

Environmental concentrations of fibers with fluoro-edenitic composition and population exposure in Biancavilla (Sicily, Italy)

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Abstract

Introduction. The town of Biancavilla (Sicily) was included in the National Priorities List of Contaminated Sites due to environmental dispersion of amphibole fibers owing to the extraction of materials from a local quarry. The present report summarizes results from several, hitherto unpublished, environmental surveys carried out in the area, as well as from published analyses of the chemistry and composition of fibers.

Methods. Data included here comprises environmental fiber concentrations by scanning electron microscopy with energy dispersive spectroscopy (SEM-EDS) analysis in soil, indoor and outdoor air, personal monitoring, as well as a chemical characterization of the fibers. The full chemical structure and spectroscopic characterization of fibers were obtained through a multi-analytical approach: SEM-EDS, X-ray powder diffraction (XRPD), as well as Mössbauer (MS) and Fourier transform infrared (FT-IR) spectroscopies.

Results. Data analyzed provided a spatial and temporal picture of fiber concentrations in Biancavilla, and a qualitative assessment of population exposure. Results suggest that until 2000, the population had been exposed to high levels of amphibole fibers. Mitigation measures adopted since 2001, gradually reduced exposure levels to about 0.1-0.4 ff/l. Previous studies on fibrous amphiboles from Biancavilla reported considerable chemical variability. Differences in composition, especially concerning the presence of Si, Ca, Fe, and Na, were found both within and between samples. Compared to the previously investigated prismatic fluoro-edenite, these fibrous fluorine amphiboles consistently showed higher average values of Si and Fe content, whereas Ca was significantly lower, which we consider a distinctive characteristic of the fluorine fibrous variety.

Conclusions. The population of Biancavilla had been highly exposed to a suite of fibrous amphiboles for over 50 years. Dust mitigation measures have gradually reduced exposure, but continuous environmental follow-up is necessary in order to monitor exposure levels and prevent adverse health effects for future generations.

Key words

- fluoro-edenite
- fibrous amphiboles
- Biancavilla
- population exposure
- air fiber concentrations
- topsoil fiber concentrations

INTRODUCTION

A study on mortality from malignant pleural mesothelioma in Italy from 1988 to 1997 reported an unusual cluster among people living in Biancavilla [1, 2], a small town (about 20 000 inhabitants) located on the southwestern slopes of Mt. Etna in Sicily. Environmental and mineralogical surveys in Biancavilla showed no asbestos exposure either from occupational activities or from the use of manufactured products. Nevertheless, environ-

mental exposure from a quarry located in the area of Mt. Calvario, southeast of Biancavilla, was documented. The quarry had been widely exploited by the local construction industry for the extraction of sand and rubble. This altered the morphology of the region by pulling down the hill of Mt. Calvario, which from a geological point of view was composed of brecciated domes of highly viscous, benmoreitic lavas [3]. An abundance of altered incoherent and very friable materials was found in the quarry,



originating from both brecciated benmoreitic lavas and pyroclastic deposits. Mineralogical analysis of these materials revealed the presence of a fluorine amphibole with acicular and prismatic habit, identified as fluoro-edenite - a new end-member of the calcic amphibole group [4].

Amphibole minerals with fibrous habit, on the other hand, were found in proximity to the Mt. Calvario quarry [5, 6]. Comba *et al.* 2003 [7] therefore suggested that the unusual mesothelioma cluster in Biancavilla may have been caused by exposure to these fibrous amphiboles.

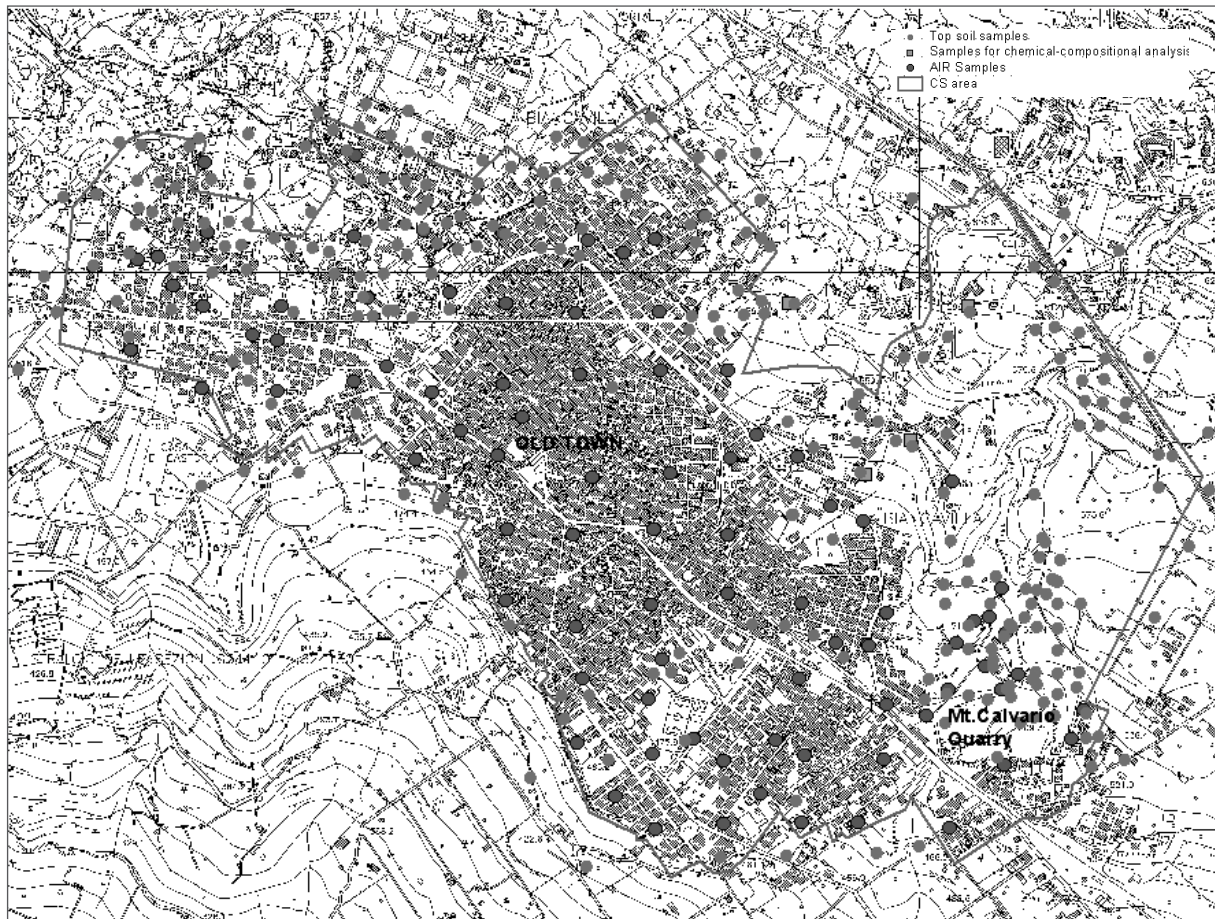


Figure 1
Sampling points of the 2004-2005 survey. The red line delimits the contaminated site, as per NPL-CS.

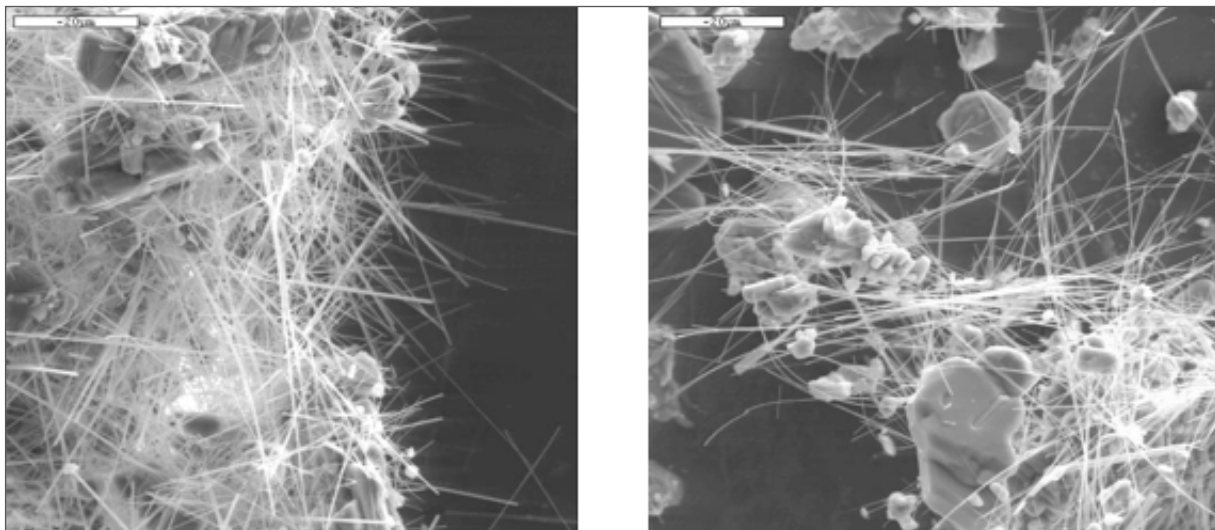


Figure 2
SEM photographs of two fibrous amphibole samples from Biancavilla: sample 3 (left), and sample 4 (right). The other associated minerals are mostly alkali-feldspars, clinopyroxenes, fluorapatite and Fe-Ti oxides. Reproduced with kind permission from [10].

Since 2000, the area of Biancavilla has been extensively studied in order to assess the environmental concentration of fibers in soil, as well as in outdoor and indoor air. In addition, personal monitoring was performed, and the fiber content of plaster/mortar in construction materials analyzed. High environmental concentrations of fibers were found, highlighting the need to adopt a series of dust mitigation measures in order to reduce population exposure. As of 2009, ongoing monitoring has documented a descending trend in environmental fiber concentrations in Biancavilla.

The present report summarizes the results of previous scientific publications on the chemical and structural characterization of fibrous amphiboles from Biancavilla, as well as results of environmental surveys on fiber concentrations in the town.

METHODS

Geological background

On the lower southwestern flank of Mt. Etna, Romano [3] identified three aligned domes of the early alkaline volcanic activity of Mt. Etna (Mt. Calvario, Santa Maria di Licodia and Ragalna). The Mt. Calvario lava dome, near Biancavilla, is well known for the occurrence of fluorine-rich mineral phases, specifically, fluoro-edenite, fluorophlogopite and fluorapatite [4, 8]. Fluorine-rich mineral phases are unusual for Mt. Etna, although similar phases have been found close to the mountain's summit, in lavas of the so-called Ellittico volcano, a caldera dating back to the Pleistocene [9].

Mineralogical and geochemical investigations have been carried out to ascertain the areal extent of these volcanic materials, and identify the genetic process underlying the crystallization of fluorine-rich minerals,

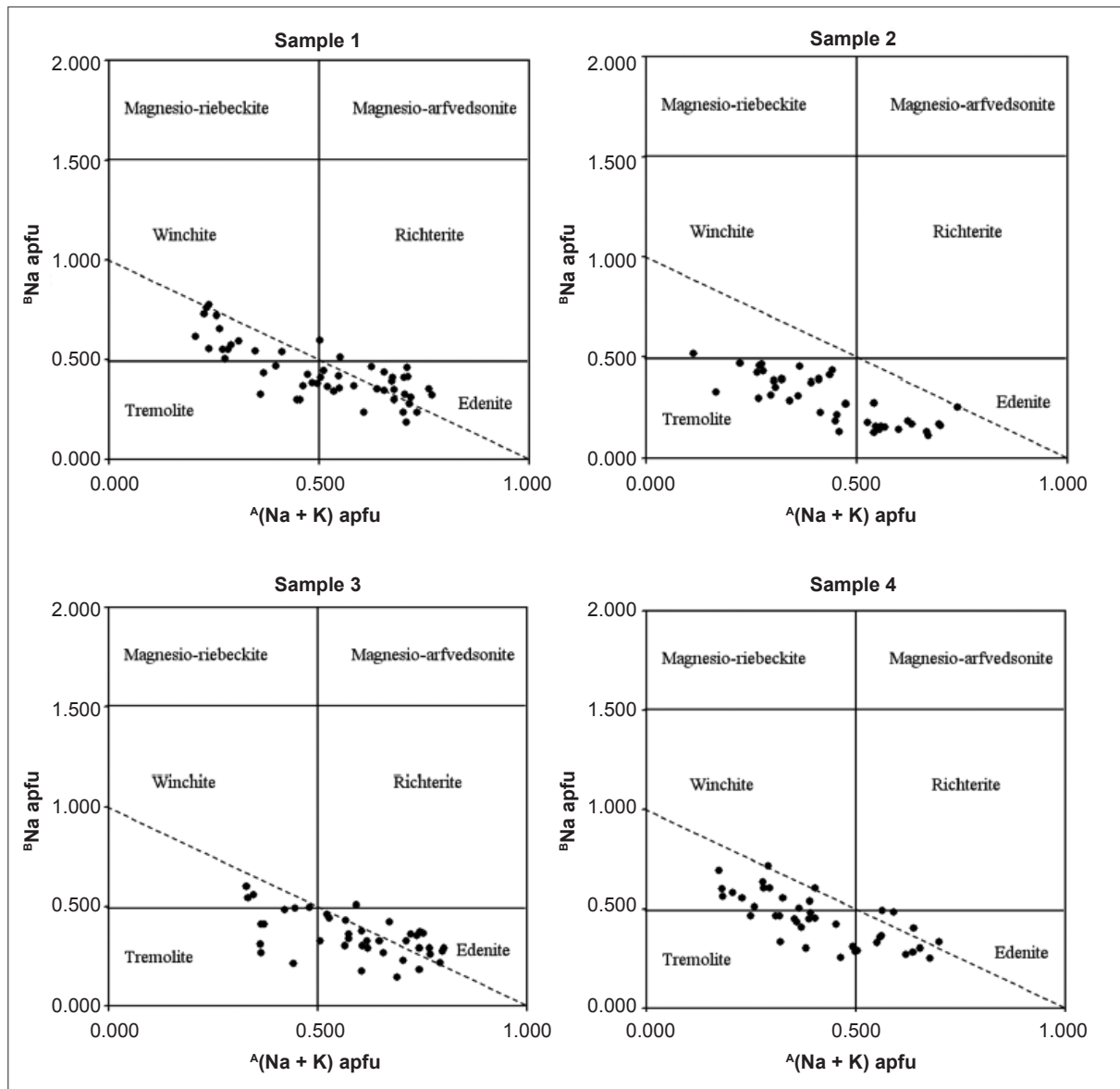


Figure 3

All results obtained from the four fibrous amphibole samples from Biancavilla, plotted against the $^{Na}/^{(Na+K)}$ diagram (Leake *et al.*, 1997). Reproduced with kind permission from [10].

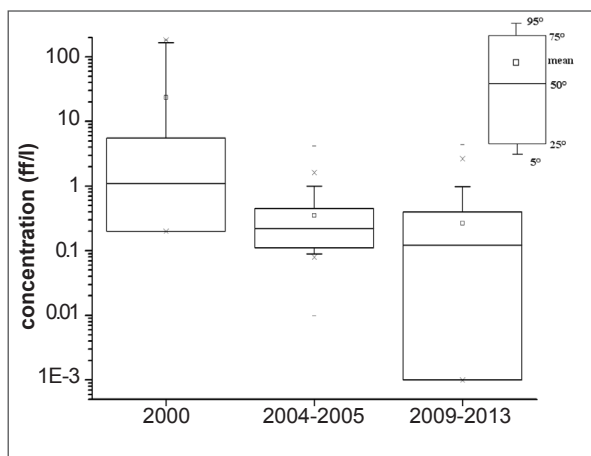


Figure 4
Distributions of air fibres concentrations acquired during the different surveys.

particularly those of fibrous morphology [9]. The dome and dyke complex consists of locally metasomatized benmoreitic and autoclastic breccias (*i.e.*, highly viscous lavas fragmented by the degassing of volatile components). The primary mineral assemblage of benmoreite lava consists of plagioclase, clinopyroxene, olivine, fluorapatite and iron oxides, whereas secondary mineralization comprises fluoro-edenite and fluorophlogopite, ferroan-enstatite, hematite, pseudobrookite and tridymite. Fluoro-edenite was found mainly in the metasomatized portion of the dome. The central portion of the structure is intensely fractured and is characterized by the presence of fluoro-edenite of variable morphology, from prismatic to acicular. The external portion of the dome consists of breccia with fibrous amphibole of micrometric dimensions. Importantly, the fluoro-edenite fibers, dispersed in a grey-reddish friable matrix, were not homogeneously distributed.

Geochemical data revealed enrichment in several major and trace elements (*e.g.*, Fe, Ti, P, and alkali), mainly fluorine and chlorine, which cannot be attributed solely to magma differentiation processes in the feeding system. The transfer of magmatic fluids from the deeper to the upper portions of the magma storage zones [9] has been suggested as a possible explanation for the presence of these elements. In the Mt. Calvario dome, selective enrichments in certain elements led to the crystallization of fluorine-rich mineral phases during the syn- and post-eruptive stages.

Fiber characterization

The location of sampling points is reported in *Figure 1*. As reported by Mazziotti-Tagliani *et al.* [10], the starting material for fiber characterization consisted of lava pieces in a fine and friable matrix, which contained an assemblage of amphibole fibers and other minerals of micrometric and sub-micrometric dimensions. To avoid or at least reduce any influence of other minerals on the experimental data, fiber characterization was performed on samples enriched in amphibole fibers. Briefly, a fiber content of > 90% in samples was obtained through a simple sedimentation in water, followed by a withdrawal of the supernatant solution after 30 to 35 hours.

Figure 2 displays scanning electron microscopy (SEM) photographs of two amphibole samples from Biancavilla. These fluorine-rich fibrous amphiboles are generally less than 1 μm (200 to 600 nm) thick, and up to 100-150 μm long. Samples 1, 2 and 3 were characterized by an acicular-fibrous morphology and shorter fibers (mean length, ca. 50 μm), while sample 4 showed a more filamentous-asbestiform morphology with length up to 150 μm [10].

The full chemical structural and spectroscopic characterization of the fibrous amphibole samples from Biancavilla was performed using a multi-analytical approach: SEM-EDS, X-ray powder diffraction (XRPD), as well as Mössbauer (MS), and Fourier transform infrared (FT-IR) spectroscopies. Quantitative chemical analyses (SEM-EDS) were performed by Mazziotti-Tagliani *et al.* [10], applying Paoletti and co-workers' standardization procedure [11]. In addition, cation site partitioning was performed by Adreozzi *et al.* [12] by optimizing average chemical, XRPD, MS, and FT-IR data.

Environmental characterization

In the past 15 years, *ad-hoc* surveys of environmental dispersion of amphibole fibers in Biancavilla have been carried out, with the aim of determining the levels of outdoor pollution, indoor contamination and personal exposure. Only data obtained by SEM-EDS were included in the present analysis. The first survey, in 2000, studied fiber levels in indoor and outdoor air, as well as the fiber content of plaster/mortar in Biancavilla buildings [13]. Later, in 2004, the University of Catania was charged with characterizing the area of Biancavilla [14], which was included, by law, in the National Priorities List of Contaminated Sites (NPL-CS) [15]. The survey in question, carried out between August of 2004 and July of 2005, aimed, among other things, at assessing the efficacy of the dust mitigation measures adopted after 2001, through the measurement of amphibole fiber concentrations in outdoor air and topsoil (0-50 cm). Airborne fiber concentrations were measured, and the fiber content of particulate depositions analyzed at 90 sampling points distributed throughout the area, of which 55 were located within the built-up area, 9 were in and around the quarry and 26 near sensitive targets such as schools and hospitals. Of the 90 particulate deposition samples, 22 were analyzed by SEM-EDS. Topsoil analysis was carried out at 840 sampling points. Two-hundred-and-fifty-seven of these samples were analyzed by SEM-EDS. *Figure 1* shows the geographical distribution of air and topsoil sampling points.

Data from an ongoing environmental monitoring system operated, since 2009, by the Regional Environmental Agency of Sicily (ARPA Sicilia, Dipartimento Provinciale di Catania), were also included. ARPA airborne fiber sampling is performed 1-3 times a week. Here, we analyze 465 samples collected between July 2009 and October 2013.

RESULTS

Fiber characterization

Upon FT-IR spectroscopy, none of the samples showed absorption bands in the O-H stretching region (3800-3600 cm^{-1}), indicating the complete substitution



Table 1

Chemical composition of the four samples of fibrous amphibole from Biancavilla. Reproduced with kind permission from [10]

N. Analyses	Sample 1		Sample 2		Sample 3		Sample 4	
	Average	Range	Average	Range	Average	Range	Average	Range
SiO ₂	54.12	52.39-56.70	52.66	50.61-55.19	53.49	51.47-5.56	53.86	51.68-55.92
TiO ₂	0.03	0.00-0.06	0.03	0.01-0.05	0.02	0.00-0.06	0.03	0.00-0.06
Al ₂ O ₃	1.95	1.38-3.28	2.91	1.96-3.81	2.51	1.56-3.27	2.31	1.52-3.32
MgO	21.34	19.28-23.11	20.50	19.07-21.36	22.63	21.21-24.19	21.94	20.56-23.39
CaO	8.48	7.03-9.88	10.20	9.01-11.32	9.19	7.62-10.84	8.59	7.22-10.58
MnO	0.56	0.00-1.06	0.45	0.18-0.79	0.49	0.23-0.78	0.44	0.00-1.00
FeO _{tot}	5.43	3.74-6.68	5.98	4.36-7.28	3.59	1.88-5.18	5.03	3.41-6.74
Na ₂ O	3.10	2.30-3.82	2.29	1.49-3.10	3.08	2.02-3.80	2.78	2.09-3.76
K ₂ O	0.53	0.18-1.30	0.52	0.00-0.79	0.55	0.11-1.02	0.54	0.16-1.04
^a F	4.40		4.40		4.40		4.40	
^a Cl	0.06		0.06		0.06		0.06	
^b Total	100.00		100.00		100.00		100.00	
^c Fe ₂ O ₃	3.26		4.45		3.67		5.25	
^c FeO	2.50		1.97		0.29		0.30	

^a fixed values for all samples; ^b normalized analyses; ^c obtained through Mössbauer investigation.

1 $T(Si_{7.676}^{IV}Al_{0.324})_{\Sigma 8.000} C(Al_{0.002}^{VI}Fe^{3+}_{0.348}Fe^{2+}_{0.297}Mg_{4.283}Ti_{0.003}Mn_{0.067})_{\Sigma 5.000} B(Mg_{0.227}Ca_{1.289}Na_{0.484})_{\Sigma 2.000} A(Na_{0.368}K_{0.096})_{\Sigma 0.464} O_3(F_{1.974}Cl_{0.014})_{\Sigma 1.988}$

2 $T(Si_{7.495}^{IV}Al_{0.488})_{\Sigma 7.984} C(Fe^{3+}_{0.477}Fe^{2+}_{0.235}Mg_{4.229}Ti_{0.003}Mn_{0.067})_{\Sigma 5.000} B(Mg_{0.121}Ca_{1.555}Na_{0.324})_{\Sigma 2.000} A(Na_{0.307}K_{0.094})_{\Sigma 0.401} O_3(F_{1.981}Cl_{0.014})_{\Sigma 1.995}$

3 $T(Si_{7.544}^{IV}Al_{0.417})_{\Sigma 7.961} C(Fe^{3+}_{0.389}Fe^{2+}_{0.034}Mg_{4.516}Ti_{0.002}Mn_{0.059})_{\Sigma 5.000} B(Mg_{0.242}Ca_{1.389}Na_{0.369})_{\Sigma 2.000} A(Na_{0.473}K_{0.099})_{\Sigma 0.572} O_3(F_{1.963}Cl_{0.014})_{\Sigma 1.977}$

4 $T(Si_{7.587}^{IV}Al_{0.384})_{\Sigma 7.971} C(Fe^{3+}_{0.557}Fe^{2+}_{0.035}Mg_{4.356}Ti_{0.003}Mn_{0.053})_{\Sigma 5.000} B(Mg_{0.256}Ca_{1.297}Na_{0.447})_{\Sigma 2.000} A(Na_{0.312}K_{0.097})_{\Sigma 0.409} O_3(F_{1.960}Cl_{0.014})_{\Sigma 1.974}$

Table 2

Fe³⁺/Fe_{tot} ratios, and Fe²⁺ and Fe³⁺ contents for the four analyzed samples. Reproduced with kind permission from [10]

Samples	1	2	3	4
Fe ³⁺ /Fe _{tot}	0.540	0.670	0.920	0.939
Fe ³⁺	0.348	0.477	0.390	0.557
Fe ²⁺	0.296	0.235	0.034	0.036
Sum (Fe ³⁺ + Fe ²⁺)	0.644	0.712	0.424	0.593

of the hydroxyl OH⁻ with fluorine in the fibrous amphiboles analyzed, as previously observed in prismatic fluoro-edenite samples [4, 12]. The compositional range (min-max), average chemical composition and mean crystal-chemical formula for each sample are reported in Table 1. Having plotted the results of their analyses on a ^A(Na+K)/^BNa diagram [12], Mazziotti-Tagliani *et al.* [10] concluded that the four samples had reasonably similar, albeit slightly different compositional trends (Figure 3). Point analyses of the four samples fell close to the 1:1 edenite-winchite line. A significant tremolite component is present in all samples. Sample 3 was the closest in composition to prismatic fluoro-edenite (Tables 1 and 2). Notably, the FeO_{tot} content of fibrous amphiboles was always higher than that observed for prismatic fluoro-edenite (Table 1). For each sample, Andreozzi *et al.* [12] reported possible site occupancies obtained by combining chemical data with Rietveld refinement results. A high level of agreement was observed between refined site scattering (s.s.) values, and those calculated from possible site occupancies, being the largest differences (for C sites) smaller than 3% [12]. Samples 2 and 4 showed refined s.s. values at C sites higher than samples 1 and 3, due to the larger amount of heavier atoms (e.g., Fe). Finally, the s.s. val-

ues for the A site in fibrous samples (Table 3) were significantly lower than those in prismatic fluoro-edenite [4, 10], due to the lower ^ANa content in the former.

Environmental characterization

The analysis of data acquired in 2000, before mitigation measures were taken, found amphibole contamination levels ranging from 0.4 to 8.2 ff/l, with an average of 1.76 ff/l. The highest concentrations were detected on unpaved roads covered with inert material, especially during heavy traffic, when up to 93-183 ff/l were measured.

In the same period, a survey on the indoor environment found concentrations ranging from < 0.4 ff/l to 4.8 ff/l, with an average of 1.18 ff/l. Starting from 2001, a series of dust mitigation measures were taken, notably roads paving, to address what had emerged as the main risk factor for population exposure.

The 2004-2005 survey carried out by the University of Catania, demonstrated the efficacy of these clean up interventions, measuring between 0.01 and 4.19 ff/l (mean, 0.35 ff/l) in outdoor air.

Presently, ARPA monitoring shows a descending trend in the concentrations of airborne fibers from an average 0.46 ff/l in 2009, to an average of 0.1 ff/l in 2013, although few peaks have been observed in concomitance

Table 3

Site scattering (s.s.) values for the fibrous amphiboles: experimentally obtained from the structural refinement (left); calculated from the possible site occupancy (right). Reproduced with kind permission from [12]

Sample 1			
	s.s. from refinement	Possible site-occupancy	s.s. from site-occupancy
A	4.6(2)	$K_{0.10}Na_{0.37}$	6.0
A(m)	–	–	–
Sum A sites	4.6(2)		6.0
M(4)	37.6(4)	$Ca_{1.29}Na_{0.48}Mn^{2+}_{0.07}Fe^{2+}_{0.16}$	37.0
Sum B sites	37.6(4)		37.0
M(1)	25.0(3)	$Mg_{1.90}Fe^{2+}_{0.10}$	25.3
M(2)	28.0(3)	$Mg_{1.61}Fe^{2+}_{0.04}Fe^{3+}_{0.35}$	29.5
M(3)	11.8(2)	$Mg_{1.00}$	12.0
Sum C sites	64.8(5)		66.8

Sample 2			
	s.s. from refinement	Possible site-occupancy	s.s. from site-occupancy
A	2.9(8)	$K_{0.09}$	1.7
A(m)	3.3(8)	$Na_{0.31}$	3.4
Sum A sites	6.2(11)		5.1
M(4)	37.3(4)	$Ca_{1.56}Na_{0.32}Mn^{2+}_{0.05}Fe^{2+}_{0.07}$	37.8
Sum B sites	37.3(4)		37.8
M(1)	25.3(4)	$Mg_{1.92}Fe^{2+}_{0.08}$	25.1
M(2)	30.6(4)	$Mg_{1.44}Fe^{2+}_{0.08}Fe^{3+}_{0.48}$	31.8
M(3)	12.2(3)	$Mg_{0.99}Fe^{2+}_{0.01}$	12.1
Sum C sites	68.1(6)		69.0

Sample 3			
	s.s. from refinement	Possible site-occupancy	s.s. from site-occupancy
A	3.3(3)	$K_{0.10}$	1.9
A(m)	4.4(3)	$Na_{0.47}$	5.2
Sum A sites	7.7(4)		7.1
M(4)	34.1(1)	$Ca_{1.39}Na_{0.37}Mn^{2+}_{0.06}Mg_{0.18}$	35.5
Sum B sites	34.1(1)		35.5
M(1)	25.3(1)	$Mg_{1.87}Fe^{3+}_{0.12}$	25.6
M(2)	27.7(1)	$Mg_{1.70}Fe^{2+}_{0.03}Fe^{3+}_{0.27}$	28.2
M(3)	11.8(1)	$Mg_{1.00}$	12.0
Sum C sites	64.8(2)		65.8

Sample 4			
	s.s. from refinement	Possible site-occupancy	s.s. from site-occupancy
A	6.8(2)	$K_{0.10}Na_{0.31}$	5.3
A(m)	–	–	–
Sum A sites			5.3
M(4)	30.8(3)	$Ca_{1.30}Na_{0.45}Mn^{2+}_{0.05}Mg_{0.20}$	34.6
Sum B sites	30.8(3)		34.6
M(1)	24.1(2)	$Mg_{1.96}Fe^{3+}_{0.04}$	24.6
M(2)	30.3(2)	$Mg_{1.48}Fe^{2+}_{0.04}Fe^{3+}_{0.48}$	31.3
M(3)	12.7(2)	$Mg_{0.96}Fe^{3+}_{0.04}$	12.6
Sum C sites	67.1(5)		68.5

Note: The possible site-occupancy is the result of combining data from averaged chemical composition, Mössbauer spectroscopy and Rietveld refinement.



with specific kinds of public works (projects involving excavation) or under certain meteorological conditions.

Figure 4 shows the downward trend in fiber concentrations, as observed in the three surveys carried out in 2000, 2004-2005 and 2009-2013, a trend mainly attributable to the dust mitigation measures adopted since 2001. It should be noted however, that the three surveys had different aims and followed different protocols. ARPA, for example, performs measurements not only in everyday situations, but also with the aim of monitoring the dispersion of airborne fibers in high-risk situations (e.g., excavation work), resulting in greater variability in the data observed.

The fact that for decades, starting from about 1950, material from the Mt. Calvario quarry had been widely used for urban construction, prompted a study to examine plaster/mortar for amphibole fiber levels [16]. Amphibole fibers were found in all samples from pre-1960 buildings, in about 70% of samples from buildings constructed between 1960 and 1990, and in about 40% of samples from post-1990 buildings. Mt. Calvario materials were no longer used after 1999. In addition, in 2000, a small study assessed the personal exposure of people working outdoors as traffic policemen and garbage collectors. The survey revealed personal exposure levels ranging from 0.4 to 4.6 ff/l. The highest levels of exposure were associated with work in areas with unpaved roads.

More recently (2008-2012), further mitigation measures were adopted as the remedy of plasters of some public buildings as schools, the town hall and the cemetery surrounding wall and the envelopment of the ridge rock, surrounding the quarry, with Spritz Beton, i.e. a material able to avoid the atmospheric dispersion of particulate.

Spatial analysis, on data acquired in 2000, revealed peak concentrations (mean, ca. 4 ff/l) in the northeast and northwest of Biancavilla and high concentrations in the south (mean, ca. 2 ff/l). The lowest concentrations (ca. 1 ff/l) were measured around the quarry. The 2004-2005 survey showed mean amphibole concentrations of about 0.34 ff/l and 0.31 ff/l in the north and south of town, respectively. In the east, including the Mt. Calvario quarry, fiber concentrations averaged 0.38 ff/l. Comparable fiber levels were observed in the old town, with an average value of 0.34 ff/l.

No fibers were identified in 9% of topsoil and in 32% of particulate deposition samples. Fiber concentrations in 234 topsoil samples ranged from 8.9 ppm to 3173.4 ppm, and in particulate deposition samples, from 183.7 ppm to 1541.9 ppm. The highest values were observed in the north and east of Biancavilla, in agreement with the spatial pattern of fiber concentrations in outdoor air.

DISCUSSION AND CONCLUSIONS

In the case of Biancavilla, the environmental and health relevance of amphibole fiber pollution has been clearly documented by epidemiological studies. Published results [10, 12] on the crystal-chemical characterization of amphibole fibers from Biancavilla revealed considerable variation in fiber composition. Specifically, while a fluoro-edenite component was dominant,

significant tremolite and minor winchite components were also present. According to Andreozzi *et al.* [12], this complicates both the classification of these fibers and the definition of the mineral species to which they belong. From the 1950s and until the late 1990s, the population of Biancavilla had been exposed to high concentrations of amphibole fibers, both indoors and outdoors. Exposure was at its highest between 1950 and 1970, when Mt. Calvario quarry materials were widely used for construction.

Population exposure to amphibole fibers in Biancavilla may be attributed to the following three factors: the outdoor concentration of fibers in residential areas, the fiber content of building materials, and fiber concentrations in places frequented by the residents for work and other daily activities. The relative weight of each of these factors in determining exposure may have changed over time. Conceivably, in the quarry's early years, occupational exposure and exposure through daily activities were the most significant, while since the 1990s, the area of residence may have assumed a greater relative importance.

Considering data from surveys carried out before 2000, different population exposure levels by area of residence can be roughly presumed:

- in the old part of town: a low level of both indoor and outdoor exposure;
- in the northwest and northeast of Biancavilla: high levels of airborne fibers, both indoors and outdoors;
- in the southern part of the town: lower levels of exposure compared to the north, but higher than in the old part of town;
- in the rural eastern part of town: exposure levels lower than the north, and comparable to the south.

The mitigation measures implemented since 2001 have reduced the exposure of the population to concentrations below 1 ff/l. The long duration of exposure and the long latency of pleural mesothelioma, however, suggest that cases will continue to be observed in the Biancavilla population in the next few years.

The continuous monitoring of the area remains necessary, however, in order to control air fiber dispersion and to prevent high population exposure.

Acknowledgments

The authors wish to thank the Biancavilla Municipality for their active collaboration in the study and Pinizzotto MR, Cantaro C, Chiarenza L, Petralia C, Turrisi S of ARPA-Catania, for their technical support in the monitoring and laboratory analysis of airborne fibers in Biancavilla. A special thank to Pistorio A, for his contribution to the historical reconstruction of events in Biancavilla and the recovery of useful documentation.

Conflict of interest statement

The Authors declare no potential conflict of interest or any financial or personal relationships with other people or organizations that could inappropriately bias conduct and findings of this study.

Submitted on invitation.

Accepted on 18 April 2014.

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