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Product Safety Plan Scope

This Product Safety plan has been created using a multi-disciplinary approach, with creation of the plan overseen by a HARA Team Leader.
The scope of this plan includes Flexographic, letterpress, and offset printing on continuous roll and pressure-sensitive labels for use with consumer products.

Product Safety Team

Name:	Position:	Review Signature/Date
Joeseph DeAngelo	President	J. DeAngelo 10/20/23
Alfred Knapp	Vice President of Operations / QA Production	A.Knapp 10/20/23
Suzette Remy	Director of Office Operations	S. Remy 10/20/23
Janet Tropiano	Human Resources	J. Tropiano 10/20/23
Reuben Luna	Press Supervisor	Reuben Luna 10/20/23
Milan Brusic	Quality Assurance/Compliance *HARA Team Leader	M. Brusic 10/20/23

Product Safety Team Meetings:

The Product Safety Team meets on a bi-annual basis, or as relevant events occur requiring more frequent meetings.

Characteristics of End Products

Product Name or Similar Identification:	
Pressure Sensitive Label	
Composition:	
Face Stock, Adhesive, Liner, Decoration, Protective Coating	
Characteristics Relevant for Product Safety:	
Biological:	Printed labels (inks on substrate, paper or resin based). Product is unlikely to support microbiological growth
Physical:	Printed labels (inks on substrate, paper or resin based). Product is not likely to support physical hazards
Chemical:	Printed labels (inks on substrates, paper or resin based). Product is not likely to support chemical hazards
Functional:	Aesthetic (color, quality) and regulatory (smeared, missing copy), functional integrity (wind direction, size) defects and quality issues as described in risk assessment
Shelf Life and Storage Conditions:	
1-2 years when stored in dry, ambient conditions	
Packaging:	
Rolls in Poly bags/Shrink, inside of a corrugated shipper	
Labelling Relating to Product Safety and/or Instructions for Handling, Preparation, and Usage:	
No special product safety labelling or instructions required. Product is ready for use as is	
Method(s) of Distribution:	
Delivered by courier to customer.	

Intended Use

For use in labeling of consumer products
Target Consumer Groups:
N/A

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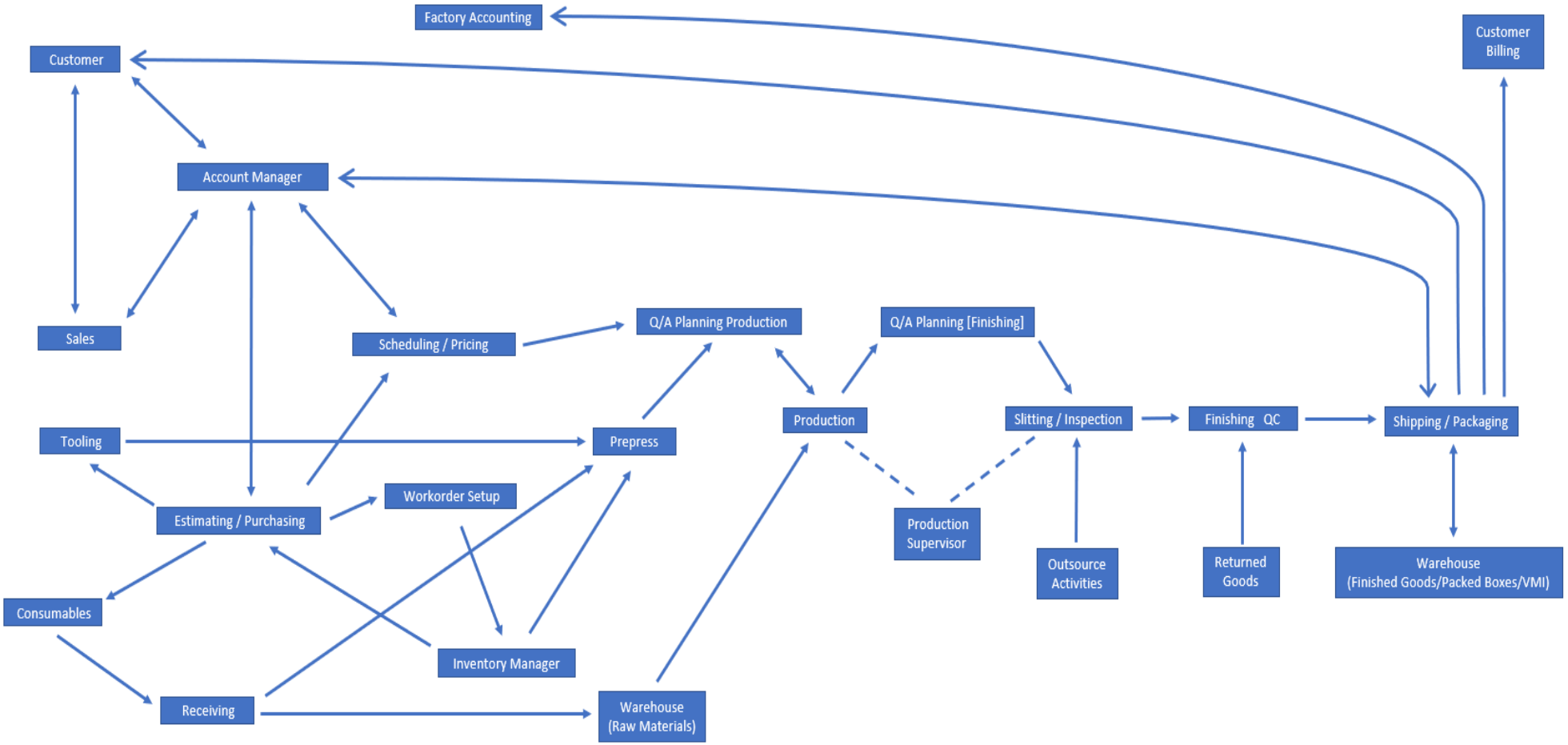
Process Flow Diagram



Description of Process Steps

#	Step and Description
1	Receipt of Art/Specs/PO Work with Customer to identify the needs and collect necessary information to proceed to manufacturing
2	Generate Work Order Create work order ticket that identifies all specifications required to produce end product
3	Receiving Collect all incoming raw materials and consumables required for production
4	Pre-press Review and confirm all items received are correct and available to fulfill work order
5	Production Manufacture of required goods as per SOP to conform to required specifications
6	Slitting/Inspection Convert master rolls into finished rolls and ensure conformability to final specifications
7	Packing Package finished rolls in a way that maintains the quality of the project when shipped
8	Storage Finished packages are stored in warehouse awaiting distribution
9	Distribution Physical act of sending finished goods via courier to final destination
10	Outsourced Processes In-process materials returned to Kroger packaging to inspection prior to shipping to client
11	Customer Returns Approved returns that are segregated and treated as non-conforming product.

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Product Safety Hazard Analysis and Risk Assessment

Materials

(1) Material Type / Description	(2) Known or reasonably foreseeable product safety hazards inherent to this material		(3) Likelihood of Occurrence (1-5)	(4) Severity of Potential Quality Defects (1-5)	(5) Overall Risk Rating (column 3 X column 4)	(6) Justification for Column (5)	(7) Based on the decision matrix, does a hazard exist requiring additional control?			(8) Description of PRP or other control measure applied, if applicable; if hazard is not controlled, provide justification
							Yes	No	If yes, list step; if no, refer to column 8	
<u>Consumables:</u> Substrate (Paper, laminate, etc.)	Biological	None	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Chemical	None	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Physical	Damaged/ Contamination	1	1	1	Receiving SOP/Supply Chain SOP		X	N/A	Receiving SOP/Supply Chain SOP
	Functional	Wrong Product	1	1	1	Production/QA Verification SOP		X	N/A	Production/QA Verification SOP
<u>Consumables:</u> Inks / Foil	Biological	None	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Chemical	None	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Physical	Damaged/ Contamination	1	1	1	Receiving SOP/Supply Chain SOP		X		Receiving SOP/Supply Chain SOP
	Functional	Wrong Product	1	1	1	Production/QA Verification SOP		X	N/A	Production/QA Verification SOP

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Consumables: Varnish	Biological	None	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Chemical	None	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Physical	Damaged/ Contamination	1	1	1	Receiving SOP/Supply Chain SOP		X		Receiving SOP/Supply Chain SOP
	Functional	Wrong Product	1	1	1	Production/QA Verification SOP		X	N/A	Production/QA Verification SOP

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Product Safety Hazard Analysis and Risk Assessment

Process Steps

(1) Material Type / Description		(2) Known or reasonably foreseeable product safety hazards inherent to this material	(3) Likelihood of Occurrence (1-5)	(4) Severity of Potential Quality Defects (1-5)	(5) Overall Risk Rating (column 3 X column 4)	(6) Justification for Column (5)	(7) Based on the decision matrix, does a hazard exist requiring additional control?			(8) Description of PRP or other control measure applied, if applicable; if hazard is not controlled, provide justification
							Yes	No	If yes, list step; if no, refer to column 8	
Artwork	Biological	None	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Chemical	None	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Physical	None	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Functional	Inconsistent Art with Spec (Size, color etc. doesn't match)	3	1	3	Comparison of work order and specs to art in Production QA SOP		X	N/A	Comparison of work order and specs to art in Production QA SOP
		Artwork received is filed/saved as incorrect item #	1	1	1	Though incorrectly label art can cause an issue in producing the wrong product it is highly unlikely that this event will happen.		X	N/A	Item # is listed on actual printout of art and QA is also responsible to verify item # on art as per SOP.

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	Biological	None	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Chemical	None	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Physical	None	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Generate Workorder	Functional	Incorrect Information	1	3	3	SOP in Front Office as well as secondary checks for existing items and comparison to supporting documents when available ensure minimal likelihood of error.		X	N/A	SOP
	Biological	None	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Chemical	None	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Physical	Damaged/ Contamination	1	1	1	Receiving SOP/Supply Chain SOP		X		Receiving SOP/Supply Chain SOP
Receiving	Functional	Wrong Product	1	1	1	Production/QA Verification SOP		X	N/A	Production/QA Verification SOP

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Pre-Press	Biological	None	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Chemical	None	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Physical	Damaged/ Contamination	1	1	1	Pre-Press SOP requires physical review of tooling		X	N/A	Pre-press SOP
	Functional	Tooling/Spec/Workorder does not match	1	1	1	Pre-Press requires review and comparison of documents before going into production		X	N/A	Pre-press SOP
Production	Biological	None	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Chemical	None	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Physical	Dust, Machine Contaminates	1	1	1	This minimized through PM SOP and confirmed not to effect finished product through QC SOP		X	N/A	This minimized through PM SOP and confirmed not to effect finished product through QC SOP
	Functional	Does not meet specification.	1	1	1	Managed through process checks as defined by Production and QC SOPs		X	N/A	Managed through process checks as defined by Production and QC SOPs

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	Biological	None	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Chemical	None	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Slitting/Inspection	Physical	Machine Contaminates	1	1	1	This minimized through PM SOP and confirmed not to effect finished product through QC SOP		X	N/A	This minimized through PM SOP and confirmed not to effect finished product through QC SOP
	Functional	Does not meet specification.	1	1	1	Managed through process checks as defined by Production and QC SOPs		X	N/A	Managed through process checks as defined by Production and QC SOPs
	Biological	None	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Chemical	None	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Physical	Contaminate and Pest Issues	1	1	1	Checked through Pest Control and Shipping SOPs		X	N/A	SOPs
Packing	Functional	Incorrect paper work and/or packaging specs	1	1	1	Shipping SOP ensures packaging specs and Front Office confirms paperwork matches expected information		X	N/A	Shipping and Office SOP's

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Storage	Biological	None	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Chemical	None	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Physical	Contaminate and Pest Issues	1	1	1	Checked through Pest Control and Warehouse SOPs		X	N/A	SOPs
	Functional	Storage Conditions don't meet specified criteria.	1	1	1	SOPs to monitor conditions		X	N/A	SOP's
		Lot # Identification marked incorrectly	1	1	1	SOP's ensure proper storage and markings as well as retrieval.		X	N/A	SOP's
Distribution	Biological	None	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Chemical	None	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Physical	Contamination on Courier trucks	1	1	1	SOP's require use of reliable couriers and require routine checks of vehicle's prior to shipping.		X	N/A	SOP's
	Functional	Incorrect Courier or Method of Shipment is used and/or wrong destination.	1	1	1	Information is communicated via the Packing slip from the office and verified as part of the Shipping SOP.		X	N/A	SOP's

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Outsourced Processes	Biological	None	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Chemical	None	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Physical	Contamination on Courier trucks and outside facility	1	1	1	Quality Inspection Program, Pest Control Program, Supply Chain Program		X	N/A	N/A
	Functional	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Customer Returns	Biological	None	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Chemical	None	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Physical	Contamination on Courier trucks and outside facility	1	1	1	Quality Inspection Program, Pest Control Program, Supply Chain Program		X	N/A	N/A
	Functional	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

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Control Measure Decision Matrix

Raw Materials, Processing Aids, and Packaging Materials

	1	*3*	*5*
1	1	3	5
3	3	9	15
5	5	15	25

Key:

Score	Level of Control Required
1-14	Hazard present at a level that may be controlled through GMP. No additional control beyond PRP required.
15-25	Hazard present requiring control via CCP or measure applied later in the supply chain; refer to process hazard analysis or written assurance from customer as appropriate

Process Steps

	1	*3*	*5*
1	1	3	5
3	3	9	15
5	5	15	25

Key:

Score	Level of Control Required
1-9	Hazard insignificant or very minimally present such as to present no consumption hazards; no additional control required
15-25	Hazard present requiring control via CCP or a measure applied later in the supply chain; refer to CCP monitoring plan or written assurance from customer

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Preventive Control / CCP Monitoring Plan

Process Step	#	Hazard to be Controlled	Critical Limit	Monitoring Procedure				Record(s)	Corrective Actions	Verification
				What	When	How	Who			
We have no Preventative Control Points in our Process.										

PC / CCP Validation Evidence

Preventive Control / Critical Control Point
N/A - no hazards requiring preventive control have been identified. PRP control measures listed in the hazard analyses are validated on a continual basis through the performance of regular verification activities, as described in the PRP verification plan.

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PRP Verification Plan

PRP	Potential Hazard Controlled by PRP	Supporting SOP	Verification Activities			
			What	When	Who	Records
Construction - Walls, Floors, Ceilings, etc.	Harborage of pests and other unsanitary conditions; parts of infrastructure detaching and posing a foreign material risk	N/A	GMP Audit	Monthly	Rotating	GMP Audit Form
Lighting	Poor visibility to detect unsanitary conditions; shatter causing potential contamination	Product Contamination	GOBP Audit	Annually	Rotating	GOBP Form
Pest Prevention	Product contamination with pest bodies and residues	Pest Control	GMP Audit	Monthly	Rotating	GMP Audit Form

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PRP Verification Plan

PRP	Potential Hazard Controlled by PRP	Supporting SOP	Verification Activities			
			What	When	Who	Records
Product Handling Equipment and Protective Clothing	Product contamination due to inadequate/failing equipment; contamination resulting from improperly worn/designed workwear.	Personnel Hygiene	GMP Audit	Monthly	Rotating	GMP Audit Form
Maintenance	Contamination from improperly maintained equipment - foreign matter, grease, etc.	Maintenance	Monthly	Rotating	GMP Audit Form	Monthly
Calibration	Inaccurate data measurement leading to uncertain status of parameter being measured	Calibration	Calibration Review	2x/year	Quality	Equipment Calibration Records
Housekeeping	Unsanitary conditions leading to product contamination	Housekeeping	1. GMP Audit 2. Review of Cleaning Records	Monthly	Rotating	Cleaning Records GMP Audit Form

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PRP Verification Plan

PRP	Potential Hazard Controlled by PRP	Supporting SOP	Verification Activities			
			What	When	Who	Records
Personnel Hygiene and Welfare	Unsanitary personnel practices leading to product contamination	Personnel Hygiene	GMP Audit	Monthly	Rotating	GMP Audit Form
Water, Ice, and Air	Concentration of contaminants at drying step; water used for handwashing not potable	N/A	Potable Water Certificate	Annually	Quality	Potable Water Certificate
Storage and Transport	Contamination from water, dust, pests, foreign matter, allergenic materials, chemicals, etc.	Warehousing	GMP Audit	Monthly	Rotating	GMP Audit Form
Receiving	Use of plant materials that are damaged, contaminated, or otherwise unfit for use	Receiving	Inspection of materials upon arrival	All incoming materials	Warehouse employees	Receiving Log

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PRP Verification Plan

PRP	Potential Hazard Controlled by PRP	Supporting SOP	Verification Activities			
			What	When	Who	Records
Control of Foreign Matter	Contamination of products with foreign material	Product Contamination	GMP Audit GOBP Audits	Monthly Annually	Rotating	GMP Audit Form GOBP Log
Waste Disposal	Accumulation of waste causing unsanitary conditions; unauthorized use of trademarks	Waste	GMP Audit	Monthly	Rotating	GMP Audit Form
Exterior Conditions	Allowance of pest harborage, accumulation of waste, entry of contaminants into building, tracking of contaminants into building, etc.	N/A	GMP Audit	Monthly	Rotating	GMP Audit Form
Allergen Control	Undeclared allergens in products	N/A	N/A	N/A	N/A	N/A

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REVISION HISTORY

Rev.	Revision Date	Modified by	Reason for Modification
01	1/6/22	J. Lott	New
02	6/24/22	M. Brusic	Separated consumables; updated flow chart and scope; risk analysis of returns & outsourced activities
03	10/20/23	M. Brusic	Updated details of Product Safety Team on first page

APPROVED BY

Name	Signature	Date
Joe DeAngelo	*Joseph DeAngelo*	10/20/2023