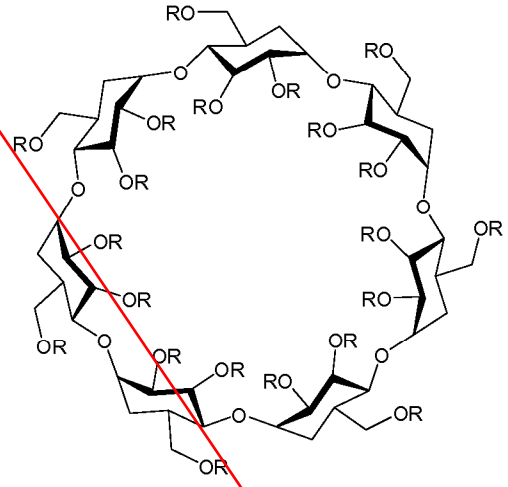
[0005] A sulfobutyl ether derivative of β-cyclodextrin ("SBE-β-CD") has been commercialized by CyDex Pharmaceuticals, Inc. as CAPTISOL® and ADVASEP®. The anionic sulfobutyl ether substituent improves the aqueous solubility and safety of the parent β-cyclodextrin, which can reversibly form complexes with active pharmaceutical agents, thereby increasing the solubility of active pharmaceutical agents and, in some cases, increase the stability of active pharmaceutical agents in aqueous solution. CAPTISOL® has a chemical structure according to Formula X:

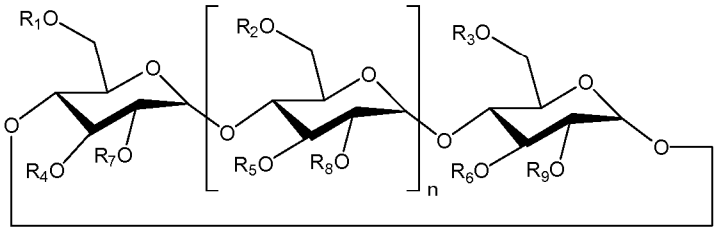


X,

where R is $(-H)_{21-n}$ or $((-CH_2)_4\text{-}SO_3^-Na^+)_n$, and n is 6 to 7.1.

[0006] Sulfoalkyl ether derivatized cyclodextrins (such as CAPTISOL®) are prepared using batch methods as described in, e.g., U. S. Patent Nos. 5,134,127, 5,376,645 and 6,153,746, each of which is hereby incorporated by reference in its entirety.

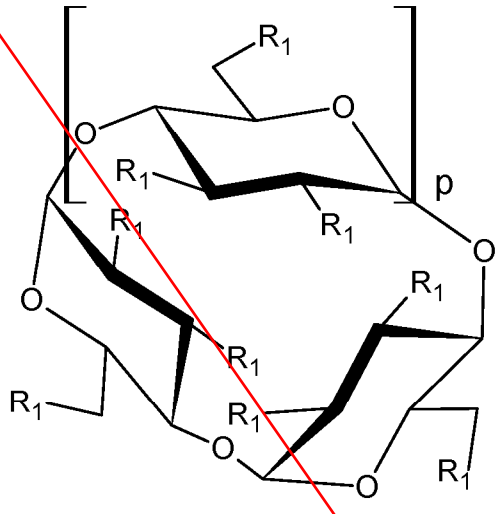
[0007] Sulfoalkyl ether cyclodextrins and other derivatized cyclodextrins can also be prepared according to the methods described in the following patents and published patent applications: US 3,426,011, US 3,453,257, US 3,453,259, US 3,459,731, US 4,638,058, US 4,727,06, US 5,019,562, US 5,173,481, US 5,183,809, US 5,241,059, US 5,536,826, US 5,594,125, US 5,658,894, US 5,710,268, US 5,756,484, US 5,760,015, US 5,846,954, US 6,407,079, US 7,625,878, US 7,629,331, US 7,635,773, US2009/0012042, JP 05001102, and WO 01/40316, as well as in the following non-patent publications: Lammers *et al.*, *Recl. Trav. Chim. Pays-Bas 91*:733 (1972); *Staerke 23*:167 (1971), Adam *et al.*, *J. Med. Chem. 45*:1806 (2002), Qu *et al.*, *J. Inclusion Phenom. Macrocyclic Chem. 43*:213 (2002), Tarver *et al.*, *Bioorg. Med. Chem. 10*:1819 (2002), Fromming *et al.*, *Cyclodextrins in Pharmacy* (Kluwer Academic Publishing, Dordrecht, 1994), *Modified Cyclodextrins: Scaffolds and Templates for Supramolecular Chemistry* (C.J. Easton *et al.* eds., Imperial College Press, London, UK, 1999), *New*



I,

wherein: n is 4, 5 or 6; wherein R_1, R_2, R_3, R_4, R_5, R_6, R_7, R_8 and R_9 are independently -H, a straight-chain or branched C_1-C_8-(alkylene)-SO_3^- group, or an optionally substituted straight-chain or branched C_1-C_6 group; wherein at least one of R_1, R_2, R_3, R_4, R_5, R_6, R_7, R_8 and R_9 is a straight-chain or branched C_1-C_8-(alkylene)-SO_3^- group.

[0059] In some embodiments, a SAE-CD composition comprises a water-soluble alkylated cyclodextrin of Formula II:



II,

wherein: p is 4, 5 or 6;

R_1 is independently selected at each occurrence from -OH or -SAE-T;

-SAE- is a -O-(C_2-C_6 alkylene)-SO_3^- group, wherein at least one SAE is independently a -O-(C_2-C_6 alkylene)-SO_3^- group, a -O-$(CH_2)_gSO_3^-$ group, wherein g is 2 to 6, or 2 to 4, (e.g.-$OCH_2CH_2CH_2SO_3^-$ or -$OCH_2CH_2CH_2CH_2SO_3^-$); and -T is independently selected at each occurrence from the group consisting of pharmaceutically acceptable cations, which group includes, for example, H^+, alkali metals (e.g., Li^+, Na^+, K^+), alkaline earth metals (e.g., Ca^{+2}, Mg^{+2}), ammonium ions and amine cations such as the cations of (C_1-C_6)-alkylamines, piperidine, pyrazine, (C_1-C_6)-alkanolamine, ethylenediamine and (C_4-C_8)-cycloalkanolamine among others; provided that at least one R_1 is a hydroxyl moiety and at least one R_1 is -SAE-T.

[0060] When at least one R_1 of a derivatized cyclodextrin molecule is -SAE-T, the degree of substitution, in terms of the -SAE-T moiety, is understood to be at least one (1). When

the term -SAE- is used to denote a sulfoalkyl-(alkylsulfonic acid)-ether moiety it being understood that the -SAE- moiety comprises a cation (-T) unless otherwise specified. Accordingly, the terms "SAE" and "-SAE-T" can, as appropriate, be used interchangeably herein.

[0061] Since SAE-CD is a poly-anionic cyclodextrin, it can be provided in different salt forms. Suitable counterions include cationic organic atoms or molecules and cationic inorganic atoms or molecules. The SAE-CD can include a single type of counterion or a mixture of different counterions. The properties of the SAE-CD can be modified by changing the identity of the counterion present. For example, a first salt form of a SAE-CD composition can possess greater osmotic potential or greater water activity reducing power than a different second salt form of same SAE-CD.

[0062] In some embodiments, a sulfoalkyl ether cyclodextrin is complexed with one or more pharmaceutically acceptable cations selected from, e.g., H^+, alkali metals (e.g., Li^+, Na^+, K^+), alkaline earth metals (e.g., Ca^{+2}, Mg^{+2}), ammonium ions and amine cations such as the cations of (C_1-C_6)-alkylamines, piperidine, pyrazine, (C_1-C_6)-alkanolamine, ethylenediamine and (C_4-C_8)-cycloalkanolamine, and the like, and combinations thereof.

[0063] Further exemplary sulfoalkyl ether (SAE)-CD derivatives include:

Table 2.

SAE_x-α-CD	SAE_x-β-CD	SAE_x-γ-CD
(Sulfoethyl ether)$_x$-α-CD	(Sulfoethyl ether)$_x$-β-CD	(Sulfoethyl ether)$_x$-γ-CD
(Sulfopropyl ether)$_x$-α-CD	(Sulfopropyl ether)$_x$-β-CD	(Sulfopropyl ether)$_x$-γ-CD
(Sulfobutyl ether)$_x$-α-CD	(Sulfobutyl ether)$_x$-β-CD	(Sulfobutyl ether)$_x$-γ-CD
(Sulfopentyl ether)$_x$-α-CD	(Sulfopentyl ether)$_x$-β-CD	(Sulfopentyl ether)$_x$-γ-CD
(Sulfohexyl ether)$_x$-α-CD	(Sulfohexyl ether)$_x$-β-CD	(Sulfohexyl ether)$_x$-γ-CD

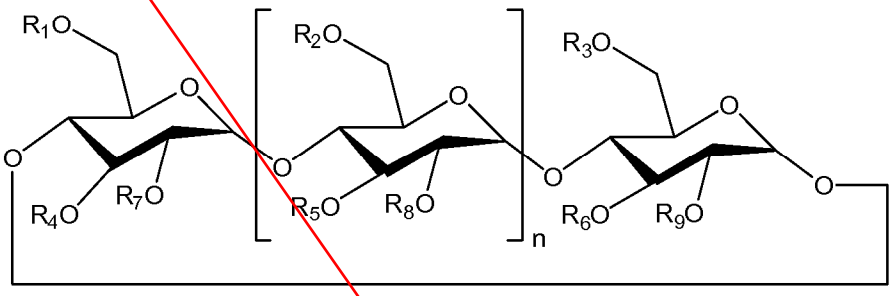
wherein x denotes the average degree of substitution. In some embodiments, the alkylated cyclodextrins are formed as salts.

[0064] Various embodiments of a sulfoalkyl ether cyclodextrin include eicosa-O-(methyl)-6G-O-(4-sulfobutyl)-β-cyclodextrin, heptakis-O-(sulfomethyl)-tetradecakis-O-(3-sulfopropyl)-β-cyclodextrin, heptakis-O-[(1,1-dimethylethyl)dimethylsilyl]-tetradecakis-O-(3-sulfopropyl)-β-cyclodextrin, heptakis-O-(sulfomethyl)-tetradecakis-O-(3-sulfopropyl)-β-cyclodextrin, and heptakis-O-[(1,1-dimethylethyl)dimethylsilyl]-tetradecakis-O-(sulfomethyl)-β-cyclodextrin. Other known alkylated cyclodextrins containing a sulfoalkyl moiety include sulfoalkylthio and sulfoalkylthioalkyl ether derivatives such as octakis-(S-sulfopropyl)-octathio-γ-cyclodextrin, octakis-O-[3-[(2-

sulfoethyl)thio]propyl]-β-cyclodextrin], and octakis-S-(2-sulfoethyl)-octathio-γ-cyclodextrin.

[0065] In some embodiments, an alkylated cyclodextrin composition of the present invention is a sulfoalkyl ether-β-cyclodextrin composition having an ADS of 2 to 9, 4 to 8, 4 to 7.5, 4 to 7, 4 to 6.5, 4.5 to 8, 4.5 to 7.5, 4.5 to 7, 5 to 8, 5 to 7.5, 5 to 7, 5.5 to 8, 5.5 to 7.5, 5.5 to 7, 5.5 to 6.5, 6 to 8, 6 to 7.5, 6 to 7.1, 6.5 to 7.1, 6.2 to 6.9, or 6.5 per alkylated cyclodextrin, and the remaining substituents are -H.

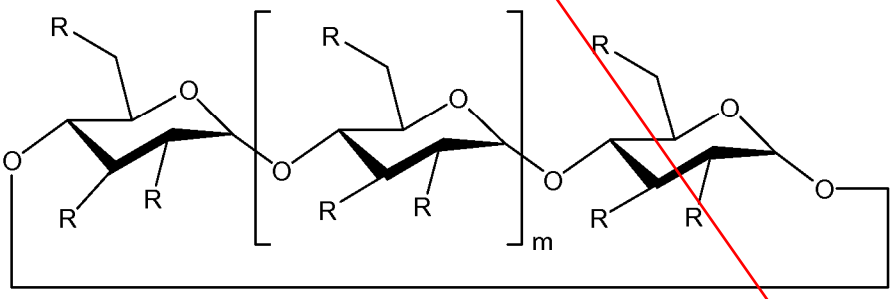
[0066] In some embodiments, the alkylated cyclodextrin is a compound of Formula III:



III,

wherein n is 4, 5 or 6, wherein R_1, R_2, R_3, R_4, R_5, R_6, R_7, R_8 and R_9 are independently selected from: -H, a straight-chain or branched C_1-C_8-(alkylene)-SO_3^- group, and an optionally substituted straight-chain or branched C_1-C_6 group.

[0067] A water soluble alkylated cyclodextrin composition can comprise an alkyl ether (AE)-cyclodextrin compound, or mixture of compounds, of the Formula IV:



IV,

wherein: m is 4, 5 or 6; R is independently selected at each occurrence from the group consisting of -OH and AE; and AE is -O-(C_1-C_6 alkyl); provided that at least one R is -OH; and at least one AE is present.

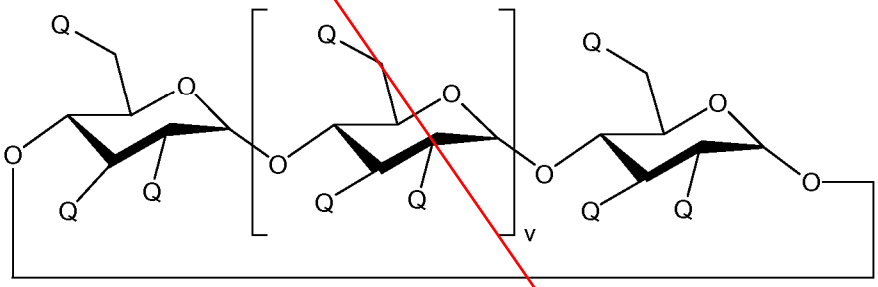
[0068] Further exemplary AE-CD derivatives include:

Table 3.

(Alkylether)$_y$-α-CD	(Alkylether)$_y$-β-CD	(Alkylether)$_y$-γ-CD
ME$_y$-α-CD	ME$_y$-β-CD	ME$_y$-γ-CD
EE$_y$-α-CD	EE$_y$-β-CD	EE$_y$-γ-CD
PE$_y$-α-CD	PE$_y$-β-CD	PE$_y$-γ-CD
BE$_y$-α-CD	BE$_y$-β-CD	BE$_y$-γ-CD
PtE$_y$-α-CD	PtE$_y$-β-CD	PtE$_y$-γ-CD
HE$_y$-α-CD	HE$_y$-β-CD	HE$_y$-γ-CD

wherein ME denotes methyl ether, EE denotes ethyl ether, PE denotes propyl ether, BE denotes butyl ether, PtE denotes pentyl ethyl, HE denotes hexyl ether, and y denotes the average degree of substitution.

[0069] A water soluble alkylated cyclodextrin composition can comprise a HAE-cyclodextrin compound, or mixture of compounds, of the Formula V:



V,

wherein: "v" is 4, 5 or 6; "Q" is independently selected at each occurrence from the group consisting of -OH, and -HAE; and HAE is HO(C_1-C_6 alkyl)-O-, provided that at least one -HAE moiety is present.

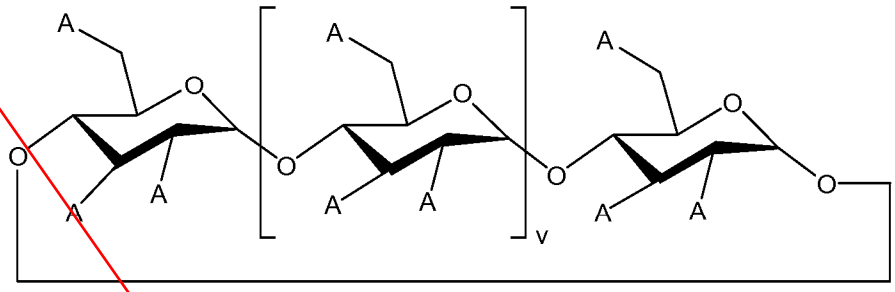
[0070] Further exemplary hydroxyalkyl ether (HAE)-CD derivatives include:

Table 4.

(HAE)$_z$-α-CD	(HAE)$_z$-β-CD	(HAE)$_z$-γ-CD
HMEz-α-CD	HMEz-β-CD	HMEz-γ-CD
HEEz-α-CD	HEEz-β-CD	HEEz-γ-CD
HPEz-α-CD	HPEz-β-CD	HPEz-γ-CD
HBEz-α-CD	HBEz-β-CD	HBEz-γ-CD
HPtEz-α-CD	HPtEz-β-CD	HPtEz-γ-CD
HHEz-α-CD	HHEz-β-CD	HHEz-γ-CD

wherein HME denotes hydroxymethyl ether, HEE denotes hydroxyethyl ether, HPE denotes hydroxypropyl ether, HBE denotes hydroxybutyl ether, HPtE denotes hydroxypentyl ether, HHE denotes hydroxyhexyl ether, and z denotes the average degree of substitution.

[0071] A water soluble alkylated cyclodextrin composition can comprise a SAE-AE-CD compound, or mixture of compounds, of Formula VI:

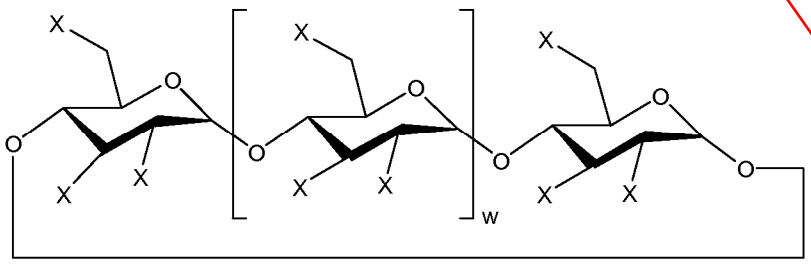


VI,

wherein: "v" is 4, 5 or 6; "A" is independently selected at each occurrence from the group consisting of -OH, -SAET and -AE; x is the degree of substitution for the SAET moiety and is 1 to 3v + 5; y is the degree of substitution for the AE moiety and is 1 to 3v + 5; -SAE is -O-(C_2-C_6 alkylene)-SO_3^-; T is independently at each occurrence a cation; and AE is -O(C_1-C_3 alkyl); provided that at least one -SAET moiety and at least one -AE moiety are present; and the sum of x, y and the total number of -OH groups in an alkylated cyclodextrin is 3v + 6.

[0072] Specific embodiments of the derivatives of the present invention include those wherein: 1) the alkylene moiety of the SAE has the same number of carbons as the alkyl moiety of the AE; 2) the alkylene moiety of the SAE has a different number of carbons than the alkyl moiety of the AE; 3) the alkyl and alkylene moieties are independently selected from the group consisting of a straight chain or branched moiety; 4) the alkyl and alkylene moieties are independently selected from the group consisting of a saturated or unsaturated moiety; 5) the ADS for the SAE group is greater than or approximates the ADS for the AE group; or 6) the ADS for the SAE group is less than the ADS for the AE group.

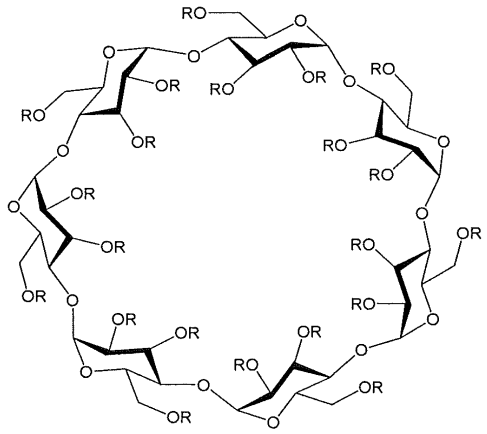
[0073] A water soluble alkylated cyclodextrin composition can comprise a SAE-HAE-CD compound, or mixture of compounds, of Formula VII:



VII,

wherein: "v" is 4, 5 or 6; "X" is independently selected at each occurrence from the group consisting of -OH, SAET and HAE; x is the degree of substitution for the SAET moiety

[0005] A sulfobutyl ether derivative of β-cyclodextrin ("SBE-β-CD") has been commercialized by CyDex Pharmaceuticals, Inc. as CAPTISOL® and ADVASEP®. The anionic sulfobutyl ether substituent improves the aqueous solubility and safety of the parent β-cyclodextrin, which can reversibly form complexes with active pharmaceutical agents, thereby increasing the solubility of active pharmaceutical agents and, in some cases, increase the stability of active pharmaceutical agents in aqueous solution. CAPTISOL® has a chemical structure according to Formula X:

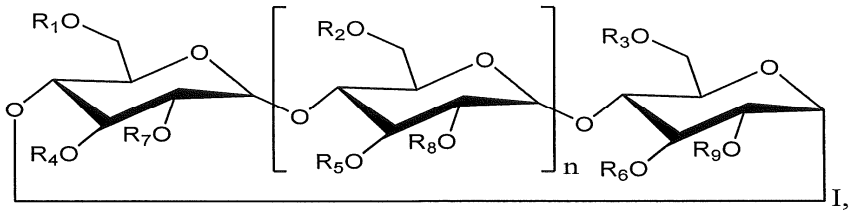


X,

where R is $(-H)_{21-n}$ or $((-CH_2)_4\text{-}SO_3^-Na^+)_n$, and n is 6 to 7.1.

[0006] Sulfoalkyl ether derivatized cyclodextrins (such as CAPTISOL®) are prepared using batch methods as described in, e.g., U. S. Patent Nos. 5,134,127, 5,376,645 and 6,153,746, each of which is hereby incorporated by reference in its entirety.

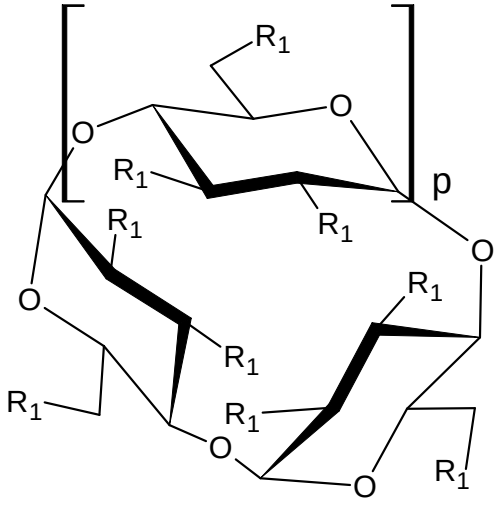
[0007] Sulfoalkyl ether cyclodextrins and other derivatized cyclodextrins can also be prepared according to the methods described in the following patents and published patent applications: US 3,426,011, US 3,453,257, US 3,453,259, US 3,459,731, US 4,638,058, US 4,727,06, US 5,019,562, US 5,173,481, US 5,183,809, US 5,241,059, US 5,536,826, US 5,594,125, US 5,658,894, US 5,710,268, US 5,756,484, US 5,760,015, US 5,846,954, US 6,407,079, US 7,625,878, US 7,629,331, US 7,635,773, US2009/0012042, JP 05001102, and WO 01/40316, as well as in the following non-patent publications: Lammers *et al.*, *Recl. Trav. Chim. Pays-Bas 91*:733 (1972); *Staerke 23*:167 (1971), Adam *et al.*, *J. Med. Chem. 45*:1806 (2002), Qu *et al.*, *J. Inclusion Phenom. Macrocyclic Chem. 43*:213 (2002), Tarver *et al.*, *Bioorg. Med. Chem. 10*:1819 (2002), Fromming *et al.*, *Cyclodextrins in Pharmacy* (Kluwer Academic Publishing, Dordrecht, 1994), *Modified Cyclodextrins: Scaffolds and Templates for Supramolecular Chemistry* (C.J. Easton *et al.* eds., Imperial College Press, London, UK, 1999), *New*



I,

wherein: n is 4, 5 or 6; wherein R_1, R_2, R_3, R_4, R_5, R_6, R_7, R_8 and R_9 are independently -H, a straight-chain or branched C_1-C_8-(alkylene)-SO_3^- group, or an optionally substituted straight-chain or branched C_1-C_6 group; wherein at least one of R_1, R_2, R_3, R_4, R_5, R_6, R_7, R_8 and R_9 is a straight-chain or branched C_1-C_8-(alkylene)-SO_3^- group.

[0059] In some embodiments, a SAE-CD composition comprises a water-soluble alkylated cyclodextrin of Formula II:



II,

wherein: p is 4, 5 or 6;

R_1 is independently selected at each occurrence from -OH or -SAE-T;

-SAE- is a -O-(C_2-C_6 alkylene)-SO_3^- group, wherein at least one SAE is independently a -O-(C_2-C_6 alkylene)-SO_3^- group, a -O-$(CH_2)_gSO_3^-$ group, wherein g is 2 to 6, or 2 to 4, (e.g.-$OCH_2CH_2CH_2SO_3^-$ or -$OCH_2CH_2CH_2CH_2SO_3^-$); and -T is independently selected at each occurrence from the group consisting of pharmaceutically acceptable cations, which group includes, for example, H^+, alkali metals (e.g., Li^+, Na^+, K^+), alkaline earth metals (e.g., Ca^{+2}, Mg^{+2}), ammonium ions and amine cations such as the cations of (C_1-C_6)-alkylamines, piperidine, pyrazine, (C_1-C_6)-alkanolamine, ethylenediamine and (C_4-C_8)-cycloalkanolamine among others; provided that at least one R_1 is a hydroxyl moiety and at least one R_1 is -SAE-T.

[0060] When at least one R_1 of a derivatized cyclodextrin molecule is -SAE-T, the degree of substitution, in terms of the -SAE-T moiety, is understood to be at least one (1). When

the term -SAE- is used to denote a sulfoalkyl-(alkylsulfonic acid)-ether moiety it being understood that the -SAE- moiety comprises a cation (-T) unless otherwise specified. Accordingly, the terms "SAE" and "-SAE-T" can, as appropriate, be used interchangeably herein.

[0061] Since SAE-CD is a poly-anionic cyclodextrin, it can be provided in different salt forms. Suitable counterions include cationic organic atoms or molecules and cationic inorganic atoms or molecules. The SAE-CD can include a single type of counterion or a mixture of different counterions. The properties of the SAE-CD can be modified by changing the identity of the counterion present. For example, a first salt form of a SAE-CD composition can possess greater osmotic potential or greater water activity reducing power than a different second salt form of same SAE-CD.

[0062] In some embodiments, a sulfoalkyl ether cyclodextrin is complexed with one or more pharmaceutically acceptable cations selected from, e.g., H^+, alkali metals (e.g., Li^+, Na^+, K^+), alkaline earth metals (e.g., Ca^{+2}, Mg^{+2}), ammonium ions and amine cations such as the cations of (C_1-C_6)-alkylamines, piperidine, pyrazine, (C_1-C_6)-alkanolamine, ethylenediamine and (C_4-C_8)-cycloalkanolamine, and the like, and combinations thereof.

[0063] Further exemplary sulfoalkyl ether (SAE)-CD derivatives include:

Table 2.

SAE_x-α-CD	**SAE_x-β-CD**	**SAE_x-γ-CD**
(Sulfoethyl ether)$_x$-α-CD	(Sulfoethyl ether)$_x$-β-CD	(Sulfoethyl ether)$_x$-γ-CD
(Sulfopropyl ether)$_x$-α-CD	(Sulfopropyl ether)$_x$-β-CD	(Sulfopropyl ether)$_x$-γ-CD
(Sulfobutyl ether)$_x$-α-CD	(Sulfobutyl ether)$_x$-β-CD	(Sulfobutyl ether)$_x$-γ-CD
(Sulfopentyl ether)$_x$-α-CD	(Sulfopentyl ether)$_x$-β-CD	(Sulfopentyl ether)$_x$-γ-CD
(Sulfohexyl ether)$_x$-α-CD	(Sulfohexyl ether)$_x$-β-CD	(Sulfohexyl ether)$_x$-γ-CD

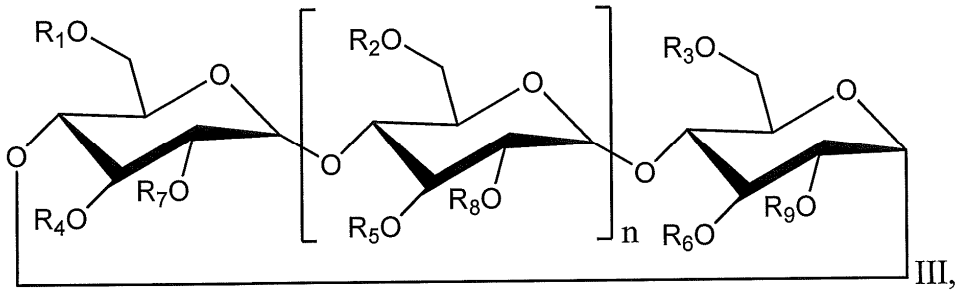
wherein x denotes the average degree of substitution. In some embodiments, the alkylated cyclodextrins are formed as salts.

[0064] Various embodiments of a sulfoalkyl ether cyclodextrin include eicosa-O-(methyl)-6G-O-(4-sulfobutyl)-β-cyclodextrin, heptakis-O-(sulfomethyl)-tetradecakis-O-(3-sulfopropyl)-β-cyclodextrin, heptakis-O-[(1,1-dimethylethyl)dimethylsilyl]-tetradecakis-O-(3-sulfopropyl)-β-cyclodextrin, heptakis-O-(sulfomethyl)-tetradecakis-O-(3-sulfopropyl)-β-cyclodextrin, and heptakis-O-[(1,1-dimethylethyl)dimethylsilyl]-tetradecakis-O-(sulfomethyl)-β-cyclodextrin. Other known alkylated cyclodextrins containing a sulfoalkyl moiety include sulfoalkylthio and sulfoalkylthioalkyl ether derivatives such as octakis-(S-sulfopropyl)-octathio-γ-cyclodextrin, octakis-O-[3-[(2-

sulfoethyl)thio]propyl]-β-cyclodextrin], and octakis-S-(2-sulfoethyl)-octathio-γ-cyclodextrin.

[0065] In some embodiments, an alkylated cyclodextrin composition of the present invention is a sulfoalkyl ether-β-cyclodextrin composition having an ADS of 2 to 9, 4 to 8, 4 to 7.5, 4 to 7, 4 to 6.5, 4.5 to 8, 4.5 to 7.5, 4.5 to 7, 5 to 8, 5 to 7.5, 5 to 7, 5.5 to 8, 5.5 to 7.5, 5.5 to 7, 5.5 to 6.5, 6 to 8, 6 to 7.5, 6 to 7.1, 6.5 to 7.1, 6.2 to 6.9, or 6.5 per alkylated cyclodextrin, and the remaining substituents are -H.

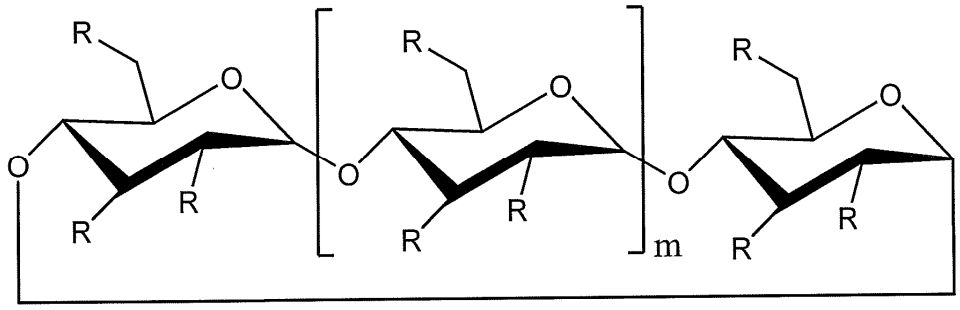
[0066] In some embodiments, the alkylated cyclodextrin is a compound of Formula III:



III,

wherein n is 4, 5 or 6, wherein R_1, R_2, R_3, R_4, R_5, R_6, R_7, R_8 and R_9 are independently selected from: -H, a straight-chain or branched C_1-C_8-(alkylene)-SO_3^- group, and an optionally substituted straight-chain or branched C_1-C_6 group.

[0067] A water soluble alkylated cyclodextrin composition can comprise an alkyl ether (AE)-cyclodextrin compound, or mixture of compounds, of the Formula IV:



IV,

wherein: m is 4, 5 or 6; R is independently selected at each occurrence from the group consisting of -OH and AE; and AE is -O-(C_1-C_6 alkyl); provided that at least one R is -OH; and at least one AE is present.

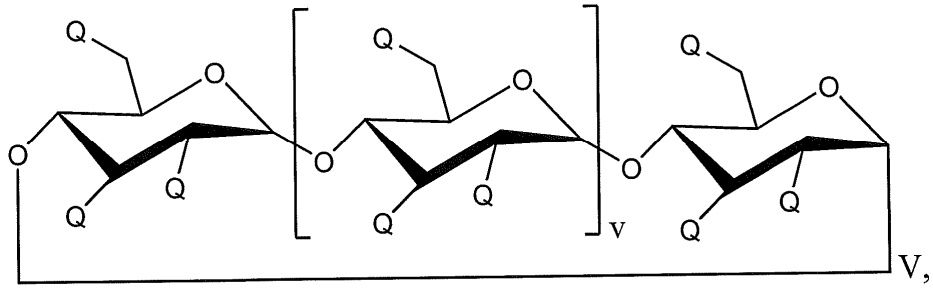
[0068] Further exemplary AE-CD derivatives include:

Table 3.

(Alkylether)$_y$-α-CD	(Alkylether)$_y$-β-CD	(Alkylether)$_y$-γ-CD
ME$_y$-α-CD	ME$_y$-β-CD	ME$_y$-γ-CD
EE$_y$-α-CD	EE$_y$-β-CD	EE$_y$-γ-CD
PE$_y$-α-CD	PE$_y$-β-CD	PE$_y$-γ-CD
BE$_y$-α-CD	BE$_y$-β-CD	BE$_y$-γ-CD
PtE$_y$-α-CD	PtE$_y$-β-CD	PtE$_y$-γ-CD
HE$_y$-α-CD	HE$_y$-β-CD	HE$_y$-γ-CD

wherein ME denotes methyl ether, EE denotes ethyl ether, PE denotes propyl ether, BE denotes butyl ether, PtE denotes pentyl ethyl, HE denotes hexyl ether, and y denotes the average degree of substitution.

[0069] A water soluble alkylated cyclodextrin composition can comprise a HAE-cyclodextrin compound, or mixture of compounds, of the Formula V:



V,

wherein: "v" is 4, 5 or 6; "Q" is independently selected at each occurrence from the group consisting of -OH, and -HAE; and HAE is HO(C_1-C_6 alkyl)-O-, provided that at least one -HAE moiety is present.

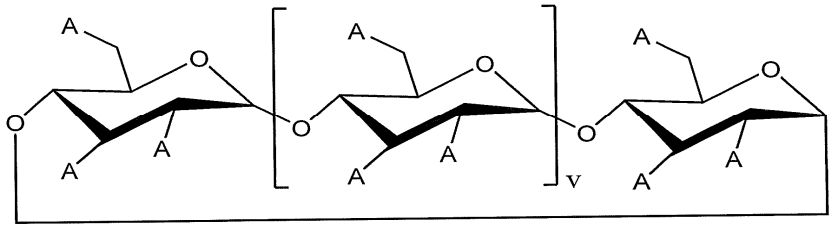
[0070] Further exemplary hydroxyalkyl ether (HAE)-CD derivatives include:

Table 4.

(HAE)$_z$-α-CD	(HAE)$_z$-β-CD	(HAE)$_z$-γ-CD
HMEz-α-CD	HMEz-β-CD	HMEz-γ-CD
HEEz-α-CD	HEEz-β-CD	HEEz-γ-CD
HPEz-α-CD	HPEz-β-CD	HPEz-γ-CD
HBEz-α-CD	HBEz-β-CD	HBEz-γ-CD
HPtEz-α-CD	HPtEz-β-CD	HPtEz-γ-CD
HHEz-α-CD	HHEz-β-CD	HHEz-γ-CD

wherein HME denotes hydroxymethyl ether, HEE denotes hydroxyethyl ether, HPE denotes hydroxypropyl ether, HBE denotes hydroxybutyl ether, HPtE denotes hydroxypentyl ether, HHE denotes hydroxyhexyl ether, and z denotes the average degree of substitution.

[0071] A water soluble alkylated cyclodextrin composition can comprise a SAE-AE-CD compound, or mixture of compounds, of Formula VI:

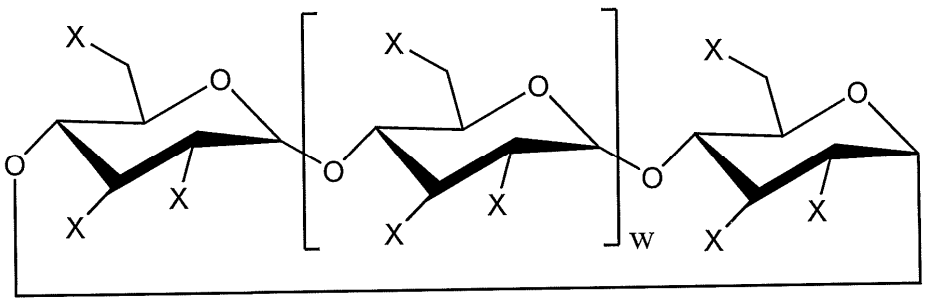


VI,

wherein: "v" is 4, 5 or 6; "A" is independently selected at each occurrence from the group consisting of -OH, -SAET and -AE; x is the degree of substitution for the SAET moiety and is 1 to 3v + 5; y is the degree of substitution for the AE moiety and is 1 to 3v + 5; -SAE is -O-(C_2-C_6 alkylene)-SO_3^-; T is independently at each occurrence a cation; and AE is -O(C_1-C_3 alkyl); provided that at least one -SAET moiety and at least one -AE moiety are present; and the sum of x, y and the total number of -OH groups in an alkylated cyclodextrin is 3v + 6.

[0072] Specific embodiments of the derivatives of the present invention include those wherein: 1) the alkylene moiety of the SAE has the same number of carbons as the alkyl moiety of the AE; 2) the alkylene moiety of the SAE has a different number of carbons than the alkyl moiety of the AE; 3) the alkyl and alkylene moieties are independently selected from the group consisting of a straight chain or branched moiety; 4) the alkyl and alkylene moieties are independently selected from the group consisting of a saturated or unsaturated moiety; 5) the ADS for the SAE group is greater than or approximates the ADS for the AE group; or 6) the ADS for the SAE group is less than the ADS for the AE group.

[0073] A water soluble alkylated cyclodextrin composition can comprise a SAE-HAE-CD compound, or mixture of compounds, of Formula VII:



VII,

wherein: "v" is 4, 5 or 6; "X" is independently selected at each occurrence from the group consisting of -OH, SAET and HAE; x is the degree of substitution for the SAET moiety