

FORM 2

THE PATENTS ACT, 1970
(39 of 1970)
AND
THE PATENTS RULES, 2003

**COMPLETE
SPECIFICATION**

(See Section 10; rule 13)

TITLE OF THE INVENTION

“WATER-BASED STERILIZATION INDICATOR COMPOSITION”

APPLICANT

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The following specification particularly describes
the invention and the manner in which
it is to be performed

What is Claimed is:

1. An indicator formulation comprising an indicating composition dispersed in water, wherein the indicating composition comprises

- (a) an organic Bi(III) compound;
- (b) a sulfur source; and
- (c) a carbonate salt;

wherein at least one of the organic Bi(III) compound and the sulfur source has solubility in water at 20 °C of less than 5 grams/100 ml.

2. An indicator formulation comprising an indicating composition dispersed in water, wherein the indicating composition is prepared by combining in water

- (a) an organic Bi(III) compound;
- (b) a sulfur source; and
- (c) a carbonate salt;

wherein at least one of the organic Bi(III) compound and the sulfur source has solubility in water at 20 °C of less than 5 grams/100 ml.

3. The indicator formulation of claim 1 or 2, wherein the indicating composition comprises bismuth subcarbonate formed in situ.

4. The indicator formulation according to any one of the preceding claims, wherein both the organic Bi(III) compound and the sulfur source have solubility in water at 20 °C of less than 5 grams/100 ml.

5. The indicator formulation of claim 4, wherein at least one of the organic Bi(III) compound and the sulfur source have solubility in water at 20 °C of less than 1 gram/100 ml.

6. The indicator formulation according to any one of the preceding claims, wherein the organic Bi(III) is selected from the group consisting of bismuth subsalicylate, bismuth citrate, bismuth tartrate, and combinations thereof.

7. The indicator formulation according to any one of the preceding claims, wherein the sulfur source is selected from the group consisting of sulfur, 1,3-diphenylthiourea, sodium thiosulfate, and combinations thereof.

8. The indicator formulation according to any one of the preceding claims, wherein the carbonate salt is selected from the group consisting of lithium carbonate, potassium carbonate, magnesium carbonate, sodium carbonate, sodium bicarbonate, and combinations thereof.

9. The indicator formulation according to any one of the preceding claims, wherein the carbonate salt is selected from the group consisting of lithium carbonate, magnesium carbonate, sodium carbonate, sodium bicarbonate, and combinations thereof.
10. The indicator formulation according to any one of the preceding claims, further comprising an acidic compound.
11. The indicator formulation of claim 10, wherein the acidic compound is non-polymeric.
12. The indicator formulation of claim 11, wherein the acidic compound is selected from the group consisting of citric acid, gallic acid, oxalic acid, and combinations thereof.
13. The indicator formulation according to any one of the preceding claims, further comprising a resin.
14. The indicator formulation of claim 13, wherein the resin comprises an acrylic resin.
15. An indicator tape comprising a substrate and an indicator composition on a portion of at least one surface of the substrate, wherein the indicator tape was prepared by the process of applying the indicator formulation according to any one of the preceding claims to the surface of the substrate and drying the formulation.
16. A method of preparing an indicator formulation comprising combining an organic Bi(III) compound; a sulfur source; and a carbonate salt in water; wherein at least one of the organic Bi(III) compound and the sulfur source has solubility in water at 20 °C of less than 5 grams/100 ml, and reacting the organic Bi(III) compound with the carbonate salt to form bismuth subcarbonate.

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