

From: s22(1) [REDACTED]
To: [REDACTED]
Subject: Testing [DLM=For-Official-Use-Only]
Date: Wednesday, 1 November 2017 7:21:09 AM
Attachments: [image002.png](#)

Hi [REDACTED],

We are conducting a product review of chlorhexidine products on the ARTG. These products that are on the ARTG as 'Other Therapeutic Goods' (OTGs) as hard surface disinfectants. However, we are aware that these products are being used as skin disinfectants and as such are working with sponsors to ensure that the labelling reflects this.

In addition to labelling there is the matter of tinting of the solutions. The sponsors all state that tinting is necessary so that the user knows where they have used the hard surface disinfectant. There are various tints; blue, red and pink. Of most concern is pink as this tint can be quite indistinct from clear solution. There are adverse event reports about the injection of pink tinted chlorhexidine and there is a reporter who is continuing to pressure for changes. We are also communicating with sponsors that the tinting must be sufficient that the pink is distinct from clear solutions. We would like to test that the colour is distinct and agree with sponsors to a formula so that there can be no issues with using pink tinted chlorhexidine in the future. Is the labs able to undertake this testing?


Kind regards

[REDACTED]

[REDACTED]
Director
Device Vigilance and Monitoring Section
Medical Devices Branch | Therapeutic Goods Administration
Department of Health

[REDACTED]

 136 Narrabundah Lane, Symonston, ACT, 2609

 PO Box 100, Woden, ACT, 2606