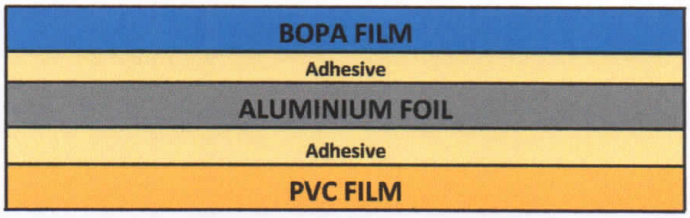
- **Estructura del Producto:**



Aplicaciones Típicas: Material utilizado especialmente en envasado de productos farmacéuticos y médicos que exigen la más alta barrera al oxígeno, vapor de agua, gases en general y luz, mediante el procesamiento de blisters a baja temperatura.

- **Datos técnicos:**

Materiales	**CFF254560**	**CFF255060**
Espesor [µm]		
BOPA Film	25.0	25.0
Adhesivo	-	-
Foil de Aluminio	45.0	50.0
Adhesivo	-	-
PVC Film	60.0	60.0
Total	138.0	143.0
Tolerancia	+/-10 %	+/-10 %
Gramaje [g/m^2]		
BOPA Film	28.8	28.8
Adhesivo	4.0	4.0
Foil de Aluminio	121.5	135.0
Adhesivo	4.0	4.0
PVC Film	78.6	78.6
Total	236.9	250.4
Tolerancia	+/-10 %	+/-10 %
Rendimiento [m^2/kg]	4.22	3.99

- **Contacto con Alimentos**

La composicion del presente producto se encuentra archivada en la Food and Drug Administration (FDA) de los Estados Unidos bajo el *Drug Master File nro. 030678 type III.*

- **Aprobaciones de sus componentes:**

- BOPA Film: Se encuentra de acuerdo pero no limitado a las siguientes legislaciones:
European Pharmacopeia with Directive 2002/72/EC
U.S. FDA Code of Federal Regulations CFR 21 aplicables
UE Directive 94/62/EC
cGMP

- PVC Film: Se encuentra de acuerdo pero no limitado a las siguientes legislaciones:
European Pharmacopeia with Directive 2002/72/EC
USP / U.S. FDA Code of Federal Regulations CFR 21 aplicables
U.S. CONEG Regulations
UE Directive 94/62/EC
cGMP

- Aluminio Foil: De acuerdo al proceso de fabricación, el foil de aluminio empleado es completamente estéril, no contiene plastificantes y es ambientalmente seguro. Se encuentra de acuerdo pero no limitado a las siguientes legislaciones:
DIN EN 602:2004 (Aluminium and aluminium alloys)
Directivas EN 515, EN 546, EN 573 y AFCO – Aluminium Foil Conference (Recomendaciones A, B, C y D).
U.S. FDA Code of Federal Regulations CFR 21 178.3910
U.S. CONEG Regulations
EU-Directive 94/62/EC

- Adhesivos: Se encuentran de acuerdo con las siguientes legislaciones:

DM 21/3/1973 y posteriores updates
FDA 21 CFR 175105
BGA, parag. XXVIII

- **Presentación:**

- Buje: Cartón 3" o 6" (Estándar) o Plástico 3".

- Diámetro Exterior de Bobina: De acuerdo a solicitud del cliente. Máximo 600 mm.

- Cantidad Máxima de Empalmes por bobina: 3 cada 1500 m (en color rojo).

- Bobinado: PVC interno o de acuerdo a lo solicitado..

- Embalaje: Sobre tarima de madera estándar, dentro de bolsa de polietileno cerrada con plug inyectado, strechada y sunchado, o de acuerdo a especificación del cliente.

- Identificación: Dentro del buje, sobre la bobina y fuera del pallet.

- **Uso final:** Formado en frío para medicinales.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

DMF 030678

DMF ACKNOWLEDGEMENT

SILILABEL S.A.
ATTENTION: ENG. NICOLAS GERZENSTEIN
PTEFRONDIZI 2501, PILAR
PROVINCIA DE BUENOS AIRES, ARGENTINA

Dear Eng. Nicolas Gerzenstein,

The Food and Drug Administration acknowledges receipt of the following Drug Master File (DMF) submission:

DMF NUMBER ASSIGNED:	030678
DATE OF SUBMISSION:	AUGUST 14, 2016
DMF TYPE:	III
SUBJECT (TITLE):	BLISTER MATERIALS
HOLDER:	SILILABEL S.A.
SUBMITTED BY:	SILILABEL S.A.

All subsequent correspondence to this DMF should be identified with the information as provided above.

Your DMF will be reviewed only in connection with a New Drug Application, Abbreviated New Drug Application, Investigational New Drug Application, Biological License Application, New Animal Drug Application, Abbreviated New Animal Drug Application, Investigational New Animal Drug Application, or DMF it is intended to support when a Letter of Authorization (LOA) is submitted to the DMF and a copy of the LOA is submitted in the application e.g., NDA, that references the DMF.

You are responsible for compliance with 21 CFR314.420. See "The Guideline for Drug Master Files" http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/DrugMasterFilesDMFs/ucm073164.htm

You are required to submit all changes in information regarding the DMF (21 CFR 314.420(c)). In particular the FDA must be notified of any changes in the holder name or ownership and/or the agent and/or the name of the contact person.

The types of information to be submitted may be found at the DMF Web Site. See "**Submission of Amendments, Annual Reports, and Letters of Authorization.**

You are expected to:

- Adhere to the statement of commitment you have provided.
- Provide the following submissions to the DMF:

a. Letters of Authorization (LOAs) granting permission to a third party (authorized party) to reference the DMF and for FDA to review the DMF. Listing an authorized party in the Annual Report (see below) is not sufficient to authorize that party to reference the DMF. Submission of a copy of the LOA to the authorized party without submitting the original LOA to the DMF is also not sufficient to authorize that party to reference the DMF.
b. Annual Reports to the DMF containing:
    i. Date(s) of the amendment(s) reporting changes since the last Annual Report or the original DMF filing date, whichever is most recent or a statement that no amendments have been submitted since the last Annual Report or the original DMF filing date, whichever is most recent.
    ii. A complete list of all parties authorized to make reference to the DMF, identifying by name, reference number, volume, date, and page number the information that each person is authorized to incorporate and the date of the LOA or a statement that there are no Authorized Parties.
    iii. A list of all parties whose authorization has been withdrawn, if applicable.

Submissions containing multiple types of information e.g. administrative changes, an annual report, or changes in technical information should specify the different types of information in the header in the cover letter.

Electronic submissions that are 10GB or smaller in size must be submitted through the Electronic Submission Gateway (ESG). Submissions that are over 10GB may be submitted on physical media (such as compact disc)[1] to the following address:

Food and Drug Administration
Center for Drug Evaluation and Research
Central Document Room
Drug Master File Staff
5901-B Ammendale Road
Beltsville MD 20705-1266

If you have any questions, please email dmfquestion@cder.fda.gov

Sincerely,
{See appended electronic signature page}
Vathsala Selvam
Drug Master File
Division of Life Cycle API/ONDP/OPQ
Center for Drug Evaluation and Research
Food and Drug Administration

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[1] See FDA eCTD Web Page for further information.
http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/ucm153574.htm.

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

CLAUDE THEOPHIN
08/16/2016