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Occupational Exposure to Industrial Enzymes

Sampling, Monitoring, and Analytical Methods

- White Paper -

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Introduction

Enzymes are biological agents (generally proteins) that increase the rate of chemical and biochemical reactions. All living organisms produce enzymes and use them to regulate biological processes. The earliest known uses of enzymes by humans were to make bread and to ferment sugar into alcohol. This has been done for thousands of years, but the scientific study and characterization of enzymes didn't begin until the late 1800s. Today, enzymes are commonly used in a wide range of applications, including the manufacturing of pharmaceuticals, detergents, textiles, and food products.

Large-scale manufacturing processes potentially expose workers to high levels of enzymes, increasing the risk of allergic sensitization and related health issues. Occupational exposure can occur through inhalation, ingestion, and skin contact of powder or liquid enzymes. Studies conducted over the past 20-30 years indicate that 12 to 27% of enzyme manufacturing workers become sensitized to at least one enzyme. In response to this increase in enzyme-related occupational allergies and asthma, many manufacturers have implemented a program for monitoring exposure to enzymes in the workplace.

Enzyme Sampling

A successful enzyme exposure monitoring program begins with a sampling strategy conducted by trained personnel. Many companies and institutions have an Office of Occupational Health and Safety (or similar) that is responsible for ensuring their workers' well-being. This may include a program for monitoring air quality and exposure to potentially harmful substances. In the absence of such a department, a specialist, such as an Industrial Hygienist, is often contracted to perform the sampling and offer guidance based on test results.

Air sampling is most commonly used to monitor enzyme exposure, although swabs and wipes are sometimes used to collect enzyme samples from solid surfaces. Currently, there are no official enzyme sampling guidelines or protocols provided by (US) government agencies. The International Association for Soaps, Detergents, and Maintenance Products has published a useful resource: Guidelines for the Safe Handling of Enzymes in Detergent Manufacturing, which includes a chapter on air sampling (last updated in 2018).

Personal Sampling

Air samples for personal monitoring can be collected using either a 25mm IOM or 37mm PVC cassette (shown below). A variety of filter media can be used, including glass fiber, PVC, PTFE, and MCE. The ideal pore size is 0.5 – 2.0 microns. For 37mm cassettes, either the 2- or 3-piece design is suitable. A 3-piece cassette allows for samples to be collected open-face by removing the inlet side of the cassette, exposing the whole filter. There is debate about which method is better (open vs. closed-face) but there is evidence that open-face sampling tends to result in slightly higher levels of measured enzyme. There is potential for filter contamination (splashing)

when sampling liquid enzymes using the open-face method, which should be considered when developing a sampling strategy.

25mm Disposable IOM Cassette

3-piece 37mm Cassette

The air sampling cassette is attached to a worker's collar or shirt/lab coat pocket. A specific holder with collar clip is required for 37mm cassettes; the disposable version of IOM cassettes include the housing and collar clip as a single unit. The cassette is connected to a pump programmed for a flow rate of 2 liters per minute (LPM).

NOTE: *it is important to calibrate the pump before use, which requires an adapter specifically designed for each type of cassette.*

One common approach for personal exposure monitoring is to collect the air sample during a specific task, which may only last 15-30 minutes, but has the potential for high exposure. Alternatively, an air sample can be collected for a longer duration while the person is performing other routine tasks to determine average exposure over a set period of time. For this type of sampling, a minimum of 100 liters of air is recommended. For personal sampling, a variety of small and (relatively) lightweight pumps are available, such as the Zefon Escort Elf Air Sampling Pump and the Gilian 5000. These are designed to be portable and can be attached to the worker's belt or waistband.

Area Sampling

For general exposure monitoring within a specified area, such as a room or hallway, air sampling can be performed using a 37mm cassette (holder not needed). A high-flow pump can be used (flow rate of 10-15 LPM is typical) to collect the air sample for as long as possible, with a recommended target volume of approximately 1,000 liters. A larger sample will increase the likelihood of capturing a detectable level of enzyme.

InBio has recently released a new ambient air sampling device, Apollo, which has been validated for airborne allergen and endotoxin detection. Apollo is a user-friendly air sampling option compared to IOM sampling pumps which can be expensive, complicated, or cumbersome. Apollo has a high flow rate (~500L/min) and is designed to sample large volumes

of air from whole rooms. Unlike other air samplers, Apollo is a quiet, lightweight sampling device. Apollo has been proven to capture allergens and endotoxin from the air in residential homes, with ongoing studies being performed on its ability to sample enzymes in manufacturing settings.

Surface Sampling
Swabs and polyester wipes can be used to detect the presence of enzymes on hard surfaces that may have accumulated over time. For this type of sampling, a defined area is designated for sample collection performed by moving the swab or wipe across the surface, covering the entire area. Although there are no specifications regarding the surface area to be sampled, it is recommended to be consistent to allow comparison of results for multiple and/or future samples.

Sample Storage
Collected air and surface samples can be stored refrigerated or frozen until they are ready to be shipped to the analysis laboratory. It is important to properly label each sample with a unique identifier and to include the volume of air collected. Samples should be packaged in a way that ensures they are protected from potential contamination (e.g. covers on cassette inlet/outlet, swabs and wipes placed in individual resealable bag or other container). Ideally, samples are shipped to the lab in an insulated container with ice packs.

Enzyme Analysis

The analysis methods used for enzyme quantification require samples to be in liquid form, which is straightforward if the sample happens to be a liquid. For air and surface samples, the enzyme(s) must be extracted from the collection media (filter or swab/wipe) into a buffer solution. The sample can then be tested using an assay that targets a specific type of enzyme. It is important to note that most enzyme assays cannot distinguish between unique enzymes within a specific enzyme category. For example, the assay for subtilisin (a protease enzyme) will also detect other proteases, such as trypsin. This also applies to amylases, lipases, and most other broad categories of enzymes, which may be an important consideration for facilities that use or manufacture different types of enzymes.

Enzyme concentration is measured in units of weight per volume, typically nanograms per milliliter (ng/mL). However, the units can be converted to nanograms per sample (for surface samples) or nanograms per cubic meter of air (ng/m^3) for exposure monitoring.

Currently, there are no established occupational exposure limits (OEL) for enzymes. However, a report published by NIOSH and OSHA references an exposure limit for subtilisin of 60 nanograms per cubic meter (ng/m^3) from a 60-minute air sample. This OEL of 60 ng/m^3 has been adopted for enzymes, in general. It may be unrealistic to expect that the level of airborne enzymes can be reduced below 60 ng/m^3 in areas where enzymes are being manufactured or processed. Results from enzyme analysis may be best utilized for identifying specific areas that

can benefit from improved engineering controls or specifying tasks that require use of personal protective equipment.

Conclusion

Occupational exposure to enzymes puts workers at risk of sensitization and allergic disease. Reducing exposure to enzymes through procedures, engineering controls, and PPE needs to be a high priority. Implementing and monitoring exposure controls requires sensitive and specific methods for detection of airborne and/or settled enzymes. Airborne and surface sampling combined with enzyme analysis methods allows facility managers and industrial hygienists to manage and improve occupational health and reduce worker allergic sensitization.

InBio Services

InBio has over 10 years of experience in monitoring occupational enzyme exposure for clients in the pharmaceutical and detergent industries. InBio provides custom air sampling solutions and testing/monitoring services for enzymes in industrial environments. These services cover most any enzyme, including proteases, amylases, and lipases.

Contact InBio at mail@inbio.com to learn how we assist in enzyme testing needs.