

Johnson & Johnson

BABY PRODUCTS COMPANY

PROCESS SPECIFICATION - RESTRICTED

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SUBJECT:

MANUFACTURE OF JOHNSON'S BABY POWDER FORMULA 499 AT ESDP

SPEC. NO.

40116

ORIGINAL ISSUE DATE

10/1/73

REV.	DATE	DESCRIPTION OF CHANGE	AUTHORIZATION
	11/12/76	Specification converted to Baby Products Company format. Sec. 7 <u>Fineness</u> revised and <u>Appearance (TM 2060)</u> added.	BCR 000256
A	6/16/77	Sec. 6 revised to conform with Baby Products Company Quality Assurance Requirements for Manufacturing.	BCR 000624

RELEASED BY:

Eileen M. Scott/WJS

LOCATION:

ESDP - Baby

ISSUE DATE:

6/16/77

PRODUCT:

30-8

FORM 752-11 NEW 1/76

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SUBJECT:

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DESCRIPTION/OPERATING REQUIREMENTS/OPERATING PROCEDURES

1. This process specification is to be used in blending of ingredients for Baby Powder Formula 499 at ESDP
2. MATERIALS

	<u>R.M. Code</u>	<u>Spec. No.</u>
Perfume, Synfleur P	717-258-4	04-015
Windsor 66 Talc	712-003-4	01-011
3. EQUIPMENT
 - A. Talc Handling - Bag dumper, hopper and screw.
 - Allis Chalmers talc sifter fitted with 2 sets of screens; upper 4 mesh and lower 40 mesh.
 - Talc conveying and distribution system consisting of an air conveyor and interlocked diverting valves.
 - B. Perfume Distribution - Perfume system consisting of a perfume reservoir.
 - Precision metering pump and necessary interlocked valving and piping.
 - C. Powder Compounding - Nauta blenders having connections for talc and perfume.
 - Blender(s) mounted on a pneumatic-hydraulic weight control system.
 - The perfume unit has a special head for finely dispersing perfume into the talc.
 - Lump breaker.
 - D. Powder Delivery - Sifter fitted with 2 sets of screens, upper are 8 mesh, lower are 36 mesh.
 - Air conveying system for transporting powder to filling line.
 - E. Automatic programming equipment for control of the system.
4. QUANTITATIVE FORMULA - A copy of Operating Log Sheet 52-0173 shall be used to record the processing of the powder.

	<u>% w/w</u>	<u>Lbs/batch</u>
A. <u>Preblend</u>		
Perfume, Synfleur P	0.22	7.50
Windsor 66 Talc	2.93	100.00
Windsor 66 Talc	96.85	3300.00
	100.00	3407.50

 - B. *The following process control points shall be checked for each batch produced.
 - *Reference Paragraph 6.

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- | | |
|-----------------------------------|---|
| B. <u>Log Sheet Control</u> | <ul style="list-style-type: none"> - Time of each process step - Initials of compounder - Initials of checker - Pertinent data - Material control numbers |
| <u>Print Weight Control</u> | <ul style="list-style-type: none"> - Material identification - Material control number - Batch identification - Initials of compounder - Initials of checker |
| <u>Tank Identification</u> | <ul style="list-style-type: none"> - Batch identification - Batch control number |
| <u>Temperature Control Charts</u> | <ul style="list-style-type: none"> - Chart identification - Temperature characteristics - Timing and printing |

5. OPERATING PROCEDURE

- A. Perfume Preblend - Add talc through talc delivery system to blender. Add perfume to cylinder and position valves to feed the correct blender. With the lump breaker running, inject and disperse the perfume into the talc. After the perfume addition has been completed, blend the perfume with the talc for 6 minutes with the lump breaker running.
- B. Talc Delivery - After the 6 minute blending of the preblend perfume mixture, turn the talc delivery switch to "start" and add talc. The system will shut down automatically when the correct amount has been added. The blender full light will come on followed by a blender "ready" light after a 10 minute mix. Following Quality Control acceptance of the batch, the blender "release" light must be activated.
- C. Powder Delivery - After the batch is released, it is transferred by an air conveying system to the vacuum powder filler surge hopper as demanded by the surge hopper level controls. No powder can be delivered unless the blender "release" light has been activated.

6. BABY PRODUCTS COMPANY QUALITY ASSURANCE REQUIREMENTS FOR MANUFACTURING

Shall comply with JOHNSON & JOHNSON Baby Products Company "Minimum Requirements for Manufacturing Operations", B.P.P. #7-01.

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7. FINISHED MATERIAL PROPERTIES & REQUIREMENTS

Water Soluble Color (TM 1346) No more than a very pale greenish or gray off-white with no blue or other color visible.

Fineness (TM 1231) 98.5% minimum through 200 mesh sieve.
 99.7% minimum through 100 mesh sieve.
 99.98% minimum through 60 mesh sieve.

Odor (TM 2061) Characteristic perfume as compared to a reference standard.

Foreign Matter (TM 2060) Free of dirt and foreign matter. A magnet drawn through the powder shall show no evidence of metal particles.

Appearance (TM 2060) Free of dirt, foreign matter, grittiness and clumps of talc.