

# *Sandstorm:* Current Issues Surrounding Silica

*Understanding the latest developments*

By David D. Glenn

**I**F YOU BELIEVE SILICA is no longer a significant occupational health hazard, think again. While silicosis-related deaths are declining and some industries with silica exposures employ fewer U.S.-based workers, other factors have increased the significance of this topic for SH&E professionals (CDC, 2005, pp. 401-402). Toxic tort litigation and a new exposure limit are the principal developments in this long-known hazard area. Reactions to these developments have involved the insurance industry as well as state and federal legislators and rule makers.

## **Silica & Its Effects**

Silica consists of the chemical compound silicon dioxide (SiO<sub>2</sub>). Separately, silicon and oxygen comprise 75% of the earth's crust (U.S. Bureau of Mines, 1992, p. 4). Silica's physical structure can include crystalline and amorphous forms. The crystalline structure can be classified further into seven polymorphs. The three most common polymorphs are quartz, cristobalite and tridymite. Although silicon is a component in silicates and silicones, those are separate compounds from silica (Figure 1, p. 38). Crystalline silica can be inhaled deeply into the lungs when it is a respirable size of less than 10 µm (NIOSH, 2002, p. xvi). Crystalline silica of respirable size (hereafter referred to as "silica") is the occupational health concern of this article.

Occupational exposure to silica can result in silicosis and other diseases. Respiratory effects of working with stone were observed in ancient times and by the pioneers of occupational health. The term *silicosis* dates from the 1870s (Rosenman, Reilly, Yoder, et al., 2006, p. 3). The disease consists of inflammation of the respiratory system tissues that eventually causes fibrosis, which reduces the ability to breathe efficiently (Spraycar, 1995, p. 1620). Although silicosis is most often associated with chronic exposures, acute silicosis can occur as well (NIOSH, 2002, p. 23).

Other silica-related respiratory diseases include emphysema, pulmonary tuberculosis, bronchitis, asthma and lung cancer. Nonrespiratory diseases that appear to have an epidemiological relationship to sili-

ca exposures include autoimmune diseases, scleroderma and chronic renal disease (NIOSH, 2002, p. 2).

In 1997, the International Agency for Research on Cancer (IARC) changed its classification of "inhaled crystalline silica in the form of quartz or cristobalite" to "carcinogenic to humans (Group 1)" (p. 7). In the U.S., the National Toxicology Program (NTP) followed suit in 2000 by classifying "silica, crystalline (respirable size)" as "known to be a human carcinogen" (2005, p. 1). Both the IARC and NTP classifications are binding for OSHA's hazard communications requirements for chemical hazard determination in regard to carcinogenicity (OSHA, 1996).

## **Exposures, Mortality & Epidemiology**

Exposures to silica exist in mining, agriculture, construction and some manufacturing sectors. OSHA estimates that more than 2 million employees are exposed to silica in general industry, construction and maritime industries (U.S. Department of Labor, 2007). NIOSH acknowledges that an unknown number of the 3.7 million workers engaged in agriculture have exposure to silica from dust-generating activities (NIOSH, 2002, p. 22). Silica is present in nearly all mining operations (U.S. Bureau of Mines, 1992, p. 15).

The mere presence of silica does not necessarily constitute exposure. Mechanical processes can create an exposure by reducing the silica to respirable size, entraining the particles in breathable air and possibly altering the particles' surface characteristics (NIOSH, 2002, p. 41). Freshly fractured silica particle surfaces are more reactive than aged ones (IARC, 1997, p. 3).

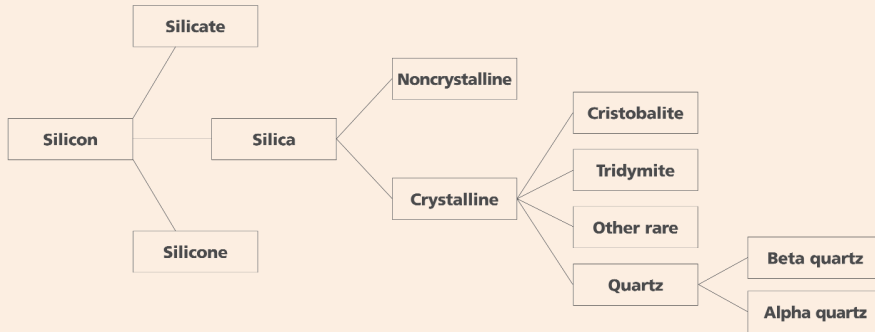
Although the exposure is present in many occupational environments, are the exposure levels problematic? A study initiated by American Conference of Governmental Industrial Hygienists' (ACGIH) Construction Committee compiled exposure data from 1,374 breathing zone samples collected from 1992 to 2002 (Flanagan, Seixas, Becker,

**Abstract:** *While many SH&E professionals may view exposure to respirable crystalline silica as an issue of declining significance, recent developments in the legal, regulatory and insurance fields have increased its contemporary importance. A controversial threshold limit value for silica and toxic tort litigation are the primary initiators of reactions by respirator manufacturers, the insurance industry, state legislatures and Congress. Intertwined chronologically with these developments has been safety research in areas of silica exposure and mortality, as well as revised and developing national standards on the subject.*

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Figure 1

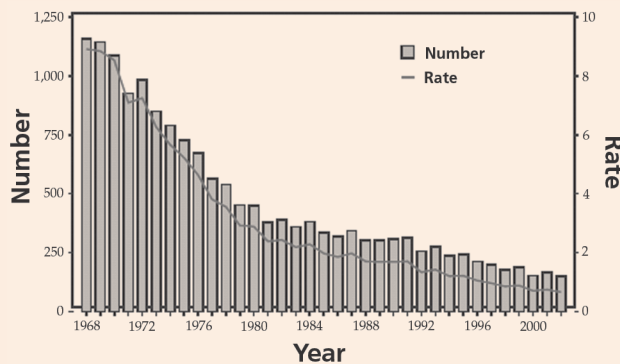
## Relationship Between Forms of Silica



Note. From *Crystalline Silica Primer* (p. 11), by U.S. Bureau of Mines, Washington, DC: Author, Branch of Industrial Minerals.

Figure 2

## Silicosis Deaths & Mortality



Note. Number of silicosis deaths and age-adjusted mortality rate, per million persons aged  $\geq 15$  years, by year—National Occupational Respiratory Mortality System, U.S., 1968-2002. Reprinted from "Silicosis Mortality, Prevention and Control—United States 1968-2002," by Centers for Disease Control and Prevention (CDC), Apr. 29, 2005, *Morbidity and Mortality Weekly Report*, 54(16), pp. 401-405.

et al., 2006, p. 145). The measured airborne concentrations had a central tendency of  $0.13 \text{ mg/m}^3$ . This level is 260% of ACGIH's pre-2006 exposure limit. A 13-year review of silica samples obtained during OSHA inspections found average exposure levels exceeded that agency's exposure limit in 48% of the 255 sampled industries (NIOSH, 2002, p. 6). The number of workers exposed at these levels is not known nor is the level of protection offered by respiratory protection programs.

In April 2005, NIOSH published silicosis annual fatality data in the U.S. during 1968 to 2002 based on data from the National Center for Health Statistics. Of the 16,305 death certificates that coded silicosis as the leading or contributing cause of death, the annual total decreased steadily each year from 1,157 to 148 (CDC, 2005, p. 401). Figure 2 displays the number of silicosis-related deaths by year. It has also been noted that the highest concentrations of silicosis-related deaths generally appear to occur in areas associated with mining industries.

Less information appears to be available concerning the prevalence of silicosis cases among the living.

Bureau of Labor Statistics (BLS, 2002) acknowledges that its annual survey of injuries and illnesses undercounts "long-term latent illnesses" because such cases are more likely to be underrecorded by sampled employers. Some experts in the occupational medicine and toxicology fields believe the available national disease prevalence data for silica is inadequate (Nash, 2004).

An August 2006 report from the state of Michigan's silicosis surveillance program estimates that between 3,600 and 7,300 new cases of silicosis are diagnosed each year in the U.S. (Rosenman, et al., 2006, p. 1). This estimate was extrapolated from actual counts of confirmed silicosis cases from the following Michigan sources: hospital reports, doctor reports, death certificates and state fund claims (Rosenman, et al., p. 4). Most other states do not have as meticulous a process for collecting this information.

### Enter the Mississippi Cases

Regardless of the actual prevalence of silicosis, the state of Mississippi began to show an anomalous increase in silicosis claims in 2002. From annual totals of less than 100 claims before that year, the next 3 years saw silicosis claim frequencies of 10,642, 7,228 and 2,609 (Jack, 2005, p. 12). Compare this to the silicosis-related deaths in one of "America's worst industrial tragedy—the Hawk's Nest Tunnel," where approximately 764 died of acute exposure and approximately 1,500 more manifested the disease (Stalnaker, 2006, p. 27, 31).

Even if silicosis cases are underdiagnosed, the state of Mississippi seemed to be one of the least likely locations for an epidemic. For the period 1990 to 1999, NIOSH (2003, p. 58) ranked Mississippi 43rd in a state ranking of age-adjusted mortality rates for silicosis.

The Mississippi cases entered the tort system and eventually named approximately 250 corporate defendants that made products which contained silica, worked with silica or protected workers from exposure to silica (Jack, 2005, p. 16). A panel of federal judges may consolidate pretrial proceedings to a single district where common questions of fact are pending in different districts (Jack, p. 15). In September 2003, such "multidistrict litigation" (MDL) was established for the 107 Mississippi cases and four more cases from Kentucky, Texas and Missouri (Jack, p. 10, p. 17). More than 10,000 plaintiffs were included in this litigation (Jack, p. 1).

### The Next Asbestos?

Within a week of the MDL's establishment, several national news outlets drew parallels between this silica litigation and the early stages of asbestos litigation (Stocker, 2006, p. 1). At the time, liability arising from asbestos exposures was estimated to have involved 8,400 companies and 600,000 claimants

with associated costs to defendants and their insurers of \$54 billion (Hartwig & Wilkinson, 2004, p. 13). Associating silica with the ever-escalating costs of asbestos liability could be expected to result in defensive measures by potentially liable parties.

By April 2004, insurance companies had, for the first time, begun to exclude coverage for silica in its renewing policies, according to a survey of insurance agents and brokers (The Council of Insurance Agents & Brokers, 2004, p. 2). Standard & Poor's, which provides insurance-company-specific "financial strength ratings," added silica exposure to its insurer evaluation process by June 2004 (Hartwig & Wilkinson, 2004, p. 11). In July 2004, the Insurance Information Institute, referring to the lessons from asbestos claims, cited a reinsurance company's analysis that policy exclusions of silica coverage appear to be the most reliable defensive measure (Hartwig & Wilkinson, p. 17). Common wording for exclusion endorsements to commercial liability and commercial umbrella policies were issued by ISO Properties Inc. in March 2005.

In the author's experience, insurance companies took several measures in addition to changing wording in policies. By mid-2004, many underwriters and loss control representatives began asking current and prospective insureds about present and past silica exposures. The process involved identification of exposure sources, review of quantified exposure assessments and review of control measures. Unfavorable responses in these areas sometimes resulted in nonrenewal/declination of coverage or urgent compliance with the insurance carrier's improvement recommendations. In several instances, the silica issue outweighed other underwriting considerations.

Complicating some of these decisions were questions about whether to apply OSHA's or ACGIH's exposure limit, the differences between which are discussed shortly. In its financial statements, one insurer cited "intentional underwriting actions, including reductions in certain silica-related risks . . ." to explain lost premium income in 2004 (Mense, 2006, p. 35). An underwriting journal advised providing at-risk insureds only with "claims made" general liability coverage with a retroactive inception date so coverage would not apply to any claims not reported previously (Brauer, 2005, p. 9).

### Testifying Medical Experts Are Examined

While the insurance industry was reacting to silica's toxic tort potential, the MDL had some interesting developments. Justice Janice Graham Jack (2005) had requested submission of plaintiff-specific factsheets to help sort through relevant details (p. 22). From this, she identified that all 9,083 plaintiffs who submitted factsheets were diagnosed by only 12 doctors and that 9 of those doctors had diagnosed 99% of those plaintiffs (Jack, p. 117, 144). Furthermore, 8,201 plaintiffs were involved with only two screening companies (p. 63). The doctor with the largest number of these diagnoses—3,617—provided the following when he was deposed in October 2004 (pp. 32-38):

- He did not know the criteria for diagnosing silicosis.

- He reviewed an average of 75 files per day, often after his regular workday.

- Every one of his diagnoses used identical language that he later agreed overstated both what he did and what degree of medical certainty was involved in the diagnosis.

According to his deposition, this doctor believed he was only confirming diagnoses made by another doctor. This understanding allegedly was provided by the screening company that hired the doctor for this function, coordinated the information collection process and added the diagnosis language to his verbal report. The doctor's testimony essentially withdrew the diagnoses upon which much of the MDL depended.

To determine whether that deposition was anomalous or representative, Justice Jack arranged for hearings of the remaining diagnosing doctors and two screening companies. In the interim, two more diagnosing doctors, involved in approximately 600 of the MDL cases, were deposed. They, too, denied making diagnoses and allowed the screening company to generate the written reports. They differed from the first doctor in that they actually saw their patients and signed their reports.

A fourth doctor, who had a primary diagnostic role in 2,600 cases, distinguished the legal diagnoses he made from "a real diagnosis" (Jack, 2005, p. 81). He did not write, read or sign any of the reports issued in his name (Jack, p. 84). The defense demonstrated that this doctor had previously diagnosed 1,807 of the claimants in the silicosis litigation with asbestosis in earlier litigation (Jack, p. 90). Although concurrent manifestation of silicosis and asbestosis is a clinical rarity, 60% of the silicosis claimants had previously filed asbestos-related claims (Brickman, 2006, p. 14).

Testimony from the next five doctors in February 2005 revealed that most diagnoses had the following methodological problems:

- Exposure and medical histories were cursory and/or collected by nonmedical professionals.

- Physical exams usually did not occur.

- Rate of diagnoses generated strained credibility (e.g., one doctor performed 1,239 evaluations in 72 hours).

- Interpretations of X-rays resulted in far more consistent readings than would be statistically plausible.

Inconsistencies were uncovered between how a few of these physicians treated patients in their private practices and how they treated the plaintiffs. In

## Hawk's Nest Tunnel

To provide water from the New River to a power station in Gauley Bridge, WV, a 3-mile-long tunnel was burrowed through Gauley Mountain in 1930-31. The Hawk's Nest Tunnel was mined through silica-rich material. Although wet drilling methods were used on some of the drills at least some of the time, the speed with which the project was completed suggests that such controls were not used consistently. Similarly, other control methods, such as settling time following detonation and forced air ventilation were not applied reliably. Respiratory protection was not provided at all. Monitoring of air contaminant levels or workers' medical conditions was not performed. Most workers were transient and from a Depression-era labor pool that could be replaced easily. Of the estimated 2,500 people who worked underground on the project, approximately 764 died from acute silicosis and an additional 1,500 had the disease.

*Note. Summarized from "Hawk's Nest Tunnel: A Forgotten Tragedy in Safety's History," by C. Keith Stalnaker, October 2006, Professional Safety, pp. 27-33.*

fact, the doctor who provided 1,389 diagnoses for the MDL failed to follow the silicosis diagnosis criteria he had published in textbooks (Jack, 2005, p. 103). Another doctor distinguished between his “patients” and his “clients” (Jack, p. 110).

Highlights from the primary screening company’s testimony included the following (Jack, pp. 63-79):

- The screening company had no medical director, medical supervision or medical doctor order to perform X-rays.
- The law firms that hired the screening company indicated what medical information to collect, such as X-rays, pulmonary function tests or exposure histories.
- Tested personnel were identified either from prior asbestos claims or mass advertising, asked cursory exposure questions by nonmedical personnel, then given X-rays in a mobile trailer at a prearranged parking lot, such as at a hotel or retail business.
- The screening company was paid by the law firm only if tested personnel were diagnosed with silicosis and engaged the law firm to represent their claim.

### The Ruling

Justice Jack (2005) ultimately ruled that, with one exception, she did not have jurisdiction to decide the cases originally in the MDL. However, her ruling detailed the pervasive methodological flaws in the plaintiffs’ medical evidence so that downstream jurisdictions would know what was uncovered in the MDL (p. 154). She summarized the exposure and occupational histories of the claimants as follows:

... the evidence shows that none of the challenged experts took an occupational or exposure history. They all relied upon a history taken by lawyers and clerks with no medical training or supervision. The questions asked were not drafted by physicians, testifying or otherwise; indeed, the challenged physicians were not even aware of what questions were asked (p. 126).

Jack (2005) summarized the flawed diagnosis process as follows:

By dividing the diagnosing process among multiple people, most of whom had no medical training and none of whom had full knowledge of the entire process, no one was able to take full responsibility over the accuracy of the process. This is assembly line diagnosing. And it is an ingenious method of grossly inflating the number of positive diagnoses (p. 146)

In a section of her ruling titled “Lawyers Practicing Medicine and Doctors Practicing Law,” Jack (2005) contrasted the nine doctors who made 99% of the factsheet-supported MDL diagnoses with the 8,000 treating physicians with whom the plaintiffs were otherwise associated:

This small cadre of nontreating physicians, financially beholden to lawyers and screening companies rather than to patients, managed to notice a disease missed by approximately

8,000 other physicians—most of whom had the significant advantage of speaking to, examining and treating the plaintiffs (p. 144).

Jack (2005) described the plaintiff attorneys’ conduct as follows:

... the lawyers determined first what disease they would search for and then what criteria would be used for diagnosing that disease. The lawyers controlled what information reached the diagnosing physicians, stymying (*sic*) the physician’s normal ability to ask targeted follow-up questions and perform follow-up exams. The lawyers also controlled what information reached the patients, stymying the patient’s normal ability to learn from a medical professional details about their diagnosis, their prognosis, and what, if any, follow-up care they should receive. ... In the majority of cases, these diagnoses are more the creation of lawyers than of doctors (pp. 148-149).

After noting that none of the involved parties had notified public health authorities about the apparent outbreak of silicosis, Jack (2005) asserts “these diagnoses were about litigation rather than healthcare ... these diagnoses were driven by neither health nor justice: They were manufactured for money” (p. 150). The ruling was issued at the end of June 2005.

### Effects of the Ruling

The aftermath of this ruling impacted mass tort litigation prospects for both silicosis and asbestosis. State-level legislation has specified medical criteria for silica and asbestos cases that decreased related claims 90% in Mississippi and 65% in Texas (Behrens & Cruz-Alvarez, 2006, p. 1). Several other states have current or pending legislation to ensure that future medical testimony in this area is credible.

In the U.S. House of Representatives, a subcommittee of the Energy and Commerce Committee held hearings on this issue starting in March 2006 in which most of the testifying MDL doctors and screening companies invoked their Fifth Amendment right against self-incrimination (Hofmann, 2006, p. 4). In September 2005, the organization that settles most asbestos-related claims suspended acceptance of medical reports from the nine doctors and two screening companies challenged by the silica MDL (Austern, 2005, p. 1).

Will the insurance industry’s view of silica improve in light of the discredited litigation and favorable legislation? As of this writing, the answer appears to be “not yet.” As one legal analyst contrasted future claims with those of the MDL, “This provides no assurance, however, that judges will permit the same level of discovery as allowed by Justice Jack where equally bogus silica and asbestos litigation is brought in other venues” (Brickman, 2006, p. 20). Another analyst warns that lobbying by plaintiff attorneys may limit or undo legislative or judicial barriers to the growth of such litigation (Stocker, 2006, p. 16).

At the 2006 Risk & Insurance Management Society conference, an industry executive listed silica among the “emerging issues” of concern to workers’ compensation underwriters (Zolkos, 2006, p. 16). In a 2006 overview of the U.S. primary casualty, umbrella and excess liability insurance markets, an industry publication listed silica among the “next asbestos” subjects for which underwriters continue to restrict or exclude coverage (Lloyd’s List, 2006, p. 18).

### **A New Exposure Limit for Silica**

While the risk management and legal aspects of silica have been significant, of more immediate relevance to SH&E professionals are the changing exposure limits. In its 2006 annual update of threshold limit values (TLVs), ACGIH (2006b) adopted its previously proposed 8-hour time-weighted average concentration for Silica, Crystalline:  $\alpha$ -Quartz and Cristobalite to 0.025 mg/m<sup>3</sup> (p. 50). The pre-2006 TLV was double that concentration or 0.05 mg/m<sup>3</sup>. This change is based on avoidance of lung cancer (ACGIH, 2006a, p. 13).

The adoption of TLVs for silica and three concurrent substances was opposed unsuccessfully in federal court by industry groups primarily on the grounds that these limits would become governmentally binding without having to go through the process of regulatory rulemaking (BNA, 2005, p. 254). ACGIH’s TLVs continue to be challenged by additional industry-backed litigation and developing federal legislation for reasons related to whether OSHA unlawfully delegates its rulemaking authority to a private corporation and whether ACGIH’s processes are sufficiently transparent (BNA, 2006, p. 483).

Objecting to the silica TLV in particular, a panel of the American Chemistry Council wrote to Labor Secretary Elaine Chao in March 2006 to request that MSDS preparers not be required to include the new TLV (Crolius, 2006, p. 1). This is a remarkable development given that the American Chemistry Council is secretariat to the ANSI standard for MSDS preparation which lists TLVs among the criteria for determining the existence of health hazards (ANSI, 2004, p. 27).

SH&E professionals—for whom reliance on the TLVs is axiomatic—will be surprised to learn that the 2006 TLV is omitted from the most comprehensive occupational health standard for silica, ASTM’s Standard Practice for Health Requirements Relating to Occupational Exposure to Respirable Crystalline Silica (E1132-2006). The 1999 version of this standard referenced the TLV in effect at that time; when the updated standard was published in early 2007, it made no reference to either TLV. This omission is emphasized by the standard’s inclusion of an appendix of 23 other occupational exposure limit values (ASTM, 2007, p. 15).

In the regulatory area, both OSHA and MSHA are revisiting their silica-related requirements according to the April 2007 rulemaking agenda published by the Department of Labor (2007, p. 22857, 22861). Although both regulatory actions are far from becoming final rules, exposure limits are among the silica-related sub-

jects currently being considered by the agencies. Both agencies’ exposure limits for silica are based on ACGIH TLVs from the 1960s and early 1970s.

Both *Federal Register* notices reference more current exposure limits recommended by ACGIH (pre-2006) and NIOSH. The current OSHA permissible exposure limit (PEL) varies with the percentage of quartz present in a given sample (OSHA, 1997). Therefore, the PEL is compared to the concentration of respirable dust while the TLV is compared to the concentration of silica quartz (Hofman & Hofman, 2003, p. 6). If new regulatory exposure limits are based on the current TLV, the legally enforceable limits will be reduced drastically. One analyst cites this development as one factor that could fuel additional silica-related litigation because it calls into question the effectiveness of earlier standards (Stocker, 2006, p. 16).

### **Respirator Manufacturer Liability**

An aspect of silica-related litigation that affects SH&E professionals in many unexposed industries is the claims involving respirator manufacturers. According to a June 2006 letter to President Bush from six CEOs of disposable respirator-manufacturing companies, the industry received more than 300,000 silica-related claims between 2002 and 2004 that alleged defective design and inadequate warnings (McLain, Hornstein, Magidson, et al., 2006, p. 2). In the letter, the industry says it will “exit the marketplace” or otherwise reduce production capacity if protective legislation is not passed.

Given the recommended use of disposable respirators in the response to a flu pandemic (DHHS, 2006), this constraint on supply could have grave consequences for responders in contact with infected individuals. The product liability protection offered a bill that was introduced in February 2007 in the House of Representatives (HR 961), however, covers more than silica-related issues by offering blanket immunity to respirator manufacturers and sellers against all defect claims if the subject respirator’s design and labeling is NIOSH-compliant (Shuster, 2007).

### **Conclusion**

For SH&E professionals in industries associated with past or current silica exposure, the liability and insurance coverage considerations increase the importance of developing and maintaining credible documentation related to site-specific exposure assessments and exposure control measures. Interpretation of exposure assessments should include comparisons to both the OSHA PEL and the 2006 ACGIH TLV. Loss control professionals should be aware that underwriting decisions in this area are influenced more by litigation risk than by health risk. All SH&E professionals should be aware that the silica TLV is undergoing significant legal and industry acceptance challenges and that OSHA’s and MSHA’s limits may change.

While there has been much opportunistic claim filing in this occupational disease area, SH&E professionals should remind all parties that there are

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true victims of silica-related diseases. This is especially important because while the severe effects of silica exposure are known the actual prevalence of silica-related diseases is not measured rigorously. ■

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