RISK ASSESSMENT REPORT

TITLE:	Screening Level Exposure and Risk Assessment of Formaldehyde in
AUTHOR(S):	
COMPLETED ON:	November 26, 2012
CAS # :	50-00-0
CHEMICAL NAMES:	Formaldehyde
REPORT #:	

Introduction:

Scope and Objective

The goals of this screening level exposure and risk assessment are to identify any hazards and potential associated risks, and then determine if any identified risks can be appropriately managed. The early PS&R consultations and assessments will help identify show stoppers early on and allow the technical team to make adjustments to or select an alternative candidate product. Changes in product candidates are much easier to accommodate early on rather than in the later development stages when things are more locked down. The goal is to assure that a successful product will be developed from this program in the shortest time possible.

The purpose of this document is to assess the potential for worker exposure to formaldehyde and potential associated risks when 1) fabricating , 2) processing at high temperature (100-150C) and 3) storing in warehouses prior to use.

Hazard Summary

The AEL for formaldehyde is 0.5 ppm (8 and 12-hour TWA). This is equivalent to 0.6 mg/m^3 8 and 12-hour TWA. The TLV establishes a ceiling for formaldehyde of 0.3 ppm. Formaldehyde is considered a known human carcinogen by the National Institute of Environmental Health Sciences (NIEHS). Exposure to formaldehyde can lead to nasopharyngeal cancer, a rare (http://ntp.niehs.nih.gov/?objectid=03C9AF75-E1BF-FF40-DBA9EC0928DF8B15 and http://ntp.niehs.nih.gov/ntp/roc/twelfth/addendum.pdf). Formaldehyde is also recognized as a human skin sensitizer.

Relevant Substance Information

Physical Chemical Properties

Component	CAS No	Mol Wt	Boiling Point	Vapor Pressure (mmHg)	Reference
Formaldehyde	50-00-0	30.03	-19.5°C	25 at 25°C	AEL, NC Dept of Labor,

Substance Composition

Component	CAS No	Matrix Percent Composition	Reference
Formaldehyde	50-00-0		email, MSDS

Water solubility: 100% soluble, IRIS

Conversion Factors: 1 ppm = 1.2 mg/m3

Exposure Assessment

The focus of these screening level exposure and risk assessments is inhalation exposure. Spray applications are anticipated to present the highest exposure during application and thereby encompass dip coatings. Absorption of formaldehyde through the skin appears to be negligible (OEHHA, 1992), and thus is assumed to pose a negligible risk. However, dermal sensitization (contact dermatitis) and irritation from formaldehyde exposure is clearly documented. No significant routes for oral exposure were identified. Workers are expected to practice general hand washing when leaving the work area to minimize hand to mouth transfer.

Inhalation Exposure Estimation

Worker inhalation exposure was estimated by determining the mass of formaldehyde that could be emitted 1) during application , 2) via offgasing during high temperature processing, and 3) via offgasing during storage.

1) Inhalation Exposure Estimate for

Spray applications are anticipated to result in the highest inhalation exposure potential versus dipped coating methods. The Advanced REACH Tool model (TNO, 2009) was used to estimate exposure during the surface spray applications. This model was developed by a European academic, governmental and contract lab consortium and is accepted for the European REACH regulation. Model inputs and outputs are attached in the appendix.

Exposure assumptions:
Room temperature with vapor pressure of 3000 Pa (25C), indoor application
Coating is sprayed downward onto a surface using no or low compressed air. Workers are in the near field, re: < $1m^3$ from the emission source during entire work day. Conservative assumption.
Emission controls: Local ventilation (e.g. fixed capturing hood) or containment resulting in 90% exposure reduction
Processing rate = max 15 m/min for 8 hr workday generating 7200 m, assuming 1 m width
Amount of processed in workday =
15 m/min x 1 m width x 8 hr/day x 60 min/hr = 7200 m^2
Maximum coating product weight basis = 5 gsm = 5 g/m^2 or 0.5 mg/cm^2
Resulting mass of coating processed in a workday = 36000 g (7200*5) resulting product applied per minute = 36000/480min/(1000L/mL) = 0.075 L/min assuming a density of 1 g/mL
Maximum composition of formaldehyde in coating is 0.08%
Room size (based on 65 ft x 65 ft x 25 ft room) = 105,625 ft3 = 3000 m^3
Air Exchange Rate: 3 per hour (typical for industrial facilities would be 3-5)

The model output and input are attached, and the inhalation exposure results were **0.051 mg/m^3, 8 hr TWA** using local ventilation to minimize exposure. Given formaldehyde is water soluble and applied in an aqueous solution the model was considered appropriate for use. Note that the model domain for gases is not well validated. The HQ is 0.1 (0.051 mg/m^3/0.6 mg/m^3) for workers present during spray coating.

2) Inhalation Exposure Estimate During Curing

After application and prior to use by downstream customers, is cured in a well-ventilated oven (100-150C) that removes any offgassing from the oven and sends it outside protecting workers from inhalation exposure. No significant release of formaldehyde to the atmosphere is anticipated during curing because formaldehyde reacts and forms the melamine-formaldehyde resin. In addition, the substance is degraded in air (half-life<17 hrs via indirect mechanisms) and is ready biodegradable (OECD, 2002). These properties indicate that the substance will degrade in the environment. Further information on release of formaldehyde from by headspace analysis immediately after curing and after storage would facilitate refinement of worker exposure estimates.

3) Inhalation Exposure Estimate for Industrial Storage

are anticipated to be stored after curing for up to 30 days prior to shipping to downstream customers. The ConsExpo 4.1 model (RIVM, 2010) was used to estimate high end exposures from coated surfaces into a room during storage. Given formaldehyde forms cross linkages with-in the melamine-formaldehyde resins migration out of the coatings will be reduced, however, no data is currently available to refine this release and subsequent exposure estimate. Exposure estimates could additionally be further refined by applying known local ventilation practices.

Exposure assumptions:
Room temperature, indoor storage
Workers are present 8 hrs/day.
are stored for 30 days prior to shipping to downstream customers. Assuming 36 kg processed per day for 30 days, the total accumulated product is 1080 kg coating or 36 kg per day.
are assumed to be cured prior to storage. The total mass of formaldehyde present in is estimated to be 0.008%, assuming 90% reacts or is removed during curing.
The warehouse room size = 500 m^3
Air Exchange Rate: 3 per hour (typical for industrial facilities would be 3-5)
Instantaneous release is assumed.

The model output and input are attached. Inhalation exposure results for 7200 m2 (one day of processing) placed in storage were **0.24 mg/m^3, 8 hr TWA,** assuming all the formaldehyde is all instantaneously released the day it is placed in storage. This is a conservative exposure estimate given are stored in rolls and migration out is limited to the outer layers and edges of the rolls. After 30 days of processing, assuming formaldehyde accumulates as additional is placed in storage, the exposure estimate is **7.2 mg/m3, 8 hr TWA**.

The HQ is 0.4 (0.24 mg/m^3/0.6 mg/m^3) for workers present in a storage area with one day of processed . Accumulated material in the storage area for a month results in exposures exceeding a HQ of 1.

Risk Characterization

Spray coating results in a HQ of 0.1 for workers present and is not anticipated to result in adverse health effects to workers when local ventilation is present for spray coating equipment. Further refinement of this assessment is possible with additional information such as the spray application (low or high pressure), duration workers are present at the spray source and background ventilation.

Curing Industrial Coated after application and prior to use by downstream customers in a well-ventilated oven (100-150C) is anticipated to remove any offgassing from the oven and sends it outside protecting workers from inhalation exposure. Further information on release of formaldehyde from immediately after curing and after storage would facilitate refinement of worker exposure estimates.

Industrial Storage of results in a HQ of 0.4 for workers present in a storage area with one day of processed and is not anticipated to result in adverse health effects. Accumulated material in the storage area for a month results in exposures exceeding a HQ of 1.

Gathering realistic exposure information would allow for refinement of this assessment. Given this is a storage area, workers are not likely to be present 8 hrs a day resulting in lower exposure. In addition, migration is not likely instantaneous and existing data, not available at the time of this exposure assessment, shows residual formaldehyde less than the assumed 10% in . Future work will gather the information needed and be used to refine the exposure and risk assessment.

References

TNO, 2009. Development of a mechanistic model for the Advaned Reach Tool (ART). ReportV9009. Version 1.0. Last accessed. November 2, 2012 http://www.advancedreachtool.com/

OECD, 2002. Formaldehyde OECD SIDS Initial Assessment Report. March.

OEHHA, 1992. Initial statement of reasons for rulemaking. Final report on the identification of formaldehyde as a toxic air contaminant. Last accessed. November 2, 2012 http://oehha.ca.gov/air/toxic_contaminants/html/Formaldehyde.htm.

RIVM, 2010. ConsExpo 4.1 Model. Last accessed. November 2, 2012. http://www.rivm.nl/en/Library/Scientific/Models/Download_page_for_ConsExpo_software

ConsExpo 4.1 report

Report date: 10/22/2012

Product

Compound

Compound name :	50-00-0	
CAS number :		
molecular weight	30	g/mol
vapour pressure	23	mmHg
KOW		linear

General Exposure Data

exposure frequency	1	1/day
body weight	65	kilogram

Inhalation model: Exposure to vapour : instantaneous release

weight fraction compound	8E-5	fraction
exposure duration	480	minute
room volume	500	m3
ventilation rate	3	1/hr
applied amount	36	kilogram

Uptake model: Fraction

uptake fraction	1	fraction
inhalation rate	34.7	m3/day

Dermal model: Direct dermal contact with product : instant application

weight fraction compound	8E-5	fraction
exposed area	108	cm2
applied amount	0.1	gram

Uptake model: fraction

uptake fraction	0.5	fraction

Output

Inhalation (point estimates)

inhalation mean event concentration :	0.24	mg/m3

ConsExpo 4.1 report

Report date: 10/22/2012

Product

Compound

Compound name :	50-00-0	
CAS number :		
molecular weight	30	g/mol
vapour pressure	23	mmHg
KOW		linear

General Exposure Data

exposure frequency	1	1/day
body weight	65	kilogram

Inhalation model: Exposure to vapour : instantaneous release

weight fraction compound	8E-5	fraction
exposure duration	480	minute
room volume	500	m3
ventilation rate	3	1/hr
applied amount	1.08E3	kilogram

Uptake model: Fraction

uptake fraction	1	fraction
inhalation rate	34.7	m3/day

Dermal model: Direct dermal contact with product : instant application

weight fraction compound	8E-5	fraction
exposed area	108	cm2
applied amount	0.1	gram

Uptake model: fraction

uptake fraction	0.5	fraction

Output

Inhalation (point estimates)

inhalation mean event concentration :	7.2	mg/m3

ART REPORT – – 05-Nov-12

spray coating

Chemical details	
Chemical	50-00-0
CAS No.	(unknown)

Scenario details	
Number of activities	1
Total duration (mins)	480
Nonexposure period (mins)	0

Metadata	
ART version	1.00
Creator	
Date created	20-Sep-12
Date last edited	05-Nov-12

Details for Activity spray coating

Emission sources: Near field ✓ Duration (mins): 480

Far field

Near-field exposure

Operational Conditions

Substance emission potential	
Substance product type	Liquids
Process temperature	Room temperature
Vapour pressure	3000 Pa

Activity emission potential	
Activity class	Surface spraying of liquids
Situation	Low application rate (0.03 – 0.3 l/minute)
Spray direction	Only downward
Spray technique	Spraying with no or low compressed air use

Surface contamination	
Process fully enclosed?	No
Effective housekeeping practices in place?	Yes

Dispersion	
Work area	Indoors
Room size	3000 m^3

Risk Management Measures

Localised controls	
Primary	Fixed capturing hood (90 % reduction)
Secondary	No localized controls (0 % reduction)

Dispersion	
Ventilation rate	3 air changes per hour (ACH)

Predicted exposure levels

ART v1 predicts air concentrations in a worker's personal breathing zone outside of any Respiratory Protection Equipment (RPE). The use of RPE must be considered separately.

Mechanistic model results

The predicted 75th percentile full-shift exposure is 0.051 mg/m³.

The inter-quartile confidence interval is 0.026 mg/m³ to 0.1 mg/m³.

Improved Self Discharge Performance in

Screening Level Risk Assessment

November 2, 2012

Draft

Goals

Identify any hazards and potential associated risks early in project

Allow team to optimize or select an alternative candidate product

Ensure successful product development in shortest time possible

Physical Chemical Properties

Component, CAS No	Mol Wt	Boiling Point	Vapor Pressure (mmHg)	Reference
Formaldehyde, 50-00-0	30.03	-19.5°C	25 at 25°C	AEL, NC Dept of Labor

Substance Composition

Component, CAS No	Matrix Percent Composition	Reference
Formaldehyde, 50-00-0		email, MSDS

Water solubility: 100% soluble, IRIS

Conversion Factors: 1 ppm = 1.2 mg/m3

Formaldehyde AEL: 0.5 ppm (8 and 12 h TWA), 0.6 mg/m^3

Screening level exposure and risk assessment

Assess the potential for worker exposure to formaldehyde and potential associated risks when

1) fabricating via dip, spray or gavure coating in-line manufacturing processes

2) processing (curing) at high temperature (100-150C)

3) storing in warehouses prior to use

Routes of Exposure

Inhalation:

Focus on inhalation exposure given spray applications are anticipated to present the highest exposure during application and thereby encompass dip coatings.

Dermal:

Absorption of formaldehyde through the skin appears to be negligible (OEHHA, 1992), and thus is assumed to pose a negligible risk. However, dermal sensitization (contact dermatitis) and irritation from formaldehyde exposure is clearly documented.

Oral:

No significant routes for oral exposure were identified. Workers are expected to practice general hand washing when leaving the work area to minimize hand to mouth transfer.

Industrial Coating of

Worker exposure estimate using ART1.0 Model

Room temperature, indoor application

Downward surface spray using no or low compressed air. Workers near field, re: < 1m^3 from the emission source for 8 hrs

Emission controls: Local ventilation (e.g. fixed capturing hood) or containment resulting in 90% exposure reduction

Amount of processed in 8 hr workday: 7200 m^2

Maximum coating product weight basis = 5 gsm = 5 g/m^2 = 0.5 mg/cm^2

Coating mass processed in 8 hrs = 36000 g (7200*5) resulting product applied per minute = 36000/480min/(1000L/mL) = 0.075 L/min

Maximum formaldehyde composition in coating = 0.08%

Room size (based on 65 ft x 65 ft x 25 ft room) = 105,625 ft3 = 3000 m^3

Air Exchange Rate: 3 per hour (typical for industrial facilities would be 3-5)

Inhalation exposure estimate = 0.051 mg/m^3, 8 hr TWA

Curing Industrial Coated

Worker exposure estimate

After application and prior to use by downstream customers,
is cured in a well-ventilated oven (100-150C) that removes any offgassing from the oven (sent outside) protecting workers from inhalation exposure.

No significant release of formaldehyde to the atmosphere is anticipated during curing because formaldehyde reacts and forms the melamine-formaldehyde resin.

Further information on release of formaldehyde from
by headspace analysis immediately after curing and after storage would facilitate refinement of worker exposure estimates.

Storage of

Worker exposure estimate using ConsExpo4.1 Model

stored for up to 30 days

Given formaldehyde forms cross linkages with-in the melamine-formaldehyde resins migration out of the coatings will be reduced, however, no data is currently available to refine this release and subsequent exposure estimate. Exposure estimates could additionally be further refined by applying known local ventilation practices.

Room temperature, indoor storage. Workers are present 8 hrs/day.

Assuming 36 kg/day * 30 days total accumulated product is 1080 kg coating. Rolls of are assumed to be cured prior to storage. The total mass of formaldehyde present in is estimated to be 0.008%, assuming 90% reacts or is removed during curing.

Warehouse size = 500 m^3 Air Exchange Rate: 3 per hour, Instantaneous release

Inhalation exposure estimate:

- **1 day of processing 0.24 mg/m^3, 8 hr TWA**
- **30 days accumulated processing 7.2 mg/m^3, 8 hr TWA**

Consexpo evaporation model

The air concentration of the compound at time *t* for the instantaneous release mode is calculated as follows:

$$C_{air} = \frac{A_o \times wf}{V} \times e^{-qt}$$

where:

C_{air}	: concentration of compound in the room air	[kg/m3]
A_o	: product amount	[kg]
wf	: weight fraction of the compound in the total product	[fraction]
V	: room volume	[m3]
q	: ventilation rate of the room (number of air changes per time unit)	[1/s]
t	: exposure duration	[s]