9 September 2015

ResMed Material Declarations
for
BPA, LATEX, DEHP and PHTHALATES

Material Declaration - Use of bisphenol A in the manufacture of ResMed devices

ResMed monitors scientific studies and regulatory assessments around the world concerning the safety of bisphenol A (BPA). BPA is a chemical used to make a hard, clear plastic known as polycarbonate, which is used in many consumer products, including reusable water bottles and baby bottles.

Some countries have recently introduced new legislation affecting the use of BPA in baby bottles. In March 2010, Health Canada introduced a ban on polycarbonate baby bottles. Since June 1, 2011, the European Commission does not permit sale of BPA-based polycarbonate baby bottles. These decisions are not a consequence of any proven adverse effects from BPA, but rather a highly precautionary approach.

Regulators and scientists globally continue to state that BPA does not pose a risk to adults, teenagers or children. The Canadian Minister for Health stated that consumers can continue to use polycarbonate products as the level of exposure from these products is very low. In 2010, the European Food Safety Authority (EFSA) and a WHO-expert panel analyzed the currently available scientific data. Both authorities concluded that BPA-based materials can safely be used, and that any public health measures on BPA would be premature. The U.S. Food and Drug Administration (FDA) maintains its position that there is insufficient evidence of harm to children or adults from the current levels of BPA exposure.

Many of ResMed's products include polycarbonates in which BPA is a raw material. The use of polycarbonates in these products is approved in every country where these products are sold, including the USA, Canada and the European Union.

As a manufacturer of medical devices, ResMed and its products are subject to strict regulation. ResMed must satisfy global regulators that every product is safe and effective for its intended use. One of the requirements is to demonstrate an appropriate level of biocompatibility for every material to which a patient is exposed. All ResMed positive airway pressure devices, humidifiers, heated tubing and masks are thoroughly tested to comply with ISO 10993-1, the international standard for the biological evaluation of medical devices. To this end, the biocompatibility of the polycarbonate in question has been tested and confirmed by ResMed.

ResMed remains confident in the safety of its products containing BPA for their intended use.

Material Declaration- Latex, DEHP and Phthalates

ResMed products are not made with any natural rubber latex, DEHP or other Phthalates. No latex components, latex-derived materials or natural rubber latex are used in the design or manufacture of ResMed products.

Please contact ResMed Customer Service with any questions.

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Kind regards,

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