

Chemical regulations and Laerdal's requirements for managing unwanted substances

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REACH:

REACH (Registration, Evaluation, Authorization, and restriction of Chemicals Regulation) is the regulation (EC No 1907/2006), enacted in 2007, aims to enhance the protection of human health and the environment from risks posed by chemicals. EU REACH applies to all suppliers (both within and outside Europe) who wish to sell, import, or manufacture chemicals or goods containing certain chemicals in the European Union.

The REACH list of Substances of Very High Concern (SVHC) is updated twice a year, in January and July. Laerdal closely monitors these updates and assesses whether any newly added substances are present in Laerdal's products. Appropriate measures will be taken if necessary.

For more information: [Candidate List of substances of very high concern for Authorization - ECHA \(europa.eu\)](#)

RoHS:

The European RoHS (Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment) is a 2011/65/EU European Union Directive and amendment (EU) 2015/863, which restricts the use of 10 hazardous substances. RoHS 2 is also a CE-marking directive, meaning that products with CE marks must comply with RoHS requirements.

Laerdal requires that all parts and materials supplied to us comply with the substance restrictions outlined in the RoHS Directive. Suppliers must also inform us of any exemptions that apply to those parts or materials.

For more information: [RoHS Directive - European Commission](#)

Proposition 65:

California Proposition 65 (Safe Drinking Water and Toxic Enforcement Act of 1986) aims to protect the state's drinking water from chemicals known to cause cancer, birth defects, or reproductive harm. It mandates businesses to notify Californians about potential exposures. The State maintains a list of over 1,000 such chemicals.

Laerdal requires suppliers to disclose the presence of Prop 65 chemicals and actively evaluate any notifications received to ensure compliance.

For more information: [The Proposition 65 List - OEHHA](#)

POPs:

Regulation (EU) No 2019/1021 of the European Parliament and of the Council on persistent organic pollutants (POPs) entered into force on July 15, 2019. Its aim is to restrict and reduce the manufacturing, marketing, and use of POPs within the EU. Persistent organic pollutants are organic substances that remain in the environment, accumulate in living organisms, and pose significant risks to human health and the environment.

Laerdal requires all parts and materials supplied to us comply with the substance restrictions specified in the POPs Regulation.

For more information: [Regulation - 2019/1021 - EN - EUR-Lex \(europa.eu\)](#)

PFAS:

PFAS (Per- and polyfluoroalkyl substances) are synthetic chemicals used for their resistance to heat, water, and oil, known as "Forever Chemicals" due to their slow breakdown and accumulation in the environment and human tissue. With over 12,000 substances in the PFAS group and no master list, global analysis and restrictions are ongoing. On October 11, 2023, the EPA published PFAS reporting and recordkeeping requirements under TSCA, with the reporting period from April 13, 2026, through October 13, 2026, for PFAS containing articles in any year from January 1, 2011, to November 13, 2023.

For more information: [TSCA Section 8\(a\)\(7\) Reporting and Recordkeeping Requirements for Perfluoroalkyl and Polyfluoroalkyl Substances | US EPA](#)

All Phthalates Restriction:

Phthalates are a group of chemicals, commonly used as plasticizers in PVC, to make plastics softer and more durable. They are considered as endocrine-disrupting chemicals, and some are toxic to reproduction.

Laerdal wishes to avoid all phthalates in their products. Some of the phthalates are already restricted/prohibited and some have application specific restrictions. Phthalates can be found in e.g. soft plastics.

Natural Rubber Latex Restriction:

Latex is a natural substance found in many plants, especially rubber trees, with elastic qualities widely used in both medical and non-medical products. However, latex contains proteins that can trigger allergies in some individuals.

The presence of Natural Rubber Latex in any amount is not prohibited, however due to risk of allergic reaction, Laerdal aims to avoid latex in products and requires suppliers to disclose if any items contain Natural Rubber Latex to better serve our customers.

Chemical Compliance Inquiries & Customer Response Guidelines:

If you have a question regarding unwanted substances or environmental chemical compliance in general, please send a request using this e-mail address: Chemical.Compliance@laerdal.com

Our aim is to respond to your request as promptly as possible. In some cases, there may be delays due to updates to the SVHC list, which involve contacting suppliers and awaiting their responses. According to Article 33 of the REACH Regulation, "Duty to communicate information on substances in articles," relevant information must be provided free of charge within 45 days of receiving the request.