



30 Spur Drive
El Paso, Texas 79906
United States

Effective Date: 26 December 2018

Dear Valued Customer, Users and Distributors:

Statement Concerning EU Directive 2011/65/EU (RoHS)

The products supplied by Salter Labs® comply with the requirements of Article 4.1 of the EU Directive 2011/65/EU (RoHS). The products are not intentionally manufactured or formulated with cadmium, hexavalent chromium, lead, mercury, polybrominated biphenyls (PBB) or polybrominated diphenyl ethers (PBDE). Salter Labs® uses non-lead alternative solder where necessary.

Statement Concerning REACH List of Substances of Very High Concern.

As a medical device manufacturer, Salter Labs® manufactures articles, which in most cases will not require registration or notification under REACH to be imported into Europe. Article 7 of REACH defines circumstances under which article producers and importers are required to register or notify of substances in articles and details the requirements. Along with other requirements, Article 7 requires that any producer or importer of articles to notify the European Chemical Agency when an article contains Substances of Very High Concern (SVHC) in a concentration above 0.1% (w/w). Based on manufacturing process knowledge, SVHCs have been removed from the PVC components used in Salter Labs® tubing, connectors, face masks and facepieces. The only product line containing Phthalates such as Bis(2-ethyl(hexyl)phthalate) (DEHP) is the Parker Endotracheal Tube product line. This information is based on the disclosures of our suppliers.

Use the product as recommended per the applicable product specification and do not consume food or drink while handling the product. Please see below for detailed information meeting the requirement in Article 33 of REACH.

Substance name	CAS No.	Classification
Bis(2-ethyl(hexyl)phthalate) (DEHP)	117-81-7	Repr. Cat. 2: R60-61 (May impair fertility; may cause hard to unborn child)

Salter Labs® current conforms to the 27 June 2018 Amendment and will continue to conform to the requirements of REACH as new amendments are released. Based on information from suppliers and the knowledge of the process, Salter Labs® believes that the products do not contain any other SVHCs in amounts greater than 0.1%. The current SVHC list can be found at the following link:

<https://echa.europa.eu/candidate-list-table>

While Salter Labs® does not test each raw material purchased, nor test products for trace amounts of these substances, Salter Labs® does exercise good product stewardship practices and seeks information concerning raw material composition from suppliers.



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These statements do not cover

- Any modification of the product by any addition of any other product to it
- Any modification of the product resulting from processing of the product; or
- An inadequate use and/or storage of the product or the finished articles by the end user.

This status is based on Salter Labs® understanding of REACH and Salter Labs' knowledge of the materials that are contained in the products as of the date of 27 June 2018 disclosure of REACH compliance.

Sincerely:

A handwritten signature in black ink, appearing to read 'Megan Gustafson', followed by a horizontal line.

Megan Gustafson, CHMM
Independent Consultant for Salter Labs

Salter Labs Parker Endotracheal Tube product lines, containing DEHP