

Safe Use Determinations : A Tool to Avoid Unnecessary Proposition 65 Warnings



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Purpose of a SUD

- OEHHA determines a product containing a Proposition 65-listed chemical does not pose a “significant risk”
 - ✓ No Proposition 65 warning is required
 - ✓ Proposition 65 warnings distributed worldwide
- Furthers goals of Proposition 65
 - ✓ Prevents unnecessary warnings
 - ✓ Provide accurate information to stakeholders
 - ✓ Facilitate informed decision-making
 - ✓ “Immunizes” products within scope of SUD
- Re-initiated as reform measure under Gov. Brown & OEHHA Director Alexeeff
 - ✓ Bill Hall & Dean Thompson @ RFCI
 - ✓ Bill Hall & Susan Young @ CFFA
 - ✓ Jeff Margulies & Tandus/Renee Kalmes & Exponent

Preparing a SUD Request

- Answer nine questions regarding product and reasons for seeking a SUD
 - ✓ Identify additional benefits of obtaining SUD Request
 - Enhance recycling & reuse
- Identify products & chemical(s) within scope of SUD Request
 - ✓ Describe product characteristics
 - ✓ Identify chemical(s) and content
- Exposure assessment
 - ✓ Data – existing or develop it
 - ✓ OEHHA Sources
 - Interpretive Guidelines
 - AB2588 risk assessment guidance
 - ✓ Federal sources
 - USEPA
 - USFDA
 - CPSIA
 - ✓ Other sources
 - ASTM
 - EU
 - Literature

Proposition 65

Interpretive Guideline No. 2008-001

Guideline for Hand-to-Mouth Transfer
of Lead through Exposure to Fishing
Tackle Products

March 2008

Reproductive and Cancer Hazard Assessment Branch
Office of Environmental Health Hazard Assessment
California Environmental Protection Agency



Preparing a SUD Request (cont'd)

- Costs
 - ✓ Preparation of SUD Request
 - \$1,000 check accompanies submittal
 - Attorneys
 - Consultants
 - Analytical chemistry
 - ✓ OEHHA review
 - ✓ Range from \$50 K to \$100s K depending on complexity
- Timing
 - ✓ Completeness determination – one month to a year+
 - ✓ Approval – several months to year+
 - ✓ OEHHA bandwidth limited
 - Hired several FTEs to work on SUD Requests
 - Communicate with local electeds

Crystalline Silica in Pet Litter

- Crystalline silica in sorptive mineral-based pet litter – issued 6/99
 - ✓ Silica, crystalline (airborne particles of respirable size)
 - ✓ 12 conventional & 9 “scoopable” pet litters
- Met with OEHHA prior to preparing SUD Request
 - ✓ Receptors and exposure pathways
 - ✓ Analytical methods
 - ✓ Sampling height & duration
 - ✓ Pouring & scooping
- Annual average exposure
 - ✓ Range = $0.00053 \mu\text{g}/\text{m}^3$ to $0.060 \mu\text{g}/\text{m}^3$
- No NSRL – multiple CPFs identified
 - ✓ 10^{-5} risk = $0.54 \mu\text{g}/\text{m}^3$ to $15 \mu\text{g}/\text{m}^3$
- Max. annual average exposure 9X less than lowest air concentration @ 10^{-5} cancer risk
 - ✓ Does not pose a “significant risk”



DINP in Tandus PVC-backed tile

- DINP @ 9% in PVC backing – issued 5/16
 - ✓ Installers
 - ✓ Residents
- Met with OEHHA prior to preparing SUD Request
 - ✓ Receptors & exposure pathways
 - ✓ Analytical & sample collection methods
 - ✓ Volunteers handling tiles
- “Upper-end estimate”
 - ✓ More conservative than “average” user
 - ✓ Max. values used to estimate installer exposure
 - ✓ Resident exposure based on modeling & literature
- Lifetime Average Daily Dose < NSRL
 - ✓ DINP @ 9% for residents
 - ✓ DINP @ 8.7% for installers



DINP in PVC Roofing Membrane

- DINP @ 15% in PVC membrane – issued 11/15
 - ✓ Installers
- Met with OEHHA to prior to preparing SUD Request
 - ✓ Receptor & pathways
 - ✓ Data to be used
- “Upper-end estimate”
 - ✓ Inhalation exposure based on modeling & literature
 - ✓ Ingestion & dermal exposure based on Tandus data
- Lifetime Average Daily Dose < NSRL
 - ✓ DINP @ 15%



DINP in Vinyl Flooring Products

- DINP in vinyl flooring products - <1% to 22%
Residents SUD – issued 6/16
 - ✓ Installers SUD – issued 12/16
- Met with OEHHA to prior to preparing SUD Request
 - ✓ Receptor & pathways
 - ✓ Data to be used
- “Upper-end estimate”
 - ✓ Ingestion & dermal exposure for installers based on Tandus data
 - ✓ Resident exposure based on modeling & literature
- Lifetime Average Daily Dose < NSRL
 - ✓ Residents - DINP @ 18.9%
 - ✓ Installers – DINP @ 8.7%



DINP in Interface PVC-backed tile

- DINP up to 9% by weight – issued 12/17
 - ✓ Installers
 - ✓ Residents
- Met with OEHHA prior to preparing SUD Request
 - ✓ Receptors & exposure pathways
 - ✓ Analytical & sample collection methods
 - ✓ Volunteers handling tiles
- “Upper-end estimate”
 - ✓ Max. values used to estimate installer exposure
 - ✓ Resident exposure based on modeling & literature
- Lifetime Average Daily Dose < NSRL
 - ✓ DINP @ 9% for residents
 - ✓ DINP @ 9% for installers



DINP in Patio Furniture Fabric

- McKenna Long & Aldridge/TSG
 - ✓ Greg Gorder & Artie Lawyer
- DINP up to 25% by weight in Phifertex® patio fabric – issued 1/17
 - ✓ Consumer users
- “Upper-end estimate”
 - ✓ Dermal absorption based on Deisinger *et al.* (1998)
 - ✓ DINP transfer from product to the fingertips based on Tønning *et al.* (2008) for estimating ingestion via HTM contact
 - ✓ Did not apply 20- to 40-fold upward adjustment factor from AB 1108 Phthalate Report for AG
- Lifetime Average Daily Dose < NSRL
 - ✓ DINP @ 25% for consumer users



Thank you....



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