

Are My Personal Care Products Safe to Use? Interactive Risk Assessment Training for Summer Interns

L. Aleksunes^{1,2}, M. Fortin², D. Laskin^{1,2}

¹Environmental and Occupational Health Sciences Institute, Piscataway, NJ; ²Department of Pharmacology and Toxicology, Rutgers University, Ernest Mario School of Pharmacy, Piscataway, NJ

Abstract

Background and Purpose: Students enrolled in college are often unaware of toxicology and its basic tenet. To increase awareness of toxicology principles, we designed an interactive training in risk assessment for students participating in a 10-week summer research internship at Rutgers University.

Methods: This training session was comprised of a 1) 25-minute didactic lecture on risk assessment, 2) two team-based activities, and 3) design of a custom hand soap. For the first team activity, students were provided with index cards with the names of 6 chemicals and asked to order them according to their predicted LD₅₀ values. For the second team activity, students were provided preclinical toxicity data for a new hydrating lotion formulation and asked to identify the NOAEL and LOAEL and calculate a reference dose. Six pre- and post-test knowledge questions were conducted. For the custom hand soap, each student was provided a base liquid soap along with colorants, fragrances, and materials for mixing, packaging, and labelling their final products. Activities were rated using a 5-point Likert scale (1-poor to 5-excellent).

Results: Twenty summer interns participated in the risk assessment training and response rates on pre-/post-test questions ranged between n=18-20. The percentage of correct responses increased for all 6 questions with a mean normalized gain of knowledge of 62% (range: 21%-94%). At the end of the internship, the personal care product safety lesson was one of the most favorably rated career development activities (mean: 4.4, SD: 1.3).

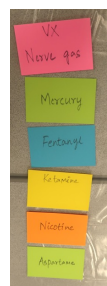
Conclusions: An interactive approach that combines didactic instruction, case studies, and a fun activity can be used to convey the fundamental principles of risk assessment.

Session Design



Activity #1 – Which Chemical is Most Toxic at Small Amounts?

Each group of students were given note cards with the names of 6 toxicants and ask to put them in order from least-to-most toxic (based on LD₅₀).

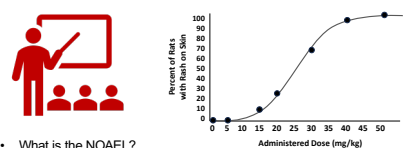


Activity #2 – How Do You Use Preclinical Safety Data to Perform Risk Assessment?

Each group of students worked on the below case study and questions.

Your company is developing a new hydrating lotion for dry skin. One of the ingredients that you would like to include in the final product is an emollient, GRS-45. Emollients are chemicals that help to soften the skin.

There are existing safety data for GRS-45 from a rat study conducted 10 years ago that you can use for your risk assessment. In that study, male and female adult rats were randomized to one of seven treatment groups (0, 5, 15, 20, 30, 40, 50 mg/kg GRS-45) and the emollient was applied to a shaved area of skin (3 cm x 3 cm area) once daily for 28 days. After 28 days, the rats were evaluated for signs of toxicity. The most sensitive toxicity that was observed for GRS-45 were rashes at the site of application. Very little (<1%) of GRS-45 was absorbed into the body/blood of the rats. The below graph shows the percentage of rats in each treatment group that exhibited rash after 28 days.



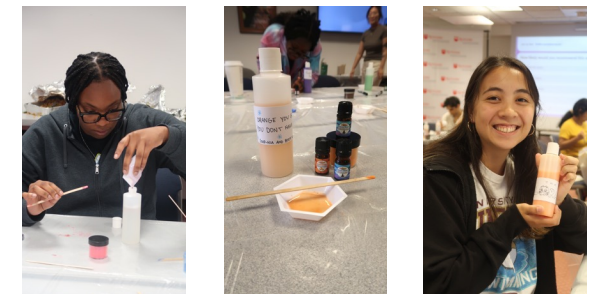
- What is the NOAEL?
- What is the LOAEL?
- What is the reference dose you calculate for estimated human exposure for potential skin toxicity (i.e., rash)?

Overview of Learning Session

Competition for Best Hand Soap Formulation

Each individual student was provided the below instructions as well as materials to design their own hand soaps including packaging and labels. After 20 minutes, judges selected their favorite products.

- You will be making your own liquid hand soap today
- Start with unscented hand soap
- Add coloring and/or fragrances to your liking
- Use stickers and markers to label your hand soap
- Be creative and decorative!
- Pour some of your final product into a nearby weigh boat for final judging
- When everyone is ready for judging, we will shift tables and select the best hand soap at the table



Students added fragrances and colorants to base hand soap in weigh boats and then diluted in a larger volume of base soap.

Learning Outcomes

Polling was used to assess learner knowledge across 6 pre- and post-lesson questions.

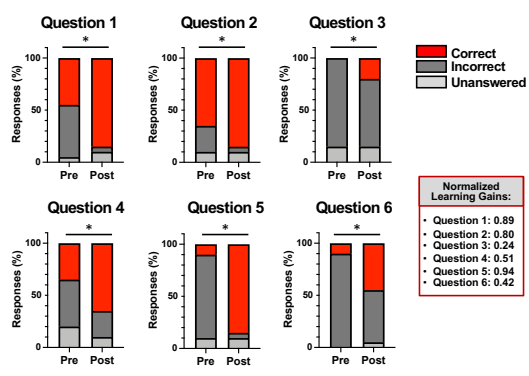


Figure 1. Pre- and Post-Assessment of Participant Knowledge. Students were asked three polling questions at the start and the end of the didactic and interactive sessions. Students had approximately 1 minute to answer each question, N=20 participants. Data shown as % correct, incorrect, and unanswered and analyzed with a two-sided Fisher's exact test. * p<0.05.

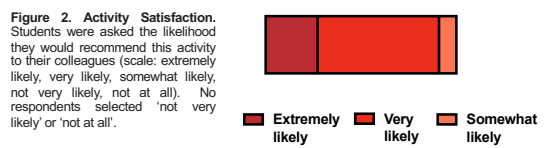


Figure 2. Activity Satisfaction. Students were asked the likelihood they would recommend this activity to their colleagues (scale: extremely likely, very likely, somewhat likely, not very likely, not at all). No respondents selected 'not very likely' or 'not at all'.

Pre- and Post-Lesson Questions:

- Which of the following is not a step in the assessment of toxicity risk?
 - Dose-Response Assessment
 - Hazard Identification
 - Risk Management
 - Exposure Assessment
 - Risk Characterization
- Risk is defined as which of the following?
 - Inherent ability of a chemical to cause harm
 - Likelihood that a hazard will cause toxicity following exposure
 - Measure of the frequency and duration of exposure of humans to toxicants
- Estimation of the incidence of adverse effects following the exposure of humans is defined as:
 - Dose-Response Assessment
 - Hazard Identification
 - Risk Management
 - Exposure Assessment
 - Risk Characterization
- Which of the following is an advantage of *in vitro* testing of a chemical's potential toxicity?
 - Increases number of animals used for safety testing
 - Easy to validate the reliability of *in vitro* tests
 - High relevance to accurately determine physiology responses
 - Can evaluate multiple variables at the same time
- To calculate a reference dose for use of a personal care product in humans based on a rat study, which values are most important?
 - No observable adverse effect level (NOAEL) and Systemic Exposure Dose (SED)
 - Low observable adverse effect level (LOAEL) and Systemic Exposure Dose (SED)
 - No observable adverse effect level (NOAEL) and Uncertainty Factors (UFs)
 - Low observable adverse effect level (LOAEL) and Uncertainty Factors (UFs)
- True or False: Proposition 65 was enacted by the US Congress that requires businesses to provide warnings to US citizens about how chemicals in their products can cause toxicity (such as cancer, birth defects, etc).

False

Acknowledgments

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Target Learning Community:
20 Undergraduate Students in a Summer Research Program

Learning Goals

- ✓ Understand how cosmetics are regulated in the US and across the globe.
- ✓ Dissect the steps for assessing risk of chemical toxicity for individual ingredients.
- ✓ Learn about the advantages and challenges of the various types of studies to assess safety of chemicals.
- ✓ Practice calculations used in assessing risk of chemicals for humans exposed.
- ✓ Discuss ways to address gaps in the available safety data for chemicals.
- ✓ Understand how personal care products can impact the environment.
- ✓ Consider steps to enhance sustainability of personal care products.

Take Home Message

An interactive approach that combines didactic instruction, case studies, and a fun activity can be used to convey the fundamental principles of risk assessment.

<https://surf.rutgers.edu>