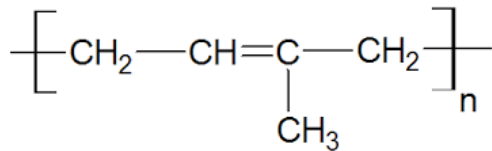


Primary Packaging Materials, part II: Elastomers

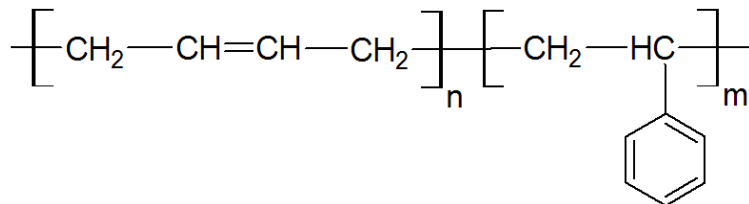
Material properties

Material properties

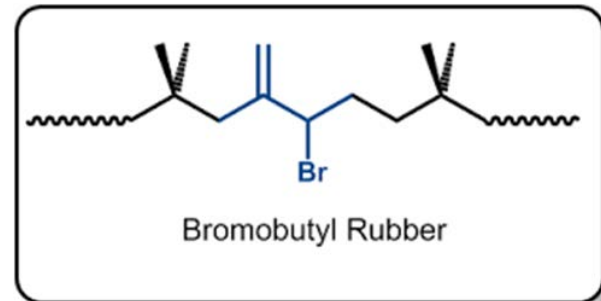
Chemistry of base elastomer



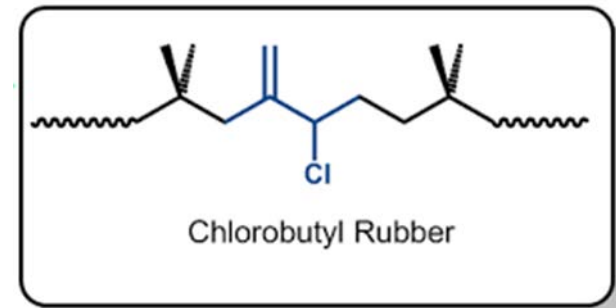
Polyisoprene Rubber



Styrene-butadiene Rubber



Bromobutyl Rubber



Chlorobutyl Rubber

Material properties

Component design



Material properties

Rubber composition

- Base elastomer/ polymer
- Filler
- Pigment
- Antioxidant
- Plasticizer
- Curing agent
- Accelerator
- Activator
- Additives
- Processing aids

Material properties

Surface treatment

- Silicone oil
 - to improve of processability or maintain quality
 - to enable functionality e.g. of pre-filled syringes
- Silicone polymerized directly on the surface
 - to improve processability e.g. lyophilization/ stoppering
- ETFE foil
 - to seal the bulk material and improve product compatibility
- Other inert coatings
 - to seal the bulk material and improve product compatibility
 - to enable functionality e.g. of pre-filled syringes

Primary Packaging Materials, part II: Elastomers

Compendial Background

Compendial Background

- Ph.Eur. - 3.2.9. Rubber closures for aqueous parenteral preparations, for powders and for freeze-dried powders
- USP - <381> Elastomeric closures for injections

Compendial Background

- Comparison of Ph.Eur. and USP

Parameter	Ph.Eur. 3.2.9	USP <381>
Identification	IR spectroscopy, total ash	Not specified
Physicochemical testing	Aqueous extractables, volatile sulfides	Aqueous extractables, volatile sulfides
Physical testing	Penetrability, fragmentation, self-sealing	Penetrability, fragmentation, self-sealing
Biological testing	Not specified	USP <87>, <88>