

Date: 08/23/10 Revision: 3 Form: 4.4-005

PROOF CHECKLIST

Job No. #2721

Customer Ony BiotechDate sent 9/4/2019 1st ☒ 2nd ☐ 3rd ☐ 4th ☐☐ Kodak Approval☐ Kodak MPI☒ PDF☐ Black and White

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Composition: Infasurf is an off-white suspension derived from calf lung surfactant. It includes phospholipids, neutral lipids and hydrophobic surfactant-associated proteins B and C (SP-B and SP-C) at a pH of 5.0-6.2 (target pH 5.7). Each mL contains 35 mg phospholipids (including 26mg phosphatidylcholine of which 16 mg is disaturated phosphatidylcholine) and 0.7 mg protein (including 0.26 mg of SP-B) suspended in 0.9% sodium chloride aqueous solution. (105 mg phospholipids and 2.1 mg protein in 3 mL).

LOT
MFG
EXP
MAL13085059AZ

JAUHI DARI KANAK-KANAK
KEEP OUT OF REACH OF CHILDREN
UBAT TERKAWAL/CONTROLLED
MEDICINE

PRH: TRANSMEDIC HEALTHCARE
SDN BHD
B4-1-1, SOLARIS DUTAMAS, NO 1
JALAN DUTAMAS 1, 58100 KL,
MALAYSIA

Rev. 07/19

NDC 61938-456-03
Single Use Vial

Infasurf® 3mL
(calfactant)

Intratracheal Suspension
Sterile, Non-Pyrogenic
Suspension for Intratracheal
Instillation Only.

NOT FOR INJECTION
Each mL contains
35 mg phospholipids and
0.7 mg protein

Rx only
STORE AT 2° - 8° C (36° - 46° F)
PROTECT FROM LIGHT STORE UPRIGHT

Swirl gently to resuspend
before use

Single use vial:
discard unused portion

For Intratracheal
use only.

NOT FOR INJECTION

Dosage: 3mL of Infasurf
per kg of body weight.

See package insert for full
prescribing information.

 **onybiotech**

Manufactured by
ONY Biotech Inc., Amherst, NY 14228

Infasurf is stored refrigerated
(2-8°C). Date and time need to
be recorded on the carton
when Infasurf is removed from
the refrigerator.

Infasurf SHOULD NOT BE REMOVED
FROM THE REFRIGERATOR FOR
MORE THAN 24 HOURS. Infasurf
SHOULD NOT BE RETURNED TO THE
REFRIGERATOR MORE THAN ONCE.

Removal

Date: _____ Time: _____

Return

Date: _____ Time: _____



Customer: ONY INC.	Size: 1.375 x 1.187 x 2.125	DESIGNER
Job No: 181483 181686	Style: FST	SRC
Cad No: INFASURF 3ML	Stock: 016SBS	
Date: 02/02/11	Blank: 5.718 x 5.874	

Do not alter carton structure or dimensions. Do not alter drawing informational data above

PRINT
SIDE