

STATEMENT ON A NONPROPRIETARY NAME ADOPTED BY THE USAN COUNCIL

USAN (FG-106)

ELIFACTANT

PRONUNCIATION

el" i fak' tant

THERAPEUTIC CLAIM

Treatment of respiratory distress syndrome (RDS)
in pre-term babies

CHEMICAL DESCRIPTION

The drug product CHF5633 is a synthetic surfactant available as a sterile, non-pyrogenic suspension at a concentration of 80mg/mL in 0.9% sodium chloride solution. CHF5633 contains 4 active ingredients (two phospholipids and two proteins) and a pH adjuster.

CHEMICAL NAMES

DPPC:

1. 3,5,9-Trioxa-4-phosphapentacosan-1-aminium, 4-hydroxy-N,N,N-trimethyl-10-oxo-7-[(1-oxohexadecyl)oxy]-, inner salt, 4-oxide, (7R)-
2. 1,2-Dipalmitoyl-3-sn-phosphatidylcholine

POPG, Na:

1. 9-Octadecenoic acid (9Z)-, (1R)-1-[[[(2,3-dihydroxypropoxy)hydroxyphosphinyl]oxy]methyl]-2-[(1-oxohexadecyl)oxy]ethyl ester, sodium salt (1:?)
2. 1-Palmitoyl-2-oleoyl-sn-glycero-3-[phospho-rac-(1-glycerol)] sodium salt

SP-B analogue:

L-Serine, L-cysteinyl-L-tryptophyl-L-leucyl-L-cysteinyl-L-arginyl-L-alanyl-L-leucyl-L-isoleucyl-L-lysyl-L-arginyl-L-isoleucyl-L-glutaminy-L-alanyl-L-leucyl-L-isoleucyl-L-prolyl-L-lysylglycylglycyl-L-arginyl-L-leucyl-L-leucyl-L-prolyl-L-glutaminy-L-leucyl-L-valyl-L-cysteinyl-L-arginyl-L-leucyl-L-valyl-L-leucyl-L-arginyl-L-cysteinyl-, cyclic (1→33),(4→27)-bis(disulfide)

SP-C analogue:

L-Leucine, L-isooleucyl-L-prolyl-L-seryl-L-seryl-L-prolyl-L-valyl-L-histidyl-L-leucyl-L-lysyl-L-arginyl-L-leucyl-L-lysyl-L-leucyl-L-leucyl-L-leucyl-L-leucyl-L-leucyl-L-leucyl-L-isooleucyl-L-leucyl-L-leucyl-L-leucyl-L-isooleucyl-L-leucylglycyl-L-alanyl-L-leucyl-L-leucyl-L-leucylglycyl-

MOLECULAR FORMULA	DPPC: C ₄₀ H ₈₀ NO ₈ P POPG, Na: C ₄₀ H ₇₆ O ₁₀ P x Na SP-B analogue: C ₁₇₄ H ₃₀₂ N ₅₄ O ₃₈ S ₄ SP-C analogue: C ₁₇₈ H ₃₂₀ N ₄₀ O ₃₆
MOLECULAR WEIGHTS	DPPC: 734.0 POPG, Na: 771.0 SP-B analogue: 3886.9 SP-C analogue: 3596.7
TRADEMARK	None as yet
SPONSOR	Chiesi Farmaceutici SpA
CODE DESIGNATIONS	CHF5633.00; CHF5301.02; CHF5736.03; CHF4902.03; CHF5300.00
<u>CAS</u> REGISTRY NUMBERS	DPPC: 63-89-8 POPG, Na: 202070-86-8 SP-B analogue: 2056154-08-4 SP-C analogue: 1018791-84-8
UNII	DPPC: 319X2NFW0A POPG, Na: T52TI8BMQ6 SP-B analogue: ZKZ1GWO03M SP-C analogue: 9P7G9J82TG

SCS