2721-6ml Pantone 607 Pantone 225 Black Die Line Does Not Print

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

PROOF CHECKLIST

Job No. #2721

Customer Ony Biotech

Date sent 9/4/2019 1st [X] 2nd [ ] 3rd [ ] 4th [ ]

[ ] Kodak Approval [ ] Kodak MPI

[X] PDF [ ] Black and White

This Proof is submitted for the approval of process color, color separation, size, copy, position, and cropping. Spot colors (if any) may not match actual production colors. Refer to Match or PANTONE® Color Chips for correct color.

Clearly indicate any corrections and/or changes on the Proof or attachment. All instructions must be in writing. Sign this form and return the Proof. If a "New Proof" is required due to customer alterations, the changes will be made and charged to the job.

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THIS FORM MUST BE SIGNED

Sign here _____
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Sign here _____
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Sign here _____
Correct and show revised proof

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

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. (210 mg phospholipids and 4.2 mg protein in 6 mL).

NDC 61938-456-06

Single Use Vial

Infasurf® 6mL

(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

℞ only

STORE AT 2°- 8° C (36° - 46° F)

PROTECT FROM LIGHT

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:**_____

N 3 61938 45606 3

McCowat-Mercer Packaging, Inc.	Customer: ONY INC.	Size: 1.375 x 1.187 x 2.125	DESIGNER SRC
	Job No: 181483 181686	Style: FST	PRINT SIDE
	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