generally, OELs suggest levels of exposure that most employees may be exposed up to 10 hours per day, 40 hours per week for a working lifetime without experiencing adverse health effects. However, not all employees will be protected from adverse health effects even if their exposures are maintained below these levels. A small percentage may experience adverse health effects because of individual susceptibility, a preexisting medical condition, and/or a hypersensitivity (allergy). In addition, some hazardous substances may act in combination with other workplace exposures, the general environment, or with medications or personal habits of the employee to produce health effects even if the occupational exposures are controlled at the level set by the exposure limit. Also, some substances can be absorbed by direct contact with the skin and mucous membranes in addition to being inhaled, which contributes to the individual's overall exposure.

Most OELs are expressed as a TWA exposure. A TWA refers to the average exposure during a normal 8- to 10-hour workday. Some chemical substances and physical agents have recommended STEL or ceiling values where health effects are caused by exposures over a short period. Unless otherwise noted, the STEL is a 15-minute TWA exposure that should not be exceeded at any time during a workday, and the ceiling limit is an exposure that should not be exceeded at any time.

In the United States, OELs have been established by Federal agencies, professional organizations, state and local governments, and other entities. Some OELs are legally enforceable limits, while others are recommendations. The U.S. Department of Labor OSHA PELs (29 CFR 1910 [general industry]; 29 CFR 1926 [construction industry]; and 29 CFR 1917 [maritime industry]) are legal limits enforceable in workplaces covered under the Occupational Safety and Health Act. NIOSH RELs are recommendations based on a critical review of the scientific and technical information available on a given hazard and the adequacy of methods to identify and control the hazard. NIOSH RELs can be found in the *NIOSH Pocket Guide to Chemical Hazards* [NIOSH 2005]. NIOSH also recommends different types of risk management practices (e.g., engineering controls, safe work practices, employee education/training, personal protective equipment, and exposure and medical monitoring) to minimize the risk of exposure and adverse health effects from these hazards. Other OELs that are commonly used and cited in the United States include the TLVs recommended by ACGIH, a professional organization, and the WEELs recommended by the American Industrial Hygiene Association, another professional organization. The TLVs and WEELs are developed by committee members of these associations from a review of the published, peer-reviewed literature. They are not consensus standards. ACGIH TLVs are considered voluntary exposure guidelines for use by industrial hygienists and others trained in this discipline “to assist in the control of health hazards” [ACGIH 2010]. WEELs have been established for some chemicals “when no other legal or authoritative limits exist” [AIHA 2010].

Outside the United States, OELs have been established by various agencies and organizations and include both legal and recommended limits. Since 2006, the Berufsgenossenschaftliches Institut für Arbeitsschutz (German Institute for Occupational Safety and Health) has maintained a database of international

APPENDIX B: OCCUPATIONAL EXPOSURE LIMITS AND HEALTH EFFECTS (CONTINUED)

OELs from European Union member states, Canada (Québec), Japan, Switzerland, and the United States available at http://www.dguv.de/bgia/en/gestis/limit_values/index.jsp. The database contains international limits for over 1250 hazardous substances and is updated annually.

Employers should understand that not all hazardous chemicals have specific OSHA PELs, and for some agents the legally enforceable and recommended limits may not reflect current health-based information. However, an employer is still required by OSHA to protect its employees from hazards even in the absence of a specific OSHA PEL. OSHA requires an employer to furnish employees a place of employment free from recognized hazards that cause or are likely to cause death or serious physical harm [Occupational Safety and Health Act of 1970 (Public Law 91-596, sec. 5(a)(1))]. Thus, NIOSH investigators encourage employers to make use of other OELs when making risk assessment and risk management decisions to best protect the health of their employees. NIOSH investigators also encourage the use of the traditional hierarchy of controls approach to eliminate or minimize identified workplace hazards. This includes, in order of preference, the use of: (1) substitution or elimination of the hazardous agent, (2) engineering controls (e.g., local exhaust ventilation, process enclosure, dilution ventilation), (3) administrative controls (e.g., limiting time of exposure, employee training, work practice changes, medical surveillance), and (4) personal protective equipment (e.g., respiratory protection, gloves, eye protection, hearing protection). Control banding, a qualitative risk assessment and risk management tool, is a complementary approach to protecting employee health that focuses resources on exposure controls by describing how a risk needs to be managed. Information on control banding is available at <http://www.cdc.gov/niosh/topics/ctrlbanding/>. This approach can be applied in situations where OELs have not been established or can be used to supplement the OELs, when available.

Volatile Organic Compounds

VOCs are a large class of low molecular weight chemicals that are organic (i.e., containing carbon) and have a sufficiently high vapor pressure to allow some of the compounds to exist in the gaseous state at room temperature. The health effects associated with VOCs depend on the toxicity of the specific VOC, the level of exposure, and the duration of the exposure [EPA 2009]. Symptoms experienced from exposure to VOCs may include eye and respiratory tract irritation, headaches, dizziness, visual disorders, and memory impairment [NIOSH 2005]. The most common route of exposure to VOCs is through inhalation, but some solvents may contribute to systemic health effects through skin absorption [LaDou 2004; Klaassen 2008]. The rate of systemic elimination of solvents depends on how volatile and lipophilic the chemicals are. Some subpopulations may be more susceptible to health effects from solvents based on age, sex, and genetics [Klaassen 2008]. Heating, burning, or chemical reactions may cause materials to emit VOCs. The most common work practice leading to solvent-related dermatitis is washing the hands with a solvent. Because solvents tend to combine with lipids, they can dry out the skin. NIOSH and ACGIH have recommended OELs for many VOCs [NIOSH 2005; ACGIH 2010]. OSHA also has standards and/or PELs for many VOCs [29 CFR 1910.1000].

APPENDIX B: OCCUPATIONAL EXPOSURE LIMITS AND HEALTH EFFECTS (CONTINUED)

Contact Dermatitis

Contact dermatitis makes up 90% to 95% of all occupational skin diseases [Ingber and Merims 2004; Lushniak 2004]. Contact dermatitis, both irritant and allergic, is an inflammatory skin condition caused by skin contact with agents such as chemical irritants (irritant contact dermatitis) or allergens (allergic contact dermatitis). Irritant contact dermatitis is skin inflammation due to direct cell damage from a chemical or physical agent, while allergic contact dermatitis is a delayed immune reaction. Over 57,000 chemicals are reported to cause skin irritation, but only 3,700 chemicals are known skin allergens [Belsito 2005]. Usually only a small percentage of people are susceptible to skin allergens.

In contact dermatitis, the skin initially turns red and can develop bumps and small, oozing blisters. After several days, crusts and scales form. Stinging, burning, and itching often occur. With no further contact with the agent, the dermatitis usually disappears in 1 to 3 weeks. With chronic exposure, deep fissures, scaling, and darkening of the skin can occur. Exposed areas of the skin, such as hands and forearms, have the greatest contact with irritants or allergens and are most commonly affected. Over 80% of occupational contact dermatitis involves the hands. [Warshaw et al. 2003; Belsito 2005; Flyvholm et al. 2007]. If the agent gets on clothing, it can bring on dermatitis at areas of greatest contact, such as thighs, upper back, armpits, and feet. Dusts can produce dermatitis at areas where the dust accumulates and is held in contact with the skin, such as under the collar and belt line, at the tops of socks or shoes, and in skin creases, such as inside elbows and behind knees. Mists can produce dermatitis on the face and neck. Irritants and allergens can be transferred to distant areas of the body, such as the trunk or genitalia, by unwashed hands or from areas of accumulation, such as under rings or in finger webs. It is often impossible to clinically distinguish irritant contact from allergic contact dermatitis, as both can have a similar appearance and both can result in an acute, subacute, or chronic condition.

Irritant contact dermatitis can be caused by many factors. The most common skin irritant at work is wet work, defined as exposure of skin to liquid for more than 2 hours per day, use of occlusive gloves for more than 2 hours per day, or frequent hand washing [Chew and Maibach 2003; Slodownik et al. 2008]. Other common causes of irritant contact dermatitis include soaps and detergents, solvents, food products, cleaning agents, plastics and resins, petroleum products and lubricants, metals, and machine oils and coolants [Chew and Maibach 2003; Slodownik et al. 2008]. Frictional irritant contact dermatitis can be caused by low humidity, heat, paper, tools, metals, fabrics, plastics, fibrous glass and other particulate dusts, and cardboard, among other causes [Morris-Jones et al. 2002; McMullen and Gawkrödger 2006]. Causes of allergic contact dermatitis include plants (e.g., poison ivy), metallic salts, germicides, plastic resins, rubber additives, and fragrances [Mathias 1990]. In patients with occupational contact dermatitis who were skin-patch tested, the most common relevant allergens included thiuram mix, carba mix, bacitracin, methyldibromo glutaronitrile/phenoxyethanol, formaldehyde, glutaraldehyde, methylnmethacrylate, nickel, cobalt, and chromium [Warshaw et al. 2007, 2008].

Studies on the prognosis of occupational contact dermatitis stress the importance of primary prevention. One study found that 32% of 124 surveyed patients had severe hand dermatitis 5 years after they were initially diagnosed with irritant hand dermatitis. Severity was measured by self-reported frequency of

APPENDIX B: OCCUPATIONAL EXPOSURE LIMITS AND HEALTH EFFECTS (CONTINUED)

relapses, frequency of dermatologist visits, and use of topical corticosteroids [Jungbauer et al. 2004]. Another study found that 25% of 540 surveyed patients had persistently severe or aggravated symptoms 1 year after initial diagnosis of occupational hand dermatitis. Poor prognosis was associated with the presence of atopic dermatitis and being 25 years of age or older. Prognosis was not affected by whether the dermatitis was irritant or allergic. Those with severe occupational hand dermatitis at baseline had a higher risk of taking sick leave and job loss in the following year than those with mild cases. The study found no significant improvement in the disease after the change of job [Cvetkovski et al. 2006]. Widespread hand dermatitis on initial examination was found to be the greatest factor for a poor long-term prognosis in a third study [Meding et al. 2005]. In addition, many skin disorders, including contact dermatitis, have been shown to have a significant impact on quality of life [Kadyk et al. 2003; Cvetkovski et al. 2005; Fowler et al. 2006; Lan et al. 2008].

Prevention of Contact Dermatitis

Avoiding irritants and allergens, in addition to wet work, is the first step in dermatitis prevention. Liberal use of skin moisturizers helps to prevent contact dermatitis by maintaining a healthy skin barrier, and also helps to repair this barrier if it has been compromised [Chew and Maibach 2003].

The following list provides strategies in the prevention of occupational contact dermatitis:

- Identifying irritants and allergens
- Substituting chemicals that are less irritating or allergenic
- Establishing engineering controls to reduce exposure
- Emphasizing personal and occupational hygiene
- Establishing educational programs to increase awareness in the workplace
- Utilizing PPE, such as gloves and special clothing [NIOSH 1988]

Chemical changes in industrial materials have been beneficial. For example, the addition of ferrous sulfate to cement to reduce the hexavalent chromium content has been effective in reducing occupational allergic contact dermatitis in Europe. Protective gloves can reduce or eliminate skin exposure to hazardous substances if used correctly, but may actually cause or worsen hand dermatitis (by permeation and penetration) if selected poorly and used improperly (by contamination) [Foo et al. 2006]. The use of PPE may occlude irritants or allergens next to the skin, and PPE components may directly irritate the skin, so the correct use of PPE is at least as important as the correct selection of materials [Kwon et al. 2006]. Similarly, the excessive pursuit of personal hygiene in the workplace may actually lead to misuse of soaps and detergents and cause irritant contact dermatitis. Proper hand washing methods and adequate moisturizing are valuable in preventing contact dermatitis [Warshaw 2003]. The effectiveness of barrier creams is controversial because data on the protective nature of these topical products during actual

APPENDIX B: OCCUPATIONAL EXPOSURE LIMITS AND HEALTH EFFECTS (CONTINUED)

working conditions involving high-risk exposures are limited. Educating the workforce about skin care, exposures, and PPE use is an especially important measure in the prevention of occupational contact dermatitis [Schwanitz et al. 2003; Loffler et al. 2006; Weisshaar et al. 2006].

The following list provides tips on proper hand washing [Warshaw et al. 2003]:

- Avoid hot water; use lukewarm or cool water instead.
- Use mild cleansers without perfume, coloring, or antibacterial agents.
- Pat hands dry, especially between fingers.
- Apply skin moisturizer generously after hand washing and repeat throughout the day.
- Avoid rubbing, scrubbing, the use of washcloths, and the overuse of soap and water.

The following list provides tips for the workplace [Warshaw et al. 2003]:

- Remove rings before work.
- Wear protective gloves in cold weather and for dusty work.
- Wear tight-fitting leather gloves for frictional exposures.
- When performing “wet work,” wear cotton gloves under vinyl or other nonlatex gloves.
- Avoid immersing hands; use running water if possible.

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APPENDIX B: OCCUPATIONAL EXPOSURE LIMITS AND HEALTH EFFECTS (CONTINUED)

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APPENDIX C: SKIN PATCH TESTING

Eligibility

Eligible study participants were employees who completed the March 2008 health questionnaire and answered “yes” to either “Have you had dermatitis on your hands, wrists, or forearms (excluding fronts of elbows) in the past 4 weeks?” or “Did you have dermatitis on your hands, wrists, or forearms (excluding fronts of elbows) in the month before the NIOSH visit (August 7–9, 2007)?” Eligible comparison participants were employees who completed the March 2008 questionnaire and answered “no” to “Have you had dermatitis on your hands, wrists, or forearms (excluding fronts of elbows) since you began working at [this company]?”

What We Did

We patch tested participants with a history of dermatitis to the North American Standard Series of 50 common environmental allergens found outside the workplace, and some allergens found both in the workplace and outside of work (e.g., glove additives and soap ingredients). We also tested these participants and participants with no dermatitis history, to specific workplace substances that we found to be allergens in mice (i.e., Coating C, Chemical X, Chemical Y, polyvinyl butyral, and blue hand wipes) and to possible workplace allergens (i.e., Ink Ribbon A top side, Ink Ribbon A back side, and green hand wipes).

Components of Skin Patch Test

We used the Chemotechnique® North American Standard Series (NA-1000) patch test allergens to identify standard skin allergies. Chemotechnique Diagnostics® laboratory in Sweden performed feasibility studies and prepared skin patch test dilutions of nonstandard workplace substances identified by NIOSH as skin sensitizers in animal testing (LLNA).

Procedure

On the first appointment, the participants underwent a brief medical history and skin examination.

On the second appointment, the participants had patches with chambers filled with the suspect allergens applied to their backs.

On the third appointment, 48 hours after the patches were applied, the patches were removed and the first skin reaction readings were performed, followed by photos of the participants’ backs.

On the fourth appointment, (2–3 days after the patches were removed), the second skin reaction readings were performed, followed by photos of the participants’ backs.

APPENDIX C: SKIN PATCH TESTING

(CONTINUED)

On the final appointment (5 days after the patches were removed), the NIOSH physician and Dr. David Cohen, board certified in dermatology and occupational medicine, performed the final skin reaction readings, and interpreted the final skin patch test results using standard clinical practice methods used in dermatology clinics [Li et al. 2003]. These results were explained to each participant.

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Table D1. Charcoal tube air sampling results for VOCs (August 2007)

Work Location	Sampling Time (minutes)	Air Concentration (ppm)							
		MEK	Methyl isobutyl ketone	Xylene (meta and para)	Xylene (ortho)	Toluene	Methyl vinyl ketone	Trichloro ethylene	PGMEA
Solvent Ink Area	519	2.1	ND*	(0.026)†	ND	5.3	ND	ND	0.049
SMM Center	516	3.8	ND	(0.046)	ND	9.0	ND	ND	ND
Backing Room	334	3.8	ND	(0.049)	ND	3.8	ND	ND	0.32
Coating Area CP1 (OTC 3)	331	3.1	ND	ND	ND	3.2	ND	ND	(0.039)
Wax Ink Area	460	0.12	ND	0.11	(0.0041)	0.34	ND	ND	ND
Coating Area CP2 (MSC 2)	471	8.5	ND	ND	ND	10	ND	ND	0.55
Renzmann Room	274	7.7	ND	ND	ND	11	ND	ND	0.46
NIOSH REL		200	100	100	100	200		100	‡
OSHA PEL		200	50	100	100	100		25	
ACGIH TLV		200	50	100	100	20		50	
MDC\$		0.016	0.012	0.022	0.011	0.013		0.0089	0.013
MQC¶		0.054	0.039	0.074	0.037	0.043		0.029	0.043

*Not Detected, concentration is below the MDC

†Concentrations between the MDC and MQC are listed in the table but are contained within parentheses to acknowledge that there is more uncertainty surrounding concentrations below the MQC.

‡AIHA WHEEL for PGMEA is 50 ppm.

\$MDC = Minimum detectable concentration calculated by dividing the method limit of detection by the average sample volume collected (0.021 cubic meter of air).

¶MQC¶ = Minimum quantifiable concentration calculated by dividing the method limit of quantitation by the average sample volume collected (0.021 cubic meter of air).

APPENDIX D: TABLES

(CONTINUED)

Table D2. Potentially irritating and sensitizing ingredients in workplace hand-wipe products used in August 2007

Product	Potential sensitizing ingredients	Potential irritant ingredients	MSDS statement concerning skin hazard
Green Hand Wipes	Methyldibromo glutaronitrile [Warshaw et al. 2007]; methylparaben [Shaw et al. 2010]; propylene glycol [Warshaw et al. 2007]; D-limonene [Karlberg and Dooms-Goossens 1997]; DMDM Hydantoin (2,3-Imidazolidinedione) [Warshaw et al. 2007]	Terpenes and terpenoids (solvents) [Slowdownik et al. 2008]	Prolonged skin contact may cause mild irritation in sensitive individuals. Patch testing does not indicate a potential for sensitization or a potential for dermal irritation in humans. May possibly aggravate dermatitis, psoriasis, and other skin conditions. European Union classifications: irritant, flammable, irritating to eyes, may cause sensitization by skin contact.
Blue Hand Wipes	Hexahydro-1,3,5-tris (2-hydroxyethyl)-s-triazine [DeGroot et al. 2009]; D-limonene [Karlberg and Dooms-Goossens 1997]; propylene glycol [Warshaw et al. 2007]; fragrance [Warshaw et al. 2007]	Sodium lauryl sulfate [Slowdownik et al. 2008]; ethoxylated alcohols (C12-15 Pareth-7) [Bodin et al. 2000]	May cause mild eye or skin irritation, redness, burning, drying or cracking of skin. Pre-existing skin conditions such as dermatitis may be adversely affected by this and other oil and grease effective cleaners.

APPENDIX D: TABLES

(CONTINUED)

Table D3. Reported dermatitis, PPE use, and hygiene practices among two high risk groups: wet ink-exposed group and finished product dust-exposed group, March 2008

	Wet ink-exposed* (N = 68-72)‡ Number (%)	Finished product dust-exposed† (N = 42-44)‡ Number (%)
Dermatitis in August 2007	11 (16)	9 (21)
Dermatitis in March 2008	8 (11)	5 (11)
Average number of times lotion applied over 24 hours	1.8	2.0
Average number of times hands washed in 24 hours	6.2	6.9
Used green hand wipes	58 (82)	32 (73)
Used Tyvek sleeves	27 (38)	0 (0)
Used cotton sleeves	51 (72)	2 (5)
Used gloves during work	68 (94)	15 (34)
Of those who used gloves:		
Average number of hours per day gloves were used	5.9 N = 68	3.9 N = 14
Average number of times per day gloves changed to clean pair	6.4 N = 65	1.5 N = 12
Reused gloves	37 (55) N = 67	10 (67) N = 15

*Wet-exposed employees include kitters, inkmakers, coaters, solvent recovery, and utility operators

†Finished product dust-exposed employees include slitters.

‡Range of denominators (i.e., the number of employees answering each question differed)

APPENDIX D: TABLES

(CONTINUED)

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