

Review pipeline and current portfolio of products and compounds.

Determine which products or compounds meet the **definition of a potent compound**.

Prioritize list of compounds for classification.

## What is a potent compound?

- 1 A pharmacologically active ingredient or intermediate with biological activity at 15 µg/kg of body weight or below in humans or daily therapeutic dose of 1 mg or below per day.
- 2 An active pharmaceutical ingredient or biotechnology ingredient with an occupational exposure limit (OEL) at or below 10 µg/m<sup>3</sup> in air as an 8-hour time-weighted average.
- 3 A pharmacologically active ingredient or intermediate with the ability to bind to specific receptors or inhibit specific enzymes, and/or the potential to cause cancer, mutations, developmental effects, or reproductive toxicity at low doses.
- 4 A novel compound of unknown potency and toxicity.

## What is control banding?

Control banding is a process of assigning to a hazard category that correspond to a range of airborne concentrations—and the engineering controls, administrative controls, and personal protective equipment—to ensure safe handling.

## 5-band system (Affygitly)



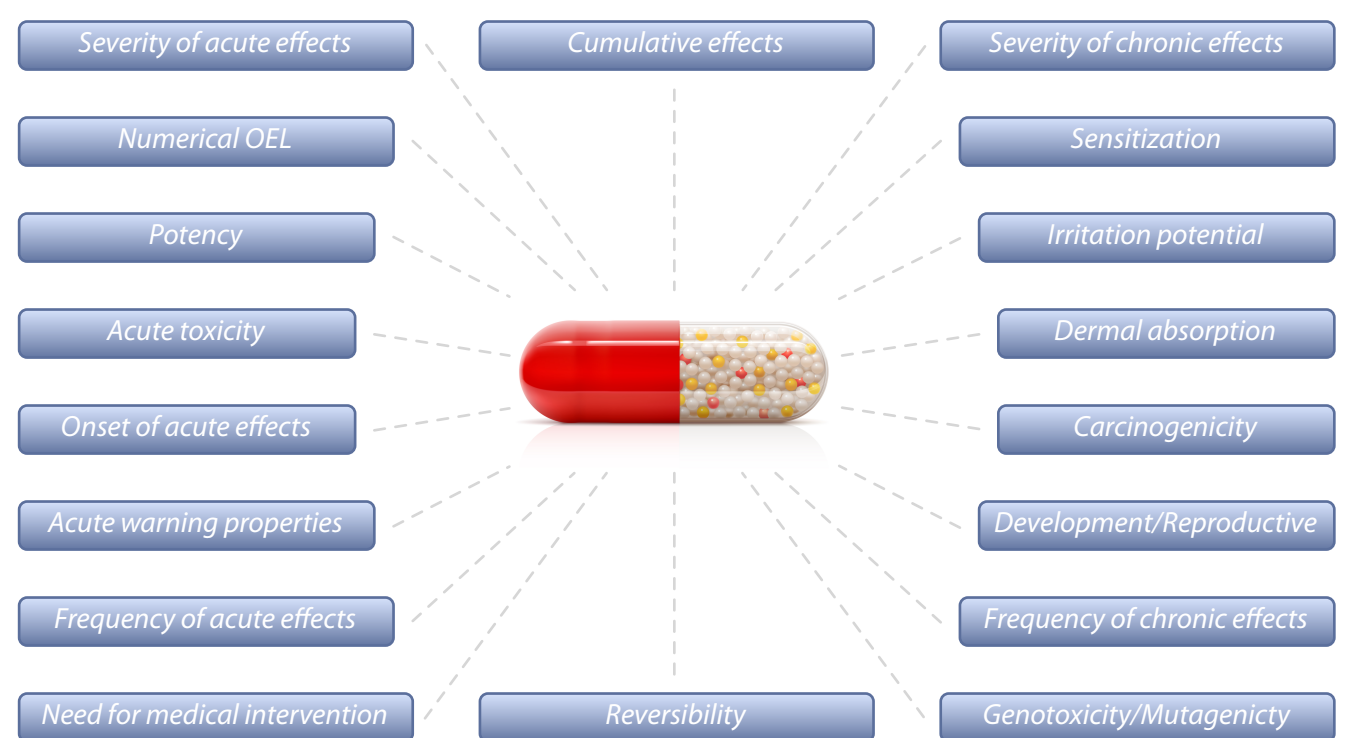
## OEL Equation

$$OEL \left( \frac{mg}{m^3} \right) = \frac{NOAEL \left( \frac{mg}{kg} \right) \times BW (kg)}{UF_c \times MF \times V (m^3) \times S \times \alpha}$$

## Uncertainty and modifying factors

Inter-individual variability. Inter-species extrapolation. LOEL-to-NOAEL extrapolation. Sub-chronic-to-chronic extrapolation. Route-to-route extrapolation. Modifying factor. (List not comprehensive.)

## Compound Classification Factors



## Training

Employees involved in the handling of potent compounds need to be trained in the hazards of the specific compounds, control banding concepts, proper use of engineering controls, gowning/de-gowning, waste disposal, etc.

## Containment Validation

All engineering controls and procedures need to be validated prior to use. Surrogate monitoring can be performed using either lactose, naproxen sodium. Both personnel and area samples should be collected.

## Industrial Hygiene

An industrial hygiene program should be implemented to evaluate exposures. An adequate number of samples should be collected.

## OEL Examples (µg/m<sup>3</sup>)

Acamprosate Calcium	2,000	
Doxepin	139	Band 1
Nadolol	40	
Acitretin	25	Band 2
Ergotamine Tartrate	10	
Bumetanide	5	Band 3
Amphetamine	5	
Reserpine	1	Band 4
Fentanyl Citrate	0.1	
Dihydroxyvitamin D3	0.08	Band 5

Determine appropriate **control band** for each compound.

Classify compounds.

Determine OELs for late stage compounds.

Train employees.

Install and validate engineering controls through industrial hygiene monitoring.

Determine program effectiveness through auditing.

