International Journal of Science and Research (IJSR)
ISSN: 2319-7064
Impact Factor 2025: 7.089

Comprehensive Evaluation of White Patch Formation in Polypropylene (PP) Carboys Manufactured by Extrusion Blow Molding

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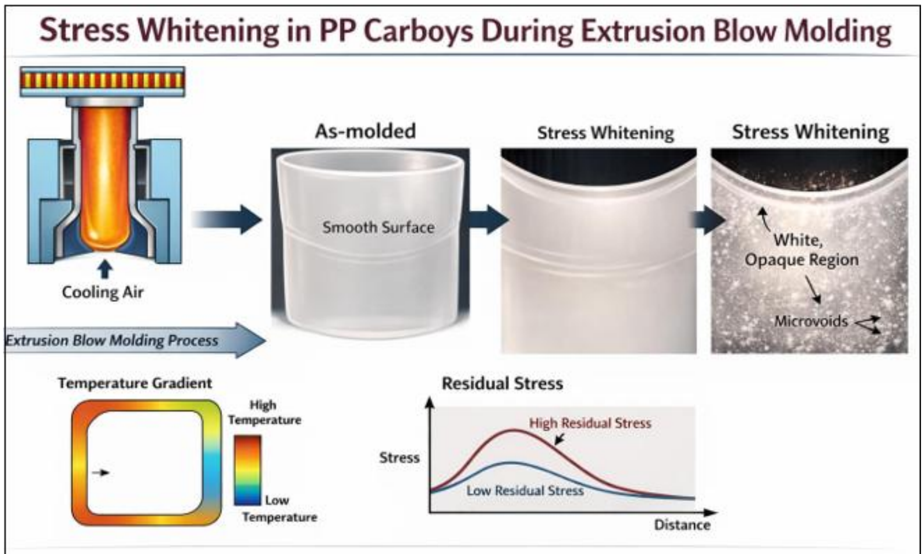
Abstract: ***Background**: Surface stress whitening was observed on the lower regions of extrusion blow-molded polypropylene (PP) carboys during routine quality inspections. Although stress whitening is commonly regarded as a cosmetic phenomenon. **Objective**: This study aimed to characterize the morphology, origin, and performance impact of stress-induced whitening observed in PP carboys and to assess whether the phenomenon poses any risk to mechanical integrity, containment performance, or sterilization compatibility. **Methods**: Carboys exhibiting visible white patches were subjected to a comprehensive evaluation including visual and tactile inspection, wall-thickness analysis, mechanical impact testing, Chemical impact testing, hydrostatic leak testing, vacuum integrity testing, thermal, and gamma sterilization. Morphological and risk-based assessments were supported by failure mode and effects analysis (FMEA). **Results**: Stress whitening was confirmed to be superficial and localized, with no evidence of crack initiation, polymer degradation, or material embrittlement. Mechanical performance, structural stability, leak integrity, and sterilization resistance were unaffected. Whitening did not progress following thermal or irradiation exposure. **Conclusion**: A comprehensive evaluation of polypropylene (PP) carboys exhibiting visible white patches confirmed that the observed condition is surface-level stress whitening only, caused by handling-related surface stress. It is cosmetic in nature and does not indicate material degradation or structural weakness. **Highlights**: 1) Whitening confirmed superficial; no cracks or embrittlement 2) Impact, leak, and vacuum tests showed no product failures 4) Wall thickness remained within specification across samples after tested with chemical 5) Autoclave (121°C) and gamma did not worsen whitening 6) FMEA confirmed cosmetic defect with low integrity risk.*

Keywords: Stress whitening; Polypropylene carboys; Extrusion blow molding; Surface morphology; Environmental stress cracking; Thermal cycling; Mechanical integrity; Leak integrity



Formation of microvoids leading to stress whitening in polypropylene (PP) carboys during extrusion blow molding.

1. Introduction

Stress whitening is a common visual phenomenon observed in semicrystalline polymers, including polypropylene, when subjected to localized mechanical deformation, impact, or handling-induced stress [1–4]. It manifests as white or opaque regions and is typically associated with micro-void formation, craze development, or orientation-induced fibrillation within the polymer structure [1–4]

2. Background

In pharmaceutical fluid handling and bioprocess storage applications, visible surface anomalies in polymer containers can raise concerns regarding structural integrity, long-term reliability, and regulatory acceptability [1–3,11,12]. During routine quality inspections, localized white hazy patches were observed on extrusion blow-molded polypropylene (PP) carboys, predominantly near the base and other high-stress regions [1–3,11,12]. Although stress whitening in semicrystalline polymers is commonly regarded as a cosmetic phenomenon, its occurrence in critical applications warrants systematic evaluation. This study investigates the origin and morphology of the observed whitening, distinguishes cosmetic stress whitening from structurally significant defects, and establishes a risk-based framework for defect classification, acceptance, and quality decision-making [1–3,11,12]

3. Materials and Methods

3.1 Material grade and technical detail

Category	Typical Properties	Value (Units)	Test Method
Physical	Melt Flow Rate (230 C/2.16 kg)	0.45 g/10 min	ASTM D1238
	Density (23 C, Method A)	0.90 g/cmb3	ISO 1183-1
Mechanical	Flexural Modulus (23 C)	1180 MPa	ISO 178
	Tensile Stress at Yield (23 C)	26 MPa	ISO 527-1,-2
	Tensile Strain at Yield (23 C)	11 %	ISO 527-1,-2
Impact	Charpy Impact Strength Notched (23 C)	66 kJ/mb2	ISO 179
	Charpy Impact Strength Notched (-40 C)	2.9 kJ/mb2	ISO 179
	Notched Izod Impact Strength (23 C)	64 kJ/mb2	ISO 180
	Notched Izod Impact Strength (-40 C)	4.0 kJ/mb2	ISO 180
Hardness	Rockwell Hardness (R-Scale)	79	ISO 2039-2
Thermal	Deflection Temperature Under Load (0.45 MPa, Unannealed)	78 C	ISO 75B-1,-2
	Deflection Temperature Under Load (1.80 MPa, Unannealed)	49 C	ISO 75A-1,-2

3.2 Mechanical properties

Polypropylene (PP) is a versatile polymer with numerous applications that has undergone substantial changes in recent years, focusing on the demand for next-generation polymers [1,2]. This study builds upon recent research on polypropylene and its advanced functional applications. The versatile applications of PP across sectors like biomedical, automotive, aerospace, and air/water filtration are highlighted [1,2]. However, challenges such as limited UV resistance, bonding issues, and flammability are noted. The study emphasizes the promising potential of PP while addressing unresolved concerns, with the goal of guiding future research. Similar damage mechanisms, including crazing and surface disruption, have been reported in scratch-induced polymer deformation [5]

4. Extrusion Blow Molding (EBM) Process Overview

4.1 Overview of Extrusion Blow Molding (EBM)

Extrusion blow molding (EBM) involves continuous extrusion of a molten PP parison, which is captured within a mold cavity, inflated using compressed air, cooled against the mold surface [1–3], and subsequently ejected. Controlled parison temperature, wall-thickness distribution, inflation ratio, and cooling uniformity are critical to minimizing residual stress and morphological gradients. Cooling rate strongly influences crystallization behaviour and optical properties in semicrystalline polypropylene [6].

4.2 Key Process Steps in Extrusion Blow Molding

The extrusion blow molding process parameters used in this study are consistent with industrial guidelines [7].

1) Parison Extrusion: Molten PP is extruded vertically as a hollow tube with controlled wall thickness.
2) *Mold Capture and Pinch-Off:* The mold closes around the parison, sealing the bottom and forming the container base.
3) *Air Inflation and Orientation:* Compressed air inflates the parison, stretching the polymer biaxially to conform to the mold cavity.
4) *Cooling and Solidification:* The molten polymer cools against the mold surface, solidifying into its final shape.
5) *Mold Opening and Part Ejection:* After adequate cooling, the mold opens and the finished part is removed.

5. Mechanism of Stress Whitening in Polypropylene

Stress whitening in PP arises from localized plastic deformation rather than chemical degradation. At the microstructural level, whitening is caused by: Formation of micro-voids and localized crazing [1–4].

- Polymer chain fibrillation and orientation
- Variations in crystallinity induced by uneven cooling or strain
- Improper handling of material
- Material contamination
- Regrind material mixing

1) While differential crystallinity can increase local stiffness, experimental evaluation confirmed that the observed whitening in this study did not induce structural weakness or crack initiation.
2) Faster-cooling sections → higher crystallinity, stiffer, more brittle.
3) Rapid cooling traps the polymer chains before they can relax, causing locally higher crystallinity.
4) High-crystallinity zones are stiffer, harder, and less ductile than their surroundings.
5) When such regions undergo bending or tensile strain, internal microcracks form at the interface between crystalline lamellae.

6) Slow cooling gives polymer chains time to reorganize into a more relaxed, less crystalline structure.
7) These areas remain softer, more flexible, and more impact-resistant compared with fast-cooled regions.
8) When the part flexes, stress concentrates at the interface between stiff (fast-cooled) and ductile (slow-cooled) zones
These microcracks scatter light, producing stress whitening.
9) High-crystallinity zones are stiffer, harder, and less ductile than their surroundings (a white, chalky appearance under stress).
10) This mismatch creates a mechanical gradient in the part.

Result: Even if nominal wall thickness is in spec, over cooled regions behave like weak spots.

Engineering implication: Even if nominal wall thickness is in spec, over-cooled regions behave like weak spots.
Slower Cooling Sections → Lower Crystallinity → Softer, More Ductile.

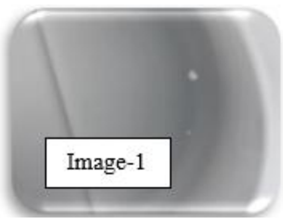
6. Mechanism of White Patch Formation and Assessment

Industry guidance attributes stress whitening to excessive orientation and recommends controlled processing conditions [11,12].

6.1 Exact Location

Most of the "stress whitening regions" appear (e.g., near bottom, on the base, where direct contact with hard surface). Marks often appear in areas of abrupt thickness transition.

Most of stress whitening appears at bottom of carboys



Result: Higher risk of brittle fracture, environmental stress cracking, and reduced service life.

Engineering implication: Even if nominal wall thickness is in spec, over-cooled regions behave like weak spots.
Slower Cooling Sections → Lower Crystallinity → Softer, More Ductile.

6.2 Appearance/Morphology

This stress whitening hazy spots / stress whitening without any fine crack or pronounced stress crack

6.3 Extent and Density

Measure the size of the area, count the number of marks, and determine if they are increasing in size or quantity over time.

7. White Patch Phenomenon and Inspection Findings

Drop and impact tests conducted after thermal aging demonstrated full retention of mechanical integrity. Whitening did not propagate or transition into cracking.

7.1 Appearance/Morphology

This stress whitening hazy spots / stress whitening without any fine crack or pronounced stress crack

7.2 Extent and Density

Measure the size of the area, count the number of marks, and determine if they are increasing in size or quantity over time.

7.3 Tactile Assessment

Checked with fingernail and fingernail test confirmed that the marks were limited to surface whitening and did not involve surface rupture.

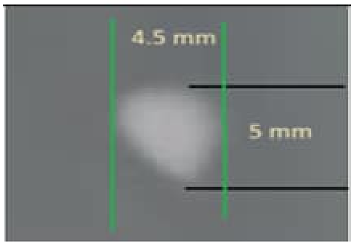
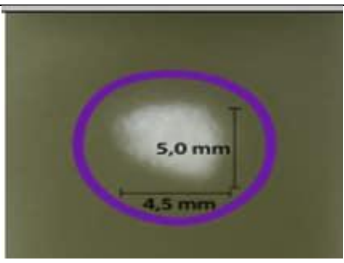
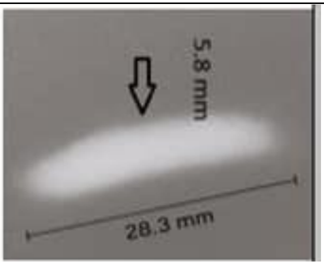
7.4 Dimensional Stability

The stability of polypropylene under gamma irradiation has been extensively investigated [8,9,10]

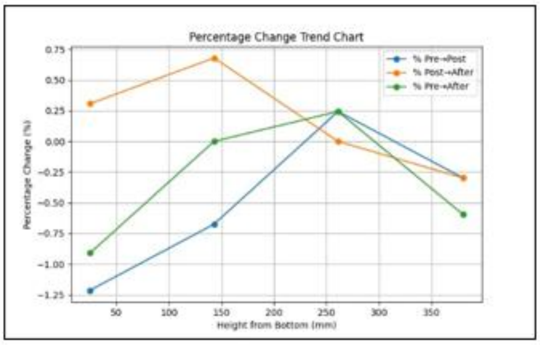
7.4.1 Structural Deformation

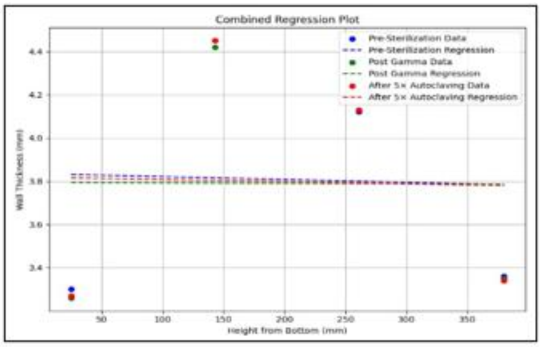
Checked the bowing, warping, or distortion near the mark and found no shape deformation near the stress whitening

Paper ID: SR26519123955 DOI: https://dx.doi.org/10.21275/SR26519123955

Image-1	Image-2	Length	Width
Pre Gamma			
		28.3 mm	5.7 mm
		4.5 mm	5.0 mm
Post Gamma			
		28.3 mm	5.8 mm
		4.5 mm	5.0 mm
Remark: 0.1 mm width increased, approximately 1.72%which is not significant before and after Gamma irradiation.			

7.4.2 Wall thickness impact:





Conclusion: Wall thickness performance met and exceeded typical extrusion blow molding tolerance expectations.

7.5 Chemical compatibility:

7.5.1 Chemical Compatibility Assessment

Specialized polymer structures have been explored for peroxide storage applications [13]

Polypropylene (PP) is well recognized for its chemical resistance to hydrogen peroxide at moderate concentrations. To evaluate compatibility, PP carboys exhibiting surface whitening were assessed under controlled exposure conditions using 7.6% hydrogen peroxide (H_2O_2).

The exposure was intermittent and controlled, representative of intended disinfectant use rather than continuous chemical contact. The evaluation focused on identifying any potential impact on material integrity, chemical compatibility, surface characteristics, and the risk of stress cracking or degradation.

Following 10 days of storage with the oxidizing agent, no adverse effects were observed. Specifically:

- No increase in stress whitening
- No surface cracking or stress crack initiation
- No Evidence of deformation, embrittlement, or material weakening were detected.

Day	Sample-1		Sample-2	
	L (mm)	W (mm)	L (mm)	W (mm)
1st	5.0	4.5	28.3	5.8
2nd	5.0	4.5	28.3	5.8
3rd	5.0	4.5	28.3	5.8
4th	5.0	4.5	28.3	5.8
5th	5.0	4.5	28.3	5.8
6th	5.0	4.5	28.3	5.8
7th	5.0	4.5	28.3	5.8
8th	5.0	4.5	28.3	5.8
9th	5.0	4.5	28.3	5.8
10th	5.0	4.5	28.3	5.8

Conclusion

The material remains chemically compatible and structurally stable, and the observed whitening is not impacted to chemical degradation or oxidative stress.

Mechanical Stress

8.1 Structural Integrity Evaluation

a) Vacuum Leak test: Check the impact, vacuum leakage after filling the liquid for any leakage or stress crack effect and no adverse effects were observed. The observed whitening is consistent with handling-related contact with hard surfaces.

b) Leak Check: Test performed for the carboy leaks at the location of the stress marks and found No Leakage observed in any sample of carboys which were affecting with stress whitening (small to large size

8.2 Impact and Handling Simulation

Trial	Process	Test	Results
1	Reduce the cooling time & reduce the chiller temp.	Drop the carboy on hard surface at 12" static height with same angle	Slightly white mark
2	Increase the cooling time & increase the chiller temp		No stress whitening
3	Reduce the chiller temp. and adequate cooling time		No stress whitening
4	Increase the cooling time & reduce chiller temp.		Slightly white mark
Conclusion: Stress whitening in these trials is caused by impact-induced release of residual molding stresses, which originate from non-optimal cooling time and chiller temperature combinations. Proper control of both parameters ensures sufficient molecular relaxation, preventing microstructural damage and visible whitening during drop testing [6,7,11,12].			

8.3 Thermal and Sterilization Stability

Five autoclave cycles at 121 °C and gamma sterilization exposure resulted in no deformation, embrittlement, or increase in surface roughness. Mechanical and dimensional properties remained unchanged.

Parameters	Cycle -1	Cycle-2	Cycle-3	Cycle-4	Cycle-5
Visual	No micro or macro cracks and no increase in stress whitening was observed	No micro or macro cracks were found, and no increase in stress whitening was observed	No micro or macro cracks were found, and no increase in stress whitening was observed	No micro or macro cracks were found, and no increase in stress whitening was observed	No micro or macro cracks were found, and no increase in stress whitening was observed
Hydrostatic Pressure Test	Passes the test of Leakage	Passes the test of Leakage	Passes the test of Leakage	Passes the test of Leakage	Passes the test of Leakage
Impact Resistance Test (filled with 20 liters of water)	NA	NA	NA	NA	Passes the Drop test
Degree of whitening / opacity index	Complied	Complied	Complied	Complied	Complied
Surface roughness change	Complied	Complied	Complied	Complied	Complied
Impact on Mechanical Integrity	Thermal Tests – DSC (Differential Scanning Calorimetry)				Complied
	Fourier Transform Infrared Spectroscopy (FTIR)				Complied
	Gamma (dose – 28-33 kGy)/ Autoclave Sterility Cycle Evaluation				Complied
	Wall thickness (mm)				Complied
Remark	Drop test is destructive test and performed only final cycle of Autoclaving				

8. Impact on Mechanical Properties

(Tested from Kiyo R&D Centre and Laboratory)

9.1 Differential Scanning Calorimetry (DSC)

Differential Scanning Calorimetry (DSC) was used to evaluate the thermal behaviour, crystallinity, and structural integrity of polypropylene (PP) carboys. DSC is sensitive to polymer degradation, recycled content, contamination, mixed grades, and variations in processing history that may affect mechanical strength, chemical resistance, and long-term durability. Testing was performed in accordance with ASTM D3418 [14]

9.2 FTIR Analysis – Chemical Identity and Purity

Fourier Transform Infrared Spectroscopy (FTIR) was conducted to confirm the chemical identity and purity of PP and to assess whether visible stress whitening were associated with contamination, oxidation, recycled material, or polymer degradation. Spectra from affected regions were compared with unaffected controls and reference PP spectra.

Acceptance Criteria: Spectra shall match reference polypropylene, exhibiting characteristic PP absorption bands:

- CH_3/CH_2 stretching: 2950–2838 cm^{-1}
- CH_3 bending: 1450–1375 cm^{-1}
- C–C skeletal vibrations: 1160–800 cm^{-1}

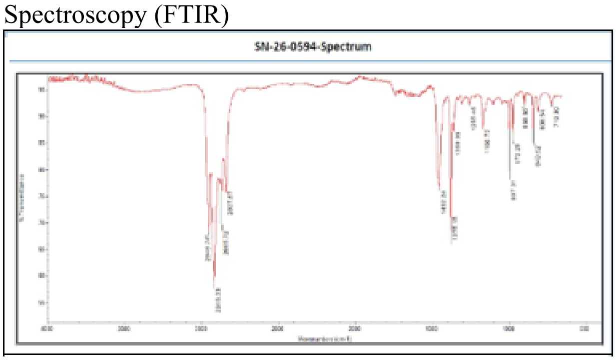
No peaks attributable to oxidation (carbonyl ~1700–1750 cm^{-1}), hydroxyl groups (3200–3600 cm^{-1}), foreign polymers, or additive-related contamination were permitted.

9.3 Sample Description

Samples were collected from the base of the carboys:

Sample 1: Minor stress whitening	**Sample 2:** Large stress whitening	**Sample 3:** No stress whitening (CS)

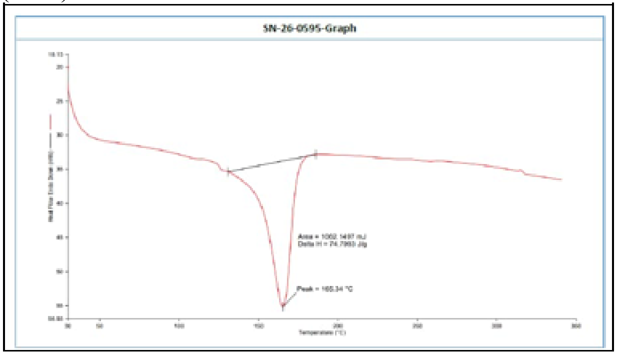
Sample 1: SN-26-0594 Fourier Transform Infrared Spectroscopy (FTIR)



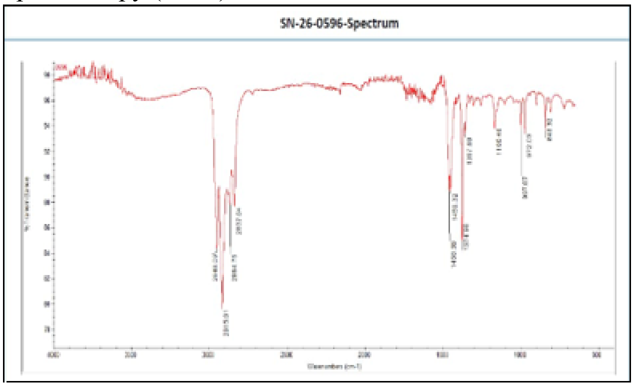
Paper ID: SR26519123955 DOI: https://dx.doi.org/10.21275/SR26519123955

International Journal of Science and Research (IJSR)
ISSN: 2319-7064
Impact Factor 2025: 7.089

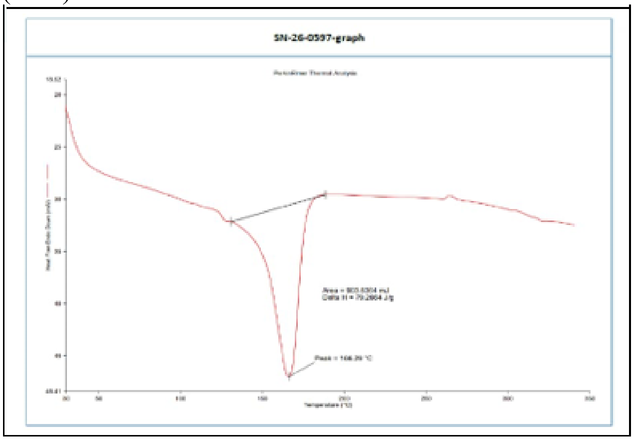
Sample 1: SN-26-0595 Differential Scanning Calorimetry (DSC)



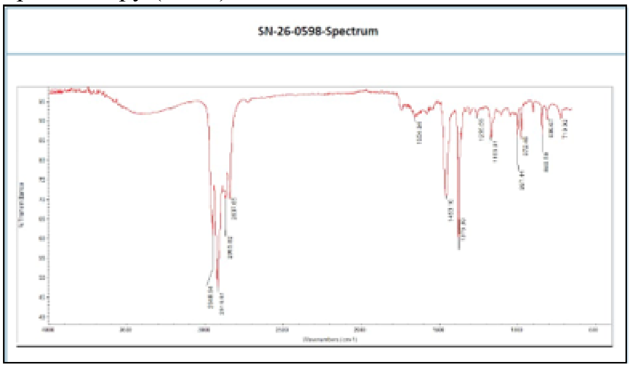
Sample 2: SN-26-0596 Fourier Transform Infrared Spectroscopy (FTIR)



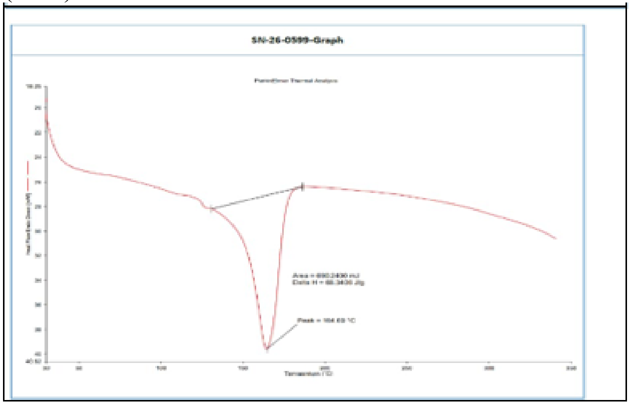
Sample 2: SN-26-0597 Differential Scanning Calorimetry (DSC)



Sample 2: SN-26-0598 Fourier Transform Infrared Spectroscopy (FTIR)



Sample 2: SN-26-0599 Differential Scanning Calorimetry (DSC)



9.4 Data Evaluation

FTIR confirmed chemical purity and consistency across all samples. DSC revealed no abnormal melting behaviour, peak broadening, or crystallinity loss in whitened regions. The presence of stress whitening did not correlate with chemical or thermal degradation.

Sample #	FTIR Temp (cm^{-1})	FTIR Peak	DSC Temp (°C)	DSC Peak / Crystallinity
Sample-1: Minor stress whitening	2950–2838	CH_3 / CH_2 stretching of PP	163–165	Single melting endotherm; %Xc ≈ **52–56 %**
Sample-2: Large stress whitening	2950–2838	PP backbone peaks; no carbonyl	162–164	Single melting endotherm; %Xc ≈ **50–54 %**
Sample-3: No stress whitening (control)	2950–2838	Reference PP spectrum	164–166	Reference peak; %Xc ≈ **55–58 %**

FTIR spectra of all samples matched reference polypropylene, with no evidence of oxidation, contamination, or mixed polymer grades. DSC analysis showed a single, well-defined melting endotherm for all samples, with melting temperatures in the range of 162–166 °C. Calculated crystallinity values were:

- Sample 1: ~52–56 %
- Sample 2: ~50–54 %
- Sample 3 (control): ~55–58 %

Crystallinity Acceptance Criteria
Crystallinity was calculated using:
$\%Xc = (\Delta H_m / \Delta H_0) \times 100$, where $\Delta H_0 = 209$ J/g for 100% crystalline PP [15]

Acceptance limits:

- Crystallinity: 45–65 %
- Inter sample variation: ≤ ±10 % vs control
- Rejection indicators:

- %Xc < 40 % (degradation/poor molding)
- %Xc > 70 % (abnormal cooling/brittleness risk)

9.5 Results Summary

Test No.	Sample	Test Method	Acceptance Criteria	Key Observations	Conclusion
1	Sample-1 (Minor stress whitening)	FTIR	Spectrum shall match reference polypropylene; no additional peaks attributable to foreign polymers, oxidation (carbonyl/hydroxyl), or additives	Characteristic polypropylene absorption bands observed with no extraneous or degradation-related peaks	PASS – Material chemically conforms to virgin polypropylene; whitening not caused by contamination or degradation
2	Sample-1 (Minor stress whitening)	DSC	Single, well-defined melting endotherm within typical PP melting temperature range; no peak broadening, secondary transitions,	Normal PP melting behaviour observed; sharp melting peak with expected profile	PASS – Thermal behaviour confirms intact crystallinity; whitening is cosmetic / stress-induced
3	Sample-2 (Large stress whitening)	FTIR	FTIR spectrum must align with polypropylene reference; absence of oxidation, recycled polymer markers, or mixed polymer signatures	FTIR spectrum fully matches PP reference; no carbonyl or hydroxyl absorption observed	PASS – Chemical integrity retained even in heavily whitened regions
4	Sample-2 (Large stress whitening)	DSC	Melting peak position and shape consistent with reference PP; no shoulders, secondary peaks, or enthalpy loss indicative of degradation	DSC melting profile unchanged compared to reference; no abnormal thermal transitions	PASS – Large stress whitening do not indicate thermal or structural polymer damage
5	Sample-3 (Without stress whitening)	FTIR	Clean polypropylene spectrum with stable baseline and characteristic PP peaks	Baseline polypropylene spectrum observed with no abnormal features	PASS – Confirms reference material quality and suitability as control
6	Sample-3 (Without stress whitening)	DSC	Stable baseline and smooth melting endotherm typical of isotactic polypropylene	Ideal melting behaviour and baseline stability observed	PASS – Confirms optimal crystallinity and consistent processing conditions

9.6 Overall Conclusion

All polypropylene carboys meet material integrity, thermal stability, and chemical conformity requirements. The observed whitening is attributed to localized mechanical deformation and is non-structural in nature. Mechanical performance, safety, and product reliability are not impacted.

9. Risk-Based Defect Classification (FMEA)

A structured FMEA approach was applied to differentiate cosmetic whitening from structurally significant defects:

- Grades 1–2: Superficial whitening with no cracks – *Acceptable*
- Grades 3–4: Whitening associated with micro-cracks or surface rupture – *Not acceptable*

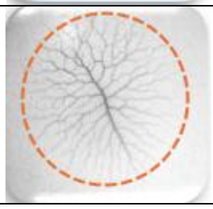
The observed defects were classified as Grades 1–2, corresponding to low severity, low occurrence, and high detectability

Stress Whitening Grade	Description	Potential Failure Mode	Impact on Function / Quality	Severity (S)	Occurrence (O)	Detectability (D)	RPN	Risk Assessment Outcome	Acceptability
Grade 1	Very light surface whitening, no cracks	Optical change only	No impact on container integrity, strength, cleanability, or product quality	2	1	1	2	Negligible risk; no failure pathway	✅ Acceptable
Grade 2	Mild whitening, superficial, no depth	Localized stress indication	No loss of containment or mechanical performance; verified by testing	3	2	2	12	Low risk; effectively controlled & detectable	✅ Acceptable
Grade 3	Pronounced whitening with suspected micro-cracks	Potential loss of integrity	Possible crack initiation, reduced load tolerance, potential E&L risk	7	2	3	42	High risk; credible failure pathway	❌ Not Acceptable
Grade 4	Severe whitening with visible cracks	Structural failure	High likelihood of leakage, breakage, sterility loss	9	3	4	108	Critical risk; unacceptable	❌ Not Acceptable

10.1 Defect: Stress Whitening in PP Carboys

10.2 Risk-Based Justification (Summary Statement): Grades 1 & 2 represent surface-level stress whitening only, with no evidence of crack propagation, loss of mechanical strength, chemical incompatibility, or container closure integrity failure. Existing controls and detection methods ensure low residual risk. Grades 3 & 4 indicate material damage and crack initiation, creating a credible risk pathway for leakage, breakage, and product quality impact. These defects cannot be reliably mitigated and are therefore not acceptable.

Defects Category

Grade	Severity Level	Risk Category	Description	Area / Size	Image	Acceptance Decision
Grade 1	Mild	Safe	Cosmetic whitening, no texture change	≤ 0.5 cm²		✅ Accept
Grade 2	Moderate	Conditionally Safe	Visible whitening, no crack growth	> 0.5 cm² to <2 cm²		✅ Accept with documented justification
Grade 3	Severe	Unsafe	Large patches, roughness, localized crazing	>2 cm²		❌ Reject
Grade 4	Critical	Unsafe	Cracks, spreading, structural weakening	NA		❌ Reject immediately

10. Sample Size and Sampling Rationale

11.1 Sampling date: 08-Nov-2025 and 09-Nov-2025.

11.2 Tool ID: LOT-#9098

A total of 20 polypropylene (PP) carboys were evaluated to compare performance between containers exhibiting stress whitening and controls. The study included 10 carboys with visible stress whitening (selected to represent a range of whitening area/appearance observed during routine inspection, including mild to moderate presentations consistent with Grade 1–2) and 10 carboys with no visible whitening from the same product family (control group). Samples were selected to be representative of routine manufacturing output and typical handling conditions. Where destructive testing was required (e.g., drop/impact), those tests were performed on designated units after completion of all planned non-destructive inspections (visual/tactile assessment, wall thickness checks, leak/vacuum integrity, and compatibility/sterilization conditioning), to avoid biasing subsequent measurements.

11. Discussion

Stress whitening observed in extrusion blow-molded polypropylene (PP) carboys was identified as a surface-localized microstructural phenomenon rather than an indication of bulk material degradation. The whitening was attributed to micro void formation, micro crazing [1–4], and localized variations in crystallinity, which increase light scattering at the surface and result in visible opacity. No evidence of polymer chain scission, chemical degradation, or macroscopic crack initiation was observed. Mechanical and functional testing demonstrated that stress whitening did not adversely affect container performance. Impact resistance, hydrostatic pressure resistance, vacuum integrity, and fatigue durability were fully retained, including at locations exhibiting whitening. Repeated handling simulations showed no propagation of whitening or development of cracks, indicating that the phenomenon does not represent an incipient failure mechanism. Thermal aging and sterilization studies further confirmed the non-deleterious nature of the observed whitening. Multiple autoclave cycles at 121 °C and gamma irradiation resulted in no measurable changes in surface morphology, wall thickness distribution, or mechanical integrity, confirming suitability for sterilized pharmaceutical and bioprocess applications [8–10].

Stress whitening was predominantly associated with localized handling contact and stress-concentration regions, potentially influenced by processing-induced residual stresses. Risk-based evaluation classified mild to moderate whitening as acceptable, while severe whitening associated with surface damage remains unacceptable.

12. Conclusion

Stress whitening observed in polymer carboys was determined to be purely superficial and non-structural. The phenomenon did not indicate crack initiation, chemical degradation, or thermal instability. Structural integrity, leak resistance, and mechanical performance remained fully intact. The whitening is attributable to handling contact with hard surfaces and does not affect safety, durability, or suitability for intended use.

List of Equipment's used:

S. No.	Equipment	Equipment ID
1	Illuminated Inspection Bench –.	FLS-2025
2	Magnifying Lamp / Low-Power Inspection Microscope	FLI-2056
3	Magna Mike	072323011
4	Digital Camera / Imaging System –	FLS-0657
5	Glassware Set (Measuring Cylinders)	FLI-0464
6	Hydrogen Peroxide (Analytical Grade)	CAS- 7722-84-1
7	Autoclave (121 °C, Pressure Sterilization Unit)	FLI-0473
8	Drop/Impact Handling Simulation Platform	FLS-2026
9	Vacuum Integrity Tester	FLI-P4-0510
10	Leak Testing Apparatus	FLS-2026-1
11	Digital Vernier Caliper	FLI-P4-0502
12	Flatness/Level Plate	P4-0562
13	Digital Thermo-Hygrometer	FLI-P4-0523
14	Timer or Automated Data Logger	FLS-2026-2
15	Lab PPE	FLS-2026-3

List of Abbreviations

Abbreviation	Full Term
DSC	Differential Scanning Calorimetry
H_2O_2	Hydrogen Per Oxide
°C	Degrees Celsius
QA	Quality Assurance
QC	Quality Control
PP	Polypropylene
Autoclave Cycle	Standard high-temperature steam sterilization cycle (121 °C)
mm	Millimetre
N/A	Not Applicable
RPN	Risk Priority Number
FMEA	Failure Mode and Effects Analysis

Author Contributions

Conceptualization, S. R. Rizvi and Thomas Foxx Taylor; methodology, Rupendra Singh and S. R. Rizvi; investigation, Rupendra Singh and S. R. Rizvi; data curation, Rupendra Singh; formal analysis, Rupendra Singh and S. R. Rizvi; validation, S. R. Rizvi; resources, Thomas Foxx Taylor ; writing- original draft preparation, Rupendra Singh; writing- review and editing, S. R. Rizvi and Thomas Foxx Taylor; visualization, Rupendra Singh; supervision and project administration, S. R. Rizvi. All authors have read, critically reviewed, and approved the final version of the manuscript to be published.

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