

BASIC HEALTH AND SAFETY CHECKLIST: UNCONTROLLED

MANUFACTURER'S NAME: Ohlone Press LLC, San Francisco, California 94109 USA

BRAND: VOGMASK®

PRODUCT FAMILIES: Vogmask VMCV, Vogmask Organic VM and VMC2V

REQUIREMENT	APPLICABLE SECTION (Specification & Method)	COMPLIANCE (Yes/N/A)	COMMENTS (State how compliance is achieved and where demonstrated)	
<p align="center">FILTERING HALF MASK</p> <p align="center">PARTICLE MASK</p> <p align="center">FOR PROTECTION FROM INHALED PARTICLES</p>				
<p>1 GENERAL REQUIREMENTS</p> <p>PRODUCT must provide adequate protection against all risks encountered.</p>		Yes	Risk Assessment provided in Section 3.1 of Vogmask VMCV Technical File, QR-05-01.	
<p>1.1 Design principles</p>				
<p>1.1.1 Ergonomics</p> <p>Product must be so designed and manufactured that in the foreseeable conditions for use for which it is intended the user can perform the risk related activity normally whilst enjoying appropriate protection of the highest possible level</p>	<p>7.7 (Practical Performance):</p> <p>Test Method IAW EN149, 8.4 - Practical performance (General, Walking test, Working simulation test)</p> <p>7.9 (Leakage):</p> <p>Test Method IAW EN149, 8.5 – Leakage</p>	<p>Yes</p> <p>Yes</p>	<p>Test report provided in Section 7.0 of Vogmask VMCV Technical File, QR-05-01.</p> <p>Test report provided in Section 7.0 of Vogmask VMCV Technical File, QR-05-01.</p>	
<p>1.1.2 Levels and classes of protection</p>				
<p>1.1.2.1 Highest level of protection possible</p> <p>The optimum level of protection to be taken into account in the design is that beyond which the constraints imposed by the wearing of the product would prevent its effective use during the period of exposure to the risk or normal performance of the activity</p>	<p>7.7 (Practical Performance):</p> <p>Test Method IAW EN149, 8.4 - Practical performance (General, Walking test, Working simulation test)</p> <p>7.9 (Leakage):</p> <p>Test Method IAW EN149, 8.5 – Leakage</p> <p>7.12 (Carbon dioxide content of the inhalation air):</p>	<p>Yes</p> <p>Yes</p> <p>Yes</p>	<p>Test report provided in Section 7.0 of Vogmask VMCV Technical File, QR-05-01.</p> <p>Test report provided in Section 7.0 of Vogmask VMCV Technical File, QR-05-01.</p> <p>Test report provided in Section 7.0 of Vogmask VMCV Technical File, QR-05-01.</p>	

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	Test Method IAW EN149, 8.7 (Carbon dioxide content of the inhalation air)		
1.1.2.2 Classes of protection appropriate to different levels of risk Where differing foreseeable conditions of use are such that several levels of the same risk can be distinguished, appropriate classes of protection must be taken into account in the design of the product.	Test Method # 1 IAW EN149, 8.5 – Leakage	Yes	Test report provided in Section 7.0 of Vogmask VMCV Technical File, QR-05-01.

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1.2 Innocuousness of Product			
1.2.1 Absence of risks and other 'inherent' nuisance factors Product must be so designed and manufactured as to preclude risks and other nuisance factors under foreseeable conditions of use.	7.6 (Cleaning and disinfecting): Test Method # 1 IAW EN149, 8.4 - Practical performance (General, Walking test, Working simulation test) Test Method # 2 IAW EN149, 8.5 – Leakage Test Method # 3 IAW EN149, 8.11 – Penetration of filter material	Yes	Test report provided in Section 7.0 of Vogmask VMCV Technical File, QR-05-01.
	7.12 (Carbon dioxide content of the inhalation air): Test Method IAW EN149, 8.7 (Carbon dioxide content of the inhalation air)	Yes	Test report provided in Section 7.0 of Vogmask VMCV Technical File, QR-05-01.
	7.14 (Field of vision): See Test Method #1 above.	Yes	Test report provided in Section 7.0 of Vogmask VMCV Technical File, QR-05-01.
	7.16 (Breathing resistance):	Yes	Test report provided in Section 7.0 of Vogmask

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	Test Method IAW EN149, 8.9 (Breathing resistance)		VMCV Technical File, QR-05-01.	
<p>1.2.1.1 Suitable constituent materials</p> <p>Product materials and parts, including any of their decomposition products, must not adversely affect user hygiene or health.</p>	<p><u>7.5 (Material):</u> Test Method IAW EN149, 8.2 (Visual inspection)</p> <p><u>7.6 (Cleaning and disinfecting):</u> Test Method # 1 IAW EN149, 8.4 - Practical performance (General, Walking test, Working simulation test) Test Method # 2 IAW EN149, 8.5 – Leakage Test Method # 3 IAW EN149, 8.11 – Penetration of filter material</p> <p><u>7.7 (Practical Performance):</u> Test Method IAW EN149, 8.4 - Practical performance (General, Walking test, Working simulation test)</p> <p><u>7.10 (Compatibility with skin):</u> Test Method # 1 IAW EN149, 8.4 - Practical performance (General, Walking test, Working simulation test) Test Method # 2 IAW EN149, 8.5 – Leakage</p> <p><u>7.11 (Flammability):</u> Test Method IAW EN149, 8.6 - Flammability</p>	<p>Yes</p> <p>Yes</p> <p>Yes</p> <p>Yes</p>	<p>Test report provided in Section 7.0 of Vogmask VMCV Technical File, QR-05-01.</p> <p>Test report provided in Section 7.0 of Vogmask VMCV Technical File, QR-05-01.</p> <p>Test report provided in Section 7.0 of Vogmask VMCV Technical File, QR-05-01.</p> <p>Test report provided in Section 7.0 of Vogmask VMCV Technical File, QR-05-01.</p>	

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<p>1.2.1.2 Satisfactory surface condition of all parts in contact with the user</p> <p>Any part in contact or in potential contact with the user when such equipment is worn must be free of roughness, sharp edges, projections and the like which could cause excessive irritation or injuries.</p>	<p><u>7.7 (Practical Performance):</u> Test Method IAW EN149, 8.4 - Practical performance (General, Walking test, Working simulation test)</p> <p><u>7.8 (Finish of parts):</u> Test Method IAW EN149, 8.2 (Visual inspection)</p>	<p>Yes</p> <p>Yes</p>	<p>Test report provided in Section 7.0 of Vogmask VMCV Technical File, QR-05-01.</p> <p>Test report provided in Section 7.0 of Vogmask VMCV Technical File, QR-05-01.</p>	
<p>1.2.1.3 Maximum permissible user impediment</p> <p>Any impediment caused by Product to movement to be made, postures to be adopted and sensory perception must be minimised; nor must PPE cause movements which endanger the user or other persons.</p>	<p><u>7.7 (Practical Performance) & 7.14 (Field of vision):</u> Test Method IAW EN149, 8.4 - Practical performance (General, Walking test, Working simulation test)</p>	<p>Yes</p>	<p>Test report provided in Section 7.0 of Vogmask VMCV Technical File, QR-05-01.</p> <p>Test report provided in Section 7.0 of Vogmask VMCV Technical File, QR-05-01.</p>	

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<p>1.3 Comfort and efficiency</p>				
<p>1.3.1 Adaptation of Product to user morphology</p> <p>Product must be so designed and manufactured as to facilitate correct positioning on the user and to remain in place for the foreseeable period of use, bearing in mind ambient factors, movements to be made and postures to be adopted. For this purpose, it must be possible to optimise Product adaptation to user morphology by all appropriate means, such as adequate</p>	<p><u>7.7 (Practical Performance):</u> Test Method IAW EN149, 8.4 - Practical performance (General, Walking test, Working simulation test)</p>	<p>Yes</p>	<p>Test report provided in Section 7.0 of Vogmask VMCV Technical File, QR-05-01.</p>	

REQUIREMENT	APPLICABLE SECTION (Specification & Method)	COMPLIANCE (Yes/N/A)	COMMENTS (State how compliance is achieved and where demonstrated)	
adjustment and attachment systems or the provision of an adequate size range.				
1.3.2 Lightness and design strength Product must be as light as possible without prejudicing design strength and efficiency. Apart from the specific additional requirements which they must satisfy in order to provide adequate protection against the risks in question (see 3), Product must be capable of withstanding the effects of ambient phenomena inherent under the foreseeable conditions of use.	<u>7.4 (Packaging) & 7.5 (Material):</u> Test Method IAW EN149, 8.2 (Visual inspection) <u>7.7 (Practical Performance):</u> Test Method IAW EN149, 8.4 - Practical performance (General, Walking test, Working simulation test)	Yes Yes	Test report provided in Section 7.0 of Vogmask VMCV Technical File, QR-05-01. Test report provided in Section 7.0 of Vogmask VMCV Technical File, QR-05-01.	
1.3.3 Compatibility of different classes or types of PPE designed for simultaneous use If the same manufacturer markets several Product models of different classes or types in order to ensure the simultaneous protection of adjacent parts of the body against combined risks, these must be compatible.	N/A, manufacturer does not market PPE models of different classes or types.	N/A	N/A	N/A

REQUIREMENT	APPLICABLE SECTION OF EN149 (Specification & Method)	COMPLIANCE (Yes/N/A)	COMMENTS (State how compliance is achieved and where demonstrated)	BSI Use Only
1.4 Information supplied by the manufacturer In addition to the name and address of the manufacturer and/or his authorised representative established in the Community, the notes that must be drawn up by the former and supplied when Product is placed on the market must contain all relevant information on:	<u>10 Information to be supplied by the manufacturer</u> 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. 10.4 The information shall be clear and comprehensible. If helpful, illustrations, part numbers, marking shall be added.	Yes Yes Yes	See Section 9.0 of Vogmask VMCV Technical File, QR-05-01.	

REQUIREMENT	APPLICABLE SECTION OF EN149 (Specification & Method)	COMPLIANCE (Yes/N/A)	COMMENTS (State how compliance is achieved and where demonstrated)	BSI Use Only
	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.	N/A	N/A	N/A
(a) storage, use, cleaning, maintenance, servicing and disinfection, Cleaning, maintenance or disinfectant products recommended by manufacturers must have no adverse effect on Product or users when applied in accordance with the relevant instructions;	<p>10.3 The information supplied by the manufacturer shall contain all information necessary for trained and qualified persons on</p> <ul style="list-style-type: none"> - 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. 	Yes	The user information includes all necessary information. See Section 9.0 of Vogmask VMCV Technical File, QR-05-01.	
(b) performance as recorded during technical tests to check the levels or classes or protection provided by the Product in question;		Yes	See Section 7.0 of Vogmask VMCV Technical File, QR-05-01..	
(c) suitable Product accessories and the characteristics of appropriate spare parts;		Yes	Information on an accessory head strap is provided in Section 4.2 of Vogmask VMCV Technical File, QR-05-01.	
(d) the classes of protection appropriate to different levels of risk and the corresponding limits of use;	<p>10.5 Warning shall be given against problems likely to be encountered, for example:</p> <ul style="list-style-type: none"> - 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. 	Yes	Warnings are provided. See Section 9.0 of Vogmask VMCV Technical File, QR-05-01.	

REQUIREMENT	APPLICABLE SECTION OF EN149 (Specification & Method)	COMPLIANCE (Yes/N/A)	COMMENTS (State how compliance is achieved and where demonstrated)	BSI Use Only
(e) the obsolescence deadline or period of obsolescence of Product or certain of its components;	10.6 The information shall provide recommendations as to when the particle filtering half mask shall be discarded.	Yes	Box marking and IFY shows use by date in yyyy/mm format in universal pictogram. See Section 9.0 of Vogmask VMCV Technical File, QR-05-01.	
(f) the type of packaging suitable for transport;		Yes	Packaging specifications are provided. See Section 3.0 and 9.0 of Vogmask VMCV Technical File, QR-05-01.	
(g) the significance of any markings (see 2.12).		Yes	The user instructions provide information on the significance of the markings on the product package. See Section 9.0 of Vogmask VMCV Technical File, QR-05-01.	
(h) where appropriate the references		Yes	See Section 3.0 of Vogmask VMCV Technical File, QR-05-01.	
These notes, which must be precise and comprehensible, must be provided at least in the official language(s) of the Manufacturer		Yes	The Technical File is provided in English.	

REQUIREMENT	APPLICABLE SECTION (Specification & Method)	COMPLIANCE (Yes/N/A)	COMMENTS (State how compliance is achieved and where demonstrated)	BSI Use Only
2. ADDITIONAL REQUIREMENTS COMMON TO SEVERAL CLASSES OR TYPES OF PPE				
2.1 PPE incorporating adjustment systems				

REQUIREMENT	APPLICABLE SECTION (Specification & Method)	COMPLIANCE (Yes/N/A)	COMMENTS (State how compliance is achieved and where demonstrated)	
<p>If Product incorporates adjustment systems, the latter must be so designed and manufactured as not to become incorrectly adjusted without the user's knowledge under the foreseeable conditions of use.</p>	<p><u>7.13 Head harness</u></p> <p>Test Method # 1 IAW EN149, 8.4 - Practical performance (General, Walking test, Working simulation test)</p> <p>Test Method # 2 IAW EN149, 8.5 – Leakage</p>	<p>Yes</p>	<p>Test report provided in Section 7.0 of Vogmask VMCV Technical File, QR-05-01.</p>	
<p>2.2 Product 'enclosing' the parts of the body to be protected</p> <p>As far as possible, Product 'enclosing' the parts of the body to be protected must be sufficiently ventilated to limit perspiration resulting from use; if this is not the case, it must if possible be equipped with devices which absorb perspiration.</p>	<p>N/A – EN 149 Annex ZA lists no requirement to the BSHR section 2.2</p>	<p>N/A</p>	<p>Protected areas are ventilated by means of air filter and exhalation valve.</p>	
<p>2.3 Product for the face, eyes and respiratory tracts</p> <p>Any restriction of the user's field of vision or sight by Product for the face, eyes or respiratory tract must be minimised.</p> <p>The degree of optical neutrality of the vision systems of these Product classes must be compatible with the type of relatively meticulous and/or prolonged activities of the user.</p> <p>If necessary, they must be treated or provided with facilities to prevent moisture formation. Product models intended for users requiring sight correction must be compatible with the wearing of spectacles or contact lenses.</p>	<p><u>7.14 Field of vision</u></p> <p>Test Method # 1 IAW EN149, 8.4 - Practical performance (General, Walking test, Working simulation test)</p>	<p>Yes</p>	<p>Test report provided in Section 7.0 of Vogmask VMCV Technical File, QR-05-01.</p>	

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<p>2.4 PPE subject to ageing</p> <p>If it is known that the design performances of new Product may be significantly affected by ageing, the date of manufacture and/or, if possible, the date of obsolescence, must be indelibly inscribed on every Product item or interchangeable component placed on the market in such a way as to preclude any misinterpretation; this information must also be indelibly inscribed on the packaging.</p> <p>If the manufacturer is unable to give an undertaking with regard to the useful life of Product, his notes must provide all the information necessary to enable the purchaser or user to establish a reasonable obsolescence date, bearing in mind the quality level of the model and the effective conditions of storage, use, cleaning, servicing and maintenance.</p> <p>Where appreciable and rapid deterioration in Product performance is likely to be caused by ageing resulting from the periodic use of a cleaning process recommended by the manufacturer, the latter must, if possible, affix a mark to each item of PPE placed on the market indicating the maximum number of cleaning operations that may be carried out before the equipment needs to be inspected or discarded; failing that, the manufacturer must give this information in his notes.</p>	<p><u>7.6 (Cleaning and disinfecting):</u></p> <p>Test Method # 1 IAW EN149, 8.4 - Practical performance (General, Walking test, Working simulation test)</p> <p>Test Method # 2 IAW EN149, 8.5 – Leakage</p> <p>Test Method # 3 IAW EN149, 8.11 – Penetration of filter material</p>	<p>Yes</p>	<p>Test report provided in Section 7.0 of Vogmask VMCV Technical File, QR-05-01.</p>	
	<p><u>9 Marking</u></p> <p>9.1 Packaging</p> <p>The following Information shall be clearly and durably marked on the smallest commercially available packaging or legible through it if the packaging is transparent.</p>	<p>Yes</p>	<p>See Section 9.0 of Vogmask VMCV Technical File, QR-05-01.</p>	

REQUIREMENT	APPLICABLE SECTION OF (Specification & Method)	COMPLIANCE (Yes/N/A)	COMMENTS (State how compliance is achieved and where demonstrated)	
	9.1.1 The name, trademark or other means of identification of the manufacturer or supplier.	Yes	Box – Ohlone and Vogmask trademark	
	9.1.2 Type-Identifying marking.	Yes	Box – Type ID “R”	
	9.1.3 Classification	Yes	Class: KN-94	
	9.1,4 Year	Yes	Box – Standard and revision	
	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.	Yes	Box – Pictogram for expiry See Section 9.0 of Vogmask VMCV Technical File, QR-05-01.	
	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.	Yes	Pictogram for IFU See Section 9.0 of Vogmask VMCV Technical File, QR-05-01.	
	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.	Yes	See Section 9.0 of Vogmask VMCV Technical File, QR-05-01.	
	9.1.8 The packaging of those particle filtering half masks passing the dolomite clogging test shall be additionally marked with the letter "D".	N/A	Product has not passed dolomite clogging test.	
	9.2 Particle filtering half mask Particle filtering half masks 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,	Yes	See Section 8.0 of Vogmask VMCV Technical File, QR-05-01.	
	9.2.2 Type-Identifying marking.	Yes		

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			See Section 8.0 of Vogmask VMCV Technical File, QR-05-01.	
	9.2.3 The number and year of publication of this European Standard.	Yes	See Section 8.0 of Vogmask VMCV Technical File, QR-05-01.	
	9.2.4 The symbols FFP1, FFP2 or FFP3 according to class.	Yes	"FFP2" marked. See Section 8.0 of Vogmask VMCV Technical File, QR-05-01.	
	9.2.5. If appropriate the letter D. (dolomite) in accordance with clogging performance. This letter shall follow the class designation (see 9.2.4).	N/A	Product has not passed dolomite clogging test.	
	9.2.6 Sub-assemblies and components with considerable bearing on safety shall be marked so that they can be Identified	N/A	No sub-assemblies or components with considerable bearing on safety.	
	<p><u>10 Information to be supplied by the manufacturer</u></p> <p>10.1 Information supplied by the manufacturer shall accompany every smallest commercial available package.</p> <p>10.2 Information supplied by the manufacturer shall be at least in the official language(s) of the country of destination.</p> <p>10.3 The information supplied by the manufacturer shall contain all information necessary for trained and qualified persons on</p> <ul style="list-style-type: none"> - application/limitations; - the meaning of any colour coding; - checks prior to use; - donning, fitting; 	Yes	See Section 9.0 of Vogmask VMCV Technical File, QR-05-01.	

REQUIREMENT	APPLICABLE SECTION OF (Specification & Method)	COMPLIANCE (Yes/N/A)	COMMENTS (State how compliance is achieved and where demonstrated)	
	<ul style="list-style-type: none"> - use; - maintenance (e.g. cleaning, disinfecting), if applicable; storage - the meaning of any symbols/pictograms used of the equipment. <p>10.4 The information shall be clear and comprehensible. If helpful, illustrations, part numbers, marking shall be added.</p> <p>10.5 Warning shall be given against problems likely to be encountered, for example:</p> <ul style="list-style-type: none"> - 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. <p>10.6 The information shall provide recommendations as to when the particle filtering half mask shall be discarded.</p> <p>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.</p>			

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<p>2.9 Product incorporating components which can be adjusted or removed by the user</p> <p>Any Product components which can be adjusted or removed by the user for the purpose of replacement must be so designed and manufactured as to facilitate adjustment, attachment and removal without tools.</p>	<p><u>7.13 Head harness</u></p> <p>Test Method # 1 IAW EN149, 8.4 - Practical performance (General, Walking test, Working simulation test)</p> <p>Test Method # 2 IAW EN149, 8.5 – Leakage</p> <p><u>7.18 (Demountable parts)</u></p> <p>Test Method IAW EN149, 8.2 (Visual inspection)</p>	<p>Yes</p> <p>N/A</p>	<p>Test report provided in Section 7.0 of Vogmask VMCV Technical File, QR-05-01.</p> <p>N/A</p>	
<p>2.10 Product for connection to another, external complementary device</p> <p>If Product incorporates a system permitting connection to another complementary device, the attachment mechanism must be so designed and manufactured as to enable it to be mounted only on appropriate equipment.</p>	<p>N/A</p>	<p>N/A</p>	<p>N/A</p>	
<p>2.11 Product incorporating a fluid circulation system</p> <p>If Product incorporates a fluid circulation system, the latter must be so chosen, or designed, and incorporated as to permit adequate fluid renewal in the vicinity of the entire part of the body to be protected, irrespective of user gestures, posture or movement under the foreseeable conditions of use.</p>	<p>N/A</p>	<p>N/A</p>	<p>N/A</p>	

The requirements of Section 3 are not applicable to this product.