



30 Spur Drive
El Paso, Texas 79906
United States

Effective Date: 25 March 2020

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), polybrominated diphenyl ethers (PBDE), bis(2ethylhexyl) phthalate (DEHP) except as identified in table 1, butyl benzyl phthalate (BBP), dibutyl phthalate (DBP), diisobutyl phthalate (DIPB); products containing DEHP are identified below.

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. Products containing DEHP are identified below. 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 16 January 2020 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% except as identified in Table 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 16 January 2020 disclosure of REACH compliance.

Sincerely:

A handwritten signature in black ink, appearing to read 'Mara Caler'.

Mara Caler
Regulatory Affairs, Salter Labs

Table 1

Salter Labs product lines, containing DEHP

I-NPA	Parker Nasopharyngeal Airway with Parker Flex-Tip including slidable depth ring and 15mm connector (NPA)
I-PFEC	EasyCurve Endotracheal Tube, Articulating Cord, Cuffed (PFEC)
I-PFHV	Endotracheal Tube, High Volume Low Pressure (PFHV), Cuffed
I-PFLP	Endotracheal Tube, Low Profile (PFLP), Cuffed
H-PFNC	Endotracheal Tube, Preformed Nasal, Cuffed (PFNC) H-
I-PFNU	Endotracheal Tube, Preformed, Nasal, Uncuffed (PFNU)
I-PFOC	Endotracheal Tube, Preformed, Oral, Cuffed (PFOC)
I-PFOL	Endotracheal Tube, Preformed, Oral, Low Profile Cuffed (PFOL)
I-PFOU	Endotracheal Tube, Preformed, Oral, Uncuffed (PFOU)
I-PFRC	Endotracheal Tube, Reinforced, Cuffed (PFRC) H-
I-PFRU	Endotracheal Tube, Reinforced, Un-Cuffed (PFRU)
I-PFST-	Endotracheal Tube, High Volume/Low Pressure (PFHV), Cuffed, pre-loaded with sheathed malleable aluminum stylet
I-PFTDL	Parker Endo-Bronch Double Lumen Endobronchial Tube
I-PFTDR	Parker Endo-Bronch Double Lumen Endobronchial Tube
I-PFUO	Endotracheal Tube, Uncuffed (PFUO)
I-PMLT	Endotracheal Tube, MicroLaryngeal (PMLT), Cuffed
I-STLT	Parker Intubating Stylet (STLT), Sheathed
FLEX-IT	Flex-It Directional Stylet, Fits Tube sizes 7.5mm and 8.0mm
1004-0-25	Female Luer Adapter
1200-0-25	Female/Male Luer Adapter
5500	BiNAPS Transducer_sensor cables only
5700-0-1	Thermisense_sensor cables only
5700A3-0-1	Thermisense_sensor cables only
5700A5-0-1	Thermisense_sensor cables only
5700B-0-1	Thermisense_sensor cables only
5700CK-2-0-1	Thermisense_sensor cables only
5700E-0-1	Thermisense_sensor cables only
5700EK-0-1	Thermisense_sensor cables only
5700EK-2-0-1	Thermisense_sensor cables only
5700P-0-1	Thermisense_sensor cables only
5700PA3-0-1	Thermisense_sensor cables only
5700PA5-0-1	Thermisense_sensor cables only
5700PE-0-1	Thermisense_sensor cables only
5700PEK-0-1	Thermisense_sensor cables only
5700PEK-2-0-1	Thermisense_sensor cables only
5700PS20-0-1	Thermisense_sensor cables only
5700PT-0-1	Thermisense_sensor cables only
5700S20-0-1	Thermisense_sensor cables only
5700T-0-1	Thermisense_sensor cables only
5800-0-1	PneumoTherm Sensor_sensor cables only
5800T-0-10	PneumoTherm Sensor_sensor cables only
5810-5-1	PneumoTherm Sensor_sensor cables only
5811-0-1	PneumoTherm Sensor_sensor cables only