

Health Consultation

FLINTKOTE COMPANY

27975 SHINN STREET

FREMONT, ALAMEDA COUNTY, CALIFORNIA

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U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Agency for Toxic Substances and Disease Registry

Division of Health Assessment and Consultation

Atlanta, Georgia 30333

Health Consultation: A Note of Explanation

An ATSDR health consultation is a verbal or written response from ATSDR to a specific request for information about health risks related to a specific site, a chemical release, or the presence of hazardous material. In order to prevent or mitigate exposures, a consultation may lead to specific actions, such as restricting use of or replacing water supplies; intensifying environmental sampling; restricting site access; or removing the contaminated material.

In addition, consultations may recommend additional public health actions, such as conducting health surveillance activities to evaluate exposure or trends in adverse health outcomes; conducting biological indicators of exposure studies to assess exposure; and providing health education for health care providers and community members. This concludes the health consultation process for this site, unless additional information is obtained by ATSDR which, in the Agency's opinion, indicates a need to revise or append the conclusions previously issued.

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Prepared By:

California Department of Public Health
Under Cooperative Agreement with the
Agency for Toxic Substances and Disease Registry

References

Foreword.....	3
Background.....	3
Flintkote Operations and Worker and Community Exposure to Asbestos.....	5
Discussion.....	5
Vermiculite Use and Handling in Wallboard Manufacture.....	6
Sampling for Worker Exposure at Gypsum Wallboard Facilities.....	8
Exposure Pathway and Health Implications.....	9
Occupational (Past Flintkote Employees).....	10
Occupational—Past (Before 1967 and After 1979), Current, and Future Employees at the Flintkote Site.....	12
On-site Soils.....	12
Household Contacts.....	13
Ambient Air.....	13
Consumer Products.....	14
Toxicology of Asbestos.....	14
Asbestos and Cancer.....	14
Asbestos and Respiratory Illness.....	15
Health Outcome Data Analysis.....	16
Diseases Evaluated in the Health Statistics Review.....	16
Evaluating Mesothelioma.....	17
Populations Evaluated.....	18
Time Periods of Health Statistics Review.....	22
Demographic Information on the Study Populations.....	22
Statistical Analysis.....	22
Statistical Measures of Comparison.....	23
Interpreting the Expected Number of People to Develop or to Die from a Disease.....	24
Accounting for Differences between the Study Populations and the Comparison Population.....	24
Statistical Tests.....	24
Sources of Information on Incidence and Mortality Rates.....	25
Results of the Cancer Statistics Review.....	25
Results of the Mortality Statistics Review.....	29
Limitations of the Health Statistics Review.....	32
Child Health Considerations.....	36
Conclusions.....	36
Recommendations.....	38

Public Health Action Plan.....	38
Actions Completed	39
Ongoing Actions	39
Planned Actions	39
References.....	40
Preparers of Report	44
Certification	45
Appendix A—Glossary.....	46
Appendix B—Standardized Incidence Ratio	48
Appendix C—Standardized Rate Ratio	49
Appendix D—Standardized Mortality Ratio	50

Foreword

Libby vermiculite was distributed to and processed by facilities located throughout the United States. Because human exposure to asbestos has possibly occurred in communities near these facilities, the Division of Health Studies of the federal Agency for Toxic Substances and Disease Registry (ATSDR) initiated a nationwide follow-up effort. This project is designed to screen for similar impacts on the health of populations living near facilities that received shipments of Libby vermiculite. As part of that effort, the Environmental Health Investigation Branch of the former California Department of Health Services, now the California Department of Public Health (CDPH), received funding to conduct health statistics reviews on communities located near facilities that received Libby vermiculite.

In this health consultation, CDPH presents the findings of the Health Statistics Review and an evaluation of the environmental data, exposure pathways, and toxicological information. The objectives of the health consultation are to:

1. determine the possible pathways of past, current, and future exposure to workers and the community from Libby asbestos used at the Flintkote Company site using available environmental data and researching the wallboard production process;
2. review the toxicological implications for those exposure pathways where exposure is or has occurred and for which there is environmental data that can be used to evaluate the health implications;
3. identify the residential area at highest risk of exposure to hazardous levels of asbestos from the use of Libby vermiculite at the Flintkote Company;
4. determine whether the population living in this area had higher incidence rates of asbestos-related cancers than the U.S. population; and

Asbestos and Asbestos-related Disease

Asbestos is the name of a group of minerals that occur naturally in the environment. Asbestos minerals have long, thin, and separable fibers. Asbestos fibers do not evaporate into air or dissolve in water, and they are resistant to heat, fire, and chemical and biological degradation (1). Asbestos fibers in vermiculite entered the air when Libby vermiculite was handled, processed, or disturbed after processing at the Flintkote Company (3). Small diameter fibers and fiber-containing particles may remain in the air for a long time and may be carried long distances by wind or water currents before settling to the ground (1).

Asbestos fibers can enter the body when inhaled (breathed in) or ingested (eaten or drunk). When asbestos fibers are inhaled, some of the fibers can become lodged in the lungs. Because asbestos fibers are very durable, they remain in lung tissue throughout life. Asbestos fibers can accumulate in lung tissue and cause scarring and inflammation. Repeated scarring and inflammation can affect breathing and lead to disease.

Exposure to asbestos does not cause disease immediately; instead, disease develops many years later. The time period between when someone is first exposed to asbestos and when they develop disease is called the latency period.

5. determine whether the population residing in this area had higher mortality rates from asbestos-related disease than the U.S. population.

Background

In 1881, miners searching for gold unearthed a mica-like material from an area 7 miles northeast of the town of Libby, Montana. It was not until 1919 that a local businessman discovered the unique properties of this mineral: while he was walking through an abandoned mine, his torch contacted the surface of the mine, resulting in an expansion or "popping" of the vermiculite. The newly formed Zonolite Company opened a mine at this location during the following year. Since then, vermiculite has been marketed for many uses, such as loose-fill insulation, fireproofing, a fertilizer carrier, a soil conditioner, and an aggregate in many construction products.

WR Grace and Company purchased the vermiculite mine from the Zonolite Company in 1963 and expanded operations. Between the 1960s and 1980s, as much as 80% of the vermiculite used worldwide came from the WR Grace and Company mine near Libby (6). (Vermiculite from the WR Grace and Company mine near Libby will be referred to as Libby vermiculite in this document.) Libby vermiculite was shipped to over 200 locations in 30 states in this country for processing or packaging. Twenty of these facilities were located in California, including the Flintkote Company gypsum wallboard manufacturing plant in Fremont, California. (This facility will be referred to as Flintkote in this document.) Libby vermiculite was shipped to Flintkote between the years 1967 and 1979 (3). WR Grace and Company mining operations in Libby, Montana closed in 1990, and the last shipments of Libby vermiculite occurred in 1992 (7).

All vermiculite contains a range of other minerals that were formed along with the vermiculite in the rock. The vermiculite found near Libby contains 21% to 26% asbestos (8), a mineral toxic to humans when inhaled (breathed in). Inhalation of asbestos is known to cause asbestosis (a non cancerous scarring of the lungs), lung cancer, and mesothelioma (cancer of the tissues lining the lung and abdomen). (The asbestos contained in Libby vermiculite will be referred to as Libby asbestos in this document.)

In 1999, a series of Seattle Post-Intelligencer articles about high rates of asbestos-related disease brought national attention to the WR Grace and Company vermiculite mine in Libby, Montana. ATSDR, in cooperation with the Montana Department of Public Health and Human Services, analyzed mortality statistics (information on causes of death obtained from death certificates) for the Libby community for a 20-year period (1979-1998). This review found that death due to asbestosis was 40 times more common in the Libby population than in the rest of the state of Montana, and 80 times more common than in the rest of the U.S. population. Death due to lung cancer was 20% to 30% (1.2 to 1.3 times) higher than expected. Although rates of mesothelioma were elevated, it was not possible to quantify by how much. Still, these elevations were high enough that they were considered unlikely to have been due to natural fluctuations in the occurrence of these diseases (9). Findings from the review of mortality statistics led to several follow-up activities to address the health impacts to those who lived and worked in Libby (10, 11).

Health statistics reviews are statistical analyses of information from cancer registry and death certificate records that investigate whether people in a particular community have developed

cancer or have died from a particular disease more often than another comparison population. The health statistics reviews are being conducted in communities located near facilities that received Libby vermiculite, regardless of whether that community was in fact exposed to hazardous levels of asbestos from the vermiculite. (Usually, reviews of health information are conducted only when exposure to a harmful chemical is known to have occurred.) Communities are being screened because, given the experience in the Libby community, it is not unrealistic to think that exposure to levels of asbestos high enough to have caused disease might have occurred in these communities.

Finding an excess of asbestos-related cancers or disease in a community would alert ATSDR and CDPH to the possibility that workers or community members might have been exposed to hazardous levels of asbestos as a result of the facility's handling or processing of Libby vermiculite. If, however, the health statistics review does not find an excess of asbestos-related disease, this does not prove that the community was not exposed to Libby asbestos.

Flintkote Operations and Current Conditions

Flintkote is located at 27975 Shinn Street, in Fremont. Flintkote is no longer an operating gypsum wallboard facility. North of the former Flintkote facility site is a Union Pacific Railroad right of way (12). West of the site is a light industrial area including storage yards, truck loading areas, and dirt parking lots. Residential areas are located about 200-300 feet away to the south of the site, and 150 feet to the east of the site.

From 1967 through 1979, the facility received approximately 2,804 tons of Libby vermiculite (3). During this time period, Flintkote used vermiculite to manufacture gypsum wallboard, a building product. Most gypsum wallboard does not contain vermiculite. Vermiculite is added to stucco to create a gypsum board that is considered fire resistant. Approximately 28% of wallboard manufacturing is fire resistant (13). In certain situations, building codes require the use of fire resistant wallboard. Adding vermiculite to gypsum keeps the wallboard from collapsing during a fire. In a fire, the gypsum in the wallboard becomes dehydrated (removal of water). Dehydrated gypsum is not rigid. In the heat of a fire, the vermiculite added to the gypsum will expand, and thus help to create stability in the wallboard while the gypsum is becoming dehydrated and collapsing.

Flintkote went bankrupt in 2004 due to asbestos-related lawsuits (14). The former Flintkote site is currently owned by United States Gypsum. United States Gypsum does not currently manufacture gypsum wallboard at the former Flintkote facility. United States Gypsum uses the site as a reloading, distribution center (Personal communication, Don Schaefer, January 2007).

Discussion

Asbestos fibers in the Libby vermiculite were released into the air during the handling and processing of vermiculite. People who worked at Flintkote between 1967 and 1979 could have been exposed to hazardous levels of asbestos. People who lived with former workers could have been exposed to hazardous levels of asbestos from fibers carried home on workers' hair and clothing. There is not enough information to determine whether people who lived near Flintkote between 1967 and 1979 were exposed to hazardous levels of asbestos from Libby vermiculite.

Based on information from the U.S. Environmental Protection Agency (EPA) and United States Gypsum explained later in this document, it is unlikely that there is Libby vermiculite-type asbestos contamination inside the former Flintkote facility building or in soil outside the building. Therefore, people who currently work for United States Gypsum at the former Flintkote facility site are probably not exposed to hazardous levels of asbestos. Current operations at the former Flintkote site are not causing community exposure to asbestos from Libby vermiculite.

Vermiculite Use and Handling in Wallboard Manufacture

United States Gypsum provided a short explanation of vermiculite storage and usage to EPA (15). It should be noted that United States Gypsum did not purchase the former Flintkote site until 1983. Therefore, steps described here may or may not be applicable to how vermiculite was processed by Flintkote when it received Libby vermiculite from 1967-1979. United States Gypsum described how vermiculite was delivered to the plant in bags weighing about 80-100 pounds. Then, vermiculite was unloaded into a 2-ton bin. In addition, screw conveyors transported vermiculite from the bin to the mixer. According to WR Grace invoices, vermiculite was also delivered in railcars to the former Flintkote facility site (3).

Additional information on vermiculite handling was also gained when personnel from ATSDR, CDPH, and the CDPH Occupational Health Branch, toured a gypsum wallboard facility in May 2004 (note: a different facility than the Flintkote facility in Fremont) (16). The purpose of the tour was to assess the wallboard manufacturing process for the potential to release Libby asbestos into the neighboring communities. Staff from the three agencies observed the entire wallboard manufacturing process, including the mixing of the dry ingredients, the production of the wallboard, cutting the wallboard, and storage and shipping procedures. It should be noted that the process viewed by investigators may differ significantly from the process in use when Libby vermiculite was handled. However, interviews were conducted with employees who were present during the 1970s and/or 1980s to obtain information about how vermiculite was handled during that time at the particular facility visited by investigators. It is possible that the two gypsum wallboard facilities (i.e., the one where observations were recently made vs. the Flintkote facility in Fremont) differed in terms of process, for example, how vermiculite was delivered to or handled within the facility, or how ventilation controls may or may not have been used.

Gypsum wallboard is manufactured in the following steps:

1. gypsum rock is crushed to form small pieces, dried to evaporate surface moisture, and ground;
2. the dried gypsum is “calcined” or heated to remove excess water that is chemically bonded to the gypsum, forming what is called “stucco;”
3. dry additives (e.g., vermiculite, perlite, starch, fiberglass, or sugar) are mixed into the stucco depending on the properties needed in the specific product;
4. water is added to produce a slurry;
5. the slurry is mechanically spread over a paper backing;
6. a top layer of paper backing is applied to form a “sandwich” with the slurry in the middle;

7. the long, continuous sheet of wallboard moves on conveyor belts while the slurry hardens, and the sheets are cut into specified lengths;
8. the cut boards are flipped and sent into a multi-stage kiln to dry and become hard; and
9. the hardened wallboards are trimmed to an exact length, end-taped, stacked, and placed onto skids, ready to be shipped.

Dust from the vermiculite may become airborne within the facility at several stages in the manufacturing process, including 1) when the raw material first arrives at the facility, depending on the way it is packaged and handled; 2) when vermiculite is introduced into a batch; 3) when any spilled or released vermiculite or mixture of dry ingredients is cleaned up; and 4) during maintenance of the ventilation system, dust collector, or other equipment in the facility where dry material is present. In addition, airborne dust may escape from the facility itself through openings to the outdoor air.

At the wallboard plant visited by investigators, employees stated that Libby vermiculite was delivered in 50-pound (lb) paper bags that were lifted manually, slit open, and dumped into a hopper (16). The worker whose primary responsibility was to fill the hopper with the vermiculite will be referred to as the "hopper filler." When the hopper filler dumped the dry vermiculite into the hopper, there was the potential for a significant amount of dust to be generated. This is particularly true if local exhaust ventilation was not present or was inadequate. Investigators could not determine if local exhaust ventilation on the hopper had been present in the past at the site visited, although it is in place currently and is connected into a dust capture device (baghouse). Workers present during the 1970s at the site reported that, whether or not local exhaust ventilation was present, they remember seeing a visible cloud of dust whenever the vermiculite bag was dumped. During their site visit in 2004, investigators still observed substantial dry material (much of it gypsum but presumably with some percentage of additives as well) near the mixing hoppers and mixing tank. The observed cutting and shipping areas were similarly covered in beige-colored dust, although to a lesser degree than the mixing area and blending areas. Investigators noted visible dust in the air when outdoor sunlight shined in through the factory windows, suggesting that exposure to airborne dust could continue during the shift, even when vermiculite was not being handled directly.

Exposure to dust that contained vermiculite (and asbestos) could occur when any clean-up tasks or tasks involving maintenance of equipment in dusty areas were conducted. Although clean-up and equipment maintenance processes were not observed, dry clean-up methods such as sweeping were reportedly used in the past (16). Dry sweeping would be expected to generate significant levels of dust into the air.

In addition to exposure to dust occurring within the plant, there is the potential for community exposure due to escape of dry ingredients from a wallboard manufacturing facility, through open doors or windows, or from railcars if that was the method of vermiculite product delivery. At the facility visited by investigators, it was reported that there had been several community complaints over the years regarding the amount of dust present in the neighborhood (16). However, the gypsum material itself is very dusty, and the extent to which Libby asbestos may have been contained in the released dust is unknown.

Laboratory Methods for Detecting Asbestos

The detection and analysis of asbestos in samples involves both fiber quantification and mineral identification. A fiber is defined as any particle with a length greater than 5 micrometers (μm) and a length: width ratio greater than 3:1 in air, or greater than 5:1 in soil or dust (1). A number of different analytical methods are used to characterize the presence of asbestos; each method has its advantages and disadvantages. For air, sample fiber quantification is traditionally done through phase contrast microscopy (PCM). PCM does not accurately distinguish between asbestos and non-asbestos fibers, and cannot detect fibers thinner than about 0.25 μm . PCM measurements are reported in fibers per milliliter (f/ml). Polarized light microscopy (PLM) uses polarized light to compare refractive indices of minerals to distinguish the asbestos fibers from other minerals. PLM can detect fibers with lengths greater than 1 μm with detection limits around 0.25%-1% asbestos. PLM is often used to determine asbestos content in bulk samples. PLM results are reported as percent asbestos (%). Scanning electron microscopy (SEM) and, more commonly, transmission electron microscopy (TEM) are more sensitive methods that can detect smaller fibers than PLM. However, one disadvantage of electron microscopy is that it is not easily used to measure fibers in soil. TEM and SEM results are expressed as structures per square centimeter for dust and structures per centimeter cubed or structures per cubic centimeter for air. Electron diffraction and energy-dispersive X-ray methods can determine crystal structure and elemental composition and are used to identify the mineral group to which a fiber or particle belongs. For risk assessment purposes, the correlation between these different analytical methods is poor and conversion factors between the different measurements have not been fully accepted by EPA.

It is highly likely that family members of workers at wallboard plants using Libby vermiculite were exposed to asbestos carried home from the workplace on the clothing, shoes, or bodies of workers. At the plant visited, workers reported it was commonplace in the 1970s and 1980s for workers to wear dusty clothing home (16).

Sampling for Worker Exposure at Gypsum Wallboard Facilities

No sampling of the air when Libby vermiculite was used at the Flintkote facility was available for review. However, at another gypsum facility, the gypsum manufacturer conducted short-term (15-minute) air sampling in the area of the dry ingredient mixing when an employee was dumping Libby vermiculite into the hopper (17). The air samples were collected in 1965. The air samples showed 50 to 70 fibers per cubic centimeter (f/cc). No further air sampling data was available. It is not clear if the air sampling conducted at the other gypsum facility would be directly applicable to Flintkote.

In addition, there was no sampling of site soil, dust, and air done at the Flintkote facility. However, EPA's Region 9 office directed site soil, dust, and air sampling of several gypsum wallboard manufacturing facilities (note: different facilities than the Flintkote facility in Fremont) that received Libby vermiculite. This sampling did not yield any results showing hazardous levels of Libby vermiculite type asbestos (tremolite and actinolite) at any of these sites (Personal communication, Hedy Ficklin, March 2002). It was thus assumed that no hazardous levels of Libby vermiculite type asbestos existed at other gypsum wallboard manufacturing facilities as well. Furthermore, upon purchase of the former Flintkote facility in 1983, United States Gypsum conducted an environmental assessment of this facility (Personal communication, Don Schaefer, January 2007). CDPH did not review this report. This assessment did not find any asbestos hazards at the former Flintkote facility. Based on EPA and United States Gypsum data, it seems unlikely that current and future employees at the former Flintkote site are at risk for asbestos exposure from Libby vermiculite.

Exposure Pathway and Health Implications

An exposure pathway is how a person comes in contact with chemicals originating from a source of contamination. Every exposure pathway consists of the following five elements: 1) a source of contamination; 2) a media such as air or soil through which the contaminant is transported; 3) a point of exposure where people can contact the contaminant; 4) a route of exposure by which the contaminant enters or contacts the people; and 5) a receptor population. A pathway is considered complete if all five elements are present and connected (see Appendix A for definitions). A pathway is considered potential if the pathway elements are (or were) likely present, but insufficient information is available to confirm or characterize the pathway elements. A pathway may also be considered potential if it is currently missing one or more of the pathway elements, but the element(s) could easily be present at some point in time. A pathway may be considered eliminated if one or more of the pathway elements are missing and it is likely that the elements were never present and not likely to be present at a later point in time.

CDPH identified several exposure pathways for gypsum manufacturing facilities. All pathways have a common source (vermiculite from Libby contaminated with Libby asbestos) and a common route of exposure, inhalation. Although asbestos ingestion and dermal exposure could exist, health risks from these pathways are minor in comparison to those resulting from inhalation exposure to asbestos, and will not be evaluated. The exposure pathways considered for this site are listed in the following table. An evaluation of the pathways for this site is presented in the following paragraphs.

Summary of Pathways Considered for the Flintkote Company

Pathway Name	Exposure Scenario(s)	Past (1967-1979) Pathway Status	From 1979-Present Pathway Status	Future Pathway Status
Occupational				Not applicable
	Workers exposed to airborne asbestos from residual Libby vermiculite inside the Flintkote facility (after 1979)	Not applicable	Potential	Potential
On-site Soils	On-site workers or contractors disturbing contaminated on-site soils containing residual Libby vermiculite	Eliminated	Eliminated	Eliminated
Household Contact	Household contacts exposed to airborne asbestos brought home on workers clothing after they worked with Libby vermiculite	Potential	Eliminated	Eliminated
Ambient Air	Community members or nearby workers exposed to airborne asbestos from plant emissions during handling and use of Libby vermiculite	Potential	Eliminated	Eliminated
Wallboard	Community members, contractors, and repairman disturbing wallboard containing Libby vermiculite	Potential	Potential	Potential

Occupational (Past Flintkote Employees)

Occupational exposure for people who worked at the Flintkote facility when Libby vermiculite was used at the plant (1967-1979) is considered a completed pathway. In particular, the employees whose job was to unload the Libby vermiculite from the railroad car into bags and who dumped the bags of Libby vermiculite into the hopper would be exposed to the greatest amount. Data from another gypsum facility showed that the asbestos levels in the air during the filling of the hopper were 5 to 7 times (50-70 f/cc) the Occupational Safety and Health Administration (OSHA) ceiling limit (10 f/cc) that was adopted in 1971 (17). This exposure was measured at the filling events, thus, the total exposure for a particular shift depends on how often the employee fills the hopper per shift, how long it takes them to fill the hopper, how long the fibers stay in the air after the filling event, and how long the employee stays in the area where the Libby vermiculite is airborne.

Occupational exposure is regulated by OSHA. OSHA's current permissible exposure limit (PEL) is 0.1 f/cc when determined using PCM (18). This value represents a time-weighted average (TWA) exposure level based on 8 hours a day for a 40-hour work week. In addition, OSHA has defined an excursion limit in which no worker should be exposed in excess of 1 f/cc as averaged over a sampling period of 30 minutes (19). Historically, OSHA's PEL has decreased from an initial standard of 12 f/cc established in 1971 (20). PELs prior to 1983 were determined on the basis of empirical worker health observations, while the levels set from 1983 forward employed a form of quantitative risk assessment. ATSDR has used the current PEL of 0.1 f/cc as a reference point for evaluating asbestos inhalation exposure of past workers (20).

In order to compare the concentration of air measured in that 15-minute period when the vermiculite was being dumped into the hopper (17) to the current PEL, it is necessary to convert the concentration to a time-weighted average for an 8-hour day and 40-hour work week. In order to make this conversion, it is necessary to make use of some known information and to make some assumptions. According to interviews with workers at the gypsum facility inspected by CDPH and ATSDR staff (16), a worker (hopper filler) might fill the hopper one time per shift when the facility was producing fire-resistant wallboard. Assuming it takes 15 minutes to fill the hopper, after which the hopper filler leaves the dry ingredient area, ending any significant exposure to asbestos. This means that the exposure in the 15-minute period would then be averaged over 8 hours. This results in a time-weighted concentration for the hopper filler of 1.56 to 2.19 f/cc. This amount of asbestos exceeds the current PEL, though it did not exceed the PEL at the time the air sample was taken.

CDPH evaluated the two main concerns for the hopper filler exposed to asbestos, cancer, and noncancerous respiratory problems.

Noncancerous Respiratory Problems

Deposition of asbestos fibers in the lung can lead to substantial noncancerous, fibrotic injury and may even cause death. This disease, called asbestosis, results from a prolonged inflammatory response stimulated by the presence of the fibers in the lung. Signs of fibrosis and increased mortality associated with asbestosis or noncancerous disease have been observed in groups of

workers with chronic cumulative exposures as low as 15-70 fibers-year/milliliter (f-year/ml) for signs of lungs fibrosis and 32-1,271 f-year/ml for asbestosis-associated mortality (1). In order to evaluate a long-term exposure to the Libby asbestos at the Flintkote site, the exposure level for the hopper filler was averaged over the 40-hour work week based on an assumption that 28% of the production time at the plant on a weekly basis was devoted to producing fire-resistant wallboard (13). Assuming the air samples taken in 1977 at the gypsum facility that the investigators visited were similar to the conditions in the Flintkote facility when Libby vermiculite was used from 1967-1979 (17), a hopper filler would have received 285 to 401 f-yr/ml cumulative dose. Thus, the hopper filler may have experienced noncancerous respiratory effects, such as asbestosis, from the Libby vermiculite used at the Flintkote facility.

Cancer

Inhalation of asbestos can lead to increased risk of lung cancer and mesothelioma (1). Asbestos exposure is also suspected of increasing the risk of cancer in the gastrointestinal tract, though the evidence is less consistent than for lung cancer or mesothelioma (1).

For lung cancer, the magnitude of the risk appears to be a complex function of a number of parameters, the most important of which are 1) the level and the duration of the exposure; 2) the time since the exposure occurred; 3) the age at which exposure occurred; 4) the tobacco-smoking history of the exposed person; and 5) the type and size distribution of the asbestos fibers (1). The last parameter is of special practical importance, since the variability in potency in fibers means that cancer risk from asbestos exposure may vary widely from location to location. Because of the large number of variables, it is difficult to make reliable predictions of the magnitude of the cancer risk for the hopper filler exposed to Libby asbestos from 1967-1979. Qualitatively, the risk would range from moderate to high¹.

Exposure to Libby asbestos probably occurred to other workers in the gypsum facility but to a lesser extent than the hopper filler or the worker who emptied the railroad car. It is not known how asbestos measured in the air near the hopper gets distributed to other parts of the facility. Nor is it known how much Libby asbestos dust would have been generated at other points in the gypsum board manufacturing process. Without additional information about the concentrations of Libby asbestos in other parts of the facility, it is not possible to predict what risks there may have been to other workers in the gypsum facility when Libby vermiculite was used.

CDPH contacted United States Gypsum to obtain contact information for former workers at the Flintkote gypsum wallboard manufacturing facility. United States Gypsum had no records for these former workers and no information on the union status of the Flintkote plant (Personal communication, Don Schaefer, March 2007).

¹ Risk calculations derived from the air sampling at the gypsum facility ranged from 5.7 to 8.0 premature cancer deaths per thousand hopper fillers, assuming the hopper filler was exposed for 13 years, 40 hours per week, 50 weeks per year. These risk ranges were based on EPA risk modeling of workers exposed to chrysotile asbestos. It is thought that the kind of asbestos in Libby vermiculite (tremolite and actinolite) is more toxic than chrysotile.

Occupational—Past (Before 1967 and After 1979), Current, and Future Employees at the Flintkote Site

Exposure to asbestos for people who worked at Flintkote, after Flintkote stopped receiving Libby vermiculite (1979), is considered eliminated. Invoice records from WR Grace show that 2,804 tons of Libby vermiculite was shipped to Flintkote from 1967 to 1979. It is possible that Libby vermiculite was delivered to Flintkote before 1967 or after 1979, until the last shipments from Libby occurred in 1992, and there are no invoice records to show these other shipments. It is also possible that residual contamination from the Libby vermiculite was present in the dust found at the Flintkote facility several months to years after the last shipment. However, EPA dust and air sampling done at other gypsum wallboard manufacturing facilities did not show any Libby vermiculite type asbestos (tremolite and actinolite) (Personal communication, Hedy Ficklin, March 2002). Therefore, exposure to asbestos through this pathway is not likely.

There has been no sampling of the air and dust in the Flintkote facility. However, EPA Region 9 office directed site soil, dust, and air sampling of several gypsum wallboard manufacturing facilities (note: different facilities than the Flintkote facility in Fremont) that received Libby vermiculite. The investigations did not yield any results showing hazardous levels of Libby vermiculite-type asbestos (tremolite and actinolite) at any of these sites (Personal communication, Hedy Ficklin, March 2002). Therefore, EPA decided that sampling at further gypsum wallboard manufacturing facilities was unnecessary.

CDPH reviewed the sampling data from three other gypsum facilities and found that actinolite asbestos was not found in the air and dust at these other gypsum facilities. Based on these results and the fact that gypsum wallboard is fabricated in an identical manner by manufacturers, CDPH concludes that it is highly unlikely that any contamination remains inside the Flintkote facility that poses a risk to current or future workers. However, since there is not data for this site, the possibility exists that there could be a potential exposure pathway to vermiculite for current or future workers from the dust and air inside the building. Further sampling at the facility could be used to confirm this conclusion.

On-site Soils

Exposure to current on-site workers or contractors disturbing contaminated on-site soils, including residual contamination or buried waste, is considered eliminated for the past (since July 1967), present, and future. It has been shown that disturbing soil containing even trace amounts of Libby asbestos can result in airborne levels of Libby asbestos fibers (21, 22). However, EPA's on-site soil sampling at other gypsum wallboard manufacturing facilities did not show any vermiculite-type asbestos (tremolite and actinolite) (Personal communication, Hedy Ficklin, March 2002). Therefore, exposure to asbestos through this pathway is not likely.

CDPH reviewed the sampling data from the other gypsum facilities and found that actinolite asbestos was not found at hazardous levels in the soil at these other gypsum facilities. Based on these results and the fact that gypsum wallboard is fabricated in an identical manner by the manufacturers, CDPH concludes that it is highly unlikely that any contamination remains at the Flintkote facility that poses a risk to current or future workers. However, since there is no data

for this site, the possibility exists that there could be a potential exposure pathway to vermiculite for current or future workers disturbing the soil. Soil sampling at the facility could be used to confirm this conclusion.

Household Contacts

Exposure of household members, including the worker, to airborne Libby asbestos brought home on the clothing of former workers (i.e., those who worked at the facility from 1967 to 1979) is considered potentially complete. Flintkote workers exposed to Libby asbestos fibers and who did not shower and change clothes before leaving work could have resulted in the spread of the asbestos to their household contacts. Family or other household contacts could have come in contact with Libby asbestos by direct contact with the worker, by laundering clothing, or the re-suspension of dusts during cleaning activities. Exposures to household contacts cannot be estimated without information concerning Libby asbestos levels on worker clothing and behavior-specific factors (e.g., worker practices or household laundering practices). CDPH does not know if Flintkote employees wore disposable clothing or clothing that was left at the facility for laundering. CDPH does not know if on-site showers were available at Flintkote and whether employees used them. When CDPH and ATSDR staff visited a different gypsum site in 2004, the workers wore reusable jumpsuits (16). However, the workers reported it was commonplace in the 1970s and 1980s for workers to wear dusty clothing home. If the same practices took place at Flintkote, then it is highly likely that family members of Flintkote workers were exposed to asbestos carried home from the workplace on the clothing, shoes, or bodies of workers. It is not possible to determine how much exposure occurred to the household members. Inhalation of Libby asbestos fibers by household contacts as a result of worker take-home contamination from 1967 to 1979 is therefore considered an indeterminate public health hazard.

Exposure of household contacts to airborne Libby asbestos brought home on the clothing of Flintkote workers who worked after 1979, currently, and in the future, is considered eliminated. Based on air, dust, and on-site soil sampling of other gypsum wallboard manufacturing facilities by EPA, these workers are probably not likely to be exposed to residual Libby asbestos fibers inside the facility. No apparent public health hazard exists for the household contacts of current, future, or past (except for 1967 to 1979) employees at the Flintkote facility.

Ambient Air

Past exposures (1967 to 1979) to airborne Libby asbestos fibers from plant emissions is considered a potentially complete pathway for the community surrounding the site, as well as for nearby workers. Community members and area workers could have been exposed to Libby asbestos fibers released into the air from fugitive dust and vent emissions, when the plant was using Libby vermiculite. Specific information concerning historical emissions from the plant is not available; therefore, an estimate of risk from this exposure cannot be made. An individual's exposure will be determined by wind direction, plant operational cycles, and where the individual lives, works, or goes to school in relation to the facility.

At the former Flintkote site in Fremont, approximately 18% of the wind comes from the north, 19% comes from the east, 14% comes from the south, and 48% comes from the west (23).

Approximately 1% of the time, it is calm. Because a large proportion of wind comes from the west direction, some exposure of the nearby residents located east of the site to airborne emissions may have occurred. Due to a moderate percentage of the wind coming from the north and east directions, little contamination of the residential neighborhood located to the south of the site and a light industrial area located to the west of the site is likely to have occurred from the airborne dispersal of asbestos fibers. However, exposure of the public to airborne emissions downwind of the site would have been at much lower concentrations than that experienced by the Flintkote workers.

Air emissions of Libby asbestos before 1967 and after 1979, and in the future, have been eliminated from further discussion because the facility did not use Libby asbestos except for the time period between 1967 and 1979.

Consumer Products

People who purchased and used company products that contain Libby vermiculite may be exposed to asbestos fibers from using those products in and around their homes (21, 22, 24-26). Much of the vermiculite from the WR Grace mine in Libby was used to produce attic insulation products, often sold under the brand name Zonolite. Vermiculite was commonly sold in gardening and hardware stores. It was used as a soil amendment (a conditioner to improve soil quality), fertilizer carrier, and was an ingredient in many potting soil mixes. Vermiculite was also used in fireproofing materials, gypsum wallboard, and as a lightweight aggregate in construction materials (27).

Current and future exposure to asbestos from use of products made with Libby vermiculite is possible, though the extent of this risk depends on which product and how the product is being used or disturbed. However, determining the public health implication of commercial or consumer use of company products, such as gypsum wallboard, that contain Libby vermiculite, is beyond the scope of this evaluation.

In addition, ATSDR has created a fact sheet providing information on products containing Libby vermiculite and how to protect against exposure to asbestos. This fact sheet is accessible via the CDPH website.

Toxicology of Asbestos

Asbestos and Cancer

Asbestos has been classified by U.S. and international health agencies as a substance that is known to cause cancer in humans. Numerous studies of occupational exposure to asbestos (exposure to asbestos during work) have shown that exposure to asbestos can cause two types of cancer: mesothelioma and lung cancer. Other studies have suggested that asbestos exposure might also increase the risk of some gastrointestinal and digestive cancers.

- Mesothelioma is the uncontrolled growth of abnormal cells in the tissue that lines the lungs and abdomen. Mesothelioma is relatively rare in the general population (approximately two out of one million people will get mesothelioma), but does occur more frequently in

populations of workers in industries that use asbestos. About 5% of people who are exposed to asbestos develop mesothelioma (28). Mesothelioma has a latency period of 30 to 40 years (29).

- Lung cancer is the uncontrolled growth of abnormal cells in one or both of the lungs. While normal lung tissue cells reproduce and develop into healthy lung tissue, these abnormal cells reproduce rapidly and never grow into normal lung tissue. Lumps of cancer cells (tumors) then form and disrupt lung function (30). Studies have shown that people who were exposed to asbestos at work are five times more likely to develop lung cancer than workers who are not exposed to asbestos. In addition, people exposed to asbestos at work who also smoke are 50 to 90 times more likely to develop lung cancer than workers who do not smoke and who were not exposed to asbestos. The latency period for asbestos-caused lung cancer is 20 to 30 years (29).
- A number of studies suggest that asbestos exposure may increase the risk of some gastrointestinal (digestive organ) cancers. Some studies have observed slightly higher rates of death from gastrointestinal cancer among workers exposed to asbestos. This is presumed to be due to the transfer of inhaled fibers from the lung to the gastrointestinal tract. However, these studies were not able to determine whether the excess death from gastrointestinal cancer was due to asbestos or to other factors (e.g., exposure to other chemicals, misdiagnosis, dietary factors, alcohol intake) (1). Currently, there is no conclusive evidence that exposure to asbestos does or does not cause gastrointestinal cancer.

Asbestos and Respiratory Illness

Exposure to asbestos can also lead to several non-cancer respiratory illnesses, including asbestosis and abnormalities in the pleural (the lining of the lungs).

- Asbestosis is a serious, chronic, respiratory illness that occurs when asbestos fibers lodged in lung tissue cause scarring. Scarred lung tissue does not expand and contract like normal lung tissue and so breathing becomes difficult. Oxygen and carbon dioxide do not pass through the lungs as easily and blood flow to the lungs may also be decreased, which can cause the heart to enlarge (1). Asbestosis can lead to heart failure. The latency period for asbestosis is typically 10 to 20 years (31).
- Pleural abnormalities are changes in the lining of the lung (called the pleura). The most common change is the formation of thick, fibrous areas called plaques. Other effects of asbestos exposure include diffuse (wide-spread) thickening of the pleura, fibrosis (the formation of fibrous, scar-like tissue), and areas of pleural effusions (an abnormal collection of fluid between the pleura and the wall of the chest cavity). Small areas of pleural plaques are not thought to be of significant health concern. However, diffuse thickening of the pleura and large areas of pleural plaques or pleural effusions can impair respiratory function (1). Pleural abnormalities are not likely to be identified as a cause of death.

Health Outcome Data Analysis

- A cancer registry is a center that collects, organizes and analyzes information on cancer cases that have been diagnosed or treated in a geographic area (for example, California).
- A death certificate is an official legal record of a death. They include information on the cause of death (determined by a physician) and demographic characteristics of the deceased.
- Incidence rate is a measure of the occurrence of disease in a population. It is the number of people in a population who get a disease in a specific time period, per (divided by) the number of people in that population during the time period. For example, the incidence rate of lung cancer in California for the year 1997 was 60.1 per 100,000 people (4).
- Mortality rate is a measure of the occurrence of death from a disease in a population. It is the number of people in a population who die from a disease in a specific time period divided by the number of people in that population during the time period. For example, the mortality rate for lung cancer in California for the year 1997 was 41.8 per 100,000 people (5).

The analysis of incidence rates of asbestos-related cancers will be referred to as the "cancer statistics review" and the analysis of mortality rates of asbestos-related disease will be referred to as the "mortality statistics review."

Diseases Evaluated in the Health Statistics Review

The ATSDR Division of Health Studies selected a variety of diseases for evaluation in order to 1) assess the full burden of disease and death that exposure to asbestos could have had on a population, and 2) confirm information obtained from cancer registries and vital statistics records for this review as consistent and therefore comparable.

Exposure to asbestos is known to cause lung cancer, cancer of the mesothelioma, and asbestosis. Some studies suggest that exposure to asbestos might also increase the risk of certain digestive organ cancers. It is also possible that exposure to asbestos might worsen and cause premature death from certain diseases of the pulmonary and circulatory system.

One factor complicating the study of asbestos-related diseases is that physicians often misdiagnose these diseases, particularly when establishing a cause of death. This review also evaluated the number of people getting or dying from certain diseases because these people might have had an asbestos-related disease that was misdiagnosed.

Incidence rates of eight types of cancers or cancer groups were evaluated in the cancer statistics review (see list, at right). Lung and bronchus cancer, mesothelioma, and digestive organ cancers were studied because of their known or suspected association with asbestos exposure. Cancer of the peritoneum, retroperitoneum and pleura, and cancer of the respiratory system and intrathoracic organs were evaluated because people with these diagnoses might actually have had an asbestos-related cancer instead.

Lastly, all types of cancer, female breast cancer, and prostate cancer were evaluated to determine whether cancer was underreported to the cancer registries that provided information for this review.

Mortality rates from 13 types of diseases or disease groups were evaluated as part of the mortality statistics review (see list, at right). Lung and bronchus cancer, cancer of the peritoneum, retroperitoneum and pleura (including mesothelioma), asbestosis, and digestive organ cancers were evaluated because of their known or suspected association with asbestos exposure.

Respiratory system and intrathoracic organ cancers, cancer (no specification of site), pneumoconioses, and chronic obstructive pulmonary disease were evaluated because these deaths might have included people with misdiagnosed asbestos-related diseases. Chronic obstructive pulmonary disease, disease of the pulmonary circulation, and other diseases of the respiratory system were evaluated because asbestos-exposure might have worsened these conditions and led to premature death. Lastly, all types of cancer, female breast cancer, and prostate cancer were evaluated to determine whether causes of death were underreported to the registries that provided information for the mortality statistics review.

Evaluating Mesothelioma

During the years that were evaluated in this review, cancer and causes of death were coded in cancer registries and on death certificates according to two classification systems: International Classification of Diseases, Oncology Codes, Revision 2 (ICD-O-2) (used by cancer registries), and International Classification of Diseases, Injury, and Causes of Death Codes, Revision 9 (ICD-9) (used for death certificates).

The cancer statistics review evaluated the following types of cancer:

- Lung and bronchus
- Mesothelioma
- Digestive organs
- Peritoneum, retroperitoneum, and pleura
- Respiratory system and intrathoracic organs
- All types of cancer
- Female breast
- Prostate

The mortality statistics review evaluated death from the following diseases:

- Lung and bronchus cancer
- Cancer of the peritoneum, retroperitoneum, and pleura including mesothelioma
- Asbestosis
- Digestive organ cancers
- Respiratory system and intrathoracic organ cancers
- Cancer (no specification of site)
- Pneumoconioses
- Chronic obstructive pulmonary disease
- Diseases of pulmonary circulation
- Other diseases of respiratory system
- All types of cancer
- Female breast cancer
- Prostate cancer

The ICD-O-2 system has a specific code for mesothelioma, which makes it possible to evaluate the incidence rate of this cancer in the Fremont community. In contrast, the ICD-9 system does not have a specific code for mesothelioma. Therefore, it is not possible to analyze mortality rates for mesothelioma alone; only a larger group of diseases (cancer of the peritoneum, retroperitoneum, and pleura (including mesothelioma) can be evaluated. Nearly all of the deaths in this cancer group are, in fact, deaths from mesothelioma (W. Kaye, ATSDR, personal communication, 2004). Therefore, evaluating mortality from this group of cancers reflects, with relative accuracy, the occurrence of death from mesothelioma.

Populations Evaluated

Whether people who lived near Flintkote between 1967 and 1979 were exposed to hazardous levels of asbestos from Libby vermiculite, and if so, which areas of Fremont experienced such exposure, is currently unknown.

Therefore, the first step of the health statistics review was to determine which area near Flintkote was most likely to have experienced an increased burden of asbestos-related disease (assuming that Flintkote did pollute the surrounding air with hazardous levels of asbestos). CDPH concluded that the population living within ¼ mile of Flintkote site was most likely to have been exposed to levels of asbestos high enough to cause a detectable excess burden of asbestos-related disease. This distance was selected based on information presented in this health consultation, as well as on information from health studies of lung cancer and mesothelioma rates in communities near asbestos industries (32-35).

Figure 1 shows the location of the Fremont plant and the area of Fremont that is located within ¼ mile of the facility. The health statistics review would ideally evaluate the incidence and mortality rates of asbestos-related disease in the population residing in this area. But the smallest geographic area on which cancer statistics are publicly available is the census tract (providing information on a smaller geographic area could make it possible to identify a cancer patient, and thus would violate their right to privacy). For similar reasons pertaining to privacy, the smallest geographic area on which mortality statistics are publicly available is the ZIP Code.

Census tracts are small geographic areas defined by the U.S. Census Bureau. Census tracts usually have 2,500 to 8,000 residents with similar population characteristics, economic status, and living conditions.

Therefore, for the cancer statistics review, CDPH studied the population living in census tract 4419.01. For the mortality statistics review, CDPH studied the population residing in ZIP Code 94536. Figure 2 shows the location of Flintkote, the area that CDPH determined was most likely to experience an excess of asbestos-related disease, and census tract 4419.01. Figure 3 shows the location of Flintkote, the area that CDPH determined was most likely to experience an excess of asbestos-related disease, and ZIP Code 94536.

Figure 1: Area of Fremont that is most likely to have been exposed to levels of asbestos high enough to cause a detectable excess burden of asbestos-related disease, assuming that Flintkote polluted the outside air with hazardous levels of asbestos, Flintkote Company, Fremont, California.

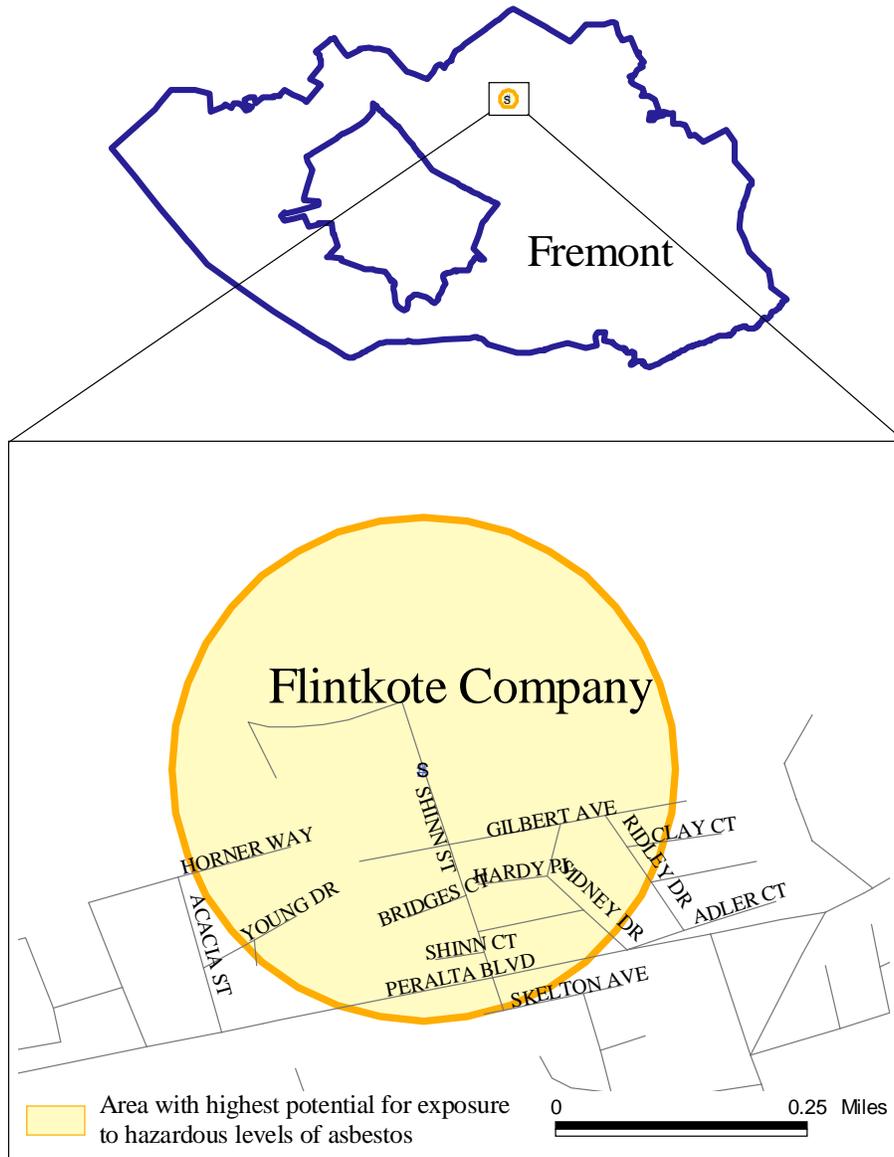


Figure 2: Map of Census Tract 4419.01 in Relationship to the Area Located Within ¼ Mile of Flintkote Company, Fremont, California.

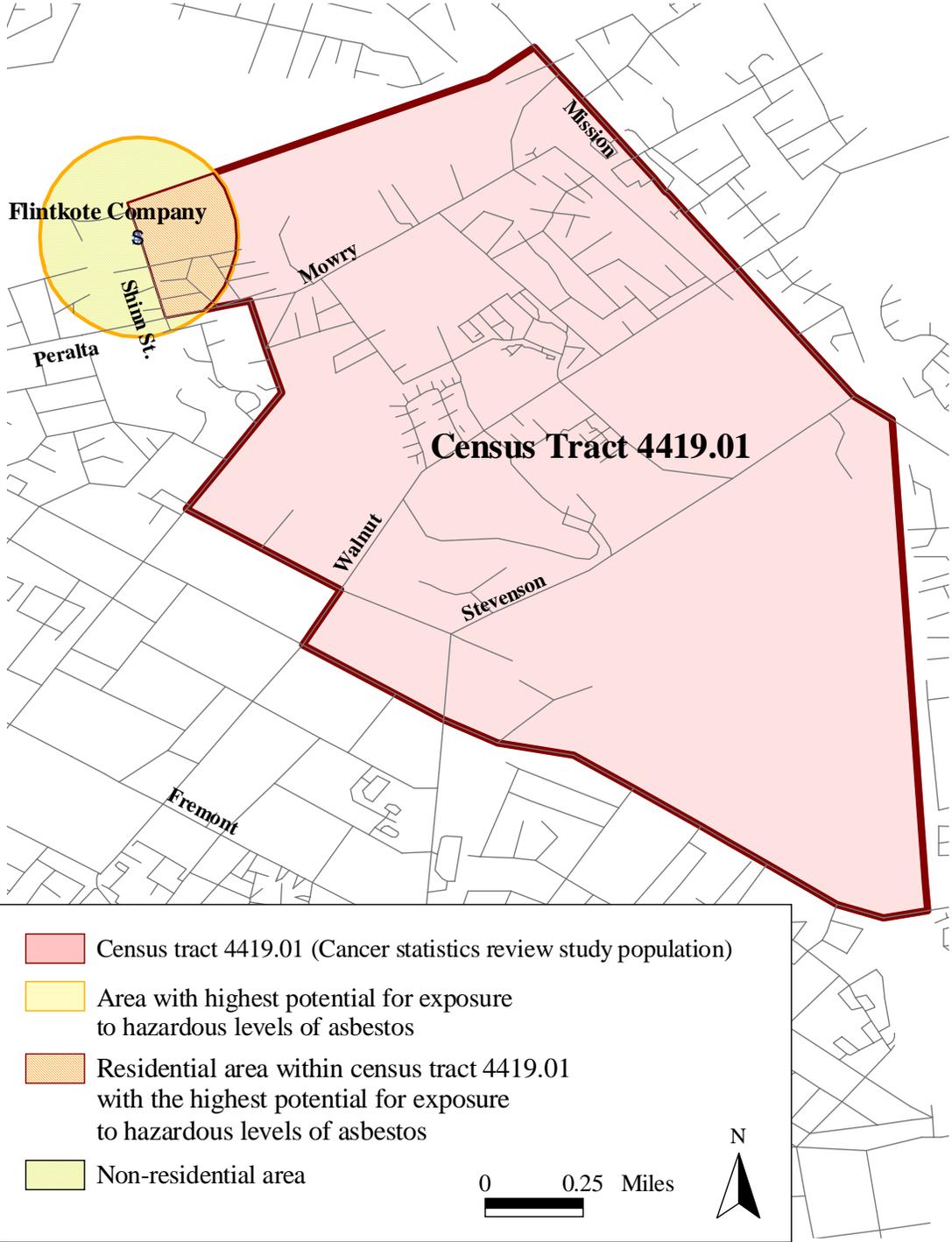
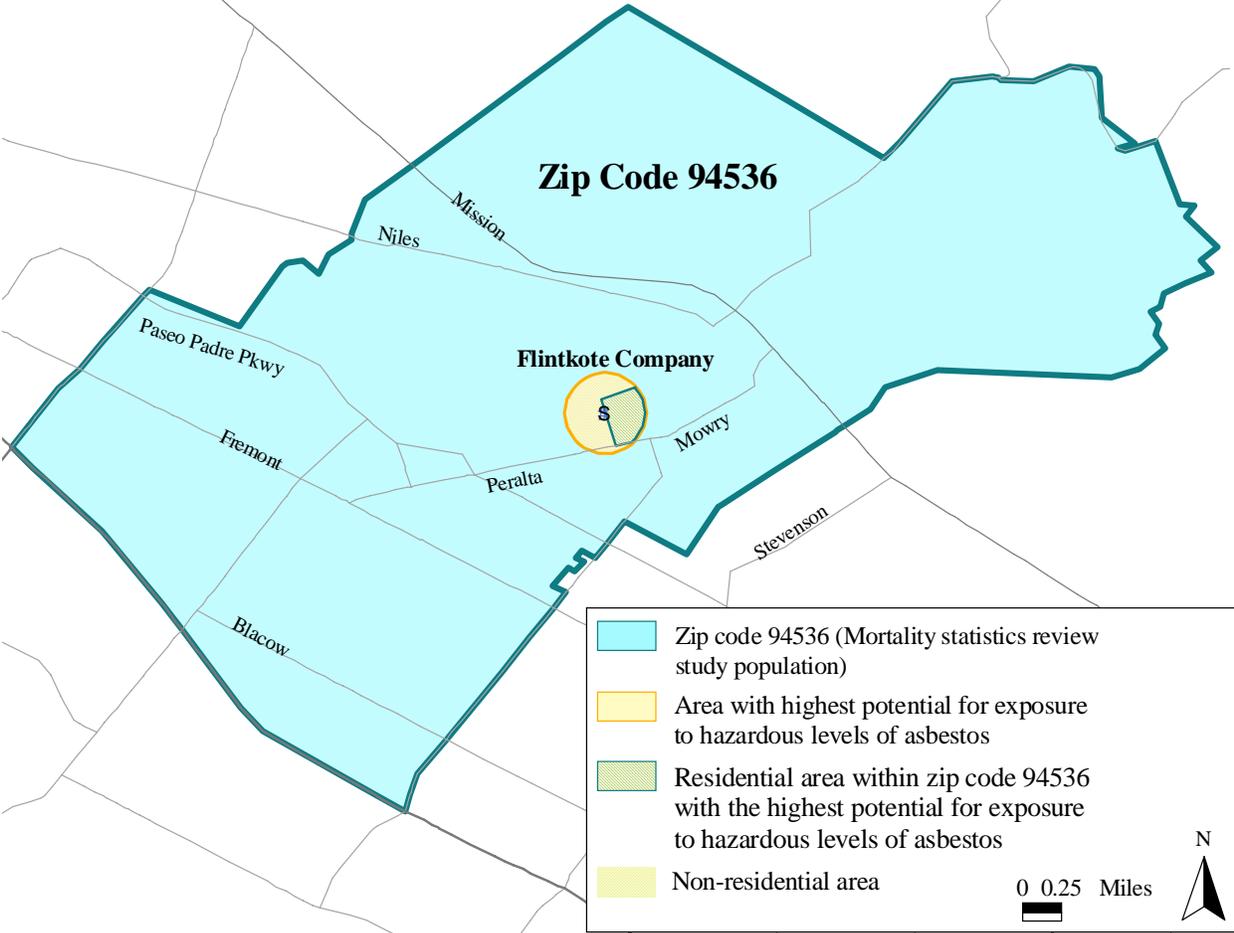


Figure 3: Map of ZIP Code 94536 in Relationship to the Area Located Within ¼ Mile of Flintkote Company, Fremont, California.



Time Periods of Health Statistics Review

The cancer statistics review studied the period from January 1, 1986, through December 31, 1995, and the mortality statistics review studied the period January 1, 1989, through December 31, 1998. ATSDR selected these periods for two reasons: 1) they come closest to corresponding to the time of exposure and the latency period of asbestos-related disease; and 2) a 10-year period provides the minimum amount of data required for informative statistical analysis (36).

Demographic Information on the Study Populations

In 1990, there were 6,124 people residing in census tract 4419.01 and 58,581 people residing in ZIP Code 94536 (see Table 1). Both study populations had almost equal number of males and females and were primarily white, with a sizeable Asian/Pacific Islander population. Compared with the U.S. population, the study populations had fewer people age 65 and older and had a higher socioeconomic status, as measured by education level, the percentage of people in the labor force, employment status and poverty status.

Statistical Analysis

CDPH followed a health statistics review protocol developed by the ATSDR Division of Health Studies (36). The statistical analysis was designed to screen for an excess of asbestos-related disease in communities with facilities that received Libby vermiculite. Specifically, the following questions are explored:

1. Is the number of people who were diagnosed with an asbestos-related cancer while residing in census tract 4419.01 from 1986-1995 higher than what we

Table 1. Demographic Characteristics of the Populations Living in Census Tract 44119.01, ZIP Code 94536 and in the United States (2), Flintkote Company, Fremont, California.

	Census Tract 4419.01	ZIP Code 94536	U.S.
Total population	6,124	58,581	--
Sex			
Males	51%	49%	49%
Females	49%	51%	51%
Race/Ethnicity			
<i>Non-Hispanic</i>			
White	64%	68%	76%
Black	4%	4%	12%
American Indian	0%	1%	1%
Asian/Pacific Islander	19%	13%	3%
<i>Hispanic</i>			
White	6%	8%	5%
Asian/Pacific Islander	19%	0%	0%
Other	5%	6%	4%
Age			
Under 18 years old	20%	24%	26%
18-64 years old	75%	68%	62%
65 and over	4%	9%	13%
Education			
Less than 9th grade	2%	5%	9%
Some high school	4%	10%	15%
High school graduate	24%	26%	30%
Some college or higher	69%	59%	45%
Employment			
In labor force	80%	75%	65%
Not in labor force	20%	25%	35%
Employed	98%	95%	94%
Unemployed	2%	5%	6%
Poverty			
Income below poverty level	5%	6%	13%

would expect if the incidence rates of these cancers in census tract 4419.01 population were the same as the rates in the U.S. population?

2. Are the incidence rates of asbestos-related cancers in census tract 4419.01 population from 1986-1995 higher than the rates in the U.S. population?
3. Is the number of people who died from asbestos-related disease while residing in ZIP Code 94539 from 1989-1998 higher than what we would expect if mortality rates in the ZIP Code 94536 population were the same as the mortality rates in the U.S. population?
4. Are the mortality rates for asbestos-related disease in the ZIP Code 94536 population from 1989-1998 higher than the mortality rates in the U.S. population?

These four questions are similar in that they all compare the incidence and mortality rates in the Fremont community with the incidence and mortality rates in the U.S. population. They differ, however, in how the comparison is made.

Statistical Measures of Comparison

The first question is explored by calculating a statistical measure called the standardized incidence ratio (SIR). SIR is a numerical expression that compares how many people in the census tract 4419.01 population were diagnosed with cancer and how many diagnoses would be expected (hypothetically) if the incidence rate of cancer in the census tract 4419.01 population was the same as the incidence rate of cancer in the U.S. population. Details on how SIR is calculated are provided in Appendix B. If the number of people who were diagnosed with an asbestos-related cancer while residing in census tract 4419.01 is the same as the expected number, SIR will equal 1. If the number of people in the census tract 4419.01 population who were diagnosed with an asbestos-related cancer is less than the expected number, SIR will be less than 1. If the number of people in the census tract 4419.01 population who were diagnosed with an asbestos-related cancer is more than one would expect, SIR will be greater than 1.

The second question is explored by calculating a statistical measure called the standardized rate ratio (SRR). SRR is the ratio of the number of expected cancer diagnoses in the U.S. population, based on incidence rates of cancer in the census tract 4419.01 population, to the number of observed cancer diagnoses in the U.S. population. Details on how SRR is calculated are provided in Appendix C. If the incidence rate of cancer in the census tract 4419.01 population is the same as the incidence rate of cancer in the U.S. population, SRR will equal 1. If the incidence rate of cancer in the census tract 4419.01 is higher than the incidence rate of cancer in the U.S. population, then SRR will be greater than 1. If the incidence rate of cancer in the census tract 4419.01 is lower than the incidence rate of cancer in the U.S. population, then SRR will be less than 1.

The third question is explored by calculating a statistical measure called the standardized mortality ratio (SMR). SMR is essentially the same measure as SIR except that it evaluates the number of people who died from a disease rather than the number of people who were diagnosed with a disease. Thus, SMR is a numerical expression that compares how many people in ZIP Code 94536 died of an asbestos-related disease, and how many would be expected to die

(hypothetically) if the mortality rates of asbestos-related disease in the ZIP Code 94536 population were the same as the mortality rates in the U.S. population. Details on how SMR is calculated are provided in Appendix D. If the number of people who died from an asbestos-related disease while residing in ZIP Code 94536 is the same as the expected number, SMR will equal 1. If the number of ZIP Code 94536 residents who died from an asbestos-related disease is less than the expected number, SMR will be less than 1. If the number of people in ZIP Code 94536 who died from an asbestos-related disease is more than one would expect, SMR will be greater than 1.

Lastly, the fourth question is also answered by calculating SRR for mortality rates instead of cancer incidence rates. So SRR in this case is the ratio of number of expected cancer deaths in the U.S. population, based on mortality rates of cancer in ZIP Code population 94536, to the number of observed cancer deaths in the U.S. population.

Interpreting the Expected Number of People to Develop or to Die from a Disease

SIR, SMR, and SRR all compare the actual number of people to get or to die from a disease with an expected number. This expected number of people is a calculated and theoretical number that is often not a whole number. For example, the expected number might be 2.6 people. Because it is not possible for a fraction of a person to get or die from a disease, the expected number can be thought of as an approximation. In this example, the expected number 2.6 people can be interpreted to mean that either two or three people are expected to get or die from a disease.

Accounting for Differences between the Study Populations and the Comparison Population

In this review, the incidence and mortality rates of disease in the Fremont and U.S. populations are compared because it is thought that the Fremont population might have higher rates of disease due to past exposure to harmful levels of asbestos. However, other characteristics can also increase the risk for developing many of the diseases linked to asbestos. If the study populations differ from the U.S. population in terms of how common these characteristics are, then these differences can bias (i.e., create a faulty appearance) the results of the comparison unless they are accounted for in the analysis. For example, smoking can increase the risk of developing lung cancer. If smoking rates in the Fremont populations are lower than the smoking rates in the U.S. population, but the analysis does not adjust for this difference, then the study populations might appear to have lower rates of lung cancer in comparison with the U.S. population than they in fact do. This bias can hide a true excess of disease or it can create the appearance of an excess when none really exists.

This analysis did account for differences in age and sex, but did not account for other risk factors for asbestos-related disease (e.g., smoking, race/ethnicity, socioeconomic status).

Statistical Tests

The number of people who get or die from cancer or other diseases in a given geographic area changes from year to year; this fluctuating pattern is characteristic of the occurrence of disease and is expected. Because of this, the values of SIR, SMR, and SRR will also change, depending

on which time period is under study. If the number of cases occurring in one time period under study is higher than average, then SIR, SMR, or SRR will be higher than 1 (e.g., 1.2). If a different time period was under study when the number of cases was lower than average, SIR, SMR, and SRR will be less than 1 (e.g., 0.9). Some degree of fluctuation in the SIR, SMR, and SRR values from one time period to another is normal and expected.

An important question is, when is SIR, SMR, or SRR higher or lower than what would be expected, given that the number of people getting disease in a given geographic area normally varies over time? Is the incidence rate or mortality rate in the Fremont population the same as that in the U.S. population, or is disease or death occurring less or more frequently in the Fremont population than in the U.S. population?

To answer this question, a statistical test measure called a confidence interval (CI) was calculated for SIR, SMR, and SRR using Byar's approximation method (37). A confidence interval is a range of possible values for SIR, SMR, or SRR that are consistent with the normal variation in disease over time in a geographic area. If the CI range includes the value one, then there is no "statistically significant" difference between the incidence or mortality rates in the Fremont and U.S. populations, as represented by SIR, SMR, or SRR. That is, the incidence or mortality rate in the Fremont population is the same as the incidence or mortality rate in the U.S. population. If the CI range is less than 1 or greater than 1, then there is a "statistically significant" difference between the incidence or mortality rates in the two populations: the incidence rate or mortality rate in the Fremont population is not the same as the incidence rate or mortality rate in the U.S. population.

Part of the process of calculating a CI includes selecting a level of certainty for this statistical test. CDPH used a 95% level of certainty that is the standard value selected for these types of analyses.

Sources of Information on Incidence and Mortality Rates

Information on the number of people who developed cancer while residing in census tract 4419.01 was obtained from the California Cancer Registry (CCR). Information on cancer rates in the U.S. population was obtained from the Surveillance, Epidemiology, and End Results program of the National Cancer Institute (SEER) (38 Surveillance Epidemiology and End Results (SEER)).

Information on the number of people who died while residing in ZIP Code 94536 was obtained from CDPH, Center for Health Statistics, Office of Vital Records (CDPH-OVR). Information on mortality rates in the U.S. population was obtained from the National Center for Health Statistics (NCHS) (39).

Results of the Cancer Statistics Review

SIRs and SRRs for the census tract 4419.01 population are presented in Table 2. Table 2 shows:

For each cancer group evaluated

- the reason for evaluating that type of cancer.

For the SIR analysis

- the number of people who were diagnosed with the type of cancer while residing in census tract 4419.01;
- the number of people expected to be diagnosed (if the census tract 4419.01 population had the same incidence rate as the U.S. population); and
- SIR and 95% CI for SIR.

For the SRR analysis

- the number of people who were diagnosed with the type of cancer while residing in the United States;
- the number of people expected to be diagnosed (if the U.S. population had the same incidence rate as the census tract 4419.01 population); and
- SRR and 95% CI for SRR.

Table 2. Standardized Incidence Ratio (SIR), Standardized Rate Ratio (SRR), and 95% Confidence Intervals (CI) of Selected Cancers in the Census Tract 4419.01 Population, 1986-1995. Flintkote Company, Fremont, California.

Cancer Group (ICD-O-2 Code)	Reason*	Census Tract 4419.01			U.S. Population		
		Number of diagnoses	Number expected	SIR (95% CI)	Number of diagnoses	Number expected	SRR (95% CI)
Lung and bronchus (C340:C349†)	1	13	19.7	0.66 (0.35, 1.13)	148,246	142,574.2	0.96 (0.50, 1.84)
Mesothelioma (M-9050:9053)	1	1	0.3	3.19 (0.04, 17.76)	2,360	7,991.9	3.39 (0.52, 21.86)
Digestive organs (C150: C218, C260:C269†)	2	19	20.5	0.93 (0.56, 1.45)	163,384	159,687.2	0.98 (0.51, 1.88)
Respiratory system and intrathoracic organs (C320:C399†)	3	15	21.8	0.69 (0.39, 1.14)	162,067	153,197.1	0.95 (0.51, 1.74)
Peritoneum, retroperitoneum, and pleura (C480:C488, C384†)	3	1	0.6	1.76 (0.02, 9.80)	3,814	7,991.9	2.10 (0.32, 13.52)
All cancers (C000:C809†)	4	132	155.1	0.85 (0.71, 1.01)	1,045,968	950,392.4	0.91 (0.71, 1.16)
Female breast (C500:C509†)	4	29	24.6	1.18 (0.79, 1.69)	154,568	143,995.3	0.93 (0.63, 1.38)
Prostate (C619†)	4	25	18.3	1.37 (0.88, 2.02)	153,845	240,626.8	1.56 (1.03, 2.38)

†Excluding M-9590:9989. **Bold** typeface indicates a statistically significant result. *Reason for studying: 1) exposure to asbestos is known to cause a type of cancer in this cancer group or this disease; 2) there is some, but inconclusive, evidence that exposure to asbestos might be associated with some digestive organ cancers; 3) this cancer group might include people with an asbestos-related cancer that was misdiagnosed; 4) exposure to asbestos might have exacerbated the condition of people with these diseases and thereby led to premature or increased chance of death; and 5) this cancer or cancer group was studied to confirm that information is reported to CDPH-OVR and NCHS in a consistent manner.

Between 1986 and 1995, the incidence rates of asbestos-related cancers in the census tract 4419.01 population were not statistically significantly different from the incidence rates in the U.S. population. Thirteen people were diagnosed with lung or bronchial cancer, when 19.7 diagnoses would be expected if the incidence rate in the census tract 4419.01 population was the same as the incidence rate in the U.S. population (SIR=0.66). 95% CI (0.35-1.13) indicates that there is no statistically significant difference between the incidence rates of lung and bronchus cancer in the census tract 4419.01 population and the U.S. populations, as measured by SIR.

Similarly, SRR for lung and bronchus cancer was 0.96, with 95% CI of (0.50-1.84). Thus, there is also no statistically significant difference between the incidence rates of lung and bronchus cancer in the census tract 4419.01 population and U.S. populations, as measured by SRR. One person was diagnosed with mesothelioma, when 0.3 diagnoses would be expected if the census tract 4419.01 population had the same incidence rate as the U.S. population (SIR=3.19). Also, SRR for mesothelioma was 3.39. However, 95% CIs for SIR (0.04-17.76) and the SRR (0.52-21.86) indicate that there is no statistically significant difference between the incidence rate of mesothelioma in the census tract 4419.01 population and that in the U.S. population during the years 1986-1995.

Between 1986 and 1995, the incidence rate of digestive organ cancers in the census tract 4419.01 population was not statistically significantly different from the incidence rate in the U.S. population, as measured by the SIR analysis (SIR=0.93; 95% CI, 0.56-1.45) and the SRR analysis (SRR=0.98; 95% CI, 0.51-1.88).

The incidence rate of cancer of the respiratory system and intrathoracic organs in the census tract 4419.01 population was not statistically significantly different from the incidence rate in the U.S. population, as evaluated by the SIR analysis (SIR=0.69; 95% CI, 0.39-1.14) and the SRR analysis (SRR=0.95; 95% CI, 0.51-1.74). Neither was the incidence rate of cancer of the peritoneum, retroperitoneum, and pleura in the census tract 4419.01 population statistically significantly different from that in the U.S. population (SIR=1.76; 95% CI 0.02-9.80) and (SRR=2.10; 95% CI, 0.32-13.52).

In terms of the reference outcome analyses, according to both the SIR and SRR analysis, the incidence rates of all types of cancer and female breast cancer in the census tract 4419.01 population were not statistically significantly different from the incidence rates in the U.S. population. For all types of cancer, SIR=0.85 and 95% CI, 0.71-1.01; and SRR=0.91 and 95% CI, 0.71-1.16. For female breast cancer, SIR=1.18 and 95% CI, 0.79-1.69; and SRR=0.93 and 95% CI, 0.63-1.38.

The only statistically significant result in the cancer statistics review was the SRR analysis of prostate cancer. According to this analysis, the mortality rate from prostate cancer in the census tract 4419.01 population was statistically significantly higher than the mortality rate in the U.S. population (SRR=1.56; 95% CI, 1.03-2.38). According to the SIR analysis, the census tract 4419.01 population did not have a statistically significantly different mortality rate due to prostate cancer than the U.S. population (SIR=1.37 and 95% CI, 0.88-2.02). These reference analyses did not show a systematic problem with reporting or other data anomalies affecting the study area.

Results of the Mortality Statistics Review

SMRs and SRRs for the ZIP Code 94536 population are presented in Table 3. Table 3 shows:

For each disease group evaluated

- the reason for evaluating the disease.

For the SMR analysis

- the number of people who died from the disease while residing in ZIP Code 94536;
- the number of people expected to die (if this population had the same disease mortality rate as the U.S. population); and
- SMR and 95% CI for SMR.

For the SRR analysis

- the number of people who died from the disease while residing in the United States;
- the number of people expected to die (if the U.S. population had the same disease mortality rate as the ZIP Code 94536 population); and
- SRR and 95% CI for SRR.

Table 3. Standardized Mortality Ratio (SMR), Standardized Rate Ratio (SRR) and 95% Confidence Intervals (CI) of Selected Causes of Death Occurring in ZIP Code 94536, 1989-1998. Flintkote Company, Fremont, California.

Cause of Death (ICD-9 Code)	Reason*	ZIP Code 94536			U.S. Population		
		Number of deaths	Number expected	SMR (95% CI)	Number of deaths	Number expected	SRR (95% CI)
Cancer of the lung and bronchus (162.2-162.9)	1	260	251.9	1.03 (0.91, 1.17)	1,476,326	1,586,801.5	1.07 (1.01, 1.14)
Cancer of the peritoneum, retroperitoneum and pleura (including mesothelioma) (158, 163)	1	1	1.8	0.55 (0.01, 3.08)	10,615	8,827.5	0.83 (0.15, 4.72)
Asbestosis (501)	1	0	0.5	0 (0, 7.23)†	3,367	0.0	0‡
Cancer of the digestive organs (150-154, 159)	2	150	137.6	1.09 (0.92, 1.28)	832,523	972,803.8	1.17 (1.08, 1.27)
Cancer of the respiratory system and intrathoracic organs (161-165)	3	267	260.5	1.02 (0.91, 1.16)	1,524,872	1,634,494.9	1.07 (1.01, 1.14)
Cancer (no site specified) (199)	3	76	54.9	1.38 (1.09, 1.73)	327,646	466,377.9	1.42 (1.27, 1.60)
Pneumoconiosis (500-505)	3	0	1.7	0 (0, 2.17)†	11,617	0.0	0‡
Chronic obstructive pulmonary disease (490-496)	3, 4	186	153.3	1.21 (1.05, 1.40)	986,772	1,241,389.1	1.26 (1.17, 1.35)
Other diseases of the respiratory system (510-519)	4	32	28.0	1.14 (0.78, 1.61)	172,155	211,143.1	1.23 (1.03, 1.46)
Diseases of pulmonary circulation (415-417)	4	11	20.6	0.53 (0.27, 0.95)	119,554	67,949.7	0.57 (0.42, 0.77)
All cancers (140-208)	5	789	891.5	0.89 (0.82, 0.95)	5,259,810	4,847,610.4	0.92 (0.89, 0.96)
Female breast cancer (174)	5	59	76.7	0.77 (0.59, 0.99)	430,680	329,372.8	0.76 (0.67, 0.87)
Prostate cancer (185)	5	63	49.7	1.27 (0.97, 1.62)	334,151	447,294.7	1.34 (1.18, 1.52)

†Exact confidence interval based on Poisson distribution. ‡Confidence interval not calculated since the expected number of deaths was 0. **Bold** typeface indicates a statistically significant result. *Reason for studying: 1) exposure to asbestos is known to cause a type of cancer in this cancer group or this disease; 2) there is some, but inconclusive, evidence that exposure to asbestos might be associated with some digestive organ cancers; 3) this cancer group might include people with an asbestos-related cancer that was misdiagnosed; 4) exposure to asbestos might have exacerbated the condition of people with these diseases and thereby led to premature or increased chance of death; and 5) this cancer or cancer group was studied to confirm that information is reported to CDPH-OVR and NCHS in a consistent manner.

The mortality statistics review found inconsistent evidence that the ZIP Code 94536 population experienced statistically significantly higher rates of death from cancer of the lung and bronchus than the U.S. population. According to the SRR analysis, the mortality rate of cancer of the lung and bronchus in the ZIP Code 94536 population was statistically significantly higher than the rate in the U.S. population (SRR=1.07; 95% CI, 1.01-1.14). However, the SMR analysis did not show the mortality rate of cancer of the lung and bronchus in the ZIP Code 94536 population to be statistically significantly different from the rate in the U.S. population (SMR=1.03; 95% CI, 0.91-1.17). The mortality statistics review did not find any evidence that the ZIP Code 94536 population had statistically significantly different mortality rates from mesothelioma or from asbestosis than the U.S. population. For cancer of the peritoneum, retroperitoneum, and pleura (including mesothelioma), SMR=0.55 and 95% CI, 0.01-3.08, and SRR=0.83 and 95% CI, 0.15-4.72. For asbestosis, SMR=0 and 95% CI, 0-7.23, and SRR=0.

The mortality statistics review also found inconsistent evidence that the ZIP Code 94536 population experienced statistically significantly higher rates of death from digestive organ cancers, which have been inconclusively linked to asbestos exposure in previous epidemiologic studies. The rate of death from digestive organ cancers in the ZIP Code 94536 population was not statistically significantly different from the rate in the U.S. population, as measured by the SMR analysis (SMR=1.09; 95% CI, 0.92-1.28). In contrast, the SRR analysis did indicate that the mortality rate for digestive organ cancers in the ZIP Code 94536 population was statistically significantly higher than the rate in the U.S. population (SRR=1.17; 95% CI, 1.08-1.27).

The mortality statistics review found consistent evidence that the ZIP Code 94536 population experienced statistically significantly higher rates of death from cancer (no site specified) and chronic obstructive pulmonary disease than the U.S. population. For cancer (no site specified), SMR=1.38 and 95% CI, 1.09-1.73; and SRR=1.42 and 95% CI, 1.27-1.60. For chronic obstructive pulmonary disease, SMR=1.21 and 95% CI, 1.05-1.40; and SRR=1.26 and 95% CI, 1.17-1.35. In contrast, the evidence that the ZIP Code 94536 population experienced statistically significantly higher rates of death from cancer of the respiratory system and intrathoracic organs was inconsistent. While the SMR analysis found no difference between the mortality rates in the ZIP Code 94536 population and the U.S. population (SMR=1.02 and 95% CI, 0.91-1.16), SRR did find a statistically significant difference (SRR=1.07 and 95% CI, 1.01-1.14). Lastly, neither the SMR nor the SRR analysis indicated that the ZIP Code 94536 population and U.S. population experienced statistically significantly different rates of death from pneumoconioses (SMR=0, 95% CI 0-2.17; and SRR=0).

According to the SMR analysis, the mortality rate for other diseases of the respiratory system in the ZIP Code 94536 population was not different from the mortality rate in the U.S. population (SMR=1.14; 95% CI, 0.78-1.61). However, according to the SRR analysis, the mortality rate for other diseases of the respiratory system in the ZIP Code 94536 population was statistically significantly higher than the U.S. population (SRR=1.23; 95% CI, 1.03-1.46). Both the SMR and the SRR analysis indicate that the ZIP Code 94536 population had statistically significantly lower mortality rate for diseases of pulmonary circulation than the U.S. population: SMR=0.53 and 95% CI 0.27-0.95; and SRR=0.57 and 95% CI 0.42-0.77.

The reference outcomes analyzed using the SMR analysis were not completely uniform, although generally consistent with the SRR analysis. The analyses indicate that the mortality

rates for all cancers and for female breast cancer in the ZIP Code 94536 population were statistically significantly lower than the rates in the U.S. population. For all cancers, SMR=0.89 and 95% CI 0.82-0.95, while SRR=0.92 and 95% CI 0.89-0.96. For female breast cancer, SMR=0.77 and 95% CI 0.59-0.99, while SRR=0.76 and 95% CI 0.67-0.87. The male population of ZIP Code 94536 did have statistically significantly higher mortality rates from prostate cancer than the U.S. population according to the SRR analysis: SRR=1.34 and 95% CI 1.18-1.52. According to the SMR analysis, there was no statistically significant difference between the rates in the two populations: SMR=1.27 and 95% CI 0.97-1.62.

Deficits were noted in rates for all cancers and female breast cancer, although not in prostate cancer, which showed an excess. The deficit in female breast cancer, one of the most common cancer sites, would affect the rates of cancer overall because of its relatively greater contribution. Other factors which may contribute to these variations are unknown, but may be due to other aspects of the risk factors beyond the scope of this analysis, such as residual confounding especially due to race/ethnicity, or other aspects of the available numerator or denominator data. The magnitude of this deficit was modest, and overall the data analysis did not suggest the presence of systematic bias in reporting or other data anomalies affecting the results.

Limitations of the Health Statistics Review

Five limitations of this analysis are worth discussion and exploration because they might 1) affect the accuracy of the results, 2) limit the ability of the analyses to observe an excess of asbestos-related disease attributable to vermiculite processing at Flintkote, if one exists, or 3) limit the degree to which this analysis can serve as an indicator of community exposure to Libby asbestos.

- 1. The SIR, SMR, and SRR results might be biased if the analyses do not account for the ways that the Fremont and U.S. population differ with respect to other risk factors for asbestos-related diseases (e.g., race/ethnicity, socioeconomic status, or smoking).*

As discussed previously, this analysis does not account for all the ways that the Fremont population differs from the U.S. population with respect to risk factors for diseases that can be caused by exposure to asbestos (e.g., smoking, race/ethnicity, or socioeconomic status). As a result, this analysis might not accurately identify an excess or lack of excess of disease attributable to asbestos exposure.

To assess whether the Fremont and U.S. populations differ with respect to other risk factors for asbestos-related disease, CDPH gathered information from the U.S. Census. Table 1 shows that the population in census tract 4419.01 differs substantially from the U.S. population in terms of race/ethnicity and socioeconomic status (measured by education level and poverty status). Also, the ZIP Code 94536 population differ substantially from the U.S. population in terms of these characteristics. No information on smoking rates in the study populations is available. However, smoking has historically been less common in California (40), and, since the late 1980s, smoking rates in California have been declining more rapidly than the rest of the country (41). Smoking rates also tend to be higher among people of low socioeconomic status (42) and tend to differ by race and ethnicity (43-45). Using these statewide trends, it is likely that the smoking rates in the Fremont study populations are different from those in the U.S. population.

It is not possible to predict whether or how the combined racial, ethnic, and socioeconomic differences between the study and U.S. populations could bias the analysis (that is, whether they could be masking a true elevation in rates of asbestos-related disease.) However, any conclusions drawn from this health statistics review could be made more definitively, if these differences were accounted for in the SIR, SMR, and SRR analyses.

- 2. The results of the analyses might be inaccurate if the study populations are larger or smaller than they are assumed to be.*

Information on the size of the study populations during the study periods (1986-1995 for the cancer statistics review and 1989-1998 for the mortality statistics review) is needed to calculate SIR, SMR, and SRR as well as 95% CIs. Information on the size of the populations in census tracts and ZIP Codes is collected by the U.S. Census once every decade, but not during the intervening years. Therefore, to calculate the statistical measures of comparison, ATSDR made the customary assumption that the size of the study populations in 1990 (as determined by the U.S. Census) represents the average size of the populations during the study periods.

If this assumption does not hold true, then the results of the SIR, SMR, and SRR analyses will be biased (inaccurate). Specifically, if the size of the study populations in 1990 is smaller than the average size of the study populations during the study periods, then SIR, SMR, and SRR will be inaccurately high numbers, and the statistical tests might falsely indicate a statistically significant excess of disease. And, if the size of the study populations in 1990 is larger than the average size of the study populations during the study periods, then SIR, SMR, and SRR will be inaccurately low numbers, and the statistical tests might falsely indicate a lack of disease excess.

Without knowing the true size of the study populations during the study periods, it is not possible to predict whether, or in what way, these statistical measures might be biased. However, it is possible to obtain some sense of whether any bias is occurring by referring to information on the size of these populations during U.S. Census years.

According to U.S. Census data, the census tract 4419.01 population grew by 88% between 1980 and 1990, and by 87% between 1990 and 2000 (46). If these trends represent the growth of the census tract population between 1986 and 1995, then the assumed size of the cancer statistics review study population is slightly smaller than the true size. This difference will bias the values of SIR, SRR, and 95% CIs in a way that makes them higher than they actually are, but not by a substantial amount.

The ZIP Code 94536 population grew 14% between the years 1990 and 2000 (47). If this trend represents the growth of this population during the years 1989 and 1998, then the assumed size of the mortality statistics review study population is smaller than the true size. This difference will bias the values of SMR, SRR, and 95% CIs in a way that makes them higher than they actually are.

In summary, if more accurate information on population size was used in the analysis, then the values of SIRs, SMRs, and SRRs would be lower than they were in these results: the incidence and mortality rates in the Fremont study populations might be even lower, in comparison to the rates in the U.S. population, than this analysis indicates.

- 3. The analysis might fail to observe a true excess of asbestos-related cancers and disease if the study populations include people who could not have been exposed to asbestos from the processing of vermiculite at Flintkote.*

This health statistics review would ideally evaluate the health status of only those people who were exposed to asbestos from the processing of Libby vermiculite at Flintkote, assuming that off-site contamination and exposure did occur. The effect of including people who were not exposed to asbestos in the study population is to lessen the ability to see an excess of asbestos-related disease in the population. This occurs because the people who were never exposed to asbestos can make the population appear healthier than it would otherwise appear if they were not included in the analysis.

Due to several reasons (e.g., lack of information on whether asbestos pollution from Flintkote occurred, lack of information on how far the asbestos pollution would have traveled in the air, and restrictions on the geographic area for which cancer and mortality statistics are available), it is likely that this health statistics review evaluated the occurrence of asbestos-related cancers and death in a population that included people who were never exposed to asbestos. Therefore, SIRs, SMRs, SRRs, and 95% CIs are likely to be smaller numbers than they would otherwise be if unexposed people were not included in the study population. The incidence and mortality rates in the Fremont population might be higher, in comparison to the rates in the U.S. population, if the study populations only included people who were exposed to Libby asbestos from the processing of Libby vermiculite at Flintkote.

- 4. The analysis might fail to observe a true excess of asbestos-related cancers and disease, attributable to vermiculite processing at Flintkote if the study periods do not correspond to the years that this excess of disease would be expected to occur.*

The diseases caused by exposure to asbestos take many years to develop. Current knowledge is that lung cancer will develop 20 to 30 years after exposure to asbestos, mesothelioma will develop 30 to 40 years after exposure, and asbestosis will develop 10 to 20 years after exposure. Flintkote received shipments of Libby vermiculite between the years 1967 and 1979. Therefore, we would expect that any lung cancer caused by exposure to Libby asbestos would occur between 1987-2009, any mesothelioma caused by exposure to Libby asbestos would occur between 1997-2019, and any asbestosis caused by exposure to Libby asbestos would occur between 1977-1999.

This health statistics review evaluated the incidence rates and mortality rates from asbestos-related diseases between the years 1985-1996 and 1989-1998, respectively. These study periods do not correspond entirely to the years that disease caused by exposure to Libby asbestos is most likely to occur (see Table 4). Most notably, the study periods occur before the time that mesothelioma caused by exposure to Libby asbestos is expected to occur.

Table 4. Years that Disease Due to Exposure to Libby Asbestos from Vermiculite Processing at Flintkote would Be Expected to Occur (Assuming that Hazardous Exposure Occurred), and Number of Period Years During which Exposure-Related Disease Is Expected to Occur. Flintkote Company, Fremont, California.

Disease	Years During which Asbestos-Related Disease Is Most Likely to Occur (Based on Latency Period)	Number of Years of Overlap between the Period Evaluated and the Years that Asbestos-Related Disease Is Most Likely to Occur	
		<i>Cancer Statistics Review (1986–1995)</i>	<i>Mortality Statistics Review (1989–1998)</i>
Cancer of the lung and bronchus	1987-2009	9	10
Mesothelioma	1997-2019	0	2
Asbestosis	1977-1999	—	10

5. *The results of the health statistics review can serve as an indicator of community exposure to Libby asbestos only if the study populations include the people who were living near Flintkote at the time that Libby vermiculite was processed.*

According to the protocol for this health statistics review, finding a statistically significant elevation in asbestos-related disease in a community would alert CDPH and ATSDR to the possibility that community members might have been exposed to asbestos as a result of the facility's handling or processing of vermiculite from Libby. This interpretation is based on an assumption that the study population consists of people who were exposed to Libby asbestos. Therefore, this interpretation is appropriate only if the study populations include the people who were living near Flintkote during the time that Libby vermiculite was processed.

Cancer registry and vital statistics records do not collect information on residential history. Therefore, it is not possible to determine whether the people in the study populations lived near Flintkote during the years that Libby vermiculite was processed. However, information on population mobility from the U.S. Census can provide some insight into the likelihood that the study populations included the people who were living near Flintkote during the years that Libby vermiculite was processed (1967-1979).

According to the 1990 and 2000 U.S. Census, 90% to 97% of the people residing in census tract 4419.01 moved into their home after 1979, and 93% of the people residing in ZIP Code 94536 in 2000 moved into their home after 1979 (48). Therefore, nearly all of the people in the study populations are unlikely to have had the potential to be exposed to Libby asbestos, since they moved into their homes after Flintkote stopped using Libby vermiculite.

Child Health Considerations

ATSDR and CDPH recognize that infants and children may be more vulnerable to exposures than adults in communities faced with environmental contamination. Children could be especially vulnerable to asbestos exposure because they are more likely to disturb fiber-laden soils or indoor dust while playing. Children also breathe air that is closer to the ground and may thus be more likely to inhale airborne fibers from contaminated soils or dust.

Furthermore, children who are exposed could be more at risk of actually developing asbestos-related disease than people exposed later in life because of the long latency period between exposure and onset of asbestos-related respiratory disease. Children might also be more biologically susceptible to the toxic effects of asbestos. Whether the latency period for asbestos-related disease is different for people exposed during childhood is unknown.

This review of health statistics screened people of all ages, including the people who were infants or children during the years that Libby vermiculite was shipped to the WR Grace and Company facility. This group of people who were 18 years old or younger during the years of potential exposure to Libby asbestos (1972-1988) would be between the ages of 0 and 41 during the years that the cancer statistics review evaluates (1986-1995), and between 1 and 44 during the years that the mortality statistics review evaluates (1989-1998).

Conclusions

Flintkote received approximately 2,804 tons of asbestos containing vermiculite from Libby, Montana, between 1967 and 1979. CDPH was able to identify possible times in the gypsum wallboard manufacturing process in which workers could be exposed to dust from handling vermiculite contaminated with asbestos. Because of the lack of company records, CDPH was not able to contact former workers of Flintkote and inform them about the health hazards of exposure to Libby vermiculite.

The cancer statistics review did not find any evidence that the census tract 4419.01 population experienced statistically significantly higher incidence rates of asbestos-caused cancers (lung cancer and mesothelioma) than the U.S. population during the years 1986-1995. The cancer statistics review for cancer of the respiratory system and intrathoracic organs, and cancer of the peritoneum, retroperitoneum, and pleura indicated that an excess of asbestos-related cancers in this Fremont population is not being obscured by physician misdiagnosis.

The mortality statistics review produced scattered evidence that the ZIP Code 94536 population may have experienced higher mortality rates from asbestos-related disease than the U.S. population during the years 1989-1998. Although the SRR analysis indicated that the ZIP Code 94536 population had a 7% higher rate of death from lung and bronchus cancer and a 17% higher rate of death from digestive organ cancers, the SMR analysis did not produce evidence of a statistically significant difference between the mortality rates from these diseases in the two populations. If the 76 deaths coded as cancer (no site specified) represent misdiagnosed deaths from mesothelioma, then the ZIP Code 94536 population had statistically significantly higher rates of death from mesothelioma than the U.S. population. Otherwise, it did not have a statistically significantly higher rate of death from mesothelioma than the U.S. population.

Similarly, if the deaths from chronic obstructive pulmonary disease are actually misdiagnosed cases of asbestosis, then the ZIP Code 94536 population did have statistically significantly high rates of death from this disease. It is also possible that asbestos exposure could have led to premature or increased rates of death from chronic obstructive pulmonary disease, other diseases of the respiratory system, or diseases of pulmonary circulation, thereby contributing to the higher rates of death from this disease in the ZIP Code 94536 population. The SMR and SRR analyses for chronic obstructive pulmonary disease, the SRR analysis for other diseases of the respiratory system, and the SMR and SRR analyses for diseases of the pulmonary circulation showed statistically significantly higher rates of death for the ZIP Code 94536 population.

Cancers overall and selected outcomes assumed to have no causal relationship with asbestos were reviewed for comparison. Results of these analyses were inconsistent, with cancers overall showing a slight deficit. The reasons for this were unknown, possibly reflecting aspects of data collection or differences in health risk factors between populations beyond the scope of this analysis. However, this modest deficit would not be adequate cause to invalidate the overall study results.

A very similar protocol to the one used in this health statistics review identified a statistically significant excess of asbestos-related disease in the Libby, Montana, community. If the Fremont study populations were similar to the Libby community in terms of level of exposure to Libby asbestos, population mobility, and other characteristics, then this type of analysis would be expected to also be able to detect a statistically significant excess of asbestos-related disease in the Fremont community.

The Fremont study populations differ from the Libby community in ways that increase the limitations of this type of analysis. Therefore, although the results of this health statistics review could be correctly reflecting that the health of the Fremont community was not impacted by exposure to Libby asbestos, the lack of consistent evidence of disease excess could be due to any or all of the following reasons:

1. this analysis did not account for the ways in which the Fremont and U.S. populations differ with respect to other risk factors for asbestos-related disease;
2. the assumptions about the size of the Fremont study populations made the incidence and mortality rates in the Fremont study populations appear more similar to the rates in the U.S. population than they truly are;
3. the study populations included people who were never exposed to Libby asbestos from Flintkote, which also made the incidence and mortality rates in the Fremont study populations appear more similar to the rates in the U.S. population than they truly are; and
4. given the years that exposure to Libby asbestos would have occurred, combined with the amount of time that asbestos-related disease takes to develop, this analysis might be failing to observe an excess of disease or death (in particular, mesothelioma), because the time period it evaluates precedes the time period that disease attributable to Libby asbestos would occur.

More important than these limitations, perhaps, is the likelihood that the study populations do not include the people who were living near the Flintkote facility during the years that Libby vermiculite was processed. Because the study populations do not appear to consist of people who were potentially exposed to Libby asbestos, the results of this analysis do not serve as a reliable indicator of past community exposure. Therefore, the lack of consistent evidence of high rates of asbestos-related disease or death during the years 1986-1995 and 1989-1998, respectively, does not establish that the community neighboring the Flintkote Company was not exposed to Libby asbestos.

Residents living in the neighborhood surrounding the former Flintkote facility may have been exposed to asbestos from Libby vermiculite during 1967 to 1979. The cancer statistics review presented in this health consultation did not show consistent evidence of elevated rates of asbestos-related disease during 1986-1995 and 1989-1998. There are many limitations to this review, as described in earlier in this section. However, based on the best available evidence, ATSDR and CDHS categorized this site as “No Apparent Public Health Hazard” to communities surrounding the former Domtar facility.

Based on our understanding of gypsum wallboard manufacturing and calculations of probable exposure levels outlined in this document, it is likely that hopper fillers at the former Flintkote facility were exposed to harmful levels of asbestos during their handling of Libby vermiculite. Consequently, ATSDR and CDHS has categorized this site as “Public Health Hazard” for hopper fillers who worked at the Flintkote facility from 1967 to 1979. Because we do not have knowledge about how other employees besides the hopper fillers may have handled Libby vermiculite, ATSDR and CDHS has categorized this site as “Indeterminate Public Health Hazard” for other (not hopper filler) employees who worked at Flintkote from 1967 to 1979.

If residual contamination in the air, dust or soil exists at the facility from past use of Libby vermiculite, there are potential pathways of exposure to current and future workers. No air, dust or soil samples have been taken at the Flintkote facility. Data from other gypsum manufacturing plants suggest that it is unlikely that there is any risk to current or future workers at the Flintkote facility from past Libby vermiculite use. Sampling at the facility could be used to confirm this conclusion.

Recommendations

CDPH recommends efforts to:

1. expand public awareness of the potential for, and ways to, avoid or reduce exposure to asbestos in consumer products made with WR Grace-Libby vermiculite; and
2. make information available to former workers at Flintkote of their potential exposure to asbestos and of ways to reduce risk of asbestos-related disease (e.g., smoking cessation) via the CDPH website.

Public Health Action Plan

The Public Health Action Plan is a collection of activities intended to ensure that this health statistics review also provides a plan of action to mitigate and to prevent adverse effects on human health resulting from exposure to asbestos from Libby vermiculite. Some activities have already been taken by CDPH or ATSDR. Others activities are either ongoing or planned for the future.

Actions Completed

1. CDPH conducted a needs assessment with the Alameda County Health Officer and Environmental Health Departments, the goals of which were to educate the department about the vermiculite health statistics review project, to obtain information about the extent and level of stakeholder concerns, to develop an information dissemination plan, and to identify ways CDPH can support local efforts or activities pertaining to Flintkote.
2. CDPH disseminated information materials on consumer products made with Libby vermiculite to increase public awareness of the potential for, and ways to, reduce or avoid current or future exposure to asbestos from this source.
3. CDPH briefed the Occupational Health Branch (of CDPH) about asbestos contamination of Libby vermiculite, the facilities in California that processed this vermiculite, and the potential for workers at these facilities to have been exposed to asbestos.
4. Information on the potential for, and ways to, reduce exposure to asbestos in vermiculite consumer products was included in this health consultation and provided to the Alameda County Health Officer and Environmental Health Director.

Ongoing Actions

CDPH will continue to provide technical assistance to the Alameda County Health Officer and Environmental Health Director about the vermiculite health statistics review.

Planned Actions

1. ATSDR has funded health statistics reviews in 25 states with facilities that received Libby vermiculite. Once all of the results from participating states have been received, ATSDR will compare SRRs for all the sites examined, in order to identify trends that might not be apparent when each facility is evaluated individually. The results of the health statistics reviews will also be evaluated in combination with all information on environmental exposures to asbestos produced by research by the National Asbestos Exposure Review project of ATSDR. ATSDR will distribute the results of these analyses to contributing state health departments and other interested parties.
2. Using the results of ATSDR's review of health statistics for all vermiculite facilities nationwide, CDPH will conduct follow-up activities with the Alameda County Health Officer and Environmental Health Department. The specifics of these activities will depend on what is learned from the nationwide review.

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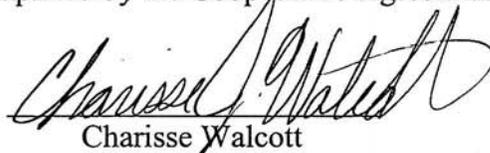
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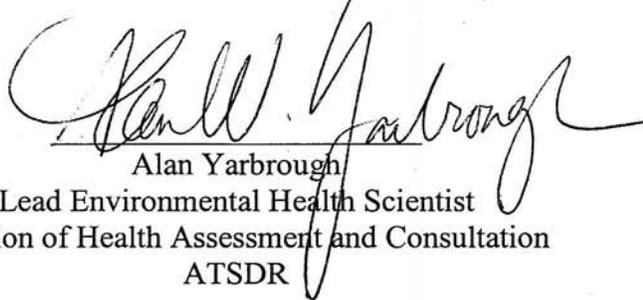
The health consultation Flintkote Company, 27975 Shinn Street, Fremont, Alameda County, was prepared by the California Department of Public Health under a cooperative agreement with the Agency for Toxic Substances and Disease Registry (ATSDR). It was completed in accordance with approved methodology and procedures existing at the time the health consultation was initiated. Editorial review was completed by the Cooperative Agreement partner.



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Appendix A—Glossary

ATSDR

The Agency for Toxic Substances and Disease Registry. ATSDR is a federal health agency based in Atlanta, Georgia, that deals with hazardous substance and waste site issues. ATSDR provides information to the public on harmful chemicals in the environment and on how to be safe from contact with chemicals.

Cancer Risk

The potential for exposure to a contaminant to cause cancer in an individual or population is evaluated by estimating the probability of an individual developing cancer over a lifetime as the result of the exposure. This approach is based on the assumption that there are no absolutely “safe” toxicity values for carcinogens. The U.S. Environmental Protection Agency has developed cancer slope factors for many carcinogens. A slope factor is an estimate of a chemical’s carcinogenic potency, or potential, for causing cancer.

If adequate information about the level of exposure, frequency of exposure, and length of exposure to a particular carcinogen is available, an estimate of excess cancer risk associated with the exposure can be calculated using the slope factor for that carcinogen. Specifically, to obtain risk estimates, the estimated chronic exposure dose (which is averaged over a lifetime or 70 years) is multiplied by the slope factor for that carcinogen.

Cancer risk is the likelihood, or chance, of getting cancer. We say “excess cancer risk” because we have a “background risk” of about one in four chances of getting cancer. In other words, in a million people, it is expected that 250,000 individuals would get cancer from a variety of causes. If we say that there is a “one in a million” excess cancer risk from a given exposure to a contaminant, we mean that if one million people are exposed to a carcinogen at a certain concentration over their lifetime, then one cancer above the background chance, or the 250,000th cancer, may appear in those million persons from that particular exposure. In order to take into account the uncertainties in the science, the risk numbers used are plausible upper limits of the actual risk based on conservative assumptions. In actuality, the risk is probably somewhat lower than calculated, and in fact may be zero.

Concern

A belief or worry that chemicals in the environment might cause harm to people.

Exposure

Coming into contact with a chemical substance. (For the three ways people can come in contact with substances, see Route of Exposure.)

Hazardous Waste

Substances that have been released or thrown away into the environment and, under certain conditions, could be harmful to people who come into contact with them.

Health Statistics Review

The analysis of existing health information (i.e., from death certificates, birth defects registries, and cancer registries) to determine if there is excess disease in a specific population, geographic area, and time period. A health statistics review is a descriptive epidemiologic study.

Incidence

The number of new cases of disease in a defined population over a specific time period.

Mortality

Death. Usually the cause (a specific disease, a condition, or an injury) is stated.

Population

A group of people living in a certain area or the number of people in a certain area.

Registry

A systematic collection of information on persons exposed to a specific substance or having specific diseases.

Source (of Contamination)

The place from which a chemical comes, such as a landfill, pond, creek, incinerator, tank, or drum.

Toxic

Harmful. Any substance or chemical can be toxic at a certain dose (amount).

Toxicology

The study of the harmful effects of chemicals on humans or animals.

Appendix B—Standardized Incidence Ratio

The standardized incidence ratio (SIR) is a measure that compares the incidence rate of disease in two populations. In this health statistics review, SIR compares, for the time period 1986 through 1995, the number of people who were diagnosed with a type of cancer while residing in census tract 4419.01 and the number of people expected to be diagnosed with cancer if the incidence rate of cancer in the census tract 4419.01 population was the same as the incidence rate in the U.S. population. SIR was calculated to account for ways in which census tract 4419.01 and U.S. populations differ in terms of age and sex. SIR is calculated in two steps.

Step 1

The expected number is calculated by 1) multiplying the incidence rate in various age and sex groups in the U.S. population by the number of people in those age and sex groups in the census tract 4419.01 population; then 2) summing the products to obtain the total number of expected cases in the census tract 4419.01 population.

Step 2

SIR is calculated by dividing the actual number of people who were diagnosed with cancer by the expected number.

These steps are demonstrated at right for all types of cancer.

	U.S. Incidence Rate, All Cancers 1986-1995		Number of People in Census Tract 4419.01 1986-1995	=	Number Expected of Cases in Census Tract 4419.01
STEP 1					
<i>Females</i>					
0 to 4	0.000188	X	2,200	=	0.4
5 to 9	0.000097	X	1,820	=	0.2
10 to 14	0.000116	X	1,530	=	0.2
15 to 19	0.000205	X	1,290	=	0.3
20 to 24	0.000351	X	2,940	=	1
25 to 29	0.000605	X	4,820	=	2.9
30 to 34	0.000948	X	4,080	=	3.9
35 to 39	0.001601	X	3,090	=	4.9
40 to 44	0.002631	X	2,590	=	6.8
45 to 49	0.004182	X	1,560	=	6.5
50 to 54	0.005868	X	1,160	=	6.8
55 to 59	0.008014	X	950	=	7.6
60 to 64	0.010734	X	690	=	7.4
65 to 69	0.013577	X	680	=	9.2
70 to 74	0.016334	X	370	=	6.0
75 to 79	0.018378	X	360	=	6.6
80 to 84	0.019683	X	160	=	3.1
85 and up	0.019640	X	30	=	0.6
<i>Males</i>					
0 to 4	0.000216	X	2,610	=	0.6
5 to 9	0.000123	X	1,950	=	0.2
10 to 14	0.000124	X	1,540	=	0.2
15 to 19	0.000210	X	1,600	=	0.3
20 to 24	0.000333	X	2,440	=	0.8
25 to 29	0.000573	X	5,330	=	3.1
30 to 34	0.000871	X	4,430	=	3.9
35 to 39	0.001191	X	3,340	=	4.0
40 to 44	0.001630	X	2,610	=	4.3
45 to 49	0.002697	X	1,890	=	5.1
50 to 54	0.004991	X	1,140	=	5.7
55 to 59	0.008856	X	640	=	5.7
60 to 64	0.014763	X	560	=	8.3
65 to 69	0.022620	X	550	=	12.4
70 to 74	0.030244	X	310	=	9.4
75 to 79	0.035267	X	180	=	6.3
80 to 84	0.038441	X	230	=	8.8
85 and up	0.037822	X	40	=	1.5
Total number of expected cases in census tract = 155.0					
STEP 2					
SIR = $\frac{132}{155.0} = 0.85$					

Appendix C—Standardized Rate Ratio

The standardized rate ratio (SRR) is a measure that compares the incidence rate or the mortality rate for a disease in two populations. For the cancer statistics review, SRR compares the number of people in the United States who were diagnosed with a type of cancer, and the number of people expected to be diagnosed if the incidence rate in the U.S. population was the same as the incidence rate in the census tract 4419.01 population. For the mortality statistics review, SRR compares the number of people in the United States who died from a disease and the number of people expected to die if the mortality rate in the U.S. population was the same as the mortality rate in the ZIP Code 94536 population.

SRR is calculated in a manner that accounts for ways in which the study populations and the U.S. population differ in terms of age and sex. SRR is calculated in two steps.

Step 1

The expected number of cases or deaths in the U.S. population is calculated by 1) multiplying the incidence or mortality rate in various age and sex groups in the study population by the number of people in those age and sex groups in the U.S. population, then 2) summing the products to obtain the total number of expected cases or deaths in the U.S. population.

Step 2

SRR is calculated by dividing the expected number of cases or deaths (calculated in step 1) by the actual number of cases or deaths that occurred.

These steps are demonstrated at right for the mortality rate of all types of cancer.

	ZIP Code 94536 Mortality Rate, All Cancers 1989- 1998		Number of People in the United States 1989-1998	=	Number of Expected Deaths in the United States 1989-1998
STEP 1					
<i>Females</i>					
0 to 4	0.000047	X	93,966,244	=	4,445.0
5 to 9	0.000051	X	91,867,322	=	4,677.6
10 to 14	0.000000	X	89,304,231	=	0.0
15 to 19	0.000060	X	87,811,833	=	5,296.3
20 to 24	0.000000	X	90,427,466	=	0.0
25 to 29	0.000061	X	98,755,306	=	6,016.2
30 to 34	0.000194	X	108,681,120	=	21,103.1
35 to 39	0.000187	X	107,902,167	=	20,176.2
40 to 44	0.000367	X	98,780,341	=	36,227.5
45 to 49	0.000562	X	82,737,629	=	46,481.8
50 to 54	0.001092	X	67,120,643	=	73,329.2
55 to 59	0.002065	X	57,368,622	=	118,489.4
60 to 64	0.003269	X	54,716,238	=	178,871.2
65 to 69	0.004395	X	54,396,949	=	239,049.1
70 to 74	0.010880	X	48,337,651	=	525,913.6
75 to 79	0.010926	X	39,220,867	=	428,524.3
80 to 84	0.011139	X	27,563,804	=	307,039.8
85 and up	0.010452	X	24,880,271	=	260,048.0
<i>Males</i>					
0 to 4	0.000082	X	98,444,382	=	8,099.1
5 to 9	0.000000	X	96,375,416	=	0.0
10 to 14	0.000114	X	93,779,769	=	10,723.8
15 to 19	0.000000	X	92,727,275	=	0.0
20 to 24	0.000000	X	93,916,511	=	0.0
25 to 29	0.000096	X	99,300,884	=	9,569.6
30 to 34	0.000156	X	107,836,073	=	16,791.7
35 to 39	0.000256	X	106,638,555	=	27,333.2
40 to 44	0.000412	X	96,528,396	=	39,741.8
45 to 49	0.000641	X	79,706,353	=	51,093.8
50 to 54	0.002053	X	63,474,519	=	130,284.3
55 to 59	0.002954	X	52,786,640	=	155,929.3
60 to 64	0.004901	X	48,333,937	=	236,886.4
65 to 69	0.007602	X	44,815,676	=	340,704.0
70 to 74	0.012791	X	36,773,021	=	470,352.6
75 to 79	0.021333	X	26,482,551	=	564,961.1
80 to 84	0.019149	X	15,345,068	=	293,841.7
85 and up	0.022059	X	9,774,311	=	215,609.8
Total number of expected deaths in U.S. = 4,847,610.4					
STEP 2					
SRR = $\frac{4,847,610.4}{5,259,810} = 0.92$					

Appendix D—Standardized Mortality Ratio

The standardized mortality ratio (SMR) is a measure that compares the mortality rate for a disease in two populations. In this health statistics review, SMR compares, for the time period 1989 through 1998, the number of people who died from a disease while residing in ZIP Code 94536 to the number of people expected to die, if the mortality rate for the disease in the ZIP Code 94536 population was the same as the mortality rate for the disease in the U.S. population.

SMR was calculated in a manner that accounts for ways in which the ZIP Code 94536 and U.S. populations differ in terms of age and sex. SMR is calculated in two steps.

Step 1

The expected number of deaths is calculated by 1) multiplying the mortality rate in various age and sex groups in the U.S. population by the number of people in those age and sex groups in the ZIP Code 94536 population; then 2) summing the products to obtain the total number of expected deaths in the ZIP Code 94536 population.

Step 2

SMR is calculated by dividing the actual number of deaths that occurred by the expected number (calculated in step 1).

These steps are demonstrated at right for death from all types of cancer.

	U.S. Mortality Rate, All Cancers 1989-1998		Number of People in ZIP Code 94536 1989-1998	=	Number of Expected Deaths in ZIP Code 94536
STEP 1					
<i>Females</i>					
0 to 4	0.000027	X	21,140	=	0.6
5 to 9	0.000026	X	19,640	=	0.5
10 to 14	0.000024	X	16,970	=	0.4
15 to 19	0.000033	X	16,580	=	0.6
20 to 24	0.000045	X	22,560	=	1.0
25 to 29	0.000082	X	32,830	=	2.7
30 to 34	0.000162	X	30,900	=	5.0
35 to 39	0.000319	X	26,740	=	8.5
40 to 44	0.000591	X	24,540	=	14.5
45 to 49	0.001075	X	17,800	=	19.1
50 to 54	0.001851	X	13,730	=	25.4
55 to 59	0.002916	X	11,620	=	33.9
60 to 64	0.004336	X	11,930	=	51.7
65 to 69	0.005933	X	10,240	=	60.8
70 to 74	0.007832	X	6,250	=	49.0
75 to 79	0.009567	X	5,400	=	51.7
80 to 84	0.011546	X	3,950	=	45.6
85 and up	0.014049	X	3,540	=	49.7
<i>Males</i>					
0 to 4	0.000031	X	24,310	=	0.8
5 to 9	0.000032	X	19,280	=	0.6
10 to 14	0.000032	X	17,490	=	0.6
15 to 19	0.000047	X	16,970	=	0.8
20 to 24	0.000064	X	22,430	=	1.4
25 to 29	0.000090	X	31,130	=	2.8
30 to 34	0.000145	X	32,110	=	4.7
35 to 39	0.000252	X	27,310	=	6.9
40 to 44	0.000498	X	21,860	=	10.9
45 to 49	0.001033	X	21,940	=	22.6
50 to 54	0.002057	X	12,180	=	25.1
55 to 59	0.003744	X	11,510	=	43.1
60 to 64	0.006262	X	10,610	=	66.4
65 to 69	0.009319	X	8,550	=	79.7
70 to 74	0.012953	X	5,160	=	66.8
75 to 79	0.016628	X	3,000	=	49.9
80 to 84	0.021582	X	2,350	=	50.7
85 and up	0.027371	X	1,360	=	37.2
Total number of expected deaths = 891.5					
STEP 2					
$\text{SMR} = \frac{789}{891.5} = 0.89$					