

Sticky Bubble Gum

**Sticky Bubble Gum
Documents and Records**



Section 4.2 Documentation requirements

The documentation of the quality management systems includes our quality policy, quality objectives, a quality manual, procedures required by this standard, and other documents needed by the organization to ensure the effective planning, operation and control of the processes. Quality records will be maintained as objective evidence of the effective operation of the system.

The quality manual includes the scope of the quality management system, any exclusions, reference documented procedures required to operate the quality system, and a description of the interaction between the processes of the quality management system.

Documents required by the quality management system are controlled. Procedure P 4.2 defined how the requirements of this standard are met, including review and approval prior to issue, proper distribution and control of obsolete documents.

Records are established and maintained to provide evidence of conformity to requirements. They shall be legible, identifiable and retrievable according to the documented procedure for control of quality records.



P 7.2-005

Customer-related processes

- 5.6.1 When either the customer of SBG need to make a change to the requirements specified in the contract, customer service documents the change on the “Lets Make a Change Form”.
- 5.6.2 Customer service is responsible for getting approval from the customer for SBG initiated changes. Customer Service Manager must record the client responsible for authorizing the changes as evidence of approval on the “Lets Make a Change Form”.
- 5.6.3 Customer Service is responsible for approving any customer initiated changes. Customer service manager signature is required as evidence of approval on the “Lets Make a Change Form”.
- 5.7 Production
 - 5.7.1 Customer service reviews the production control data base to determine if SBG has the capacity to meet the order.
 - 5.7.2 Use increasing indents to clarify individual steps in the process.

6.0 Forms and Records

- 6.1 Purchase Order
- 6.2 Standard Quote Form
- 6.3 Let’s Make a Change Form

7.0 Attachments

- 7.1 None

8.0 Related Documents

- 8.1 None

9.0 References

- 9.1 None

10.0 Revisions

REV.	SECTION	SUB-SEC.	PARA.	CHANGE REQUEST #	DATE	AUTHORIZED BY
001				Original issue	1/7/01	Mary Tyler Moore
002	2.0			Changed responsibilities	2/8/01	Mary Tyler Moore

Sticky Bubble Gum

Center City, MN 56211
(218) 435-5478

Quotation for Bubble Gum:

Sticky Bubble Gum is a company committed to providing the best quality bubble gum in the world today. We strive to keep the quality of our product high by using quality ingredients, stringent quality control, and highly trained bubble gum makers. We are expected to provide you with this quote for Sticky Bubble Gum Product.

Cases : 1000
Flavor : Big Bubble
Package : Individual Packs
Delivery : 4 weeks

SPECIAL REQUESTS: _____

Price: \$ 40.00/case

Approval: Mary Tyler Moore
Sales and Marketing Manager
Sticky Bubble Gum

1.0 PURPOSE

1.1 The purpose of this document is to provide instructions for texturizing bubble gum.

2.0 SCOPE

2.1 This instruction is to be used for all of the SBG "big bubble" product line.

3.0 RECORDS

- 3.1 Daily Log sheets
- 3.2 Machine Sanitation Log
- 3.3 Lot routing card

4.0 ASSOCIATED DOCUMENTS

- 4.1 Machine Sanitation Manual
- 4.2 824-W-102 Texture Analyzer instructions
- 4.3 824-W-106 Tensile Tester

5.0 DEFINITIONS

5.1 None

6.0 RESPONSIBILITY

6.1 The Production Manager is responsible for this work instruction

7.0 TOOLS, GAGES, FIXTURES

- 7.1 Thermometer
- 7.2 SBG Texture Analyzer
- 7.3 Tensile Strength Tester

8.0 SAFETY REQUIREMENTS

- 8.1 Safety shoes
- 8.2 Hair net
- 8.3 Safety glasses

9.0 INSTRUCTIONS

- 9.1 Dump bulk gum from tote into the Texturizer
- 9.2 Turn the heaters on to 325 degrees. The temperature should be plus or minus 10 degrees

Corrective Action Log

Date	CAR #	Issue	Due Date	Completion Date
2/12/01	101	Machine 8 is too hot	4/15/01	4/12/01
2/20/01	102	Calibration	4/30/01	4/26/01
3/25/01	103	Finger Marks in the gum	5/1/01	5/3/01
3/21/01	104	Broken Thermometer	5/1/01	6/2/01
3/23/01	105	Strawberry flavor tastes like raspberry	5/26/01	
3/25/01	106	Texture of lot 09867 is lumpy	5/6/01	
3/25/01	107	Client complaint	6/29/01	
4/5/01	108	No follow up on corrective action	5/2/01	5/2/01
4/5/01	109	Procedure missing	4/15/01	6/1/01
6/4/01	110	Master list is not current		
6/4/01	111	Management did not review the quality policy during management review	8/4/01	7/1/01
7/20/00	112	Client complaint	8/4/00	



Corrective Action Request

Initiator: *Sam Shelberg*

Type of Problem: *Equipment*

Date: *2 - 12 - 01*

CAR #: *101*

Description of the problem: *Machine 8 runs at 450 degrees.
It should be at 325.*

Investigative Report: *The thermostat is set wrong.
It is on #8. It should stay on #5.*

Corrective Action Closed Date: *4/12/01*

Closed By: *Somersby*

F 8.5-001
1/1/00



Corrective Action Request

Initiator: Angela Toms

Type of Problem: Equipment

Date: 2/20/01

CAR #: 102

Description of the problem: Balance # 1302 has not been calibrated. Calibration due date was 3/1/00.

Investigative Report: *Toledo missed this balance when they were in. They have been called in to calibrate it next month.*

Corrective Action Closed Date: 4/26/01

Closed By: *Sumersby*



Corrective Action Request

Initiator: *Merv Griffen*

Type of Problem: *Product nonconformance*

Date: *3/25/01*

CAR #: 103

Description of the problem: *There are finger prints in the gum.*

Investigative Report: WHEN PRODUCTION STAFF HAS TO PICK UP CONTAINERS, THERE IS NO ROOM TO PUT FINGERS TO LIFT THE CONTAINER. WE MUST STICK THEM IN THE GUM.

Corrective Action Closed Date: *5/3/01*

Closed By: *Somersby*



Corrective Action Request

Initiator: *Meg Ryan*

Type of Problem: *Equipment*

Date: *3/21/01*

CAR #: 104

Description of the problem: *In Flavor Line B a thermometer has the top broken & f.*

Investigative Report: *Merv bumped it with the fork lift. It was replaced 6/1*

Corrective Action Closed Date: *6/2/01*

Closed By: *Sumersby*

F 8.5-001
1/1/00



Corrective Action Request

Initiator: *Dilbert Delany*

Type of Problem: *Product Nonconformance*

Date: *3/23/01*

CAR #: 105

Description of the problem: *All of yesterdays product tasted raspberry.
It should have been Strawberry.*

Investigative Report: *The Kool-aid packets are all the
same color. Ra. pberry was used for all lots that d̄y.*

Corrective Action Closed Date: *6/2/01*

Closed By: *Meg Ryan*



Corrective Action Request

Initiator: *Merv Griffin*

Type of Problem: *Product nonconformance*

Date: *3/25/01*

CAR #: 106

Description of the problem: *Lot 09867 has lumps that do not go away during final texturizing.*

Investigative Report:

Corrective Action Closed Date:

Closed By:



Corrective Action Request

Initiator: Somersby

Type of Problem: *Client complaint*

Date: 3/25/01

CAR #: 107

Description of the problem: *Client called to complain again. Says "Big Bubble" still does not hold a bubble, cancelled all 1000 on order.*

Investigative Report:

Corrective Action Closed Date:

Closed By:

F 8.5-001
1/1/00



Corrective Action Request

Initiator: Somersby

Type of Problem: *Audit nonconformance*

Date: 4/5/01

CAR #: 108

Description of the problem: *Corrective Action forms have no record of the corrective action taken to prevent recurrence.*

Investigative Report: *The form does not prompt staff to write the cause and action taken.*

Corrective Action Closed Date: 5/2/01

Closed By: Somersby



Corrective Action Request

Initiator: *Somersby*

Type of Problem: *Audit nonconformance*

Date: *4/5/01*

CAR #: *109*

Description of the problem: *A procedure is missing from book 4*

Investigative Report: *Distribution missed it.*

Corrective Action Closed Date: *6/1/01*

Closed By: *Somersby*



F-852-001-A

Corrective/Preventive Action Request (CPAR)

CA X PA

(Check appropriate box to indicate corrective or preventive action)

Corrective Action # 111

or

Date: 6/4/01

Preventive Action # _____

	Date Due	By/Assigned to	Completed Initials & Date
Investigation	6/11/01	Mary Tyler Moore	MTM 6/11/01
Implementation	7/1/01	Mary Tyler Moore	MTM 7/1/01
Audit			
CAR closed	7/1/01		Somersby 7/1/01

Description of Issue

Management did not review the Quality Policy during Management Review.

Investigation Finding / Root Cause

Insufficient time allowed for the meeting. The meeting was ended early.



Sticky Bubble Gum

F-852-001
Corrective/Preventive Action Request (CPAR)

Corrective / Preventive Action

Meetings will not be ended until all agenda items have been completed.

Agreed to by: *Management Review team*
Date: 7/1

Auditor's Comments

Was action taken effective? Yes No If no. new CA/PA number:



Corrective Action Request

Initiator: *Sam Shelberg*

Type of Problem: *Equipment*

Date: *2 - 12 - 01*

CAR #: *101*

Description of the problem: *Machine 8 runs at 450 degrees.
It should be at 325.*

Investigative Report: *The thermostat is set wrong.
It is on #8. It should stay on #5.*

Corrective Action Closed Date: *4/12/01*

Closed By: *Somersby*