Exposure Risk Assessment: Production to Pressroom UV Misting Exposure Study

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“In the current regulatory climate, the focus on energy-curable materials needs to be tempered with an understanding of real exposures based on actual conditions of use...The focus, therefore, needs to center around managing exposures, wherever possible, rather than believing that removing substances eliminates risk.”

--Lisa Fine
Past President RADTECH
2018 Editorial UV+EB Technology
The Story: Finding a Path on an Ever-Changing Landscape

- Globally Harmonized System of Classification and Labeling of Chemical by the UN (GHS)
- REACH regulations adopted by the European Union
- TSCA Section 5(a)
  - Significant New Use Rules—requires notice to the EPA before chemical substances and mixtures are used in new ways that might create concerns.
  - Application process and inclusion could hinder innovation.

https://www.unece.org/trans/danger/publi/ghs/ghs_welcome_e.html
https://echa.europa.eu/regulations/reach/understanding-reach
The Story: Finding a Path on an Ever-Changing Landscape

- **California Proposition 65—Prop 65**
  - Has grown to over 900 chemicals
  - **Acetaminophen**—Hearings for inclusion
  - “Inclusion of a chemical on the Prop 65 list does not ban it…rather the law requires a clear and reasonable warning”

- **Global Markets**
  - Supply Chain
  - Country of Origin
  - Synthetic and Manufacturing Processes

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**California Proposition 65 Warning**

**WARNING:** This product contains chemicals known to the State of California to cause cancer, and birth defects or other reproductive harm. For more information: [www.P65Warnings.ca.gov](https://www.P65Warnings.ca.gov)

Ubiquitous Signage

[https://oehha.ca.gov/proposition-65](https://oehha.ca.gov/proposition-65)
The Story: Finding a Path on an Ever-Changing Landscape

- Changes in Systems
  - Led to *reevaluating* the *hazard classifications* of common chemicals
  - Resulted in ink manufacturers needing to *reevaluate* ink formulations
  - Created a need to *revisit safety* and *exposure* of employees, customers, and consumers.
EuPIA Exclusion Policy

European Printing Ink Association

- Policy whereby member companies agree to avoid raw materials if one or more components are listed in Group A and B of the exclusion criteria the exclusion criteria.

- Criteria is defined by the hazard statement/code in the CLP*.

<table>
<thead>
<tr>
<th>Group A</th>
<th>Group B</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute Toxicity Cat. 1&amp;2 [H300, H310, H330]</td>
<td>Acute Toxicity Cat. 3 (oral, dermal) [H301, H311]</td>
</tr>
<tr>
<td>Acute Toxicity Cat. 3 (inhalation) [H331]</td>
<td></td>
</tr>
<tr>
<td>Carcinogen or Mutagen Cat. 1A &amp; 1B [H350, H340]</td>
<td>Toxic to Reproduction Cat. 1A &amp; 1B [H360] (if threshold exists)</td>
</tr>
<tr>
<td>Toxic to Reproduction Cat. 1A &amp;1B [H360]</td>
<td>STOT Single Exposure Cat. 1 [H370]</td>
</tr>
<tr>
<td>STOT Single Exposure Cat. 1 [H370]</td>
<td>STOT Repeated Exposure Cat. [H372]</td>
</tr>
</tbody>
</table>

*Classification, Labeling, and Packaging of substances and mixtures EC 1272/2008

Changes in the classification and labeling of mixtures resulted in substances now having GHS pictograms.
- It is **foreseeable** that lists will change and evolve

- Think Globally

K Kazarian, Packaging Strategies, 2019
It is *foreseeable* that lists will change and evolve

Think Globally

K Kazarian, Packaging Strategies, 2019
Every problem has in it the seeds of its own solution

- How do we, as manufacturers, respond to an **Ever-Changing Landscape**?
- **Hazard Based Solution**
  - Accept a Hazard, change formula accordingly.
  - **PI379 replacement**
- **Risk Based Solution**
  - Assess the Risk by determining the **Actual Exposure**

https://echa.europa.eu/substance-information/-/substanceinfo/100.100.600
https://echa.europa.eu/registry-of-svhc-intentions/-/dislist/details/0b0236e183ae60b7
The Risk Based Solution: Finding the seed of the solution within the problem.

- EuPIA Exclusion Policy also states that if there is no suitable substitution exemptions can be approved for hazards in Group A.

- For hazards in Group B, individual member companies can conduct a risk assessment to demonstrate that safe use is assured.
Risk Assessment

Reclassification of Photoinitator 369 (PI369)
2-Benzyl-2-dimethylamino-1-(4-morpholinophenyl)-butanone-1
PI369 reclassification by REACH Committee of the European Chemicals Agency (ECHA)

Category 1B: H360D; may damage the unborn child

EuPIA Group B of the Exclusion Criteria*

*At the time of the study and writing the paper; Currently SVHC by ECHA

SVHC: Substance of Very High Concern
Most people spend more time and energy going around problems than in trying to solve them. ~Henry Ford

- How do we
  1) Measure PI369?
  2) Quantify PI369?
  3) Relate quantity to exposure level?

The No Observed Adverse Effect Level (NOAEL) in EFSA is **100mg/kg body weight**

*Pregnant female (applying the average weight of 68 kg, France)*
The Study Design

- **Arm 1**: Determine the exposure by monitoring the air quality in a production facility.
- **Arm 2**: Proof of concept study: Simulate a pressroom using an inkometer. Measure air quality.
- **Arm 3**: Measure air quality in a press trial. Run UV inks with PI369.
For our study, pumps were not worn to mimic "worst case scenario"

We asked: Where is the worst cumulative 8-hour exposure?

Constant air flow pumped through the filter for collection

Active Air Filter—Zefon International 37 mm 3pc, cassettes; 1 um glass fiber filter
Pumps were placed at fixed locations around facility:

- “Area 1”—area away from PI weigh up and mixer—Expected to be low exposure/control
- Flexo Mixer
- PI Kettle

Continual production over trial, this is not considered a “normal production day”.

PI369 was extracted from the filters and analyzed by LC/MS/MS
HPLC-MS/MS

Internal and external standards were utilized.

Parent Ion
Positively Charged
PI369: m/z = 367

Daughter Ions
367 → 190, 176
“transition”

Arm 1 Results

For the Worst-Case Sample:
- 64 microgram (ug) PI369 / 8 hour = 0.064 mg / 8 hour

What does this tell us?
- Proof of concept for method
- Amount detected near PI Kettle and mixer is below the NOAEL

NOAEL in EFSA is 100mg/kg body weight
⇒ 6800 mg / day for a 68 kg female
Arm 1 Results—Perspective

- Worst case sample: 64 microgram/8 hour
- Best case sample: 1 microgram (ug) /8 hour

0.001 g = 1 mg = 100 ug

6 g = 6000 mg
Arm 1 Results

- Worst case sample: 64 microgram/8 hour
- Best case sample: 1 microgram (ug) /8 hour

0.001 g  
=  
1 mg  
=  
100 ug

1 sugar cube = 4 g
1.5 sugar cubes = 6 g

6 g  
=  
6000 mg
Arm 2

Simulated Press Trial

• Proof of concept study by simulating a pressroom environment using an inkometer

Distance to filter 3: 15 ft; End of table

- Filters
  - On shelf inline with the rollers
  - Distance 9.5 in

- Inkometer rollers
  - Distance from center of rubber roller: 2 ft

- Filters
  - Front: 2 ft
  - Back: 2 ft

- Filter
  - 12 in
Arm 2

Simulated Press Trial

Distance to filter 3: 15 ft; End of table

Front: from center of rubber roller 2 ft

Back: from center of rubber roller 2 ft

Inkometer rollers

15 feet away
Arm 2
Simulated Press Trial

Distance to filter 3: 15 ft; End of table
Front: from center of rubber roller 2 ft
On shelf inline with the rollers 9.5 in
Inkometer rollers Back: from center of rubber roller 2 ft

2 feet away
Simulated Press Trial

Distance to filter 3: 15 ft; End of table
Front: from center of rubber roller 2 ft
Back: from center of rubber roller 2 ft
Inkometer rollers

Filter
On shelf inline with the rollers
9.5 in

Filter

Filter

Filters

Extraction Vials

Filters

Extraction Vials
### Arm 2 Results

- 1200 rpm roller speed
- 1-hour testing with ink replenished every 5 or 15 minutes

<table>
<thead>
<tr>
<th>Trial</th>
<th>Ink Changed Every 5 minutes</th>
<th>Ink Changed every 15 minutes</th>
<th>PI369 microgram / 8-hour day / 68 kg bdw Worst Case</th>
</tr>
</thead>
<tbody>
<tr>
<td>End of Table</td>
<td>Microgram PI369 collected / filter 1-hour trial (8-hour trial)</td>
<td>0.021 (0.168)</td>
<td>0.014 (0.112)</td>
</tr>
<tr>
<td>Front, 24 inches from the middle of the roller</td>
<td>0.081 (0.648)</td>
<td>0.029 (0.232)</td>
<td>0.0096</td>
</tr>
<tr>
<td>Back, 24 inches from the middle of the roller</td>
<td>3.391 (27.128)</td>
<td>6.262 (50.096)</td>
<td>0.7368</td>
</tr>
</tbody>
</table>

\[ \text{NOAEL} = 100 \text{mg/kg bdw} \Rightarrow 6800 \text{ mg / 8-hour day} = 6,800,000 \text{ microgram / 8-hour day} \]

\[ 0.000011\% \text{ of NOAEL} \]
Pressroom Trial

• Pressroom Air quality trial
• Run UV inks with PI369

Printing Press Schematic

• Number represents filter and location
• Filters were positioned at various locations on the Print Unit

![Pressroom Air Quality Trial Diagram]

1
2
3
10
11
12
4
5
6
7
8
9

Bottom of Press

Top of Press
Arm 3

Pressroom Trial

- Pressroom Air quality trial
- Run UV inks with PI369

<table>
<thead>
<tr>
<th>Front (Finish)</th>
<th>Back (Feed)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>7</td>
</tr>
<tr>
<td>2</td>
<td>8</td>
</tr>
<tr>
<td>3</td>
<td>9</td>
</tr>
</tbody>
</table>
Pressroom Trial

- Pressroom Air quality trial
- Run UV inks with PI369

Front (Finish)

<table>
<thead>
<tr>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>12</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Back (Feed)

<table>
<thead>
<tr>
<th>7</th>
<th>8</th>
<th>9</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Arm 3

Pressroom Trial

- Pressroom Air quality trial
- Run UV inks with PI369

<table>
<thead>
<tr>
<th>Front (Finish)</th>
<th>Back (Feed)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>7</td>
</tr>
<tr>
<td>2</td>
<td>8</td>
</tr>
<tr>
<td>3</td>
<td>9</td>
</tr>
<tr>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>5</td>
<td>6</td>
</tr>
</tbody>
</table>
Arm 3

Pressroom Trial

- Pressroom Air quality trial
- Run UV inks with PI369
Variables worth noting

- 3 press trials over three different days
- 3 ink companies' inks
  - Where only the INX formula was known
- Analysis for only PI369, no other UV material was quantified
- Pumps were turned off when press was idle (max risk assessment)

- 3 different print units
- The press trial was conducted during other press runs.
  - 1 of 3 press units
- Various Press Speeds
Arm 3 Recovery Trials

- Recovery 75-125%*
  - PI369 in acetonitrile spotted directly onto blank filter
  - Ink containing PI369 spotted directly onto filter
- Met accuracy (N≥3) and repeatability (N≥6) levels for method validation
- %Relative standard deviation ≤20%

- Neat samples provided were extracted and quantified for the content of PI369

<table>
<thead>
<tr>
<th>Vendor</th>
<th>Average gram PI 369 / gram ink</th>
<th>SEM</th>
<th>%Relative Standard Deviation</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>0.035</td>
<td>0.0011</td>
<td>0.051</td>
</tr>
<tr>
<td>B</td>
<td>0.014</td>
<td>0.0005</td>
<td>0.061</td>
</tr>
<tr>
<td>C</td>
<td>0.013</td>
<td>0.0003</td>
<td>0.039</td>
</tr>
</tbody>
</table>

Norwood and Feilden, 2018*
### Filters Categorized and Averaged by Placement

<table>
<thead>
<tr>
<th>Press Location</th>
<th>Total Per Filter microgram / day / kg bdw</th>
<th>Total Microgram / day / kg bdw as a Percentage of the Level of Reasonable Certainty of No Harm</th>
<th>PPB Extrapolated (8 hours)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Front Finish side</td>
<td>0.00006</td>
<td>0.000017</td>
<td>0.00027</td>
</tr>
<tr>
<td></td>
<td>0.00046</td>
<td>0.000140</td>
<td>0.00218</td>
</tr>
<tr>
<td>Top of Press</td>
<td>0.0405</td>
<td>0.012277</td>
<td>0.15555</td>
</tr>
<tr>
<td></td>
<td>0.0066</td>
<td>0.002004</td>
<td>0.19245</td>
</tr>
<tr>
<td></td>
<td>0.0049</td>
<td>0.001473</td>
<td>0.18677</td>
</tr>
<tr>
<td></td>
<td>0.2344</td>
<td>0.071025</td>
<td>0.03125</td>
</tr>
<tr>
<td></td>
<td>0.2730</td>
<td>0.082740</td>
<td>0.02242</td>
</tr>
<tr>
<td></td>
<td>0.0079</td>
<td>0.002407</td>
<td>0.18677</td>
</tr>
<tr>
<td>Back Feed side</td>
<td>0.0002</td>
<td>0.000058</td>
<td>0.0134</td>
</tr>
<tr>
<td></td>
<td>0.0001</td>
<td>0.000016</td>
<td>0.03125</td>
</tr>
<tr>
<td></td>
<td>0.0003</td>
<td>0.000034</td>
<td>0.02242</td>
</tr>
<tr>
<td></td>
<td>0.0005</td>
<td>0.000058</td>
<td>0.02242</td>
</tr>
<tr>
<td></td>
<td>0.0001</td>
<td>0.000004</td>
<td>0.02242</td>
</tr>
</tbody>
</table>

**Total PI369 as a percentage of the Level of Reasonable Certainty of No Harm**

<table>
<thead>
<tr>
<th>Press Location</th>
<th>Average total microgram / day / kg bdw</th>
<th>Total Microgram / day / kg bdw as a Percentage of the Level of Reasonable Certainty of No Harm</th>
<th>PPB Extrapolated (8 hours)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Front of Press</td>
<td>0.0320</td>
<td>0.009687</td>
<td>0.62513</td>
</tr>
<tr>
<td></td>
<td>0.03185</td>
<td>0.0096501</td>
<td>1.50483</td>
</tr>
<tr>
<td></td>
<td>0.00001</td>
<td>0.000004</td>
<td>0.00006</td>
</tr>
<tr>
<td></td>
<td>0.000257</td>
<td>0.000412</td>
<td>0.00412</td>
</tr>
<tr>
<td></td>
<td>0.1179</td>
<td>1.98781</td>
<td>1.98781</td>
</tr>
<tr>
<td></td>
<td>0.234530</td>
<td>3.75103</td>
<td>3.75103</td>
</tr>
<tr>
<td></td>
<td>0.049464</td>
<td>0.79111</td>
<td>0.79111</td>
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<td></td>
<td>0.000450</td>
<td>0.06316</td>
<td>0.06316</td>
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<td>0.105464</td>
<td>1.82734</td>
<td>1.82734</td>
</tr>
<tr>
<td></td>
<td>1.96376</td>
<td>1.96376</td>
<td>1.96376</td>
</tr>
<tr>
<td></td>
<td>1.02338</td>
<td>1.02338</td>
<td>1.02338</td>
</tr>
<tr>
<td></td>
<td>1.10757</td>
<td>1.10757</td>
<td>1.10757</td>
</tr>
<tr>
<td></td>
<td>1.32333</td>
<td>1.32333</td>
<td>1.32333</td>
</tr>
<tr>
<td></td>
<td>1.04821</td>
<td>1.04821</td>
<td>1.04821</td>
</tr>
</tbody>
</table>

**PPB: measure of air concentration over 8 hours**

<table>
<thead>
<tr>
<th>Press Location</th>
<th>Average total microgram / day / kg bdw</th>
<th>Total Microgram / day / kg bdw as a Percentage of the Level of Reasonable Certainty of No Harm</th>
<th>PPB Extrapolated (8 hours)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Back of Feed side</td>
<td>0.0194</td>
<td>0.006902</td>
<td>0.11039</td>
</tr>
<tr>
<td></td>
<td>0.0154</td>
<td>0.004669</td>
<td>0.07281</td>
</tr>
<tr>
<td></td>
<td>0.0099</td>
<td>0.003015</td>
<td>0.04821</td>
</tr>
<tr>
<td>Bottom of Press side</td>
<td>0.006902</td>
<td>0.11039</td>
<td>0.11039</td>
</tr>
<tr>
<td></td>
<td>0.004669</td>
<td>0.07281</td>
<td>0.07281</td>
</tr>
<tr>
<td></td>
<td>0.003015</td>
<td>0.04821</td>
<td>0.04821</td>
</tr>
<tr>
<td>Press Location</td>
<td>Total Per Filter microgram / day / kg bdw</td>
<td>Total Microgram / day / kg bdw as a Percentage of the Level of Reasonable Certainty of No Harm</td>
<td>PPB Extrapolated (8 hours)</td>
</tr>
<tr>
<td>----------------</td>
<td>------------------------------------------</td>
<td>------------------------------------------------------------------------------------------------</td>
<td>----------------------------</td>
</tr>
<tr>
<td>Front Finish</td>
<td>0.00006</td>
<td>0.000017</td>
<td>0.00027</td>
</tr>
<tr>
<td>Top of Press</td>
<td>0.0329</td>
<td>0.009975</td>
<td>0.15555</td>
</tr>
<tr>
<td>Middle</td>
<td>0.0407</td>
<td>0.012341</td>
<td>0.19245</td>
</tr>
<tr>
<td></td>
<td>0.0405</td>
<td>0.012277</td>
<td>0.18677</td>
</tr>
<tr>
<td></td>
<td>0.0066</td>
<td>0.002004</td>
<td>0.03125</td>
</tr>
<tr>
<td></td>
<td>0.0049</td>
<td>0.001473</td>
<td>0.02242</td>
</tr>
<tr>
<td></td>
<td>0.2344</td>
<td>0.071025</td>
<td>1.10757</td>
</tr>
<tr>
<td></td>
<td>0.2730</td>
<td>0.082740</td>
<td>1.32333</td>
</tr>
<tr>
<td></td>
<td>0.0079</td>
<td>0.002407</td>
<td>0.03753</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Press Location</th>
<th>Average total microgram / day / kg bdw</th>
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<th>PPB Extrapolated (8 hours)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Front Finish</td>
<td>0.3185</td>
<td>0.096501</td>
<td>1.50483</td>
</tr>
<tr>
<td>Top of Press</td>
<td>0.0329</td>
<td>0.009687</td>
<td>0.16785</td>
</tr>
<tr>
<td>Middle</td>
<td>0.0328</td>
<td>0.009833</td>
<td>0.16785</td>
</tr>
<tr>
<td>Bottom of Press</td>
<td>0.0318</td>
<td>0.009873</td>
<td>0.16785</td>
</tr>
</tbody>
</table>

No Observed Adverse Effect Level (NOAEL) = 100 milligram/ day / kg bdw

Level of Reasonable Certainty of No Harm = 330 microgram / day / kg bdw
### Arm 3 Results

<table>
<thead>
<tr>
<th>Press Location</th>
<th>Microgram PI369 / 8-hour day/ kg bdw *</th>
<th>PPB PI369</th>
<th>Total as a Percent NOAEL Limit NOAEL = 100 mg / day / kg bdw</th>
</tr>
</thead>
<tbody>
<tr>
<td>Front Finish (1)</td>
<td>0.00024</td>
<td>0.0011</td>
<td>0.00000002%</td>
</tr>
<tr>
<td>Top of Press, Side (4)</td>
<td>0.2837</td>
<td>1.4097</td>
<td>0.0003%</td>
</tr>
<tr>
<td>Bottom of Press, Side (10)</td>
<td>0.3318</td>
<td>1.6335</td>
<td>0.0003%</td>
</tr>
<tr>
<td>Top of Press, Middle (5)</td>
<td>0.0890</td>
<td>0.4259</td>
<td>0.00009%</td>
</tr>
<tr>
<td>Bottom of Press, Middle (11)</td>
<td>0.3225</td>
<td>1.5850</td>
<td>0.0003%</td>
</tr>
<tr>
<td>Back Feed, Side (7)</td>
<td>0.00012</td>
<td>0.00063</td>
<td>0.0000001%</td>
</tr>
</tbody>
</table>

### Press Data

- Front Finish (1)
- Top of Press, Side (4)
- Bottom of Press, Side (10)
- Top of Press, Middle (5)
- Bottom of Press, Middle (11)
- Back Feed, Side (7)

### Averaged Data

**Press Area:**
- Front Finish
- Top of Press
- Bottom of Press
- Top of Press, Middle
- Bottom of Press, Middle
- Back Feed

**Assuming 68 kg Woman:**

**Data Averaged:**

- Front Finish (1)
- Top of Press, Side (4)
- Bottom of Press, Side (10)
- Top of Press, Middle (5)
- Bottom of Press, Middle (11)
- Back Feed, Side (7)

**PPB PI369:**

- 0.0011
- 1.4097
- 1.6335
- 0.4259
- 1.5850

**Total as a Percent NOAEL Limit NOAEL = 100 mg / day / kg bdw:**

- 0.000002%
- 0.0003%
- 0.0003%
- 0.0009%
- 0.0003%
- 0.00001%
### How does the Number of Breaths a Day Impact Calculated Exposure

<table>
<thead>
<tr>
<th>Average Air Flow in the Filter Pump</th>
<th>At Rest</th>
</tr>
</thead>
<tbody>
<tr>
<td>Constant set flow</td>
<td>7-8 L of air / min</td>
</tr>
<tr>
<td>Average flow</td>
<td>3840 L of air over 8-hour period</td>
</tr>
<tr>
<td>941 L over 8-hour period</td>
<td></td>
</tr>
<tr>
<td>Ratio of Liters of air from breath to the filter pump</td>
<td>$= 4.1$</td>
</tr>
<tr>
<td>Implies a person would inhale $4.1X$ liters of air more than the filter</td>
<td></td>
</tr>
</tbody>
</table>
# How does the Number of Breaths a Day Impact Calculated Exposure

<table>
<thead>
<tr>
<th>Average Air Flow in the Filter Pump</th>
<th>At Rest</th>
<th>At Moderate Activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Constant set flow</td>
<td>7-8 L of air / min</td>
<td>37 L of air / min</td>
</tr>
<tr>
<td>Average flow</td>
<td>3840 L of air over 8-hour period</td>
<td>16800 L of air over 8-hour period</td>
</tr>
<tr>
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<td></td>
<td></td>
</tr>
<tr>
<td>Ratio of Liters of air from breath to the filter pump</td>
<td>= 4.1</td>
<td>= 17.8</td>
</tr>
<tr>
<td>Implies a person would inhale $4.1X$ liters of air more than the filter</td>
<td>Implies a person would inhale $17.8X$ liters of air more than the filter</td>
<td></td>
</tr>
</tbody>
</table>

**Moderate Activity:**

- Brisk Walk
- Mowing the Lawn
## Normalized to Rate of Breathing

<table>
<thead>
<tr>
<th>Press Location</th>
<th>Total as a Percent NOAEL Limit NOAEL = 100 mg / day / kg bdw</th>
<th>A Person At Rest Over 8 Hours 4.1 X</th>
<th>A Person During Moderate Activity Over 8 Hours 17.8X</th>
</tr>
</thead>
<tbody>
<tr>
<td>Front Finish (1)</td>
<td>0.0000002%</td>
<td>0.00000082%</td>
<td>0.0000034%</td>
</tr>
<tr>
<td>Top of Press, Side (4)</td>
<td>0.0003%</td>
<td>0.0012%</td>
<td>0.0053%</td>
</tr>
<tr>
<td>Bottom of Press, Side (10)</td>
<td>0.0003%</td>
<td>0.0012%</td>
<td>0.0053%</td>
</tr>
<tr>
<td>Top of Press, Middle (5)</td>
<td>0.00009%</td>
<td>0.00037%</td>
<td>0.0015%</td>
</tr>
<tr>
<td>Bottom of Press, Middle (11)</td>
<td>0.0003%</td>
<td>0.0012%</td>
<td>0.0053%</td>
</tr>
<tr>
<td>Back Feed, Side (7)</td>
<td>0.0000001%</td>
<td>0.00000041%</td>
<td>0.0000018%</td>
</tr>
</tbody>
</table>

**Assuming 68 kg woman**

---

**Oklahoma City, OK · 2020**

72nd Annual Technical Conference · Oklahoma City, OK · 2020
What’s safe? Generally Recognized As Safe (GRAS)

- To be considered GRAS:
  - The use of the substance must meet the same safety standard as a food additive: there must be a level of reasonable certainty of no harm under the conditions of its intended use; and
  - The use of the substance must meet the general recognition standard: the intended use of the substance in food must be recognized as safe by qualified experts based on publicly available scientific information.
Independent Toxicologist recommended an exposure level for “Reasonable Certainty of No Harm”

- NOAEL 100 mg/kg/day
  - Extrapolates animal data to safe levels in humans
  - Divided by 10 for intraspecies difference
  - Divided by 10 for interspecies difference
  - Divided by 3 for lack of database completeness

330 microgram / kg / day
Perspective...Moderate Activity

<table>
<thead>
<tr>
<th>Front Finish</th>
<th>Top Press, Side 1.53%</th>
<th>Bottom of Press, Side 1.78%</th>
<th>Back Feed, Side 0.00065%</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.0012%</td>
<td>1.78%</td>
<td>1.53%</td>
<td>0.00065%</td>
</tr>
</tbody>
</table>

Percentage of the Level of Reasonable Certainty of No Harm

330 microgram / day / kg bdw
Perspective...Moderate Activity

Percentage of the Level of Reasonable Certainty of No Harm
330 microgram / day / kg bdw

Bottom of Press, Side 1.78%
Top Press, Side 1.53%

Front (Finish)
1 10 4
2 11 5
3 12 6

Back (Feed)
7
8
9

Mow Lawns for 8 hours
March in place for 8 hours
We have the data, now what do we do with it?

**So What?**

Finding a Path in an *Ever-Changing* Regulatory Climate
One Under *Constant Flux*

**Look Backward, Live forward:**

- Navigate changes by *applying* established methods
- Resulting in *improved* and *quicker* responses to changes

*Life can only be understood backwards; but it must be lived forwards… S. Kierkegaard*
What does this mean for Exposure?

- Ability to go beyond **Modeling**
  - **Modeling is Predictive**

- In the **Ever-Changing Landscape**
  - **Changing Global Markets**—Supply chain changes
  - **Regulatory Changes**

- **Determine and create benchmarks**
  - Assess Actual Hazards
  - Assess Actual Risks in a **Real-World Setting**
  - Do so in a multi-factorial, multi-site study

---

Effective decision making on PPE requirements

= Improved safety for employees and customers
“Exercise Prudent Avoidance”

“In the current regulatory climate, the focus on energy-curable materials needs to be tempered with an understanding of real exposures based on actual conditions of use…The focus, therefore, needs to center around managing exposures, wherever possible, rather than believing that removing substances eliminates risk.”

--Lisa Fine
Past President RADTECH
2018 Editorial UV+EB Technology
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INX Regulatory Affairs

INX Operational S&E

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Matthew Welmers

72nd Annual Technical Conference · Oklahoma City, OK · 2020
How does the Number of Breaths a Day Impact Calculated Exposure

- **Active Filter pumps:**
  - Average airflow of the filter pumps = 941 L

- **Estimated breaths at rest:** 7 - 8 L of air / minute
  - 3840 Liters over an 8-hour period
  - Ratio of Liters of air a person breaths at rest to the filter pumps = 4.1
    - This implies at rest a person would inhale 4.1X more Liters of air than the filter, or 4.1X greater PI369 than the filter

- **Estimated breaths during a moderate level of activity:** 35 L of air /min
  - 16800 Liters over an 8-hour day with moderate activity
  - Ratio of Liters of air a person breaths during moderate activity to the filter pumps = 17.8
    - This implies during moderate activity a person would inhale 17.8 X more Liters of air than the filter, or 17.8X greater PI369 than the filter
PI Comparison

PI369

PI379