Covid-19 – Which Masks?

There has been a lot of discussion in the past weeks and months about which mask to use to protect against COVID-19 and the associated problems with a worldwide shortage of protective respirators/masks.

This document is a guideline to highlight any equivalence between EN and NIOSH rated respirators, as the governments of different countries are now more open on an emergency temporary basis to accept respirators not being certified to the EN149 standard but offering the same or equivalent level of protection against the virus spread, even if not CE marked.

INTRO – UK GOVERNMENT OFFICIAL POSITION

Biological Agents (such as SARS-CoV-2) are covered under the Control of Substances Hazardous to Health (COSHH) Regulations 2002.

HSE guidance document HSG53 states 'when in an airborne state, micro-organisms can be classed as particles, so can usually be removed by filter-type Respiratory Protective Equipment (RPE). You should always use equipment fitted with the highest efficiency filter possible (protection factor of at least 20) to control exposure down to the lowest levels.'

Therefore, the UK HSE recommends the use of an FFP3 (Filtering Face Piece – high efficiency respirator) for protection against viruses.

Due to global shortages in the supply of FFP3 respirators during the COVID-19 pandemic, it may not always be reasonably practicable to use or source these FFP3 rated masks. In this scenario, an FFP2 (medium efficiency) could be used as an alternative, as this is consistent with WHO guidance.
The HSE has also recently undertaken a Rapid Evidence Review in March. Part 1 looked at the equivalence of N95 and FFP2 masks and the evidence to support their use in the UK as part of the PPE ensemble worn for aerosol generating procedures on patients with COVID-19.

The HSE has stated that FFP2 and N95 respirators (filtering at least 94% and 95% of airborne particles respectively) offer protection against COVID-19 and may be used if FFP3 respirators are not available.

**WHO Guidance**

The World Health Organisation (WHO), also recommends the use of N95, FFP2 respirators or equivalent for protection against Corona Virus during aerosol generating procedures (AGP).

CE MASKS FFP2 and NIOSH N95 - comparison

It is widely accepted by industry that the N95 is comparable to an FFP2: Portwest recommends it is therefore reasonable to consider N95 and FFP2 masks are equivalent for filtering non-oil based particles including bioaerosols (e.g. viruses).

Table 1 Comparison of key requirements of N95, FFP2 and FFP3 respirators. Requirement N95

The requirements detailed above show the N95 to be comparable to an FFP2 in assigned protection factor (APF), filter efficiency and breathing resistance.

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<tr>
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<tbody>
<tr>
<td>Assigned Protection Factor (APF)</td>
<td>10</td>
<td>10</td>
<td>20</td>
</tr>
<tr>
<td>Filter Efficiency</td>
<td>≥95% (85 l/min)</td>
<td>≥94% (95 l/min)</td>
<td>≥99% (95 l/min)</td>
</tr>
<tr>
<td>Test agent used</td>
<td>NaCl</td>
<td>NaCl and Paraffin Oil</td>
<td>NaCl and Paraffin Oil</td>
</tr>
<tr>
<td>Total Inward Leakage (TIL)</td>
<td>N/A</td>
<td>≤8%</td>
<td>≤2%</td>
</tr>
<tr>
<td>Inhalation resistance</td>
<td>≤343 Pa (85 l/min)</td>
<td>≤240 Pa (95 l/min)</td>
<td>≤300 Pa (95 l/min)</td>
</tr>
<tr>
<td>Exhalation resistance</td>
<td>≤245 Pa (85 l/min)</td>
<td>≤300 Pa (160 l/min)</td>
<td>≤300 Pa (160 l/min)</td>
</tr>
<tr>
<td>Rebreathed CO2</td>
<td>N/A</td>
<td>≤1%</td>
<td>≤1%</td>
</tr>
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</table>

The N95 is not tested against a number of requirements and in particular it is not tested for oil-based particulates. N95 and FFP2 are equivalent at filtering non-oil-based particles such as bioaerosols, and that the WHO guidance confirms N95 will provide adequate protection against the Corona Virus.
Total Inward Leakage (TIL) - this consists of face seal leakage, exhalation valve leakage (if fitted) and filter penetration, all while being worn by a human test subject and performing a series of exercises. TIL is tested on the EN standard while the N95 masks are fit tested prior to use, this would provide reassurance on face seal leakage during exercises.

The EN standard requires a specific test on Carbon Dioxide in the mask (dead space) while - NIOSH does not address any requirements over rebreathed CO2. However, there is little concern with this as the size of the N95 masks are small and comparable to the FFP2 and therefore should have a similar rebreathed CO2 result.

**INTERNATIONAL POSITION – EUROPE**

In Europe a number of national Health and Safety Laboratories also provided their position on the question of equivalence between N95 and FFP2 masks and different governments are now open to masks meeting the requirements of certain international standards to be used against COVID-19.

The filtration performance of the filter material is very similar between:

- FFP2 masks (European standard EN 149),
- N95 masks (American standard NIOSH 42C-FR84),
- Korea 1st Class masks KF94 (Korean standard KMOEL 2017-64),
- KN95 (Chinese standard GB2626-2006),
- DS2 masks (Japanese standard JMHLW2000) and

N95 masks are now generally accepted as an FFP2 EN equivalent, however there is still an open discussion and to date non harmonised decisions with respect to the other international standards, for example, Korean and Chinese masks are still not accepted in the UK and in many other European Countries.
Sources:

N95 NIOSH- 42 CFR Part 84 Respiratory Protective Devices


Respiratory protection at Work - https://www.hse.gov.uk/pubns/books/hsg53.htm

Working with substances harmful to health https://www.hse.gov.uk/pubns/indg136.pdf
