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Pollution characteristics and health risk assessment of atmospheric VOCs in the pharmaceutical enterprises.

Xie Chen[1], Lei Ma[2*], Min Zhao[1]

[1]Business School of Hohai University, PR China

[2]Business Administration School of Nanjing Audit University, PR China

Abstract

Owing to rapid economic and industrial development, China has been suffering from degraded air quality and visibility. Volatile Organic Compounds (VOCs) are important precursors to the formation of ground-level ozone and hence photochemical smog. To investigate the impact of VOCs produced in concentrated areas of pharmaceutical enterprises on environment and human health, 168 samples were collected at 8 sites around the concentrated areas of pharmaceutical enterprises. The content of VOCs was determined by prethickening-GC-MS method, and the health risk assessment model of United States Environmental Protection Agency (EPA) was used to evaluate the Volatile Organic Compounds (VOCs) pollution in the concentrated areas of pharmaceutical enterprises. The results showed that the total of 32 substances were detected in concentrated areas of pharmaceutical enterprises, and concentration of Total Volatile Organic Compounds (TVOC) was 2.04 mg•m^{-3}. Among them, the proportion of aromatic hydrocarbons and ketones were higher, respectively accounting for 43% and 28%; most VOCs concentrations were ten times or 100 times the background value. The 19 detected VOCs which had health hazards did not pose a significant non-carcinogenic health risk to humans; but 5 kinds of VOCs such as 1, 3- butadiene, chloroform, carbon tetrachloride, benzene and 1, 1, 2-, methyl chloroform, etc. have carcinogenic health hazard to human body. The cumulative carcinogenic risk index of total VOCs was much higher than the acceptable quantity level, indicating that the VOCs emitted from concentrated areas of pharmaceutical enterprises was the main cause of carcinogenic health damage to human body.

Keywords: Concentrated areas of pharmaceutical enterprises, Volatile organic compounds (VOCs), Pollution characteristics, Health risk assessment.

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Introduction

Volatile Organic Compounds (VOCs) are a large class of atmospheric pollutants [1], which generates photochemical reactions with compounds of nitrogen and oxygen under the condition of strong light, low wind speed, low humidity and so on, forming photochemical smog. VOCs could affect the formation of atmospheric photochemical smog and atmospheric fine particles, and some VOCs species have strong toxicity and carcinogenicity. AT present, this type of pollution has almost become a common problem in major cities all over the world [2,3]. At the same time, volatile organic compounds and compounds of nitrogen and oxygen, oxidants will generate O_3 with secondary pollution under certain conditions [4], while volatile organic compounds react with oxidants such as O_3 in atmosphere to form secondary organic aerosol [5,6]. In addition to stimulating function on the sense organs, VOCs may also be toxic and have a variety of adverse effects on human health [7,8]. Studies have shown that VOCs has become an important precursor and participant affecting the regional composite air pollution in China [4,9], and the study on emission characteristics of VOCs has attracted more widely attention.

Regionalization of industrial concentration is the carrier of the development of urban industrial economic development [10], and the centralization of pharmaceutical enterprises has become a trend. However, pharmaceutical enterprises will produce various VOCs in the process of production, the incidents of waste gas from pharmaceutical factories disturbing residents often occur, and pollution problems have become increasingly serious, while improving the economic level, it has also become the 'base camp' of environmental pollution enterprises. At present, there are many domestic and international researches on the VOCs pollution and the harm to human health caused by indoor, wastewater, soil and industry, etc. [11-17], however, there are few study reporting about the characteristics and risk assessment of VOCs pollution in the concentrated areas of pharmaceutical enterprises.

With the accelerated process of urbanization in China, the pollution of VOCs in the atmosphere has become more prominent. Therefore, it is necessary for the quantitative assessment of atmospheric benzene, halogenated hydrocarbons and aldehydes and other pollutants on VOCs carcinogenic risk exposure, and to take further control measures to control it in the safe range, to ensure that exposure to the health of the people. In this study, an actual survey was conducted in the concentrated areas of pharmaceutical enterprises, the pollution status of VOCs in this area was analysed, and the health risk assessment model of the United States Environmental Protection Agency (US EPA) was used to assess the health risks of VOCs to the surrounding residents.

Materials and Methods

Research area overview

This research was approved by the Ethical Committee of Hohai University, the approval number is 2016002. The research area was a concentrated area of certain pharmaceutical enterprises in Jiangsu Province with an area of factory about 1 million 800 thousand square meters. Dozens of pharmaceutical companies are gathering here, which were involved in a total of six major categories of pharmaceutical industry such as chemical synthesis, fermentation, mixed preparation, extraction, Chinese medicine and biology.

The geographical location of concentrated area of the pharmaceutical enterprise had warm, semi humid, semi-arid, monsoon continental climate with prevailing northerly and southeast winds and least frequency of westerly and southwest wind. The annual static wind frequency was as high as 30%, there is obvious transformation from winter to summer wind direction, and from March to August each year, the southeast and southerly wind were the dominant wind direction. The average temperature was 12.7°C with average temperature of 3.5°C on the coldest month and average temperature of 26.4°C on the hottest month. The annual amount of sunshine was 2710 h with frost free period 210 D and the average atmospheric pressure was 1008 Pa.

Sample collection

Through overall consideration of wind direction, road, workshop distribution and other factors, the checkerboard sampling method was used to determine 8 sampling points around the boundary of the concentrated area of pharmaceutical enterprises. The sampling time interval was 4 h with 3 times per points per day. During April 20-26, 2017 as 7 d' continuous sampling, a total of 168 samples were collected. The meteorological parameters such as wind direction, wind speed, temperature and air pressure were recorded synchronously.

Samples were collected by SUMMA tank which was cleaned by an automatic cleaning instrument before sampling to ensure that the background value of the tank met the requirements of the analysis. The SUMMA tank was connected to automatic cleaning instrument, and then the electric heating sleeve matched with the cleaning instrument were covered outside the SUMMA tank which was heated to about 100°C. Fill the SUMMA tank with moist high pure nitrogen to the pressure of 138 kPa for lasted 10 min, and then the vacuum pump was adopted to transform the inside SUMMA tank into vacuum. Repeat this process until the GC/MS detected that the background value of the SUMMA tank was below the method detection limit, and then it could be used for actual sample collection. Pump the cleaned SUMMA tank to 266 Pa, and install the sample filter for reserve. Open the SUMMA tank valve at sampling site, then the outside air would pass through a sampling filter and entered a SUMMA tank in a negative pressure state, and a clear inspiratory sound could be heard at this time. When there was no inspiratory sound, then wait about 1 min, close the tank valve, and complete the sampling.

Analysis method

Referring to the method of USA EPA TO-14 [18], the VOCs content in the gas sample was analysed by GC-MS, and the sum concentration of each VOCs mass was obtained, which was called the concentration of Total Volatile Organic Compounds (TVOC).

The experimental conditions of pre concentration system were divided into three grades, the first stage adopted the capture temperature -150°C, analytic temperature 20°C; the second stage adopted the capture temperature -30°C, analytic temperature 180°C; the third stage adopted the capture temperature -150°C, analytic temperature 60°C. Chromatographic condition inlet: temperature: 200°C, split ratio: 5:1; carrier gas: helium; column flow amount: 1.5 $ml \cdot min^{-1}$; column temperature: 35°C, keep for 5 min, raise the temperature to 150°C at the speed of $5°C \cdot min^{-1}$, and then raise the temperature to 220°C at the speed of $15°C \cdot min^{-1}$, keep for 2 min. Mass spectrometry conditions EI ion source, temperature: 230°C, MS quadrupole rod temperature: 150°C, electronic energy 70 eV, interface temperature: 280°C, collect data through scanning method, m/z range: 30-450 amu.

Quality assurance and quality control: At each sampling, 1 scene blank samples, 2 parallel samples, 1 laboratory blank sample were collected with random choice for sampling points. Before and after standard sample analysis, Zero air blank analysis was performed, and the results showed that the concentrations of various targets were all lower than the method detection limit to ensure that no measured object stayed in the analysis system, the experimental result of target material recovery rate was 74%-96%, and all quality control indexes met the requirements. Besides, the instrument should be continuously calibrated before each analysis.

Health risk assessment method

To evaluate the potential public health risk posed by inhalation exposure to air toxics, a screening human health risk assessment was performed. The health risk assessment methods of the US Environmental Protection Agency (US

EPA) [19,20] were used to assess the possible health risks for the surrounding population from concentrated areas of pharmaceutical enterprises. Risk assessment was carried out through the following 4 steps: 1. hazard identification; 2. dose-effect evaluation; 3. exposure amount evaluation; 4. risk value assessment.

Hazard identification

Hazard identification belonged to qualitative assessment, and according to the classification of human carcinogenicity chemicals from International Institute for Cancer Research (IARC), carcinogenic risk assessment and non-carcinogenic risk assessment were conducted.

Dose-effect evaluation

Long-term inhalation exposure non-carcinogenic reference concentration (RfC), long-term inhalation exposure non-carcinogenic reference dose (RfD), Inhalation Unit Risk (IUR) and reference dose [21] recommended by IRIS database of the US Environmental Protection Agency were adopted to assess the dose-effect relationship between chemical carcinogens and non-chemical carcinogens.

Exposure amount assessment

VOCs in the air entered the internal organs mainly through the human respiratory pathway. Exposure amount assessment was estimated by daily exposure dose of a certain toxic substance. The assessment model is referred to related report [22].

Results and Discussion

VOCs pollution analysis

The mass concentration of VOCs produced by the concentrated area of pharmaceutical enterprises and related statistical results are shown in Table 1. A total of 32 kinds of VOCs were monitored, with a total VOCs concentration of 2.04 $mg \cdot m^{-3}$. VOCs with higher concentrations were ketones and benzene series, mainly acetone, m-xylene and p-xylene, 1, 3- butadiene and 1, 3, 5- three methyl benzene, the average concentrations of which were respectively 3.39×10^{-1}, 2.02×10^{-1}, 1.72×10^{-1}, 1.28×10^{-1} $mg \cdot m^{-3}$. There were 11 kinds of VOCs with a coefficient of variation greater than 1: aldehydeester class (ethyl acetate, vinyl acetate, tetrahydrofuran, methyl tert butyl ether), halogenated hydrocarbons (methylene chloride, 1, 2, 4-, three methyl benzene, 1, 2-two chlorobenzene, 1, 4-two chlorobenzene) and Olefins (1, 3-butadiene). Aldehydeester and chlorobenzene were common organic solvents in pharmaceutical techniques, and the intermittent operation of the production process and so on had a greater impact on the emission changes of these substances; 1, 3-butadiene was an important chemical raw material. Because of its lively chemical properties, it was easy to be oxidized to superoxide in air. The coefficients of variation of other substances were small, indicating that the distribution of pollutants in this concentrated area was more uniform, and the related pharmaceutical production process is more even, and related pharmaceutical production techniques were more stable.

Comparing most of the detected VOCs pollutants and concentration limit of unorganized monitoring in 'integrated emission standard of air pollutants' in China (GB16297-1996) and level 1 standard value for factory in the 'odor pollutants emission standard' (GB14554-1993), all pollutants did not exceed standard. But except 1, 2, 4-three chlorobenzene, 1, 2, 4-three methyl benzene and 1, 3-two chlorobenzene slightly higher than VOCs background values of ambient air in Hebei Province, other VOCs mass concentrations were ten times or even hundreds times the background value. It could be seen that VOCs in the surrounding ambient air of concentrated area of pharmaceutical enterprises had many types and high concentrations. Although all pollutants met the stipulates and requirements of the existing standards in China, they still affected the surrounding ambient air and sometimes they smelt bad. The reasons might be analysed as mainly there were no VOCs pollution emission standards in pharmaceutical industry in China, and evaluation of current emission standards adopted for the ambient air quality around the pharmaceutical concentrated area was difficult to meet the basic requirements of protecting the ecological environment and population health. In addition, for atmospheric VOCs standards, the control data varied considerably, for example, the maximum allowable concentration of styrene in atmosphere in residential quarters stipulated by 'hygienic standards for the design of industrial enterprises' (TJ36-79) was 0.01 $mg \cdot m^{-3}$, and level 1 standard value for factory stipulated by emission standards for odor pollutants in China (GB14554-93) was 3 $mg \cdot m^{-3}$. Standard values varied widely, causing pollution complaints to occur from time to time, not only affecting the quality of ambient air, but also may pose a health hazard to nearby residents.

Table 1. *Concentration of VOCs in air of concentrated area of pharmaceutical enterprise.*

	Pollutant	Concentration/(mg·m-3)	Standard deviation	Coefficient of variation	Relative standard value/($mg \cdot m^{-3}$)	Background level [23]/ for VOCs ($mg \cdot m^{-3}$)	Times background value
1	N-hexane	2.61×10^{-2}	1.55×10^{-2}	0.59	-	-	
2	Acetic ether	6.80×10^{-3}	7.80×10^{-3}	1.15	-	-	-
3	Vinyl acetate	2.60×10^{-3}	7.30×10^{-3}	2.81	-	-	-
4	Ethylbenzene	3.08×10^{-2}	7.20×10^{-3}	0.2358	-	0.53×10^{-3}	58

5	Butylene oxide	7.00×10^{-3}	1.38×10^{-2}	1.97	-	-	-
6	Carbon tetrachloride	2.68×10^{-2}	1.75×10^{-2}	0.65	-	0.92×10^{-3}	29
7	Benzyl chloride	2.00×10^{-4}	4.00×10^{-4}	2	-	-	-
8	Chloroform	2.73×10^{-2}	6.60×10^{-3}	0.24	-	1.14×10^{-3}	24
9	Chlorobenzene	4.84×10^{-2}	5.00×10^{-4}	0.01	0.5^{Δ}	0.21×10^{-3}	230
10	O-xylene	9.99×10^{-2}	9.00×10^{-3}	0.09	1.5^{Δ}	0.01×10^{-1}	100
11	M-xylene	2.02×10^{-1}	7.23×10^{-2}	0.36	1.5^{Δ}	0.87×10^{-3}	232
	p-xylene						
12	MTBE	3.00×10^{-3}	3.30×10^{-3}	1.1	-	-	-
13	Methylbenzene	2.67×10^{-2}	5.50×10^{-3}	0.21	3.0^{Δ}	1.39×10^{-3}	19
14	Cyclohexane	1.90×10^{-3}	1.40×10^{-3}	0.74	-	-	-
15	Heptane	7.40×10^{-3}	3.70×10^{-3}	0.5	-	-	-
16	Carrene	9.90×10^{-3}	1.68×10^{-2}	1.7		0.96×10^{-3}	10
17	Carbon disulfide	1.28×10^{-2}	4.30×10^{-3}	0.34	-	-	-
18	Acetone	3.39×10^{-1}	2.61×10^{-1}	0.77	-	-	-
19	Styrene	9.92×10^{-2}	8.35×10^{-2}	0.84	$3.0^{\Delta\Delta}$	0.85×10^{-3}	117
20	Benzene	1.20×10^{-2}	1.20×10^{-3}	0.1	0.5^{Δ}	0.65×10^{-3}	18
21	2-hexanone	1.89×10^{-2}	1.57×10^{-2}	0.83	-	-	-
22	2-butanone	6.32×10^{-2}	5.63×10^{-2}	0.89	-	-	-
23	1, 4-dichlorobenzene	1.35×10^{-2}	1.87×10^{-2}	1.39	0.5^{Δ}	2.36×10^{-3}	5.7
24	1, 3- two chlorobenzene	3.50×10^{-3}	6.50 × 10-3	1.86	0.5	1.97×10^{-3}	1.8
25	1, 3-butadiene	1.72×10^{-1}	2.52×10^{-1}	1.47	-	-	-
26	1, 3, 5-three methyl benzene	1.28×10^{-1}	9.00×10^{-4}	0.01		0.79×10^{-3}	162
27	1, 2-dichloropropane	3.10×10^{-3}	1.30×10^{-3}	0.42	-	0.22×10^{-3}	14
28	1, 2-two chlorobenzene	2.15×10^{-2}	3.98×10^{-2}	1.85	0.5^{Δ}	3.73×10^{-3}	5.8
29	1, 2, 4-trichlorobenzene	3.08×10^{-2}	1.24×10^{-2}	0.4	0.5^{Δ}	1.6×10^{-2}	1.9
30	1, 2, 4-three methyl benzene	2.90×10^{-3}	8.20×10^{-3}	2.83	_	1.68×10^{-3}	1.7
31	1, 1, 2-Trichloroethane	3.70×10^{-3}	3.00×10^{-3}	0.81	_	0.08×10^{-3}	46

Note: $^{\Delta}$integrated emission standard of air pollutants' in China (GB16297-1996) Table 1 VOCs pollutants and concentration limit of unorganized monitoring; $^{\Delta\Delta}$odor pollutants emission standard' (GB14554-1993) level 1 standard value for factory.

In term of the VOCs category, it mainly included a total of 8 types such as chlorinated hydrocarbon (chlorobenzene, chloroform, methylene chloride), aromatic hydrocarbons (1, 3, 5-, three methyl benzene, xylene, toluene, etc.), aliphatic hydrocarbons (hexane, heptane, cyclohexane), ketones (acetone, 2-, butanone, 2-, etc.), esters (ethyl acetate, vinyl acetate), low molecular sulfur compounds (carbon disulfide), furans, ether and so on. Among them, aromatic hydrocarbons and ketones had the highest proportion, respectively accounting for 43% and 28% of the total VOCs concentration, which was related to the use of large amounts of acetone, toluene and other organic solvents in the pharmaceutical process.

VOCs health risk assessment

According to the classification method of carcinogenic chemicals in humans in the International Tumor Institute (IARC), hazard identification of the 32 VOCs detected was conducted. The results showed that 13 substances were not included in the list, and 19 substances were harmful to human health (Table 2). Among them, there were 2 kinds (benzene, 1, 3-butadiene) of substances determined to have carcinogenic

effects on the human body, 1 kind (benzyl chloride) of possibly carcinogenic substances (chemical compound with limited carcinogenicity evidence but sufficient carcinogenicity evidence of laboratory animals), 7 kinds (vinyl acetate, ethylbenzene, etc.) of suspected carcinogen (chemical compound with limited carcinogenicity evidence and insufficient carcinogenicity evidence of laboratory animals). The carcinogenicity evidence of most pollutants was inadequate and belonged to unclassified human carcinogens, however, this did not mean the substance didn't have any toxicity, but there was not enough experimental evidence to determine their carcinogenicity under the existing economic and technological conditions.

Table 2. *Hazard identification of VOCs.*

Classification	Group standard	Category of pollutant
1	Carcinogenic to humans	Benzene, 1, 3- butadiene
2A	Probably carcinogenic to humans	Benzyl chloride
2B	Suspicious carcinogen to humans	Vinyl acetate, ethylbenzene, carbon tetrachloride, chloroform, methylene dichloride, styrene, 1, 4-two chlorobenzene
3	Cannot classify human carcinogenicity through existing evidence	O-xylene , m-xylene, p-xylene, Methyl tertiary butyl ether, MTBE, Toluene, 1, 3-, two chlorobenzene, 1, 2-two chloropropane, 1, 2-two chlorobenzene, 1, 1, 2-three dichloroethane
4	May be non-carcinogenic to humans	

The health risk assessment model of exposed population was used to calculate the identified 19 kinds of VOCs substances which had health hazard, the non-carcinogenic risk index R^n_i and the carcinogenic risk index R^c_i were shown in Table 3.

Due to lack of reference dose, concentration, and the inhalation unit risk value of 1, 3-two chlorobenzene, benzyl chloride, they were not included in the table. In real life, carcinogens also had risk effect like non-carcinogens. According to the requirements of US EPA, when the non-carcinogenic risk index exceeded 1, it was considered to be harmful to human health. As can be seen from Table 3, the non-carcinogenic risk indexes of various VOCs substances were far below 1, indicating that these pollutants did not produce significant non-carcinogenic health risks to humans; for carcinogenic risk, acceptable carcinogenic risk index recommended by US EPA was 1×10^{-6}-1×10^{-4}. In this paper, the most stringent acceptable carcinogenic risk 1×10^{-6} was considered as evaluation criteria [24]. The carcinogenic risk was not exceeded except for dichloromethane, and carcinogenic risk index of the other VOCs exceeded the standard value, the cumulative carcinogenic risk index for total volatile organic compounds was much more than an acceptable order of magnitude, showing that the VOCs produced by this concentrated area of pharmaceutical enterprises mainly had carcinogenic health hazards. The ranking of carcinogenic risk value size was 1, 3-, butadiene>chloroform>carbon tetrachloride>benzene>1, 1, 2-three chloro ethane>1×10^{-6}, thus in the formulation of VOCs control standards for the pharmaceutical industry, these substances should be paid enough attention to, and the above risk value ranking could also be used as a reference.

Table 3. *Health risk assessment results of VOCs.*

Substance name	RfD/ ($mg \cdot kg^{-1} \cdot d^{-1}$)	RfC/($mg \cdot m^{-3}$)	IUR/($\mu g \cdot m^{-3}$)	Dig inhalation[1]/ ($mg \cdot kg\text{-}1 \cdot d^{-1}$)	Dig inhalation[2]/ ($mg \cdot kg^{-1} \cdot d^{-1}$)	R_n^i	R_c^i
Benzene	4×10^{-3}	0.03	7.8×10^{-6}	0.1913	0.3276	1.09×10^{-5}	2.56×10^{-6}
1, 3-butadiene	-	2×10^{-3}	3×10^{-2}	2.7356	4.6847	2.34×10^{-3}	1.41×10^{-1}
O-xylene, m-xylene, p-xylene	0.2	0.1	-	2.4048	4.1182	4.12×10^{-5}	-
MTBE	-	3	-	0.0478	0.0819	2.73×10^{-8}	-
Methylbenzene	0.08	5	-	0.4256	0.7289	1.46×10^{-7}	-
1, 2-dichloropropane	-	4×10^{-3}	-	0.0494	0.0846	2.12×10^{-5}	-
1, 2-two chlorobenzene	9×10^{-2}	-	-	0.3427	0.587	3.81×10^{-6}	-
1, 4-dichlorobenzene	-	0.8	-	0.2152	0.3686	4.61×10^{-7}	-
1, 1, 2-Trichloroethane	4×10^{-3}	-	1.6×10^{-5}	0.059	0.101	1.47×10^{-5}	1.62×10^{-6}
Vinyl acetate	-	0.2	-	0.0414	0.071	3.55×10^{-7}	-

Ethylbenzene	0.1	1	-	0.491	0.8408	8.41×10^{-7}	-
Carbon tetrachloride	4×10^{-3}	0.1	6×10^{-6}	0.4272	0.7316	7.32×10^{-6}	4.39×10^{-6}
Chloroform	1.0×10^{-2}	-	2.3×10^{-5}	0.4352	0.7453	4.35×10^{-5}	1.71×10^{-5}
Carrene	6×10^{-3}	0.6	1×10^{-8}	0.1578	0.2703	4.50×10^{-7}	2.7×10^{-9}
Styrene	0.2	1	-	1.5814	2.7082	2.71×10^{-6}	-
Total	-	-	-	-	-	2.49×10^{-3}	1.4×10^{-1}

Note: There were temporarily no relevant data.

Conclusion

(1) 32 kinds of VOCs were detected in the air around the concentrated area of pharmaceutical enterprises, including aromatic hydrocarbons, chlorinated hydrocarbons, aliphatic hydrocarbons, ketones, esters, low molecular thio compounds, furans, ethers, etc., of which acetone, xylene, 1, 3-butadiene and 1, 3, 5-three methyl benzene had higher concentration. Part of VOCs concentrations were ten times or 100 times the background value, not only affecting ambient air quality, but also being possible health risks to nearby residents.

(2) 19 substances of the detected VOCs produced in concentrated area of the pharmaceutical industry had health hazards, and these VOCs did not pose a significant non-carcinogenic health risk to the population. But most VOCs had carcinogenic effects on the population, and the ranking of the carcinogenic risk value size was 1, 3-, butadiene>chloroform>carbon tetrachloride>benzene>1, 1, 2-three dichloroethane>1×10^{-6}. It is suggested that the region's production enterprises should strengthen VOCs governance, and at the same time, in formulating the VOCs control standards of the pharmaceutical industry, strict emission limits should be formulated for some certain pollutants.

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*Correspondence to

Lei Ma

Business Administration School of Nanjing Audit University

Jiangsu Province

PR China