RISK ASSESSMENT REPORT

TITLE:	**PROP 65 EXPOSURE RISK ASSESSMENT FOR** [redacted]
AUTHOR(S):	
COMPLETED ON:	January 30, 2014
PRODUCT :	
CHEMICAL NAME (CAS #):	Formaldehyde (50-00-0), Antimony Trioxide (1309-64-4)
REPORT #:	

1.0 INTRODUCTION

is a new product which is comprised of several fibers. The hazard assessment for the new product identified that the finish that is applied to the final product contains formaldehyde, a PROP 65 substance. The have already been assessed for PROP 65 substances but the . This report focuses on the final product with 1 wt% applied. Therefore there is 0.0004 wt% or 4 ppm of formaldehyde applied to the fabric. The potential for dermal absorption of the 2.8 wt% antimony trioxide, present in the that makes up 31.4% of the final fabric composition, was also assessed.

There is no production of fiber in California only the fabric form is used. can be made into garments and sold in California. is used to make protective garments. Sources of potential exposure are the sewing garments and the customer use of finished products. The route of exposure that is considered relevant for formaldehyde is inhalation. Formaldehyde boils at -19°C so it would not reside on the skin long enough for dermal exposure to be relevant. The fabric composition is shown below as well as the finish.

Product Composition

Modacrylic fiber Composition	Modacrylic Fiber	Final Fabric
Acrylonitrile-vinylidene chloride copolymer	91.00%	28.6%
Antimony trioxide	9.00%	2.83%

Finish Composition	%
Water	67%
Polymer solids (Generic chemical name)	33%
Formaldehyde	0.04%

2.0 EXPOSURE ASSESSMENT RESULTS

The results are tabulated in Table 1 and the detailed calculations can be found in Section 6.

Table 1: Formaldehyde Exposure Assessment Results

Scenario	Inhalation Lifetime Exposure Estimate (μg/day)	PROP 65 NSRL (μg/day)	Risk Characterization Ratio (must be <1)
Workers: Sewing Garments	34	40	0.8
Workers: Wearing Coveralls	20	40	0.5

Table 2: Antimony Trioxide Exposure Assessment Results

Scenario	Dermal Lifetime Exposure Estimate (μg/day)	Estimated PROP NSRL (μg/day)	Risk Characterization Ratio (must be <1)
Workers: Sewing Garments	500	9,800	0.05
Workers: wearing coveralls	50	9,800	0.005

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 the safe harbor condition was met and no labeling for PROP 65 is required. The exposure assessment is extremely conservative and assumes all the formaldehyde present off gasses the first day of use in its entirety. The workers sewing garments is also extremely conservative since each contact is much shorter than 24 hrs.

3.0 HEALTH BENCHMARKS

For formaldehyde the health benchmarks are well established and the most conservative health benchmark is set by California Prop 65 which is listed in Table 3. Formaldehyde is considered a carcinogen under Prop 65 and the health benchmark is the No Significant Risk Level (NSRL). The exposure is assessed over a lifetime for carcinogens. PROP 65 has not set a NSRL for antimony trioxide so a conservative estimate was based on the EU REACH general population dermal DNEL/1000: 169 mg/kg/day x 58 kg/1000 = 9.8 mg/day, where the PROP 65 body weight for women was used (58 kg). The DNEL is based on oral repeated dose toxicity.

Table 3. Health Benchmarks used for Exposure Assessment

Substance	Selected Health Benchmark (μg/day)	Source
Formaldehyde NSRL (μg/day)	40	California Prop 65
Antimony Trioxide	9,800	Based on REACH general population DNEL/1000 as a conservative NSRL estimate since no value is listed for PROP 65

4.0 FORMALDEHYDE EXPOSURE ESTIMATION

For workers this would be sewing garments and for consumers it would be wearing garments. Therefore the worst case scenarios that were used for exposure assessment previously referenced were used for this assessment .

The fiber is made with of various basis weights. The highest basis weight for is 8.6 oz/yd^2 (0.0292 g/cm^2). This basis weight was used as the representative basis weight for all scenarios as a conservative approach.

The exposure is assessed over the user's lifetime and reported as a lifetime average daily intake (LADI)

LADI = daily exposure x days used per year x years exposed/average lifetime in days

For the exposure assessments it was assumed workers or consumers were exposed 250 days per year for a 40 year period and that the average lifetime is 70 years or 25550 days. These conservative defaults are recommended for worker scenarios. Since the "consumers" of the final product are workers the 40 year was applied to that scenario also. If there is specific information regarding a use then these PROP 65 defaults can be modified.

4.1. Industrial Use: Inhalation Exposure Assessment for Manufacture of Garments

There is one company that does small piece work in their CA facility. This is not a routine operation, it is estimated that they have workers sewing garments less than 1 day per week (12 days/yr). Otherwise the same defaults were used as in the DMAC PROP 65 report

Assume room size is small: 10 m³ (each worker has their own little volume cube (3 m x 3 m x 1.12 m) for worst case so independent of the # of workers in room)
Assume there is just a minimal air exchange = 1/hr (conservative)
Amount of processed per day = 1.4E+05 cm² (based on each worker sewing 8 garments per day)
Basis weight = 0.029 g/cm² (supplied by business as 8.6 oz/sq yard)
Mass of processed per day = 1.4E+05 cm² x 0.029 g/cm² = 4060 g
Amount of formaldehyde applied to fabric = 4 ppm
Exposure Time and Emission duration = 8 hr for workers
CONSEXPO constant release rate exposure estimation for staple handling = 0.18 mg/m³
Exposure estimation for worker spending 8 hr/day = 10 m³/day x 0.18 mg/m³ = 1.8 mg/day

LADI = 1.8 mg/day x 12 days/yr x 40 yrs/25550 days = 0.034 mg/day or 34 μg/day
Risk Characterization Ratio = 34/40 = 0.8

The result is below the PROP 65 NSRL indicating safe harbor and no requirement for labeling under the PROP 65 regulation.

4.2. Service Life: Inhalation Exposure Assessment for Protective Garments

The typical users of fabric will be industrial workers. The same scenario defaults as used for DMAC PROP 65 report were used except since it is industrial workers a 12 hr

exposure time was selected as worst case. To estimate a worst case inhalation exposure the following assumptions were made:

The worker is in a small space (1.5 m x 1.5 m x 1.35 m = 3 m^3)
Assume there is just a minimal air exchange = 0.3/hr (very conservative)
Amount of material worn = 17250 cm^2 (see explanation in section 9.6)
Basis weight for coverall = 0.029 g/cm^2
Mass of worn = 17250 cm^2 x 0.029 g/cm^2 = 500 g
Amount of formaldehyde applied to fabric = 4 ppm
Exposure Time and Emission duration = 12 hr for workers
Volume breathed in 12-hr workday for worker = 15 m^3
CONSEXPO instantaneous release rate exposure estimation for worker = 0.18 mg/m^3
Exposure estimation for worker spending 8 hr/day = 15 m^3/day x 0.18 mg/m^3 = 2.7 mg/day

The exposure estimate is based on a new coverall and all the residual formaldehyde coming off in one day. Workers are typically issued coveralls for the year and 3-5 would be typical. For conservatism it is assumed 6 coveralls/year are used for every work year. The workers are only potentially exposed when wearing the new coverall (6 days/yr).

LADI = 2.7 mg/day x 6 days/yr x 40 yrs/25550 days = 0.02 mg/day or 20 μg/day
Risk Characterization Ratio = 20/40 = 0.5

The result is well below the PROP 65 NSRL indicating safe harbor and no requirement for labeling under the PROP 65 regulation.

5.0 ANTIMONY TRIOXIDE EXPOSURE ASSESSMENT

has performed in-vitro testing of modacrylic fibers to investigation the dermal absorption of antimony trioxide. Two studies have been performed for fabric with different antimony trioxide levels: Both studies were completed on July 13, 2005. Both studies indicate that about 0.01% of the antimony trioxide present is released into saline solution at 32°C over 24 hrs and of that amount only about 0.1% is dermally absorbed based on 24 hrs at 32°C.

A simple dermal exposure assessment can be performed based on the use information presented in Section 3 and assuming the amount antimony trioxide absorbed to be 0.001%. For this scenario it will be assumed that the amount absorbed could occur each time the garment is worn (250 days) over a lifetime since there is an excess of antimony trioxide present.

5.1. Industrial Use: Dermal Exposure Assessment for Manufacture of Garments

Amount of processed per day = 1.4E+05 cm^2 (based on each worker sewing 8 garments per day)
Basis weight = 0.029 g/cm^2 (supplied by business as 8.6 oz/sq yard)
Mass of processed per day = 1.4E+05 cm^2 x 0.029 g/cm^2 = 4060 g
Wt% Antimony Trioxide present in fabric = 2.83 or 28,300 μg/g
Antimony Trioxide dermal absorption = 0.01% x 0.1% = 0.001%

Amount of Antimony Trioxide absorbed per day = 4060g x 28,300 μg/g x 0.001%
=1150 μg/day or 1.2 mg/day

LADI = 1.2 mg/day x 250 days/yr x 40 yrs/25550 days = 0.5 mg/day or 500 μg/day
Risk Characterization Ratio = 0.5/12 = 0.04

This exposure assessment is very conservative since workers are only in contact with each piece of fabric for a short time and the amount available would be less than the 24 saline extraction data or the 24 hr in-vitro testing.

5.2. Service Life: Dermal Exposure Assessment for Protective Garments

Amount of material worn = 17250 cm^2 (see explanation in section 9.6)
Basis weight for coverall = 0.029 g/cm^2
Mass of worn = 17250 cm^2 x 0.029 g/cm^2 = 500 g
Wt% Antimony Trioxide present in fabric = 2.83 or 28,300 μg/g

Amount of Antimony Trioxide absorbed per day = 500g x 28,300 μg/g x 0.001%
=0.14 μg/day or 0.14 mg/day

LADI = 0.14 mg/day x 250 days/yr x 40 yrs/25550 days = 0.05 mg/day or 50 μg/day
Risk Characterization Ratio = 0.05/12 = 0.004

6.0 REFERENCES

OEHHA, 2013. Latest NSRLs and NSRLs were downloaded in Sept 2013 from website: http://oehha.ca.gov/prop65/pdf/090412Safeharbor.pdf