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Technical specification of daily protective mask

日常防护型口罩技术规范

（English Translation）

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Foreword

This standard is drafted in accordance with the rules given in the GB/T 1.1—2009 *Directives for standardization—Part 1: Structure and drafting of standards*.

This standard was proposed by China National Textile and Apparel Council.

This standard was prepared by SAC/TC209 (National Technical Committee 209 on Textiles of Standardization Administration of China).

Technical specification of daily protective mask

1 Scope

This standard terms and definitions, classification, technical requirements, test method, inspection rules, packaging, label and storage requirements of daily protective mask.

This standard is applicable to protective mask for filtering out particles under air pollution environment in our daily life.

This standard is not applicable to hypoxia environment, underwater operation, escape, fire control, medical and industrial dust suppression and other special industries. This standard is not suitable for infants and young children.

2 Normative references

The following reference documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the reference document (including any amendments) applies.

GB 2890—2009, *Respiratory protection—Non-powered air-purifying respirators*

GB/T 2912.1, *Textiles—Determination of formaldehyde—Part1: Free and hydrolyzed formaldehyde (water extraction method)*

GB/T 7573, *Textiles—Determination of pH of aqueous extract*

GB/T 10586, *Specifications for damp heat chambers*

GB/T 10589, *Specifications for low temperature test chambers*

GB/T 11158, *Specifications for high temperature test chambers*

GB/T 13773.2, *Textiles — Seam tensile properties of fabrics and made-up textile articles — Part 2: Determination of maximum force to seam rupture using the grab method*

GB/T 14233.1—2008, *Test methods for infusion, transfusion and injection equipments for medical use — Part 1: Chemical analysis methods*

GB/T 17592, *Textiles—Determination of the banned azo colourants*

GB/T 23344, *Textiles—Determination of 4-aminoazobenzene*

GB/T 29865, *Textiles—Tests for colour fastness—Colour fastness to abrasion—Small areas*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1

Particulate matter （PM2.5）

It refers to the particulate matters with air dynamics equivalent diameter less than or equal to 2.5 microns in the ambient air.

[GB 3095—2012，definition 3.4]

3.2

Filter efficiency

The ability of the mask body to filter out particulate matter under specified conditions , expressed as a percentage.

3.3

Particle protective performance

The ability of the mask to block particulate matter under specified conditions, expressed as a percentage.

4 Classification

The protection effect of mask is divided into class A, B, C, D from high to low, and corresponding air quality at all levels are shown in table 1. (Masks at all levels should be able to reduce the concentration of inspiratory particulate matter to 75 μg/m³ or less (air quality index is “good” or above) in the corresponding air pollution environment.)

Table 1 the applicable environment air quality for different levels of protection effect

The level of protection effect	**A**	**B**	**C**	**D**
Applicable air quality index category	severe pollution	severe pollution and below	heavy pollution and below	moderate pollution and below

5 Technical requirements

5.1 Basic requirements

5.1.1 Mask shall be able to cover mouth and nose safely and firmly.

5.1.2 Mask shall not be made from recycled materials and materials with high toxicity, carcinogenicity, or potentially carcinogenic. Mask also shall not be made from materials known to cause skin irritation or other adverse reactions. The residues of other restrictions on the material shall comply with the relevant requirements, no odor.

5.1.3 Masks shall not have accessible sharp angle and edges, and shall not cause injury to the wearer.

5.1.4 Masks should be easy to wear and remove, have no obvious pressure or tenderness phenomenon in the process of wearing, and do not influences head activity.

Note: Conditions and notes of a mask see annex C.

5.2 Appearance requirement

The surface of a mask shall be free of breakage, oil stains, deformation and other obvious defects.

5.3 Internal quality

Internal quality requirements, see Table 2.

Table 2 Internal quality

Items		Requirements
Colour fastness to abrasion(dry/wet）[a]/level	≥	4
Formaldehyde content /（mg/kg）	≤	20
pH value		4.0~8.5
Decomposable carcinogenic aromatic amine dyes[a]/（mg/kg）		Forbidden
Ethylene oxide residues[b]/（μg/g）	≤	10
Inhalation resistance /Pa	≤	175
Exhalation resistance /Pa	≤	145
Breaking strength of mask band and the joint of mask band and mask body /N	≥	20
Fastness of exhalation valve cover[c]		No slippage, fracture and

			deformation
Microorganism	Coliforms		Forbidden
	Pathogenic purulent bacteria[d]		Forbidden
	Total fungal colonies /（CFU/g）	≤	100
	Total bacterial colonies /（CFU/g）	≤	200
Fliled of Version（Downside）		≥	60°

a Assess dyeing and printing only.

b Assess ethylene oxide treated mask only.

c Assess mask equipped with exhalation valve only.

d Refers to pseudomonas aeruginosa, staphylococcus aureus and hemolytic streptococcus.

5.4 Filter efficiency

Divide levels into Ⅰ, Ⅱ and Ⅲ based on filter efficiency. Corresponding indexes at all levels, see Table 3.

Table 3 Filter efficiency levels and requirements

Filter efficiency levels		Ⅰ	Ⅱ	Ⅲ
Filter efficiency /% ≥	Salt medium	99	95	90
	oil medium	99	95	80

5.5 Protection effect

5.5.1 The requirements for the protection effect of masks with different protection effect levels, see Table 4.

Table 4 The requirements for the protection effect of masks with different protection effect levels

Protection effect level	A	B	C	D
Protection effect/% ≥	90	85	75	65

5.5.2 When the Protection effect level of a mask is class A, filter efficiency should reach level Ⅱ and above; When the Protection effect level of a mask is class B, C ,D, filter efficiency should reach level Ⅲ and above.

6 Test method

6.1 Appearance inspection

Extract 10 masks and adopt the method of visual the inspection to test. Inspection will be subject to normal natural light; if adopting fluorescent lighting, illumination should not less than 400 lx.

6.2 Colour fastness to abrasion

Execute according to the provisions of GB/T 29865. The outer layer of a mask shall be tested when testing colour fastness to dry abrasion; the contact layer between mask and face shall be tested when testing colour fastness to wet abrasion.

6.3 Formaldehyde content

Execute according to the provisions of GB/T 2912.1.

6.4 pH value

Execute according to the provisions of GB/T 7573. Cropping sample from the contact layer between mask and face.

6.5 Decomposable carcinogenic aromatic amine dyes

Execute according to the provisions of GB/T 17592 and GB/T 23344.

Note: In general, test according to GB/T 17592 first, when aniline or 1, 4－phenylenediamine is detected, test according to GB/T 23344 again.

6.6 Ethylene oxide residues

According to the product label, the ethylene oxide treated mask shall be tested according to the provisions of chapter 9 in GB/T 14233.1-2008. Parallel Samples which are cropped on the mask body shall be tested. If one result is qualified, another is unqualified, it is not allowed to adopt the average calculation, we shall take samples and test again and adopt the highest value as test results. The result calculation is expressed in relative content, with one decimal.

6.7 Inhalation resistance

6.7.1 Samples and pretreatment

Four samples, two of which are untreated samples and the other two are samples after pretreatment in accordance with A.3.2 of Annex A. If the tested samples have different models, there should be two samples for each model, one of which is an untreated sample and the other one is a pretreated sample according to A.3.2.

6.7.2 Test equipment

6.7.2.1 The detecte device of Inhalation resistance is composed of the test head breathing tube, piezometric tube, micro pressure meter, flow meter, valve, switch valve, pump and air compressor, see Figure 1.

6.7.2.2 Flowmeter range is 0-100L/min, accuracy is 3%.

6.7.2.3 Micropressure meter range is 0-1000Pa, accuracy is 1 Pa.

6.7.2.4 Head model. A breathing tube is installed at the mouth of the head model. The main dimensions of the head model should meet the requirements of Annex B. There are three models: large, medium, and small..

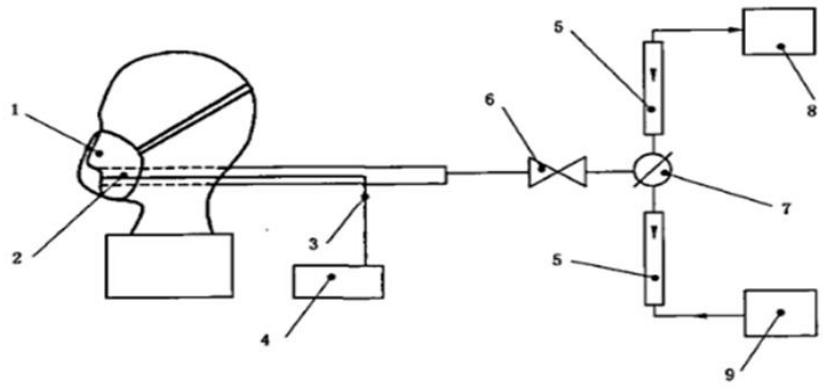
6.7.2.5 Swept volume of pump shall not be less than 100 L/min.

6.7.3 Test conditions

Airflow constant at （85±1）L/min.

6.7.4 Test method

Check the air tightness and working status of the detection device. Adjust the Airflow to (85 + 1) L/min and set the system resistance of detection device to 0. Wear the tested sample on the matching head model, adjust the wear position of mask and head with firmness, ensure that the mask fits closely with head. Then adjust Airflow to (85±1)L/min, measure and record the suction resistance. In the process of test, take appropriate methods to avoid sample attaching on the breathing tube opening .



Key:

1——Tested sample

2——Head model breathing tube

3——Manometer

4——Micromanometer

5——Flowmeter

6——Control valve

7——Switch valve

8——pump (for testing inhalation resistance)

9——air compressor (for testing expiratory resistance)

Figure 1 test device of exhalation resistance and inhalation resistance

6.8 Exhalation resistance

6.8.1 Samples and pretreatment

Requirements are the same as 6.7.1.

6.8.2 Test equipment

6.8.2.1 Test device of exhalation resistance is seen in Figure 1.

6.8.2.2 Flowmeter is the same as 6.7.2.2.

6.8.2.3 Micromanometer is the same as 6.7.2.3.

6.8.2.4 The size of head model is the same as 6.7.2.4.

6.8.2.5 Air compressor discharge capacity is not less than 100 L/min.

6.8.3 Test conditions

Requirements are the same as 6.7.1.

6.8.4 Test method

Check the air tightness and working status of the detection device. Adjust the Airflow to (85 + 1) L/min and set the system resistance of detection device to 0. Wear test sample on the matching head model, adjust the wear position of mask and head with firmness, ensure that the mask fits closely with head. Then adjust Airflow to (85±1)L/min, measure and record the suction resistance. In the process of test, take appropriate methods to avoid sample attaching on the breathing tube.

6.9 Breaking strength of mask band and the joint of mask band and mask body

6.9.1 Take 5 mask samples.

6.9.2 Execute according to the provisions of GB/T 13773.2. the tensile speed is 100 mm/min. Test hook is installed on the top clamp of a tensile instrument, mask bands suspend on the test hook vertically.The mask body should be sandwiched loosely in the bottom clamp in the axial direction.

6.9.3 Test hook is strip-type and made of steel. The width of the test hook is （10±0.1） mm, the thickness of the test hook is（2±0.1）mm. One end bends at right angles hooked, the length of which is at least （12±0.1） mm. The edge of the hook should be smooth. The test hook should be convenient to install in the clamp of the tensile tester, see Figure 2.

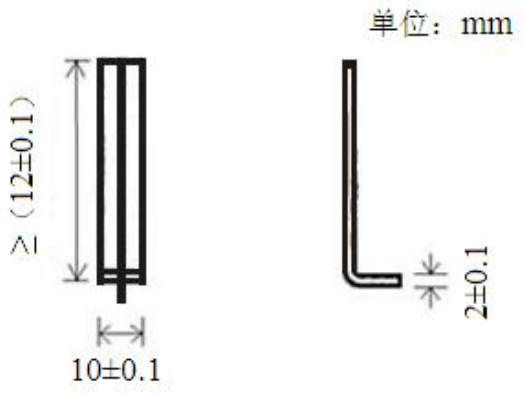


Figure 2 test hook

6.10 Fastness of exhalation valve cover

6.10.1 Samples and pretreatment

Three untreated samples.

6.10.2 Test equipment

6.10.2.1 Measurement range of the material testing machine is 0—1000 N, accuracy is 1%

6.10.2.2 Fixture shall have proper structure and Clamping tightness.

6.10.2.3 The accuracy of timer is 0.1s

6.10.3 Test method

The exhalation valve cover and the mask body of testing samples shall be fixed with appropriate fixture (fixed point shall be reasonably close to the corresponding connection parts). Start the tensile tests machine, and apply axial tension to 10N for 10s, then record for breaks, slippage and deformation.

6.11 Microorganism index

Execute according to the provisions of GB 15979.

6.12 Filed of Version

Execute according to the provisions of 6.8 in GB 2890—2009.

6.13 Filter efficiency

Execute according to the provisions of Annex A.

6.14 Protection effect

Execute according to the provisions of Annex B.

7 Inspection rules

7.1 Sampling

Inspection lot shall be taken from products with same category and specification according to the lot number. Randomly select a corresponding number of samples from each inspection lot according to the test requirements. When the delivery quantity of the same delivery lot is more than 100,000, the sampling quantity is doubled.

7.2 Quality evaluation

7.2.1 Appearance quality evaluation

Test appearance quality according to article 6.1, and at least 8 or more samples shall conform to the

requirements of 5.2. Fulfil the requirements of 5.2 can be evaluated as qualified, otherwise not qualified.

7.2.2 Internal quality evaluation

Test results of inner quality, filter efficiency and protection effect fulfil the requirements of 5.3, 5.4 and 5.5 can be evaluated as qualified, otherwise not qualified.

7.2.3 Result evaluation

If appearance quality, inner quality, filter efficiency and protection effect of all the batch are qualified, they can be evaluated as qualified, otherwise not qualified.

8 Packaging, Label and storage

8.1 Packaging

Each mask shall be packaged hermetically.

8.2 Label

Each packaging unit shall have a certificate of inspection, and the obvious parts shall be accompanied by a clearly label. The label shall include the following content.:

a）Name and address of manufacturer；

b）Product name；

c）Main raw material (inner, outer, filter layer)；

d）Number of executive standard；

e）Protection effect level；

f）Product specifications (small, medium and large);

g）Instructions for use (wear method, note, etc.);

h）Date of manufacture, recommended usage time (hour) and storage time;

i）If disinfection is used, **indicate the** disinfection method .

8.3 Storage

Products shall be sealed, not damaged, not stained, and protected from moisture during storage and transportation. Pay attention to fire, rain, acid, alkali and avoid direct light.

Annex A
(annex normative)
Test method of filter efficiency

A. 1 Scope

This annex defines the test method for filtration efficiency of mask body.
This annex is applicable to daily protective mask.

A. 2 Test principle

Aerosol particles of a certain concentration and particle size distribution are generated by the aerosol generator, pass through the mask cover at a predetermined gas flow rate, and use appropriate particle detection devices to detect the particle concentration before and after passing through the mask cover. The percentage of particulate matter reduction after the aerosol passed through the mask body was used to evaluate the filtering efficiency of the mask body on the particulate matter.

A. 3 Samples and pretreatment

A. 3.1 Sixteen samples are divided into two groups, one will be tested by salt medium and the other one will be tested by oily medium. Five samples are untreated and the other three samples are pretreated as specified in A3.2 in each group.
A. 3.2 Pretreatment by temperature and humidity
A. 3.2.1 Pretreatment equipment
a) The technical performance of hot and humid test chamber shall meet the requirements of GB/T 10586.
b) The technical performance of high temperature test chamber shall meet the requirements of GB/T 11158.
c) The technical performance of low temperature test chamber shall meet the requirements of GB/T 10589.
A. 3.2.2 Pretreatment method
Take the samples from the original package, pretreated under the following steps:
a) Kept in the (38±2.5)℃ and (85±5) % relative humidity environment for (24±1)h.
b) Kept in (70±3)℃ dry environment for (24±1) h.
c) Kept in (- 30±3)℃ environment for (24±1) h.
Before each step, the temperature of samples shall return to room temperature at least 4h, then start the follow-up test steps. The pretreated samples shall be placed in a closed container and tested within 10h.

A. 4 Test equipment

A. 4.1 Filter efficiency test system for NaCl particles
The requirements of Filter efficiency test system for NaCl particles are as following:

a) The concentration of NaCl particles is less than 30 mg/m^3. The count median diameter (CMD) is (0.075±0.020)μm, and the geometric standard deviation of particle size distribution is less than 1.86.

b) The detected dynamic range of particles is 0.001~100 mg/m^3, and the accuracy is 1%.

c) The detected flow range is 30 ~ 100L/min, and the accuracy is 2%.

d) The testing range of Filter efficiency is 0~99.999%.

e) There shall be a neutralized device for neutralizing the charge of particles.

A. 4.2 Filter efficiency testing system for oil particles

The requirements of Filter efficiency test system for oily particles are as following:

a) Test medium is dioctyl sebacate (DEHS) or other applicable oily particles, such as paraffin oil. The particle concentration is less than 30 mg/m^3, and the count median diameter (CMD) is (0.185±0.020) μm. The geometric standard deviation of particle size distribution is less than 1.60.

b) The detected dynamic range of particles is 0.001~100 mg/m^3, and the accuracy is 1%.

c) The detected flow range is 30 ~ 100L/min, and the accuracy is 2%.

d) The test range of Filter efficiency is 0~99.999%.

A. 5 Test conditions

The test ambient temperature is (25±5) ℃ and the relative humidity is (30±10) %.

A. 6 Test process

a) Test air flowing is (85±4) L/min (the air flowing should be divided equally if adopt multiple filtering element, such as dual filter element. The test flow of each filter element should be (42.5±2) L/min; if the multiple filter element may be used alone, the test shall be applied as single filter element).

b) Adjust Filter efficiency test system and the relevant parameters into test condition.

c) Fix the main body of the mask or filter element to the detection device airtight.

d) Record sample Filter efficiency after test start and the sampling frequency is no less than 1 time/ min. The test shall be continued until particles on mask loaded to 30 mg.

A. 7 Data processing

Take the minimum value in the course of the entire test as the Filter efficiency for the batch of test samples. The value keeps a decimal.

Annex B
(annex normative)
Test methods for protection effect

B. 1 Scope

This annex specifies the test method for particle protective performance of daily protective mask.
This annex is applicable to daily protective mask, can refer to other masks.

B. 2 Principle

Aerosol particles of a certain concentration and particle size distribution are generated by the aerosol generator, pass through the mask cover at a predetermined gas flow rate, and use appropriate particle detection devices to detect the particle concentration before and after passing through the mask cover. The percentage of particulate matter reduction after the aerosol passed through the mask body was used to evaluate the protection effect of the mask body on the particulate matter.

B. 3 Samples and pretreatment

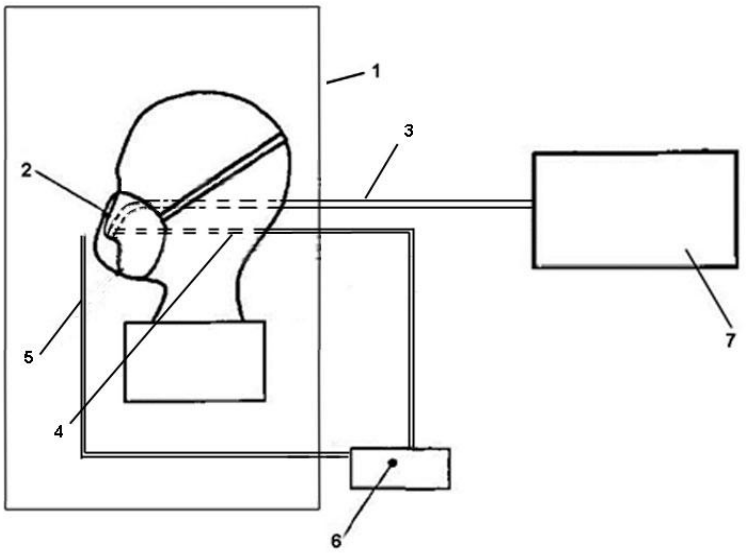
Sixteen samples are divided into two groups, one group will be tested by salt medium and the other one group will be tested by oily medium. Five samples are untreated and the other three samples are pretreated as specified in A3.2 in each group.

B.4 Test conditions

The test ambient temperature is (25±5) ℃ and relative humidity is (30±10) %.

B. 5 Protective performance test device

B. 5.1 The test device diagram of protective performance see in Figure B. 1.



Key:

1 - test chamber;

2 - tested samples;

3 - head model's breathing tube;

4 - inhaling gas sampling tube;

5 - environment gas sampling tube;

6 - aerosol concentration monitoring device;

7 - breathing simulator.

Figure B.1 diagrammatic sketch of protective performance test device

B. 5.2 Test chamber of protection effect

A closable chamber with a large observation window should be easy to operate by the inspector. The test medium is fed in uniformly from the top of the chamber, and after the test, it is discharged through the bottom opening of the chamber.

B. 5.3 Test medium

B. 5.3.1 NaCl particles, the initial concentration in the valid test space of silo is 20～30mg/m^3, the concentration fluctuation during test shall be less than 10%. The aerodynamic size distribution of particles should be 0.02～2μm and the mass median diameter is 0.6μm approximately.

B. 5.3.2 Corn oil particles, the initial concentration in the valid test space of silo is 20 ~ 30 mg/m^3, the concentration fluctuation during test shall be less than 10%. The aerodynamic size distribution of particles shall be 0.02 ~ 2μm and the mass median diameter is 0.3μm approximately.

B. 5.4 Aerosol concentration monitoring devices

The sampling gas flow is 1～2 L/min, the sampling frequency is more than 1 time/ min. The dynamic range is 0.001～100 mg/m^3, the accuracy is 1%. The inhaling gas sampling tube shall be close to the model nostril, the distance from environment gas sampling tube to mask muzzle shall less than 3 cm.

B. 5.5 Test head model sizes see in Table b.1.

Table b.1 test head model size

Unit：mm

Size item	Small	Medium	Large
Head length	169	181	191
Head width	140	148	157
Two intertragic wide	127	137	145
Face wide	136	143	148
Morphological facial length	109	120	129

Head sagittal arc	349	361	363
Sagittal arc	329	349	368
Nasal height	48	51	59
Nasal depth	17	18.6	20
Nasal breadth	35	37	40
Tragus chin long	138	142	150
Length of the mandibular angle	58	66	72.2
Distance between nasospinale and gnathion	62	64	71.4

B. 5.6 Breathing simulator

Sinusoidal airflow, breathing rate is 20 times/ min and breathing flow is (30±1) L/m.

B. 6 Test process

a) Check the test equipment and confirm the equipment in normal working condition.

b) Fix the mask to the proper-sized head model firmly according to manufacturer instructions, then open air simulator and aerosol concentration monitoring device. After the display value is stable, record the particles concentration of the gas flow， which get into head model from the breathing tube (i.e. the background particle concentration in the masks, C_0).

c) Close breathing simulator and let the test medium get into the test silo. Monitor the concentration of test medium through the environment air sampling tube by using aerosol concentration monitoring device. Open the breath simulator after concentration of test medium reached the concentration value which described in B.5.3.

d) Record the test medium concentration in testing silo, C_1, and the test medium concentration in breathing tube of head model, C_2, by using aerosol concentration monitoring device.

e) Monitor the C_1 and C_2 values during the whole testing process for 1 h, which are used to calculate the protective performance.

B.7 Calculation of protection effects

Protection effect is calculated according to the Formula (B.1):

$$P = (C_1 - C_2 + C_0)/C_1 \times 100\% \quad \text{(B.1)}$$

Formula:

C_1 --- The test medium concentration in the testing chamber during process, mg/m^3;

C_2 --- The test medium concentration in breathing tube of head model during process, mg/m^3;

C_0 ---The background particle concentration in the mask, mg/m^3.

The values of C_1 and C_2 should be monitored at the same time during testing, and calculate the protection effect of samples at every sampling time. Using the minimum value during the whole test process as the sample's protective performance.

Annex C
(annex normative)
Conditions and notes of mask

C. 1 Scope

This annex gives the conditons and the notes for different protective performance daily masks.

C. 2 Ambient air quality for masks with different protection levels

C. 2.1 When the main pollutants in the ambient air is particulate matters, the concentration of fine particles which breathed in human body could reach the good or better environmental air quality requirement ($PM_{2.5}$ concentration ≤ 75μg /m^3) after wearing the right mask.

C. 2.2 Ambient air quality for masks with different protection levels and the according allowed highest concentration limits of fine particulate matter ($PM_{2.5}$) see in Table C. 1.

Table c.1 the applicable environmental air quality for different protective performance masks and the according highest exposure concentration limits of fine particulate matter ($PM_{2.5}$)

Table C. 1

Protective performance level	Level A	Level B	Level C	Level D
Applicable air quality index category	severe pollution	severe pollution and below	heavy pollution and below	moderate pollution and below
Applicable PM2.5 concentration limit/（μg/m3） ≤	500	350	250	150
The allowed highest exposure PM2.5 concentration limit/（μg/m3）	700	500	300	200

C. 3 Notes

C. 3.1 Choose suitable masks to wear according to the air pollution situation.

C. 3.2 Check and confirm if the mask packages are intact.

C. 3.3 Check the mask appearance and read the using method before usage, then wear the mask correctly according to the wear method.

C. 3.4 The protective masks shall be timely replaced and a long time use is not recommended.

C. 3.5 If discomfort or adverse reactions happened during wear, you should stop using.

C. 3.6 We suggest to reduce outdoor activities when the concentration of fine particulate matter in the air is more than 500μg/m^3.

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