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Prepared By: Approved By:

FSTL CEO

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Amendment sheet

Sr.No	SECTION NO.			NATURE REVISIION	OF	APPROVED PRESIDENT	ВҮ
		Rev No	Rev Date				

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Terms & Definitions:

 $\underline{\textbf{HACCP}} \text{ - a system which identifies, evaluates, and controls hazards which are significant for food safety.}$

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<u>Food Safety</u> - assurance that food will not cause harm to the consumer when it is prepared and/or eaten according to its intended use.

HACCP Plan: The written document which is based upon the principles of HACCP and which delineates the procedures to be followed.

<u>Hazard</u> - a biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect.

Hazard Analysis: The process of collecting and evaluating information on hazards associated with the packaging under consideration to decide which are significant and must be addressed in the HACCP plan. A list of hazards associated with raw materials and each process step is compiled. Each hazard will be evaluated when determining Critical Control Points. The HACCP Team must consider where the end product will be used. Product safety concerns are considered during the hazard analysis.

Control Measure:

Any action or activity that can be used to prevent, eliminate or reduce a significant hazard.

Control Point:

Any step at which biological, chemical, or physical factors can be controlled.

Critical Control Point:

A step at which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce it to an acceptable level.

Critical Limit:

A maximum and/or minimum value to which a biological, chemical or physical parameter must be controlled at a CCP to prevent, eliminate or reduce to an acceptable level the occurrence of a food safety hazard.

Hazard Analysis:

The process of collecting and evaluating information on hazards associated with the food under consideration to decide which are significant and must be addressed in the HACCP plan.

Prerequisite Programs:

Procedures, including Good Manufacturing Practices, that address operational conditions providing the foundation for the HACCP system.

Validation:

That element of verification focused on collecting and evaluating scientific and technical information to determine if the HACCP plan, when properly implemented, will effectively control the hazards.

Verification:

Those activities, other than monitoring, that determine the validity of the HACCP plan and that the system is operating according to the plan.

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1. PRODUCT INFORMATION

Name of the Product: Polyester Metalized Film

Production Technique: Film is manufactured from PET Chips through the extrusion process, casting, orientation, coating, metallizing, slitting and packing. Film is chemically nontoxic and has a good barrier to both oxygen and moisture. Entire production is carried in clean, hygienic and controlled environment. Each roll has an identification number with traceability and final slit rolls are also have a proper bar code to find roll information and product detail. Metallizing is the secondary process of film to increase the barrier properties

Packaging: Slit rolls are wrapped in blue polyethylene and air bubble film for Metallize rolls, sides are protected by side foam if required and suspended on wooden end fitments along with core plug and kept on wooden pallets ensuring that they do not come in contact with the pallet. Pallets are further stretch wrapped for controlling atmospheric contamination. Sachets of silica gel are placed on every pallet during container loading intended for export.

Best for use: Film recommended to store in non-humid environment should be in packed conditions till the final usage. Film should be stored in non-humid environment to protect from moisture. Metalized film is recommended to be used within 6 months after dispatch.

Transportation Mechanism: Packed rolls are transported through containers with clean inside and it is checked regularly by Quality Section. Stuffed containers are fumigated after loading.

Specifications: Company specifications have been documented in the Plant Work Instructions.

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2.1 Hazard and Risk Management Team

It is ensured that all the team members are competent in hazard and risk analysis principles and updated with factory changes and customer requirements as they occur.

Hazard and Risk Management Team

Name	Department	Role	
	Quality	Team Leader	
	Engineering	Team Member	
	Production	Team Member	
	Store & Purchase	Team Member	
	Packing & Dispatch	Team Member	

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2.2 Hazard Analysis and Risk Assessment (HARA)

Scope of hazard analysis and risk assessment is to manufacture and supply of Polyester Film and its Metallization. Scope includes the raw materials, ingredients, packaging materials and other processing aides.

Team maintains awareness and takes into account of all relevant information such as the origin of the raw materials, addictive, packing materials etc required to conduct the hazard analysis are collected, maintained and updated and the records are maintained. Information on historical, known and foreseeable product safety hazards, likely product defects that affects safety, relevant codes of practices or recognized guidelines and legislative requirements.

Intended use

Metallized film does not come directly in contact with Food. Film is produced for packaging applications intended for packaging of food stuff, etc as an insulating material for electrical application, decorative application, etc.

Polyester film is being used for food application as below.

Polyester film is used for reverse printing. This reverse printed film is laminated with Al foil or metallized film and then with polyethylene. Laminate is used for making pouch in which food material is packed. Film will not come in direct contact with polyester film.

Jumbo roll of polyester film is manufactured from Jumbo rolls, slit rolls are produced on slitting machine.

Slit rolls are wound on paper cores. Film is attached with adhesive tape on paper cores. After completing of slit rolls, rolls are wrapped with polyethylene and ensure that polyethylene is entered in the paper core. Rolls are supported with plywood and end cup.

During processing at customer end initial film is waste for adjusting their process, printing is done till end of roll. Initial few meters are not used due to wrinkles and ripples on the rolls. Before making final pouch they take trim from printed roll.

Metallized film are sold internationally and locally to traders etc.

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Process Flow Diagram

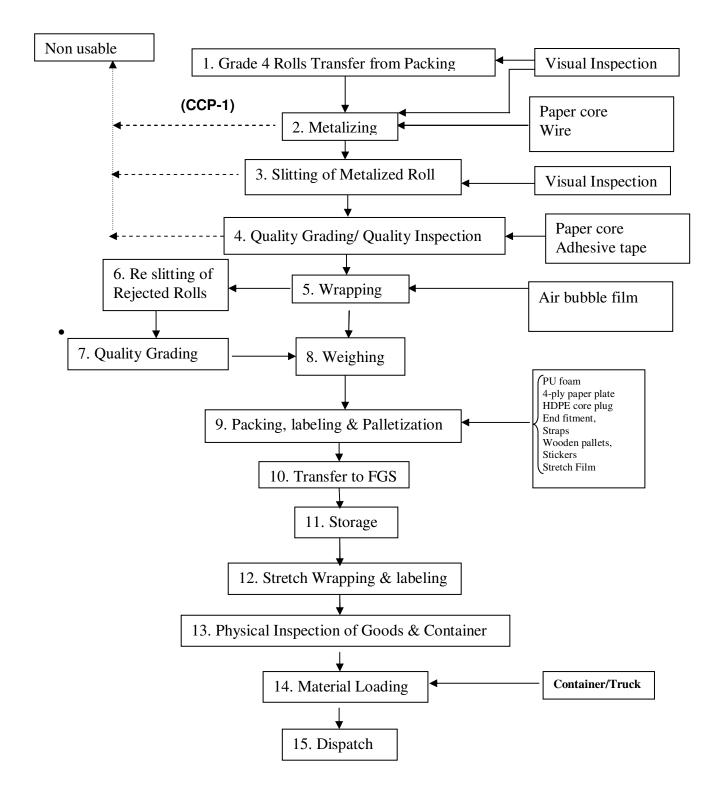
Processes stages of the product category are involved in the production, have documented a schematic production supply and storage processes. The process flow diagrams for production of metallized coated film process are given in this section of the manual provides an insight into the control of operations.

While preparing flow diagram considered aspects are detailed below:

- Receipt and preparation of raw materials
- Use of recycled materials
- Any subcontracted process
- Customer returns

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Flow Diagram -- Metallizer Plant



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Flow Diagram on Site Confirmation

Food safety team has verified on-site checking of the flow diagram for its adequacy and the records of the same are maintained.

Hazard Assessment

Food safety team conducts a hazard analysis to determine which hazards to be controlled, the degree of control required to ensure food safety, and which combination of control measures is required.

Hazard Identification and Determination of Acceptable Levels

All food safety hazards that are reasonably expected to occur in relation to the type of product, type of process and actual processing facilities are identified and recorded. The identification is based on

- Preliminary information and data collection from inputs.
- Experience,
- External information including, to the extent possible historical data and
- Information from the food chain on food safety hazards that may be relevance for the safety of the end products, intermediate products and the food at consumption.

Steps from the (raw material, processing and distribution) at which each food safety hazard can introduced are indicated.

When identifying the hazards, consideration is given to

- Steps preceding and following the specified operation,
- Process equipment, utilities/services and surroundings, and
- Preceding and following links in the food chain.

For each of the food safety hazard identified, the acceptable level of the food safety hazard in the end product shall be determined whenever possible. The determined level shall take into account established statutory and regulatory requirements, customer food safety requirements, the intended use by the customer and other relevant data.

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Hazard Analysis

A hazard assessment is conducted to determine, for each food safety hazard identified, its elimination or reduction to acceptable levels. This is essential for the production of PET suitable for food contact. Whether its control is needed to assure that the defined acceptable levels will be met.

Each food safety hazard is evaluated according to the possible severity of adverse health effects and the likelihood of their occurrence based on the following parameters:

Sr. No	Likelihood	Point
1	Most likely (daily)	4
2	Likely (Weekly)	3
3	Least likely (Monthly)	2
4	Negligible(Six months)	1

Sr. No	Severity	Point
1	Hospitalization	4
2	Illness	3
3	Medication	2
4	Inconvenience	1

Calculation of the risk factor

Likelihood * severity = Risk.

If the risk = 9 or higher than this item will be considered as significant and further evaluated for CCP determination using decision tree.

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Hazard Analysis Work sheet

PRODUCT: Metalized Film

Process	Hazard	Source or cause	Assessment				
step	Туре	of hazard	Likelihoo d	Severity	Risk	Control measure	Signif icant
1 Transfer	B-Y	Contamination from facility	2	1	2	GMP	N
from Packing	P-Y	Foreign bodies: dust	1	2	2	Cleaning of Dust before removing wrapping	N
	C-Y	Contamination from sources	2	1	2	GMP	N
2	B-Y	Nil	2	1	2	Nil	N
Metalizing	P-Y	Uneven Metalizing Process	3	4	12	Wire feeding, boat temperature, machine speed and vacuum condition controlled.	Υ
	C-N	Nil	2	1	1		N
4,7	B-N	Nil	1	1	1	Nil	N
Quality Gradation /Inspectio n	P-Y	Foreign particles from surrounding Like—dust	1	2	2	Good Housekeeping practices, Air Filtration, Floor wiping, Use of air curtains , restricted access to the area	N
	C-Y	Contamination with water	1	2	2	Visual inspection Prev. maintenance	N
3,5,6,8 Slitting of	B-Y	Contamination from facility	2	1	2	GMP	N
Metalized film, Wrapping Re slitting of rejected rolls, Weighing	P-Y	Foreign bodies: dust,	1	2	2	Good Housekeeping practices, Air Filtration, Floor wiping, Use of air curtains , restricted access to the area	N
	C-Y	Contamination from sources	2	1	2	GMP	N

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Process	Hazard	Source or cause		Assessment				
step	Туре	of hazard	Likelihoo d	Severity	Risk	Control measure	Signifi cant	
9,10,11,12 Packing, Labeling & Palletization , Transfer to FGS, Stretch Wrapping & Labeling Storage	B-Y	Nil	2	1	2	Nil	N	
	P-Y	Dust, Soot from Fork lift contamination	2	2	4	Good Housekeeping practices, Air Filtration, Floor wiping, Use of air curtains, restricted access to the area	N	
	C-N	Nil	2	1	1	Nil	N	
13,14,15 Physical	B-N	Nil	1	1	1	Nil	N	
Inspection of goods and	P-Y	Foreign particles from surrounding	1	2	2	Checking of container, Use of Desiccant material	N	
Container Loading of material to container/Tr uck, Dispatch	C-N	Nil	1	2	2	Visual inspection	N	

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Identification of critical control points / monitoring CCPs / monitoring results by decision tree

Process step	Significa nt Hazard	Q1a - Do preventive measures exist at this or subsequen t steps for the identified hazard? If no →go to Q1b If yes → go to Q2	Q1b - Is control at this step necessary for safety? If no → not a CCP If yes → modify step, process or product and return to Q1a	Q2 - Does this step eliminates the hazard or reduces the likelihood of its occurrence to an acceptable level? If no → go to Q3 If yes → CCP	Q3 - Could contamination with identified hazard(s) occur in excess of acceptable levels or could these hazard(s) increase to an unacceptable level? If no → not a CCP If yes → go to Q4	Q4 - Will a subsequent step eliminate the identified hazard(s) or reduce the likelihood of occurrence to an acceptable level? If no → CCP If yes → not a CCP	CCP
10, 13 Ferrous material can be released and contaminate the product	Foreign bodies: Ferrous particles	Y		N	Y	Y	
18,19,22,23,2 5Product will be contaminated with foreign particle	Foreign particles	Y		N	Υ	Y	
2 Metalizing	Uneven metalizin g	N	N	N	N	N	CCP1

B: Biological, C: Chemical, P: Physical.

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HACCP Plan Establishment

HACCP plan is documented to include information for each identified critical control point (CCP) as detailed below:

- Food safety hazard(s) to be controlled at the CCP
- Control measures
- Critical limits
- Monitoring procedures
- Corrections and corrective actions to be taken if critical limits are exceeded
- · Responsibilities and authorities;
- Record of monitoring.

HACCP plan

Step	Critical limit	Monitoring		Corrective Action	Verification Procedure	Record		
		Who	What	How	When			
2 Metalizi ng	Ordered value of optical density - 0.2	Shift In charge and operator	Wire Speed, film speed, boat power	Auto contro I	Continuou sly by plc , and manually once in a roll	Line: PLC suitably adjusts the wire and film speed and boat power Product: Reclassify the product	periodic audit by verification	printout and process parameter Log book

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HACCP Plan Verification and Validation

Verification confirms that the HACCP plan is being followed and Validation confirms that the HACCP plan properly addresses the appropriate activities.

Verification

The activities such as: an annual internal (or external) audit to confirm the HACCP plan is being followed as written; confirmation of operator training; confirmation of operator competence with respect to monitoring OPRPs/CCPs and addressing out-of compliance occurrences; HACCP record review; previous HACCP plan audits; and, spot-checking prerequisite program.

Verification assures that the HACCP plan is operating effectively on a day-to-day basis.

HACCP Plan Verification Schedule

Activity	Frequency	Responsibility	Reviewer
Initial Review of HACCP Plan	Prior to and during initial implementation of plan	3rd Party Auditor	Food safety Team
Verification Activities Scheduling	Yearly or upon HACCP System change	FSTL	Plant Manager
Subsequent Review of HACCP Plan	When Critical Limits changed, significant changes to process, equipment changed, after system failure, etc.	3rd Party Auditor	Food safety Team
Verification of CCP Monitoring as Described in the Plan	According to HACCP Plan	According to HACCP Plan	According to HACCP Plan
Review of Monitoring Corrective Action Records to Show Compliance with the Plan	Quarterly	Quality Assurance	Food safety Team
Comprehensive HACCP System Verification	Yearly	3rd Party Auditor	Plant Manager

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HACCP Validation Schedule

Activity	Frequency	Responsibility	Reviewer
Were all hazards considered?	Yearly or when Critical Limits changed, significant changes to process, equipment changed, after system failure, etc.	Food safety Team	Plant Head
Were correct CCP's /OPRPs chosen?	Yearly or when Critical Limits changed, significant changes to process, equipment changed, after system failure, etc.	Food safety Team	Plant Head
Are Critical Limits meaningful/ actionable?	Yearly or when Critical Limits changed, significant changes to process, equipment changed, after system failure, etc.	,	Plant Head
Are the correct parameters monitored at the correct frequency?	Yearly or when Critical Limits changed, significant changes to process, equipment changed, after system failure, etc.	Food safety Team	Plant Head

HACCP Plan Reassessment

HACCP plan will be reassessed on an annual basis at minimum and/or when there are: changes to the plant; changes in key processing equipment; changes to primary raw materials; industry alerts concerning materials, processes, or equipment; industry/facility recalls; repeated/trended customer complaints; and; any change in materials, processing, or equipment that would lead to challenges to the HACCP Plan.