RISK ASSESSMENT REPORT

TITLE:	**FORMALDEHYDE EXPOSURE RISK ASSESSMENT FOR**
AUTHOR(S):	
COMPLETED ON:	October 21, 2014
PRODUCT :	
CHEMICAL NAME (CAS #):	Formaldehyde (50-00-0)
REPORT #:	
TSCA Reportable:	No

1.0 INTRODUCTION

is a new product comprising several fiber types. In some of the fabrics, finish components are applied, and these finish components have the potential to release formaldehyde. A sample of containing both finish components was tested by Oeko-Tex and the reported formaldehyde concentration was 41 ppm. The product is not expected to exceed 75 ppm based on the Oeko-Tex formaldehyde test and this risk assessment is based on a maximum limit of 75 ppm. The Oeko-Tex formaldehyde method is similar to the Japanese Law test based on a one hour extraction in water at 40°C (GAO, 2010). It is designed to inform on potential for dermal exposure. The *Formaldehyde in Textiles* report by the Government Accountability Office is very informative regarding the potential for exposure from textile finishes and methodologies available to measure formaldehyde (GAO, 2010). The formaldehyde is typically released under high humidity conditions and has appreciable solubility in water. Sources of potential worker exposure are when sewing garments and wearing protective garments. Both inhalation and dermal exposure were assessed. Several regulations were considered in the assessment, including OSHA, REACH and PROP 65. Section 3 describes the regulations and the selection of health benchmarks.

2.0 EXPOSURE ASSESSMENT RESULTS

The results are presented in Table 1-3. The detailed calculations can be found in Sections 4-5.

Table 1: Worker Sewing Garments Risk Assessment Results

Scenario	Exposure Estimate	Applicable Health Benchmark	Risk Characterization Ratio (must be <1)
Inhalation Exposure	0.11 mg/m^3 (0.06 ppm)	0.12 mg/m^3	0.9
Dermal Exposure	2.0 mg/kg/day	240 mg/kg/day	0.008

Table 2: Worker Wearing Coveralls Risk Assessment Results

Scenario	Exposure Estimate	Applicable Health Benchmark	Risk Characterization Ratio (must be <1)
Inhalation Exposure	0.014 mg/m^3 (0.016 ppm)	0.12 mg/m^3	0.1
Dermal Exposure	2.1 mg/kg/day	240 mg/kg/day	0.009

Table 3: California PROP 65 Safe Harbor Assessment

Scenario	Exposure Estimate (μg/day)	NSRL (μg/day)	Risk Characterization Ratio (must be <1)
Worker Sewing Garments	430	40	11
Worker Wearing Garments	4	40	0.1

The risk characterization ratio (RCR) is the exposure divided by the health benchmark. The RCR must be below 1 in order to show safe use. The results indicate that there is minimal risk to workers since the RCR is below 1. In addition, based on the exposure assessment, no hazard communication for formaldehyde per OSHA regulation (1910.1048) is required for the product for these intended uses. These results are in agreement with Oeko-Tex Standard 100 certification that requires textiles intended for adults to contain less than 75 ppm formaldehyde based on the Oeko-Tex test to minimize formaldehyde local effects.

Based on this assessment and the defined scenario for California, there is a need to inform downstream users for PROP 65 if sewing garments in California is an intended use. There is no need to label the final sewn garments as the PROP 65 safe harbor was met for scenarios wearing the garments.

3.0 HEALTH BENCHMARKS

Several health benchmarks were evaluated to determine if any hazard declarations for formaldehyde are necessary. The most appropriate worker health benchmarks are the Derived No Effect Levels (DNELs) from the ECHA website (ECHA, 2014). The worker DNELs are listed in Table 3. The local effect DNELs are the lowest and drive the exposure scenario. However, there is human patch testing from the supplier (Huntsman Chemical) on fabric with a higher loading (80 g/l) than will be used on . Additionally, skin patch testing was conducted in guinea pigs with 3 fabrics, each containing the finish, but not the finish component . The human and guinea pig patch test results showed no positive skin reactions. Therefore for dermal exposure the systemic effect need only be assessed.

In addition there is an OSHA regulation (1910.1048) for workers and the action level is 0.5 ppm or 0.6 mg/m^3 for an 8 hr TWA which is very similar to the worker long term inhalation DNEL. Section 1910.1048(m)(1)(iv) also indicates that the requirements of the Hazard Communication Standard must also be met for materials capable of releasing formaldehyde into the air at concentrations reaching or exceeding 0.1 ppm (0.12 mg/m^3). Section 1910.1048(m)(1)(v) states "in making the determinations of anticipated levels of formaldehyde release, the employer may rely on objective data indicating the extent of potential formaldehyde release under reasonably foreseeable conditions of use". Since 0.12 mg/m^3 is the lowest health benchmark for the inhalation route it is used in the risk assessment.

Table 3. Formaldehyde Health Benchmarks used for Exposure Assessment

Population and Route of Exposure	Health Benchmarks	Used for Risk Assessment
DNEL Worker-long term inhalation (local effects)	0.5 mg/m^3	
DNEL Worker-long term inhalation (systemic effects)	9 mg/m^3	
DNEL Worker-long term dermal (local effects)	37 μg/cm^2	human patch data showing no local dermal effect
DNEL Worker-long term dermal (systemic effects)	240 mg/kg/day	X
OSHA regulation: Materials releasing formaldehyde to result in exposure (inhalation local effects)	0.12 mg/m^3 (0.1 ppm)	X
PROP 65 NSRL (inhalation)	40 μg/day	X

4.0 FORMALDEHYDE EXPOSURE ESTIMATION

The worst case scenarios that were used for the DMAC exposure assessment were the starting point for this assessment . The exposure assessment was refined based on feedback from the product steward for the extremely conservative parameters that had been used in the past. The 75 ppm formaldehyde Oeko-Tex test limit is suitable for estimating exposure for contact with a wet fabric (such as coated in sweat) based on 1 hr at 40^{o}C. However, it is not suitable for inhalation exposure since formaldehyde is released from the urea resins, and water (100% humidity) helps promote the hydrolysis to create the formaldehyde. A literature review found several articles examining releases of formaldehyde from coated fabrics. Roberts et al determined that there are 2 separate first order releases for fabrics with the urea resin coatings (Roberts, 1983). The first (smaller portion) being formaldehyde that is chemisorbed to the fabric which comes off quickly and then the second release (larger portion) that comes off slower which is the hydrolysis reaction. There is also monitoring data from textile plants indicating formaldehyde is detected in the room air. In a publication by Eero Priha of the Finland Regional Institute of Occupational Health, the author reviewed formaldehyde air monitoring data from textile production facilities, measured formaldehyde in textiles by both the Japanese Law test and the AATCC-112 method (20 hrs at 49^{o}C in a sealed with fabric sitting above water, water is analyzed) and compared to worker health statistics. The conclusion was that results less than 100 ppm by the Japanese Law test would result in formaldehyde air concentrations in textile factories of less than 0.5 mg/m^3 (even if they are performing steam creases which should release more formaldehyde due to the steam treatment of fabric). Measured data from three production facilities performing steam pressing, cutting and sewing with fabrics having 60-80 ppm formaldehyde from the wet extraction method (Japanese Law Test) was reported. There were 5 measurements and the range of formaldehyde concentration in the air was 0.05 – 0.11 mg/m^3 (Priha, 1995). Therefore based on this publication, when the Oeko-Tex results for formaldehyde are below 75 ppm, air concentrations in the workplace are not anticipated to exceed 0.11 mg/m^3.

Based on the literature review 100% release of the 75 ppm to air and dermal exposure for the day of sewing is not anticipated, as 100% humidity for the entire workday is not a reasonable assumption. An article by Kamath et al reports that the amounts of formaldehyde released in water are 100X higher than what is released in the gas phase and it is because the sorption equilibrium is in favor of water in the former case and in favor of the fiber in the latter (Kamath, 1983). For the purposes of this risk assessment, it was assumed that 100% of the 75 ppm is available for dermal exposure but only 25% is available for inhalation exposure. For the wearing of the fabric all day it will be assumed that 100% of the 75 ppm is available for dermal and 50% available for inhalation since a worker could be sweating part of the day. These assumptions remain conservative as they assume >100% release for each scenario. The basis weight for is 7.6 oz/yd^2 (260 g/m^2 or 0.026 g/cm^2). During discussions with the product steward it was identified that previously used conservative work station area volume of 10 m^3 was extremely small and that 25 m^3 was more reasonable (10ft x 10ft x 9 ft) considering all the material that is considered to be stored in the work area.

4.1. Industrial Use: Exposure Assessment for Sewing of Garments

A. <u>Inhalation Exposure</u>

The inhalation exposure was compared to the OSHA article release requirement of not exceeding a room concentration of 0.12 mg/m^3 since it was the most stringent. For sewing of garments the following assumptions were used:

Assume room size is small: 25 m^3 (each worker has their own workspace for worst case, so independent of the # of workers in room)
For industrial locations assume basic ventilation = 3/hr (conservative as 3-5 is typical)
Amount of processed per day = 1.4E+05 cm^2 (based on each worker sewing 8 garments per day)
Basis weight = 0.026 g/cm^2
Mass of processed per day = 1.4E+05 cm^2 x 0.026 g/cm^2 = 3640 g
Oeko-Tex Formaldehyde Result = 75 ppm (assume only 25% available for inhalation, 19 ppm)
Exposure Time and Emission duration = 8 hr for workers
CONSEXPO constant release rate exposure estimation for staple handling = 0.11 mg/m^3

Risk Characterization Ratio = 0.11/0.12 = 0.9

Inhalation Exposure Conclusion: The risk characterization ratio (RCR) is below 1 indicating safe use which is in agreement with the data reported by Priha (Priha, 1995). This indicates that the assumptions are reasonable. The CONSEXPO model inputs and outputs are included in the appendix. Table 1 contains the final risk assessment results for the garment sewing scenario.

B. Dermal Exposure

The formaldehyde available for exposure is based on the Oeko-Tex data and the basis weight of the fabric. It will be assumed 100% of the detected formaldehyde is available for transfer. There will not be 100% transfer of this available formaldehyde during the brief contact. Typical risk assessments have used 25% transfer (FT) for contacts that are less than 5 minutes Since the duration of extraction for the Oeko-Tex test is 1 hr the results are considered conservative for a 5 minute contact.

$$\text{Applied Dermal Daily Dose (mg/kg/day)} = \frac{Xa \times FT \times EV \times SA}{BW}$$

Basis weight = 0.026 g/cm^2
Oeko-Tex Formaldehyde Result = 75 ppm or 0.075 mg/g
Xa = 0.075 mg/g/hr x 0.026 g/cm^2 x <1 hr = 0.002 mg/cm^2/event
FT = 0.25 (transfer factor)
EV = 960 (contact events per day, based on every 30 sec for 8 hr/day)
SA = contact surface area = 265 cm^2 ($1/4^{th}$ the 95^{th} percentile for female adults from Table 7-2b, EFH)
Body Weight = 65 kg (REACH default)

$$\text{Applied Dermal Daily Dose} = \frac{0.002\ mg/cm^2/event \times 0.25 \times 960\ events/day \times 265\ cm^2}{65\ kg}$$
$$= 2.0\ mg/kg/day$$

Risk Characterization Ratio = 2.0/240 = 0.008

Dermal Exposure Conclusion: The RCR is below 1 indicating safe use. Since the exposure routes are based on different effects (systemic versus local) the two routes do not have to be combined but can be considered separately. These results are in agreement with Oeko-Tex certification that says for adults <75 ppm formaldehyde should be present in textiles based on

the Oeko-Tex test to minimize formaldehyde dermal local effects. Table 1 contains the final risk assessment results for the garment sewing scenario.

4.2. Service Life: Exposure Assessment for Wearing Protective Garments

A. Inhalation Exposure

The typical users of fabric will be industrial workers. To estimate a worst case inhalation exposure the following assumptions were made:

The worker is in a small industrial room = (25 m^3)
For industrial locations assume basic ventilation = 3/hr (conservative as 3-5 is typical)
Amount of material worn = 17250 cm^2 (average male body surface area)
Basis weight for coverall = 0.026 g/cm^2
Mass of worn = 17250 cm^2 x 0.026 g/cm^2 = 448 g
Oeko-Tex Formaldehyde Result = 75 ppm (assume only 25% available for inhalation, 19 ppm)
Exposure Time and Emission duration = 8 hr for workers
CONSEXPO instantaneous release rate exposure estimation for worker = 0.014 mg/m^3

Risk Characterization Ratio = 0.014/0.12 = 0.1

This is a conservative estimate because the exposure estimate is based on a new coverall and all the residual formaldehyde coming off on the first day of use. Workers are typically issued no more than 3-5 coveralls each year. Coveralls are expected to last 3-5 years, and workers are only issued enough covers to cover the laundering cycle time. Therefore the estimated inhalation exposure would not be a daily exposure and it does not account for any loss of formaldehyde during garment manufacturing. The RCR is well below 1 as expected and exposure is negligible for the inhalation route. The CONSEXPO model inputs and outputs are included in the appendix. Table 2 contains the final risk assessment results for the workers wearing coveralls scenario.

B. Dermal Exposure

The formaldehyde loading is estimated based on the Oeko-Tex data and the basis weight of the fabric. It will be assumed 100% of the detected formaldehyde is available for transfer. There will not be 100% transfer of this available formaldehyde since it is unlikely that the worker will be completely sweat soaked with all the fabric in contact with the skin all day. Typical risk assessments have used 50% transfer (FT) for contacts exceeding 5 minutes .
Since the Oeko-Tex test is for 1 hr and the exposure scenario if for 8 hrs the most conservative approach is to assume that the extraction increases with time in a linear fashion. Therefore the extraction results were multiplied by the exposure time

$$\text{Applied Dermal Daily Dose (mg/day)} = \frac{Xa \times FT \times EV \times SA}{BW}$$

Basis weight = 0.026 g/cm^2
Oeko-Tex Formaldehyde Result = 75 ppm or 0.075 mg/g
Xa = 0.075 mg/g/hr x 0.026 g/cm^2 x 8 hrs= 0.016 mg/cm^2/event
FT = 0.50 (transfer factor)
EV = 1 (contact events per day)
SA = contact surface area = 17250 cm^2
Body Weight = 65 kg (REACH default)

Applied Dermal Daily Dose = $\frac{0.016\ mg/cm^2/event \times 0.5 \times 1\ events/day \times 17250\ cm^2}{65\ kg}$

=2.1 mg/kg/day

Risk Characterization Ratio = 2.1/240 = 0.009

The RCR is below 1 indicating safe use. These results are in agreement with Oeko-Tex certification that says for adults <75 ppm formaldehyde should be present in textiles based on the Oeko-Tex test to minimize formaldehyde local effects. Table 2 contains the final risk assessment results of dermal exposure for the workers wearing coveralls scenario.

5.0 PROP 65 SAFE HARBOR ASSESSMENT

For PROP 65 the cancer risk assessment based on inhalation of formaldehyde includes the lifetime. The previously reported daily inhalation exposures are converted into lifetime exposures based on the conservative PROP 65 defaults. Table 3 contains the final safe harbor assessment results for workers.

A. Sewing of Garments

Lifetime exposure = $\frac{0.11\ mg/m^3 \times 10\ m^3/day \times 250\ days/yr \times 40\ yr\ working}{70\ yr \times 365\ days/yr}$

Lifetime exposure = 0.43 mg/day or 430 μg/day.
This exceeds the Safe Harbor NSRL of 40 μg/day. Therefore downstream users sewing garments in California would need to be warned of the PROP 65 hazard for formaldehyde.

B. Wearing of Garments

Lifetime exposure = $\frac{0.014\ mg/m^3 \times 10\ m^3/day \times 50\ days/yr \times 40\ yr\ working}{70\ yr \times 365\ days/yr}$

Where it was assumed a worker had 5 new garments/yr and that each garment released formaldehyde for 10 days since little formaldehyde is detectable after 3 laundry cycles (Reinhardt, 1987). This results in 50 days of exposure/yr.

Lifetime exposure = 0.01 mg/day or 10
μg/day which is below the NSRL

6.0 REFERENCES

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7.0 APPENDIX

1) Human Patch Testing

Epicutaneous test for the examination regarding skin compatibility of

DERMA TRONNIER
Institute for experimental Dermatology

Number of persons tested:	**50**
of which:	
allergy sufferers:	**13**
those with sensitive skin:	**15**
female:	**36**
male:	**14**
Age:	**18 - 65**

Test time: 48 - 72 hours
Test area: Back

CO twill, blue dry/wet
treated with: no positive skin reaction *)

5 g/l
30 g/l
9 g/l
80 g/l

Pad pick-up: 81 %
dry: 10 min. at 110°C
cure: 5 min. at 150°C

**) No irritative, doubtful skin reaction,* i.e. the material does not give rise to any pathological skin reaction and is skin-compatible.

2) ConsExpo Model results (worker sewing garments)

Inhalation model: Exposure to vapour : constant rate

weight fraction compound	0.0019	% (based on 25% of 75 ppm)
exposure duration	8	hour
room volume	25	m3
ventilation rate	3	1/hr
applied amount	3.64E3	gram
release duration	8	hour

Uptake model: Fraction

Output

Inhalation (point estimates)

inhalation mean event concentration :	0.11	mg/m3

3) ConsExpo Model results (worker wearing garments)

Inhalation model: Exposure to vapour : constant rate

weight fraction compound	0.0019	%
exposure duration	8	hour
room volume	25	m3
ventilation rate	3	1/hr
applied amount	448	gram
release duration	8	hour

Uptake model: Fraction

Output

Inhalation (point estimates)

inhalation mean event concentration :	0.014	mg/m3