

Protected when completed

Summary of Net Changes Form (SNC)

Please refer to the attached Instructions for Completing the Summary of Net Changes Form before completing.

Note: This form must be completed for each Canadian and/or foreign site listed on the application form. This renewal process only applies to activities that were already authorized, and therefore amendments (addition of activities or sites) are not authorized during this process; a separate application must be submitted.

HC Use Only

Submission Number
File Number
Date/Time of Receipt

Part 1: Site Information

Company/Building Information

Name of Company

Associated Production Services, Inc.

Building Address

100 Louise Drive, Ivyland, Pennsylvania 18974 USA

Site Licence or Foreign Site Reference Number

300664

Part 2: Attestation

"I hereby attest that I have knowledge of the information provided in this application for site licence renewal or foreign site reference number renewal and that the building(s), practice(s), and procedure(s) used in conducting activities in our facility comply with Good Manufacturing Practices as set out in Part 3 of the *Natural Health Products Regulations*."

Name of Quality Assurance Person

Peter Eccles

Signature of Quality Assurance Person

Date (yyyy-mm-dd)

2022-12-08

Part 3: List of Observations and Corrective Actions with Date of Completion (if applicable)

- No observations were noted** in our last site licence cover letter or foreign site reference number notice of acceptance issued by the NNHPD. (If checked, please proceed to part 4.)
- Observation(s) were noted** in our last site licence cover letter or foreign site reference number notice of acceptance issued by the NNHPD. (If checked, please complete the table below.)

Observation(s)	Corrective Action(s) Taken	Date(s) of Completion

Part 4: Summary of Net Changes and Description

- There have been no changes** to the building(s), practice(s), and procedure(s) used in conducting activities in our facility, from the information supplied in our previous site licence or renewal application in support of GMP compliance, as per Part 3 of the Natural Health Products Regulations (the Regulations). (If checked, please complete Parts 5 and 6.)
- There have been changes** to the building(s), practice(s), and procedure(s) used in conducting activities in our facility from the information supplied in our previous site licence or renewal application in support of GMP compliance, as per Part 3 of the Regulations. (If checked, please identify the change(s) by checking the appropriate box(es) in the Summary of Net Changes Table (below) and submit a detailed description by completing the relevant section(s) of the QAR form or by providing another form of acceptable GMP evidence to support the change(s)). Then complete Parts 5 and 6.

Summary of Net Changes Table (Check if applicable)

GMP Categories	GMP Sub Categories	Sections of NHPR	QAR Questions	SQAR Questions
Places	<input type="checkbox"/> Premises	45	1-3	1
	<input type="checkbox"/> Equipment	46	4	2
People	<input type="checkbox"/> Personnel	47	5	3
	<input type="checkbox"/> Quality Assurance	51	6	N/A
Processes	<input type="checkbox"/> Sanitation Program	48	7	4
	<input type="checkbox"/> Operations	49	8	5
	<input type="checkbox"/> Operations - Recall	50 & 62	9	N/A
Products	<input type="checkbox"/> Specifications	44	10	6
	<input type="checkbox"/> Stability	52	11	7
	<input type="checkbox"/> Samples	61	12	N/A
	<input type="checkbox"/> Records	53-58	13	N/A
	<input type="checkbox"/> Sterile Products	59 & 60	14	N/A

Part 5: Records (Please provide records dated from within the last 12 months)

Record	Check Box	Record Type	Relevant Section(s) of Part 3 of NHPR	Instructions	Example of Acceptable Record Types
1	<input checked="" type="checkbox"/>	Storage Controls	45(2)	Supply records demonstrating that natural health products (NHPs) are stored under conditions that maintain quality and safety.	Data logs recording temperature, humidity, and light controls
2	<input checked="" type="checkbox"/>	Pest Control	45(d,e)	Supply records demonstrating that NHPs are manufactured, packaged, labeled and stored in premises that are maintained in a manner that prevents the contamination of the products.	Contractor pest control invoice, internal pest activity inspections logs
3	<input checked="" type="checkbox"/>	Personnel Training	47	Supply records demonstrating that NHPs are manufactured, packaged, labeled and stored by personnel that are qualified by education, training or experience to perform their respective tasks.	Certificates or data logs (with trainee signature) of on-going GMP training (internal or external)
4	<input checked="" type="checkbox"/>	Sanitation	46(a), 48	Supply records demonstrating that NHPs are manufactured, packaged, labeled and stored in compliance with a sanitation program.	Data logs of site/facility cleaning and equipment cleaning (include schedules and frequencies)
5	<input checked="" type="checkbox"/>	Finished Product Testing	44(1,2), 51(4)	Supply: <ul style="list-style-type: none"> Records demonstrating that every NHP complies with its specifications with respect to medicinal ingredients, identity, quantity and potency if applicable, and product purity (a record of full testing for one NHP). Note: Importers may provide records of testing conducted by the manufacturer Records of raw material testing only if it is part of the finished product specifications. 	Certificate of analysis (CoA), batch records of finished products and raw materials, if applicable
6	<input checked="" type="checkbox"/>	Quality Assurance and Product Release	51	Supply records demonstrating that every lot or batch of NHPs has been approved by a quality assurance person before being made available for sale.	Finished product release record or release certificate
7	<input checked="" type="checkbox"/>	Product recall Procedure	50, 62	Supply records demonstrating that the manufacturer, packager, labeller and/or importer have an established system of control that permits the rapid and complete recall of every lot or batch of the NHP that has been made available for sale.	Product recall record; or confirmation of no recall for the past 12 months
8	<input type="checkbox"/>	Stability	52, 53(g), 56(e)	Supply: <ul style="list-style-type: none"> Records demonstrating that every NHP complies with its specifications until its determined expiry date. Record of stability data (complete or ongoing). 	Data logs from accelerated or real-time stability studies (must show product meets its label claim at time of expiry)

Part 6: List of Products Manufactured (M), Packaged (P), Labelled (L), Imported (I), and/or Stored at the Site

Product Name	Dosage Form	Product Type	Route of Administration	Natural Product Number (NPN)	Storage Conditions Requirements
Please see attachment for this part.					

**SUMMARY OF NET CHANGES FORM (SNC)
ASSOCIATED PRODUCTION SERVICES, INC.**

**ATTACHMENT FOR PART 5 RECORDS
RECORD 1 STORAGE CONTROLS**

Temperature and Humidity Control Log Bagger Rooms 1-3 CD

Date	AM	PM	Bldg. #	Bagger Room # 1 Temperature - F		Bagger Room # 1 Humidity - %	
	Time	Time		AM	PM	AM	PM
10/31/2022	6:35	2:00	100 CD	71.6	72.0	36	42
11/01/2022	6:35	2:00	100 CD	71.5	72.0	53	53
11/02/2022	6:35	2:00	100 CD	71.5	71.5	50	50
11/03/2022	6:35	2:00	100 CD	71.1	72.4	43	47
11/04/2022	6:35	2:00	100 CD	71.1	71.5	43	54
T & H Monitor				S/N		Calibration Due Date	
				221385468		28 MAR 2024	

Date	AM	PM	Bldg. #	Bagger Room # 2 Temperature - F		Bagger Room # 2 Humidity - %	
	Time	Time		AM	PM	AM	PM
10/31/2022	6:35	2:00	100 CD	71.8	72.2	36	42
11/01/2022	6:35	2:00	100 CD	71.5	71.8	53	53
11/02/2022	6:35	2:00	100 CD	71.1	71.1	50	51
11/03/2022	6:35	2:00	100 CD	70.9	72.2	44	46
11/04/2022	6:35	2:00	100 CD	70.9	71.8	43	54
T & H Monitor				S/N		Calibration Due Date	
				221199191		01/31/2024	

Date	AM	PM	Bldg. #	Bagger Room # 3 Temperature - F		Bagger Room # 3 Humidity - %	
	Time	Time		AM	PM	AM	PM
10/31/2022	6:35	2:00	100 CD	70.9	70.4	37	44
11/01/2022	6:35	2:00	100 CD	70.7	70.2	54	55
11/02/2022	6:35	2:00	100 CD	70.6	70.2	54	52
11/03/2022	6:35	2:00	100 CD	72.9	77.2	41	37
11/04/2022	6:35	2:00	100 CD	73.8	77.2	40	41
T & H Monitor				S/N		Calibration Due Date	
				210734252		08/25/2024	

Temperature range: 50 degrees F to 85 degrees F Humidity:

Not to go above 65% for optimal, 75% is maximum per histograms below 65% humidity is also considered optimal

Signature of Recorder:	Date:
<i>Daniel D. Clark</i>	11/04/2022
Signature of APS QC:	Date:
<i>Michael J. Amey</i>	11/04/2022

Temperature and Humidity Control Log Bagger Rooms 4-7 CD

Date	AM	PM	Bldg. #	Bagger Room # 4 Temperature - F		Bagger Room # 4 Humidity - %	
	Time	Time		AM	PM	AM	PM
10/31/2022	6:35	2:00	100 CD	70.6	71.3	36	42
11/01/2022	6:35	2:00	100 CD	70.9	71.2 71.2	50	52
11/02/2022	6:35	2:00	100 CD	71.3	73.1	47	46
11/03/2022	6:35	2:00	100 CD	73.8	77.6	41	37
11/04/2022	6:35	2:00	100 CD	74.7	77.9	40	41
T & H Monitor				S/N		Calibration Due Date	
				221493774		04 MAY 2024	
Date	AM	PM	Bldg. #	Bagger Room # 5 Temperature - F		Bagger Room # 5 Humidity - %	
	Time	Time		AM	PM	AM	PM
10/31/2022	6:35	2:00	100 CD	72.9	75.8	33	37
11/01/2022	6:35	2:00	100 CD	75.1	76.5	47	48
11/02/2022	6:35	2:00	100 CD	76.1	78.3	42	37
11/03/2022	6:35	2:00	100 CD	74.7	78.7	40	35
11/04/2022	6:35	2:00	100 CD	75.1	78.4	38	40
T & H Monitor				S/N		Calibration Due Date	
				221381058		24 MAR 2024	
Date	AM	PM	Bldg. #	Bagger Room # 6 Temperature - F		Bagger Room # 6 Humidity - %	
	Time	Time		AM	PM	AM	PM
10/31/2022	6:35	2:00	100 CD	73.4	74.2	33	40
11/01/2022	6:35	2:00	100 CD	74.7	76.5	47	48
11/02/2022	6:35	2:00	100 CD	74.7	77.2	43	39
11/03/2022	6:35	2:00	100 CD	74.3	76.1	40	41
11/04/2022	6:35	2:00	100 CD	74.7	77.2	39	42
T & H Monitor				S/N		Calibration Due Date	
				210874924		13 OCT 2024	
Date	AM	PM	Bldg. #	Bagger Room # 7 Temperature - F		Bagger Room # 7 Humidity - %	
	Time	Time		AM	PM	AM	PM
10/31/2022	6:35	2:00	100 CD	70.0	71.5	36	42
11/01/2022	6:35	2:00	100 CD	71.8	72.9	51	52
11/02/2022	6:35	2:00	100 CD	71.5	74.2	47	44
11/03/2022	6:35	2:00	100 CD	70.9	74.2	42	42
11/04/2022	6:35	2:00	100 CD	70.9	73.4	41	48
T & H Monitor				S/N		Calibration Due Date	
				221198984		01/31/2024	

Temperature range: 50 degrees F to 85 degrees F Humidity:
Not to go above 65% for optimal, 75% is maximum per histograms below 65% humidity is also considered optimal

Signature of Recorder: <i>Dominic P. Chacko</i>	Date: 11/04/2022
Signature of APS QC: <i>Michael J. Dominguez</i>	Date: 11/04/2022

Temperature and Humidity Control Log

Date	Time AM	Building #	Building		Building		Ceiling		Ceiling		Time PM
			Temperature - F		Humidity - %		Temperature - F		Humidity - %		
			AM	PM	AM	PM	AM	PM	AM	PM	
10/31/2022	6:35	100 CD	70.4	72.2	40	44	70.6	72.4	38	41	2:00
11/01/2022	6:35	100 CD	72.9	72.6 ^①	54	54	72.0	72.5	52	51	2:00
11/02/2022	6:35	100 CD	72.2	74.7	50	47	71.6	75.1	48	44	2:00
11/03/2022	6:35	100 CD	71.5	74.7	45	45	71.5	74.7	43	43	2:00
11/04/2022	6:35	100 CD	71.5	74.3	44	51	71.6	74.7	42	49	2:00

T&H Monitor S/N: 221381037 (FL.)
221493765 (CE.)

Calibration Due Date: 24 MAR 2024 (FL.)
04 MAY 2024 (CE.)

Temperature range: 50 degrees F to 85 degrees F
Humidity: Not to go above 65% for optimal, 75% is maximum per histograms
below 65% humidity is also considered optimal

Signature of recorder:

Dominic Charto

Date:

11/04/2022

Signature of APS QA:

Michael J. Brungel

Date:

11/04/2022

① For clarity, this reads
72.6 - ma 11/04/2022

Temperature and Humidity Control Log

Date	Time AM	Building #	Building Temperature - F		Building Humidity - %		Ceiling Temperature - F		Ceiling Humidity - %		Time PM
			AM	PM	AM	PM	AM	PM	AM	PM	
			Time								
10/31/2022	6:35	100 AB	70.0	71.0	39	44	70.1	72.8	40	45	2:00
11/01/2022	6:35	100 AB	70.0	73.0	56	56	70.3	74.1	58	57	2:00
11/02/2022	6:35	100 AB	70.0	73.0	52	49	70.0	75.2	55	49	2:00
11/03/2022	6:35	100 AB	70.0	73.0	52	51	70.0	74.3	53	51	2:00
11/04/2022	6:35	100 AB	70.0	71.0	50	54	70.1	73.2	51	55	2:00

T&H Monitor S/N: 210935332 (CE.)
210520384 (FL.)

Calibration Due Date: 11/01/2023 (CE.)
06/23/2023 (FL.)

Temperature range: 50 degrees F to 85 degrees F
Humidity: Not to go above 65% for optimal, 75% is maximum per histograms
below 65% humidity is also considered optimal

Signature of recorder:

Dan... Chetko

Date:

11/04/2022

Signature of APS QA:

Michael J. Amiguel

Date:

11/04/2022

**SUMMARY OF NET CHANGES FORM (SNC)
ASSOCIATED PRODUCTION SERVICES, INC.**

ATTACHMENT FOR PART 5 RECORDS

RECORD 2 PEST CONTROL



PEST CONTROL DOWN TO A SCIENCE.™

ASSOC PRODUCTION SERVICES-100
LOUISE DR
100 LOUISE DR
IVYLAND, PA 18974-1541
(215) 672-9505 Other
(215) 399-6593 Other

Orkin, 691-PENN JERSEY COMMERCIAL,
PA
100 HENDERSON DR
STE 103
SHARON HILL, PA 19079-1033
(610) 237-3360
License # 93818A

Invoice/Service Ticket #: 230178493
Account #: 31259000
Balance: \$468.10
Current Svc: \$220.80
Tax: \$13.25
Total Amt Due: \$702.15

Date of Service 10/25/2022

Customer Since: 2017

VICTOR LY Rt# 691-12 Victor Ly

Amt Collected:

\$0.00

Time In 10/25/2022 12:49 PM Time Out 10/25/2022 01:57 PM

License # T27535

PC Standard - Semi-Monthly , PC Standard

Previous Services

10/05/2022 PC Standard
09/24/2022 Callback
09/24/2022 Callback

**Pesticide Product Labels
Are
Available Upon Request**

Services Provided

Bait Station Inspection, Clean Station, Inspect/Treated Breakroom, Inspected All Areas, Inspected Equipment (Tincats/Bait Stations/Fly Lig, Inspected/Treated Common Areas, Inspected/Treated Storage Area, Inspection/treatment dock and warehouse area, THANK YOU FOR YOUR BUSINESS.

General Comments

Orkin was here for your OCTOBER Pest Service. All monitoring glueboards and bait stations inspected and scanned. Inspected common areas, offices, break rooms and restroom areas for pests: ants, spiders, centipedes, waterbugs, crickets, bees and other pests.

Flylight #2 needs new bulbs.

All tincats with crickets and beetles have been cleared and glueboards replaced.

All flylights have been replaced with new fly boards.

OBSERVATIONS: a slight increase in crickets and ground beetles.

EXPECTATIONS: Autumn and cooler temperatures may lead to increase of spider activities and exterior webbings. Also the beginning of mice season.

Product Application Details (Consumer post application precautionary statements on back)

			<u>Active Ingredient</u>	<u>App Method</u>	<u>App Equip</u>	<u>Target Pest(s)</u>	<u>Location</u>
Product:	Glue Board Mouse	QTY:	33	Trap Placement	No Equipment used	Ants, Mice, Spiders	Warehouse
Formulation:		EPA #:	N/A				
App Rate:	As Needed	LOT #:					

CO - Commercial applicators are licensed by the Colorado Department of Agriculture

AZ - Warning - Pesticides can be harmful. Keep children and pets away from pesticide applications until dry, dissipated, or aerated. For more information, contact Orkin Pest Control - C4029BCD at 1-800-346-7546

For additional information, a copy of the Label and/or SDS may be requested from your local branch or from www.orkin.com. Item # SVPC1026iOS rev. 02.18



PEST CONTROL DOWN TO A SCIENCE.™

ASSOC PRODUCTION SERVICES-
100 LOUISE DR
100 LOUISE DR
IVYLAND, PA 18974-1541
(215) 672-9505 Other
(215) 399-6593 Other

Orkin, 691-PENN JERSEY COMMERCIAL,
PA
100 HENDERSON DR
STE 103
SHARON HILL, PA 19079-1033
(610) 237-3360
License # 93818A

Invoice/Service Ticket #:230178493
Account # 31259000
Date of Service: 10/25/2022
Time In: 10/25/2022 12:49 PM
Time Out: 10/25/2022 01:57 PM

Product Used

<u>Zone Name</u>	<u>Number</u>	<u>Description</u>	<u>Category</u>	<u>Product Name</u>	<u>Applied</u>
Interior (Main)	1		Rodent Traps	Glue Board Mouse	1
Interior (Main)	4		Rodent Traps	Glue Board Mouse	1
Interior (Main)	5		Rodent Traps	Glue Board Mouse	1
Interior (Main)	6		Rodent Traps	Glue Board Mouse	1
Interior (Main)	7		Rodent Traps	Glue Board Mouse	1
Interior (Main)	8		Rodent Traps	Glue Board Mouse	1
Interior (Main)	9		Rodent Traps	Glue Board Mouse	1
Interior (Main)	10		Rodent Traps	Glue Board Mouse	1
Interior (Main)	11		Rodent Traps	Glue Board Mouse	1
Interior (Main)	12		Rodent Traps	Glue Board Mouse	1
Interior (Main)	13		Rodent Traps	Glue Board Mouse	1
Interior (Main)	14		Rodent Traps	Glue Board Mouse	1
Interior (Main)	15		Rodent Traps	Glue Board Mouse	1
Interior (Main)	17		Rodent Traps	Glue Board Mouse	1
Interior (Main)	18		Rodent Traps	Glue Board Mouse	1
Interior (Main)	19		Rodent Traps	Glue Board Mouse	1
Interior (Main)	20		Rodent Traps	Glue Board Mouse	1
Interior (Main)	21		Rodent Traps	Glue Board Mouse	1
Interior (Main)	22		Rodent Traps	Glue Board Mouse	1
Interior (Main)	23		Rodent Traps	Glue Board Mouse	1
Interior (Main)	24		Rodent Traps	Glue Board Mouse	1
Interior (Main)	27		Rodent Traps	Glue Board Mouse	1
Interior (Main)	28		Rodent Traps	Glue Board Mouse	1
Interior (Main)	29		Rodent Traps	Glue Board Mouse	1

CO - Commercial applicators are licensed by the Colorado Department of Agriculture

AZ - Warning - Pesticides can be harmful. Keep children and pets away from pesticide applications until dry, dissipated, or aerated. For more information, contact Orkin Pest Control - C4029BCD at 1-800-346-7546

For additional information, a copy of the Label and/or SDS may be requested from your local branch or from www.orkin.com.
Item # SVPC1026iQS rev. 02.18



PEST CONTROL DOWN TO A SCIENCE.™

ASSOC PRODUCTION SERVICES-
100 LOUISE DR
100 LOUISE DR
IVYLAND, PA 18974-1541
(215) 672-9505 Other
(215) 399-6593 Other

Orkin, 691-PENN JERSEY COMMERCIAL,
PA
100 HENDERSON DR
STE 103
SHARON HILL, PA 19079-1033
(610) 237-3360
License # 93818A

Invoice/Service Ticket #:230178493
Account # 31259000
Date of Service: 10/25/2022
Time In: 10/25/2022 12:49 PM
Time Out: 10/25/2022 01:57 PM

Product Used

<u>Zone Name</u>	<u>Number</u>	<u>Description</u>	<u>Category</u>	<u>Product Name</u>	<u>Applied</u>
Interior (Main)	30		Rodent Traps	Glue Board Mouse	1
Interior (Main)	31		Rodent Traps	Glue Board Mouse	1
Interior (Main)	32		Rodent Traps	Glue Board Mouse	1
Interior (Main)	33		Rodent Traps	Glue Board Mouse	1
Interior (Main)	34	TINCAT IN CAFETERIA	Rodent Traps	Glue Board Mouse	1
Interior (Main)	35	TINCAT IN CAFETERIA	Rodent Traps	Glue Board Mouse	1
Interior (Main)	36		Rodent Traps	Glue Board Mouse	1
Interior (Main)	37		Rodent Traps	Glue Board Mouse	1
Interior (Main)	39		Rodent Traps	Glue Board Mouse	1

Station / Room Summary

<u>Name</u>	<u>Scheduled</u>	<u>Inspected</u>	<u>With Activity</u>	<u>Added</u>	<u>Replaced</u>	<u>Skipped</u>	<u>Removed</u>	<u>End Total</u>
Area Inspection	1	1	0	0	0	0	0	1
Fly Light	10	10	0	0	0	0	0	10
Glue Board/Monitor	2	2	0	0	0	0	0	2
Tin Cat Trap	39	39	0	0	0	0	0	39

Zone Summary

<u>Zone Name</u>	<u>Comments</u>	<u>New</u>	<u>Scheduled</u>	<u>Inspected</u>	<u>With Activity</u>	<u>No Activity</u>
Break Room (Main)			1	1	0	1
Fly Lights (Main)			10	10	0	10
Interior (Main)			39	39	0	39
Locker Room (Main)			2	2	0	2

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For additional information, a copy of the Label and/or SDS may be requested from your local branch or from www.orkin.com.
 Item # SVPC1026iOS rev. 02.18



PEST CONTROL DOWN TO A SCIENCE.™

ASSOC PRODUCTION SERVICES-
100 LOUISE DR
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IVYLAND, PA 18974-1541
(215) 672-9505 Other
(215) 399-6593 Other

Orkin, 691-PENN JERSEY COMMERCIAL,
PA
100 HENDERSON DR
STE 103
SHARON HILL, PA 19079-1033
(610) 237-3360
License # 93818A

Invoice/Service Ticket #:230178493
Account # 31259000
Date of Service: 10/25/2022
Time In: 10/25/2022 12:49 PM
Time Out: 10/25/2022 01:57 PM

Customer Signature:

CUSTOMER NAME: DENNIS GAROT

CUSTOMER EMAIL: cgeer@apspackage.com, DGAROT@APSPACKAGE.COM

* This work has been performed to my satisfaction.

If you experience pest issues between scheduled visits, we will come back and address the problem at no additional charge.

Remit To: Orkin, 691-PENN JERSEY COMMERCIAL, PA
P O BOX 740847
CINCINNATI, OH 45274-0847

CO - Commercial applicators are licensed by the Colorado Department of Agriculture

AZ - Warning - Pesticides can be harmful. Keep children and pets away from pesticide applications until dry, dissipated, or aerated. For more information, contact Orkin Pest Control - C4029BCD at 1-800-346-7546

For additional information, a copy of the Label and/or SDS may be requested from your local branch or from www.orkin.com.
Item # SVPC1026iOS rev. 02.18

CONSUMER NOTIFICATION(S) / POST APPLICATION STATEMENTS

Treated Area(s) - Do not allow unprotected person(s), children, or pets to touch, enter or replace items or bedding, to contact or enter treated area(s) until dry.

Ventilation/Reoccupying - Vacate and keep area(s) closed up to 30 minutes after treatment, then ventilate area(s) well for up to 2 hours before reoccupying.

Equipment/Processing/Food - Thoroughly wash dishes, utensils, food preparation/processing equipment and surfaces with an effective cleaning compound and rinse with clean water if not removed or covered during treatment. This area should be odor free before food products are placed in the area.

Exterior Applications (baits) - Do not allow grazing of feed, lawn or sod clippings to livestock after bait applications.

Granular Application(s) - Do not water to the point of run off.

Do not burn treated fire wood for one month after treatment.

National Poison Control Center: 1-800-222-1222

**SUMMARY OF NET CHANGES FORM (SNC)
ASSOCIATED PRODUCTION SERVICES, INC.**

**ATTACHMENT FOR PART 5 RECORDS
RECORD 3 PERSONNEL TRAINING**

Re-Training (Sayukay Forkay)

1. Line Clearances (Like and Unlike Products)

Trainer (Must demonstrate 3 times)

Debra Kay Sherk / Date 09/07/2022

Debra Kay Sherk / Date 09/08/2022

Debra Kay Sherk / Date 09/10/2022

Trainee (Must demonstrate to Trainer knowledge and Performance)

Sayukay Forkay / Date 09/13/2022

2. IPCS Review (Completion and legibility) – No blank entries – Document Film / Carton Lot numbers

Trainer (Must demonstrate 3 times)

Debra Kay Sherk / Date 09/07/2022

Debra Kay Sherk / Date 09/08/2022

Debra Kay Sherk / Date 09/08/2022

Trainee (Must demonstrate to Trainer knowledge and Performance)

Sayukay Forkay / Date 09/12/2022
09/14/2022

entry error say 09/13/2022

3. Retain Sample Procedure

Debra Kay Lusk / Date 09/10/2022

Debra Kay Lusk / Date 09/08/2022

Debra Kay Lusk / Date 09/09/2022

Trainee (Must demonstrate to Trainer knowledge and Performance)

Sanykay Forkay / Date 09/12/2022

4. Inspect / Review End of Purchase Report, Log Books, Film and Carton Accountability forms or completion before your shift ends to ensure all required signatures / dates are present.

Debra Kay Lusk / Date 09/09/2022

Debra Kay Lusk / Date 09/12/2022

Debra Kay Lusk / Date 09/13/2022

Trainee (Must demonstrate to Trainer knowledge and Performance)

Sanykay Forkay / Date 09/15/2022

5. Acknowledge that any and all quality issues need to be communicated to the Machine Operator / Management.

Debra Kay Lusk / Date 09/14/2022

Sanykay Forkay 09/14/2022

**SUMMARY OF NET CHANGES FORM (SNC)
ASSOCIATED PRODUCTION SERVICES, INC.**

**ATTACHMENT FOR PART 5 RECORDS
RECORD 4 SANITATION**

Building 100 cleaning checklist (5 times per week)

Today's Date: 11-17-22 Cleaner's signature [Signature]

****This completed sheet is to be delivered to APS QA daily for filing****

Done Daily: (Please check (✓) each item as they are completed)

Bathrooms:

Every Scheduled Cleaning Day:

- ✓ Empty all trash from restrooms to dumpster
- ✓ Scrub with Comet Disinfecting Cleaner, all restrooms including: sinks, countertops, urinals, toilets, partitions handrails, door/knob/frame, and tile walls. Stand for 10 minutes then rinse with potable water (8 bathrooms)
- ✓ Wipe down mirrors with Spic and Span all Purpose Spray and Glass Cleaner
- ✓ Wet mop floors with Spic and Span Floor Cleaner
- ✓ Dust ceiling vent
- ✓ Wipe around light switch and spots on walls with Spic and Span All Purpose Cleaner
- ✓ Replenish and wipe all toilet paper and paper towel dispensers

Tuesdays & Thursdays:

- ✓ Sweep the area around the air compressors in the both the AB and CD sections of the building.

Wednesdays:

- ___ Wipe any visible plumbing and scrub floor edges where toilet/walls meet floor with Comet Disinfecting Cleaner

Offices

- ✓ Dust all desks, tables file cabinets, fixtures and tables in all offices/computer room/ staff cafeteria (7 rooms)
- ✓ Vacuum all office carpeting and area rugs outside of offices (6 offices, 1 staff cafeteria)
- ✓ Empty garbage cans to dumpster

Cafeterias

- ✓ Spray all tables and chairs Spic and Span All Purpose Cleaner then wipe down.
- ✓ Empty trash to dumpster
- ✓ Sweep and wet mop floor with Spic and Span Floor Cleaner
- ✓ Clean countertops and sink with Spic and Span All Purpose Cleaner
- ✓ Clean glass door with Spic and Span All Purpose Cleaner
- ✓ Dust the tops of vending machines daily

Entrance

- ✓ Dust, vacuum and clean windows of the entrance area
- ✓ Empty outside garbage can by entrance walkway
- ✓ Sweep under steps just inside entrance to the left

Shop Floor Schedule:

- ✓ Sweep and dust all dock door areas daily (including all surfaces)
- ✓ Refill hair net stations daily
- ✓ Refill hand sanitizers with Purell hand sanitizer as needed
- ✓ Sweep, mop and clean Zones and Perimeters... 1 through 10 (Refer to zone map and week number)

Cleaner's Initials NA Date 11-17-22

Daily Dock cleaning:

Walk the Dock areas along the whole back of building Pick up remove:

Notice: When cleaning floor zones, the floor is Swept and Mopped using floor cleaner this can be done with Scrubber and or Mopping using the two Bucket System

- Trash between and around each door sweep and mop spills as needed each day. Dust any surface as needed including eyewash stations, boxes attached to walls
- Sweep and Mop loading dock thoroughly each Friday
- Compressors/Packers/Balers in the Area you are cleaning are to be vacuumed and mopped behind
- Drapes between the AB sides Get Cleaned Daily with Spic and Span All Purpose Cleaner
- AB Module 6 Floor Mopped Daily
- AB Floor Zone 10 Cleaned and sanitized Daily

Shop Floor and Perimeter checklist:

CDE Zone 7 Ricola machine packing line cleaning (daily) Zone map 7:

- Sweep under all conveyor and table lines
- Using Spic and Span All Purpose Cleaner, wipe down the following:
- Line tables (top and trays)
 - V blocks
 - Conveyor belt surfaces
 - Tape machines

Shop Floor (Non Daily):

(Each Area of the Perimeter gets Cleaned at least every 14 Days.)

NA -Recorded on a copy of the "**100 Louise Drive Master Cleaning Schedule**" (initial each item and sign/date anywhere on the form). **Reminder: If any cleaners were used that do not come from the auto diluter** - Provide and attach "Nonfood Contact Disinfectant/Sanitizer/Detergent users log". (For example floor scrubber).

To be done last week of the month

- NA Sweep mezzanine with compound (once per month)

Cleaning Supplies:

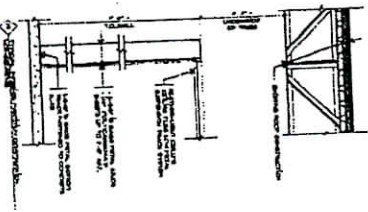
- Store and organize all cleaning supplies and equipment in the cleaning shed at the end of the shift
- Alert APS to any supplies or repairs you see or need (i.e. toilet brushes to toilet seats) and write it here: NA

APS QA Signature that this was received for filing

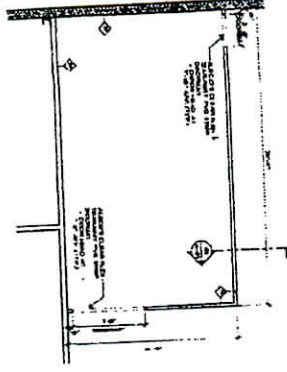
[Signature] Date: 11/17/2022



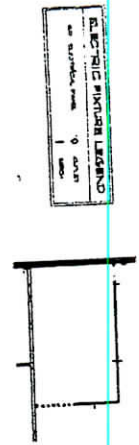
WALL TYPE / SECTION
 (EXISTING) 02



ENLARGED PARTIAL PLAN
 (EXISTING) 03

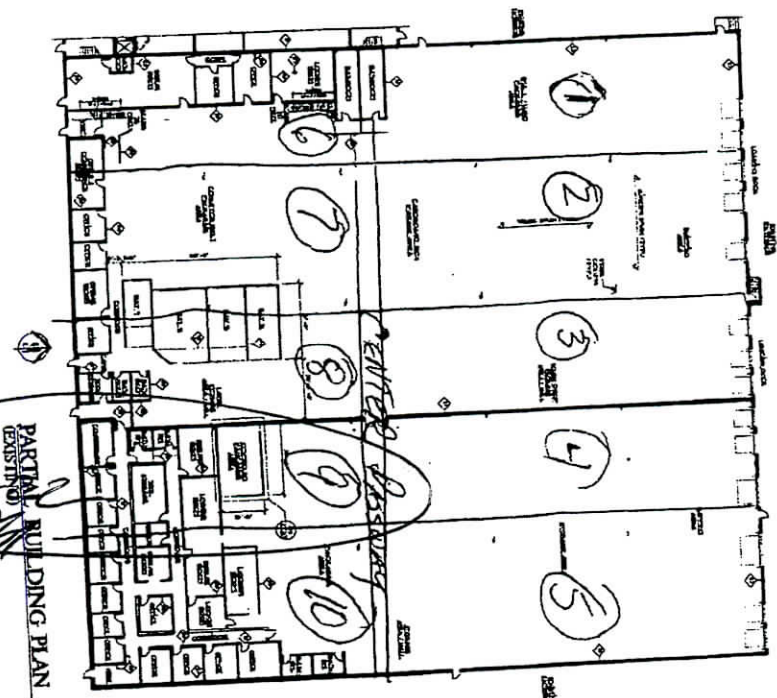
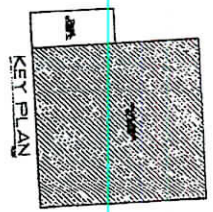
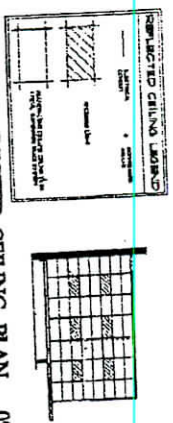


PARTIAL ELECTRICAL PLAN
 (EXISTING) 04



WALL TYPE / SECTION	
1	1'-0" CMU WALL WITH INTERIOR FINISH
2	1'-0" CMU WALL WITH EXTERIOR FINISH
3	1'-0" CMU WALL WITH INTERIOR FINISH AND CEILING
4	1'-0" CMU WALL WITH EXTERIOR FINISH AND CEILING
5	1'-0" CMU WALL WITH INTERIOR FINISH AND CEILING AND EXTERIOR FINISH
6	1'-0" CMU WALL WITH EXTERIOR FINISH AND CEILING AND INTERIOR FINISH
7	1'-0" CMU WALL WITH INTERIOR FINISH AND CEILING AND EXTERIOR FINISH AND CEILING
8	1'-0" CMU WALL WITH EXTERIOR FINISH AND CEILING AND INTERIOR FINISH AND CEILING
9	1'-0" CMU WALL WITH INTERIOR FINISH AND CEILING AND EXTERIOR FINISH AND CEILING AND INTERIOR FINISH
10	1'-0" CMU WALL WITH EXTERIOR FINISH AND CEILING AND INTERIOR FINISH AND CEILING AND EXTERIOR FINISH AND CEILING

PARTIAL REFLECTED CEILING PLAN
 (EXISTING) 05



PARTIAL BUILDING PLAN
 (EXISTING) 01

A-02

NO.	DESCRIPTION
1	EXISTING PARTIAL REFLECTED CEILING PLAN
2	EXISTING PARTIAL ELECTRICAL PLAN
3	EXISTING PARTIAL BUILDING PLAN
4	EXISTING PARTIAL WALL TYPE / SECTION
5	EXISTING PARTIAL ENLARGED PARTIAL PLAN
6	EXISTING PARTIAL KEY PLAN

DATE: 11-19-11
 DRAWN BY: [Signature]
 CHECKED BY: [Signature]
 APPROVED BY: [Signature]

100 LOUISE DRIVE
 IVYLAND PLANT
 NORTHAMPTON TOWNSHIP
 BUCKS COUNTY



APS Machine/Scale/Module Cleaning Checklist

To be performed after a batch completion as follows: (✓) as completed

Each machine/scale/module will be cleaned on a monthly schedule with a 30 day expiration date.

Use Proctor and Gamble, Dawn soap to wash all product contact surfaces with a clean cloth. Use water to rinse. Use Proctor and Gamble quaternary to sanitize. Use Proctor and Gamble window cleaner for any Plexiglas non-product contact surfaces. Use Isopropanol 99% (Isopropyl Alcohol) to clean the ink off the print head and film rollers. Use a clean cloth and wear gloves. Use Clean in place (CIP) or 3 compartment sink (3CS) where indicated

MACHINE NUMBER: 1

Date Started: 12/03/2022

Time Started: 7am

Date Completed: 12/03/2022

Time Completed: 3pm

- | | |
|---|--|
| ✓ | Record "To Be Cleaned" with date and initials of the person entering this machine status on the machine status board. |
| ✓ | Clean all outer surfaces and product contact surfaces of the bagger machine inside and out. CIP |
| ✓ | Clean machine incline takeaway conveyor. CIP |
| ✓ | Clean windows of the enclosure. CIP |
| ✓ | Clean floor (wet mop) of the enclosure. CIP |
| ✓ | Clean walls and rails of wall of the enclosure. CIP |
| ✓ | Remove and clean all scale hoppers, feeders, and dispersion table. (3CS) |
| ✓ | Clean ink from the film rollers. CIP |
| ✓ | Clean ink from the print head. CIP |
| ✓ | Clean cross feeder. CIP |
| ✓ | Clean all buckets on the bucket elevator. (3CS) |
| ✓ | Clean low level hopper. CIP |
| ✓ | Clean all railings of the catwalk. CIP |
| ✓ | Clean scale platform/catwalk. CIP |
| ✓ | Clean scale stand/frame. CIP |
| ✓ | Clean floor tracks along wall. CIP |
| ✓ | Clean tape machines. CIP |
| ✓ | Clean pack-out conveyor. CIP |
| ✓ | Clean the super-sack lift. CIP |
| ✓ | In the machine log and on the machine status board, record "Cleaned and Approved" with the cleaning completion date and the 30 day cleaning expiration date and initials of the person entering this machine status. |

Performed by

Machine Operator Signature:




Date:

12/03/2022

Approved by

Production Supervision Signature:



Date:

12/05/2022

QA Signature:



Date:

12/05/2022

This form is to be filed with Quality Assurance Document Control

**SUMMARY OF NET CHANGES FORM (SNC)
ASSOCIATED PRODUCTION SERVICES, INC.**

**ATTACHMENT FOR PART 5 RECORDS
RECORD 5 FINISHED PRODUCT TESTING
PACKAGING AND LABELLING BATCH RECORD**

Michael Smigiel

From: Mia Manubag <mia.manubag@ricola.com>
Sent: Wednesday, October 19, 2022 3:01 PM
To: QA@apspackage.com
Subject: Material Release

The following Material was released by Ricola USA

Material 3048948, RIC BG LEMON MINT 6x8x19PC, Batch 2000115345, Release date 10/19/2022, Released quantity 869.000 of 869.000

This e-mail has been sent by a Ricola employee and may contain privileged or confidential information. It is intended for the named recipients only. If you have received this e-mail in error, please notify us immediately by reply e-mail and delete this message from your system. Any use or retransmission without proper authorization is prohibited. Thank you for your cooperation.



Attachment #1
Procedure 27.0 Rev. 8
Effective Date: 02/08/2021

Associated Production Services, Inc
Trevose, PA 19053

Product Packaging Conformance Certificate

Natural Lemon Mint
Citron Menthe
Product: Throat Lozenges

Batch Number: 2000115345

Finished Product Code (Item Number): 3048948

Associated Production Services, Inc. certifies that the following bulk product and film have been used in the packaging of this batch:

Bulk Product Batch Number: 2000104867

Bulk Product Code (Bulk Material Number): 6000131

Film Job Number(s): 199020

Drop Count: 19

and Associated Production Services, Inc. certifies that the finished packaged product has satisfactorily met Associated Production Services, Inc. process controls per SOP 14.0 and was produced in accordance with the agreed upon packaging specifications provided to APS by Ricola USA, Inc.

Michael J. Smigiel
APS Quality Assurance Signature

A handwritten signature in blue ink that reads "Michael J. Smigiel".

10/07/2022
Date

In Process Control Sheet Item # 3048948

6/8 Lemon Mint Cough Drops
Citron Menthe
(Canada)

Bill of Materials:

Product: 19 pcs/bag Lemon Mint Cough Drops Mat# 6000131
Corrugated: Canada 1x8 Inner 6x8 Master
Bag film: 48 impressions- material number 9013701 CA
Labels: 1 -4"x2" Monarch Label (900313), 1-4"x6" Monarch Label (900319)

Staging: Machine Number: 4

Production date: 10/06/2022 Production start time: 12:55 PM

Machine Purged: yes
Room Pressurized: yes

Batch number (Swiss): 200010467 Batch code (USA): 2000115345

Expiration date: 13.06.2025 PO number: 4500026875

(via visual assessment)

I confirm the batch number and code as stated above

Verified by: [Signature]

Operation:

In- Process Control Hour ->	12:55 PM	1:00 PM	1:05 PM								
Pallet number	1	4	7								
Jaw seals ok	YES	YES	YES				NA				
Lap seal ok	YES	YES	YES								
Batch code legible	YES	YES	YES								
Vacuum test- mmHg burst point- (500mmHg is min.)	500	500	500								
Specified Drop Count: 19	Actual Count:	Actual Count:	Actual Count:	Actual Count:	Actual Count:	Actual Count:	Actual Count:	Actual Count:	Actual Count:	Actual Count:	Actual Count:
Target: 19 / Range: 19-21	19	19	19								
Secondary Packaging:											
1x8 label	YES	YES	YES								
GTIN#30036602079480	YES	YES	YES								
6x8 label #3048948-	YES	YES	YES								
GTIN#70036602079488	YES	YES	YES								

Production stop time: 3:08 PM

I have attached a sample bag and product identifier labels used during production for this IPCS

x [Signature] 10/06/2022 (Operator's Signature)

Reviewed by QA: [Signature] Date: 10/06/2022

Modified 05/25/2022 P. Eccles Effective by: 05/26/2022

Remarks:
Film lot # 199020

entry error 10/06/2022

RIC BG LEMON MINT 6X8X19P
RIC SAC MIEL CITRON MENTHE

BATCH/LOT NO: 2000115345
EXP. DATE: 13.06.2025

3048948

48 BAGS / SAC X 19 LOZENGES / PASTILLES
036602079489

Distributed in Canada by:
Lindt & Sprüngli (Canada) inc



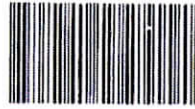
70036602079488

19/06/2022
Pur

10/06/2022
Ry

RIC BG LEMON MINT 8X19P
RIC SAC MIEL CITRON MENTHE
BATCH/LOT NO.: 2000115345
EXPIRATION DATE: 13.06.2025

3048948



30036602079480

8 BAGS / SACS X 19 LOZENGES / PASTILLES
036602078489

Distributed in Canada by:
Lindt & Sprüngli (Canada) inc

10/06/2022
PEO

10/06/2022
Ry



Lemon Mint cough suppressant - throat lozenges

Talk about tasty with a twist! These lively lemon lozenges with a hint of cooling mint go big on citrus flavour and even bigger on soothing relief. Bringing bright and juicy brilliance to our signature botanical blend.

Medicinal ingredients:

- Each lozenge contains: Extract of Ricola's herb mixture 22.19 mg, lemon balm (Melissa officinalis) part. extract 14.50 mg, peppermint (Mentha piperita) part. extract 1.80 mg, thyme (Thymus vulgaris) aerials 1.20 mg, sage (Salvia officinalis) aerials 1.55 mg, hyssop (Hyssopus officinalis) aerials 1.55 mg, elder (Sambucus nigra) flower 0.30 mg, linden (Tilia cordata) flower 0.30 mg, wild thyme (Thymus serpyllifolius) aerials 0.13 mg, marshmallow (Althaea officinalis) aerials 0.11 mg, mallow (Malva sylvestris) leaves 0.11 mg.

Non-medical ingredients: Sugar, glucose syrup, citric acid, natural flavour (lemon oil), colourant (beta-carotene).

Recommended use or purpose: For the temporary relief of coughs and sore throat. Recommended dose: Adults and children over 12 years of age: Dissolve one lozenge slowly in the mouth every 1-2 hours up to a maximum of 10 lozenges per day.

Keep out of reach of children. In case of overdose, call a poison control centre or get medical help right away. If symptoms are severe or persist for more than 7 days consult a healthcare practitioner. Consult a healthcare practitioner prior to use if you have asthma, gastro-oesophageal reflux, or if cough medicines, previously for more than 7 days or is accompanied by high fever consult a healthcare practitioner. Contraindications: Do not use during pregnancy or breast feeding. Do not purchase if package is open.



For questions or comments, contact: Ricola USA, Inc. (Distributor), 6 Campus Dr, 2nd Floor South, Parsippany, NJ 07054.

Pastilles apaisantes contre la toux Citron Menthe

Une saveur surprenante! Ces pastilles au citron et menthe avec un soupçon de menthe apaisante offrent toute la fraîcheur du citron avec un soulagement encore plus vigoureux. Offrant de la vivacité et un éclat juteux à notre mélange botanique.

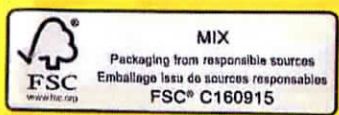
Ingredients:

- Each pastille contains: Extract of our herb mixture 22.19 mg, melissa (Melissa officinalis) part. extract 14.50 mg, peppermint (Mentha piperita) part. extract 1.80 mg, thyme (Thymus vulgaris) part. extract 1.20 mg, sage (Salvia officinalis) part. extract 1.55 mg, hyssop (Hyssopus officinalis) part. extract 1.55 mg, elder (Sambucus nigra) flower 0.30 mg, linden (Tilia cordata) flower 0.30 mg, wild thyme (Thymus serpyllifolius) part. extract 0.13 mg, marshmallow (Althaea officinalis) part. extract 0.11 mg, mallow (Malva sylvestris) leaves 0.11 mg.

Non-medical ingredients: Sugar, glucose syrup, citric acid, natural flavour (lemon oil), colourant (beta-carotene).

Recommended use or purpose: For the temporary relief of coughs and sore throat. Recommended dose: Adults and children over 12 years of age: Dissolve one lozenge slowly in the mouth every 1-2 hours up to a maximum of 10 lozenges per day.

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EXP: 13.06.2025 BATCH: 2000115345

Manufactured by / Fabriqué par: Ricola Ltd. 4242 Lutten, Switzerland. Imported by / Importé par: Limit & Sprungli (Canada) Inc. Toronto (Ontario) M5H 3K7.

Ricola logo

MADE WITH SWISS ALPINE HERBS AVEC DES HERBES ALPINES SUISSES cough suppressant - throat lozenges - pastilles apaisantes contre la toux

Advertisement for Ricola Lemon Mint Citron Menthe lozenges. Features images of the lozenges, botanical illustrations of ingredients like peppermint, sage, linden, lemon balm, hyssop, and mallow, and text describing the product's benefits and ingredients.

NP: 340

N 80014

In Process Control Sheet Item # 3048948

6/8 Lemon Mint Cough Drops
Citron Menthe
(Canada)

Bill of Materials:

Product: 19 pcs/bag Lemon Mint Cough Drops Mat# 6000131
Corrugated: Canada 1x8 Inner 6x8 Master
Bag film: 48 impressions- material number 9013701 CA
Labels: 1 -4"x2" Monarch Label (900313), 1-4"x8" Monarch Label (900319)

Staging: Machine Number: 4

Production date: 10/06/2022 Production start time: 3:30 PM

Machine Purged: NO YES

Batch number (Swiss): 2000104867 Batch code (USA): 2000115345

Room Pressurized:

Expiration date: 13.06.2025 PO number: 4500026875

(via visual assessment)

I confirm the batch number and code as stated above Grant Bark

Verified by: [Signature]

Operation:

In-Process Control Hour ->	JN 3:30pm	JN 4pm	JN 5pm	JN 6pm	JN 7pm	JN 8pm	JN 9pm				
Pallet number	8	10	13	17	20	23	29				WIA
Jaw seals ok	Yes	Yes	Yes	Yes	Yes	Yes	Yes				
Lap seal ok	Yes	Yes	Yes	Yes	Yes	Yes	Yes				
Batch code legible	Yes	Yes	Yes	Yes	Yes	Yes	Yes	JN			
Vacuum test- mmHg burst point- (500mmHg is min.)	500	500	500	500	500	500	500				
Specified Drop Count: 19	Actual Count: 19	Actual Count: 19	Actual Count: 20	Actual Count: 19	Actual Count: 19	Actual Count: 19	Actual Count: 19	Actual Count:	Actual Count:	Actual Count:	Actual Count:
Target: 19 / Range: 19-21											

Secondary Packaging:

1x8 label GTIN#30036602079480	Yes	Yes	Yes	Yes	Yes	Yes	Yes				
6x8 label #3048948- GTIN#70036602079488	Yes	Yes	Yes	Yes	Yes	Yes	Yes				

Production stop time: 9:55pm JN 10/06/2022

I have attached a sample bag and product identifier labels used during production for this IPCS

X Grant Bark 10/06/2022 (Operator's Signature)

Reviewed by QA: Sanyukta Toth Date: 10/06/2022

Remarks:
WIA JN 10/05/22
10/06/2022
error entry
JN 10/06/2022

Modified 05/25/2022 P. Eccles Effective by: 05/26/2022

RIC BG LEMON MINT 6X8X19P
RIC SAC MIEL CITRON MENTHE

BATCH/LOT NO: 2000115345

EXP. DATE: 13.06.2025

3048948

48 BAGS / SAC X 19 LOZENGES / PASTILLES
036602079489

Distributed in Canada by:
Lindt & Sprüngli (Canada) inc



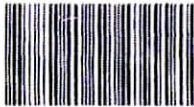
70036602079488

RB 10/06/2022

JW 10/06/2022

RIC BG LEMON MINT 8X19P
RIC SAC MIEL CITRON MENTHE
BATCH/LOT NO.: 2000115345
EXPIRATION DATE: 13.06.2025

3048948



30036602079480

8 BAGS / SACS X 19 LOZENGES / PASTILLES
036602078489

Distributed in Canada by:
Lindt & Sprüngli (Canada) inc

RB

10/06/2022

JW 10/06/2022



**Lemon Mint
cough suppressant throat lozenges**

Talk about tasty with a twist! These lively lemon lozenges with a hint of cooling mint go big on citrus flavour and even bigger on soothing relief. Bringing bright and juicy brilliance to our signature botanical blend.

Medicinal ingredients: Each lozenge contains:
 Extract of Ricola's herb mixture 23.19 mg
 lemon balm (*Melissa officinalis*) aerials 14.50 mg
 (1.25% QCE 18.13 mg)
 peppermint (*Mentha piperita*) parts aériennes 2.90 mg
 (1.25% QCE 3.63 mg)
 thyme (*Thymus vulgaris*) aerials 1.70 mg (1.25% QCE 2.13 mg)
 sage (*Salvia officinalis*) aerials 1.55 mg (1.25% QCE 1.94 mg)
 hyssop (*Hyssopus officinalis*) aerials 1.55 mg
 (1.25% QCE 1.94 mg)
 elder (*Sambucus nigra*) flower 0.30 mg (1.25% QCE 0.38 mg)
 licorice (*Licaria cordata*) flower 0.30 mg (1.25% QCE 0.38 mg)
 wild thyme (*Thymus serpyllifolius*) aerials 0.13 mg
 (1.25% QCE 0.16 mg)
 borage (*Moroccan boraginifera*) aerials 0.13 mg
 (1.25% QCE 0.16 mg)
 mallow (*Malva sylvestris*) leaves 0.13 mg (1.25% QCE 0.16 mg)
 QCE = quantity made equivalent

Non medicinal ingredients: Sugar, quinine syrup, citric acid, natural flavour (lemon oil, essential thyme concentrate).

Recommended use or purpose: For the temporary relief of coughs and sore throat.
Recommended dose: Adults and children over 7 years of age: Dissolve one lozenge slowly in the mouth every 2-3 hours up to a maximum of 30 lozenges per day.
Duration of use: Consult a healthcare practitioner if symptoms persist beyond one week.
Cautions and warnings: Keep out of reach of children. In case of overdose, call a poison control centre or get medical help right away.

- If symptoms are severe or persist for more than 7 days, consult a healthcare practitioner.
- Consult a healthcare practitioner prior to use if you have gallstones, ulcers, hiatus hernia or gastroesophageal reflux.
- If cough worsens, persists for more than 7 days or is accompanied by high fever consult a healthcare practitioner.

Contraindications: Do not use during pregnancy or breast feeding.
Do not purchase if package is open.



9013701 CA

pour questions ou commentaires, communiquer avec /
 for questions or comments, contact:
 Ricola USA, Inc. (Distributor), 6 Campus Dr.
 2nd Floor South, Parsippany, NJ 07054

APN:
340

**Pastilles apaisantes contre la toux
Citron Menthe**

Une saveur surprenante! Ces pastilles au citron vil avec un soupçon de menthe apaisante offrent toute la fraîcheur du citron avec un soulagement encore plus vigoureux. Offrant de la vivacité et un édat juteux à notre mélange botanique.

Ingredients / Ingrédients: Chaque pastille contient:
 extrait du mélange d'herbes Ricola 23,19 mg
 menthe (*Melissa officinalis*) parties aériennes 14,50 mg
 (1,25% QCE 18,13 mg)
 menthe poivrée (*Mentha piperita*) parties aériennes 2,90 mg
 (1,25% QCE 3,63 mg)
 thym (*Thymus vulgaris*) parties aériennes 1,70 mg
 (1,25% QCE 2,13 mg)
 sauge (*Salvia officinalis*) parties aériennes 1,55 mg
 (1,25% QCE 1,94 mg)
 hysope (*Hyssopus officinalis*) parties aériennes 1,55 mg
 (1,25% QCE 1,94 mg)
 sureau (*Sambucus nigra*) fleurs 0,30 mg (1,25% QCE 0,38 mg)
 réglisse (*Licaria cordata*) fleurs 0,30 mg (1,25% QCE 0,38 mg)
 thym serpyllifolius (*Thymus serpyllifolius*) parties aériennes 0,13 mg
 (1,25% QCE 0,16 mg)
 oranger (*Malva sylvestris*) feuilles 0,13 mg (1,25% QCE 0,16 mg)
 QCE = quantité faite équivalente

Ingredients / Ingrédients non-médicamentaux: Sucre, sirop de glucose, acide lactique, essence naturelle d'huile essentielle de citron, colorant (bleu, caramel).

Usage recommandé: Soulagement temporaire de la toux et de la douleur de gorge.
Dose recommandée: Adultes et enfants de plus de 7 ans: Dissolvez une pastille doucement dans la bouche toutes les 2 à 3 heures jusqu'à un maximum de 30 pastilles par jour.
Durée d'utilisation: Si les symptômes persistent au-delà d'une semaine, consultez un médecin.

Précautions et mises en garde:
 Tenir hors de portée des enfants. En cas de saignements, veuillez consulter immédiatement avec votre médecin ou votre pharmacien.
 • Si les symptômes sont graves ou persistent plus de 7 jours, consultez un médecin.
 • En cas de calculs biliaires, d'ulcères biliaires ou de reflux gastro-œsophagien, consultez un médecin avant l'utilisation.
 • Si la toux s'aggrave ou persiste pendant plus de 7 jours ou si elle est accompagnée de fièvre, consultez un médecin.
Contre-indications: Ne pas utiliser pendant la grossesse ou l'allaitement. Ne pas acheter si l'emballage est ouvert.



EXP: 13.06.2025
 BATCH: 2000115345

Manufactured by / Fabriqué par: Ricola Ltd., 4247 Laufen, Switzerland
 Imported by / Importe par: Unet & Sprangli (Canada) Inc.
 Toronto (Ontario) M5H 3M7
 Product of Switzerland / Produit de Suisse www.ricola.com

Ricola®

**MADE WITH SWISS ALPINE HERBS
 AVEC DES HERBES ALPINES SUISSES**

cough suppressant - throat lozenges - pastilles apaisantes contre la toux

LEMON MINT CITRON MENTHE



great tasting · soothing relief

soulagement apaisant
 au goût savoureux

image not actual size / l'image n'est pas à la taille réelle



peppermint · menthe poivrée

sage · sauge

linden · tilleul

lemon balm · mélisse

hyssop · hysope

mallow · mauve

thyme · thym

N
80014

Bagging Machine Module "A" Batch Line Clearance for Unlike Products

Perform the following functions at the end of each batch run and deliver this sheet to Quality Assurance to file with the batch record:

Date 10/06/2022

Batch 200015345

4

Check each as completed:

- Confirm that the Markem counter number of impressions run has been entered in the designated space "a" on the Film Impression Counts table.
- Reset the Markem counter number to "zero" unless this is automatic for the machine at the beginning of each run.
- Remove any remaining roll/partial roll of bag film from the bagging machine and place it on the pallet of film.
- Remove the pallet of film from the enclosure
- Run and drain the bagging machine to drain it, the scale and the low level hopper and all surfaces of the bucket elevator of any drops.
- Clear the low level hopper and all surfaces of the bucket elevator of any drops.
- Clear all surfaces of the scale including removing the dispersion table, each radial trough, pool hopper, weigh hopper and collection chutes to look for drops.
- Clear any drops from the scale platform.
- Clear (wet wipe) any drops or drop dust from all surfaces of the bagger.
- Clear any drops from the scale stand.
- Clear any drops from the module's floor area and from the floor track between the exposed studs along the wall.
- Remove any bags or partially filled boxes from the pack-out line
- Remove any labels from the pack-out line.
- Run and drain the bagging machine to drain it, the scale and the low level hopper and all surfaces of the bucket elevator of any drops and zero adjust the scale.
- Account for all tools used in the bagging module by checking that all are in their positions on the module tool board.

All drops, drop dust, bags and labels should now be cleared from your line and it is ok to proceed with the next batch.

Performed by: <u>[Signature]</u>	Date: <u>10/06/2022</u>
Checked by: <u>[Signature]</u>	Date: <u>10/06/2022</u>
Reviewed by QA: <u>[Signature]</u>	Date: <u>10/06/2022</u>



Purchase order

Ricola USA Inc. 6 Campus Drive, Suite 205 Parsippany, NJ 07054

PROVIDENT MARKETING
696 JACKSONVILLE RD
WARMINSTER PA 18974

Number **4500026875** Date 09/28/2022 Page 1 / 1
Vendor no. 302242
Contact person Dave Constant
Telephone +1973-984-3206
Email dave.constant@ricola.com
Delivery date 10/28/2022

Delivery address
PROVIDENT MARKETING
696 JACKSONVILLE RD
WARMINSTER PA 18974
Telephone 8007016301

Lemon Mint batch 2000104867
Exp Date : 13JUN2025 2986 kgs
4500024820 80074894 MSCU5380548 MSC MATTINA 2022-09-27
1 @ 586 & 3 @ 800 : 2986 kgs

SEP 28 2022

869 cs of 6x8
41,712 bags

Item	Material Description	GTIN	Qty.	Price USD	Price unit	Total value USD
0010	3048948 RIC BG LEMON MINT 6x8x19PC 6x8 GTIN: 70036602079488 1x8 GTIN: 30036602079480 19ct bag upc: 036602079489 TI HI 6x5 Batch 2000115345	70036602079488	810 CS = 27 PAL = 135 LG = 738,720 SSU	4.79	11 CS	3,879.90
We provide the following components:						
	6000131 Lemon Mint Bulk		Batch	Expiry date	2,916.000 KG	
	9000268 RRP Base Bag Carton 1x8				4,884.300 PC	
	9000269 Base Bag Master Case 6x8				814.050 PC	
	9000109 4" x 2" Monarch Label (900313)				4,908.600 PC	
	9000110 4" x 6" Monarch Label (900319)				818.100 PC	
	9013701 CA-neo LemonMint 19ct				40,435.20 PC	

Total value excl. tax

USD 3,879.90

Terms of delivery Incoterms 2010: FOB
Terms of payment within 15 days Due net

Container Receiving Report

To: Dave Constant, Ricola USA, Inc. Scan or Fax: 973-984-6814
 From: Associated Production Services
 100 Louise Drive, Ivyland, PA 18974
 Phone: 215-672-9505 Fax: 215-672-9507

Date of Arrival	10/03/2022	Container No.	MSCU5380548	Was Container Sealed? (Y/N)	Y	SEALD	RICOLA	Seal I.D. & No.	017485
-----------------	------------	---------------	-------------	-----------------------------	---	-------	--------	-----------------	--------

(Circle One) Number of Sacks & Labeled Weight (kg) or Number of Cases	Flavor	Batch #	Ricola USA PO #	Delivery Note #
--	--------	---------	-----------------	-----------------

1 @ 483 & 2 @ 800 : 2083 kgs	Echinacea Honey Lemon	2000101355	26874	74894
1 @ 658 & 14 @ 800 : 11858 kgs	SF Lemon Mint	2000111630	26876	74894
1 @ 586 & 3 @ 800 : 2986 kgs	Lemon Mint	2000104867	26875	74894

Comments:				

Receiver's signature: *[Signature]*

END OF PURCHASE ORDER REPORT

Affix all bulk bag labels for this P.O. to the back of this page.

Packaging Line No.: 4

Page 1 of 1

Product Flavor: Lemon Mint

Ricola, USA P.O. Number: 4500026875

Batch Code (USA): 2000115345

Entered by: DEJ

Checked by: Debra Juch

Date: 10/06/2022

Bulk bag tag flavor matches actual flavor printed on drops Yes(Y) No(N)

Performed by: (Initials)

Checked by: (Initials)

Shift	Date	Pallet #	Container No.	Swiss Batch No.	Seal No.	Weight (Kg)	Bulk bag tag flavor matches actual flavor printed on drops Yes(Y) No(N)	Performed by: (Initials)	Checked by: (Initials)
1	10/06/2022	4	MSCU5380548	2000104867	00267669	586	Y	DEJ	DEJ
2	10/06/2022	1	MSCU5380548	2000104867	00267664	804	Y	RB	RS
2	10/06/2022	2	MSCU5380548	2000104867	00267667	800	Y	RB	RS
2	10/06/2022	3	MSCU5380548	2000104867	00267668	801	Y	RB	RS
<p style="font-size: 2em; opacity: 0.5;">10/10/2022</p>									

Weight Counts (Kg)

Ricola's Total Weight

2,986

APS's Total Weight

2,991

Weight under (circle one)

5

Comments:

N/A MA 10/11/2022

Completed by:

Debra Juch

Date:

10/06/2022

Reviewed by:

Simon Joseph

Date:

10/10/2022

Ricola AG

Baselstrasse 31
CH-4242-Laufen
Schweiz/Switzerland

Distributed by:
Ricola USA Inc.
6 Campus Drive 2nd Floor South
Parsippany, NJ 07054, USA

Ricola[®]

6000131

804 kg

NATURAL LEMON-MINT HERB THROAT DROPS

.. Big-Bags at 800 Kg

267664



Charge/
Lot/ Lot

2000104867

11OKT2022 Pack until

376107004902371075

SSCC

Netto Gewicht / Net weight / Poid net	758 KG	Start-Zeit / Start time / temps du décollage	
Fullgewicht / Filling weight / Poids de remplissage	800 KG		13.06.2022 06:35
Gewicht Bag/ Weight bag/ Poid bag	805 KG	Ende-Zeit / End time / temps du fin	
Palettengewicht / Pallet weight / Poids de palette	823 KG		13.06.2022 16:04

Hiermit bestätige ich, dass die Angaben korrekt sind und die Zuordnung zur Palettenidentifikation korrekt erfolgte.
Herewith I confirm the correction of the information and the correct allocation to the pallet identification.
Je confirme par la présente que les informations et que l'attribution de l'identification des palettes sont corrects.

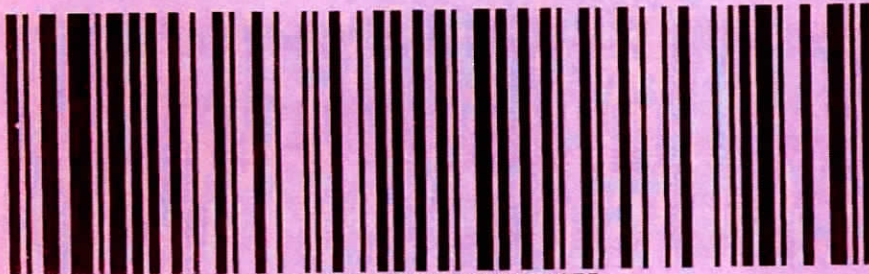
Palettenummer / Number of pallet / Numéro de palette

001

Mitarbeiter
Employee Employé

OSNT

OS

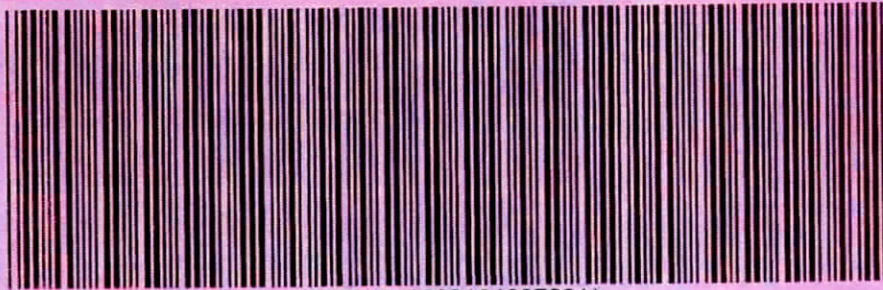


(00)376107004902371075

Paletten-Identifikation

Material: 6000131 HF ZIM GEW USA 004

Charge: 2000104867



60001312000104867001

Werk:

1200

Kochlinie:

K07 PPPI

Druck durch:

OSNT

Start Zeit:

13.06.2022 06:35

Palette Nr.:

001

Ricola AG
Baselstrasse 31
CH-4242-Laufen
Schweiz/Switzerland

Distributed by:
Ricola USA Inc.
6 Campus Drive 2nd Floor South
Parsippany, NJ 07054, USA

Ricola[®]

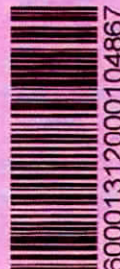
6000131

500kg

NATURAL LEMON-MINT HERB THROAT DROPS

.. Big-Bags at 800 Kg

267667



60001312000104867

Charge/
Lot/ Lot

2000104867

11OKT2022 Pack until

376107004902371207

SSCC

Netto Gewicht / Net weight / Poids net

758 KG

Start-Zeit / Start time / temps du décollage

Füllgewicht / Filling weight /

800 KG

13.06.2022 07:28

Poids de remplissage

Gewicht Bag/ Weight bag/ Poids bag

805 KG

Ende-Zeit / End time / temps du fin

Palettengewicht / Pallet weight /

823 KG

13.06.2022 16:37

Poids de palette

Hiermit bestätige ich, dass die Angaben korrekt sind und die Zuordnung zur Palettenidentifikation korrekt erfolgte.
Herewith I confirm the correction of the information and the correct allocation to the pallet identification.

Palettennummer / Number of
pallet / Numéro de palette

Je confirme par la présente que les informations et que l'attribution de l'identification des palettes sont corrects.

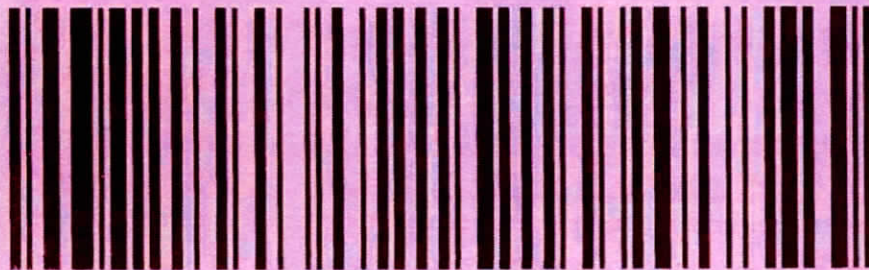
002

Mitarbeiter

Employee Employé

OSNT

OS



(00)376107004902371207

Paletten-Identifikation

Material: 6000131 HF ZIM GEW USA 004

Charge: 2000104867



60001312000104867002

Werk:

1200

Kochlinie:

K07 PPPI

Druck durch:

OSNT

Start Zeit:

13.06.2022 07:28

Palette Nr.:

002

Ricola AG
Baselstrasse 31
CH-4242-Laufen
Schweiz/Switzerland

Distributed by:
Ricola USA Inc.
6 Campus Drive 2nd Floor South
Parsippany, NJ 07054, USA

Ricola[®]

6000131

801kg

NATURAL LEMON-MINT HERB THROAT DROPS

.. Big-Bags at 800 Kg

26-7667



Charge/
Lot/Lot

2000104867

11OKT2022 Pack until

376107004902371361

SSCC

Netto Gewicht / Net weight / Poid net

758 KG

Start-Zeit / Start time / temps du décollage

Füllgewicht / Filling weight /
Poids de remplissage

800 KG

13.06.2022 16:14

Gewicht Bag/ Weight bag/ Poid bag

805 KG

Ende-Zeit / End time / temps du fin

Palettengewicht / Pallet weight /
Poids de palette

823 KG

13.06.2022 17:11

Hiernit bestätige ich, dass die Angaben korrekt sind und die Zuordnung zur Palettenidentifikation korrekt erfolgte.
Herewith I confirm the correction of the information and the correct allocation to the pallet identification.
Je confirme par la présente que les informations et que l'attribution de l'identification des palettes sont corrects.

Palettennummer / Number of
pallet / Numéro de palette

OS

003

Mitarbeiter
Employee Employé **OSNT**

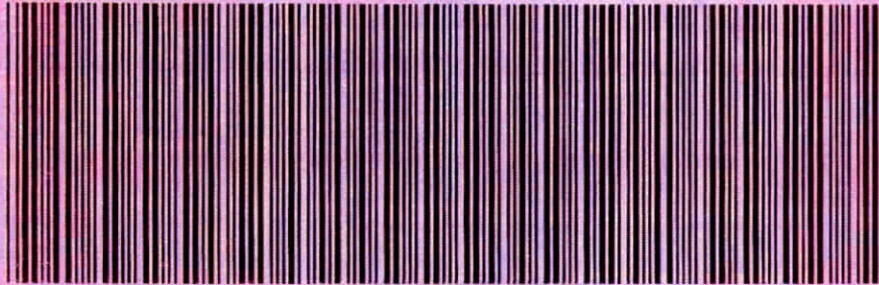


(00)376107004902371361

Paletten-Identifikation

Material: 6000131 HF ZIM GEW USA 004

Charge: 2000104867



60001312000104867003

Werk:
1200

Kochlinie:
KO7 PPPI
Druck durch:
OSNT

Start Zeit:
13.06.2022 16:14

Palette Nr.:

0003

Ricola AG
Baselstrasse 31
CH-4242-Laufen
Schweiz/Switzerland

Distributed by:
Ricola USA Inc.
6 Campus Drive 2nd Floor South
Parsippany, NJ 07054, USA

Ricola[®]

6000131

NATURAL LEMON-MINT HERB THROAT DROPS

.. Big-Bags at 800 Kg **267669**



Charge/
Lot/ Lot

2000104867

11OKT2022 Pack until

376107004902371434

SSCC

Netto Gewicht / Net weight / Poid net	556 KG	Start-Zeit / Start time / temps du décollage	
Füllgewicht/ / Filling weight / Poids de remplissage	586 KG		13.06.2022 16:44
Gewicht Bag/ Weight bag/ Poid bag	591 KG	Ende-Zeit / End time / temps du fin	
Palettengewicht / Pallet weight / Poids de palette	609 KG		13.06.2022 17:40

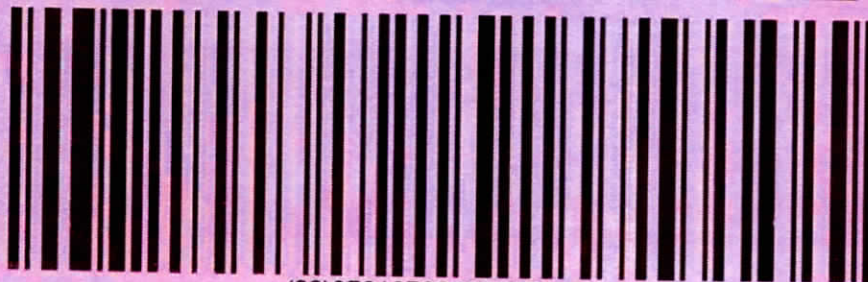
Hiermit bestätige ich, dass die Angaben korrekt sind und die Zuordnung zur Palettenidentifikation korrekt erfolgte.
Herewith I confirm the correction of the information and the correct allocation to the pallet identification.

Je confirme par la présente que les informations et que l'attribution de l'identification des palettes sont corrects.

Palettennummer / Number of
pallet / Numéro de palette

004

Mitarbeiter
Employee Employé **OSNT**

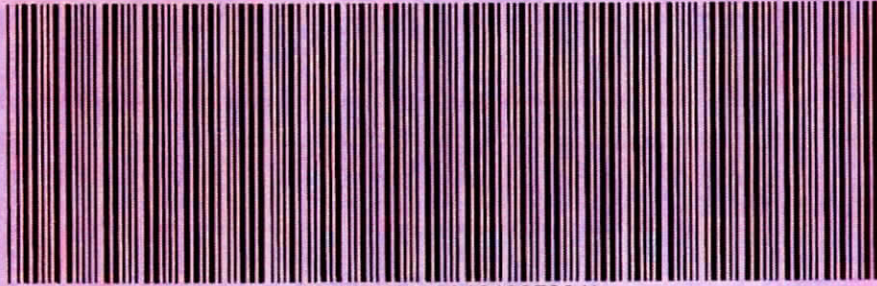


(00)376107004902371434

Paletten-Identifikation

Material: 6000131 HF ZIM GEW USA 004

Charge: 2000104867



60001312000104867004

Werk:

1200

Kochlinie:

KO7 PPPI

Druck durch:

OSNT

Start Zeit:

13.06.2022 16:44

Palette Nr.:

004

FILM ACCOUNTABILITY REPORT

Product Flavor: Lemon Mint Batch Code (USA): 2000115345 Line No.: 4
 Ricola, USA P.O. Number: 4500026875 Film Material No.: 9013701 CA
 Entered by: PEJ Checked by: Neza Munn Date: 10/06/2022 Page 1 of 1

Shin	Date	Film Roll No.	Film Set No.	Film Cut No.	Film Lot No.	Film Material Number Matches the IPCS Reference Yes(Y) No(N)	Performed by: (initials)	Checked by: (initials)
1	10/06/2022	2	2	3	199020	Y	PE	KN
1	10/06/2022	26	1	2	199020	Y	PE	KN
2	10/06/2022	2	2	1	199020	Y	RB	RS
2	10/06/2022	26	1	3	199020	Y	RB	RS
<p style="font-size: 2em; opacity: 0.5;">10/10/2022</p> <p style="font-size: 4em; opacity: 0.5;">NA</p>								

Film Impressions Counts

a	Markem counter number display at end of run	42,457
b	Markem counter Number display at start of run	0
c	Total number of film impressions used (a-b)	42,457
d	Finished packaged product film impressions	41,712
e	Film impressions wasted	745
f	Defective film impressions	0
g	Total Number of film impressions accounted for (d+e+f)	42,457

Film Lot Change Instructions: If the film lot being used changes to a new film lot, start a new sheet and reset the Markem counter to zero. If the Markem counter cannot be reset to zero, record the Markem count displayed at the start (b) of the new film.

Comments:
 N/A - MA
 10/11/2022

Completed by: [Signature] Date: 10/06/2022
 Reviewed by: [Signature] Date: 10/10/2022

STRAIGHT BILL OF LADING - SHORT FORM - File Copy

RECEIVED, subject to the classifications and tariffs in effect on the date of issue of this Original Bill of Lading.

BOL#: 5590
Date: 10/7/2022
Page: 1 of 1

AM TRANSPORT

Carrier SCAC: _____ Carrier #: _____

the property described below, in apparent good order, except as noted (contents and condition of contents of packages unknown), marked, consigned, and destined as indicated below, which said carrier (the word carrier being understood throughout this contract as meaning any person or corporation in possession of the property under the contract) agrees to carry to its usual place of delivery as said destination, if on its route, otherwise to deliver to another carrier on the route to said destination. It is mutually agreed, as to each carrier of all or any of said property over all or any portion of said route to destination, and as to each party at any time interested in all or any of said property, that every service to be performed hereunder shall be subject to all the terms and conditions of the Uniform Domestic Straight Bill of Lading set forth (1) in the Uniform Freight Classification in effect on the date hereof, if this is a rail, or a rail-water shipment, or (2) in the applicable motor carrier classification or tariff if this is a motor carrier shipment. Shipper hereby certifies that he is familiar with all the terms and conditions of said bill of lading, including those on the attachment thereof, set forth in the classification or tariff which governs the transportation of this shipment, and the said terms and conditions are hereby agreed to by the shipper and accepted for himself and his assigns.

SHIPPER (FROM)

RICOLA-PROVIDENT MARKETING
 100 LOUISE DR
 IVYLAND, PA 18974

PRO #: _____

CONSIGNEE (SOLD TO)

RICOLA USA, INC
 6 CAMPUS DRIVE, SECOND FLOOR SOUTH
 PARSIPPANY, NJ 07054

DELIVER TO (if different from Consignee)

JILLAMY
 2955 STATE RD
 CROYDON PA 19021

CUST. ORDER#: 26875

OUR ORDER#: _____

DEPT: _____

ROUTE: _____

Special Instructions:

COMPLETED PO

SEND FREIGHT BILL TO: (if different than SHIPPER above)

Freight charges are:

PREPAID

Subject to Section 7 of conditions of applicable bill of lading, if this shipment is to be delivered to the consignee without recourse on the consignor, the consignor shall sign the following statement.

C.O.D. _____ AMOUNT

The carrier shall not make delivery of this shipment without payment of freight and all other lawful charges.

C.O.D. FEE _____

Prepaid Collect

(Signature of Consignor)

NO. PKGS	HM UM (X)	DESCRIPTION OF ARTICLES, KIND OF PACKAGE, SPECIAL MARKS AND EXCEPTIONS	WEIGHT (subject to correction)	CLASS	NMFC	SUB
869	CASE	3048948 RIC BG LEMON MINT 6X8X19PC BATCH# 2000115345	8342.4			
EXP DATE: 13 JUN 2025						
28@30 1@29						

869	ON 29 PALLETS	8342.4 LBS	TOTALS
MARK "X" IN THE HM COLUMN TO DESIGNATE HAZARDOUS MATERIALS AS DEFINED IN DOT REGULATIONS			

* If the shipment moves between two ports by a carrier by water, the law requires that the bill of lading shall state whether it is "carrier's or shipper's weight."
 NOTE - Where the rate is dependent on value, shippers are required to state specifically in writing the agreed or declared value of the property.
 The agreed or declared value of the property is hereby stated by the shipper to be not exceeding

Trailer Number: W16877

Seal Number:

U.S. DOT Hazmat Reg. Number:

PER
 * The five boxes used for this shipment conform to the specifications set forth in the box maker's certificate thereon, and all other requirements of Uniform Freight Classifications.

* Shipper's imprint is lieu of stamp; not a part of bill of lading approved by the Interstate Commerce Commission.

SHIPPER'S CERTIFICATION This is to certify that the above-named materials are properly classified, described, packaged, marked and labeled, and are in proper condition for transportation according to the applicable regulations of the Department of Transportation.

EMERGENCY RESPONSE NUMBER:	SUPPLIED BY DRIVER
CONTACT:	
PLACARDS REQUIRED	N

SHIPPER: **RICOLA-PROVIDENT MARKETING**

Received by: **JILLAMY**

PER: **AMBER KENNEY 10/07/2022**

Carrier/Driver: **AM TRANSPORT**

4

Receiving & Carrier Signatures _____ Date _____

**SUMMARY OF NET CHANGES FORM (SNC)
ASSOCIATED PRODUCTION SERVICES, INC.**

**ATTACHMENT FOR PART 5 RECORDS
RECORD 6 QUALITY ASSURANCE AND PRODUCT RELEASE**



Associated Production Services, Inc
Trevose, PA 19053

Product Packaging Conformance Certificate

Extra Strength Icy Menthol
Extra Fort Menthol Glace
Product: Throat Lozenges

Batch Number: 2000115960

Finished Product Code (Item Number): 3048583

Associated Production Services, Inc. certifies that the following bulk product and film have been used in the packaging of this batch:

Bulk Product Batch Number: 2000113709

Bulk Product Code (Bulk Material Number): 6002422

Film Job Number(s): 199289

Drop Count: 19

and Associated Production Services, Inc. certifies that the finished packaged product has satisfactorily met Associated Production Services, Inc. process controls per SOP 14.0 and was produced in accordance with the agreed upon packaging specifications provided to APS by Ricola USA, Inc.

Michael J. Smigiel
APS Quality Assurance Signature

A handwritten signature in black ink, appearing to read 'Michael J. Smigiel', written over a horizontal line.

11/10/2022
Date

Peter Eccles

From: Mia Manubag <mia.manubag@ricola.com>
Sent: Tuesday, November 15, 2022 2:47 PM
To: QA@apspackage.com
Subject: Material Release


The following Material was released by Ricola USA

Material 3048583, RIC BG XSTRG ICYMNTH 6x8x19PC, Batch 2000115960, Release date 11/15/2022, Released quantity 3,470.000 of 3,470.000

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**SUMMARY OF NET CHANGES FORM (SNC)
ASSOCIATED PRODUCTION SERVICES, INC.**

**ATTACHMENT FOR PART 5 RECORDS
RECORD 4 PRODUCT RECALL PROCEDURE**

Procedure: 22.0	ASSOCIATED PRODUCTION SERVICES	Effective Date: 04/15/2020
Revision: 3	Title: RICOLA PRODUCT RECALL PROCEDURES	QA Approved By: 
Page 1 of 1	Prepared by: Peter Eccles	Supersedes No.: 22.0 Rev. 2 Supersedes Date: 06/02/2016

1.0 Purpose: To outline the authority, responsibilities and procedures for product recall.

2.0 Scope: This procedure will apply to all Ricola products or materials held at APS.

3.0 Authorities and responsibilities: QA Department will be responsible for enacting the recall procedure

4.0 Procedure:

4.1 In the event of a recall, APS will follow the guidelines set forth by Ricola USA contained in their procedure 07-02 (see attached procedure)

5.0 Records, Reports, and Forms

Attachment 1: Ricola USA SOP #07-02 Recall Policy.

Ricola USA, Inc.



Standard Operating Procedure (SOP)

Originator Donald Parriott	Signature <i>Don Parriott</i>	DocuSigned by: 4069F99D6918488...	Date 4/14/2020	Effective Date April 19, 2020
Quality William Higgins	Signature <i>Bill Higgins</i>	DocuSigned by: 889550AD736F4C1...	Date 4/9/2020	Supersedes SOP(s) 07-01
SOP For Recall Policy				SOP # 07-02

1.0 OBJECTIVE

The objective of this SOP is to both outline and specify the steps to be taken by Ricola and its agents if there is need to initiate a product recall or a market withdrawal.

2.0 SCOPE

The scope of this policy will cover all product recalls and market withdrawals. Product recalls are classified as Class I, II, and III. These are for situations where, either voluntary (self-imposed) or FDA-requested, it is essential that all of a certain material be removed from the appropriate location(s) and moved to a Ricola-controlled location for destruction or other disposition.

Market withdrawals are unclassified. These are for all other situations where there is need to remove product from the market / distribution channels and return the product to a Ricola-controlled location for destruction or other disposition.

3.0 DEFINITIONS

Class I Recall A situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death.

Class II Recall A situation in which use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.

Class III Recall A situation in which use of, or exposure to, a violative product is not likely to cause adverse health consequences.

Market Withdrawal A firm's removal or correction of a distributed product which involves a minor violation that would not be subject to legal action by the FDA or which involves no violation, e.g., normal stock rotation practices, routine equipment adjustments and repairs, etc.

SOP For Recall Policy	SOP # 07-02
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4.0 RESPONSIBILITY

It is the responsibility of Ricola USA Quality to champion all proceedings involved in recalls and withdrawals and to ensure accurate and timely completion of all applicable steps. In addition, it is Quality's responsibility to inform Management of the needed details so that key actions can be effected when warranted. It is also Ricola USA Quality's responsibility to inform, on a daily basis (at a minimum), Ricola Ltd. Quality of the status of the withdrawal / recall – if one is deemed necessary to initiate and is because of a product defect, etc. which was generated prior to that product's shipment to the US.

It is the responsibility of Ricola USA Executive Management to execute the recalls/ withdrawals, approve essential steps involved, keep abreast of all issues, and approve/ sign critical documents.

It is the responsibility of Ricola Operations to ensure that all facets involved in the documents of and the logistics of the moving of materials involved in the recall / withdrawal be completed as planned. Operations will work closely with Quality to keep management informed and to carry out the recall / withdrawal.

It is the responsibility of all other personnel involved in the recall / withdrawal (i.e., other company personnel, Ricola's brokers, etc.) to follow instructions given by Executive Management, Quality, or Operations to aid in effecting the completion of any tasks pertaining to the recall / withdrawal.

5.0 PROCEDURE

5.1 Pre-determination (to recall / withdraw or not) actions

5.1.1 Upon receipt of any communication / documentation / information which may potentially lead to the need for a product recall / withdrawal, that Ricola employee will notify Quality. Quality will evaluate the information and schedule a meeting with Operations and Executive Management if a potential recall/withdrawal is warranted.

5.1.2 Quality, Operations, or Executive Management will notify Legal of the potential need for a recall / market withdrawal.

5.1.3 A meeting involving Executive Management, Operations, Quality, and Legal (and any other parties the persons present believe are essential) will be conducted.

5.1.4 During this meeting, the following must occur:

5.1.4.1 Discussion of the information present at the time

SOP For Recall Policy	SOP # 07-02
--------------------------	----------------

- 5.1.4.2 Determination of "Is a recall / withdrawal warranted or not?"
- 5.1.4.3 Documentation of the decision of the Head of Quality
- 5.1.4.4 If the decision cannot be made, another meeting time will be decided on and step 5.1.4 will be repeated.

- 5.1.5 A decision to recall / withdrawal must be made within 72 hours of Quality, Operations, and Executive Management first learning of the situation.

- 5.1.6 The Head of Quality, in conjunction with Legal, shall file a Field Alert with the FDA District Office, within three (3) working days of the decision to recall, to notify the Agency of the deficiency or possible deficiency and any action the Company has decided to take.

- 5.2 No recall / withdrawal warranted
 - 5.2.1 Document that a decision has been made to not recall / withdrawal the product.
 - 5.2.2 This documentation shall be retained by Quality and included in the associated investigation record.

- 5.3 Recall / withdrawal warranted
 - 5.3.1 Initiation of a recall type and class or market withdrawal is made as per the conditions listed under Scope and Definitions – dependent upon the nature and severity of the product deficiency or possible deficiency.
 - 5.3.2 Executive Management, Operations, Legal, and Quality, along with any other parties deemed appropriate by the above, will convene to discuss what steps are required to effect the recall / withdrawal. Contact information of key personnel at Ricola is provided within this SOP (Attachment # 1). The steps required to conduct a recall / market withdrawal may include, but not be limited to (due to circumstances), the following items listed below.
 - 5.3.3 If applicable, any testing of product (returned / retained / or that still in warehousing) will be conducted to determine the exact properties of the product and to further evaluate the risk associated with the deficiency or the possible deficiency; thus justifying (or not justifying) the need to conduct the market withdrawal / recall and to help determine the appropriate level in the distribution chain to which the recall should extend.
 - 5.3.4 The Head of Quality will assign responsibilities to other persons or departments as required based on the recall type / class or market withdrawal. These assignments will be made in writing.

SOP For Recall Policy	SOP # 07-02
--------------------------	----------------

- 5.3.5 It is essential to understand the urgency of conducting every task involved in a recall / market withdrawal. All action items should be given top priority to ensure their expeditious completion.
- 5.3.6 Notification of a market withdrawal / recall will be made by the Head of Quality, with help from Legal, to the FDA. Pertinent information provided may include, but not be limited to, that which is included within this SOP (Attachment # 2). The specific content of such notification shall be determined on a case-by-case basis. A sample Drug Recall Letter and Return Postcard are provided for purposes of general guidance only (Attachment # 3).
- 5.3.7 In the event that a determination is made that the product subject to market withdrawal or recall may pose a significant health hazard, a press release may be issued. The decision as to whether a press release should be issued will be made by Executive Management, Quality, and Legal. Draft press releases will be generated by Marketing and will follow a general documented format (Attachment # 4). All press releases shall be reviewed and approved by Executive Management, Operations, Quality, and Legal, and FDA, if they so request, before being finalized and issued.
- 5.3.8 All public inquiries (i.e., inquiries from the press) should be directed to Executive Management for a response. The form and content of any response to such inquiry shall be determined by Executive Management, Quality, and Legal. All documentation of public inquiries and any responses thereto shall be kept as part of the recall / market withdrawal records for a period of no less than 3 years following their receipt and/or issuance
- 5.3.9 Accounts having received affected defective or possibly defective product will be determined.
- 5.3.10 These accounts will be notified of the recall / market withdrawal and will be instructed as to how to handle their portion of the recall / market withdrawal.
- 5.3.11 Ricola USA will take all reasonable steps to contact affected customers and (1) retrieve product subject to the recall/withdrawal or request he customer to dispose of such product (2) document that the product is in commercial distribution.
- 5.3.12 All returned product will be quarantined along with any remaining inventory (of the recalled / withdrawn material).

SOP For Recall Policy	SOP # 07-02
--------------------------	----------------

5.3.13 Follow-up communications will be made by Marketing for both respondent and non-respondent accounts, until product accountability is satisfactory. The method and form of such follow-up communications shall be subject to the review and approval of Executive Management, Quality, and Legal.

In addition to the follow-up communications described above, effectiveness checks may be conducted so as to verify that the targeted consignees have received notification and have taken appropriate action.

5.3.14 Satisfactory product accountability will be determined by Executive Management, Operations, and Quality. Justification for determination of satisfaction will be documented within the recall / market withdrawal report.

5.3.15 Periodic status reports will be prepared and submitted by the Head of Quality, in cooperation with Legal, to the FDA. These will include, but not be limited to, information on the effectiveness of the recall or market withdrawal and estimated time of completion.

5.3.16 The Head of Quality will notify the FDA when the recall or market withdrawal has been completed. A final recall / withdrawal report will be submitted to FDA as part of the recall/withdrawal termination

5.3.17 A recall or market withdrawal will be terminated after the FDA has reviewed the appropriate documents and has sent a letter of termination to Ricola, if applicable.

5.3.18 Disposition of the product will be made after a final accountability of all returned product and review of all documentation has been conducted by the Head of Quality.

5.3.19 Disposition may involve destruction, re-labeling, re-working, etc., and is dependent on the reason for the recall or market withdrawal.

5.3.20 A notice of proposed disposition of the product will be issued to management and FDA as required.

5.3.21 Disposition authorization (by the FDA, if applicable) will be obtained prior to actual carrying out of the disposition.

5.3.22 Disposition of the product will be witnessed by the FDA, if required or requested by the agency.

5.3.23 A final report will be issued and signed by Executive Management, Operations, and Quality. All pertinent documents involved with the recall / market withdrawal will be kept with the report. All records will be kept by

SOP For Recall Policy	SOP # 07-02
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Quality for a period of seven (7) years from the date of the receipt of notice of the deficiency or possible deficiency.

END OF SOP

Additional Approvals Required:

DocuSigned by:
Nick Fiore
5C934038507244D

Ricola USA, Inc. Operations

4/9/2020

Date

DocuSigned by:
Allison Fulton
8DB725B8A2464B1...

Ricola USA, Inc. Legal

08Apr2020

Date

ATTACHMENT 1

Ricola USA, Inc. Market Withdrawal / Recall Key Personnel Contact Information

President William Higgins	Work Phone 973-984-3200	Cell Phone 862-242-9176
Head of Quality Donald Parriott	Work Phone 973-984-3204	Cell Phone 973-903-5215
Legal Counsel Allison Fulton	Work Phone 202-747-2195	Cell Phone 202-276-8950

ATTACHMENT 2

Required information to be obtained prior to or directly after first notifying the FDA of an intended market withdrawal / recall.

Reason for recall / market withdrawal

Assessed evaluation of the risk associated with the (possible) deficiency

Brief chronology of events leading up to the need for recall / market withdrawal

Recalling firms information

Name

Address

Fax

Phone

Email address

Mailing address

Product involved

Name

Strength

Description of product

Dosage form

Product code number

Packaging

Other

Batch number(s)

Quantity produced

Quantity in distribution

Geographical assessment of distribution

Dates of distribution

Quantity still in-house

Retrieval of material

Proposed strategy for conducting the market withdrawal / recall

Notify

 Holders of in-question material

 Shipment site for in-question material

Receive initial material

Ensure that daily receipt reports (of material) are being generated and distributed to Ricola

Receive last expected material

Completion of market withdrawal / recall

Determination of "satisfactory completion"; criteria involved in such

Notification of parties that the market withdrawal / recall is complete

FDA

Product consignees

Public

Disposition of material

Determination of final disposition

Completion of disposition action (destruction, etc.)

Notification of FDA that the market withdrawal / recall material has been dispositioned

Final report

Signed

Copy sent to FDA, if required

Stored

Recall / market withdrawal contact person:

**Donald Parriott, Head of Quality, Ricola USA, Inc., 6 Campus Drive, 2nd Floor South,
Parsippany, NJ 07054**

Phone 973-984-3204

Fax 973-984-6814

E-mail don.parriott@ricola.com

ATTACHMENT 3

MODEL DRUG RECALL LETTER AND RETURN POSTCARD

[Insert name and address of customer]

[Date]

URGENT: PRODUCT RECALL – [Name of Product]

Re: [Name of Product]
Lot No(s). [Insert]

Recent information shows that the above-referenced lot number(s) of this product is [fill in test results]. Consequently, we are recalling this lot from the market. Other lot numbers are not involved.

Please examine your stocks immediately to determine if you have any of Lot No(s). on hand. If so, discontinue distributing the lot and promptly return via [insert method of delivery] to the following address:

[Insert address]
ATTENTION: RETURNED GOODS

[NOTE: If a sub-recall is indicated in a particular recall situation, the following paragraph should be added:

If you have distributed any of Lot No(s). [insert], please immediately contact your accounts, advise them of the recall situation, and have them return their outstanding recalled stocks to you. Return the stocks as indicated above.]

You will be reimbursed by check or credit memo for the returned goods and postage.

Please return the enclosed card immediately providing the requested information.

This recall is being made with the knowledge of the Food and Drug Administration. The FDA has classified this recall as class [insert].

We appreciate your assistance.

William Higgins
President

Encl.

MODEL RECALL RETURN POSTCARD

PLEASE FILL OUT AND RETURN

We do not have any stock of [Product Name, Lot No(s).] on hand.

We have requested our accounts to return their stocks of this merchandise to us.

We are returning [insert quantity and containers] of [Product Name, Lot No(s).].

Name

Address

City State Zip Code

ATTACHMENT 4

Model Market Withdrawal / Recall Ricola "Press Release"

Ricola USA, Inc. announced today that it is conducting a (market withdrawal / recall) for the product _____, batch(es) number(s) _____, in the total quantity of _____ (cases / units).

The (market withdrawal / recall) has been initiated because Ricola USA has reason to believe that the product may have been _____. Ricola has taken corrective action to ensure that all of its products are safe and meet all requirements.

No illness or injuries have been reported to Ricola USA as a result of consumption of this product.

(Distributors / consumers) who possess any of the suspect product are being asked to return it to the location below. Refunds may be obtained from _____.

This recall is being conducted in cooperation with the FDA.

Consumers: Return all product to _____. (Only Class I recalls).

Distributors: Return all product to _____.

**SUMMARY OF NET CHANGES FORM (SNC)
ASSOCIATED PRODUCTION SERVICES, INC.**

**ATTACHMENT FOR PART 6 RECORDS
LIST OF PRODUCTS PACKAGED AND LABELLED AT THE SITE**

List of Products Packaged and Labelled at Associated Production Services, Inc., 100 Louise Drive, Ivyland, Pennsylvania 18974 USA

Product Name	Dosage Form	Product Type	Route of Administration	Natural Product Number (NPN)	Storage Conditions Requirements
Ricola Berry Medley Bagged Throat Lozenges	Throat Lozenges	Cough Suppressant	Oral	80113906	Temperature 50°F-85°F Humidity <75%
Ricola Cherry Honey Cough Suppressant Bagged Throat Lozenges	Throat Lozenges	Cough Suppressant	Oral	80025378	Temperature 50°F-85°F Humidity ≤75%
Ricola Extra Strength Icy Menthol Cough Suppressant Bagged Throat Lozenges	Throat Lozenges	Cough Suppressant	Oral	80086168	Temperature 50°F-85°F Humidity ≤75%
Ricola Green Tea with Echinacea, Cough Suppressant , No Sugar Added- Bagged Throat Lozenges	Throat Lozenges	Cough Suppressant	Oral	80014874	Temperature 50°F-85°F Humidity ≤75%
Ricola Honey Lemon With Echinacea Cough Suppressant Bagged Throat Lozenges	Throat Lozenges	Cough Suppressant	Oral	80027475	Temperature 50°F-85°F Humidity ≤75%
Ricola Lemon Mint No Sugar Added Cough Suppressant Bagged Throat Lozenges	Throat Lozenges	Cough Suppressant	Oral	80079154	Temperature 50°F-85°F Humidity ≤75%
Ricola Smoothers (name change to Throat Balm) Bagged	Throat Lozenges	Cough Suppressant	Oral	80117102	Temperature 50°F-85°F Humidity ≤75%
Ricola The Original Natural Herb Cough Drops, Cough Suppressant Bagged Throat Lozenges	Throat Lozenges	Cough Suppressant	Oral	80028321	Temperature 50°F-85°F Humidity ≤75%
Ricola Action Plus Honey-Lemon, Cough Suppressant Oral Anesthetic;	Throat Lozenges	Cough Suppressant	Oral	80074184	Temperature 50°F-85°F Humidity ≤75%
Ricola Menthol Centres - Honey Lemon Bagged Throat Lozenges	Throat Lozenges	Cough Suppressant	Oral		Temperature 50°F-85°F Humidity ≤75%
Ricola Mountain Herb, Cough Suppressant Bagged Throat Lozenges, No Sugar Added;	Throat Lozenges	Cough Suppressant	Oral	80028699	Temperature 50°F-85°F Humidity ≤75%
Ricola Mountain Herb with Stevia, Cough Suppressant Throat Drops, Sugar Free; Bagged Throat Lozenges	Throat Lozenges	Cough Suppressant	Oral		Temperature 50°F-85°F Humidity ≤75%
Ricola Original Herb, Cough Suppressant Throat Lozenges, No Sugar Added	Throat Lozenges	Cough Suppressant	Oral		Temperature 50°F-85°F Humidity ≤75%
Ricola Natural Lemon Mint Cough Suppressant Bagged Throat Lozenges;	Throat Lozenges	Cough Suppressant	Oral	80014340	Temperature 50°F-85°F Humidity ≤75%
Ricola Lemon Mint Cough Suppressant Bagged Throat Lozenges	Throat Lozenges	Cough Suppressant	Oral		Temperature 50°F-85°F Humidity ≤75%