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PRODUCT SPECIFICATION SHEET

Product Name: Toyopearl® AF-rProtein A-650F (resin for purification of monoclonal antibodies)

Part Numbers:

- 22803 Toyopearl AF-rProtein A-650F, 45 µm, 10 mL
- 22804 Toyopearl AF-rProtein A-650F, 45 µm, 25 mL
- 22805 Toyopearl AF-rProtein A-650F, 45 µm, 100 mL
- 22806 Toyopearl AF-rProtein A-650F, 45 µm, 1 L
- 22807 Toyopearl AF-rProtein A-650F, 45 µm, 5 L
- 22809 ToyoScreen AF-rProtein A-650F, 45 µm, 1 mL x 5
- 22810 ToyoScreen AF-rProtein A-650F, 45 µm, 5 mL x 1
- 22811 ToyoScreen AF-rProtein A-650F, 45 µm, 5 mL x 5
- 22815 Protein A-R28 ELISA Kit

Product Description: **Toyopearl** is a methacrylic polymer incorporating high mechanical and chemical stability. Resins are available as non-functionalised “HW” series resins for size exclusion separations, and derivatised with surface chemistries for alternative modes of chromatography such as ion exchange, hydrophobic interaction or affinity separations.

Toyopearl AF- rProtein A-650F is a new generation of mechanical and chemical stabilized Protein A resins for the purification of monoclonal antibodies. The resin can be CIP cleaned by more than 100 times with 0.1 M NaOH. Because of multipoint attachment the Protein A leakage is minimized. Especially high dynamic binding capacity is possible at residence times lower than 3 min. The ligand is specially designed for a high log reduction of CHO Proteins.

Formulation: Particulate resin (spherical), available in particle sizes (mean diameter) of 45 µm = “F” grade
 Supplied as slurry in 20 % ethanol (v/v).

Physicochemical Specifications:

Appearance	White resin slurry which settles upon standing
Particle Size Distribution (>80 % within range)	30-60 µm for Toyopearl AF- rProtein A-650F
Exclusion Limit	< 5 x10 ⁶ Dalton (globular protein)
Mean Pore Diameter	1000 Å
Pressure drop across the column	max. 7 bar (recommended)
Operating Linear Flowrate	normally 60 – 600 cm/hour
Ligand	Recombinant Protein A (multipoint attachment)
IgG (static binding capacity) ^a	> 40 g/L
IgG (dynamic binding capacity) ^b	> 30 g/L (2 min residence time)
Ligand leakage ^c	> 5-25 ng/mg IgG (ELISA)
Bacterial Count	≤ 100 CFU/mL
Endotoxin Concentration	≤ 10.0 endotoxin units/mL
Pack sizes and type	10 mL, 25 mL, 100 mL, 1 L Packed in virgin Polyethylene container with Polypropylene cap.

▪ Resin Volume per Container	The indicated volume is the settled resin volume.
▪ Shipping Solvent	72 % (v/v) slurry in 20 % (v/v) ethanol
▪ Long Term Storage Conditions	20 % (v/v) ethanol, at 4° C
▪ Foreign Substance	not observed, no visual evidence
▪ Eluable Matter	< 0.1 %

^{a,b}For detailed test procedures please refer to Regulatory Support File BB-MF-5888.
^cELISA Kit from ProteNova available on request