

Managing Active Pharmaceutical Ingredients in your workplace

Supporting OEL creation and review

Safeguarding Workers and Your Business with Active Pharmaceutical Ingredient (API) Occupational Exposure Limit (OEL) Documents. Protecting workers from hazardous exposures is a requirement by law under COSHH, and these essential documents help to ensure worker safety, regulatory compliance and keeping businesses running.



WHY THESE DOCUMENTS ARE NEEDED

While pharmaceuticals are typically beneficial and limited exposure is generally safe, exposure in a manufacturing environment differs significantly from controlled medical administration. Workers in such settings should typically be in good health, making any pharmacological effects of the drugs unwanted rather than therapeutic.

Some of these effects may increase the risk of acute and chronic health issues, accidental injury, such as drug-induced drowsiness in individuals working around high-speed machinery. Additionally, there is a potential for interactions between drugs handled in the workplace and those administered for therapeutic purposes.

Pharmaceutical manufacturers are increasingly handling products containing highly potent active pharmaceutical ingredients (HPAPIs), with far greater biological activity. Estimates suggest that HPAPIs may account for almost a third of the current pharmaceutical development pipeline.

BENEFITS OF API OELs

- **Ensuring Worker Safety and Regulatory Compliance**
Hazardous workplace exposures cause thousands of illnesses every year. Our API OEL documents are key to keeping your workers safe and meeting stringent regulatory requirements. By adhering to Control of Substances Hazardous to Health (COSHH) regulations, you not only ensure legal compliance but also avoid costly penalties and fines.
- **Worker Health & Wellbeing**
API OELs protect worker health by providing clear guidelines, assuring safety, improving work environments, and increasing job satisfaction. OELs reduce the risk of acute and chronic illnesses which can reduce worker anxiety.
- **Boosting Efficiency and Reducing Costs**
Safe workplaces with healthier employees translate into higher productivity. Workers protected from hazardous exposures are less likely to fall ill, reducing absenteeism and creating a more efficient and productive workforce.

KEY FEATURES OF API OEL DOCUMENTS

Our API OEL documents are comprehensive and include:

Threshold Limit Values: Specifying maximum allowable concentrations over an 8-hour workday. The OEL is based on 1% of the therapeutic dose, taking into account inhalation.

Substance Description: Summarising the substance, chemical properties, and precautionary statements.

Animal and Human Studies: Detailing toxicity, carcinogenicity, reproductive toxicity, and clinical pharmacology.

Summary Table: Presenting acute and repeated toxicity, OELs, side effects, contraindications, and drug interactions.



THE IOM PROCESS

Leveraging a diverse range of scientific expertise, the IOM's approach encompasses the following key steps:

Toxicological Review: We thoroughly examine and present available data for the substance and related compounds.

Identification of Health Endpoints: Our experts pinpoint the primary health concerns linked to the substance.

Presentation of Health Impacts: We present potential acute and chronic health effects from exposure to the substance.

Dose-Response: We detail the lowest toxic effects dose, no observed effects levels, and therapeutic doses, providing a comprehensive understanding of reactivity.

Vulnerable Populations: We identify individuals at heightened risk, such as asthmatics and those of childbearing age.

Expert Evaluation: Our experts exercise judgment to determine if a 1% margin of therapeutic dose is sufficient for protection, accounting for various factors and uncertainties in the assessment.

GET IN TOUCH

If you need any help with API OELs please get in touch at info@iom-world.org or reach out to Emily Christopher.

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