ORPHILA™
Qingdao Orphila Medical Technology Co.,Ltd.

Documents of FFP2 Earloop

1. ISO 9001:2015 ---------- 03

2. AENOR CE Certificate ---------- 04-05

3. FFP2 EN 149:2001 TUV / GUO JIAN Test Report --- 06-22

4. TUV Reach Test Report ---------- 12-31

5. Datasheet ---------- 32-33

6. Detail of Package ---------- 34-35

7. Declaration of Conformity ---------- 36

8. Biocompatibility Test Report ---------- 37-60
(Skin sensitization & Irritation test)

ORPHILA™

FFP2 Particle Filtering Half Mask

CE

AENOR

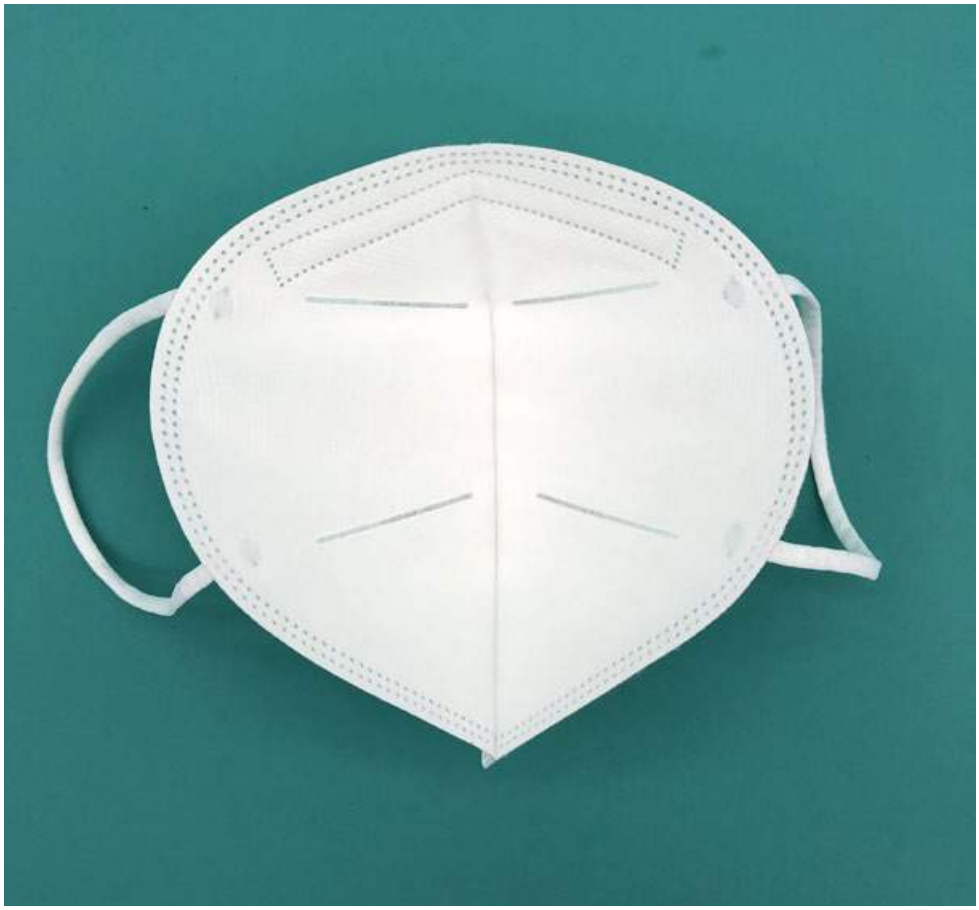
REACH NPS

FFP2 NR
Model: OM-P2195

Meets EN149:2001+A1:2009 standard requirements.

CE Certificate No.A18/000037
TUV REACH No.178141074a 001

Product Photos



BUREAU VERITAS
Certification

Qingdao Orphila Medical Technology Co., Limited

Rm0501, Futai Square No.18 Hongkong Middle Road, Qingdao, Shandong, China

Unified social credit code: 913702035990204532

Bureau Veritas Certification Holding SAS - UK Branch certifies that the Management System of the above organisation has been audited and found to be in accordance with the requirements of the management system standards detailed below

ISO 9001:2015

Scope of certification

Design, Production and Sales of Masks,

Production and Sales of Melt-blown Cloth

Original cycle start date:	**10-07-2020**
Expiry date of previous cycle:	**NA**
Certification / Recertification audit date:	**NA**
Certification / Recertification cycle start date:	**10-07-2020**

Subject to the continued satisfactory operation of the organisation's Management System, this certificate expires on: **09-07-2023**

Certificate No. : **CNBJ322095-UK** Version: **No.1**, Revision date: **10-07-2020**

Signed on behalf of BVCH SAS UK Branch

UKAS MANAGEMENT SYSTEMS
0008

Certification body address: 5th Floor, 66 Prescot Street, London E1 8HG, United Kingdom
Local office address: F22, Tower B, Beijing Global Trade Center, 36 North Third Ring Road East, Dongcheng District, Beijing, China. 100013.

Further clarifications regarding the scope of this certificate and the applicability of the management system requirements may be obtained by consulting the organisation.
To check this certificate validity please call: (+86 10 59683888)
Certified organisation has to accept and pass regular surveillance audits, then this certificate can be continuously valid. Information of this certificate may be obtained by visiting CNCA website (www.cnca.gov.cn).

AENOR

Certificado de Examen UE de Tipo
EU Type-Examination Certificate

A18/000037

AENOR, como organismo notificado (nº 0099) para el Reglamento (UE) 2016/425, ha emitido este certificado a favor de
In compliance with Regulation (EU) 2016/425, the notified body AENOR (nº 0099) has issued this certificate to

Qingdao Orphila Medical Technology Co., Limited

Domicilio social / Registered office	Room 501, Futai Square No.18 266000 Hongkong Middle Road, Qingdao, Shandong (China)
para el producto / for the product	Dispositivos de protección respiratoria. Medias máscaras filtrantes de protección contra partículas. / Respiratory protection devices. Half filter masks to protect against particles.
conforme con el Reglamento in compliance with Regulation	Reglamento UE 2016/425 de Equipos de Protección Individual (Regulation EU 2016/425 on Personal Protective Equipment)
Norma armonizada / Harmonized standard	EN 149:2001+A1:2009
	Más información en el anexo / See annex for more information.
Centro de producción / Production site	Room 501, Futai Square No.18 266000 Hongkong Middle Road, Qingdao, Shandong (China)
Esquema de evaluación Assessment scheme	Anexo V (Examen UE de Tipo – Módulo B) del Reglamento (UE) 2016/425. Annex V (EU Type-examination – Module B) of Regulation (EU) 2016/425.
Fecha de emisión / First issued on Fecha de expiración / Validity date	2020-06-22 2025-06-22

Rafael GARCÍA MEIRO
Director General / CEO

Original Electronic Certificate

AENOR INTERNACIONAL S.A.U.
Génova, 6. 28004 Madrid. España
Tel. 91 432 60 00.- www.aenor.com

Organismo de control acreditado por ENAC con acreditación Nº 1/C-PR354
Control body accredited by ENAC. Accreditation number 1/C-PR354

AENOR

Certificado de Examen UE de Tipo
EU Type-Examination Certificate

A18/000037

Anexo al Certificado
Annex to Certificate

Norma armonizada / Harmonized standard EN 149:2001+A1:2009

Marca Comercial / Trade Mark	Referencia / Reference	Clasificación / Classification	Descripción / Description
ORPHILA	OM-P2195	FFP2 NR	MEDIA MASCARILLA, DE CINCO CAPAS DE FILTRADO, DOS LAZOS FIJOS DE SUJECIÓN A OREJAS, DE TIPO PLEGABLE. DISEÑADA PARA PROTEGER CONTRA PARTÍCULAS SÓLIDAS O LÍQUIDAS SUSPENDIDAS EN EL AIRE. NO REUTILIZABLE / FILTERING HALF MASK, FIVE FILTERING LAYERS, TWO EARLOOPS, FOLDING STYLE. DESIGNED TO PROTECT AGAINST AIRBORNE SOLID OR LIQUID PARTICLES. NON-REUSABLE.

Fecha de emisión / First issued on 2020-06-22
Fecha de expiración / Validity date 2025-06-22

AENOR INTERNACIONAL S.A.U.
Génova, 6. 28004 Madrid. España
Tel. 91 432 60 00.- www.aenor.com

Organismo de control acreditado por ENAC con acreditación Nº 1/C-PR354
Control body accredited by ENAC. Accreditation number 1/C-PR354

Original Electronic Certificate

Products

TÜVRheinland®
Precisely Right.

Test Report No.: 178139762a 001

Client:

Qingdao Orphila Medical Technology Co., Limited
Rm0501, Futai Square No.18 Hongkong middle road, Qingdao, Shandong, China

Contact Person: Rocky Ma

Sample Description As Declared :

No. Of Sample	:	90 Pcs
Product Description	:	OM-KN95-FFP2
Lot No./Batch code	:	202004
Sales Destination(country)	:	Not Provided
Test type	:	Partial test
Product type	:	Single shift use only
Claimed Classification	:	FFP2 NR
Manufacturer Name	:	Qingdao Orphila Medical Technology Co., Limited
Manufacturer Address	:	Plant 20, No. 252 Weihe Road, Huangdao District, Qingdao, Shandong, China

Sample obtaining method: Sending by customer

Sample Receiving date: 2020-04-30
Delivery condition: *Apparent good, Samples tested as received*
Test Period: 2020-05-07 to 2020-06-02

Test specification:	***Test result:***
Particulate respirator-half facepiece EN 149:2001 + A1:2009 Respiratory protective devices - Filtering half masks to protect against particles - Requirements, testing, marking^	Please refer to result page

For and on behalf of

TÜV Rheinland / CCIC (Qingdao) Co., Ltd.

2020-06-03 Alex Zhou / Senior Manager

Date *Name/Position*

Test result is drawn according to the kind and extent of tests performed.
This test report relates to the a. m. test sample. Without permission of the test center this test report is not permitted to be duplicated in extracts. This test report does not entitle to carry any safety mark on this or similar products.

Material list

Material	Color	Location
Textile	White	White folding mask

Note:

	Shading shows the clauses requested
NRq	The clauses were not requested.
Pass	Requirement satisfied.
Ltd	Testing requested was insufficient completely to verify compliance with the clause. Refer to the "result details section for more information.
Fail	Requirement not satisfied. Refer to the "result details section for more information.
NAs	Assessment not carried out.
NAp	Requirement not applicable.
NT	Requested but not tested due to early termination following failure.

Result:

EN 149:2001+A1:2009 Respiratory protective devices—Filtering half masks to protect against particles—Requirement, testing, marking.

7.4 **Package^** **NRq**

Particle filtering half masks shall be offered for sale packaged in such a way that they are protected against mechanical damage and contamination before use.

7.5 **Material^** **PASS [1]**

Materials used shall be suitable to withstand handling and wear over the period for which the particle filtering half mask is designed to be used.

After undergoing the conditioning described in 8.3.1 none of the particle filtering half masks shall have suffered mechanical failure of the facepiece or straps.

When conditioned in accordance with 8.3.1 and 8.3.2 the particle filtering half mask shall not collapse.

Any material from the filter media released by the air flow through the filter shall not constitute a hazard or nuisance for the wearer.

Note 1: In accordance with the requirement.
Specimens -10,-40,-27 were conditioned in accordance with 8.3.1, None of the specimens conditioned suffered mechanical failure or collapse.
Specimens -60,-21,-58 were conditioned in accordance with 8.3.2, None of the specimens conditioned suffered collapse.

7.6 **Cleaning and disinfecting^** **NAp [2]**

If the particle filtering half mask is designed to be re-usable, the materials used shall withstand the cleaning and disinfecting agents and procedures to be specified by the manufacturer.

With reference to 7.9.2, after cleaning and disinfecting the re-usable particle filtering half mask shall satisfy the penetration requirement of the relevant class.

Note 2: Single shift use only.

7.7 **Practical performance^** **PASS** [3]

The particle filtering half mask shall undergo practical performance tests under realistic conditions

Note 3: No imperfections.

Specimen and subject details:

Specimen	Subject
-26	LCF
-69	SM

7.8 **Finish of parts^**

Parts of the device likely to come into contact with the wearer shall have no sharp edges or burrs. **PASS** [4]

Note 4: None of the specimens used in limited laboratory testing undertaken showed the evidence of sharp edges or burrs.

7.9.1 **Total inward leakage^** **PASS**[5]

For particle filtering half masks fitted in accordance with the manufacturer's information, at least 46 out of the 50 individual exercise results (i.e. 10 subjects x 5 exercises) for total inward leakage shall be not greater than: 25% for FFP1, 11% for FFP2, 5% for FFP3;

And, in addition, at least 8 out of the 10 individual wearer arithmetic means for the total inward leakage shall be not greater than: 22% for FFP1, 8% for FFP2, 2% for FFP3.

Note 5: 47 out of the 50 individual exercise results were not greater than 11%; 8 out of the 10 individual wearer arithmetic means were not greater than 8%. Detailed data are showed below.

Table 7.9.1-A Inward leakage test data

Test specification: EN149-2001 Clause 8.5

Subject	Sample No.	Condition	Walk(%)	Head Side/side(%)	Head Up/down(%)	Talk(%)	Walk(%)	Mean(%)
ZMM	-14	A.R.	2.7	8.1	14.0	10.4	5.7	8.2
YZF	-28	A.R.	5.4	7.8	5.1	10.7	3.6	6.5
LCF	-06	A.R.	4.9	6.9	8.9	8.4	5.9	7.0
NXL	-56	A.R.	4.5	6.2	8.7	4.6	5.9	6.0
SM	-16	A.R.	5.1	7.0	9.8	6.6	5.2	6.7
LZM	-37	T.C.	7.5	10.8	12.7	10.3	7.9	9.8
JLX	-07	T.C.	2.8	9.7	9.5	3.7	2.8	5.7
TS	-46	T.C.	4.0	6.9	10.1	5.2	4.0	6.0
ZH	-18	T.C.	1.5	7.9	8.8	6.5	3.5	5.7
TLX	-31	T.C.	6.3	8.7	15.5	2.6	4.8	7.6
Maximum permitted			**11**					**8**

Table 7.9.1-B Facial dimension

Subject	Face length(mm)	Face width(mm)	Face Depth(mm)	Mouth Width(mm)
ZMM	114	157	119	50
YZF	113	151	106	48
LCF	119	165	121	56
NXL	113	147	108	53
SM	116	144	109	49
LZM	118	157	124	44
JLX	119	152	109	59
TS	97	146	102	51
ZH	102	152	113	55
TLX	104	153	112	40

7.9.2 **Penetration of filter material^** **PASS**

The penetration of the filter of the particle filtering half mask shall meet the requirements:

Classification	Sodium chloride test 95 l/min	Paraffin oil test 95 l/min
FFP 1	⩽ 20%	⩽ 20%
FFP 2	⩽ 6%	⩽ 6%
FFP 3	⩽ 1%	⩽ 1%

Table 7.9.2- Penetration of filter material

Test specification: EN149-2001 Clause 8.11

Aerosol	Condition	Sample No.	Penetration (%)		Assessment
			After 3 minutes	Max. during exposure	
Sodium chloride test	A.R.	-15	0.43		**PASS**
		-70	2.10		
		-48	0.47		
	S.W.	-55	0.62		
		-24	0.43		
		-57	1.16		
	M.S. + T.C.	-71	0.48	0.49	
		-39	1.30	1.30	
		-74	1.24	1.24	
Paraffin oil test	A.R.	-23	1.22		
		-63	0.57		
		-47	1.30		
	S.W.	-59	0.77		
		-29	0.83		
		-61	0.94		
	M.S. + T.C.	-49	1.18	1.73	
		-67	0.91	1.35	
		-38	1.27	2.08	
Maximum permitted		**6**			
Flow conditioning: Single filter: 95.0 L/min					

7.10 **Compatibility with skin^** **PASS** [6]

Materials that may come into contact with the wearer's skin shall not be known to be likely to cause irritation or any other adverse effect to health.

Note 6: Specimens -04, -51, -64, -35, -75(A.R.) and specimens -20, -53, -05, -73, -42(T.C.) were tested. No irritation or any other adverse effect to health.

7.11 **Flammability^** **PASS**

When tested, the particle filtering half mask shall not burn or not to continue to burn for more than 5 s after removal from the flame.

Table 7.11- Flammability

Test specification: EN149-2001 Clause 8.6

Condition	Sample No.	Result	Assessment
A.R.	-34	Burn for 0.8 s	PASS
	-11	Burn for 0.7 s	
T.C.	-43	Burn for 0.4 s	
	-41	Burn for 0.5 s	

7.12 **Carbon dioxide content of the inhalation air^** **PASS**

The carbon dioxide content of the inhalation air (dead space) shall not exceed an average of 1,0 % (by volume).

Table 7.12- Carbon dioxide content of the inhalation air

Test specification: EN149-2001 Clause 8.7

Condition	Sample No.	Result	Assessment
A.R.	-17	0.34%	PASS
	-52	0.34%	
	-65	0.36%	
Maximum permitted		1.0%	

7.13 **Head harness^** **PASS** [7]

The head harness shall be designed so that the particle filtering half mask can be donned and removed easily.

The head harness shall be adjustable or self-adjusting and shall be sufficiently robust to hold the particle filtering half mask firmly in position and be capable of maintaining total inward leakage requirements for the device.

Note 7: Specimens -45, -32, -08, -68, -66(A.R.) and specimens -12, -44, -36, -54, -22 (T.C.) were tested. Head harness can be donned and removed easily, adjustable or self-adjusting and have sufficiently robust to hold the face mask firmly. The product satisfied the total inward leakage requirements. See 7.9.1 for results.

7.14 **Field of vision^** **PASS** [8]

The field of vision is acceptable if determined so in practical performance tests.

Note 8: Specimens -09 and -25(A.R.) were tested. Pass the practical performance tests and no adverse comments.

7.15 **Exhalation valve^** **NAp**

A particle filtering half mask may have one or more exhalation valve(s), which shall function correctly in all orientations.

If an exhalation valve is provided it shall be protected against or be resistant to dirt and mechanical damage and may be shrouded or may include any other device that may be necessary for the particle filtering half mask to comply with 7.9.

Exhalation valve(s), if fitted, shall continue to operate correctly after a continuous exhalation flow of 300 l/min over a period of 30 s.

When the exhalation valve housing is attached to the faceblank, it shall withstand axially a tensile force of 10 N applied for 10 s.

7.16 **Breathing resistance^** **PASS [9]**

Classification	Maximum permitted resistance (mbar)		
	inhalation		exhalation
	30 l/min	95 l/min	160 l/min or (25 cycles/min x 2.0 l/stroke)
FFP1	0,6	2,1	3,0
FFP2	0,7	2,4	3,0
FFP3	1,0	3,0	3,0

Note 9: FFP2 Filtering face mask. Test results are detailed below.

Table 7.16 Breathing resistance (mbar)

Test specification: EN149-2001 Clause 8.9

Specimen	Condition	Inhalation resistance(mbar)		Exhalation resistance(mbar)				
		At 30 l/min	At 95 l/min	Breathing machine(25 cycles/min x 2.0 l/stroke)				
				A	B	C	D	E
-03	A.R.	0.24	0.95	2.12	2.08	2.04	2.03	2.09
-13		0.27	1.04	2.37	2.29	2.31	2.34	2.35
-62		0.24	0.93	2.09	2.07	2.01	2.04	2.05
-72	T.C.	0.24	0.92	2.06	2.12	2.09	2.06	2.09
-19		0.25	0.97	2.11	2.08	2.04	2.03	2.07
-50		0.23	0.91	2.01	2.07	2.05	1.98	2.06
-33	S.W.	0.28	1.07	2.34	2.39	2.33	2.31	2.35
-76		0.25	0.95	2.12	2.16	2.11	2.09	2.14
-30		0.27	1.01	2.28	2.24	2.21	2.29	2.26
	A.R. + F.C.							
	T.C. + F.C.							
Maximum permitted		0.7	2.4	3.0				

A: facing directly ahead; B: facing vertically upwards; C: facing vertically downwards; D: lying on the left side; E: lying on the right side.

7.17 **Clogging^** **NRq** [10]

7.17.2 **Breathing resistance**

Valved particle filtering half masks:
After clogging, the inhalation resistances shall not exceed,
FFP1: 4 mbar, FFP2: 5 mbar, FFP3: 7 mbar at 95 l/min continuous flow;
The exhalation resistance shall not exceed 3 mbar at 160 l/min continuous flow.

Valveless particle filtering half masks:
After clogging the inhalation and exhalation resistances shall not exceed:
FFP1: 3 mbar, FFP2: 4 mbar, FFP3: 5 mbar at 95 l/min continuous flow.

7.17.3 **Penetration of filter material**

Classification	Sodium chloride test 95 l/min	Paraffin oil test 95 l/min
FFP 1	⩽ 20%	⩽ 20%
FFP 2	⩽ 6%	⩽ 6%
FFP 3	⩽ 1%	⩽ 1%

Note 10: Single shift use only.

7.18 **Demountable parts^** **NAp** [11]

All demountable parts (if fitted) shall be readily connected and secured, where possible by hand.

Note 11: No demountable parts were used.

9 **Marking^** **NRq**

9.1 **Packaging**

The following information shall be clearly and durably marked on the smallest commercially available packaging or legible through it if the packaging is transparent.

9.1.1 The name, trademark or other means of identification of the manufacturer or supplier.

9.1.2 Type-identifying marking.

9.1.3 Classification

The appropriate class (FFP1, FFP2 or FFP3) followed by a single space and then: "NR" if the particle filtering half mask is limited to single shift use only. Example: FFP3 NR, or "R" if the particle filtering half mask is re-usable. Example: FFP2 R D.

9.1.4 The number and year of publication of this European Standard.

9.1.5 At least the year of end of shelf life. The end of shelf life may be informed by a pictogram as shown in Figure 12a, where yyyy/mm indicates the year and month.

9.1.6 The sentence 'see information supplied by the manufacturer', at least in the official language(s) of the country of destination, or by using the pictogram as shown in Figure 12b.

9.1.7 The manufacturer's recommended conditions of storage (at least the temperature and humidity) or equivalent pictogram, as shown in Figures 12c and 12d.

9.1.8 The packaging of those particle filtering half masks passing the dolomite clogging test shall be additionally marked with the letter "D". ID This letter shall follow the classification marking preceded by a single space.

9.2 **Particle filtering half mask^**

Particle filtering half masks complying with this European Standard shall be clearly and durably marked with the following:

9.2.1 The name, trademark or other means of identification of the manufacturer or supplier.

9.2.2 Type-identifying marking.

9.2.3 The number and year of publication of this European Standard.

9.2.4 Classification

The appropriate class (FFP1, FFP2 or FFP3) followed by a single space and then: "NR" if the particle filtering half mask is limited to single shift use only. Example: FFP3 NR, or "R" if the particle filtering half mask is re-usable. Example: FFP2 R D.

9.2.5 If appropriate the letter D (dolomite) in accordance with clogging performance. This letter shall follow the classification marking preceded by a single space(see 9.2.4).

Examples FFP3 NR D, FFP2 R D

9.2.6 Sub-assemblies and components with considerable bearing on safety shall be marked so that they can be identified.

10 Information to be supplied by the manufacturer^ **NRq**

10.1 Information supplied by the manufacturer shall accompany every smallest commercial available package.

10.2 Information supplied by the manufacturer shall be at least in the official language(s) of the country of destination.

10.3 The information supplied by the manufacturer shall contain all information necessary for trained and qualified persons on

application/limitations; the meaning of any colour coding; checks prior to use; donning fitting; use; maintenance(e.g. cleaning, disinfecting), if applicable; storage; the meaning of any symbols/pictograms used of the equipment.

10.4 The information shall be clear and comprehensible. If helpful, illustrations, part numbers, marking shall be added.

10.5 Warning shall be given against problems likely to be encountered, for example:

- fit of particle filtering half mask (check prior to use);
- it is unlikely that the requirements for leakage will be achieved if facial hair passes under the face seal;
- air quality (contaminants, oxygen deficiency);
- use of equipment in explosive atmosphere.

10.6 The information shall provide recommendations as to when the particle filtering half mask shall be discarded.

10.7 For devices marked "NR", a warning shall be given that the particle filtering half mask shall not be used for more than one shift.

Remark: "^" indicates that the test is sub-contracted to the lab China Academy of Safey Science and Technology which complies with the requirement of ISO/IEC 17025:2017, the registration No. CNAS L0118.

Photo:

- END -

CMA 161019130764

ilac-MRA CNAS 中国认可 国际互认 检测 TESTING CNAS L10118

国检检测 CHINA COMPONENTS TEST

Test Report

（2020） WSZ FHL NO.W0614

Product Name Orphila P2195

Client Qingdao Orphila Medical Technology Co.,Limited

Manufacturer Qingdao Orphila Medical Technology Co.,Limited

Test Type Entrusted inspection

Jiangsu Guojian Testing Technology Co., Ltd.

江苏国健检测技术有限公司 检验专用章

Test Report

[2020] WSZ FHL NO.W0614

Product name	Orphila P2195	Specification	OM-KP95-P2
		Brand	—
Client/Add/Tel	Qingdao Orphila Medical Technology Co.,Limited / ROOM 501 BUILDNG 1 NO 18. HONG KONG MIDDLE ROAD, SHINAN DISTRICT, QINGDAO SHANDONG, CHINA/—		
Manufacturer/ Add/Tel	Qingdao Orphila Medical Technology Co.,Limited / ROOM 501 BUILDNG 1 NO 18. HONG KONG MIDDLE ROAD, SHINAN DISTRICT, QINGDAO SHANDONG, CHINA/—		
Sample grade	FFP2	Sample number	GWW0614-2020
Sample quantity	110 pcs	Receiving date of sample	14/05/2020
Test type	Entrusted inspection	Article number/Batch number/Style number	—
Test date	14/05/2020~22/05/2020	Testing sites	Testing room
Sample state	Meeting the requirements of testing	Sample description	—
Test standard(s)	EN 149:2001+A1:2009 Respiratory protective devices-Filtering half masks to protect against particles- Requirements,testing, marking		
Test items	Visual inspection, practical performance, finish of parts, compatibility with skin, flammability, carbon dioxide content of the inhalation air, material, head harness, field of vision, penetration of filter material, breathing resistance, total inward leakage		
Test conclusion	The sample upon testing, the test items meet the requirements of the EN 149:2001+A1:2009 standard. The detail of test results see on Pages 2-5. Issue date: 27/05/2020		
Note	For the entrusted sample test, the technical responsibilities are undertaken for the test results of the supplied samples only.		

江苏国健检测技术有限公司 检验专用章

Approver: Reviewer: Chief Tester:

Test Report

S.No.	Test item		Unit	Technical requirements	Test result		Single item decision
1	Visual inspection	Packaging	—	Particle filtering half masks shall be offered for sale packaged in such a way that they are protected against mechanical damage and contamination before use.	Packaging withstands mechanical damage and contamination.		Qualified
		Material	—	Materials used shall be suitable to withstand handling and wear over the period for which the particle filtering half mask is designed to be used.	Materials withstand handling and wear.		
2	Practical performance	Head harness comfort	—	Head harness should be comfort.	Sample 1 has the feeling of comfortable wearing		Qualified
					Sample 2 has the feeling of comfortable wearing		
		Security of fastenings	—	Fastenings are safe and reliable	Sample 1: All fastenings are firm.		
					Sample 2: All fastenings are firm		
		Field of vision	—	Field of vision is acceptable	Sample 1: Having a wider visual field		
					Sample 2: Having a wider visual field		
3	Finish of parts		—	Parts of the device likely to come into contact with the wearer shall have no sharp edges or burrs.	Parts of the device have no sharp edges and burrs		Qualified
4	Compatibility with skin		—	Materials that may come into contact with the wearer's skin shall not be known to be likely to cause irritation or any other adverse effect to health.	A.R.	5 pcs all don't cause irritation	Qualified
					T.C.	5 pcs all don't cause irritation	
5	Flammability		—	When tested,the particle filtering half mask shall not burn or not to continue to burn for more than 5s after removal from the flame.	A.R.	The Sample is burning. Burning time:0.1s	Qualified
						The Sample is burning. Burning time:0.1s	
					T.C.	The Sample is burning. Burning time:0.1s	
						The Sample is burning. Burning time:0.1s	

Test Report

S.No.	Test item		Unit	Technical requirements	Test result				Single item decision
6	Carbon dioxide content of the inhalation air		—	≤1.0% (by volume)	Sample 1	0.6300%			Qualified
					Sample 2	0.6310%			
					Sample 3	0.6320%			
					Average value	0.63%			
7	Material		—	After undergoing S.W., none of the particle filtering half masks shall have suffered mechanical failure of the facepiece or straps.	Sample 1: neither facepiece nor straps have mechanical failure				Qualified
					Sample 2: neither facepiece nor straps have mechanical failure				
					Sample 3: neither facepiece nor straps have mechanical failure				
				After undergoing S.W. and T.C. , none of the particle filtering half masks shall not collapse.	Sample 1: no collapse				
					Sample 2 : no collapse				
					Sample 3: no collapse				
8	Head harness		—	The head harness shall be designed so that the particle filtering half mask can be donned and removed easily The head harness shall be adjustable or self-adjusting and shall be sufficiently robust to hold the particle filtering half mask firmly in position	A.R.	All of 5 pieces particle filtering half mask meet the requirements			Qualified
					T.C.	All of 5 pieces particle filtering half mask meet the requirements			
9	Field of vision		—	The field of vision is acceptable if determined so in practical performance tests.	The two samples both have a wider visual field				Qualified
10	Penetration of filter material	Sodium chloride	—	≤6%	A.R.	0.4%	0.5%	0.5%	Qualified
					S.W.	0.5%	0.6%	0.5%	
					M.S+T.C.	0.8%	0.7%	0.7%	
		Paraffin oil	—	≤6%	A.R.	2.7%	2.6%	2.7%	Qualified
					S.W.	2.5%	2.6%	2.7%	
					M.S+T.C.	5.9%	5.9%	5.9%	

Test Report

S.No.	Test item		Unit	Technical requirements	Test result						Single item decision
					Exercises	Facing directly ahead	Facing vertically upwards	Facing vertically downwards	Lying on the left side	Lying on the right side	
11	Breathing resistance	Inhalation 30 L/min	mbar	≤0.7	A.R.	0.4	0.4	0.5	0.4	0.4	Qualified
						0.4	0.4	0.5	0.4	0.4	
						0.4	0.4	0.5	0.4	0.4	
					S.W.	0.4	0.4	0.4	0.4	0.4	
						0.4	0.4	0.4	0.4	0.5	
						0.5	0.4	0.4	0.4	0.4	
					T.C.	0.4	0.4	0.4	0.5	0.5	
						0.4	0.4	0.5	0.4	0.4	
						0.4	0.4	0.5	0.4	0.4	
		Inhalation 95 L/min		≤2.4	A.R.	1.3	1.3	1.4	1.3	1.3	Qualified
						1.3	1.3	1.3	1.4	1.3	
						1.3	1.3	1.2	1.3	1.3	
					S.W.	1.3	1.3	1.2	1.2	1.3	
						1.3	1.3	1.2	1.3	1.3	
						1.3	1.2	1.3	1.3	1.3	
					T.C.	1.3	1.2	1.2	1.2	1.3	
						1.3	1.3	1.3	1.2	1.2	
						1.2	1.2	1.3	1.3	1.3	
		Exhalation 160 L/min		≤3.0	A.R.	1.8	1.9	1.9	1.9	1.9	Qualified
						1.9	1.9	1.9	1.9	1.9	
						1.9	2.0	1.9	2.0	2.0	
					S.W.	1.9	1.9	1.8	1.8	1.8	
						1.8	1.9	1.9	1.9	1.9	
						1.9	1.9	1.8	1.8	1.8	
					T.C.	1.8	1.8	1.9	1.9	1.9	
						1.9	1.9	1.8	1.8	1.8	
						1.8	1.9	1.9	1.9	1.9	

Test Report

S.No.	Test item	Unit	Technical requirements	Test result								Single item decision
				Exercises		E1 (%)	E2 (%)	E3 (%)	E4 (%)	E5 (%)	TIL (%)	
12	Total inward leakage	—	At least 46 out of the 50 individual exercise results shall be not greater than 11%; And in addition,at least 8 out of the 10 individual wearer arithmetic means for the total inward leakage shall be not greater than 8%.	A.R.	1#	6.3	6.7	7.0	6.8	6.3	6.6	Qualified
					2#	6.2	7.0	7.1	7.1	6.4	6.8	
					3#	6.1	7.1	7.4	7.2	6.6	6.9	
					4#	6.2	6.8	6.7	6.9	6.2	6.6	
					5#	6.2	7.0	7.1	7.0	6.3	6.7	
				T.C.	6#	6.6	7.2	7.4	7.1	6.6	7.0	
					7#	6.0	6.4	6.4	6.6	6.0	6.3	
					8#	5.8	6.4	6.8	6.6	6.0	6.3	
					9#	6.3	6.7	6.8	6.9	6.4	6.6	
					10#	6.8	7.4	7.4	7.7	7.0	7.3	
Note												

The end

Products

TÜVRheinland®
Precisely Right.

Report No.: 178141074a 001

Client: **QINGDAO ORPHILA MEDICAL TECHNOLOGY CO.,LIMITED**

Contact Information: Rm0501, Futai Square No.18 Hongkong Middle road, Qingdao, Shangdong, China

Identification/ Model No(s): OM-KN95-FFP2, OM-P2295, OM-P3299, OM-P31100, OM-CPA-FFP2-1860, OM-CPA-FFP3-8210, OM-P31100A, OM-P2295A, OM-P3299A, OM-P2295B, OM-P3299B, OM-P2295BA, OM-P3299BA, OM-P2295D, OM-P3299D, OM-P2195, OM-P3399A, OM-N99-FFP3, OM-N99D-FFP3

Sample obtaining method: Sending by customer

Sample Receiving date: 2020-06-09

Testing Period: 2020-06-09 - 2020-06-16

Test Specification:	*Test result:*
1. Total Lead and Cadmium	PASS
2. Organotin compounds content	PASS
3. Polybrominated biphenyls (PBB)	PASS
4. Phthalates content	PASS
5. NP and NPEO content - according to REACH regulation (EC) No. 1907/2006 Annex XVII Entry 46 and 46a and amendments	PASS
6. Perfluorooctanoic acid (PFOA) and its salts	PASS
7. Screening of substances of very high concern (SVHC) subject to authorisation, according to (EU) No 143/2011, (EU) No 125/2012, (EU) No 348/2013 ,(EU) No 895/2014, (EU) No. 2017/999 and (EU) No. 2020/171 (Annex XIV of EC No 1907/2006) and candidate list by European Chemical Agency (ECHA), according to the EU Court of Justice rules on SVHCs in articles (Guidance on requirements for substances in articles, June 2017)	Please refer to page 12 - 13

Other information:

Lot No./ Batch code: 202006
Manufacturer: Qingdao Orphila Medical Technology Co., Limited. West Coast Branch
Address: Plant 20, No.252 Weihe Road, Huangdao District, Qingdao, Shandong, China

For and on behalf of
TÜV Rheinland/CCIC (Qingdao) Co., Ltd.

Alex zhou

2020-06-17 Alex Zhou / Senior Manager

Date *Name/Position*

Sample information is provided by customer. Test result is drawn according to the kind and extent of tests performed. This test report relates to the above mentioned test sample. Without permission of the test center this test report is not permitted to be duplicated in extracts. This test report does not entitle to carry any safety mark on this or similar products.

Material List:

Item: OM-KN95-FFP2, OM-P2295, OM-P3299, OM-P31100, OM-CPA-FFP2-1860, OM-CPA-FFP3-8210, OM-P31100A, OM-P2295A, OM-P3299A, OM-P2295B, OM-P3299B, OM-P2295BA, OM-P3299BA, OM-P2295D, OM-P3299D, OM-P2195, OM-P3399A, OM-N99-FFP3, OM-N99D-FFP3

Material No.	Material	Color	Location
A001	Metal	-	Silver metal wire
A002	Plastic	-	White plastic strip
A003	Plastic	-	White plastic breath valve
A004	Plastic	-	Yellow plastic breath valve
A005	Foam	-	White foam
A006	Plastic + Textile	-	White elastic cord
A007	Fabric	-	White outside leak proof non-woven fabric
A008	Fabric	-	White inner non-woven fabric
A009	Fabric	-	White direct contact layer
A010	Fabric	-	White high density filter layer
A011	Fabric	-	White high density filter layer(A)
A012	Fabric	-	White high density filter layer(B)

1.Total Lead and Cadmium

Test Method: Acid digestion, analyzed by ICP-OES

Test result:

Test No.	Material No.	Test Parameter	Unit	RL	Regulatory Requirement	Test Result	Conclusion
T001	A001	Lead	mg/kg	10	500	22	PASS
		Cadmium	mg/kg	10	100	< RL	
T002	A002 + A003 + A004	Lead	mg/kg	10	500	< RL	PASS
		Cadmium	mg/kg	10	100	< RL	
T003	A005 + A006	Lead	mg/kg	10	500	< RL	PASS
		Cadmium	mg/kg	10	100	< RL	
T004	A007 + A008 + A009	Lead	mg/kg	10	500	< RL	PASS
		Cadmium	mg/kg	10	100	< RL	
T005	A010 + A011 + A012	Lead	mg/kg	10	500	< RL	PASS
		Cadmium	mg/kg	10	100	< RL	

Abbreviation: < = less than
RL = Reporting Limit
mg/kg = milligram per kilogram
1% = 10000 mg/kg

Remark:

* Regulations on Cadmium

		Maximum Permissible Limit				
Country	**Legislation**	**Plastic materials**	**Paint (wet state)**	**Paint on the painted articles**	**Paint (high zinc content)**	**Metal parts of jewellery and imitation jewellery articles and hair assessories**
EC	REACH regulation (EC) No. 1907/2006 Annex XVII Entry 23 and its amendments	100mg/kg	100mg/kg	1000mg/kg	1000mg/kg	100mg/kg

		Maximum Permissible Limit
Country	**Legislation**	**Paint, plastic, plating/ coating of surface treatment**
Switzerland	Switzerland Chemikalien-Risikoreduktions-Verordnung-ChemRRV, 814.81, 18 May 2005	100mg/kg

* Regulations on Lead:

		Maximum Permissible Limit
Country	**Legislation**	**Substances or mixtures intended to use as paint**
EU	Paragraph 1-6 of Entry 63 of Annex XVII, REACH Regulation (EC) No. 1907/2006	For Jewellery, imitation jewellery, hair accessories, bracelets, necklaces , rings, piercing jewellery, wrist watches, wrist-wear, brooches and cufflinks and parts used for jewellery-making 0.05% (by weight of the individual part)

2.Organotin compounds content

Test Method: Organic solvent extraction, GCMS
Ref. to ISO/TS 16179:2012

			Test No.	T001	T002
			Material No.	A006	A007 + A008 + A009
Test Parameter	Unit	RL	Regulatory Requirement	Result	Result
TBT(Tributyltin) by weight of tin	%	0.01	--	< RL	< RL
TPT(Triphenyltin) by weight of tin	%	0.01	--	< RL	< RL
TOT(Trioctyltin) by weight of tin	%	0.01	--	< RL	< RL
TCyT(Tricyclohexyltin) by weight of tin	%	0.01	--	< RL	< RL
TPrT(Tripropyltin) by weight of tin	%	0.01	--	< RL	< RL
Sum of Tin of tri-substituted organotins	%	NA	0.1	<RL	<RL
DBT(Dibutyltin) by weight of tin	%	0.01	0.1	< RL	< RL
DOT(Dioctyltin) by weight of tin	%	0.01	0.1	< RL	< RL
Conclusion	--	--		PASS	PASS

Abbreviation: < = less than
RL = Reporting Limit
% = percentage
NA = Not Applicable

Remark:

* Single components with an amount of <0.01% were not considered in the calculation of the sum. In the case of all five tri-substituted orgaotins were not detected, the result is stated < RL

** The assessment for tri-substituted organotins is based on the sum of TBT, TPT, TOT, TCyT and TPrT by weight of tin only.

*** According to REACH Regulation (EC) No. 1907/2006 Annex XVII Entry 20 and amendment Commission Regulation (EU) No. 276/2010 (formerly known as 2009/425/EC), organostannic compounds shall not be used or be placed on the market.

Type of organostannic compounds	Maximum Permissible Limit	Implementation date
Tri-substituted organostannic compounds, e.g. tributyltin (TBT) compounds and triphenyltin (TPT) compounds	0.1 % by weight of tin	1 July 2010
Dibutyltin (DBT) compounds in mixtures and articles for supply to the general public	0.1 % by weight of tin	1 January 2012 The below products will not be applicable until 1 January 2015: - one-component and two-component room temperature vulcanisation sealants (RTV-1 and RTV-2 sealants) and adhesives, - paints and coatings containing DBT compounds as catalysts when applied on articles, - soft polyvinyl chloride (PVC) profiles whether by themselves or coextruded with hard PVC, - fabrics coated with PVC containing DBT compounds as stabilisers when intended for outdoor applications, - outdoor rainwater pipes, gutters and fittings, as well as covering material for roofing and facades
Dioctyltin (DOT) compounds - textile articles intended to come into contact with the skin, - gloves, - footwear or part of footwear intended to come into contact with the skin, - wall and floor coverings - childcare articles, - female hygiene products, - nappies, - two-component room temperature vulcanisation moulding kits (RTV-2 moulding kits)	0.1 % by weight of tin	1 January 2012

3. Polybrominated biphenyls (PBB)

Test method : Ref. to IEC 62321-6:2015

Test result:

Test No.	Material No.	Test Parameter	Unit	Regulatory requirement	Test Result	Conclusion
T001	A006	Polybrominated biphenyls (PBBs)	%	0.1	< RL	PASS
T002	A007 + A008 + A09	Polybrominated biphenyls (PBBs)	%	0.1	< RL	PASS

Abbreviation: < = Less than
RL = Reporting Limit
% = percentage

Remark:

(*) The reporting limit for each individual PBBs are :

Reporting Limit (%)		
PBBs	Bromobiphenyl	0.0005
	Dibromobiphenyl	0.0005
	Tribromobiphenyl	0.0005
	Tetrabromobiphenyl	0.0005
	Pentabromobiphenyl	0.0005
	Hexabromobiphenyl	0.0005
	Heptabromobiphenly	0.0005
	Octabromobiphenyl	0.0005
	Nonabromobiphenyl	0.0005
	Decabromobiphenyl	0.0005

4. Phthalates content

Test Method : Ref. to CPSC-CH-C1001-09.4

Test Result:

				Test No.	T001	T002
				Material No.:	A002 + A003 + A004	A005
Test Parameter	CAS No.	Unit	RL	Regulatory Requirement	Result	Result
Diethylhexyl phthalate (DEHP)	117-81-7	%	0.005	0.1	< RL	< RL
Dibutyl phthalate (DBP)	84-74-2	%	0.005	0.1	< RL	< RL
Benzylbutyl phthalate (BBP)	85-68-7	%	0.005	0.1	< RL	< RL
Diisobutyl phthalate (DIBP)	84-69-5	%	0.005	0.1	< RL	< RL
Sum (DEHP+DBP+BBP+DIBP)	--	%	0.005	0.1	< RL	< RL
Conclusion: REACH regulation (EC) No. 1907/2006 and its amendment regulations on Annex XVII entries 51				-	Pass	Pass

Abbreviation: < = Less than
RL = Reporting Limit
% = percentage

Remark:

- Requirement of REACH regulation (EC) No. 1907/2006 and its amendment regulations on Annex XVII entries 51:

Parameter	Unit	Maximum Permissible Limit
Plasticised materials in toys and childcare articles, or other articles# place on the market;		
Diethylhexyl phthalate (DEHP) Dibutyl phthalate (DBP) Benzylbutyl phthalate (BBP) Diisobutyl phthalate (DIBP)	%	0.1 (individually or sum of the four phthalates) Effective after 7 July 2020.

Denote:
Examples of articles that are excluded from the restriction

1) Articles exclusively for industrial / agricultural use / use in open air, provided that no plasticised material comes into contact with human mucous membranes or into prolonged contact with human skin (i.e. Continuous contact of more than 10 minutes duration or intermittent contact over a period of 30 minutes, per day.)
2) Aircraft and motor vehicles (Directive 2007/46/EC) placed on the market before 7 January 2024, or articles for use exclusively in the maintenance or repair of them
3) Measuring devices for laboratory use;
4) Food contact material and articles within the scope of Regulation (EC) No 1935/2004 or Commission Regulation (EU) No 10/2011
5) Medical devices (Directive 90/385/EEC, 93/42/EEC or 98/79/EC)
6) Electrical and electronic equipment within the scope of Directive 2011/65/EU

Immediate packaging of medicinal products (Regulation (EC) No 726/2004, Directive 2001/82/EC or Directive 2001/83/EC)

5.Nonylphenol, Nonylphenolethoxylates

Test Method: NP:
For Plastics- Organic solvent extraction, GCMS
For Textiles- Organic solvent extraction, LC-MS

NPEO:
Organic solvent extraction, LC-MS

Test Result:

Test No.	Material No.	Test Parameter	Unit	RL	Test Result
T001	A006	Nonylphenol (NP)	mg/kg	5	< RL
		Nonylphenolethoxylates (NPEO)	mg/kg	20	< RL
T002	A007 + A008 + A009	Nonylphenol (NP)	mg/kg	5	< RL
		Nonylphenolethoxylates (NPEO)	mg/kg	20	< RL
T003	A010 + A011 + A012	Nonylphenol (NP)	mg/kg	5	< RL
		Nonylphenolethoxylates (NPEO)	mg/kg	20	< RL

Abbreviation: < = less than
mg/kg = milligram per kilogram
% = percentage
RL = Reporting Limit
NA = Not Applicable
0.1% = 1000mg/kg

Remark:

* The requirement is following REACH regulation (EC) No. 1907/2006 and amendment no. 552/2009 Annex XVII Entry 46:

Nonylphenol and nonylphenol ethoxylates shall not be placed on the market, or used, as substances or in mixtures in concentrations equal to or greater than 0,1 % by weight for the following purposes:
(1) Industrial and institutional cleaning;
(2) Domestic cleaning;
(3) Textiles and leather processing;
(4) Emulsifier in agricultural teat dips;
(5) Metal working;
(6) Manufacturing of pulp and paper;
(7) Cosmetic products;
(8) Other personal care products;
(9) Co-formulants in pesticides and biocides.

** The requirement is following REACH regulation (EC) No. 1907/2006 and amendment no. 552/2009 and (EU) 2016/26 Annex XVII Entry 46a:

Nonylphenol ethoxylates shall not be placed on the market after 3 February 2021 in textile articles which can reasonably be expected to be washed in water during their normal lifecycle, in concentrations equal to or greater than 0,01 % by weight of that textile article or of each part of the textile article.

6.Perfluorooctanoic acid (PFOA) and its salts^

Test Method: In house method, LC-MS-MS / GC-PCIMS analysis

Test Result:

Test No.	Material No	Test Parameter	CAS no.	Unit	RL	Regulatory Requirement	Test Result
T001	A006 + A007	Potassiumperfluorooctanoate (K-PFOA)*	2395-00-8	ppb	10	25	< RL
		Perfluorooctane carboxylate (PFOA)*	335-67-1	ppb			
		Silverperfluorooctanoate (Ag-PFOA)*	335-93-3	ppb			
		Sodiumperfluorooctanoate (Na-PFOA)*	335-95-5	ppb			
		Ammonium pentadecafluorooctanoate (APFO)*	3825-26-1	ppb			

Test No.	Material No	Test Parameter	CAS no.	Unit	RL	Regulatory Requirement	Test Result
T002	A008 + A009	Potassiumperfluorooctanoate (K-PFOA)*	2395-00-8	ppb	10	25	< RL
		Perfluorooctane carboxylate (PFOA)*	335-67-1	ppb			
		Silverperfluorooctanoate (Ag-PFOA)*	335-93-3	ppb			
		Sodiumperfluorooctanoate (Na-PFOA)*	335-95-5	ppb			
		Ammonium pentadecafluorooctanoate (APFO)*	3825-26-1	ppb			

Test No.	Material No	Test Parameter	CAS no.	Unit	RL	Regulatory Requirement	Test Result
T003	A010	Potassiumperfluorooctanoate (K-PFOA)*	2395-00-8	ppb	10	25	< RL
		Perfluorooctane carboxylate (PFOA)*	335-67-1	ppb			
		Silverperfluorooctanoate (Ag-PFOA)*	335-93-3	ppb			
		Sodiumperfluorooctanoate (Na-PFOA)*	335-95-5	ppb			
		Ammonium pentadecafluorooctanoate (APFO)*	3825-26-1	ppb			

Test Report No.: 178141074a 001

Test No.	Material No	Test Parameter	CAS no.	Unit	RL	Regulatory Requirement	Test Result
T004	A011 + A012	Potassiumperfluorooctanoate (K-PFOA)*	2395-00-8	ppb	10	25	< RL
		Perfluorooctane carboxylate (PFOA)*	335-67-1	ppb			
		Silverperfluorooctanoate (Ag-PFOA)*	335-93-3	ppb			
		Sodiumperfluorooctanoate (Na-PFOA)*	335-95-5	ppb			
		Ammonium pentadecafluorooctanoate (APFO)*	3825-26-1	ppb			

Abbreviation: < = less than
RL = Reporting Limit
ppb = Parts per billion

Remark:

* Tested with the equivalence of pentadecafluorooctanoate

** According to REACH regulation (EC) No. 1907/2006 Annex XVII Entry 68 and amendment Commission Regulation (EU) No. 2017/1000. PFOA and its salts shall not be used in a concentration equal to or above 25 ppb or one or a combination of PFOA-related substances shall not be used in a concentration equal to or above 1000ppb in the production of, or placed on the market in another substance, as a constituent; a mixture; an article.

*** Single component with an amount below reporting limit was not considered by the calculation of the sum. In the case of all above substances were not detected, the result is stated < RL

7. Screening of substances of very high concern (SVHC) subject to authorisation, according to (EU) No 143/2011, (EU) No 125/2012, (EU) No 348/2013, (EU) No 895/2014 , (EU) No. 2017/999 and (EU) No. 2020/171 and candidate list by European Chemical Agency (ECHA), according to the EU Court of Justice rules on SVHCs in articles.

Product Classification

With reference to Corrigendum to Regulation (EC) no.1907/2006 and ECHA, this product is classified as:

[X] Article

[ ] Article with an integral substance/ mixture

[ ] Combinations of an article (functioning as a container or a carrier material) and a substance/ mixture

[ ] Substance/ mixture

Conclusion:

Conclusion			
Product Location	Acc. to **authorisation list (EU) No 143/2011, (EU) No 125/2012, (EU) No 348/2013 , (EU) No 895/2014, (EU) No. 2017/999 and (EU) No. 2020/171 (Annex XIV of EC No 1907/2006) and candidate list by ECHA, and the EU Court of Justice rules on SVHCs in articles,** the detected SVHC concentration in components level is	**Obligation of Importer (*) (For article)**	**Detected Substance (if any)**
A001	<0.1%	Not necessary	/
A002 + A003 + A004	<0.1%	Not necessary	/
A005	<0.1%	Not necessary	/
A006 + A007 + A008 + A009 + A010 + A011 + A012	<0.1%	Not necessary	/

(For article)
(*) To communicate information down the supply chain according to article. 33 of REACH. **OR**
1. Notification to ECHA, if the quantities of SVHC in the produced/imported articles are above 1 ton in total per year per company.
2. Provide sufficient information to ensure safe use of the article and, as a minimum, include the name of the substance, to their customers and on request to consumers within 45 days of the receipt of this request.

Test Results

Screening of substances of very high concern (SVHC) subject to authorisation, according to (EU) No 143/2011, (EU) No 125/2012, (EU) No 348/2013, (EU) No 895/2014, (EU) No. 2017/999 and (EU) No. 2020/171 (Annex XIV of EC No 1907/2006) and candidate list by European Chemical Agency (ECHA), according to the EU Court of Justice rules on SVHCs in articles.

Test Method: 1) Test portion is digested with acid and assisted with microwave, the elements are analysed by ICP-OES.
2) Test portion is extracted by organic solvent, semi-quantitative analysis by GC-MS / UV-Vis.
3) Test portion is extracted by organic solvent, the extraction solution is analyzed by Headspace-GC/MS / LC-DAD-MS / LC-MS/MS.

Test No.:	T001	T002	T003
Material No.:	A001	A002 + A003 + A004	A005
Result (%)	< RL	< RL	< RL

Test No.:	T004
Material No.:	A006 + A007 + A008 + A009 + A010 + A011 + A012
Result (%)	< RL

Abbreviation: < = Less than
RL =Reporting Limit
% =Percentage

Remark:

(*1) The reporting limit for each individual SVHC subject to authorisation according to (EU) No 143/2011, (EU) No 125/2012, (EU) No 348/2013, (EU) No 895/2014, (EU) No. 2017/999 and (EU) No. 2020/171 (Annex XIV of EC No 1907/2006):

	Substance	CAS No.	Reporting Limit
1	4,4'- Diaminodiphenylmethane (MDA)	101-77-9	0.01%
2	Benzyl butyl phthalate (BBP)	85-68-7	0.01%
3	Bis (2-ethylhexyl)phthalate (DEHP)	117-81-7	0.01%
4	Dibutyl phthalate (DBP)	84-74-2	0.01%
5	Hexabromocyclododecane (HBCDD) and all major diastereoisomers identified: Alpha-hexabromocyclododecane Beta-hexabromocyclododecane Gamma-hexabromocyclododecane	25637-99-4 / 3194-55-6 / 134237-50-6 / 134237-51-7 / 134237-52-8	0.01%
6	5-tert-butyl-2,4,6-trinitro-m-xylene (Musk xylene)	81-15-2	0.01%
7	2,4-Dinitrotoluene (2,4-DNT)	121-14-2	0.01%
8	Diisobutyl phthalate (DIBP)	84-69-5	0.01%
9	Tris(2-chloroethyl)phosphate	115-96-8	0.01%
10	Diarsenic pentaoxide (*3)	1303-28-2	0.01%
11	Diarsenic trioxide (*3)	1327-53-3	0.01%
12	Lead chromate (*3)(*4)	7758-97-6	0.01%
13	Lead chromate molybdate sulphate red (C.I. Pigment Red 104) (*3)(*4)	12656-85-8	0.01%
14	Lead sulfochromate yellow (C.I. Pigment Yellow 34) (*3)	1344-37-2	0.01%
15	Trichloroethylene	79-01-6	0.01%
16	Chromium trioxide (*4)	1333-82-0	0.01%

17	Acids generated from chromium trioxide and their oligomers: Names of the acids and their oligomers: Chromic acid, Dichromic acid, Oligomers of chromic acid and dichromic acid. (*4)	7738-94-5 / 13530-68-2	0.01%
18	Sodium dichromate (*3)	7789-12-0 / 10588-01-9	0.01%
19	Potassium dichromate (*4)	7778-50-9	0.01%
20	Ammonium dichromate (*4)	7789-09-5	0.01%
21	Potassium chromate (*4)	7789-00-6	0.01%
22	Sodium chromate (*4)	7775-11-3	0.01%
23	Formaldehyde, oligomeric reaction products with aniline (technical MDA) (*11)	25214-70-4	0.01%
24	1,2-Dichloroethane	107-06-2	0.01%
25	Bis(2-methoxyethyl) ether	111-96-6	0.01%
26	Arsenic acid (*3)	7778-39-4	0.01%
27	2,2'-dichloro-4,4'-methylenedianiline (MOCA)	101-14-4	0.01%
28	Dichromium tris(chromate) (*4)	24613-89-6	0.01%
29	Strontium chromate (*4)	7789-06-2	0.01%
30	Potassium hydroxyoctaoxodizincatedichromate (*4)	11103-86-9	0.01%
31	Pentazinc chromate octahydroxide (*4)	49663-84-5	0.01%
32	1-bromopropane (n-propyl bromide)	106-94-5	0.01%
33	Diisopentylphthalate	605-50-5	0.01%
34	1,2-Benzenedicarboxylic acid, di-C6-8-branched alkyl esters, C7-rich (DIHP)	71888-89-6	0.01%
35	1,2-Benzenedicarboxylic acid, di-C7-11-branched and linear alkyl esters (DHNUP)	68515-42-4	0.01%
36	1,2-Benzenedicarboxylic acid, dipentylester, branched and linear	84777-06-0	0.01%
37	Bis(2-methoxyethyl) phthalate	117-82-8	0.01%
38	Dipentyl phthalate (DPP)	131-18-0	0.01%
39	N-pentyl-isopentylphthalate	776297-69-9	0.01%
40	Anthracene oil (*7)	90640-80-5	0.01%
41	Pitch, coal tar, high temperature (*7)	65996-93-2	0.01%
42	4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated (OPEO) *[covering well-defined substances and UVCB substances, polymers and homologues]*	-	0.01%
43	4-Nonylphenol, branched and linear *[substances with a linear and/or branched alkyl chain with a carbon number of 9 covalently bound in position 4 to phenol, covering also UVCB- and well-defined substances which include any of the individual isomers or a combination thereof]*	-	0.01%
44	1,2-Benzenedicarboxylic acid, dihexyl ester, branched and linear	68515-50-4	0.01%
45	Dihexyl phthalate	84-75-3	0.01%
46	1,2-benzenedicarboxylic acid, di-C6-10-alkyl esters; 1,2-benzenedicarboxylic acid, mixed decyl and hexyl and octyl diesters with ≥ 0.3% of dihexyl phthalate (EC No. 201-559-5)	68515-51-5 / 68648-93-1	0.01%
47	Trixylyl phosphate	25155-23-1	0.01%
48	Sodium perborate,perboric acid, sodium salt (*3) (*6)	-	0.01%
49	Sodium peroxometaborate (*3) (*6)	7632-04-4	0.01%
50	5-sec-butyl-2-(2,4-dimethylcyclohex-3-en-1-yl)-5-methyl-1,3-dioxane [1], 5-sec-butyl-2-(4,6-dimethylcyclohex-3-en-1-yl)-5-methyl-1,3-dioxane [2] [covering any of the individual stereoisomers of [1] and [2] or any combination thereof]	-	0.01%
51	2-(2H-benzotriazol-2-yl)-4,6-ditertpentylphenol (UV-328)	25973-55-1	0.01%
52	2,4-di-tert-butyl-6-(5-chlorobenzotriazol-2-yl)phenol (UV-327)	3864-99-1	0.01%

53	2-(2H-benzotriazol-2-yl)-4-(tert-butyl)-6-(sec-butyl)phenol (UV-350)	36437-37-3	0.01%
54	2-benzotriazol-2-yl-4,6-di-tert-butylphenol (UV-320)	3846-71-7	0.01%

(*2) The reporting limit for each individual SVHC in Candidate List by ECHA:

	Substance	CAS No.	Reporting Limit
55	Anthracene	120-12-7	0.01%
56	Bis(tributyltin) oxide (TBTO) (*3) (*5)	56-35-9	0.01%
57	Triethyl arsenate (*3)	15606-95-8	0.01%
58	Lead hydrogen arsenate (*3)	7784-40-9	0.01%
59	Cobalt dichloride (*3)	7646-79-9	0.01%
60	Acrylamide	79-06-1	0.01%
61	Anthracene oil, anthracene paste, distn. lights (*7)	91995-17-4	0.01%(*8)
62	Anthracene oil, anthracene paste, anthracene fraction (*7)	91995-15-2	
63	Anthracene oil, anthracene-low (*7)	90640-82-7	
64	Anthracene oil, anthracene paste (*7)	90640-81-6	
65	Boric acid (*3) (*6)	10043-35-3 / 11113-50-1	0.01%
66	Disodium tetraborate, anhydrous (*3) (*6)	1303-96-4 / 1330-43-4 / 12179-04-3	0.01%
67	Tetraboron disodium heptaoxide, hydrate (*3) (*6)	12267-73-1	0.01%
68	2-Methoxyethanol	109-86-4	0.01%
69	2-Ethoxyethanol	110-80-5	0.01%
70	Cobalt(II) sulphate (*3)	10124-43-3	0.01%
71	Cobalt(II) dinitrate (*3)	10141-05-6	0.01%
72	Cobalt(II) carbonate (*3)	513-79-1	0.01%
73	Cobalt(II) diacetate (*3)	71-48-7	0.01%
74	Alkanes C10-C13, chloro (Short Chain Chlorinated Paraffins) (SCCP)	85535-84-8	0.01%
75	2-Ethoxyethyl acetate	111-15-9	0.01%
76	Hydrazine	302-01-2 / 7803-57-8	0.01%
77	1-Methyl-2-pyrrolidone (NMP)	872-50-4	0.01%
78	1,2,3-Trichloropropane	96-18-4	0.01%
79	Aluminosilicate Refractory Ceramic Fibres (RCF) (*9)	-	0.01%
80	Zirconia Aluminosilicate Refractory Ceramic Fibres (Zr-RCF) (*9)	-	0.01%
81	2-Methoxyaniline,o-Anisidine	90-04-0	0.01%
82	4-(1,1,3,3-tetramethylbutyl)phenol	140-66-9	0.01%
83	Calcium arsenate (*3)	7778-44-1	0.01%
84	Trilead diarsenate (*3)	3687-31-8	0.01%
85	N,N-dimethylacetamide (DMAC)	127-19-5	
86	Phenolphthalein	77-09-8	0.01%
87	Lead dipicrate (*3)	6477-64-1	0.01%
88	Lead diazide, Lead azide (*3)	13424-46-9	0.01%
89	Lead styphnate (*3)	15245-44-0	0.01%

90	1,2-bis(2-methoxyethoxy)ethane (TEGDME,triglyme)	112-49-2	0.01%
91	1,2-dimethoxyethane,ethylene glycol dimethyl ether (EGDME)	110-71-4	0.01%
92	Diboron trioxide (*3) (*6)	1303-86-2	0.01%
93	Formamide	75-12-7	0.01%
94	Lead(II) bis(methanesulfonate) (*3)	17570-76-2	0.01%
95	1,3,5-Tris(oxiran-2-ylmethyl)-1,3,5-triazinane-2,4,6-trione (TGIC)	2451-62-9	0.01%
96	1,3,5-tris[(2S and 2R)-2,3-epoxypropyl]-1,3,5-triazine-2,4,6-(1H,3H,5H)-trione (β-TGIC)	59653-74-6	0.01%
97	4,4'-bis(dimethylamino)benzophenone (Michler's ketone), MK	90-94-8	0.05%
98	N,N,N',N'-tetramethyl-4,4'-methylenedianiline (Michler's base), RMK	101-61-1	0.01%
99	[4-[[4-anilino-1-naphthyl][4-(dimethylamino)phenyl]methylene] cyclohexa-2,5-dien-1-ylidene] dimethylammonium chloride (C.I. Basic Blue 26) [with ≥ 0.1% of Michler's ketone (EC No. 202-027-5) or Michler's base (EC No. 202-959-2)] (*10)	2580-56-5	0.01%
100	[4-[4,4'-bis(dimethylamino) benzhydrylidene]cyclohexa-2,5-dien-1-ylidene] dimethylammonium chloride (C.I. Basic Violet 3) [with ≥ 0.1% of Michler's ketone (EC No. 202-027-5) or Michler's base (EC No. 202-959-2)] (*10)	548-62-9	
101	4,4'-bis(dimethylamino)-4''-(methylamino)trityl alcohol [with ≥ 0.1% of Michler's ketone (EC No. 202-027-5) or Michler's base (EC No. 202-959-2)] (*10)	561-41-1	
102	α,α-Bis[4-(dimethylamino)phenyl]-4 (phenylamino)naphthalene-1-methanol (C.I. Solvent Blue 4) [with ≥ 0.1% of Michler's ketone (EC No. 202-027-5) or Michler's base (EC No. 202-959-2)] (*10)	6786-83-0	
103	Bis(pentabromophenyl) ether (decabromodiphenyl ether) (DecaBDE)	1163-19-5	0.01%
104	Pentacosafluorotridecanoic acid	72629-94-8	0.01%
105	Tricosafluorododecanoic acid	307-55-1	0.01%
106	Henicosafluoroundecanoic acid	2058-94-8	0.01%
107	Heptacosafluorotetradecanoic acid	376-06-7	0.01%
108	Diazene-1,2-dicarboxamide (C,C'-azodi(formamide)) (ADCA) (*12)	123-77-3	0.05%
109	Cyclohexane-1,2-dicarboxylic anhydride [1], cis-cyclohexane-1,2-dicarboxylic anhydride [2], trans-cyclohexane-1,2-dicarboxylic anhydride [3] [The individual cis- [2] and trans- [3] isomer substances and all possible combinations of the cis- and trans-isomers [1] are covered by this entry]	85-42-7 / 13149-00-3 / 14166-21-3	0.01%
110	Hexahydromethylphthalic anhydride (MHHPA) [1], Hexahydro-4-methylphthalic anhydride [2], Hexahydro-1-methylphthalic anhydride [3], Hexahydro-3-methylphthalic anhydride [4] [The individual isomers [2], [3] and [4] (including their cis- and trans- stereo isomeric forms) and all possible combinations of the isomers [1] are covered by this entry]	25550-51-0 / 19438-60-9 / 48122-14-1 / 57110-29-9	0.01%
111	N,N-dimethylformamide	68-12-2	0.01%
112	1,2-Diethoxyethane	629-14-1	0.01%
113	Diethyl sulphate	64-67-5	0.01%

114	Methoxyacetic acid (MAA)	625-45-6	0.01%
115	Dimethyl sulphate	77-78-1	0.01%
116	N-methylacetamide	79-16-3	0.01%
117	Furan	110-00-9	0.01%
118	Methyloxirane (Propylene oxide)	75-56-9	0.01%
119	3-ethyl-2-methyl-2-(3-methylbutyl)-1,3-oxazolidine	143860-04-2	0.01%
120	Dibutyltin dichloride (DBTC) (*3)	683-18-1	0.01%
121	Dinoseb (6-sec-butyl-2,4-dinitrophenol)	88-85-7	0.01%
122	4,4'-methylenedi-o-toluidine	838-88-0	0.01%
123	4,4'-oxydianiline and its salts	101-80-4	0.01%
124	4-Aminoazobenzene	60-09-3	0.01%
125	4-methyl-m-phenylenediamine (toluene-2,4-diamine)	95-80-7	0.01%
126	6-methoxy-m-toluidine (p-cresidine)	120-71-8	0.01%
127	Biphenyl-4-ylamine	92-67-1	0.01%
128	o-aminoazotoluene	97-56-3	0.01%
129	o-Toluidine	95-53-4	0.01%
130	Acetic acid, lead salt, basic (*3)	51404-69-4	0.01%
131	Trilead bis(carbonate) dihydroxide (*3)	1319-46-6	0.01%
132	Lead oxide sulfate (*3)	12036-76-9	0.01%
133	[Phthalato(2-)]dioxotrilead (*3)	69011-06-9	0.01%
134	Dioxobis(stearato)trilead (*3)	12578-12-0	0.01%
135	Fatty acids, C16-18, lead salts (*3)	91031-62-8	0.01%
136	Lead bis(tetrafluoroborate) (*3)	13814-96-5	0.01%
137	Lead cyanamidate (*3)	20837-86-9	0.01%
138	Lead dinitrate (*3)	10099-74-8	0.01%
139	Lead monoxide (lead oxide) (*3)	1317-36-8	0.01%
140	Orange lead (lead tetroxide) (*3)	1314-41-6	0.01%
141	Lead titanium trioxide (*3)	12060-00-3	0.01%
142	Lead titanium zirconium oxide (*3)	12626-81-2	0.01%
143	Pyrochlore, antimony lead yellow (*3)	8012-00-8	0.01%
144	Pentalead tetraoxide sulphate (*3)	12065-90-6	0.01%
145	Silicic acid (H2Si2O5), barium salt (1:1), lead-doped *[with lead (Pb) content above the applicable generic concentration limit for 'toxicity for reproduction' Repr. 1A (CLP) or category 1 (DSD),the substance is a member of the group entry of lead compounds, with index number 082-001-00-6 in Regulation (EC) No 1272/2008]* (*3)	68784-75-8	0.01%
146	Silicic acid, lead salt (*3)	11120-22-2	0.01%
147	Sulfurous acid, lead salt, dibasic (*3)	62229-08-7	0.01%
148	Tetraethyllead (*3)	78-00-2	0.01%
149	Tetralead trioxide sulphate (*3)	12202-17-4	0.01%
150	Trilead dioxide phosphonate (*3)	12141-20-7	0.01%
151	Ammonium pentadecafluorooctanoate (APFO) (*13)	3825-26-1	0.01%
152	Pentadecafluorooctanoic acid (PFOA)	335-67-1	0.01%
153	Cadmium (*3)	7440-43-9	0.01%
154	Cadmium oxide (*3)	1306-19-0	0.01%
155	4-Nonylphenol, branched and linear, ethoxylated (NPEO) [*substances with a linear and/or branched alkyl chain with a carbon number of 9 covalently bound in position 4 to phenol, ethoxylated covering UVCB- and well-defined substances, polymers and homologues, which include any of the individual isomers and/or combinations thereof*]	-	0.01%
156	Imidazolidine-2-thione; (2-imidazoline-2-thiol)	96-45-7	0.01%

157	Disodium 3,3'-[[1,1'-biphenyl]-4,4'-diylbis(azo)]bis(4-aminonaphthalene-1-sulphonate) (C.I. Direct Red 28)	573-58-0	0.01%
158	Disodium 4-amino-3-[[4'-[(2,4-diaminophenyl)azo][1,1'-biphenyl]-4-yl]azo]-5-hydroxy-6-(phenylazo)naphthalene-2,7-disulphonate (C.I. Direct Black 38)	1937-37-7	0.01%
159	Lead di(acetate) (*3)	301-04-2	0.01%
160	Cadmium sulphide (*3)	1306-23-6	0.01%
161	Cadmium chloride (*3)	10108-64-2	0.01%
162	Cadmium fluoride (*3)	7790-79-6	0.01%
163	Cadmium sulphate (*3)	10124-36-4 / 31119-53-6	0.01%
164	2-ethylhexyl 10-ethyl-4,4-dioctyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate (DOTE) (*14)	15571-58-1	0.01%
165	Reaction mass of 2-ethylhexyl 10-ethyl-4,4-dioctyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate and 2-ethylhexyl 10-ethyl-4-[[2-[(2-ethylhexyl)oxy]-2-oxoethyl]thio]-4-octyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate (reaction mass of DOTE and MOTE) (*15)	-	0.01%
166	1,3-propanesultone	1120-71-4	0.01%
167	Nitrobenzene	98-95-3	0.01%
168	Perfluorononan-1-oic-acid and its sodium and ammonium salts	375-95-1 21049-39-8 4149-60-4	0.01%
169	Benzo[def]chrysene (Benzo[a]pyrene)	50-32-8	0.01%
170	4,4'-isopropylidenediphenol (bisphenol A)	80-05-7	0.01%
171	Nonadecafluorodecanoic acid (PFDA) and its sodium and ammonium salts	335-76-2 3830-45-3 3108-42-7	0.01%
172	4-heptylphenol, branched and linear [substances with a linear and/or branched alkyl chain with a carbon number of 7 covalently bound predominantly in position 4 to phenol, covering also UVCB- and well-defined substances which include any of the individual isomers or a combination thereof]	-	0.01%
173	*p*-(1,1-dimethylpropyl)phenol	80-46-6	0.01%
174	Perfluorohexane-1-sulfonic acid and its salts (PFHxS)	-	0.01%
175	Chrysene	218-01-9	0.01%
176	Benzo[a]anthracene	56-55-3	0.01%
177	Cadmium nitrate(*3)	10325-94-7	0.01%
178	Cadmium hydroxide(*3)	21041-95-2	0.01%
179	Cadmium carbonate(*3)	513-78-0	0.01%
180	1,6,7,8,9,14,15,16,17,17,18,18- Dodecachloropentacyclo [12.2.1.16,9.02,13.05,10]octadeca-7,15-diene ("Dechlorane Plus"TM) [covering any of its individual anti- and syn-isomers or any combination thereof]	-	0.01%
181	Reaction products of 1,3,4-thiadiazolidine-2,5-dithione, formaldehyde and 4-heptylphenol, branched and linear (RP-HP) [with ≥0.1% w/w 4-heptylphenol, branched and linear]	-	0.01%
182	Benzene-1,2,4-tricarboxylic acid 1,2 anhydride (trimellitic anhydride, TMA)	552-30-7	0.01%
183	Dicyclohexyl phthalate (DCHP)	84-61-7	0.01%
184	Terphenyl, hydrogenated	61788-32-7	0.01%
185	Octamethylcyclotetrasiloxane (D4)	556-67-2	0.01%
186	Decamethylcyclopentasiloxane (D5)	541-02-6	0.01%
187	Dodecamethylcyclohexasiloxane (D6)	540-97-6	0.01%
188	Ethylenediamine (EDA)	107-15-3	0.01%
189	Lead	7439-92-1	0.01%
190	Disodium octaborate (*3)	12008-41-2	0.01%
191	Benzo[ghi]perylene	191-24-2	0.01%
192	2,2-bis(4'-hydroxyphenyl)-4-methylpentane	6807-17-6	0.01%
193	Benzo[k]fluoranthene	207-08-9	0.01%

194	Fluoranthene	206-44-0	0.01%
195	Phenanthrene	85-01-8	0.01%
196	Pyrene	129-00-0	0.01%
197	1,7,7-trimethyl-3-(phenylmethylene)bicyclo[2.2.1]heptan- 2-one	15087-24-8	0.01%
198	2-methoxyethyl acetate	110-49-6	0.01%
199	Tris(4-nonylphenyl, branched and linear) phosphite (TNPP) with ≥ 0.1% w/w of 4-nonylphenol, branched and linear (4-NP)	-	0.01%
200	2,3,3,3-tetrafluoro-2-(heptafluoropropoxy)propionic acid, its salts and its acyl halides (covering any of their individual isomers and combinations thereof)	-	0.01%
201	4-tert-butylphenol	98-54-4	0.01%
202	Diisohexyl phthalate (DiHexP)	71850-09-4	0.01%
203	2-benzyl-2-dimethylamino-4'-morpholinobutyrophenone	119313-12-1	0.01%
204	2-methyl-1-(4-methylthiophenyl)-2-morpholinopropan-1-one	71868-10-5	0.01%
205	Perfluorobutane sulfonic acid (PFBS) and its salts	-	0.01%

Remark:

(*3) The substances are tested and calculated in terms of its respective elements and to the worst-case scenario.And the elements may come from the compounds other than SVHCs.

(*4) The substances are tested and calculated in terms of Cr (VI).

(*5) The substance is tested and calculated in terms of Tributyl tin.

(*6) The substances are confirmed and tested in terms of borate. Boric acid, Disodium tetraborate, anhydrous, Tetraboron disodium heptaoxide, hydrate and Diboron trioxide, Sodium perborate,perboric acid, sodium salt, Sodium peroxometaborate are detected as sum of boric acid. And the borate may come from the compounds other than SVHCs.

(*7) The substances are UVCB (substance of unknown or variable composition, complex reaction products or biological materials), which are identified by its main constituents.

(*8) Individual concentrations to the constituent of UVCB with an amount of < 0.01% were not considered by the calculation of the sum.

(*9) The test results are based on microscopic and chemical evaluation.

(*10) The substances are quantified in terms of Michler's ketone and Michler's base by LC-MS, as Michler's ketone or Michler's base was found exceeds 0.01%.

(*11) The content oligomer is determined by Py-GC/MS.

(*12) The content of diazene-1,2-dicarboxamide is analyzed in terms of its breakdown product.

(*13) The substance is tested in terms of pentadecafluorooctanoate.

(*14) The substance is tested and calculated in terms of Dioctyl tin.

(*15) The substance is tested and calculated in terms of Monooctyl tin and Dioctyl tin.

Technical Specification Sheet

Particle Filtering Half Mask

OM-P2195

Intended Usage:

This product, which is normally used in the general working environment, is designed to provide reliable respiratory protection of against certain airborne particles and dust, block body fluids and so on.

Product Composition:

- Polypropylene spunbonded non-woven fabric
- Polypropylene melt-blown fabric
- Plastomer+metal nose clip
- Spandex ear-belt
- Nano materials

Attention Before Use:

Please read these instructions thoroughly before use. The mask is non-re-usable particle filtering half mask. This mask is intended exclusively for the personal protection, and it is not medical face mask.

How To Use:

- Wash or disinfect hands before taking out the mask off the package. Avoid touching the inner surface of the mask.
- Hold the mask by the ear straps and get the nose and mouth inside the mask.
- Fix the ear belts around both ears.
- Hold the mask against your chin with the back of one hand.
- Place the fingers of both hands in the middle of the nose clip, while pressing inwards.
- Move the finger tips along the nose clip to both sides, and press the nose clip into the shape of nose bridge completely.
- Do not touch the mask while in use. If so, wash or disinfect your hands.

Instructions to remove and discard the mask:

- To remove the mask, use thumbs and index fingers to remove both ear straps
- Carefully dispose the used mask adequately
- Wash or disinfect hands

ORPHILA™

Technical Specification Sheet

Cautions and Warning:

- Please check the integrity and validity of the package before use. If the package is damaged, don't use it.
- Prior to use, pls. check fit of particle filtering half mask.
- It is unlikely that the requirements for leakage will be achieved if facial hair passes under the face.
- Pls. note air quality (contaminants, oxygen deficiency).
- Do not use it in explosive atmosphere.
- Pls. note that the particle filtering half mask shall not be used for more than one shift.
- This product is disposable. Please treat it according to the local environmental protection requirements after use, and do not discard it at will.

Model:

OM-P2195

Specifications:

10.5cm *16.5 cm (after folding)

Shelf Life:

Three Years after the production date

Symbols:

Shelf Life	Temperature Range of storage conditions	Maximum Relative humidity of storage conditions	See information Supplied by The manufacturer	CE Mark

Qingdao Orphila Medical Technology Co., Ltd.

- **Tel:** +86 400 669 6655
- **Wechat/Whatsapp:** +86 139 6488 0018
- **Email:** info@orphila.com
- **Headquarter Address:** Room 501 Building 1, No.18 Hongkong Middle Road, Shinan District, Qingdao, China
- **Manufacture Address:** Plant 20, No. 252 Weihe Road, Huangdao District, Qingdao, China

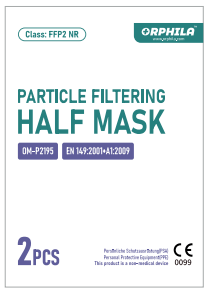
ORPHILA™

ORPHILA™

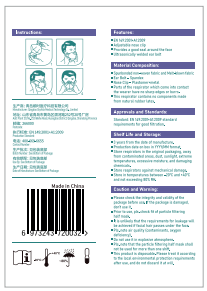
Packaging of OM-P2195

2pcs/bag*25

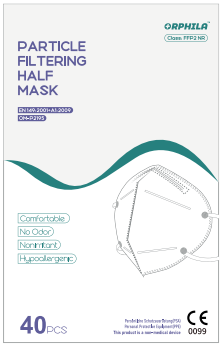
Package Details	Box Details		Carton Details		
2pcs/bag, 20 bag in a box, 40 box per carton	143*143*225mm	G.W 0.42kgs	780*650*505mm	1600 pcs	G.W 20.08kgs



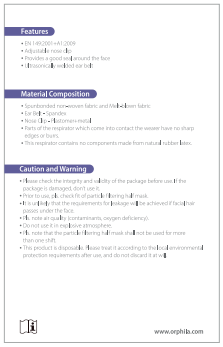
Front



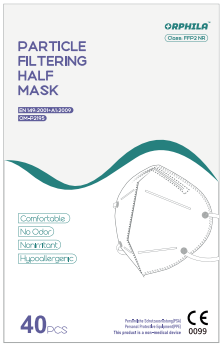
Back



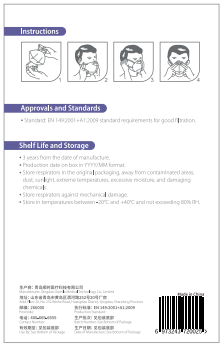
Front



Right



Back



Left

With Edge Protector

EU DECLARATION OF CONFORMITY

We Manufacturer: Qingdao Orphila Medical Technology Co., Limited

Address: Rm0501, Futai Square No.18 Hongkong Middle Road, Qingdao, Shandong, China, 266000

Declare that the product detailed below:

Particle Filtering Half Mask

Model: OM-P2195

Batch No.: 202007001a

Satisfies the requirement of the Council Directives:

2016/425/EU

Essential health and safety requirements Guaranteed
and conforms with the norms: EN 149: 2001+A1: 2009

Module B

NOTIFIED BODY: AENOR INTERNACIONAL

NUMBER: 0099

EU TYPE EXAMINATION CERTIFICATE ISSUED: 2020-06-22

Manufacturing plant surveillance through Module D:

NOTIFIED BODY: AENOR INTERNACIONAL

NUMBER: 0099

CONFORMITY TO TYPE BASED ON QUALITY ASSURANCE OF THE PRODUCTION PROCESS CERTIFICATE ISSUED: XXYYZZ

Signed for and on behalf of: Qingdao Orphila Medical Technology Co., Limited

Place and date of issue: Rm0501, Futai Square No.18 Hongkong Middle Road, Qingdao, Shandong, China, 266000. Aug. 10th, 2020

Name: Ma fangda

Function: General manager

Signature: Ma fangda

191020340175

中国认可
国际互认
检测
TESTING
CNAS L13034

Skin Sensitization Test

Guinea Pig Maximization

Final Report

Verification

Report Number: CSTBB20070197

Article Name: Particle filtering half mask

Method Standard: ISO 10993-10: 2010

Sponsor

Qingdao Orphila Medical Technology Co., Limited

Rm0501, Futai Square No.18 Hongkong Middle Road, Qingdao, Shandong, China

Test Facility

CCIC Huatongwei international inspection (Suzhou) Co., Ltd

Room 101, Building G, Ruoshui Road 388, Suzhou, Jiangsu, China

CONTENTS

Notices....3
Abstract....4
Study Verification and Signature....5
1.0 Purpose....6
2.0 Reference....6
3.0 Test and control articles....6
4.0 Identification of test system....7
5.0 Animal Managment....8
6.0 Equipment and reagents....8
7.0 Experiment design....8
8.0 The results observed....9
9.0 Evaluation criteria....10
10.0 Results of the test....10
11.0 Conclusion....10
12.0 Record....10
13.0 Confidentiality Agreement....10

Notices

1. Please apply for rechecking within 15 days of receiving the report if there is any objection.
2. Any erasure or without special testing seal renders the report null and void.
3. The report is only valid when signed by the persons who edited, checked and approved it.
4. The report is only responsible for the test results of the tested samples.
5. The report shall not be reproduced except in full without the written approval of the company.

Abstract

In this study, we took guinea pigs to observe the skin sensitization of the test article according to ISO 10993-10: 2010.

The test article were extracted in Constant Temperature Vibrator at 50 ℃, 60 rpm for 72 h by 0.9 % Sodium Chloride Injection and Sesame Oil. Mix 50:50 (by volume) stable emulsion of Freund's complete adjuvant with selected solvent. Intradermal induction and topical induction were operated in the clipped intrascapular region of each animal. After the topical induction phase was completed on day 14, all test and control animals were challenged with the test sample. The erythema and edema of the challenge site were observed to test the sensitization response of the test article. According to the Magnusson and Kligman scales, the response to erythema and edema at each application site of the skin was described and scored 24 hours and 48 hours after the challenge phase.

The results showed that the guinea pigs in the negative control group (0.9 % Sodium Chloride Injection, Sesame Oil) retained a normal appearance throughout the test and showed no skin irritants. A severe skin reactions for erythema and oedema were shown in the positive control group (DNCB). While in test article group, the response of skin on testing side did not exceed that on the control side. The skin reactions for erythema and oedema were not observed in test article group. The data of each group met the acceptance criteria, and the results of this test were considered valid.

Based on the above results, it can be concluded that under the experimental conditions, the test article has no potential skin sensitization on guinea pigs in the extraction method.

Study Verification and Signature

Protocol Number	SST2007007602BB
Protocol Effective Date	2020-07-07
Technical Initiation Date	2020-07-10
Technical Completion Date	2020-08-07
Final Report Completion Date	2020-08-10

Personnel Betty — 2020-08-10 (Date Completed)

Approved — Study Director — 2020-08-10 (Date Completed)

Supervisory — Test Facility Manager — 2020.8.10 (Date Completed)

CCIC Huatongwei international inspection (Suzhou) Co., Ltd.

1.0 Purpose

The test was designed to evaluate the potential of a test article to cause skin sensitization. The test is used as a procedure for screening of contact allergens in guinea pigs and extrapolating the results to humans, but it does not establish the actual risk of sensitization.

2.0 Reference

Biological evaluation of medical devices Part 10: Tests for irritation and skin sensitization (ISO 10993-10: 2010)

Biological evaluation of medical devices-Part 12: Sample preparation and reference materials (ISO 10993-12:2012)

Biological evaluation of medical devices-Part 2: Animal welfare requirements (ISO 10993-2:2006)

3.0 Test and control articles

Groups	Test article	Negative Control Article(Polar)	Negative Control Article(Non-Polar)	Positive Control
Name	Particle filtering half mask	Sodium Chloride Injection (SC)	Sesame Oil (SO)	2, 4-Dinitrochlorobenzene (DNCB)
Manufacture	Qingdao Orphila Medical Technology Co., Limited. West Coast Branch（Plant 20, No. 252 Weihe Road, Huangdao District, Qingdao, Shandong, China）	Shijiazhuang No.4 Pharmaceutical	Ji'an Lv yuan natural flavor oil refinery, Qingyuan District	TOKYO CHEMICAL INDUSTRY CO., LTD
Size	12.5*14.5cm	500 ml	5L	25 g
Model	OM-P3299BA (OM-KN95-FFP2、OM-P2195、OM-P31100、OM-CPA-FFP2-1860、OM-CPA-FFP3-8210、OM-N99-FFP3、OM-KN95-FFP1、OM-P31100A、OM-P2295、OM-P3299、OM-P2295A、OM-P3299A、	/	/	/

	OM-P2295B、 OM-P3299B、 OM-P2295BA、 OM-P2295D、 OM-P3299D、 OM-P2395A、 OM-P2395、 OM-P3399A、 OM-P3399、 OM-P3299BA+、 OM-P2195+、 OM-P3299B+)			
Lot Batch#	20200701	1912121907	20200528	H2UKD-DM
Test Article Material	Non-woven Fabric	/	/	/
Physical State	Solid	Liquid	Liquid	Solid
Color	White	Colorless	Light yellow	Light yellow
Package material	Plastic Bag/Box	/	/	/
Sterilized or Not	No	/	/	/
Concentration	/	0.9 %	/	Induction Concentration: 1.0 % Challenge Concentration: 0.5 % Dissolved in ethanol
Total Surface/Weight	Not provided	/	/	/
Storage Condition	Room Tep. Other -20℃~+30℃	Room Tep.	Room Tep.	Room Tep.
The information about the test article was supplied by the sponsor wherever applicable.				

4.0 Identification of test system

4.1 Test animal

Species: Hartley Guinea Pig (Cavia Porcellus)

Number: 30 (20 Test +10 Control)

Sex: 15 ♀， 15 ♂

Initial body weight: 300~500 g

Health status: Healthy, not previously used in other experimental procedures. Female animals were nul

liparous and not pregnant.

Animal identification: Ear tag

Cages: Plastic cage

Acclimation Period: 7 days under the same conditions as for the actual test

4.2 Justification of test system

The albino guinea pig has been used historically for sensitization studies (Magnusson and Kligman, 1 970). The guinea pig is believed to be the most sensitive animal model for this type of study. DNCB is the positive control article recommended in the test instructions. To ensure the sensitivity of the experime ntal system, the positive control article should be verified every three months.

5.0 Animal Management

Animal purchase: Wuxi hengtai experimental animal breeding co. LTD SCXK (SU) 2020-0003

Bedding: Corncob Jiangsu Xietong Pharmaceutical Bio-engineering Co., Ltd.

Feed: Guinea pigs were fed with full-price pellets Jiangsu Xietong Pharmaceutical Bio-engineering Co., Ltd.

Water: Drinking water met the Standards for Drinking Water Quality GB 5749-2006

Animal room temperature: 18-26 ℃

Animal room relative humidity: 30 %-70 %

Lights: 12 hours light/dark cycle, full-spectrum lighting

Personnel: Associates involved were appropriately qualified and trained

Selection: Only healthy, previously unused animals were selected

There were no known contaminants present in the feed, water, or bedding expected to interfere with the test data.

6.0 Equipment and reagents

6.1 Instruments

Constant Temperature Vibrator (SHB007, calibration data: 2020/3/16), Autoclave (SHB026, calibration data: 2020/3/16), Electronic scale (SHB017, calibration data: 2020/3/16)

6.2 Reagents

Freund's adjuvant Complete liquid (SIGMA, Lot No: SLBR3877V), Sodium dodecyl sulfate (SDS SIGMA, Lot No: SLBL2304V)

7.0 Experiment design

7.1 Sample preparation

The extracts of test article will be prepared according to the following steps:

Aseptic Sampling			Extraction in sterile vessels				
Sampling Manner	Actually sampling	Ratio	Reagent		Temperature	Time	pH
Whole	416.0 cm^2	6 cm^2: 1 ml	SC	69.3 ml	50 ℃	72 h	5.5
	416.0 cm^2		SO	69.3 ml		72 h	/

Both inducements and excitations were prepared by the number of times. The state of the leaching solution did not change visually after the leaching was advanced. After extraction, the samples were stored at room temperature for no more than 24 h. The extraction solution is clear, and the pH value has not been adjusted, filtered, centrifuged,

diluted and other processes. The control solution was prepared under the same conditions.

7.2 Test method

7.2.1 Intradermal induction phaseI

A pair of 0.1ml intradermal injections was made for each of the following, into each animal, at the injection sites (A, B and C) as shown in Figure 1 in the clipped intrascapular region.

Site A: A 50:50 (volume ratio) stable emulsion of Freund's complete adjuvant mixed with the chosen solvent.

Site B: The test sample (undiluted extract); the control animals were injected with the solvent alone.

Site C: The test sample at the concentration used at site B, emulsified in a 50:50 volume ratio stable emulsion of Freund's complete adjuvant and the solvent (50 %); the control animals were injected with an emulsion of the blank liquid with adjuvant.

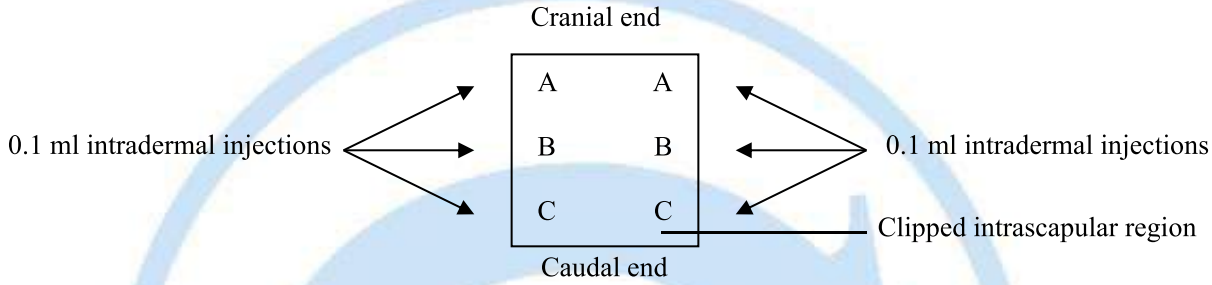


Figure 1 Location of intradermal injection sites

7.2.2 Topical induction phaseII

The maximum concentration that can be achieved in Intradermal induction phase Ⅰ did not produce irritation, animals are pretreated with 10% sodium dodecyl sulfate 24(±2) hours before the topical induction application.

At 7 d after completion of the intradermal induction phase, administer test article extract by topical application to the intrascapular region of each animal, using a patch of area approximately 8 cm^2 (absorbent gauze), so as to cover the intradermal injection sites. Secure the patches with an occlusive dressing. Remove the dressings and patches after (48±2) h.

Treat the control animals similarly, using the blank liquid alone.

7.2.3 Challenge phase

At 14d after completion of the topical induction phase, challenge all test and control animals with the test sample. Absorbent gauzes (2.5 cmx2.5 cm) were soaked respectively with test article and control article. Apply the test article extract and control article topically to two sites that were not treated during the induction stage. Secure with an occlusive dressing. Remove the dressings and patches after (24±2) h.

8.0 The results observed

The day after challenge exposure, the patch will be removed and the area cleaned gently with gauze if necessary. The site will be wiped gently with a 0.9 % saline soaked gauze sponge prior to each scoring period. The challenge sites will be observed for signs of irritation and sensitization reaction, as indicated by erythema and edema. If necessary, the fur will be shaved or clipped in advance for the convenience of dermal score.

Daily challenge observation scores will be recorded approximately 24, and 48 hours after patch removal in

accordance with the following classification system for skin reactions:

Table 1 Magnusson and Kligman scale

Patch test reaction	Grading scale
No visible change	0
Discrete or patchy erythema	1
Moderate and confluent erythema	2
Intense erythema and/or swelling	3

9.0 Evaluation criteria

Magnusson and Kligman grades of 1 or greater in the test group generally indicate sensitization, provided grades of less than 1 are seen in control animals.

If grades of 1 or greater are noted in control animals, then the reactions of test animals which exceed the most severe reaction in control animals are presumed to be due to sensitization.

If the response is equivocal, rechallenge is recommended to confirm the results from the first challenge.

The outcome of the test is presented as the frequency of positive challenge results in test and control animals.

10.0 Results of the test

All animals were survived and no abnormal signs were observed during the study.Individual results of dermal scoring for the challenge appear in Table 2.

11.0 Conclusion

The test article showed no evidence of causing delayed dermal contact sensitization in the guinea pig. Results and conclusions apply only to the test article tested. Any extrapolation of these data to other articles is the sponsor’s responsibility.

12.0 Record

All raw data pertaining to this study and a copy of the final report are retained in designated Huatongwei archive.

13.0 Confidentiality Agreement

Statements of confidentiality were as agreed upon prior to study initiation.

Table 2 Guinea pig Sensitization Dermal Reactions

Group		No.	Pretest weigh(g)	Finished weigh(g)	The Challenge patch was removed 24h later		The Challenge patch was removed 48h later		Positive rate
					Erythema	Swelling	Erythema	Swelling	
SC	Test	1	314.0	369.2	0	0	0	0	0%
		2	303.7	384.0	0	0	0	0	
		3	318.1	359.6	0	0	0	0	
		4	311.6	351.4	0	0	0	0	
		5	313.4	376.2	0	0	0	0	
		6	311.6	375.8	0	0	0	0	
		7	315.5	353.7	0	0	0	0	
		8	307.3	383.5	0	0	0	0	
		9	304.4	372.1	0	0	0	0	
		10	302.3	350.2	0	0	0	0	
	Control	11	307.3	375.2	0	0	0	0	—
		12	317.5	362.4	0	0	0	0	
		13	312.3	365.5	0	0	0	0	
		14	317.3	362.1	0	0	0	0	
		15	305.1	360.1	0	0	0	0	
SO	Test	16	310.7	369.6	0	0	0	0	0%
		17	312.3	380.6	0	0	0	0	
		18	305.3	373.4	0	0	0	0	
		19	308.3	365.0	0	0	0	0	
		20	307.7	378.2	0	0	0	0	
		21	309.0	369.8	0	0	0	0	
		22	314.2	382.6	0	0	0	0	
		23	311.6	373.4	0	0	0	0	
		24	310.7	356.7	0	0	0	0	
		25	304.8	376.7	0	0	0	0	
	Control	26	307.2	361.2	0	0	0	0	—
		27	315.9	362.3	0	0	0	0	
		28	310.6	365.6	0	0	0	0	
		29	307.5	366.5	0	0	0	0	
		30	303.7	356.5	0	0	0	0	

Table 3 Positive control

Group	No.	Pretest weigh(g)	Finished weigh(g)	The Challenge patch was removed 24 h later		The Challenge patch was removed 48 h later		Positive rate
				Erythema	Swelling	Erythema	Swelling	
Test	1	310.4	377.0	1	0	1	0	100%
	2	302.3	384.4	1	0	1	0	
	3	303.0	350.5	2	0	2	0	
	4	315.8	384.3	1	0	1	0	
	5	313.1	381.0	1	0	1	0	
	6	308.7	361.1	1	0	2	0	
	7	302.7	360.5	2	0	1	0	
	8	312.9	354.3	1	0	1	0	
	9	316.1	379.6	1	0	1	0	
	10	311.4	369.8	2	0	1	0	
Control	11	306.4	373.9	0	0	0	0	—
	12	303.6	378.2	0	0	0	0	
	13	316.4	383.8	0	0	0	0	
	14	318.6	351.7	0	0	0	0	
	15	311.9	358.4	0	0	0	0	

Note： The positive control was CSTBB20040001P1(Finish date：2020-05-08).

191020340175

中国认可
国际互认
检测
TESTING
CNAS L13034

Skin Irritation Test

Extraction Method

Final Report

Verification

Report Number: CSTBB20070138

Article Name: Particle filtering half mask

Method Standard: ISO 10993-10: 2010

Sponsor

Qingdao Orphila Medical Technology Co., Limited

Rm0501, Futai Square No.18 Hongkong Middle Road, Qingdao, Shandong, China

Test Facility

CCIC Huatongwei international inspection (Suzhou) Co., Ltd

Room 101, Building G, Ruoshui Road 388, Suzhou, Jiangsu, China

CONTENTS

Notices....3
Abstract....4
Study Verification and Signature....5
1.0 Purpose....6
2.0 Reference....6
3.0 Test and control articles....6
4.0 Identification of test system....7
5.0 Animal Managment....8
6.0 Equipment and reagents....8
7.0 Experiment design....8
8.0 The results observed....9
9.0 Evaluation criteria....10
10.0 Results of the test....10
11.0 Conclusion....10
12..0 Record....10
13.0 Confidentiality Agreement....10

Notices

1. Please apply for rechecking within 15 days of receiving the report if there is any objection.
2. Any erasure or without special testing seal renders the report null and void.
3. The report is only valid when signed by the persons who edited, checked and approved it.
4. The report is only responsible for the test results of the tested samples.
5. The report shall not be reproduced except in full without the written approval of the company.

Abstract

In this study, we took New Zealand white Rabbits to observe the skin irritation of the test article according to ISO10993-10:2010.

The test article were extracted in Constant Temperature Vibrator at 50 ℃, 60 rpm for 72 h by 0.9 % Sodium Chloride Injection and Sesame Oil. Apply 0.5 ml extracts of test article or control to 2.5 cm×2.5 cm absorbent gauze patches, and then apply the patch soaked with the extract of test article or control directly to the skin on each side of each rabbit, and then wrap the application sites with a bandage for a minimum of 4 h. At the end of the contact time, remove the dressing. The describe and score the skin reaction for erythema and oedema for each application site at each time interval. Record the appearance of each application site at (1±0.1) h, (24±2) h, (48±2) h and (72±2) h following removal of the patches.

The results showed that the rabbits in the negative control group (0.9 % Sodium Chloride Injection, Sesame Oil) retained a normal appearance throughout the test and showed no skin irritants. A severe skin reactions for erythema and oedema were shown in the positive control group (SDS). While in test article group, the response of skin on testing side did not exceed that on the control side. The skin reactions for erythema and oedema were not observed in test article group. The data of each group met the acceptance criteria, and the results of this test were considered valid.

Based on the above results, it can be concluded that under the experimental conditions, the test article has no potential skin irritation on rabbit in the extraction method.

Study Verification and Signature

Protocol Number	SST2007007603BB
Protocol Effective Date	2020-07-07
Technical Initiation Date	2020-07-10
Technical Completion Date	2020-07-17
Final Report Completion Date	2020-08-10

Personnel Betty 2020-08-10
Date Completed

Approved
Study Director 2020-08-10
Date Completed

Supervisory
Test Facility Manager 2020.8.10
Date Completed

CCIC Huatongwei international inspection (Suzhou) Co., Ltd.

1.0 Purpose

To evaluate the potential skin irritation caused by test article contact with the skin surface of rabbits and extrapolating the results to humans, but it does not establish the actual risk of irritation.

2.0 Reference

Biological evaluation of medical devices Part 10: Tests for irritation and skin sensitization (ISO 10993-10: 2010)

Biological evaluation of medical devices-Part 12: Sample preparation and reference materials (ISO 10993-12:2012)

Biological evaluation of medical devices-Part 2: Animal welfare requirements (ISO 10993-2:2006)

3.0 Test and control articles

Groups	Test article	Negative Control Article(Polar)	Negative Control Article(Non-Polar)	Positive Control
Name	Particle filtering half mask	Sodium Chloride Injection (SC)	Sesame Oil (SO)	10 % sodium dodecyl sulfate (SDS)
Manufacture	Qingdao Orphila Medical Technology Co., Limited. West Coast Branch（Plant 20, No. 252 Weihe Road, Huangdao District, Qingdao, Shandong, China）	Shijiazhuang No.4 Pharmaceutical	Ji'an Lv yuan natural flavor oil refinery, Qingyuan District	SIGMA
Size	12.5*14.5cm	500 ml	5L	25 g
Model	OM-P3299BA (OM-KN95-FFP2、OM-P2195、OM-P31100、OM-CPA-FFP2-1860、OM-CPA-FFP3-8210、OM-N99-FFP3、OM-KN95-FFP1、OM-P31100A、OM-P2295、OM-P3299、OM-P2295A、	/	/	/

	OM-P3299A、OM-P2295B、OM-P3299B、OM-P2295BA、OM-P2295D、OM-P3299D、OM-P2395A、OM-P2395、OM-P3399A、OM-P3399、OM-P3299BA+、OM-P2195+、OM-P3299B+)			
Lot Batch#	20200701	1912121907	20200528	SLBL2304V
Test Article Material	Non-woven Fabric	/	/	/
Physical State	Solid	Liquid	Liquid	Solid
Color	White	Colorless	Light yellow	Colorless
Package material	Plastic Bag/Box	/	/	/
Sterilized or Not	No	/	/	/
Concentration	/	0.9 %	/	10 %
Total Surface/Weight	Not provided	/	/	/
Storage Condition	Room Tep. Other -20℃~+30℃	Room Tep.	Room Tep.	Room Tep.
The information about the test article was supplied by the sponsor wherever applicable.				

4.0 Identification of test system

4.1 Test animal

Species: New Zealand white Rabbit

Number: 6

Sex: 3 ♀, 3 ♂

Weight: >2 kg

Health status: Healthy, not previously used in other experimental procedures. Female animals were nul liparous and not pregnant.

Animal identification: Ear tattoo

Cages: Stainless steel cage

Acclimation Period: 7 days under the same conditions as for the actual test

4.2 Justification of test system

The rabbit is specified as an appropriate animal model for evaluating potential skin irritants by the current testing standards. Positive control 10% sodium dodecyl sulfate has been substantiated at HTW with this method.

5.0 Animal Managment

Animal purchase: Wuxi hengtai experimental animal breeding co. LTD SCXK (SU) 2020-0003

Bedding: /

Feed: Experimental rabbits were fed a maintenance diet, Wuxi hengtai experimental animal breeding co. LTD

Water: Drinking water met the Standards for Drinking Water Quality GB 5749-2006

Animal room temperature: 18-26 ℃

Animal room relative humidity: 30 %-70 %

Lights: 12 hours light/dark cycle, full-spectrum lighting

Personnel: Associates involved were appropriately qualified and trained

Selection: Only healthy, previously unused animals were selected

There were no known contaminants present in the feed, water, or bedding expected to interfere with the test data

6.0 Equipment and reagents

6.1 Instruments

Constant Temperature Vibrator (SHB007, calibration data: 2020/3/16), Autoclave (SHB026, calibration data: 2020/3/16), Electronic scale (SHB017, calibration data: 2020/3/16)

7.0 Experiment design

7.1 Sample preparation

The extracts of test article will be prepared according to the following steps:

Aseptic Sampling			Extraction in sterile vessels				
Sampling Manner	Actually sampling	Ratio	Reagent		Temperature	Time	pH
Whole	416.0 cm^2	6 cm^2: 1 ml	SC	69.3 ml	50 ℃	72 h	5.5
	416.0 cm^2		SO	69.3 ml		72 h	/

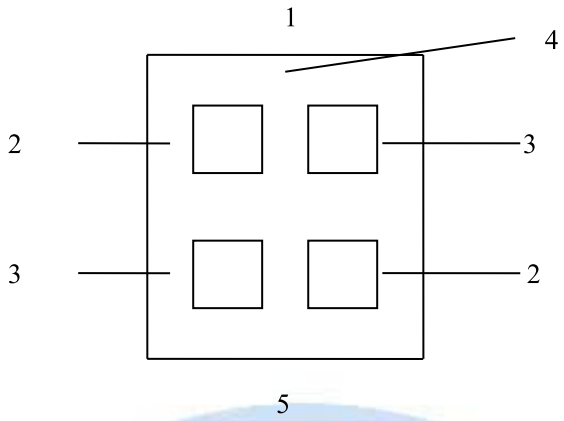
The state of the leaching solution did not change visually after the leaching was advanced. The extractions were clear, and the pH value has not been adjusted, filtered, centrifuged, diluted and other processes, before dosing stored at room temperature no more than 24 h. The control solution was prepared under the same conditions

7.2 Test method

Use the rabbits with healthy intact skin. Fur was generally clipped within 24 h period before testing on the backs of the rabbits, a sufficient distance on both sides of the spine for application and observation of all test sites (approximately 10×15 cm).

Apply 0.5 ml extract (s) of test article or control to 2.5 cm×2.5 cm absorbent gauze patches, and then apply the patch soaked with the extract of test article or control directly to the skin on each side of each rabbit as shown in Figure 1, and then wrap the application sites with a bandage (semi-occlusive or occlusive) for a minimum of 4h. At

the end of the contact time, remove the dressing.



1- Cranial end, 2- Test site, 3- Control site, 4- Clipped dorsal region, 5- Caudal end

Figure1 Location of skin application sites

8.0 The results observed

The Describe and score the skin reaction for erythema and oedema according to the scoring system given in Table 1 for each application site at each time interval. Record the appearance of each application site at (1±0.1) h, (24±2) h, (48±2) h and (72±2) h following removal of the patches.

Table 1 Classification System for Skin Reaction

Erythema and Eschar Formation:	Numerical Grading
No erythema	0
Very slight erythema (barely perceptible)	1
Well-defined erythema	2
Moderate erythema	3
Severe erythema (beet redness) to eschar formation preventing grading of erythema	4
Edema Formation:	
No edema	0
Very slight edema (barely perceptible)	1
Well-defined edema (edges of area well-defined by definite raising)	2
Moderate edema (raised approximately 1mm)	3
Severe edema (raised more than 1mm and extending beyond exposure area)	4
Maximal possible score for irritation	8
Irritation Response Categories in the Rabbit	
Response Category	Mean score
Negligible	0 to 0.4
Slight	0.5 to 1.9
Moderate	2 to 4.9
Severe	5 to 8

9.0 Evaluation criteria

Use only (24±2) h, (48±2) h and (72±2) h observations for calculation.

After the 72 h grading, all erythema grades plus oedema grades (24±2) h, (48±2) h and (72±2) h were totalled separately for each test article and blank for each animal. The primary irritation score for an animal was calculated by dividing the sum of all the scores by 6 (two test/observation sites, three time points).

To obtain the primary irritation index for the test article, add all the primary irritation scores of the individual animals and divide by the number of animals.

When blank or negative control was used, calculate the primary irritation score for the controls and subtract that score from the score using the test material to obtain the primary irritation score.

10.0 Results of the test

All animals were survived and no abnormal signs were observed during the study. According to what observed, the response of skin on testing side did not exceed that on the control side. Thus, the primary irritation index for the test article was calculated to be 0. See table 2.

11.0 Conclusion

The test result showed that the response of the test article extract was categorized as negligible under the test condition.

12.0 Record

All raw data pertaining to this study and a copy of the final report are retained in designated Huatongwei archive.

13.0 Confidentiality Agreement

Statements of confidentiality were as agreed upon prior to study initiation.

Table 2　Skin irritation response observation

Reagent	Rabbit No	Pretest weigh(g)	Finished weigh(g)	Group	Reaction	Interval (hours): score=left/right			
						1h	24h	48h	72h
SC	1	2.11	2.22	Test Article	Erythema	0/0	0/0	0/0	0/0
					Oedema	0/0	0/0	0/0	0/0
				Negative Control	Erythema	0/0	0/0	0/0	0/0
					Oedema	0/0	0/0	0/0	0/0
	2	2.03	2.11	Test Article	Erythema	0/0	0/0	0/0	0/0
					Oedema	0/0	0/0	0/0	0/0
				Negative Control	Erythema	0/0	0/0	0/0	0/0
					Oedema	0/0	0/0	0/0	0/0
	3	2.16	2.27	Test Article	Erythema	0/0	0/0	0/0	0/0
					Oedema	0/0	0/0	0/0	0/0
				Negative Control	Erythema	0/0	0/0	0/0	0/0
					Oedema	0/0	0/0	0/0	0/0
Primary irritation index						0			
SO	4	2.07	2.13	Test Article	Erythema	0/0	0/0	0/0	0/0
					Oedema	0/0	0/0	0/0	0/0
				Negative Control	Erythema	0/0	0/0	0/0	0/0
					Oedema	0/0	0/0	0/0	0/0
	5	2.12	2.21	Test Article	Erythema	0/0	0/0	0/0	0/0
					Oedema	0/0	0/0	0/0	0/0
				Negative Control	Erythema	0/0	0/0	0/0	0/0
					Oedema	0/0	0/0	0/0	0/0
	6	2.15	2.28	Test Article	Erythema	0/0	0/0	0/0	0/0
					Oedema	0/0	0/0	0/0	0/0
				Negative Control	Erythema	0/0	0/0	0/0	0/0
					Oedema	0/0	0/0	0/0	0/0
Primary irritation index						0			

Table 3 Positive control

Rabbit No	Group	Reaction	Interval (hours): score=left site/right site			
			1h	24h	48h	72h
1	Positive control	Erythema	0/0	1/2	2/3	3/3
		Oedema	0/0	2/1	2/2	3/3
	Negative Control	Erythema	0/0	0/0	0/0	0/0
		Oedema	0/0	0/0	0/0	0/0
2	Positive control	Erythema	0/1	2/1	3/3	4/3
		Oedema	1/0	2/2	3/3	3/4
	Negative Control	Erythema	0/0	0/0	0/0	0/0
		Oedema	0/0	0/0	0/0	0/0
3	Positive control	Erythema	1/0	1/2	3/3	4/3
		Oedema	0/1	2/1	3/4	3/4
	Negative Control	Erythema	0/0	0/0	0/0	0/0
		Oedema	0/0	0/0	0/0	0/0
Primary irritation index			5.2			

Positive control performed once every six months see CSTBB20020001P3(Finish date：2020-02-21)