Enzyme Safety Management

A series of web based training and Information Sessions developed and presented by the AISE Enzyme Safety Task Force

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Good Afternoon. It is my great pleasure to welcome you to the first in a series of AISE webinars that will be run over the next 6 months. The objective of these webinars is to disseminate the combined knowledge, expertise, and guidance that the Enzyme Safety Task Force, together with its predecessors and other collaborative committees and experts, have accumulated and published over the last 40 years.

This first session will provide you with some background to the Enzyme Safety Task Force, and the subject in hand, and introduce the content of the remaining sessions which will run until approximately May 2016.

It is intended to record the sessions and make them available for download from the AISE web site; as a resource for further training, development and information.

In the interests of time I will invite questions at the end of the session, so please note any that you have as we go.
Our first session will cover an introduction to enzymes, the history of their use, and the problems encountered along the way.

To be clear why we are here today; enzymes are hazardous materials but the risks are only associated with incorrect handling and use. If they are handled for example in a way that results in inhalation of dust or aerosol; or if spillages are dealt with carelessly, then employees may be exposed to them. But before we get into that first I will introduce myself.

My name is Mark Fieldsend, I am an Industrial / Occupational Hygienist and I have worked within the detergent industry for the last 25 years. During that time safe handling and use of enzymes as been a considerable part of my role; developing standards of operation, best practices for risk management, and designing control systems.

I have been fortunate to chair the AISE Enzyme Safety Task Force for many years, and together with a team of experts from across the enzyme manufacturing sector and the detergents industry we have promoted the safe handling and use of enzymes, and developed guidance, specifically for the members of AISE which has been adopted and recognized globally.

In addition the expertise of the individual members of the AISE Task Force is recognized not only within the AISE, but globally in the detergents industry and by other similar organisations and committee’s.
The objectives of our first webinar are to
- introduce the Enzyme Safety Task Force,
- provide the background about enzymes; why we use them
- Consider the hazards of enzymes & history of use, the health issues, and
- To introduce the upcoming webinars that will cover safety and risk management of enzymes in much more detail

This is an introductory session to ensure everyone starts on the same page; the upcoming webinars which I will describe later will contain a lot more practical and operational detail and will be presented by various experts from the companies represented on the AISE Enzyme Safety Task Force.
The AISE is the official representative of the detergent industry in Europe and has many committees and task forces that are dedicated to ensuring safety in everything that the industry does, for employees, consumers, and the environment. Sustainability is also a large part of the AISE mission.

The Enzyme Safety Task force is a small team of dedicated experts from across many companies whose focus is specifically enzyme safety; you will meet, albeit virtually, some of these experts during the future webinars.

Our ambition within the task force is essentially to promote the safe and responsible use of enzymes in detergent products, be they for consumers or for Industrial and Institutional use.

We have, for example, published best practice guidance, which is widely accepted throughout the world as such, and we have worked to support the registration of enzymes under REACH via the development of generic exposure scenario’s. Our deliverables over the years have been in many fora including input into regulatory committee's and scientific publications.

We work very closely with other committees and groups such as the ACI and AMFEP which have very similar aims.
So why do we use enzymes?

Because

- They are fantastic ingredients for cleaning soils, stains, and grease from a wide range of surfaces
- Tackle difficult and stubborn stains and soils that surfactant alone cannot remove
- They extend the life of garments through effective stain/soil removal, low temperature care washing, protecting/renewing color, and providing fabric care benefits
- They save us energy by allowing effective low temperature washing / cleaning
- They are very weight efficient / cost effective, present in most formulations as very minor ingredients, often at less than 1%
- Highly and very quickly biodegradable, and
- They are Non toxic

Unfortunately during the manufacture of enzymes and formulation of products some people may develop specific allergies to enzymes if they are inhaled as a dust or aerosol; as we will now describe.
Enzymes are present in all living things; they are biological catalysts that speed up biochemical reactions. They are essential for all life. We could not digest our food without them, nor could we move or function as we do, without enzymes to speed up the biochemical reactions in our bodies.

However, proteins that are foreign to our body, for example natural proteins such as pollen and house dust, can trigger the human immune system to produce antibodies if they are inhaled – this process is known as sensitisation and we will discuss that process in more detail in the next slide.

You will all be familiar with common allergies such as Hay Fever, or Asthma, well some people who are exposed to enzymes by breathing in dust or aerosol that contains them may become sensitised to them, and they may develop respiratory allergy in exactly the same way as they might for pollen or house dust.

These types of allergenic materials are called respiratory sensitizers, and they can in some cases elicit an allergic respiratory response such as Rhinitis [like Hay Fever] or Asthma.

End users of products that contain enzymes are not at risk because the products and their application are designed to minimize exposure – that specific topic will be covered in detail in a later webinar.
A foreign protein circulating around the body in the bloodstream can trigger the human immune system into defending the body against that protein. This is the function of the immune system. It works by producing antibodies which target the protein in some way and effect its removal from the body, its destruction, or its exclusion.

Enzymes, just like pollen or house dust, can trigger the immune system to produce antibodies that are absolutely specific to that protein. As we have discussed already many of us already have antibodies to foreign proteins in our bodies and we are completely unaware of – because they cause us no problems / result in no symptoms.

Similar to natural proteins, not everyone who inhales an enzyme will become sensitized. Our own genetics can make us more or less susceptible to being sensitized. However problems may subsequently occur in a sub set of sensitized individuals if significant exposure to enzymes continues or occurs after this point. We will consider what is a significant exposure level a little later on ...but first let us discuss respiratory allergy.
Just like the development of sensitisation differs from person to person, the link between sensitisation to enzymes and allergy also varies and is extremely complex. It is different for every person.

Some sensitized people will never develop any symptoms even if exposure is significant. Our own genetic make up dictates our response to a sensitizer, that is why it is impossible to set absolute no effect levels, which we will discuss in a while.

The first symptoms of allergy to enzymes that may develop in some people are called Rhinitis; these symptoms are like the common cold, or “Hay Fever” in the summer months.

Watery itchy eyes, runny nose, sneezing, etc.

If an employee has these symptoms, and it appears to relate to their presence in the working environment, then it must be reported to occupational health for further investigation. Symptoms related to the workplace often disappear at weekends, during time off or away from work, during holidays, etc. but return when the person comes back to the workplace, or shortly after.

If the this rhinitis is due to enzyme allergy, then the risk of progressing to the development of enzyme asthma is high.
Occupational Asthma can develop if the antibodies in the blood trigger the release of histamine – this may follow a significant exposure to the sensitising agent, that is a continued exposure above the exposure limit, or one or more very high peak exposures.

Histamine effects the airways, just like it does if a person suffers asthma from a natural cause such as pollen, animal fur, house dust. The airways in the lungs constrict, plug with mucus, and breathing becomes very difficult.

Asthma can be controlled, but once established it is a very serious disease Health surveillance, sensitisation, asthma and management of employees with respiratory allergy will be discussed in detail a future webinar Next we will look very briefly into the experiences of the detergent industry when enzymes were first introduced and the realisation that they were respiratory sensitizers
Enzymes were first used in large scale commercial products from about 1965. Once large scale fermentation processes were developed the availability of enzymes in bulk and their effectiveness as a cleaning agent made them an attractive ingredient to include in detergents.

Initially enzymes were dusty powders, tipped manually from sacks. Being a “natural” product it was assumed they were safe / non toxic – this was before the legal requirement to provide MSDS’s.

Enzyme products were extremely popular with consumers and volumes grew, but by 1967 the first cases of respiratory disease were recognized being due to exposure to enzymes.

By 1970, this had reached “epidemic” proportions for an occupational disease. Enzyme Asthma was diagnosed in many employees, and in UK up to 60% of employees were found to be sensitized – but they showed no symptoms.

It was clear that something now needed to be done very quickly to protect employees if use of enzymes were to continued.
IN 1969 the UK industry responded by forming the soap and detergents industry association – the SDIA
Many parallel activities were initiated by the founding members to
• Reduce the dustiness of powders
• Improve engineering containment and ventilation control
• Define safe operating practices
• Implement regular health surveillance, and
• Measure airborne enzyme within the factories
In 1971 the first detailed guidance was issued and was regularly updated every few years. Since 2000 this has been a function of the AISE Enzyme Safety Task Force. Initially people who were atopic – that is more likely to develop allergy – were excluded from any contact with enzymes / production of enzyme products - but experience showed that this was unnecessary, and would now be illegal due to disability and discrimination regulation. It is no longer required.
Risk management measures have developed continuously since 1970, but the overall strategy is still valid. Enzyme encapsulation has replaced simple agglomeration of powders to provide very low dust solids - but even the low level of dust in modern encapsulates still presents a significant risk of exposure necessitating the defined controls. We will return to this in a later webinar.
Another activity which lasted for many years was the development of occupational exposure limits. The detergent industry experience demonstrated that despite there being a recognized limit for pure enzyme, set by ACGIH, employee occupational asthma was still occurring. It was established that the presence of surfactants in the dust inhaled by employees had a synergistic effect and increased the potency of the enzyme – subtilisin – and thus a lower workplace exposure limit was required for detergent manufacturing. The UK SDIA and US SDA [Soap and Detergent Association] both adopted a limit of 0.000015mg/m³ for subtilisin [circa 1985].

Examples of current legal limits for pure subtilisin are:
- OSHA [US] 60ng/m³
- HSE [UK] 40ng/m³
- DOSH [Finland] 15ng/m³
- The most current “in house” workplace exposure limits in the detergent industry are in the 5 – 10 ng/m³ range.

Note: 0.00006mg/m³ = 60ng/m³
      0.000015mg/m³ = 15 ng/m³

Legal limits still apply to pure enzyme protein and do not account for the presence of surfactants. It is not possible to measure personal exposure to enzymes because of these very low limits, personal sampling technology just cannot achieve the required limits of detection. So high volume static sampling is undertaken. The webinar on air monitoring will provide far more detail on this subject.

With increasing enzyme activity, multiple enzyme classes, and higher potency enzymes, and the output of health surveillance programs many companies have set increasingly lower exposure limits. The majority of exposure limits for enzymes now fall into the range of 5 - 10 ng/m³. Maintaining workplaces at or below these limits has largely eradicated enzyme asthma from those companies that have adopted the industry best practices, as published by AISE.

Occasional cases still occur through accidental exposures, failure of controls, or poor operating practices, etc. But fortunately these are very rare.
Even though we can prevent the development of asthma / respiratory allergy, we know that employee sensitisation can still occur at a low level despite the best practice controls in place.

Some people are more susceptible to being sensitized at extremely low levels and we cannot predict who that will be.

This does not mean that these employees will develop occupational asthma, although they may be sensitized by low level exposures, the exposures are not significant enough to progress to symptomatic respiratory disease / asthma.

Under REACH the required DNEL Derived No Effect Level cannot be set for a sensitizer, and the AISE Task Force has defined a DMEL [Derived Minimum Effect Level] for pure enzyme as the starting point for setting limits in the detergent industry. You will hear more about this at a later date.
It would not be right to leave this session without some further but brief discussion on risk management and engineering controls – although we will devote detailed webinars to both of these topics, beginning on November 12th 2015 with a session on Risk Management.

Safe handling and use of enzymes, both solids and liquids, and manufacturing and packing of those products requires stringent controls, well defined operational procedures, and monitoring via air sampling. Health surveillance is the final step to ensure that what we are doing is actually protecting employees.

We have already discussed low dust solids, but we must not forget that we also use liquid enzymes and that these can form aerosols – sub micron liquid particles that can be inhaled and that can have the same effect.

Gentle processes [to prevent dust and aerosol] and a high level of engineering containment will ensure that any dust or aerosol produced will be physically contained. Process ventilation control will ensure that airborne dust or aerosol will not escape the process through gaps or deficiencies in containment, in addition to removing them from within that containment and allowing safer access should it be needed.

Spillages of raw materials and products must be prevented, and if they occur dealt with promptly.

Manual handling of enzymes must be avoided for all but the smallest volumes and always with stringent control measures.

For any potentially high risk task employees must utilize respiratory protection just in case an exposure occurs – afterwards is too late!
Before I take any questions I would just like to summarize this session. Enzymes are valuable and extremely beneficial ingredients in detergent products, they are safe for the environment, and have a great sustainability profile. Unfortunately they are respiratory sensitizers and can trigger a response from the human immune system, sometimes resulting in respiratory allergy – just the same as many natural proteins in our environment.

The experiences of the detergent industry in the early days of biological detergents has led to the development of best practices to manage the risk of handling and processing with enzymes. These continue to be refined as our knowledge and exposure control technologies develop, and they are now maintained and published by AISE. Enzymes can be safely handled and processed if best practice is implemented; this has been clearly demonstrated and has been the recent subject of a joint publication by ACI/AISE covering the last 10 years of the industry experience when following best practice. Those best practices will from the content of future webinars.
Any Questions?
The remaining webinars are curriculum based and will suit different audiences; but there is no restriction on who can attend them; feel free to join them all if you wish, or to download them when they are available on the AISE web site.

The topics as you can see cover everything from Risk Management Strategy, engineering controls and operational practices, through to workplace and performance monitoring, laboratory safety, health surveillance and consumer safety.

AISE will advise the dates for 2016 as soon as possible, but note that the next webinar is on 12th November 2015 at 14:00CET and will cover Risk Management Measures. That session will be presented by Anthony Panepinto from Procter & Gamble.

We strongly encourage you to join the live events because there will be opportunity for you to ask questions at the end of each session, and those questions will help the AISE team to further develop the training and guidance...so please take every opportunity to book the dates in your diaries as soon as they are published.
Thank you for attending today and I hope that you will join some or all of our future webinars.