




















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 products containing listed SVHC substances (Substances of Very High Concern) in concentrations above 0.1% (w/w). See the following website for the current version of the SVHC list: <http://echa.europa.eu/web/guest/candidate-list-table>

The table below provides an overview of all Ambu Medical Devices in relation to content of REACH Regulated SVHC substances in concentrations above 0.1% (w/w). The table also includes information on which products are made with Natural Rubber Latex. Ambu products presented in this list will be labeled as indicated below. All products that has “No” in the SVHC column (column 2) does not contain any substances currently on the SVHC list.

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 and accessories			
Ambu® aScope™ 3	No	No	
Ambu® aScope™ 4 Broncho	No	No	
Ambu® aScope™ 4 RhinoLaryngo	No	No	
Ambu® aScope 4 Cysto	No	No	
Ambu® aScope™ Duodeno	No	No	
Ambu® aScope BronchoSampler™	No	No	
Ambu® aScope BronchoSampler™ SC	No	No	
Display Units			
Ambu® aView™	Yes, Lithium battery contains 1,3-propanesultone (CASRN 1120-71-4)	No	

Product	Contents of SVHC above 0.1% (w/w) and description of substance	Natural Rubber Latex	Symbol on the product label
Ambu® aView™ 2 Advance	Yes, Lithium battery contains 1,2-dimethoxyethane; ethylene glycol dimethyl ether (EGDME) (CASRN 110-71-4)	No	
Ambu® aBox Duodeno	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	No	No	
Ambu® VivaSight™ 2 DLT	No	No	
Ambu® VivaSight™ 2 DLT Kit	No	No	
VivaSight-SL	No	No	
VivaSight-EB	No	No	
Ambu® VivaSight™ 2 Endobronchial Blocker Tube	Yes, contains D4 (CASRN 556-67-2), D5 (CASRN 541-02-6) and D6 (CASRN 540-976)	No	
Anaesthesia			
King Dual Limb Breathing Circuits	Yes, circuit kit contains part/-s with DEHP (CASRN 117-81-7) for Lot numbers up to 1000445762	No	
King F2	Yes, circuit kit contains part/-s with DEHP (CASRN 117-81-7) for Lot numbers up to 1000444160	No	
King Flex2	Yes, circuit kit contains part/-s with DEHP (CASRN 117-81-7) for Lot numbers up to 1000448208	No	
King F Flex2	No	No	
King Universal F	No	No	
King Universal F Flex	Yes, circuit kit contains part/-s with DEHP (CASRN 117-81-7) for Lot numbers up to 1000369900	No	
King Universal F Flex2	No	No	
King Ped F2 and King Flex 2 - Pediatric Breathing Circuits	Yes, circuit kit contains part/-s with DEHP (CASRN 117-81-7) for Lot numbers up to 1000444137	No	
King Jackson Rees and King Mapleson	No	No	
King Transport and PACU Kits	No	No	
King Breathing Bags (STD and colored)	No	No	

Product	Contents of SVHC above 0.1% (w/w) and description of substance	Natural Rubber Latex	Symbol on the product label
HMEs and Filters	No	No	
Xenon	No	No	
Sampling Line	Yes, Contain DEHP (CASRN 117-81-7) for Lot numbers up to 1000444142	No	
King LT-D	Yes, Contain DEHP (CASRN 117-81-7) for Lot numbers up to 1000446006	No	
King LTS-D	No	No	
Nitric Oxide	No	No	
Vent Circuits	No	No	
Extension Sets	No	No	
Flex Connectors	No	No	
Headstraps	No	No	
Tube Tree	No	No	
Manifolds	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	
Ambu® Oval Silicone resuscitator	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 Plus Silicone resuscitator	No	No	
Ambu® PEEP Valves	No	No	
Ambu® Disposable Pressure Manometer	No	No	
Ambu® ET Tube holder	No	No	
Ambu® LifeKey	No	Yes*	
Ambu® ResKey	No	Yes*	
Ambu® Res-Cue Mask	No	No	
Ambu® Twin 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