

newsletter

Diacetyl

In 2000, the first descriptions appeared of workers developing a serious pulmonary disease (bronchiolitis obliterans) after having been exposed to flavouring substances at work. The widely used butter-flavouring agent Diacetyl is suspected to be the cause.

Background and bronchiolitis obliterans

In May 2000, eight people who worked for an American popcorn producer were diagnosed as suffering from bronchiolitis obliterans – the form observed in their cases being a rare and irreversible pulmonary disease. Four of the affected employees worked in a room where fragrance and flavouring substances were mixed for microwave popcorn; the other four were employed in the packing area. Further research involving 117 employees revealed a rate of chronic coughing and shortness of breath that was 2.6 times higher than the normal population average, as well as a doubled rate of asthma and chronic bronchitis. Among the non-smokers in the studied group, the rate of airway obstruction was over 10 times higher than in the normal population. Ambient air analyses in the plant detected over 100 different volatile, organic compounds. The predominant substance was the butter-flavouring agent Diacetyl. This resulted in the establishment of a correlation between the exposure of workers and the presence of the pulmonary disease, for which the term "popcorn worker's lung" was coined. However, the cases noted up to now are not restricted to this one producer; other companies, including producers of Diacetyl, have also reported cases of bronchiolitis obliterans in their employees. Around 200 cases have been established at present.
(Lit.: Kreiss K et al.: Clinical bronchiolitis obliterans in workers at a microwave-popcorn plant. New Engl J Med 2002; 347: 330-338).

Diacetyl, occurrence, use

Diacetyl (2,3-butanedione, dimethylglyoxal), CAS No. 431-03-8, is a yellow-green liquid with a characteristic strong odour that is sweet when in diluted form. Diacetyl is perceivable by the senses even in extremely small quantities. It occurs naturally in foods such as apples, vanilla, certain types of berries and wheat. It is also found in butter and cheese. In beer and wine, diacetyl is considered an undesirable flavour that may arise through biological processes during the production process. The substance is actively added to foodstuffs to create a characteristic butter flavour, and it has been widely used in the food industry for decades. Diacetyl can be produced chemically (from methyl ethyl ketone) and biochemically (from glucose or citric acid with the help of micro-organisms).

Toxicity

Pure diacetyl is an irritant for the eyes and skin, is especially harmful when inhaled, and causes coughing and shortness of breath. When consumed orally, diacetyl is not acutely toxic for human beings, with an LD50 value (oral, rat) amounting to 1.580 mg/kg of body weight. However, it can be demonstrated in animal studies that, when inhaled, mixtures of diacetyl and other volatile organic substances can be harmful even in small concentrations, such as the concentrations measured at the workplaces of the popcorn employees mentioned above.

Newer studies have now revealed further indications that diacetyl alone is responsible for the pulmonary disease. For example, the disease has also affected workers in the chemical industry who were directly exposed to vapours during diacetyl production.

(Lit.: Hubbs AF et. al.: Necrosis of nasal and airway epithelium in rats inhaling vapors of artificial butter flavoring. Toxicol Appl Pharmacol 2002; 185:128-135 / van Rooy et. al.: Bronchiolitis Obliterans Syndrome in Chemical Workers Producing Diacetyl for Food Flavorings. Am J Respir Crit Care Med 2007;176(5):427-429).

Maximum permissible values for fragrances and flavouring substances

Further scientific studies and research conducted by public authorities support the suspected link between inhaled diacetyl exposure and bronchiolitis obliterans, although no causal relationship has as yet been established, and so no standardised IDLH (immediately dangerous to life and health) or PEL (permissible exposure limit) values have been specified for the maximum diacetyl concentrations permitted in the workplace. The same is true in general for most fragrances and flavouring substances, with only around 5% of these regulated by workplace-related limits in the USA. Furthermore, the safety data sheets (MSDS) for these substances mostly do not contain any information about work-related exposure (particularly inhalation) and are often not maintained at the latest standard of knowledge.

Diacetyl has been approved by the FDA (Food and Drug Administration, USA) for use as a foodstuff additive since the 1980s and has been granted "GRAS" (generally recognised as safe) status, which means that the use of diacetyl in food has been considered safe up to now. Here, however, it should be noted that inhalation, and especially chronic, work-related exposure has not been taken into account for evaluation purposes.

Voluntary product elimination

The safety of diacetyl is currently being examined by regulatory bodies on the basis of published findings, especially with regard to chronic inhalation exposure. Meanwhile, at least two large American popcorn producers have independently announced that they will no longer use diacetyl, as a precautionary measure (as of November 2007).

Exposed sectors and demographic groups

According to a survey (NOES, national occupational exposure survey) conducted between 1981-1983 in the USA, it is estimated that approx. 3,500 persons in the USA were exposed to diacetyl in their working environment.
(Lit.: www.cdc.gov/noes/noes4/84595sco.html)

The exposed industry branches can be divided into four groups:

- Chemical and biochemical companies that produce diacetyl
- Companies that process diacetyl, especially fragrance and flavouring producers
- Companies that produce food containing diacetyl, e.g. (microwave) popcorn, cookies and pastries, ice cream
- Logistics companies (transport, storage, packaging) in which persons come into contact with diacetyl and goods containing diacetyl

Besides those persons exposed on a work-related basis, consumers also potentially come into contact with products containing diacetyl, such as microwave popcorn. If this could be shown to have negative effects, then we would need to anticipate very high numbers of persons concerned. However, apart from the case cited below, there are presently no indications for this.

Case study

In July 2007, the following case study was published in the USA: A patient displayed the same clinical symptoms as had the employees of the popcorn producer mentioned earlier. The sufferer indicated that he had consumed large amounts of microwave popcorn on a daily basis for several years. This did not represent a case of work-related diacetyl exposure. Measurements of the diacetyl concentrations present during the production of microwave popcorn in the patient's kitchen revealed values comparable to those found at the popcorn producer workplaces. It could not be conclusively demonstrated that the patient's daily diacetyl exposure was the cause of his pulmonary disease, but the authors found no other plausible explanation for this case.

(Lit.: www.fda.gov/ohrms/dockets/dockets/06p0379/06p-0379-let0002-01-vol2.pdf)

Lawsuits

It appears that exposure to high concentrations of diacetyl at work has resulted in pulmonary damage in approx. 200 workers, and has caused at least three deaths (as of 2007). In the USA, numerous lawsuits are pending and compensation has already been granted in some cases. For example, one popcorn producer employee suffering from bronchiolitis obliterans was awarded over 2.7 million USD. Entries related to diacetyl are found on numerous American law firm websites.

Information for the underwriter

Since the first described cases of bronchiolitis obliterans in the employees of a popcorn producer in 2000, there have been increasing indications that the disease is caused by inhalation of the flavouring agent diacetyl. In the USA, compensation payments have already been made, so far on the basis of employers' liability. There are also product liability lawsuits pending for which an outcome is not yet foreseeable.

It is not yet clear how many people will eventually turn out to have been affected by it at work, for this largely depends on whether the results of new studies are able to demonstrate a scientifically founded causal connection between inhalation exposure and pulmonary damage and whether future bans and maximum limits shall be introduced. A damage potential many times higher would be indicated if it were demonstrated that consumers, e.g. regular consumers of microwave popcorn, were suffering from bronchiolitis obliterans due to this, giving them a basis to assert claims for damage. In this case, it would be necessary to anticipate very high numbers of claimants. Currently there are no indications for this, apart from a single case study.

It is recommended to continue observing the scientific developments in this area. For technical assessment, any potential work-related diacetyl exposure should be queried and evaluated, especially in the USA. Due to the long-tail character of the phenomenon, past-occurring exposure is also relevant.

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