

saypha[®] RICH

Technical factsheet

saypha [®] RICH ¹	
Indication	to improve hydration, tone and elasticity of the skin and fill small lines such as crow's feet, smile lines or smoke lines surrounding the mouth
Injection area	superficial dermal tissue
Ingredients	
Concentration HA	1.8% (18 mg/mL) high molecular weight hyaluronic acid of non-animal origin
Additional ingredients	glycerol (20 mg/mL) glycerol is a polyalcohol with the double role of stabilizing hyaluronic acid and promoting skin hydration ²
Buffer system	phosphate citrate buffer
Packaging	
Packaging unit	1 box of 1 mL syringe
Needle	2 x 30G 1/2" thin-wall Terumo [™] needles (CE 0197)

Rheology

Purpose of rheological measurements is to evaluate the physical characteristics of dermal fillers. The dynamic viscosity represents a suitable parameter to determine the viscous properties of HA-based, non-crosslinked products like saypha[®] RICH, where the viscosity is more pronounced than the elasticity.

Test method dynamic viscosity (D=5s⁻¹, T=25°C)

Result 30,104 mPa.s³

Extrusion force

Extrusion force measurements are conducted to determine the force [N] needed to eject the gel from the syringe. The tests are always performed with the enclosed needle. A low and constant extrusion force is beneficial for smooth and predictable results.

Needle 30G 1/2" thin-wall Terumo[™] (CE 0197)

Result 8N⁴

Microbiological parameters

Endotoxins

Endotoxins are components of gram-negative bacteria membranes and are released when the bacterial cells are disrupted (e.g. during sterilization). Therefore the products are tested to assure that the endotoxin concentration lies below the predefined specification limits.

Test method according to Ph.Eur.⁵

Result virtually free on endotoxins⁶

Sterility

Croma HA fillers are steam sterilized within the syringe.

¹ CE 0459, ² Fluhr et al, Glycerol and the skin: holistic approach to its origin and functions, 2008, British Journal of Dermatology 2008 159, pp 23-34, ³ Batch: 403051, specification limits: > 20,000 mPa.s, ⁴ Batch: 403054, specification limits: ≤ 12N, ⁵ Ph.Eur. = European Pharmacopoeia, ⁶ EU = Endotoxin Unit according to Ph.Eur., specification limits: < 0.5 EU/mL