

Annex A

EU (MA) number	Invented name	Strength	Pharmaceutical form	Target species	Route of administration	Packaging	Content	Package size	Withdrawal period
EU/2/09/103/001	Respiporc FLU3	--1	Suspension for injection	Pigs	Intramuscular use	Vial (type I glass)	10 doses (20 ml)	1 vial	Zero days
EU/2/09/103/002	Respiporc FLU3	--1	Suspension for injection	Pigs	Intramuscular use	Vial (type II glass)	25 doses (50 ml)	1 vial	Zero days
EU/2/09/103/003	Respiporc FLU3	--1	Suspension for injection	Pigs	Intramuscular use	Vial (type II glass)	50 doses (100 ml)	1 vial	Zero days
EU/2/09/103/004	Respiporc FLU3	--1	Suspension for injection	Pigs	Intramuscular use	Vial (PET)	10 doses (20 ml)	1 vial	Zero days
EU/2/09/103/005	Respiporc FLU3	--1	Suspension for injection	Pigs	Intramuscular use	Vial (PET)	25 doses (50 ml)	1 vial	Zero days
EU/2/09/103/006	Respiporc FLU3	--1	Suspension for injection	Pigs	Intramuscular use	Vial (PET)	50 doses (100 ml)	1 vial	Zero days
EU/2/09/103/007	Respiporc FLU3	--1	Suspension for injection	Pigs	Intramuscular use	Vial (PET)	250 doses (500 ml)	8 vials	Zero days

--1 Strains of inactivated swine influenza A virus:

Bakum/IDT1769/2003 (H3N2): $\geq 10.53 \log_2$ GMNU*

Haselünne/IDT2617/2003 (H1N1): $\geq 10.22 \log_2$ GMNU*

Bakum/1832/2000 (H1N2): $\geq 12.34 \log_2$ GMNU*

* GMNU – Geometric mean of neutralizing units induced in Guinea pigs after twice immunisation with 0.5 ml of this vaccine