Infection control is also a significant unaddressed need in debridement. Burn eschar is typically dry necrotic tissue not readily infected, but sepsis can occur with second and third degree burns; therefore, having antimicrobials in the eschar and wound bed during early stages of eschar (necrotic tissue) removal is highly desirable. In contrast to burn eschar, chronic wound (diabetic ulcer) necrotic tissue appears to promote bacterial colonization, supported by the presence of water and nutrient sources from dead cells and debris. Necrotic tissue in wounds may be associated with infection, while a majority of chronic wounds are infected with microorganism biofilm.

A difficulty in the use of proteolytic enzymes for debridement of necrotic tissue is their ability for auto-digestion in aqueous solution, in addition to their potential difficulty with adverse allergic events, hypersensitivity and/or lack of efficacy. It is thus desirable to identify a debridement composition, having a high debridement efficacy for necrotic tissue, that is clinically simple to use, exhibits a suitable shelf-life, and is non-allergenic.

SUMMARY

In one aspect, there is provided a debridement composition comprising:

0.1 to 60 wt % of an amylase component and a proteolytic enzyme component, wherein a ratio of the amylase component to proteolytic enzyme component is at least 10:1 by weight; and

at least one pharmaceutically or cosmetically acceptable carrier or excipient in an amount up to 99.9 wt %, wherein the percentages are based on a total weight of the debridement composition,

wherein said amylase component comprises at least 80 % by weight of α-amylase from porcine pancreas, and

wherein the debridement composition is capable of debriding devitalized or necrotic tissue.

In one aspect, there is provided a debridement composition comprising:

0.1 to 60 wt % of an amylase component and if a proteolytic enzyme component is present, a ratio of the amylase component to proteolytic enzyme component is at least 10:1 by weight; and

at least one pharmaceutically or cosmetically acceptable carrier or excipient in an amount up to 99.9 wt %, wherein the percentages are based on a total weight of the debridement composition,

wherein said amylase component comprises at least 80 % by weight of α-amylase from a *Bacillus* spp., and

wherein the debridement composition is capable of debriding devitalized or necrotic tissue, and

wherein the debridement composition further comprises at least one polymeric biguanide in an amount of at least 0.01 weight percent (100 ppm) to 1.0 weight percent (10,000 ppm) based on the weight of the debridement composition.

In one aspect, there is provided a kit comprising:

a debridement composition as described herein; and

instructions for using the debridement composition for debridement of devitalized tissue.

In one aspect, there is provided use of a debridement composition described herein in the manufacture of a medicament for debridement of devitalized tissue of an area of skin in need of debridement.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a graph of frequency versus modulus for collagen gels before and after treatment with different enzymes.

Figure 2 is a graph of frequency versus complex modulus for collagen gels before and after treatment with different enzymes.

Figure 3 is a graph of weight percent boiled pig skin digested verses α-amylase concentration after one hour at room temperature.

Claims:

1. A debridement composition comprising:

0.1 to 60 wt % of an amylase component and a proteolytic enzyme component, wherein a ratio of the amylase component to proteolytic enzyme component is at least 10:1 by weight; and

at least one pharmaceutically or cosmetically acceptable carrier or excipient in an amount up to 99.9 wt %, wherein the percentages are based on a total weight of the debridement composition,

wherein said amylase component comprises at least 80 % by weight of α-amylase from porcine pancreas, and

wherein the debridement composition is capable of debriding devitalized or necrotic tissue.

2. A debridement composition comprising:

0.1 to 60 wt % of an amylase component and if a proteolytic enzyme component is present, a ratio of the amylase component to proteolytic enzyme component is at least 10:1 by weight; and

at least one pharmaceutically or cosmetically acceptable carrier or excipient in an amount up to 99.9 wt %, wherein the percentages are based on a total weight of the debridement composition,

wherein said amylase component comprises at least 80 % by weight of α-amylase from a *Bacillus* spp., and

wherein the debridement composition is capable of debriding devitalized or necrotic tissue; and

wherein the debridement composition further comprises at least one polymeric biguanide in an amount of at least 0.01 weight percent (100 ppm) to 1.0 weight percent (10,000 ppm) based on the weight of the debridement composition.

3. The composition according to claim 1 or claim 2, wherein said amylase comprises up to 20 % by weight of an amylase selected from ß-amylase, γ-amylase, and combinations thereof.

4. The composition according to claim 1 or claim 2, further comprising up to 20 % by weight of hydrolytic enzymes selected from proteases, chondroitinases, *hyaluronidases,* lipases, glycosidases, heparanases, dermatanases, pullulanases, N-acetylglucosaminidase, lactases, phospholipases, transglycosylases, esterases, thioester hydrolyases, sulfatases, escharases, nucleases, phosphatases, phosphodiesterases, mannanases, mannosidases, isoamylases, lyases, inulinases, keratinases, tannases, pentosanases, glucanases, arabinosidases, pectinases, cellulases, chitinases, xylanases, cutinases, pectate lyases, hemicellulases, and combinations thereof.

5. The composition according to claim 1 or claim 2, further comprising up to 20 % by weight of enzymes selected from oxidases, peroxidases, glucose oxidases, catalases, oxidoreductases, phenoloxidases, laccases, lipoxygenases, isomerases, and ligninases.

6. The composition according to claim 2, wherein said polymeric biguanide comprises poly(hexamethylene biguanide) and its salts.

7. The composition according to claim 1 or claim 2, further comprising a water-soluble polymer at a concentration of from 0.01 weight % to 50 weight % based on the weight of the debridement composition.

8. The composition according to claim 1 or claim 2, further comprising a chelating agent at a concentration of from 0.01 weight % to 1 weight % based on a weight of the debridement composition.

9. The composition according to claim 1 or claim 2, further comprising a monoalkyl glycol selected from the group consisting of 1,2-propanediol (propylene glycol), 1,2-butanediol,

1,2-pentanediol, 1,2-hexanediol, 1,2-heptanediol, 1,2-octanediol (caprylyl glycol), 1,2-nonanediol, 1,2-decanediol, 1,2-undecanediol, 1,2-dodecanediol, 1,2-tridecanediol, 1,2-tetradecanediol, 1,2-pentadecanediol, 1,2-hexadecanediol, 1,2-heptadecanediol, 1,2-octadecanediol, 2-methyl-2,4-pentanediol, 1,3-butanediol, diethylene glycol, triethylene glycol, glycol bis(hydroxyethyl) ether, and combinations thereof.

10. The composition according to claim 1 or claim 2, further comprising a glycerol alkyl ether selected from the group consisting of 1-O-heptylglycerol, 1-O-octylglycerol, 1-O-nonylglycerol, 1-O-decylglycerol, 1-O-undecylglycerol, 1-O-dodecylglycerol, 1-O-tridecylglycerol, 1-O-tetradecylglycerol, 1-O-pentadecylglycerol,1-O-hexadecylglycerol (chimyl alcohol), 1-O-heptadecylglycerol, 1-O-octadecylglycerol (batyl alcohol), 1-O-octadec-9-enyl glycerol (selachyl alcohol), glycerol 1-(2-ethylhexyl) ether, 2-ethylhexyl glycerin, glycerol 1-heptyl ether, glycerol 1-octyl ether, glycerol 1-decyl ether, and glycerol 1-dodecyl ether, glycerol 1-tridecyl ether, glycerol 1-tetradecyl ether, glycerol 1-pentadecyl ether, glycerol 1-hexadecyl ether, glycerol 1-octadecyl ether, and combinations thereof.

11. The composition according to claim 1 or claim 2, further comprising
at least one polymeric biguanide in an amount of at least 0.01 weight %,
a chelating agent at a concentration of 0.01 weight % to 1 weight %,
and a vicinal diol component selected from a monoalkyl glycol and a monoalkyl glycerol at a concentration of 0.05 weight % to 4 weight %, based on a weight of the debridement composition.

12. The composition according to claim 1 or claim 2, further comprising at least one analgesic agent, anesthetic agent, neuropathic pain agent, or a combination thereof.

13. The composition according to claim 12, wherein the at least one analgesic agent, anesthetic agent, or neuropathic pain agent is selected from the group consisting of lidocaine, capsaicin, benzocaine, tetracaine, prilocaine, bupivacaine, levobupivacaine, procaine, carbocaine, etidocaine, mepivacaine, nortripylene, amitriptyline, pregabalin,

diclofenac, fentanyl, gabapentin, non-steroidal anti-inflammatory agents, salicylates, and combinations thereof.

14. The composition according to claim 1 or claim 2, wherein the debridement composition has a form selected from the group consisting of a powder, aqueous solution, organic liquid solution, silicone, gel, cream, film, latex, aerosol, slurry, paste, ointment and foam.

15. The composition according to claim 1 or claim 2, wherein said debridement composition is adsorbed on or in a dressing or a natural or synthetic fiber, mesh, hydrocolloid, alginate, hydrogel, semipermeable film, permeable film, or a natural or synthetic polymer.

16. The composition according to claim 1 or claim 2, further comprising a buffering agent.

17. A kit comprising:

a debridement composition according to claim 1 or claim 2; and

instructions for using the debridement composition for debridement of devitalized tissue.

18. The kit according to claim 17, wherein said instructions comprise instructions for contacting the debridement composition with an area of skin in need of debridement.

19. Use of a debridement composition according to claim 1 or claim 2 in the manufacture of a medicament for debridement of devitalized tissue of an area of skin in need of debridement.

20. The use of claim 19, wherein said medicament is to be administered repeatedly at least once a day.