PRODUCT BULLETIN

Distribution:	
International Distributors	✔
International Management	✔
US Clinical Specialists	✔
US Customer Service	✔
US Field Sales	✔
US Technical and Field Service	✔

Date: **August 5, 2011**

RE: Rapicide® High Level Disinfectant and Sterilant inactivation of hepatitis viruses

The health care community has growing concerns over the risks of disease due to infections with Hepatitis Viruses. Questions have been asked by some of you with regard to the performance of Rapicide® High-Level Disinfectant and Sterilant in relation to killing of the pathogenic viruses responsible for the diseases generally known to cause viral Hepatitis.

Rapicide has been shown to kill the Hepatitis B Group Virus and was used in the initial work that showed the analogue Duck Hepatitis Virus was a suitable test system for measuring hepadnacidal disinfectant performance. Rapicide was shown to be effective at concentrations as low as 0.5% Glutaraldehyde (MRC IS 1.5%), in five minutes at room temperature[1]. Similarly, testing against another of the Blood Borne Viruses (HIV), showed activity in less time at only 0.5% concentration[2].

However, it is important to note several issues in relation to Viral Hepatitis.

1) Hepatitis, which means “Liver Illness”, has a variety of causes. These can commonly include virus infections or alcohol damage, but there are other causes.

2) There are at least five different virus types that can cause hepatitis (liver illness). Of these, the most commonly known are the “Hepatitis Viruses”. The commonly known of the Hepatitis Viruses are designated as A, B C, D & E. Other known viruses are also able to cause Hepatitis including certain Parvoviruses[3].

3) Each of the viruses mentioned has quite separate physical and chemical characteristics giving them important differences in disease transmission and resistance to germicides. There are different ways of classifying the classes or families of viruses, even in terms of germicidal resistance/performance.

4) The viruses known generally as Hepatitis Viruses (A, B, C, D & E), each virus is quite distinct and unrelated in real terms, excepting that their major disease outcome is a virus induced Hepatitis Illness. Of the known Hepatitis Viruses, test methods to measure disinfectant efficacy are recognized only for Hepatitis viruses A and B.

Minntech Corporation, 14605 28th Avenue North, Minneapolis, MN 55447-4822

763.553.3300, fax 763.553.3387, www.minntech.com

However, in the case of "Hepatitis A Virus" (HAV), the physical and chemical characteristics are similar to other easier to culture and handle viruses such as Polio virus. Even the mode of transmission (fecal/oral) is similar to the mode of transmission for Polio viruses. Therefore, germicidal performance against Polio virus is generally accepted as analogous performance against other enteric viruses such as Hepatitis A virus and viruses such as the Coxsackie viruses.

For Hepatitis "B" Virus (HBV), for many years the only accepted test for germicidal performance used live chimpanzees[4]. More recently, a new test modality has been proven and now recognised, using an analogue virus (the Duck Hepadna virus)[5]. This is important as Polymerase Chain Reaction (PCR), has been shown to be unreliable as a measure of infectivity for at least HBV[6].

Rapicide performance has been proven and is accepted against this important infectious group of viruses. This is important as transmission of this virus has been observed via blood contaminated instruments including medical devices that have been improperly cleaned[7], or improperly reprocessed using an ineffective germicide[8].

At this time there is no recognized test method for the Hepatitis C Virus. Work has commenced in various centers on an analogue method using a Bovine Diarrhoeal virus model that can be cultured in a laboratory cell line[9]. It is widely accepted that germicidal resistance of the other Hepatitis viruses (C, D, & E), is no greater than the other tested viruses (HAV, HBV). Blood itself may shield the viruses to a greater or lesser extent. Biofilms have also been shown to shield Hepatitis viruses successfully from germicides and even ETO[10] and "flash Sterilization"[11].

It is observed that the relative infectivity risk associated with needle stick transmission or exposure is about 1 in 300 for HIV[12], approximately 1 in 30 for HCV[13], and around 1 in 3 for HBV.

In summary, Rapicide 5 Minute High Level Disinfectant and Sterilant has demonstrated a wide margin of safety against all organisms, including the Hepatitis Viruses and Blood Borne Viruses generally.

If you have any questions regarding the contents of this Technical Bulletin, please contact Medivators Technical Support at 1-800-444-4729.

Reference:

1. *Murray SM, Freiman JS, Vickery K, Lim D, Cossart YE, Whiteley RK. J Epidemiol. Infect. (1991), 106, 435-443. Duck Hepatitis Virus: A Model to Assess Efficacy of Disinfectants Against Hepadnavirus Infectivity.*
2. *Druce JD, Jardine D, Locarnini SA, Birch CJ. J Hospital Infect. (1995), 30, 167-180. Susceptibility of HIV to Inactivation by Disinfectants and Ultraviolet Light.*
3. *Cossart YE, J Clin. Virol.(2000), 17 (1) 1-3. TTV – a virus searching for a disease*
4. *Rutala W, 1990, Amer. J Infect. Control, 18, (2), 99-117. APIC Guidelines For Infection Control Practice – Selection and Use of Disinfectants.*
5. *Murray 1991, op cit.*
6. *Deva AK, Vickery K, Zou J, West RH, Harris JP, Cossart YE. J Hosp. Infect. (1996), 33 (2), 119-130. Establishment of an In-Use Testing Method for Evaluating Disinfection of Surgical Instruments Using the Duck Hepatitis B Model.*
7. *Deva AK, Vickery K, Zou J, West RH, Selby W, Benn RA, Harris JP, Cossart YE. J Hosp. Infect. (1998). 39, (2). 149-157. Detection of Persistent Vegatative Bacteria and Amplified Viral Nucleic Acid From In-Use Testing of Gastrointestinal Endoscopes.*
8. *Johnson IL, J Can Med. Assocn., (2000), 162, 1127-1131. Hepatitis B Outbreak Investigation Team: An Outbreak of Hepatitis B associated with EEGs.*
9. *Therapeutic Goods Order Number 54, 1996, Guidelines for the Evaluation of Sterilants and Disinfectants [s.6.4.5.g.] Australian Commonwealth Department of Health, Therapeutic Goods Administration.*
10. *Shaufour X, Deva AK, Vickery K, Zou J, Kumeradeva P, White GH, Cossart YE. J Vasc. Surg. (1999), 30, 277-282. Evaluation of Disinfectants and Sterilization of Reusable Angioscopes with a Duck Hepatitis B Virus Model.*
11. *Vickery K, Pajkos A, Cossart YE. Br Dent J, (2000), 189, (11), 620-624. Evaluation of the Effectiveness of Decontamination of Dental Syringes.*
12. *Gerberding JL. (1995), N Eng J Med, 332, 441-451. Management of Occupational Exposure to Blood Borne Viruses.*
13. *Puro V, Petrosillo N, Ipplito G. Amer. J Infect. Control. (1995). 23, 273-277. Risk of Haptitis C Virus Seroconversion After Occupational Exposures in Health Care Workers.*