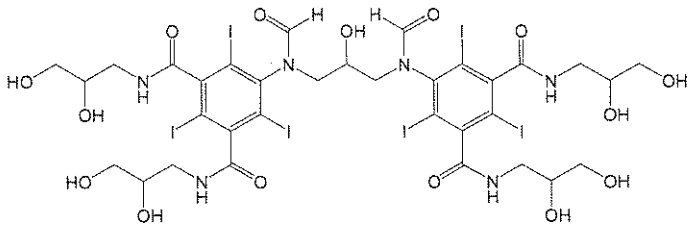


Compound I: 5-[formyl-[3-[formyl-[3,5-bis(2,3-dihydroxypropylcarbamoyl)-2,4,6-triiodophenyl]amino]-2-hydroxypropyl]amino]-N,N'-bis(2,3-dihydroxypropyl)-2,4,6-triiodobenzene-1,3-dicarboxamide.

The applicant has now surprisingly identified a new diagnostic X-ray composition which exhibits a superior cardiac safety profile as compared to Visipaque™, as shown in similar *in vivo* studies as indicated above.

Thus, in a first aspect the ~~invention~~ disclosure provides a diagnostic composition comprising a compound I

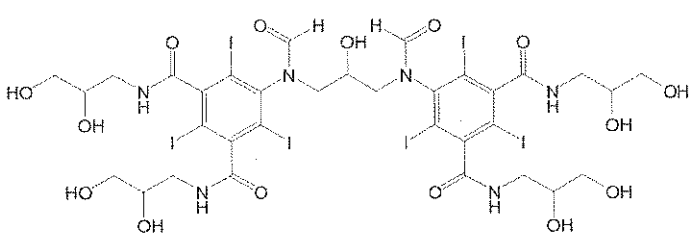


Compound I

a pharmaceutically acceptable carrier;

and dissolved therein a sodium compound and a calcium compound providing a sodium ion concentration of 40-50 mM and a calcium ion concentration of 0.1-0.7 mM.

In a second aspect, there is provided a diagnostic composition comprising a compound I



Compound I

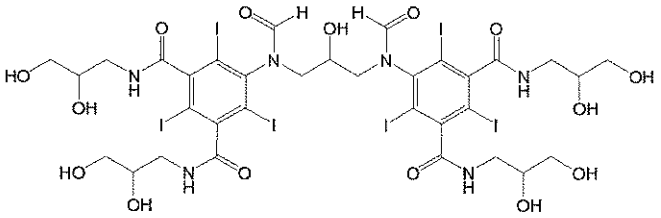
a pharmaceutically acceptable carrier;
and dissolved therein a sodium compound and a calcium compound wherein the ratio between sodium ion concentration and calcium ion concentration is between 40 and 45.

The physiochemical properties of Compound I are found below. Further information about the methods used, in addition to biodistribution and acute toxicity information, is provided in Example 1.

Protein binding: The binding of Compound I to human serum albumin (HSA) was determined using an equilibrium dialysis method. The binding of Compound I to human serum albumin was determined to be very low, 3.1 ± 1.3 %, confirming the negligible interaction of the substance with endogenous proteins.

Claims:

1. A diagnostic composition comprising a Compound I



Compound I

a pharmaceutically acceptable carrier;
and dissolved therein a sodium compound and a calcium compound providing a sodium ion concentration of 40-50 mM and a calcium ion concentration of 0.1-0.7 mM.

2. A diagnostic composition as claimed in claim 1 comprising a sodium compound providing a sodium ion concentration of 42-47 mM.

3. A diagnostic composition as claimed in claim 1 comprising a sodium compound providing a sodium ion concentration of 44-46 mM.

4. A diagnostic composition as claimed in claim 1 comprising a sodium compound providing sodium ion concentration of 45 mM.

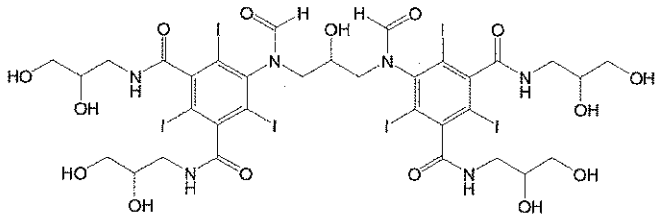
5. A diagnostic composition as claimed in any of claim 1 to 4 comprising a calcium compound providing a calcium ion concentration of 0.3-0.6 mM.

6. A diagnostic composition as claimed in any of claims 1 to 4 comprising a calcium compound providing a calcium concentration of 0.4-0.5 mM.

7. A diagnostic composition as claimed in any of claims 1 to 4 comprising a calcium compound providing a calcium concentration of 0.5 mM.

8. A diagnostic composition as claimed in claim 1 wherein the ratio between sodium ion concentration and calcium ion concentration is between 63 and 117.

9. A diagnostic composition comprising
a compound I



Compound I

a pharmaceutically acceptable carrier;
and dissolved therein a sodium compound and a calcium compound wherein the ratio between sodium ion concentration and calcium ion concentration is between 40 and 45.

10. A diagnostic composition as claimed in any of claims 1 to 9 wherein the sodium compound and calcium compound are salts comprising counter ions selected from the group of chloride, sulphate, phosphate and hydrogen carbonate.

11. A diagnostic composition as claimed in claim 10 wherein the sodium compound is sodium chloride and the calcium compound is calcium chloride.

12. A diagnostic composition as claimed in any of claims 1 to 11 further comprising EDTA and/or TRIS.

13. A method of diagnosis comprising administering a diagnostic composition as claimed in any of claims 1 to 12 to a human or animal body, examining the body with a diagnostic device and compiling data from the examination.

14. A method of in vivo imaging detection comprising the following steps;
i) administering a detectable quantity of the diagnostic composition as claimed in any of claims 1 to 12;
ii) allowing the administered composition to distribute;
iii) detecting signals emitted by the Compound I of the distributed composition,

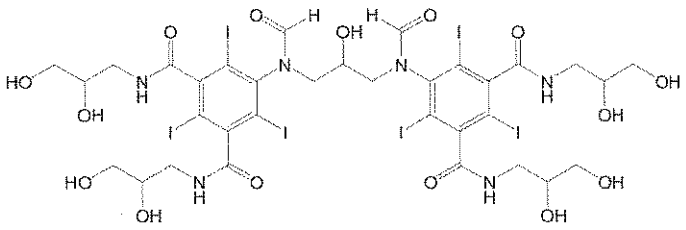
iv) generating an image representative of the location and/or amount of said signal.

15. A method as claimed in claim 14 wherein the method is a method of coronary arteriography.

16. A diagnostic composition as claimed in any of claims 1 to 12 for use as an X-ray contrast media in X-ray diagnoses or X-ray imaging.

Claims

1. A diagnostic composition comprising a Compound I



Compound I

a pharmaceutically acceptable carrier;
and dissolved therein a sodium compound and a calcium compound providing a sodium ion concentration of 40-50 mM and a calcium ion concentration of 0.1-0.7 mM.

2. A diagnostic composition as claimed in claim 1 comprising a sodium compound providing a sodium ion concentration of 42-47 mM.

3. A diagnostic composition as claimed in claim 1 comprising a sodium compound providing a sodium ion concentration of 44-46 mM.

4. A diagnostic composition as claimed in claim 1 comprising a sodium compound providing sodium ion concentration of 45 mM.

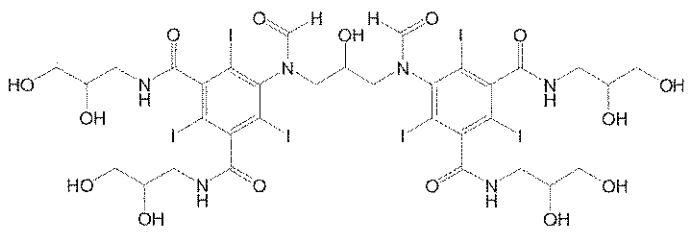
5. A diagnostic composition as claimed in any of claim 1 to 4 comprising a calcium compound providing a calcium ion concentration of 0.3-0.6 mM.

6. A diagnostic composition as claimed in any of claims 1 to 4 comprising a calcium compound providing a calcium concentration of 0.4-0.5 mM.

7. A diagnostic composition as claimed in any of claims 1 to 4 comprising a calcium compound providing a calcium concentration of 0.5 mM.

8. A diagnostic composition as claimed in claim 1 wherein the ratio between sodium ion concentration and calcium ion concentration is between 63 and 117.

9. A diagnostic composition comprising a compound I



Compound I

a pharmaceutically acceptable carrier;

and dissolved therein a sodium compound and a calcium compound wherein the ratio between sodium ion concentration and calcium ion concentration is between 40 and 45.

10. A diagnostic composition as claimed in any of claims 1 to 9 wherein the sodium compound and calcium compound are salts comprising counter ions selected from the group of chloride, sulphate, phosphate and hydrogen carbonate.

11. A diagnostic composition as claimed in claim 10 wherein the sodium compound is sodium chloride and the calcium compound is calcium chloride.

12. A diagnostic composition as claimed in any of claims 1 to 11 further comprising EDTA and/or TRIS.

13. A diagnostic composition as claimed in any of claims 1 to 12 for use as an X-ray contrast media in X-ray diagnoses or X-ray imaging.

14. A diagnostic composition as claimed in 13 wherein the use includes examining the body with a diagnostic device and compiling data from the examination.

15. A diagnostic composition as claimed in any of claims 13 and 14 wherein the use is a method of coronary arteriography