Engine/APU Halon Replacement Industry Consortium – Health and Safety Requirements for Halon Replacements – an Application-Based View

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Health Risks of Halon Replacements

- Halon 1301 has been used for engine/APU fire extinguishing applications for over 60 years
- Halon 1301 has low acute inhalation toxicity and moderate cardiac sensitization and respiratory irritation potential
 - How important is this?
 - What is the appropriate way to assess replacement candidates?
- NOAEL and LOAEL are common figures, but offer limited insight
- Proper assessment requires a broad understanding of toxicology, chemical exposure, airplane design, and airplane operations (including maintenance)

Outline of Topics

- Key terms
- Critical concepts
- Types of toxicants
- Health effects/toxicity endpoints
- Human health risk assessment
 - Toxicity assessment
 - Exposure assessment

Toxicology - The Science of Poisons

Toxicology is a broad interdisciplinary field that involves the study of the adverse health effects on living organisms (people, animals, etc.) from exposure to agents such as chemicals or particles.

Key Toxicology Terms

Toxicant: An agent that can cause a toxic effect

Dose: The amount of toxicant that enters into the body

<u>Health Effect or Endpoint</u>: Adverse effects in a person or organism from exposure to a toxicant

Toxicity Threshold Value: The highest dose at which no adverse human health effects are expected to occur based on toxicity studies

Key Exposure Terms

Exposure: The process by which a person or organism is exposed to a toxicant **Exposure route:** The way that a toxicant enters the body

• Can be by inhalation, ingestion, or dermal (skin) exposure

Exposure duration: How long a person or organism is exposed to a toxicant

Exposure frequency: How often a person or organism is exposed to a toxicant

Exposure pathway: The pathway by which a toxicant travels to reach the person exposed

Exposure control: A tool used to reduce exposure

 Can be by engineering controls (ventilation), administrative controls, personal protective equipment (PPE), substitution, elimination, or a combination

Human Health Risk Assessment

The evaluation of the potential for adverse health effects that may result from a person's exposure to a toxicant

Risk = Toxicity x Exposure

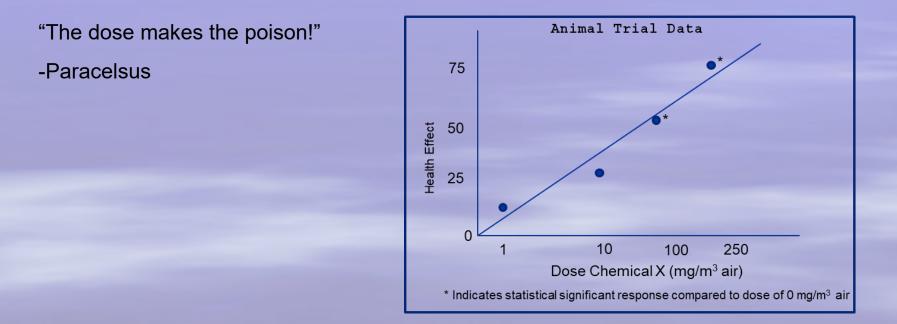
Risk is a function of both the toxic potential of a chemical and the amount of chemical to which a person is exposed

- If there is no exposure, there is no risk
- If the chemical is not toxic, there is no risk

Critical Concept: The Dose-Response Relationship

Dose-response relationship: The relationship between the level of exposure to a substance and the health effects observed from the exposure

 Generally, as dose increases, frequency of health effect occurrence and/or severity of health effect will increase



Critical Concept: NOAEL (C)

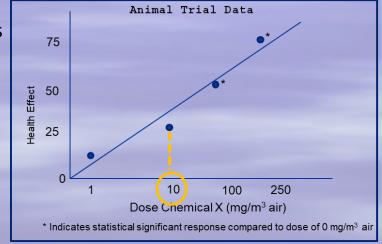
No Observable Adverse Effect Level (or Concentration):

The highest exposure level (or concentration) at which there are no statistically and biologically significant increases in frequency or severity of adverse health effects between the exposed population and the unexposed control

- Dependent on test doses and exposure route used in the study
- Generally, NOAELs are used as the basis

for toxicity threshold values or OELs

 If NOAEL is derived from animal study, is adjusted for relevance to humans (e.g., account for differences between humans and animals)



Human Health Risk Assessment

Risk = Toxicity x Exposure

- What is a "safe" level of exposure?
- Toxicity thresholds, e.g. OELs, Reference Doses, etc.
- > When exposure in workplace, short term exposure scenario, etc.
 - is lower than what is likely to cause toxicity (specific endpoints)
 - Established by government and other reputable agencies (e.g., OSHA, NIOSH, EPA, etc.)
 - Based on best scientific evidence
 - Factors taken into account for uncertainty and variability
 - Some include factors that account for time exposure
- Risks can be mitigated with "<u>exposure controls</u>"

Human Health Risk Assessment

Risk = <u>Toxicity</u> x Exposure

- When considering the toxicity of a chemical we look at :
 - 1. <u>Health effects (endpoints)</u>: what health effects can this chemical cause and how
 - 2. <u>Severity of endpoints</u>: how severe are the health effects- Reversible? Lethal?
 - 3. <u>Potency</u>: what dose is needed to cause each health effect
 - 4. <u>Sensitive populations</u>: Are there any people that would be especially sensitive to this chemical? (e.g. pregnant women, asthmatics)

Toxicity (Hazard) Assessment

- The process of collecting data and evaluating potential health effects, dose (potency), severity of effect, and sensitive populations
- Data sources
 - 1. <u>Animal studies</u>: has this chemical caused toxicity in animal studies?
 - Animal studies can be done as inhalation, oral, dermal exposures
 - 2. <u>Cell culture studies</u>: what is the mechanism by which the chemical may cause toxic effects? Can we predict whether toxicity might occur in animal studies? Which chemicals are more likely to cause toxicity?
 - 3. Epidemiology: has this chemical caused toxicity in humans in the past?
 - 4. <u>Structure activity analysis</u>: is this chemical similar to other chemicals we know to be toxic? Could it have similar effects?

Exposure Assessment

Risk = Toxicity x Exposure

- When considering the exposure to a chemical we look at :
 - 1. <u>Exposure frequency</u>: how frequently the chemical is used
 - 2. <u>Exposure duration</u>: how long a person is exposed
 - 3. <u>Concentration</u>: how much of the chemical is in the air or on surfaces
 - The concentration becomes the <u>dose</u> when it is absorbed into the body
 - Generally, the dose will be less than the concentration because not all of the chemical will be absorbed

Summary

- "The dose makes the poison"
- Dose-response is the relationship between the dose of the exposure and the severity/incidence of the effects
- NOAEL is the highest dose observed in the study at which no adverse effect was observed
- Human health risk is a function of both the toxic potential of a chemical and the amount and frequency of chemical that a person is exposed to
- Human health risk can be mitigated

Thank you!

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