



# Overview of Ambu's medical devices and the content of REACH regulated substances













According to the European chemical regulation (REACH) Ambu is obligated to inform about the products containing SVHC substances (substances of very high concern) in concentrations above 0.1 % (w/w).

The European Medical Device Directive requires labeling if the medical devices:


- Contain classified phthalates which are: DEHP (diethylhexylphthalate), DBP (dibutylphthalate), BBP (Butylbenzylphthalate), DIBP ( diisobutyl phthalate), DMEP (bis(2-methoxyethyl) phthalate), DIPP( diisopentyl phthalate), DHNUP (1,2-Benzenedicarboxylic acid, di-C7-11-branched and linear alkyl esters), N-pentylisopentylftalat(NPIPP), DPP(dipentyl phthalate), 1,2-benzenedicarboxylic acid, dipentylester, branched and linear and/or 1,2-benzenedicarboxylic acid, di-C6-8-branched alkyl esters , C7-rich 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.

For Ambu the products presented in this list will be labeled as indicated below.

At the list is also included information on which products contain Natural Rubber Latex.

Product	Substances	Classified Phthalates	Latex	Symbol at the product Label
		E.g. DEHP; DBP, BBP, DHNUP, DMEP, DIPP, DPP, DIBP	Natural Rubber Latex	
<b>Patient Monitoring &amp; Diagnostics</b>				
Blue Sensor electrodes	No	No	No	
White Sensor electrodes	No	No	No	
Neuroline electrodes	No	No	No	
Neuroline Corkscrew Electrode	No	No	No	
Neuroline Monopolar and Concentric Cables	No	No	No	
Neuroline Probes	No	No	No	
Neutralect - Mini	No	No	No	
Neutralect - Pencil and Electrode	No	No	No	
Neutralect - Diathermy Cable	No	No	No	
Snap Clip	No	No	No	
Skin Prep	No	No	No	
<b>Anaesthesia</b>				
Ambu® aScope™	No	No	No	
Ambu® aScope™ Monitor	No	No	No	
Ambu® aView™	No	No	No	
King Vision Video Laryngoscope	No	No	No	
King Vision aBlade video laryngoscope	No	No	No	
King Vision Video Out Cable	Yes	No	No	
Dual Limp Breathing Circuits	Yes, if DEHP symbol is on labeling	No	No	
King F2	Yes, if DEHP symbol is on labeling	No	No	
King Flex2	Yes, if DEHP symbol is on labeling	No	No	
King Universal F	Yes, if DEHP symbol is on labeling	No	No	
King Universal F Flex	Yes, if DEHP symbol is on labeling	No	No	
King Ped F2 and King Flex2 - Pediatric Breathing Circuits	Yes, if DEHP symbol is on labeling	No	No	
King Jackson Rees and King Mapleson	Yes, if DEHP symbol is on labeling	No	No	
King Transport and PACU Kits	Yes, if DEHP symbol is on labeling	No	No	
King Breathing Bags (STD and colored)	Yes, if DEHP symbol is on labeling	No	No	
HMEs and Filters	No	No	No	
Ambu® Disposable Face mask	No	No	No	
Ambu® Open Cuff Silicone Mask	No	No	No	
Ambu® Silicone Face Mask	No	No	No	
Ambu® Transparent Face Mask	No	No	Yes	
Ambu® UltraSeal adult (4-5-6)	Yes	No	No	

Product	Substances	Classified Phthalates	Latex	Symbol at the product Label
		E.g. DEHP; DBP, BBP, DHNUP, DMEP, DIPP, DPP, DIBP	Natural Rubber Latex	
Ambu® UltraSeal pediatric (0-1-2-3)	No	No	No	
King Mask	No	No	No	
King Scented Mask	No	No	No	
Ambu® King Mask	No	No	No	
Ambu® King Mask Scented	No	No	No	
Ambu® AuraOnce™	No	No	No	
Ambu® AuraFlex™	No	No	No	
Ambu® AuraStraight™	No	No	No	
Ambu® Aura-i™	No	No	No	
Ambu® Aura40™	No	No	No	
Ambu® Cuff Pressure Gauge	No	No	No	
Ambu® AuraGain™	No	No	No	
Berman Airway	No	No	No	
Guedel Airway	No	No	No	
Bite Blocks - Flex Blue and Expandable Blue	Product line discontinued			
<b>Emergency Care</b>				
Ambu SPUR II	No	No	No	
Ambu Mark IV	No	No	No	
Ambu Mark IV Baby	No	No	No	
Ambu Military Mark III	No	No	No	
Ambu Oval Silicone resuscitator	No	No	No	
Ambu Oval Plus Silicone resuscitator	No	No	No	
Ambu PEEP Valves	No	No	No	
Ambu Disposable Pressure Manometer	No	No	No	
Ambu Oxygen Regulators	No	No	No	
Ambu TubeChek	Yes	No	No	
Ambu ET Tube holder	No	No	No	
Ambu LifeKey	No	No	No	
Ambu ResKey	No	No	No	
ResCue Mask	No	No	No	
Ambu Suction Booster	Yes	No	No	
Ambu Res-Cue Pump	No	No	No	
Ambu Twin Pump	No	No	No	
Ambu Uni-Suction Pump	No	No	No	
Ambu Perfit ACE	No	No	No	
Ambu Mini Perfit ACE	No	No	No	
Ambu Perfit	No	No	No	
Ambu Redi-ACE Adult	No	No	No	
Ambu Redi-ACE Mini	No	No	No	
Ambu Head Wedge	No	No	No	

If you find the symbol shown here, then you have already received the new version; 



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