



## Classification of Alcohol Based Hand Sanitisers

>20% Alcohol General Sale When Sold in a Wall Mounted Automated Dispenser

55<sup>th</sup> Meeting of Medicines Classification Committee

In Australia alcohol has been classified under Appendix B as a product not requiring classification since 1974. In New Zealand products containing more than 20% alcohol are Classified General Sale.

The State of Colorado in the USA places the following restrictions on alcohol hand sanitisers:<sup>1</sup>

“No child under the age of three years old should be permitted to use hand sanitizer. No child of any age should be permitted to use hand sanitizer without supervision.”

The US FDA has the following restrictions:<sup>2</sup>

“Storage and use of alcohol-based hand sanitizers:

- Hand sanitizers do not need to be locked but must be maintained inaccessible to children.
- All children must be supervised by a staff member when using hand sanitizers.
- For programs that serve school age children only, hand sanitizer dispensers that are mounted to the wall are acceptable.”

This submission seeks the classification for hand sanitisers >20% alcohol to be General Sale when sold in a wall mounted automatic dispenser.

There are a wide variety of alcohol based hand sanitisers available on the market with >60% alcohol content and a claim of >99.999% antimicrobial kill. <sup>3</sup> The fact that these products make a therapeutic claim of killing more than 99.999% germs also brings them within the Medicines Act.

The 2006 trial of differing strengths of alcohol hand sanitisers reported that below <40% alcohol there was a mean increase in CFU of bacteria of post-wash versus prewash. A 62% ethanol gel however provided a mean 82% decrease in CFU. <sup>7</sup>

The alcohol hand sanitisers are usually scented, coloured and packaged in such a way as to make them an attractive consumer item. Furthermore, unlike meths or bleaches for example, these products are not fitted with a child proof cap or with a direction to be stored securely out of the reach of children. Instead, the hand sanitisers are ready to use and intended to be accessible to children.

A 2014 New Zealand study of the use of alcohol hand sanitisers in school classrooms found that:

“The number of absences for any reason and the length of the absence episode were measured in all primary school children enrolled at the schools. Children, school administrative staff, and the school liaison research assistants were not blind to group allocation. Outcome assessors of follow-up children were blind to group allocation. Of the 1,301 and 1,142 follow-up children in the hand sanitiser and control groups, respectively, the rate of absence episodes due to illness per 100 child-days was similar (1.21 and 1.16, respectively, incidence rate ratio 1.06, 95% CI 0.94 to 1.18). The provision of an alcohol-based hand sanitiser dispenser in classrooms was not effective in reducing rates of absence episodes due to respiratory or gastrointestinal illness, the length of illness or illness absence episodes, or the rate of subsequent infection for other members of the household in these children. The percentage of children experiencing a skin reaction was similar (10.4% hand sanitiser versus 10.3% control, risk ratio 1.01, 95% CI 0.78 to 1.30). The rate or length of absence episodes for any reason measured for all children also did not differ between groups.”<sup>4</sup>

In a 2012 randomised trial of alcohol based hand sanitisers in the prevention of HRV or HRV-associated illness the authors concluded:<sup>5</sup>

“In this study, hand disinfection did not reduce RV infection or RV-related common cold illnesses.”

A 2015 meta-analysis of school based alcohol hand sanitisers concluded:

“...evidence of the effect of hand hygiene interventions on infection incidence in educational settings is mostly equivocal...”<sup>6</sup>

A 2010 randomised trial of 30 seconds treatment with varying concentrations of ethanol hand wash versus varying concentrations of hypochlorous acid reported that 200ppm HOCl achieved  $>5\log_{10}$  kill of the norovirus surrogate (Norwalk virus) compared with  $<1\log_{10}$  kill for 100% ethanol.<sup>5</sup>

There are an increasing number of cases of alcohol poisoning from hand sanitisers worldwide. In Victoria Australia alone there were 15,000 cases reported in 2013.<sup>8</sup> Infants are sometimes comatose from consuming just a few squirts of sanitiser. The numbers are rising too. In the last 5 years the USA has reported a 400% increase in cases of child alcohol poisonings from hand sanitisers.<sup>9</sup>

Overall, the evidence for alcohol based hand sanitiser efficacy is equivocal and certainly well-short of the claimed >99.999% of germs killed.<sup>8</sup> On the other hand, the evidence of harm is unequivocal. On balance, we submit that the risks outweigh the benefits with the current classification and propose the classification of hand sanitisers >20% alcohol to be General Sale Medicine when sold in a wall mounted automatic dispenser.

The New Zealand Poisons Centre reports between 140-150 cases a year involving alcohol based hand sanitisers with around 90% of cases involving children and infants as young as 1-5 months old (enclosed).

## **References:**

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