SCHEDULE

Regulations 3 and 4

PARTICULARS REQUIRED IN INFORMATION SHEETS AND DATA SHEETS

1. Each purpose for which the contact lens substance is to be used and in particular, if it is to be used for cleaning, disinfecting, irrigating, lubricating, wetting, soaking or rinsing a contact lens or blank or as a barrier between a contact lens or blank and the human eyeball, for which of those purposes it is to be used.

2. A description of the pharmaceutical form of the contact lens substance.

3. The active ingredients of the contact lens substance and its quantitative composition.

4. The name of any antimicrobial agent which is an ingredient of the contact lens substance and the percentage of that substance which that agent comprises, calculated in terms of weight in weight (w/w), weight in volume (w/v), or volume in volume (v/v) as appropriate.

5. The quantity or amount of the contact lens substance in each size of package or container in which it is available for retail sale.

6. The compatibility and incompatibility of the contact lens substance for use with different types of contact lenses and blanks, other contact lens substances and any other substance commonly applied to the human eyeball.

7. Possibilities of interaction between the contact lens substance and any other contact lens substance or any other substance commonly applied to the human eyeball.

8. The shelf-life of the contact lens substance.

9. A recommended period within which the contact lens substance should be used after the container containing it has first been opened.

10. Any special requirements for the storage of the contact lens substance and, where appropriate, pharmaceutical precautions including recommendations as to excipients and diluents.

11. Those adverse reactions to the contact lens substance which, if experienced, should be reported to a doctor, or to the pharmacist or optician who administered that substance or who sold or supplied it for administration.

12. Appropriate remedial measures in response to any adverse reaction to the contact lens substance which may be taken by the person to whom the substance was administered, sold or supplied.

13. Recommendations as to the antidote to be administered or other action to be taken by a doctor, pharmacist or optician on his becoming aware of any adverse reaction having occurred in connection with the use of the contact lens substance.

14. Any precautions required to be observed in the use of a contact lens substance which is intended to be administered directly to the human eyeball and any warnings relating to its use, either alone or in conjunction with any other substance, which should be given to any person to whom the substance may be sold or supplied.