

Overview of Ambu's Medical Devices in relation to content of Latex and REACH Regulated SVHC substances.















According to the European Chemical regulation (REACH) Ambu is obligated to inform about the products containing listed SVHC substances (Substances of Very High Concern) in the concentrations above 0.1% (w/w). See the following website for the current version: <http://echa.europa.eu/web/guest/candidate-list-table>









The European Medical device directive requires labeling if the medical devices:




- Contain classified phthalates, which are classified and
- are intended to administer and or remove medicines, body liquids or other substances to or from the body, or devices intended for transport and storage of such body fluids or substances.

The table below provides an overview on all Ambu Medical Devices in relation to content REACH Regulated SVHC substances in concentrations above 0.1%. The table also includes information on which products that are made with Natural Rubber Latex. Ambu products presented in this list will be labeled as indicated below.

| Product | Contents of SVHC above 0.1% (w/w) and description of substance | Natural Rubber Latex | Symbol on the product label |
|--|--|----------------------|-----------------------------|
| Cardiology and Neurology | | | |
| Ambu® BlueSensor Electrodes | No | No | |
| Ambu® WhiteSensor Electrodes | No | No | |
| Ambu® Neuroline Electrodes | No | No | |
| Ambu® Neuroline needles (Inoject, concentric, monopolar, twisted, subdermal twisted) | No | No | |
| Ambu® Neuroline Ground | No | No | |
| Ambu® SkinFix | No | No | |
| Ambu® Neuroline Corkscrew Electrode | No | No | |
| Ambu® Neuroline Monopolar and Concentric Cables | No | No | |
| Ambu® Neuroline Probes | No | No | |
| Ambu® Neuroline Cup electrodes | No | No | |
| Ambu® Snap Clip | No | No | |
| Ambu® Skin Prep | No | No | |
| Ambu® Myoguide | No | No | |
| Flexible Scopes | | | |
| Ambu® aScope™ 3 | No | No | |
| Ambu® aScope™ 4 Broncho | No | No | |
| Ambu aScope™ 4 RhinoLaryngo | No | No | |

| Product | Contents of SVHC above 0.1% (w/w) and description of substance | Natural Rubber Latex | Symbol on the product label |
|--|--|----------------------|---|
| Ambu® aView™ | No | No | |
| Ambu® aScope BronchoSampler™ | No | No |  |
| Ambu® aScope BronchoSampler™ SC | No | No |  |
| Airway Management | | | |
| King Vision Video Laryngoscope | No | No | |
| King Vision aBlade video laryngoscope | No | No | |
| King Vision Video Out Cable | No | No | |
| VivaSight-DL | Yes, contain DEHP (CASRN 117-81-7) | No |  DEHP |
| VivaSight-SL | Yes, contain DEHP (CASRN 117-81-7) | No |  DEHP |
| VivaSight-EB | Yes, contain DEHP (CASRN 117-81-7) | No |  DEHP |
| Anaesthesia | | | |
| Dual Limb Breathing Circuits | Yes, contain DEHP (CASRN 117-81-7) if symbol is on labeling | No |  DEHP |
| King F2 | Yes, contain DEHP (CASRN 117-81-7) if symbol is on labeling | No |  DEHP |
| King Flex2 | Yes, contain DEHP (CASRN 117-81-7) if symbol is on labeling | No |  DEHP |
| King Universal F | Yes, contain DEHP (CASRN 117-81-7) if symbol is on labeling | No |  DEHP |
| King Universal F Flex | Yes, contain DEHP (CASRN 117-81-7) if symbol is on labeling | No |  DEHP |
| King Ped F2 and King Flex 2 - Pediatric Breathing Circuits | Yes, contain DEHP (CASRN 117-81-7) if symbol is on labeling | No |  DEHP |
| King Jackson Rees and King Mapleson | Yes, contain DEHP (CASRN 117-81-7) if symbol is on labeling | No |  DEHP |
| King Transport and PACU Kits | Yes, contain DEHP (CASRN 117-81-7) if symbol is on labeling | No |  DEHP |
| King Breathing Bags (STD and colored) | Yes, contain DEHP (CASRN 117-81-7) if symbol is on labeling | No |  DEHP |
| HMEs and Filters | No | No | |
| Ambu® aFlow Corrugated Anaesthesia Circuits | No | No | |
| Ambu® aFlow Coaxial Circuits | No | No | |
| Ambu® aFlow Extendible Anaesthesia Circuits | No | No | |
| Ambu® aFlow Heated Wire Circuits | No | No | |

| Product | Contents of SVHC above 0.1% (w/w) and description of substance | Natural Rubber Latex | Symbol on the product label |
|---|--|----------------------|---|
| Ambu® aFlow Septum Divided Single Limb Circuit | No | No | |
| Ambu® aFlow Semi-Closed Circuit and Nitrous Oxide and Oxygen Delivery Circuit | No | No | |
| Ambu® aFlow Smoothbore Anaesthesia Circuits | Yes, contain DOTE (CASRN 15571-58-1) if circuits have 15mm or 19 mm smoothbore PVC | No | |
| Ambu® catheter mounts | Yes, contain DOTE (CASRN 15571-58-1) if catheter mounts have 15mm smoothbore PVC | No | |
| Ambu® aFlow CO2 Sampling Line | No | No | |
| Ambu® aFlow Connectors | No | No | |
| Ambu® aFlow Breathing Bags | No | No | |
| Ambu® aFlow Filters | No | No | |
| Ambu® Disposable Face mask | No | No |  |
| Ambu® Open Cuff Silicone Mask | No | No | |
| Ambu® Silicone Face Mask | No | No | |
| Ambu® Transparent Face Mask | No | Yes | |
| Ambu® UltraSeal | No | No |  |
| Ambu® King Mask | No | No |  |
| Ambu® AuraOnce™ | No | No |  |
| Ambu® AuraFlex™ | No | No |  |
| Ambu® AuraStraight™ | No | No |  |
| Ambu® Aura-i™ | No | No |  |
| Ambu® Aura40™ | No | No | |
| Ambu® AuraGain | No | No |  |
| Ambu® Cuff Pressure Gauge | No | No | |
| Emergency Care | | | |
| Ambu® SPUR II | No | No | |
| Ambu® Mark IV | No | No | |
| Ambu® Mark IV Baby | No | No | |
| Ambu® Military Mark III | No | No | |

| Product | Contents of SVHC above 0.1% (w/w) and description of substance | Natural Rubber Latex | Symbol on the product label |
|---------------------------------------|--|----------------------|---|
| Ambu® Oval Silicone resuscitator | No | No | |
| Ambu® Oval Plus Silicone resuscitator | No | No | |
| Ambu® PEEP Valves | No | No | |
| Ambu® Disposable Pressure Manometer | No | No | |
| Ambu® TubeChek | Yes, contain DEHP (CASRN 117-81-7) | No |  |
| Ambu® ET Tube holder | No | No | |
| Ambu® LifeKey | No | Yes* | |
| Ambu® ResKey | No | Yes* | |
| Ambu® Res-Cue Mask | No | No |  |
| Ambu® Suction Booster | Yes, contain DEHP (CASRN 117-81-7) | No |  |
| Ambu® Res-Cue Pump | No | No | |
| Ambu® Twin Pump | No | No | |
| Ambu® Uni-Suction Pump | No | No | |
| Ambu® Perfit ACE | No | No | |
| Ambu® Mini Perfit ACE | No | No | |
| Ambu® Perfit | No | No | |
| Ambu® Redi-ACE Adult | No | No | |
| Ambu® Redi-ACE Mini | No | No | |
| Ambu® Head Wedge | No | No | |

*No patient contact with the part containing natural rubber latex