

## VI. DEVELOPMENT OF STANDARD

### Basis for Previous Standards

In 1964, the American Conference of Governmental Industrial Hygienists (ACGIH) [86] proposed 5 mg/cu m as a tentative Threshold Limit Value (TLV) for benzoyl peroxide. The TLV is a TWA concentration for an 8-hour workday, 40-hour week. This 5 mg/cu m limit was adopted by the ACGIH in 1966 and has remained unchanged [87]. In 1976, the ACGIH reported a tentative short-term exposure limit (STEL) of 5 mg/cu m for benzoyl peroxide. The ACGIH defines the STEL as the maximum allowable concentration, or absolute ceiling, not to be exceeded at any time during the 15-minute excursion period [88].

The 1974 revision of the 1971 documentation [89] and the 1966 documentation [90] cited inhalation data from the unpublished industrial hygiene survey [31] of a benzoyl peroxide manufacturer in November 1950. The two plant inspectors experienced pronounced nose and throat irritation when the concentration of benzoyl peroxide in airborne dust was 12.2 mg/cu m, but they noted no adverse symptoms at 1.34-5.25 mg/cu m. Potassium aluminum sulfate and magnesium carbonate were also present simultaneously with the airborne benzoyl peroxide. The authors, Moskowitz and Burke [31], failed to isolate a single component of the dust as the irritant.

In 1966, the Pennsylvania Department of Health [91] listed an 8-hour TWA concentration of 5 mg/cu m for benzoyl peroxide. This value was based on the ACGIH TLV [87]. Pennsylvania also listed a short-term exposure limit of 10 mg/cu m for 15 minutes for airborne benzoyl peroxide. The Pennsylvania Department of Health [91] cited a report by Kayanovich et al

[92] that exposure to starting materials in the manufacture of benzoyl peroxide or to benzoyl peroxide itself caused respiratory tract irritation, increased numbers of monocytes, and disturbances in ventilatory function. However, Kayanovich et al [92] indicated that the production of benzoyl peroxide was carried out in an enclosed system and was not accompanied by the release of any toxic substance into the air. Benzoyl chloride and phosgene were starting materials to which the workers were exposed. The authors [92] indicated that the toxic effects seen in workers were consistent with those that would be expected with exposure to phosgene and benzoyl chloride.

In 1968, a report of the International Labour Office [93] listed 5 mg/cu m as the maximum allowable concentration for benzoyl peroxide in the Federal Republic of Germany. Winell [94], in a summary of hygiene standards in different countries for chemicals in the work environment, wrote that the Committee of the German Research Association based this value on the ACGIH TLV. The Maximale Arbeitsplatzkonzentrationen 1976 stated that benzoyl peroxide has very little effect on skin [95]. The International Labour Office [96], in a 1976 tabulation of permissible levels of toxic substances, listed 0.05 mg/cu m as the limit for benzoyl peroxide in Bulgaria and 5 mg/cu m in Belgium, Finland, the Netherlands, and Switzerland. The International Labour Office did not provide the bases for these values.

The present federal standard (29 CFR 1910.1000) for exposure to benzoyl peroxide in the workplace is an 8-hour TWA concentration limit of 5 mg/cu m. This was based on the 1968 ACGIH TLV [97].

## Basis for the Recommended Standard

### (a) Permissible Exposure Limits

Inhalation of airborne dust containing benzoyl peroxide has caused irritation in humans [31] and animals [42]. Nose, eye, and throat irritation were reported by two state inspectors at a plant where benzoyl peroxide was used [31]. They experienced this irritation on 3 days when the concentration of airborne benzoyl peroxide ranged between 1.34 and 82.5 mg/cu m. The interpretation by the ACGIH TLV Committee indicated that no irritation occurred when the concentration of benzoyl peroxide in air was 5.25 mg/cu m or lower. Although this view may be correct, the lack of details in the report makes verification of this interpretation impossible. The inspection report did not specifically state that benzoyl peroxide was the cause of the discomfort or whether potassium aluminum sulfate or magnesium carbonate in the dust caused or contributed to the irritating effects. The methods of analyses were not described. Since there is no validated method of sampling and analysis for benzoyl peroxide, the method used to analyze the collected samples was probably not specific for this compound. The possible toxic effects of airborne benzoyl peroxide on humans cannot be accurately assessed because the report lacks essential data.

Studies have indicated no carcinogenic [49-51] or mutagenic [52,53] effects from benzoyl peroxide. Sharratt et al [49] found that benzoyl peroxide had no carcinogenic activity from skin painting of mice, subcutaneous injection in mice and rats, and feeding studies in mice and rats. Van Duuren et al [51] reported that benzoyl peroxide showed no carcinogenic activity when used in skin painting experiments in mice.

Hueper [50] found that rats implanted with encapsulated benzoyl peroxide developed no tumors at the site of implantation. Epstein et al [52] observed that benzoyl peroxide demonstrated no mutagenic activity when tested in a modified dominant lethal assay. Benzoyl peroxide exhibited no mutagenic activity in bacteria and yeast [53]. No teratogenic studies or epidemiologic surveys were found.

The ACGIH [90] documentation of 5 mg/cu m as the recommended limit is primarily based on the report by Moskowitz and Burke [31] which, the ACGIH interpreted, indicated that no adverse symptoms were observed by two plant inspectors when the concentration of airborne benzoyl peroxide remained under 5.25 mg/cu m. (As commented above, verification of this interpretation is impossible because the report had insufficient detail.) Few pertinent toxicologic data on humans have been found in the literature. The animal data in the literature suggest that benzoyl peroxide is not a toxic compound, although no definitive studies have been found. The major hazard is injury or death resulting from fires and explosions caused by benzoyl peroxide [3,40,41].

The available epidemiologic and toxicologic evidence on benzoyl peroxide is insufficient to allow derivation of a new environmental limit or to warrant a change in the present environmental limit. It is recommended, therefore, that the present permissible exposure limit of 5 mg/cu m as a TWA concentration be retained. Because of the apparently low degree of toxicity of benzoyl peroxide, the action level is defined as equal to the environmental limit.

(b) Sampling and Analysis

It is recommended that airborne dust containing benzoyl peroxide be collected on a glass-fiber filter and analyzed gravimetrically. If the total airborne dust concentration is 5 mg/cu m or less, no further analysis need be done. If the total airborne dust concentration is greater than 5 mg/cu m, a total peroxide analysis should be performed on the material collected on the filter. A colorimetric analysis, developed from a method by Dolin [62], was selected for benzoyl peroxide because it is simple, reliable, and sensitive. However, the selected method is not specific for benzoyl peroxide; other peroxides can interfere. A method [63] specific for benzoyl peroxide, involving high pressure liquid chromatography, as described in Chapter IV, should be used if other, nonspecific methods, such as total peroxide analysis, show concentrations greater than 5 mg/cu m.

(c) Medical Surveillance and Recordkeeping

Little information has been found on the toxicity of benzoyl peroxide, so frequent comprehensive medical examinations are not proposed as a requirement. However, there is some evidence that benzoyl peroxide and its degradation products, including benzoic acid, cause sensitization. This sensitization should especially be looked for in the preplacement examinations, which should include an examination of the skin.

(d) Personal Protective Equipment and Clothing

Clothing worn and equipment used by employees while working with benzoyl peroxide and its formulations should be constructed of materials that will not cause sparks, friction, heat, or shock. Because there is some evidence that benzoyl peroxide and its breakdown products cause irritation and sensitization, protective clothing and equipment, such as

gloves, aprons, and goggles or safety glasses with side shields, are recommended.

Respirators with cartridges or canisters containing activated charcoal or other oxidizable material should not be used because benzoyl peroxide is a strong oxidizer. On respirators, holders of replaceable filters should not have threads.

(e) Informing Employees of Hazards

The employer should initiate a continuing education program to ensure that employees have current knowledge of job hazards and of proper work practices and emergency procedures. Employees also should be informed that irritation and sensitization can possibly be caused by benzoyl peroxide and its breakdown products.

(f) Work Practices

Work practices are discussed in Chapter V. In operations involving the manufacture, use, or storage of pure benzoyl peroxide, the potential for skin, eye, throat, and nose irritation and for fire and explosion is greater than that for any of its formulations; protective clothing and equipment should be worn whenever required to prevent inhalation of benzoyl peroxide or eye and skin contact with it. Protective clothing, conductive shoes and floors, grounded machinery, and other engineering controls used to ensure a spark- and shock-proof environment will minimize the dangers from fire and explosion. Smoking, open flames, or any other source of ignition should be prohibited in benzoyl peroxide exposure areas to prevent fires and explosions. Engineering controls must be used when needed to keep concentrations of airborne benzoyl peroxide below the recommended limit.

(g) Monitoring and Recordkeeping Requirements

The workplace environment should be monitored semiannually and the records retained for 30 years. Since no chronic effects of benzoyl peroxide have been found, retention of environmental and medical records of employees for more than 30 years after termination of a worker's employment is unnecessary.

## VII. RESEARCH NEEDS

Further study is needed to properly assess the toxicity of benzoyl peroxide and to evaluate its potential hazard to the working population. Presently, little is known about its toxic effects. The effects of long-term exposure to benzoyl peroxide, particularly those caused by ingestion and inhalation, should be studied, especially to determine if there are any carcinogenic, mutagenic, teratogenic, or other systemic changes.

Little information has been found concerning the possibility of absorption benzoyl peroxide through the skin, although skin contact is the most common route of human exposure. Studies should determine if benzoyl peroxide is altered during specific manufacturing processes and if the resulting residues can cause skin irritation or other adverse effects. Metabolic studies might provide information about the extent to which metabolites of benzoyl peroxide are responsible for toxic effects.

Research is necessary to assess the explosiveness and other hazards of exposure to benzoyl peroxide and its formulations. Laboratory experiments should be designed to provide information that can be extrapolated to full-scale decompositions, fires, and explosions and thus aid the development of a standard hazard classification system which would facilitate safe, consistent labeling, handling, and storage of benzoyl peroxide and its formulations. The sampling and analytical techniques used should be ascertained to be safe and reliable.

More specific work practices should be developed. The most appropriate protective clothing and respirators for particular processes



should be determined, and waste disposal procedures that are safe and effective and that comply with current pollution control regulations should be formulated.

#### VIII. REFERENCES

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