



Amfep guidance

Safety in the use of enzyme containing reagents for medical device cleaning

The enzyme industry has a long tradition of working actively with customers on health and safety issues, including allergy and irritancy concerns. A continuing effort to advise downstream users and end-users on the safest and most effective use of enzymes in industrial, professional and consumer related applications has long been conducted.

Enzymes can act as respiratory sensitizers. At high concentrations proteolytic enzymes can also irritate skin and eyes. Hence, when working with enzymes, general precautions for safe handling must therefore be applied.

Enzymatic detergents are widely used for medical device cleaning of e.g. fiberoptic instruments/ endoscopes because of their excellent washing performance. In many cases ultrasonic cleaning is used during the process to increase the cleaning efficiency. However, studies have shown, that ultrasonic cleaning may generate enzyme containing aerosols and that the resulting level of airborne enzyme exposure may exceed the acceptable exposure level if the ultrasonic cleaning is done in an open setting. The studies have also shown that the enzyme exposure can be controlled to be below the acceptable exposure level when using ultrasonic cleaning, if this ultrasonic cleaning is performed in a bath that is closed by a lid; and by keeping the lid closed for 5 minutes after cessation of the ultrasonic treatment before opening.

As the cleaning is performed by professionals at hospitals, it is important that these users are informed and instructed thoroughly in the correct handling of the cleaning products to avoid occupational incidents.

According to the EU legislations including REACH, it is enzyme suppliers' obligation to communicate safety for workers and professional users and the safety information must be communicated further along the supply chain. The acceptable exposure limit for professionals at hospitals will be 15 ng/m³ as stated in (1). The safety guidance and appropriate risk management for end-users (professionals) should be ensured by employers. The Amfep guidance was created to help all players in the supply chain to meet this obligation and ensure safety for professional users (2).

Manufacturers of medical device cleaning agents must convey the relevant safety information given in the exposure scenarios of each ingredient. For enzyme ingredients this means that the following safety precautions must be conveyed to the users:

- Apply good housekeeping and good personal hygiene.
- Ensure that enzyme aerosols are not created.
- Use closed systems whenever possible.
- Ensure exhaust ventilation if there is a risk of exposure (open handling, openings in closed systems)
- Do not splash or stir vigorously during dosing or mixing as aerosols may be created.
- Any spill must be cleaned up immediately without creating aerosols.
- For ultrasonic cleaning the following specific safe handling procedures must be complied with:
 - The lid of the ultrasonic cleaning device must be closed during operation.
 - It is recommended to insert a lag time after cessation of the ultrasonic treatment (approx. 5 min.) before opening the device.
- During rinsing or manual cleaning care should be taken to avoid splashing and creation of aerosols and to keep instruments low in the sink.

It is strongly recommended that manufacturers of medical device cleaning agents provide a clear and detailed use description including the relevant safety precautions to the users and include safety messages on labels as well.

For safety for workers when enzyme containing reagents are formulated, please see Amfep guidance on the safe handling of industrial enzyme preparations (2).

Ref:

- (1). Toxicology 268 (2010) 165–170: Defining occupational and consumer exposure limits for enzyme protein respiratory allergens under REACH
- (2). Guide to the safe handling of industrial enzyme preparations <http://www.amfep.org/content/safe-handling-guide-2013>