

Report of Results: MVA6158

Patch Permeability

Prepared for:

**Lifewave Products, LLC
1000 Peachtree Industrial Blvd.
Suite 6-321
Suwanee, GA 30024**

Respectfully Submitted by: _____

**Richard S. Brown
Executive Director
MVA Scientific Consultants**

23 November 2004



Report of Results: MVA6158

Patch Permeability

Introduction

Two "patch" products, one brown patch and one white patch, were hand delivered to MVA Scientific Consultants on 8 November 2004. MVA Scientific Consultants was asked to examine the patch product to determine whether or not the adhesive-backed polyethylene film allowed the water soluble compounds contained in the patch products to migrate out of the patch product where they could potentially be absorbed into the skin of a person wearing a patch product. The samples were assigned the following MVA sample numbers for identification purposes; "white patch" = 6158P3148 and "brown patch" = 6158P3149. Additional patches were hand delivered to MVA Scientific Consultants on 19 November 2004. The work was performed from 12 November 2004 to 22 November 2004.

Methods

The patches were examined utilizing a combination of reflected brightfield microscopy, reflected darkfield microscopy, transmitted brightfield microscopy, scanning electron microscopy (SEM) and Fourier transform infrared microspectroscopy (FTIR). A reagent was chosen, based on information provided by the manufacturer, that would react with substances present in the brown (glucose) patch and in the white (glycerin) patch. The reagent chosen reacts with glycerin and with glucose to form a white precipitate. Sample patches at room temperature, sample patches heated to 40 degrees Centigrade for one hour and sample patches exposed to approximately 500 millitor of vacuum were tested by applying reagent to the adhesive side of the patch after removal of the release paper. The presence of a white precipitate would indicate that water soluble components contained in the blister area of the patch had migrated across the polyethylene-adhesive film and were available for absorption by the skin of a person wearing the patch.

Results and Discussion

The patch products were 41 millimeters in diameter with a central pocket or blister 32 millimeters in diameter. The central pocket contained either a brown colored 28 millimeter diameter synthetic fiber disc or a white colored 28 millimeter diameter synthetic fiber disc. The synthetic fibers comprising the discs have not been analyzed at this time. Liquid droplets were observed in the central pocket that also contained air or another gas giving it the appearance of a blister (see Figure 1).

Reportedly the patch products were composed of a polyethylene film with an acrylic adhesive backing. FTIR analysis of the film and of the adhesive revealed the film to be polyethylene and the adhesive to be an acrylic (see Figures 2 and 3). Examination of the patch product in cross-section by SEM revealed the polyethylene film to be non-porous (see Figures 4 and 5). The reagent chosen forms a white precipitate when in contact with glycerin (white patch) and glucose (brown patch). The formation of the precipitate is non-specific so the polyethylene and the acrylic adhesive were tested with the reagent and were found to be non-reactive. Sections of the polyethylene film with adhering patch ingredients and without adhering patch ingredients were analyzed with the reagent (see Figures 6 through 9).

To test the adhesive side of the patch for reaction with the reagent, two drops of the reagent were added to the adhesive side of a patch and a 22mm X 22mm glass cover slip was used to cover the reagent and spread the reagent over most of the patch surface. Patches were compromised by making a small incision through the adhesive side of the patch. The compromised patches were tested with the reagent and examined for the precipitate (see Figures 10 through 15).

Reagent testing of a white patch and of a brown patch at room temperature resulted in a negative reaction to the reagent.

Reagent testing of a white patch and of a brown patch kept at a minimum of 40 degrees Centigrade (104 degrees Fahrenheit) for one hour resulted in a negative reaction to the reagent.

Reagent testing of a white patch and of a brown patch subjected to a 500 millitor vacuum resulted in a negative reaction to the reagent. The blister area of each patch swelled slightly but retained their seal, as the blister remained intact after the patches were removed from the vacuum chamber.

Based on my examinations and testing of the construction of the white and brown patch products, I would not expect the water soluble components that reside within the patch products to migrate across the polyethylene film and be available for absorption through the skin of a person wearing the white or brown patch product.

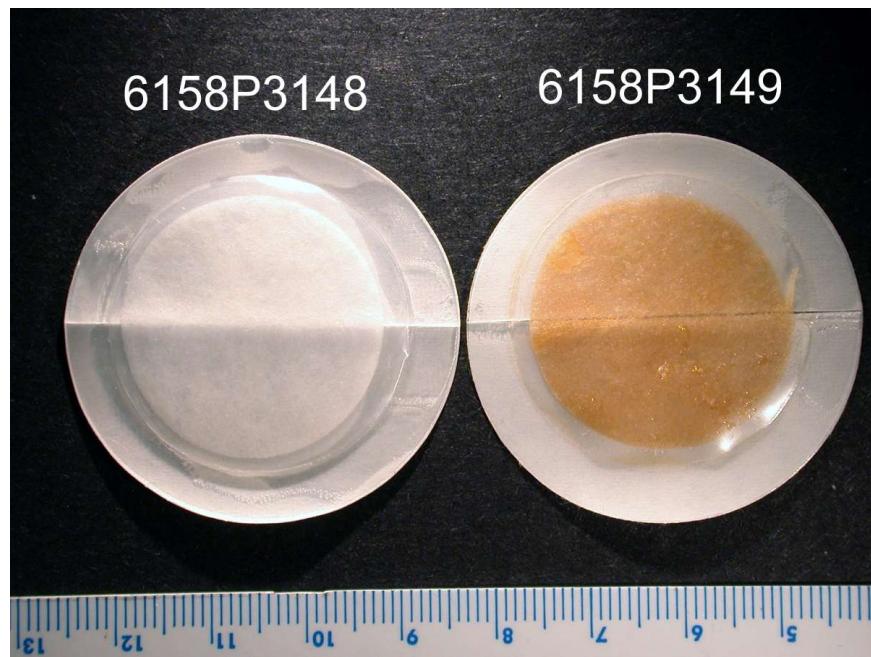


Figure 1. Reflected light image of patches “as received”.

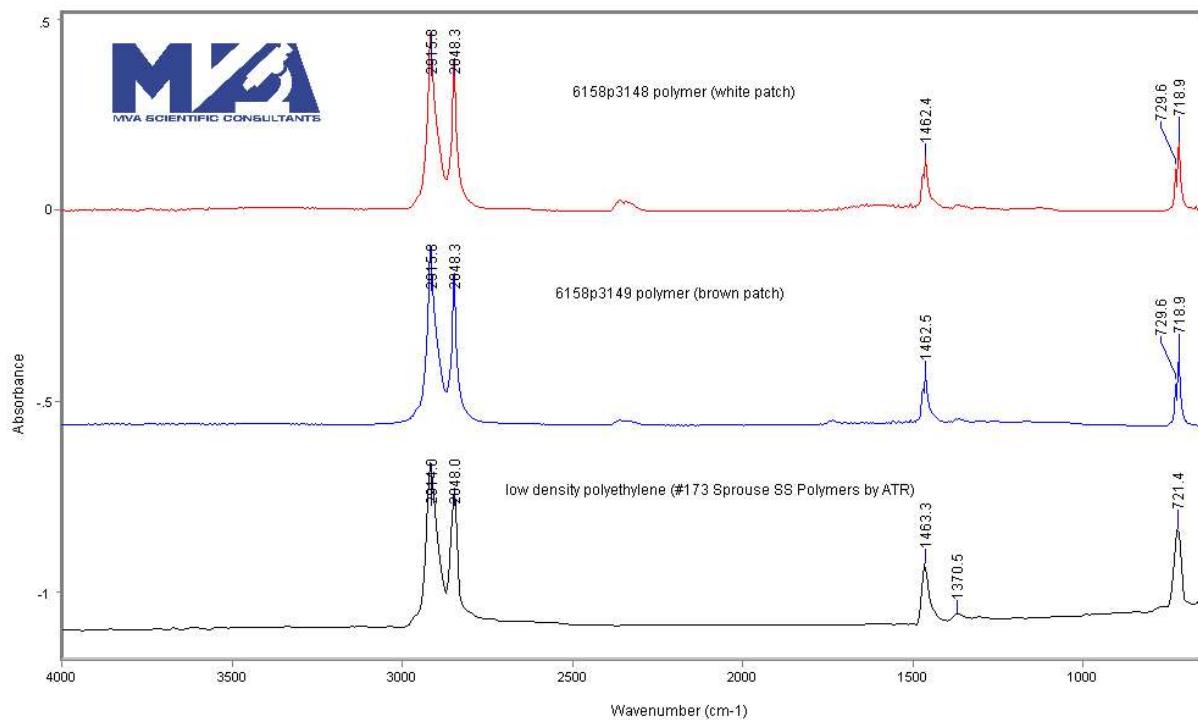


Figure 2. FTIR spectra of the polymer film comprising a white patch and a brown patch. The black spectrum at the bottom is a library spectrum of polyethylene.

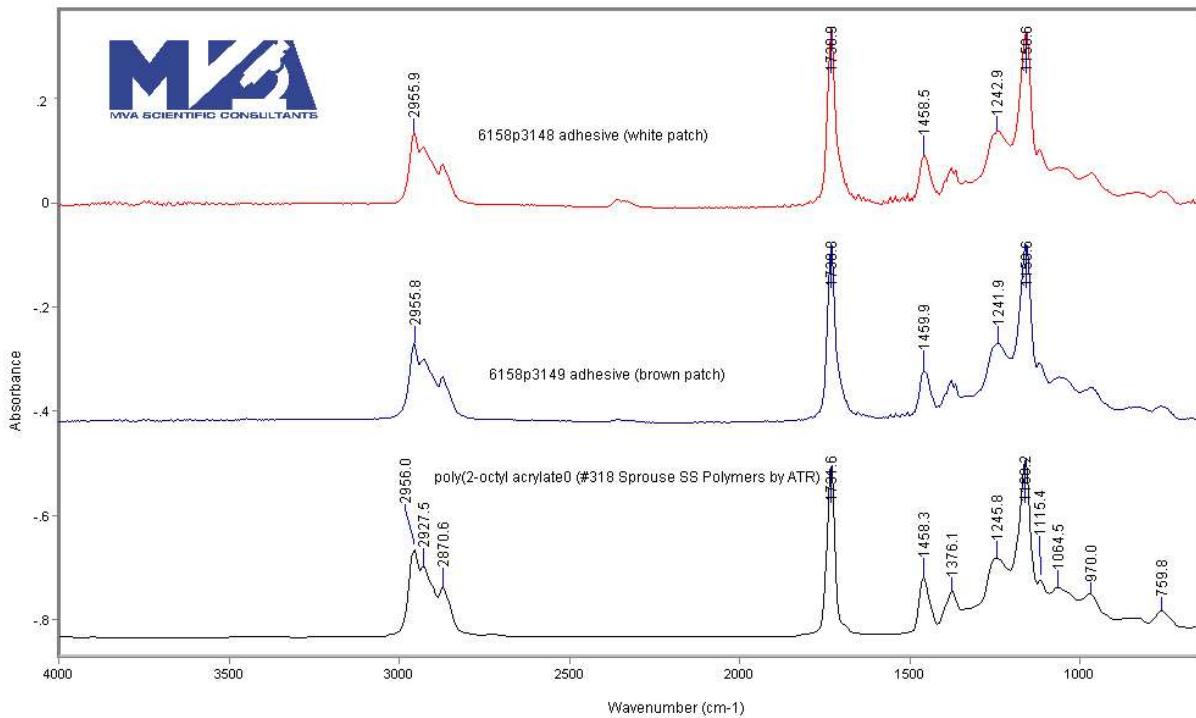


Figure 3. FTIR spectra of adhesive layer on a white patch and on a brown patch. The black spectrum at the bottom is a library spectrum of an acrylic.

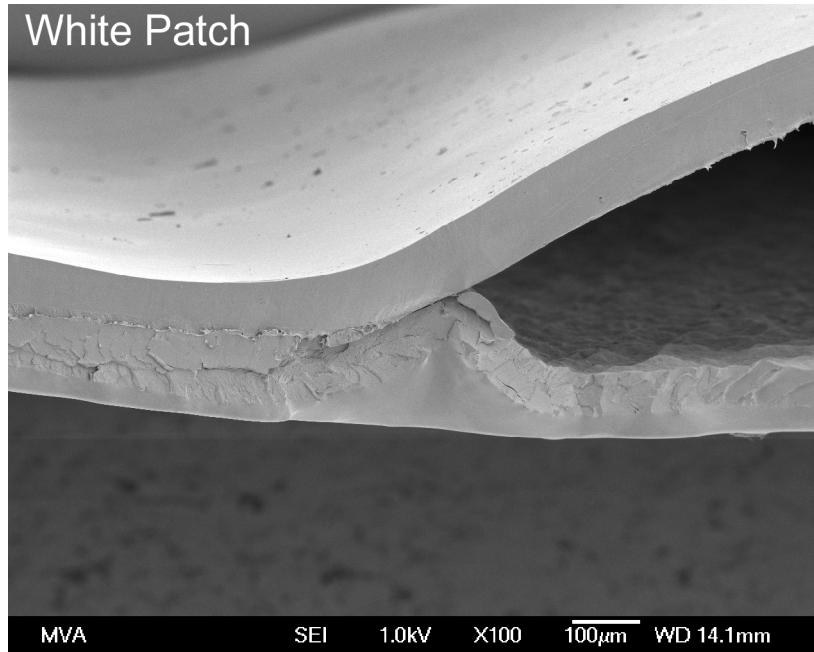


Figure 4. Secondary electron (SE) image of a portion of the white patch after freeze-fracture.

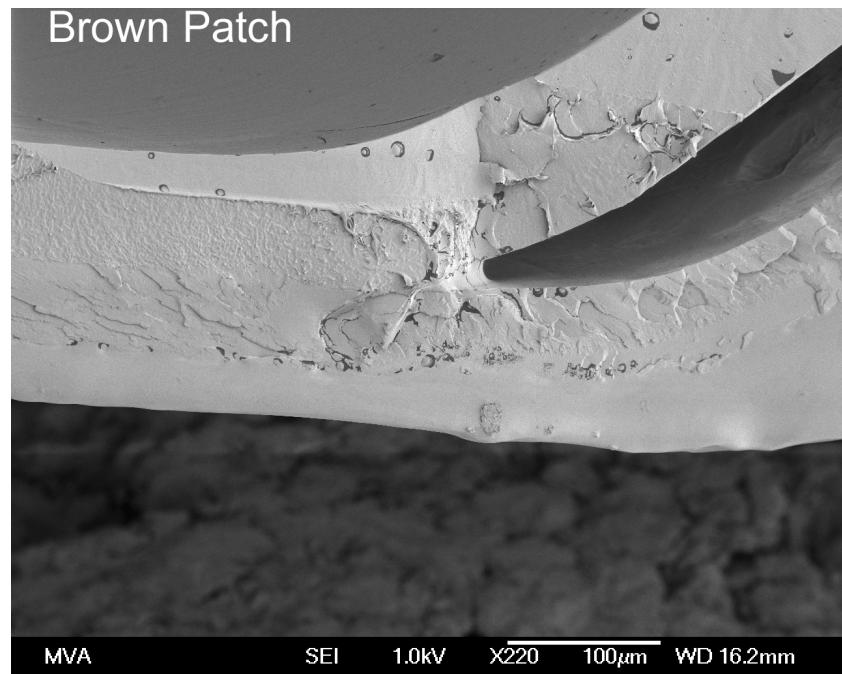


Figure 5. Secondary electron (SE) image of a portion of the brown patch after freeze-fracture.

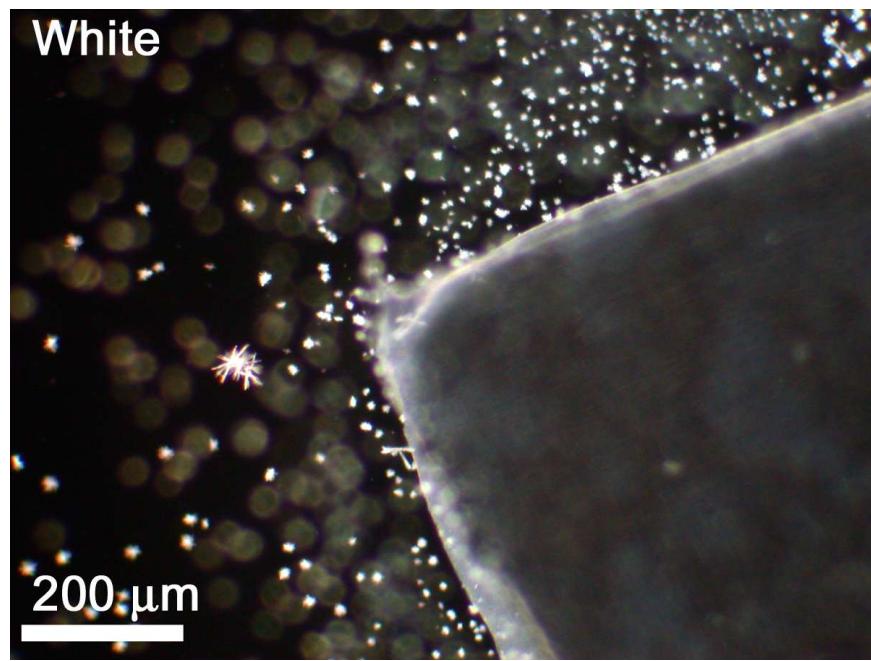


Figure 6. Reflected light darkfield image of a portion of the white patch blister (with adhering patch ingredients) reacting positively with the reagent.

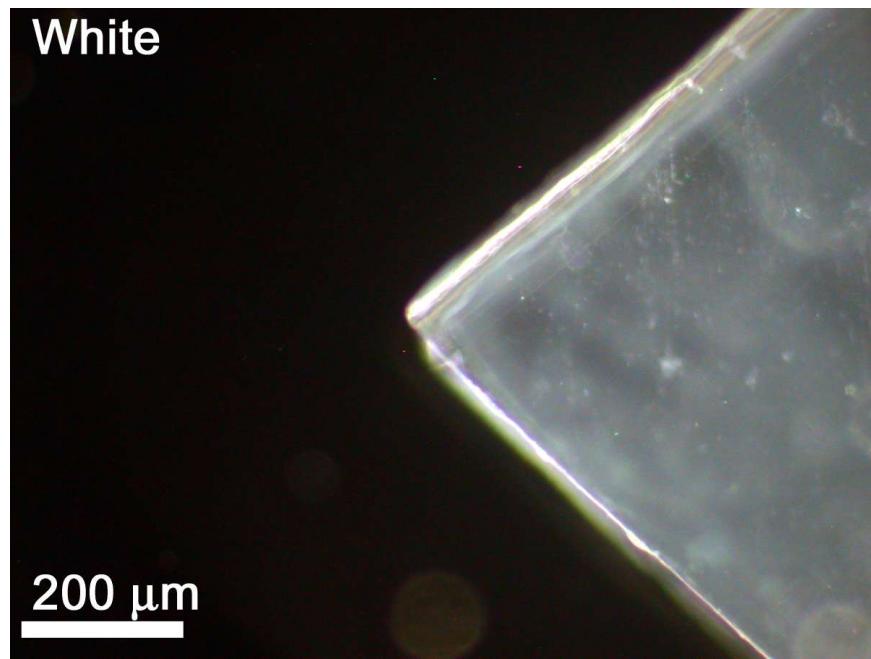


Figure 7. Reflected light darkfield image of a portion of the white patch with adhesive (without adhering patch ingredients) showing no reaction to the reagent.

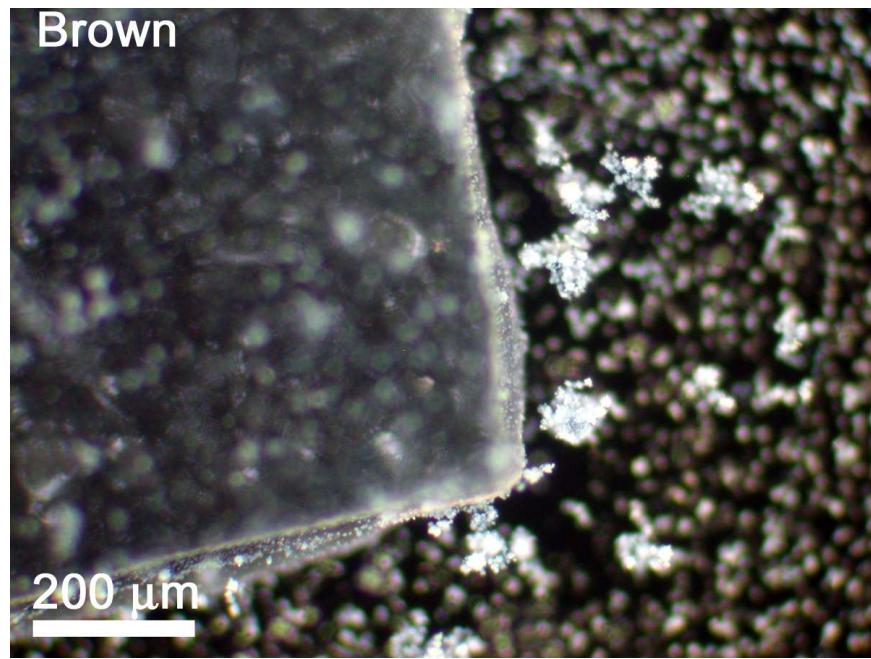


Figure 8. Reflected light darkfield image of a portion of the brown patch blister (with adhering patch ingredients) reacting positively with the reagent.

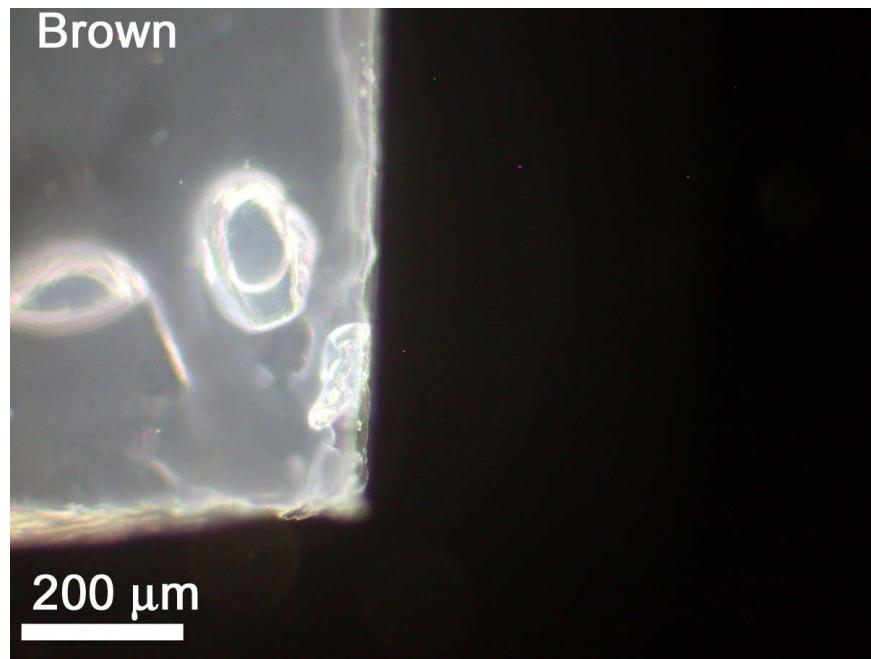


Figure 9. Reflected light darkfield image of a portion of the brown patch with adhesive (without adhering patch ingredients) showing no reaction to the reagent.

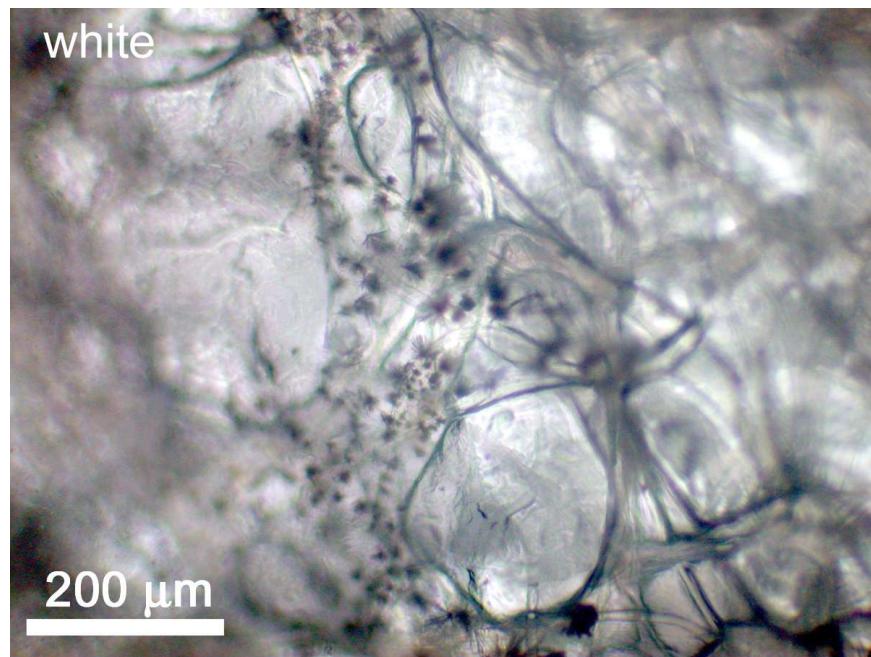


Figure 10. Transmitted light brightfield image of a compromised white patch showing a positive reaction to the reagent.

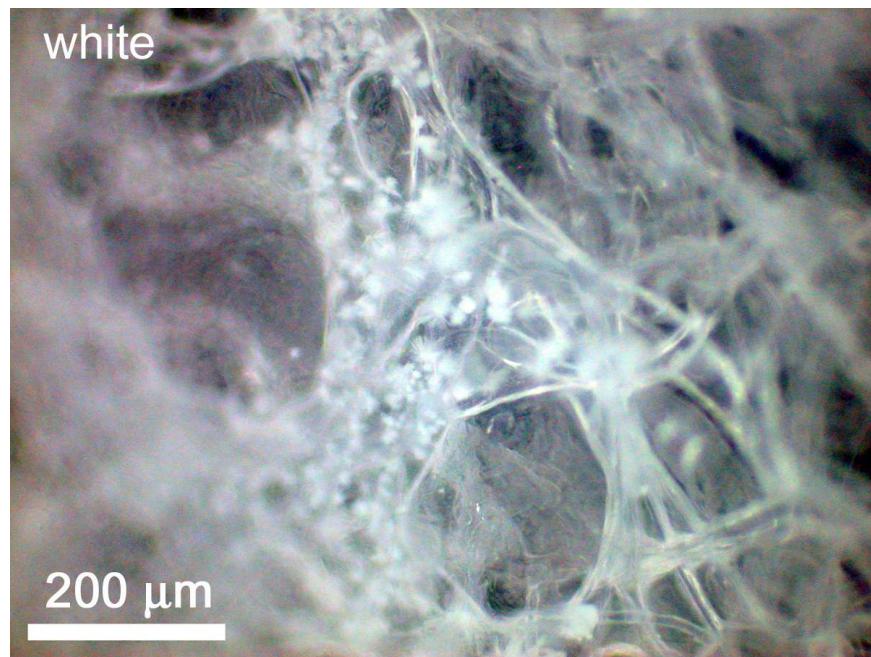


Figure 11. Reflected light darkfield image of a compromised white patch in Figure 10 showing a positive reaction to the reagent.

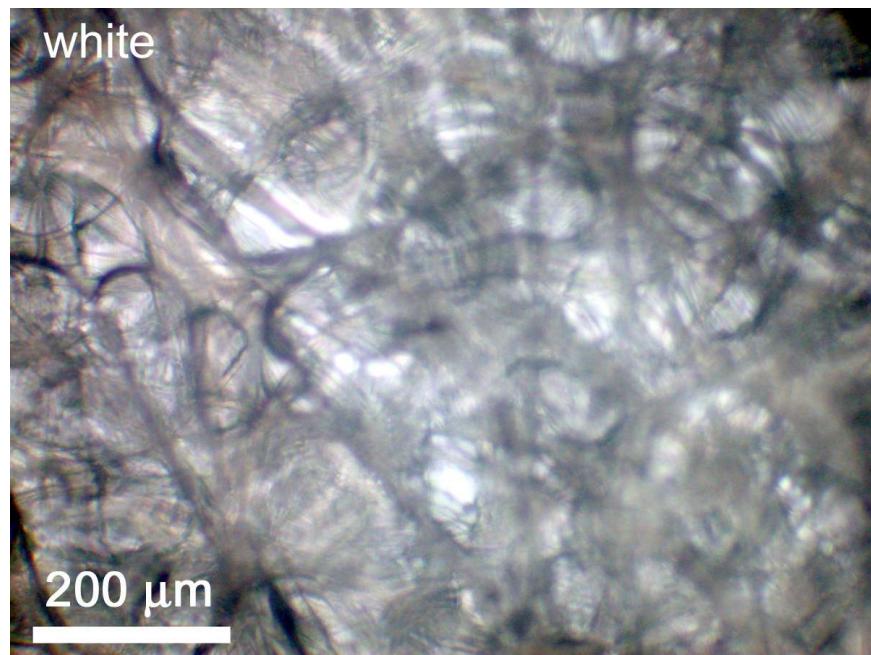


Figure 12. Transmitted light brightfield image of a white patch showing no reaction to the reagent.

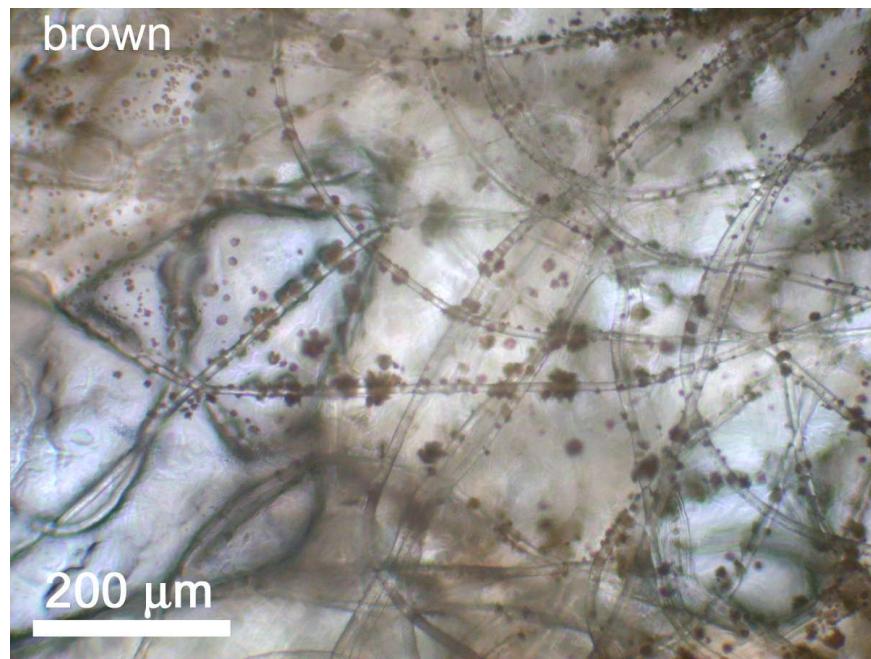


Figure 13. Transmitted light brightfield image of a compromised brown patch showing a positive reaction to the reagent.

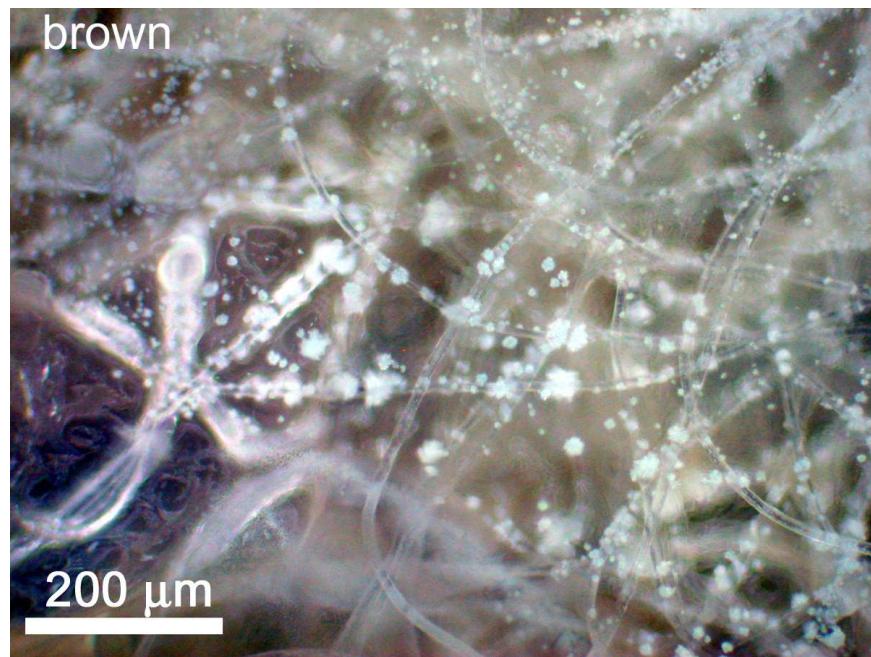


Figure 14. Reflected light darkfield image of a compromised white patch in Figure 13 showing a positive reaction to the reagent.

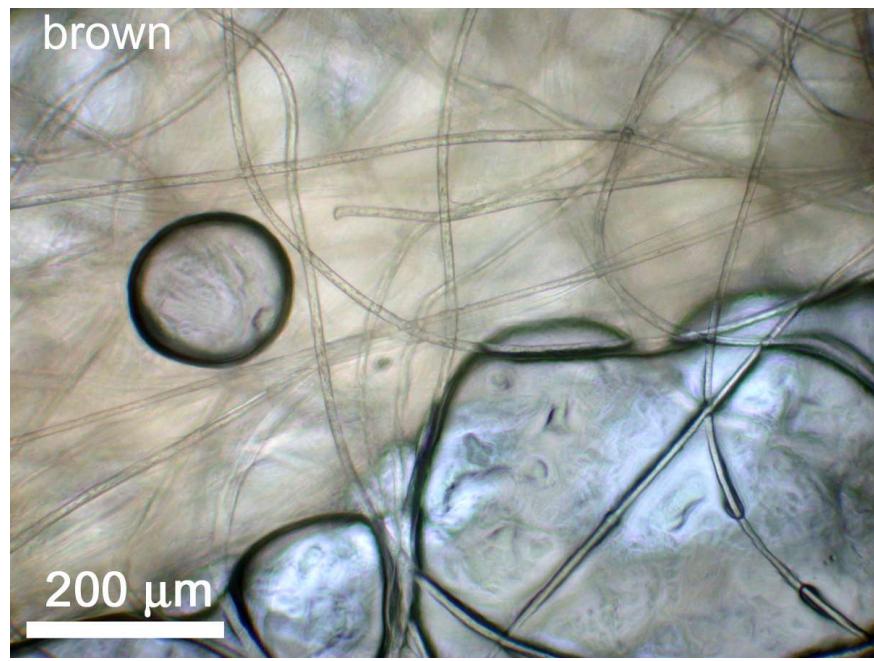


Figure 15. Transmitted light brightfield image of a white patch showing no reaction to the reagent.