

SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO			
RAD:	11-177132- -10	FECHA:	2014-09-24 10:03:21
DEP:	2020 DIRECCION DE NUEVAS CREACIONES	EVE:	378 FASE NACIONAL INCLUIDO CAPITULO I
TRA:	11 PCT-PATENTE DE INVENCION CAPITULOS I Y II	FOLIOS:	10
ACT:	519 PRESENTACION		

DIRECCIÓN DE NUEVAS CREACIONES

2020
Bogotá, D.C.,

Abogado(a)/Señor(a)
JAIME EDUARDO DELGADO VILLEGAS

Asunto: Radicación: 11-177132- -10
 Trámite: 11
 Evento: 378
 Actuación: 519
 Oficio: 12332
 Folios: 10

Patente de Invención	X			Patente de Modelo de Utilidad	
Vía Nacional					
Vía PCT (Fase Nacional)	X	Capítulo I	X	Capítulo II	
No. Solicitud Internacional	US2010/039433				
Fecha de Presentación Internacional	22/06/2010				

Como resultado del Examen de Fondo realizado, con fundamento en el Artículo 45 de la Decisión 486 de la Comisión de la Comunidad Andina, se comunica:

1. Documentos estudiados

Descripción:	Rad. N° 11-177132-00005-0000	24/Octubre/2013
Reivindicaciones:	Rad. N° 11-177132-00005-0000	24/Octubre/2013
Prioridades	US 12/489,362	22/Junio/2009

2. Análisis de la Prioridad

Se acepta la reivindicación de Prioridad porque esta solicitud fue presentada dentro del plazo establecido (Art. 9 D 486) y su contenido técnico corresponde con el de la prioridad reivindicada.

3. Objeto de la invención

De acuerdo con lo establecido en el numeral 1.2.2.2 del Capítulo Primero del Título X de la Circular Única para efectos del examen de patentabilidad, se tendrá en cuenta la tasa pagada por el solicitante al momento de comenzar el examen para las reivindicaciones adicionales; esto es que cuando la solicitud contenga más de diez (10)

reivindicaciones y no se haya pagado la tasa complementaria, sólo se estudiarán las cubiertas por la tasa pagada. Por lo tanto se estudiarán las reivindicaciones 1 a 30.

Título de la solicitud: “Procedimientos de desinfección que comprenden una composición que comprende etilhexilsulfato y un ácido alquilbencensulfónico” (Pág. 2, radicado N° 11-177132-00005-0000).

El problema planteado en esta solicitud consiste en la necesidad de suministrar composiciones y procedimientos útiles para inhibir, inactivar, destruir o eliminar eficazmente diversos patógenos que causan infecciones de transmisión alimentaria.

Para resolver este problema técnico, la solicitud en estudio proporciona un procedimiento para destruir o inhibir un microorganismo o un patógeno que comprende poner el microorganismo o patógeno en contacto con una cantidad eficaz de una composición que comprende sulfato de etilhexilo o una sal del mismo, un ácido alquilbencenosulfónico o una sal del mismo y un vehículo, durante un tiempo eficaz para destruir o inhibir el microorganismo o patógeno. Además, la invención proporciona un procedimiento de lavado de una planta, un procedimiento de lavado de una superficie de equipamiento usado en la industria alimentaria, un procedimiento de limpieza y desinfección de una superficie de preparación de alimentos o una superficie de almacenamiento de alimentos.

El objeto de la presente Solicitud se relaciona con la Clasificación Internacional de Patentes (CIP) A01N 41/10, 59/00, C11D 3/34.

4. Excepción a la patentabilidad (Art 20 D 486 literal (d))

El objeto de la reivindicación 10 que menciona la aplicación tópica de la composición a una superficie de mamífero no se considera patentable, de acuerdo con el Art citado debido a que hace referencia a un método de tratamiento

5. Reivindicaciones relativas a un uso o a un segundo uso (Art 14 y 21 D 486)

La redacción de las reivindicaciones 1 y 15 indican la utilización de composiciones que presentan sulfato de etilhexilo y un ácido alquilbenceno sulfónico, por lo que no son patentables de acuerdo con el Art. 14.

6. De la Solicitud de Patente

Reivindicaciones (Art 30 D 486, Art 22 PCT)

Las reivindicaciones 1, 4, 5, 15, 18, 19, 21 y 30 no son claras porque la expresión “*al menos*” es imprecisa, ya que en este caso el alcance de la protección de las reivindicaciones deja de ser precisa y no permite distinguir la invención del estado de la técnica. Se sugiere sustituirlas por un término preciso o un rango concreto.

Las reivindicaciones 1, 15, 22, 25 y 27 no son claras porque las expresiones “*cantidad eficaz*”, “*tiempo eficaz*”, “*vehículo*”, “*microorganismo*”, “*parte comestible*” y “*líquido fluido*” son generales, por lo cual no permite distinguir la invención del estado de la técnica. Se sugiere sustituirlas por un término preciso o un rango concreto.

Las reivindicaciones 13 y 25 no son claras porque el tiempo eficaz para matar o inhibir el microorganismo es un resultado a alcanzar, lo que no está permitido, no define al producto y/o método porque la invención no queda definida por los resultados a alcanzar, puesto que las reivindicaciones incluirían no sólo la solución propuesta por el solicitante, sino todas las alternativas presentes o futuras que lleguen a ese resultado.

Las reivindicaciones 1, 15 y 28 no son claras porque las expresiones “para destruir o inhibir el microorganismo o el patógeno”, “para aplicación de la formulación como spray” y “para lavar la planta” son características funcionales que no le pueden brindar novedad ni nivel inventivo a las reivindicaciones de las cuales dependes. Se sugiere remplazarlas por las características esenciales estructurales que contribuyen a la obtención de ese efecto.

Las reivindicaciones 1 a 7 y 15 a 21 no son claras porque presentan el mismo objeto de invención es decir el uso de una composición. Se sugiere realizar la aclaración necesaria.

La reivindicación 29 no es clara porque la luz ultravioleta no puede hacer parte de una composición por lo que presenta una falsa dependencia. Se sugiere realizar la aclaración necesaria.

Las reivindicaciones 1 y 15 no son claras porque hace referencia a un método, pero presenta características técnicas de una composición al no presentar etapas características de un método y más bien especifican el uso de una composición, lo cual no es permitido. Al respecto no debe olvidarse que las reivindicaciones de sistema y de procedimiento son diferentes y, por ello, deben redactarse de manera independiente en el pliego reivindicatorio. Sobre las mismas, el Tribunal Andino de Justicia ha dicho lo siguiente:

“El objeto de la invención de producto está constituido por un cuerpo cierto destinado a llenar una necesidad industrial que el estado de la técnica aún no ha satisfecho. En cambio, el objeto de la invención de procedimiento se encuentra conformado por “una serie o sucesión de operaciones que inciden sobre una materia (solida, liquida o gaseosa) que se encamina a la obtención de una cosa o un resultado”.¹

7. Determinación del Estado de la Técnica

El estado de la técnica se determinó con base en la fecha de presentación de la solicitud de prioridad invocada, es decir, el 22 de junio de 2009.

Consultadas las fuentes de información con que se cuenta, se encontraron los siguientes documentos que anticipan el objeto de esta solicitud.

Item	Documento	Título	Fecha de Publicación
D1	US 4124520	“Tetrasodium ethylenediamine tetraacetate, trisodium nitrilotriacetate, sodium 2-ethylhexyl sulfate, glycols”	07/Noviembre/1978
D2	Art 1 ²	“Antimicrobial Treatments for Minimally Processed Cantaloupe Melon”	2001

El documento D1³ divulga un método para destruir bacterias con una composición bactericida (Col.2, líneas 1 a 16).

El documento D2 divulga un método para destruir bacterias con una composición (Pág. 345, Abstract).

¹ Otero Lastres, José Manuel. Ob. Cit. Proceso 129aIPa2007.

² Sapers et al. Journal of food science. Vol. 66 (2). 2001. Págs. 345 a 349.

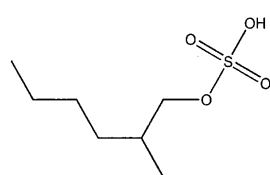
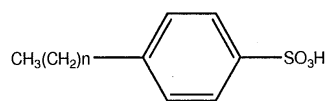
³ <http://www.google.com/patents/US4124520>

8. Examen de Patentabilidad (Art 14 D486)

Nivel inventivo (Art 18 D486)

La reivindicación 1 consiste en “*Un procedimiento para destruir o inhibir un microorganismo o un patógeno...*” (Ver Pág. 137 del Rad. N° 11-177132-00005-0000).

Comparación de las características técnicas **esenciales**, con las del Estado de la Técnica:

Características esenciales	D1	D2
Procedimiento para destruir o inhibir un microorganismo o un patógeno, comprendiendo el procedimiento las etapas de:	Método para destruir microorganismos con una composición antimicrobiana limpiadora (Col.2, líneas 1 a 16).	Método para destruir microorganismos del melón con composiciones que presentan surfactantes (Pág. 345, Abstract).
Poner en contacto el microorganismo o patógeno con una cantidad eficaz de una composición que comprende:	Se pone en contacto la composición con la superficie (Col. 2, líneas 1 a 3).	Se pone en contacto la composición con la superficie de melón tajado (Pág. 346, Col. 1, Párr. 2).
a) Sulfato de etilhexilo de fórmula 	Se tiene sulfato de 2-etilhexilo en la composición desinfectante (Col. 4, líneas 13 a 19).	Se tiene sulfato de 2-etilhexilo en una de las composiciones desinfectantes (Pág. 347, Tabla 2).
O una sal del mismo; y b) Un ácido alquilbenceno sulfónico de fórmula 	Se tiene también ácido dodecil benceno sulfónico (Col. 2, líneas 23 y 24).	Se tiene también ácido dodecil benceno sulfónico en otras composiciones haciendo parte de las formulaciones APL KLEEN y AFKO 4344 (Pág. 348, tablas 5 y 6).
O una sal del mismo, en el que n es de 5 a 20; y		
c) Un vehículo	La solución es acuosa por lo que el agua es el vehículo (Col. 4, líneas 13 a 19).	La solución es acuosa por lo que el agua es el vehículo (Pág. 347, Tabla 2).
En el que el sulfato de etilhexilo, o sal del mismo, y el ácido alquilbencenosulfónico, o sal del mismo, están presentes en una relación	Se presenta entre un 0.4 a 4% de sulfato de 2-etilhexilo y entre 0.1 a 0.5% de ácido dodecil benceno sulfónico (Col. 3, líneas 45 a 52, Col. 4, líneas 12 a 10).	No se menciona
en peso de al menos 1:2; basándose en una base en peso, la proporción de sulfato de etilhexilo, o sal del mismo	No se menciona	La relación de agentes que presentan actividad antimicrobiana en una composición es obtenida

es de al menos la mitad de la del ácido alquibencenosulfónico, o sal del mismo, donde la composición no comprende dióxido de cloro.		mediante optimización (Pág. 346 a Pág. 348, Tablas 2 a 6).
Durante un periodo de tiempo eficaz para destruir o inhibir el microorganismo o el patógeno	Se permite la acción por un tiempo de la composición antimicrobiana limpiadora (Col.2, líneas 1 a 16).	Se evalúa el tratamiento con la composición por lavado (Pág. 346, Col.2, Párr. 4).

Los documentos D1 y D2 se consideran el estado de la técnica más cercano a la invención definida en la reivindicación 1, porque divulgan procedimiento de aplicación de composiciones para la reducción de microorganismos.

La diferencia entre la invención, definida en la reivindicación 1 y el procedimiento del documento D1 consiste en que D1 no menciona una relación entre el sulfato de etilhexilo y el ácido alquilenbenceno sulfónico de $\frac{1}{2}$.

La diferencia entre la invención, definida en la reivindicación 1 y el procedimiento del documento D2 consiste en que en D2 no se menciona en una misma composición el sulfato de etilhexilo y el ácido alquilenbenceno sulfónico.

No se evidencia algún efecto técnico que logre la diferencia en la actividad antimicrobiana de la composición al tener una relación entre el sulfato de etilhexilo y el ácido alquilenbenceno sulfónico de $\frac{1}{2}$ porque la solución de la presente solicitud ya está divulgada en el documento D1 que menciona un método para destruir microorganismos con una composición antimicrobiana limpiadora.

Por lo tanto, el Problema Técnico Objetivo que pretende resolver esta invención se puede formular así “¿cómo proporcionar una composición alternativa a la revelada en el documento D1 para producir la eliminación de microorganismos?”.

Sin embargo, el empleo del sulfato de etilhexilo y el ácido alquilenbenceno sulfónico por separado para la desinfección y/o en conjunto con otros agentes antimicrobianos, ya está divulgado en el documento D2 que se refiere a composiciones para eliminar microorganismos (Pág. 346 a Pág. 348, Tablas 2 a 6, Pág. 347, Tabla 2, Pág. 348, tablas 5 y 6).

En consecuencia, una persona normalmente versada en la materia emplearía el sulfato de etilhexilo y el ácido alquilenbenceno sulfónico de las composiciones de D2 para la obtención de una composición alternativa en el proceso de la anterioridad D1, esperando con certeza lograr el procedimiento, como el de la reivindicación 1 de la solicitud, lo cual es considerado obvio y, por lo tanto, sin altura inventiva.

Asimismo, el documento D1 divulga las características de las reivindicaciones dependientes así:

Reivindicación 2: se tiene un porcentaje en peso de ácido dodecilbenceno sulfónico entre 0.1 y 0.3% y de 2-etilhexil sulfato entre 0.4 y 4% (Col. 3, reivindicación 1 y Col. 4, reivindicación 4).

Reivindicación 3: En el ácido dodecilbenceno sulfónico el grupo alquilo es de 12 carbonos, en donde n es 11 (Col. 4, reivindicación 4).

Reivindicaciones 4 y 5: se adiciona hidróxido de sodio para ajustar el pH, en donde la cantidad en sodio empleada depende del pH deseado, y en el caso de no necesitarse el hidróxido la relación hidróxido a sulfato de etilhexilo es cero (Col. 1, líneas 45 a 56).

Reivindicación 6: el vehículo es agua (Col. 4, líneas 13 a 19).

Reivindicación 7: se tiene una composición con al menos cantidades de sulfato de 2-etilhexilo, dodecilbenceno sulfonato de sodio e hidróxido de sodio en agua (Col. 2 y Col. 3, ejemplos del 1, 2, 4 y 5).

Reivindicación 14: el ambiente a controlar presenta riesgo de infección pues la composición es adecuada para su uso en sanitarios, duchas entre otros (Col. 1, líneas 19 a 25).

Reivindicación 26: En el ácido dodecilbenceno sulfónico el grupo alquilo es de 12 carbonos, en donde n es 11 (Col. 4, reivindicación 4).

Reivindicación 27: la formulación es líquida (Col. 2 y Col. 3, ejemplos del 1, 2, 4 y 5).

Reivindicación 28: la formulación se aplica en spray (Col. 2, líneas 1 a 3).

Reivindicación 30: se tiene un porcentaje en peso de ácido dodecilbenceno sulfónico entre 0.1 y 0.3% y de 2-etilhexil sulfato entre 0.4 y 4% (Col. 3, reivindicación 1 y Col. 4, reivindicación 4).

Asimismo, el documento D2 divulga las características de las reivindicaciones dependientes así:

Reivindicación 3: En el ácido dodecilbenceno sulfónico el grupo alquilo es de 12 carbonos, en donde n es 11 (Pág. 346, Col. 1, Párr. 1).

Reivindicación 6: el vehículo es agua (Pág. 346, Col. 1, Párr. 1).

Reivindicaciones 11 y 12: se presentan bacterias a tratar como *E. coli* y *Listeria monocytogenes* (Pág. 347, Col. 1, Párr. 2 y Pág. 348, Col. 2, Párr. 2).

Reivindicación 29: se emplean peróxidos en la composición desinfectante (Pág. 347, Tabla 3).

Por otra parte las reivindicaciones 8 a 10 y 14 son afectadas con el conocimiento del técnico, “*el experto medio deberá poseer experiencia y contar con un saber general en la materia y con una serie de conocimientos en el campo específico de la invención*”⁴, el cual conoce que las plantas presentan enfermedades de origen bacteriano y fúngicas sobre las cuales se aplican composiciones antimicrobiana en estudios *in vitro* o *in vivo*⁵.

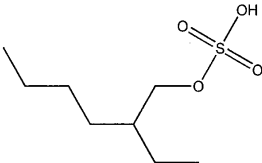
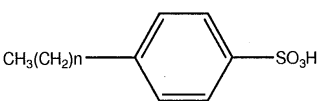
La reivindicación 13 no presenta características técnicas tangibles que puedan proporcionar nivel inventivo a las reivindicaciones de la cual depende pues está expresada como resultados a alcanzar.

La reivindicación 15 consiste en “*Un procedimiento de lavado de una planta...*” (Ver Págs. 138 y 139 del Rad. N° 11-177132-00005-0000).

⁴Proceso 43-IP-2002, publicado en la G.O.A.C. N° 870, de 9 de diciembre de 2002, caso: formulaciones de péptidos hidrosolubles de liberación retardada.

⁵Makovitzki et al. Inhibition of Fungal and Bacterial Plant Pathogens In Vitro and In Planta with Ultrashort Cationic Lipopeptides. Applied and environmental microbiology. 2007. Vol. 73 (20). Abstract.

Comparación de las características técnicas **esenciales**, con las del Estado de la Técnica:

Características esenciales	D1	D2
Procedimiento de lavado de una planta, comprendiendo el procedimiento las etapas de:	Método para destruir microorganismos con una composición antimicrobiana limpiadora (Col.2, líneas 1 a 16).	Método para destruir microorganismos del melón con composiciones que presentan surfactantes (Pág. 345, Abstract).
Poner en contacto la planta con una cantidad eficaz de una composición que comprende:	No se menciona	Se pone en contacto la composición con la superficie de melón tajado* (Pág. 346, Col. 1, Párr. 2).
a) Sulfato de etilhexilo de fórmula 	Se tiene sulfato de 2-etilhexilo en la composición desinfectante (Col. 4, líneas 13 a 19).	Se tiene sulfato de 2-etilhexilo en una de las composiciones desinfectantes (Pág. 347, Tabla 2).
O una sal del mismo; y b) Un ácido alquilbenceno sulfónico de fórmula 	Se tiene también ácido dodecil benceno sulfónico (Col. 2, líneas 23 y 24).	Se tiene también ácido dodecil benceno sulfónico en otras composiciones haciendo parte de las formulaciones APL KLEEN y AFCO 4344 (Pág. 348, tablas 5 y 6).
O una sal del mismo, en el que n es de 5 a 20; y		
c) Un vehículo	La solución es acuosa por lo que el agua es el vehículo (Col. 4, líneas 13 a 19).	La solución es acuosa por lo que el agua es el vehículo (Pág. 347, Tabla 2).
En el que el sulfato de etilhexilo, o sal del mismo, y el ácido alquilbencenosulfónico, o sal del mismo, están presentes en una relación	Se presenta entre un 0.4 a 4% de sulfato de 2-etilhexilo y entre 0.1 a 0.5% de ácido dodecil benceno sulfónico (Col. 3, líneas 45 a 52, Col. 4, líneas 12 a 10).	No se menciona
en peso de al menos 1:2; basándose en una base en peso, la proporción de sulfato de etilhexilo, o sal del mismo es de al menos la mitad de la del ácido alquilbencenosulfónico, o sal del mismo, donde la composición no comprende dióxido de cloro.	No se menciona	La relación de agentes que presentan actividad antimicrobiana en una composición es obtenida mediante optimización (Pág. 346 a Pág. 348, Tablas 2 a 6).
Durante un periodo de tiempo eficaz para lavar la planta	No se menciona	Se evalúa el tratamiento con la composición por lavado (Pág. 346, Col.2,

		Párr. 4).
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Los documentos D1 y D2 se consideran el estado de la técnica más cercano a la invención definida en la reivindicación 15, porque divulgan procedimiento de aplicación de composiciones para la reducción de microorganismos.

La diferencia entre la invención, definida en la reivindicación 15 y el procedimiento del documento D1 consiste en que D1 no menciona el lavado de una planta ni una relación entre el sulfato de etilhexilo y el ácido alquilenbenceno sulfónico de 1/2.

La diferencia entre la invención, definida en la reivindicación 15 y el procedimiento del documento D2 consiste en que en D2 no se menciona en una misma composición el sulfato de etilhexilo y el ácido alquilenbenceno sulfónico.

El efecto que logra el incluir en el método de lavado de una planta con la composición de sulfato de etilhexilo y ácido alquilenbenceno sulfónico es que permite matar y/o inhibir bacterias y/o hongos presentes en la planta de forma más eficiente.

Por lo tanto, el problema técnico objetivo que pretende resolver esta invención se puede formular así “¿cómo modificar el método de D2 para que se lleve a cabo la desinfección de una planta contra bacterias y/o hongos de forma más eficiente?”.

Sin embargo, el empleo del sulfato de etilhexilo y el ácido alquilenbenceno sulfónico en la misma composición para la desinfección con otros agentes antimicrobianos, ya está divulgado en el documento D1 que se refiere a composiciones para eliminar microorganismos en superficies duras (Col. 3, líneas 45 a 52, Col. 4, líneas 12 a 10).

En consecuencia, una persona normalmente versada en la materia emplearía el sulfato de etilhexilo y el ácido alquilenbenceno sulfónico de las composiciones de D1 para la obtención de una composición en el proceso de la anterioridad D2, esperando con certeza lograr el procedimiento, como el de la reivindicación 15 de la solicitud, lo cual es considerado obvio y, por lo tanto, sin altura inventiva.

*Adicionalmente la reivindicación 15 es afectada con el conocimiento del técnico, “*el experto medio deberá poseer experiencia y contar con un saber general en la materia y con una serie de conocimientos en el campo específico de la invención*”⁴, el cual conoce que las plantas presentan enfermedades de origen bacteriano y fúngicas sobre las cuales se aplican composiciones antimicrobiana en estudios *in vitro* o *in vivo*⁵ a plantas.

Asimismo, el documento D1 divulga las características de las reivindicaciones dependientes así:

Reivindicación 16: se tiene un porcentaje en peso de ácido dodecilbenceno sulfónico entre 0.1 y 0.3% y de 2-etilhexil sulfato entre 0.4 y 4% (Col. 3, reivindicación 1 y Col. 4, reivindicación 4).

Reivindicación 17: En el ácido dodecilbenceno sulfónico el grupo alquilo es de 12 carbonos, en donde n es 11 (Col. 4, reivindicación 4).

Reivindicaciones 18 y 19: se adiciona hidróxido de sodio para ajustar el pH, en donde la cantidad en sodio empleada depende del pH deseado, y en el caso de no necesitarse el hidróxido la relación hidróxido a sulfato de etilhexilo es cero (Col. 1, líneas 45 a 56).

Reivindicación 20: el vehículo es agua (Col. 4, líneas 13 a 19).

Reivindicación 21: se tiene una composición con al menos cantidades de sulfato de 2-etilhexilo, dodecilbenceno sulfonato de sodio e hidróxido de sodio en agua (Col. 2 y Col. 3, ejemplos del 1, 2, 4 y 5).

Asimismo, el documento D2 divulga las características de las reivindicaciones dependientes así:

Reivindicación 22: se realiza el tratamiento a un melón (Pág. 346, Col. 1, Párr. 2).

Por otra parte, las reivindicaciones 23 y 24 son afectadas con el conocimiento del técnico, *“el experto medio deberá poseer experiencia y contar con un saber general en la materia y con una serie de conocimientos en el campo específico de la invención”*⁴, el cual conoce que el tratamiento a plantas con composiciones que presenten surfactantes como el etilhexilo sulfato y ácido dodecil benceno sulfónico se realiza pre o post cosecha⁶.

La reivindicación 25 no presenta características técnicas tangibles que puedan proporcionar nivel inventivo a las reivindicaciones de la cual depende pues está expresada como resultados a alcanzar.

9. Conclusión

Los requisitos de Patentabilidad de la presente Solicitud están afectados así:

Item	Documento	Reivindicaciones afectadas	Requisito que afecta
D1	Art 1	1 a 30	Nivel inventivo
D2	US 4124520	1 a 30	Nivel inventivo

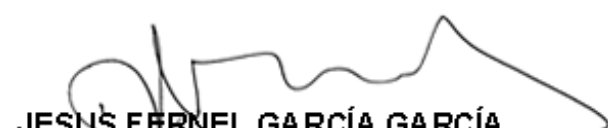
⁶Federal Register /Vol. 69, No. 82 /Wednesday, April 28, 2004 /Rules and Regulations. Pág. 6, Col. 3, Párr. 4 y Págs. 6 a 31. 7 Tabla.

En cumplimiento del artículo 45 de la Decisión 486 de la Comisión de la Comunidad Andina, se le indica que debe dar respuesta dentro del término de sesenta (60) días contados a partir del día siguiente de la fecha de notificación de la presente comunicación. En caso de no dar respuesta al presente requerimiento, o si a pesar de la respuesta subsistieran los impedimentos para la concesión, se denegará la patente.

Se invita al solicitante se sirva indicar, si así lo considera, su renuncia al término faltante de sesenta (60) días para dar respuesta a este requerimiento y presentarla por escrito.

Finalmente, se le recuerda al solicitante que si como respuesta a este requerimiento llegara a modificar el capítulo reivindicatorio y éste contenga más de diez (10) reivindicaciones, no pagará la tasa de modificación voluntaria pero sí la correspondiente al pago por reivindicación adicional.

Notifíquese el presente oficio conforme a lo dispuesto en el numeral 5.2, literal e), del capítulo quinto del título primero de la Circular Única No. 10 de 2001.



JESÚS FERNEL GARCÍA GARCÍA
Director de Nuevas Creaciones (E)

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Inhibition of Fungal and Bacterial Plant Pathogens In Vitro and In Planta with Ultrashort Cationic Lipopeptides[∇]

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Plant diseases constitute an emerging threat to global food security. Many of the currently available antimicrobial agents for agriculture are highly toxic and nonbiodegradable and cause extended environmental pollution. Moreover, an increasing number of phytopathogens develop resistance to them. Recently, we have reported on a new family of ultrashort antimicrobial lipopeptides which are composed of only four amino acids linked to fatty acids (A. Makovitzki, D. Avrahami, and Y. Shai, *Proc. Natl. Acad. Sci. USA* 103:15997–16002, 2006). Here, we investigated the activities in vitro and in planta and the modes of action of these short lipopeptides against plant-pathogenic bacteria and fungi. They act rapidly, at low micromolar concentrations, on the membranes of the microorganisms via a lytic mechanism. In vitro microscopic analysis revealed wide-scale damage to the microorganism's membrane, in addition to inhibition of pathogen growth. In planta potent antifungal activity was demonstrated on cucumber fruits and leaves infected with the pathogen *Botrytis cinerea* as well as on corn leaves infected with *Cochliobolus heterostrophus*. Similarly, treatment with the lipopeptides of *Arabidopsis* leaves infected with the bacterial leaf pathogen *Pseudomonas syringae* efficiently and rapidly reduced the number of bacteria. Importantly, in contrast to what occurred with many native lipopeptides, no toxicity was observed on the plant tissues. These data suggest that the ultrashort lipopeptides could serve as native-like antimicrobial agents economically feasible for use in plant protection.

Plants are constantly exposed and threatened by a variety of pathogenic microorganisms present in their environments. Diseases caused by pathogens, including bacteria, fungi, and viruses, significantly contribute to the overall loss in crop yield worldwide (31, 44, 51). In an effort to combat diseases, plants have devised various mechanisms and compounds to fend off microbial invaders. One of the most ancient and widespread defense strategies involves the production of cysteine-rich antimicrobial peptides (AMPs) composed of 45 to 54 amino acids (13, 14, 20, 37, 57). AMPs have been shown to be produced by a wide range of organisms and serve as their natural defense against infection (60, 61). Moreover, plant AMPs show structural and functional homology to their counterparts in animals, insects, and mammalian AMPs (8), whose involvement in host defense is well established (23, 46, 61). Many plant AMPs can rapidly inhibit the growth of a broad range of fungi and bacteria at micromolar concentrations, being nontoxic to both mammalian and plant cells (10, 39). Plant AMPs include α -defensins, lipid transfer proteins, thionins, hevein, and knottins (7, 10, 49). They are expressed either in a constitutive and organ-specific manner, in which they are most abundant in peripheral cell layers of the organ, or in a pathogen-modulated manner, possibly associated with altered tissue specificity (7, 45, 53). The locations of AMPs at the peripheries of different organs, their induction under pathogenic stress conditions, and their in vitro and in planta antimicrobial activities support the

notion that plant AMPs are important components of the plant's defense system (8).

Despite the existence of defense mechanisms, plants are exposed to attack by fungi and bacteria. Fungi attack leaves, stems, fruits, and flowers before and after harvest. Some of the most common plant-pathogenic fungi belong to the genera *Alternaria*, *Botrytis*, *Cochliobolus*, *Fusarium*, *Geotrichum*, *Penicillium*, and *Sclerotinia* (6). These fungi cause considerable loss of crop yields worldwide. Moreover, many potentially human-pathogenic fungi and the yeast *Saccharomyces cerevisiae* have their natural habitats in the environment, including on plants and food items (55). In support of that, human-pathogenic fungi have been isolated from spoiling fruits. In addition, some fungi, such as *Fusarium* spp. and *Alternaria* spp., produce mycotoxins that can seriously harm consumers of fruit (50).

Plant fungicides based on synthetic chemicals are extensively used in agriculture. In fact, there are now more than 113 active ingredients registered as fungicides worldwide (26). However, they cause severe and long-term environmental pollution, are highly and acutely toxic, and are sometimes even carcinogenic toward humans and wild animals (12). Furthermore, pathogens become resistant to many of these chemicals (12, 43). Note also that some of the antimycotic compounds, such as members of the azole family, which are widely applied for plant protection, have derivatives that either are used medically or are under clinical evaluation (59). Therefore, it is anticipated that their extensive use in agriculture will increase the risk of selection of resistance phenotypes of human-pathogenic fungi from the surrounding environment or directly from the fungal flora of the human consumer during prolonged exposure to the compounds that are used both in agriculture and in medicine (5).

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In addition to fungi, pathogenic bacteria are also responsible for great losses in crops (54). Yet, a major difficulty encountered is the lack of effective control against some severe diseases. Plant protection against these pathogens is mainly based on copper derivatives and antibiotics, which are environmental contaminants. Furthermore, resistant strains of bacteria have already been reported (19). A very destructive pathogen is the gram-negative bacterium *Pseudomonas syringae*, which grows in the intercellular spaces of plant tissues (36).

Consequently, there is an obvious need to search for alternative compounds that are nontoxic to animals and nonpolluting environmentally to control fungal and bacterial plant diseases for agricultural applications, especially compounds with activity against phytopathogenic fungi and bacteria that acquire resistance to commercial compounds.

Membrane-active compounds are under investigation as a promising group. Their membranolytic mechanism makes it difficult for the microorganisms to develop resistance (23, 47, 52, 61). These compounds include peptides and their synthetic derivatives mimicking gene-encoded AMPs from various species as well as lipopeptides, cyclopeptides, and cyclic lipopeptides (CLPs) which are produced via nonribosomal synthesis by various microorganisms (3, 31–35, 40–42). In most cases, the use of synthetic peptides is limited due to high-cost production (11, 19). Therefore, CLPs have received considerable attention for their broad antimicrobial properties against plant pathogens. They are produced by several plant-associated and soil-inhabiting bacteria, such as *Pseudomonas* and *Bacillus* spp. (3, 34, 35). Note that some CLPs and lipopeptides from microbial origins, such as syringomycin and syringopeptin, have significant phytotoxicities that limit their direct use as plant protection products (31). However, several others, such as surfactin and fengycin, have no phytotoxicity (38).

Recently, we have reported on a new family of ultrashort lipopeptides with a potent and broad spectrum of in vitro antimicrobial activity against human-pathogenic yeast, fungi, and bacteria. These lipopeptides are composed of only four L- and D-amino acids linked to fatty acids. The sequence of the peptidic moiety and the length of the fatty acyl group determine the specificities of the lipopeptides against bacteria, fungi, and mammalian cells (28). Here, we found that several ultrashort lipopeptides exert potent antifungal and antibacterial activities toward phytopathogenic fungi and bacteria in vitro and in planta. Their probably low phytotoxicities, drastic lytic modes of action, and natural amino acid compositions make them attractive candidates for future antibiotics in agriculture.

MATERIALS AND METHODS

Materials. Rink amide 4-methylbenzhydrylamine resin and 9-fluorenylmethoxy carbonyl (Fmoc) amino acids were obtained from Calbiochem-Novabiochem AG (Switzerland). Lauric acid (dodecanoic acid) was purchased from Sigma Chemical Co. (Israel). Other reagents used for peptide synthesis included trifluoroacetic acid (Sigma), piperidine (Merck), *N,N*-diisopropylethylamine (Sigma), *N*-methylmorpholine (Fluka), *N*-hydroxybenzotriazole hydrate (Aldrich), 2-(1*H*-benzotriazol-1-yl)-1,1,3,3-tetramethyluronium hexafluorophosphate, and dimethylformamide (peptide synthesis grade; Biolab). All other reagents were of analytical grade. Buffers were prepared in double-distilled water.

Fungal and bacterial strains and culture conditions. *Botrytis cinerea* strain BC03 (vine pathovar from B. Paul, Dijon, France) and *Alternaria alternata* (tobacco pathovar from I. Chet, Israel) were maintained on potato dextrose agar (PDA) at room temperature. *Cochliobolus heterostrophus* strain C4 (ATCC

48331) was maintained on complete medium at room temperature under continuous light (48). *Pseudomonas syringae* pv. tomato strain DC3000 (resistant to rifampin) was maintained on solidified Trypticase soy broth at 28°C. *Agrobacterium tumefaciens* (strain HGLO) was maintained on LB medium at 28°C.

Peptide synthesis, acylation, and purification. Peptides were synthesized by an Fmoc solid-phase method on Rink amide 4-methylbenzhydrylamine resin by using an ABI 433A automatic peptide synthesizer. The lipophilic acid was attached to the N terminus of a resin-bound peptide by standard Fmoc chemistry, followed by peptide cleavage from the resin and purification by reversed-phase high-performance liquid chromatography (RP-HPLC; >98%) as described previously (2). The lipopeptide compositions were confirmed by electrospray mass spectroscopy and amino acid analysis.

In vitro antifungal activity. The antifungal activities of the lipopeptides were examined in sterile 96-well plates (Nunc F96 microtiter plates) in a final volume of 200 μ l as follows. One hundred microliters of a spore suspension containing *B. cinerea*, *A. alternata*, or *C. heterostrophus* at a concentration of 2×10^3 CFU/ml in potato dextrose broth was added to 100 μ l of potato dextrose broth containing the lipopeptides in serial twofold dilutions. The fungi were incubated at 25°C for 48 h using a Binder KB 115 incubator. Growth inhibition was determined by measuring the absorbance at 750 nm with an E1309 microplate autoreader (Biotek Instruments). The antifungal activity is expressed as the MIC, the concentration at which no growth was observed.

To further evaluate the antifungal effect of the lipopeptides, inhibition of hyphal growth was observed under an inverted light microscope (Eclipse TE300; Nikon, Tokyo, Japan) at 48 h posttreatment. Abnormalities in the morphologies of spores and hyphae were observed and photographed with a digital camera (C4742-95; Hamamatsu, Bridgewater, NJ) attached to the photoport of the microscope.

In vitro antibacterial activity. The antibacterial activities of the lipopeptides were examined in sterile 96-well plates (Nunc F96 microtiter plates) in a final volume of 100 μ l as follows. Aliquots (50 μ l) of a suspension containing bacteria at concentrations of 10^6 CFU/ml in culture medium were added to 50 μ l of double-distilled water containing the lipopeptide in serial twofold dilutions in LB. Inhibition of growth was determined by measuring the absorbance at 600 nm with an E1309 microplate autoreader (Biotek Instruments) after an incubation of 48 h at 28°C. The antibacterial activity was expressed as the MIC, the concentration at which no growth was observed after the incubation.

Antifungal assay on detached cucumber leaves infected with *B. cinerea*. Cucumber seedlings (Kfir variety; Gedera Seeds Ltd., Israel) were grown in soil in 250-ml pots in a controlled environment. Leaves were detached from 2- to 3-week-old plants and were placed in closed plastic containers on wet filter paper to maintain high humidity. Detached cucumber leaves were inoculated with 5-mm-diameter mycelial agar discs of *B. cinerea* taken from 7- to 10-day-old cultures on PDA, with the disc ($\sim 2 \times 10^6$ spores) placed in the middle of each leaflet (16). The containers were placed in a climate chamber at 22°C. After 24 h, the discs were removed and 30 μ g/ml of the lipopeptides was applied to the leaves. The lesion development was followed for 4 days after infection and 3 days after treatment. For preventive treatment, the leaves were first sprayed with 30 μ g/ml lipopeptides, and after 24 h, the leaves were inoculated with *B. cinerea* as described above. The lesion development was followed for 3 days after treatment.

Antifungal assay on cucumber fruits infected with *B. cinerea*. Cucumbers were purchased from local supermarkets in Rehovot, Israel. Wet filter paper was placed on the bottoms of closed plastic containers to maintain high humidity. Two or three fruits were placed on the bottom of each plastic container. A small part of the fruit was removed from the central upper part, and a 5-mm-diameter mycelial agar disc of *B. cinerea* ($\sim 2 \times 10^6$ spores) taken from 7- to 10-day-old cultures on PDA was placed in the middle of each fruit. The containers were placed in a climate chamber at 22°C. The mycelial agar discs were removed at 24 h postinoculation, and the fruits were sprayed immediately with 30 μ g/ml of the lipopeptides. The treatment was repeated two more times every 24 h. The inoculum development was followed for 3 days after the last treatment.

Antifungal assay on corn seedlings infected with *C. heterostrophus*. Corn seedlings (sweet corn; Escalibur) were grown in soil in 100-ml pots in a controlled environment for 1 to 2 weeks. Inoculation of *C. heterostrophus* on corn plants was performed by spotting onto the surfaces of corn leaves 20- μ l drops (0.1% Tween in double-distilled water) of spore suspensions (2.5×10^4 spores/ml) taken from 7- to 10-day-old culture on complete medium. Corn seedlings were covered with plastic bags overnight and maintained at room temperature. Then, at 24 h postinoculation, the corn leaves were sprayed with 30 μ g/ml of C14-KLLK. The inoculum development was followed for 3 days after treatment.

TABLE 1. MICs of the lipopeptides against phytopathogenic fungi and bacteria

Peptide designation ^a	MIC (μ M) for:				
	Plant-pathogenic fungi			Plant-pathogenic bacteria	
	<i>Alternaria alternata</i>	<i>Botrytis cinerea</i>	<i>Cochliobolus heterostrophus</i>	<i>Pseudomonas syringae</i>	<i>Agrobacterium tumefaciens</i>
C16-KLLK	25	12.5	6.2	3.1	6.2
C14-KLLK	12.5	3.1	6.2	3.1	3.1
C12-KLLK	12.5	12.5	25	12.5	6.2
C16-KKKK	50	50	25	3.1	12.5
C16-KGGK	50	50	25	3.1	2.3
C16-KA4K	50	50	50	3.1	4.7
C14-KA4K	37.5	50	100	3.1	12.5
C12-KA4K	100	100	>100	50	100
C16-GIGK	100	>100	>100	>100	>100

^a Amino acids in italics are the D-enantiomers.

Antibacterial assay on *Arabidopsis thaliana* plant leaves infected with *P. syringae*. Five-week-old *A. thaliana* ecotype Colombia plants grown under a 10-h photoperiod at 21°C were sprayed with a bacterial suspension of *P. syringae* pv. tomato strain DC3000 diluted with 10 mM MgCl₂ plus 0.02% Silwet L-77 to an optical density at 600 nm corresponding to 0.025 $\times 10^7$ CFU/ml. At 4 h preinoculation or 4 h postinoculation, 30 μ g/ml (100 μ l) of peptide was infiltrated to rosette leaves by using a syringe without needle. To obtain 100% relative humidity, after inoculation the plants were covered with nylon. Two days after inoculation, the plants were assayed for bacterial colonization by grinding the rosette leaves in 10 mM MgCl₂ and plating bacteria on Kings B agar plates (24) with rifampin (100 μ g/ml).

Light microscopy of *B. cinerea*-infected cucumber leaves. Detached cucumber leaves were inoculated with *B. cinerea* as described above. After 24 h, the leaves were sprayed with 50 μ M C14-KLLK. After an additional 24 h, discs (diameters of 10 mm) were cut out, fixed, and discolored in FAA solution (formalin-ethanol-acetic acid; 1:1:1). After being stained with methyl blue solution (lactophenol cotton blue; 0.05%), the leaf discs were observed under a light binocular. Images were obtained using a digital camera attached to a Leica MZ16FA stereomicroscope (DC300F; Leica Microsystems).

Evaluation of cytotoxicity by a peptide infiltration assay. Different concentrations of melittin or C14-KLLK (100 μ l) were infiltrated into the mesophylls of fully expanded tobacco leaves with a syringe without a needle. The appearance of symptoms on the leaves was followed for 48 h after infiltration.

Examination of spores and hyphal damage by transmission electron microscopy. Samples containing *B. cinerea* spores (3.5×10^7 CFU/ml) or *C. heterostrophus* mycelium were incubated with or without the lipopeptides at their MICs for 20 min. The fungi were fixed by incubation with 1% glutaraldehyde in phosphate-buffered saline for 20 min. A drop containing the fungi was deposited onto a carbon-coated grid and negatively stained with 1% uranyl acetate. The grids were examined on a JEOL JEM 100B electron microscope (Japan Electron Optics Laboratory Co., Tokyo, Japan).

Enzymatic degradation. Trypsin (0.05%) was added to a solution of the lipopeptides in phosphate-buffered saline (4 μ M), and the reaction was monitored by using RP-HPLC and electrospray mass spectroscopy. We used a C₁₈ reverse phase Vydac analytical column (250 by 4 mm, 300-Å pore size, 7- μ m particle size). The column was eluted for 40 min using a linear gradient of 40 to 80% acetonitrile in double-distilled water containing 0.05% trifluoroacetic acid (vol/vol) at a flow rate of 0.6 ml/min. Electrospray mass spectroscopy was performed to confirm the compositions and molecular weights of the products.

RESULTS

We have synthesized a series of very short lipopeptides composed of four L- and D-amino acids linked to aliphatic acids with different lengths. The sequence of the peptidic moiety was KXXK (X designates L, A, G, or K). A peptide comprising the four N-terminal amino acids of the AMP magainin served as a negative control. All of the peptides were amidated at their C termini, and one of their amino acids was replaced with a D-enantiomer. Table 1 lists the lipopeptides investigated. In

order to test the stability of the lipopeptides toward enzymatic degradation, they were treated for 2 h with 0.05% trypsin, and the solution was analyzed by using RP-HPLC and mass spectroscopy. The data reveal that the lipopeptides were fully degraded by the enzyme (data not shown).

In vitro antifungal and antibacterial activity. The in vitro antifungal activities of the lipopeptides were assayed against different species of phytopathogenic fungi that are common in plant fungal infections and are known as major causes of disease in agriculture crops. These include *Alternaria alternata*, *Botrytis cinerea*, and *Cochliobolus heterostrophus*. Their MICs are listed in Table 1. The data reveal that only the Leu-containing lipopeptides have potent antifungal activity, with C14-KLLK being the most active lipopeptide. The lipopeptides were also assayed against two different species of plant-pathogenic bacteria known as major sources of plant disease. These include *Pseudomonas syringae* and *Agrobacterium tumefaciens*; their MICs are listed in Table 1. The data reveal that most of the lipopeptides have antibacterial activity.

Spores and hyphal-growth anomalies due to the presence of the lipopeptides. Examination by use of light microscopy (Fig. 1) revealed that C14-KLLK, at its MIC, induced large-scale damage to spores and hyphae of *A. alternata*, *B. cinerea*, and *C. heterostrophus*. The effects of the lipopeptides on spores of *B. cinerea* and *C. heterostrophus* hyphae were also visualized by using transmission electron microscopy (Fig. 2). The fungi were incubated for 20 min with C14-KLLK at concentrations corresponding to the MICs. Significant differences in the morphologies of the treated fungi were observed. More specifically, the cell membrane and the cytoplasm of *C. heterostrophus* hyphae shrank after treatment with C14-KLLK, finally detaching from the rigid cell wall (Fig. 2B). Similarly, C14-KLLK caused a disruption of a large portion of the *B. cinerea* spore membrane and cell wall that led to leakage of intracellular material, which led to shrinkage of the cytoplasm and cell membrane from the rigid cell wall (Fig. 2D).

Inhibition of fungal infection in planta. We infected leaves of corn seedlings with the pathogen *C. heterostrophus* and detached cucumber leaves and fruits with gray mold (*B. cinerea*). The lipopeptides were then applied above the infected leaves and fruits. The results with *B. cinerea* were in agreement with the in vitro assay (Fig. 3, panel 1). The fungal infection expansions were followed for 4 days after infection and 3 days after treatment. Expanded black necrotic lesions were observed in the control (untreated) leaves. In contrast, the lesion expansions were totally inhibited in infected leaves that were treated with 30 μ g/ml C14-KLLK. The same treatment with C16-KLLK was less effective. Similar results were obtained for cucumber leaves that were treated with 30 μ g/ml C14-KLLK 24 h prior to infection with *B. cinerea* conidia (data not shown). We further examined *B. cinerea* hyphal growth in infected leaves untreated or treated with C14-KLLK and stained with methyl blue solution at 24 h posttreatment (Fig. 3, panel 2). The data revealed dramatically reduced growth of hyphae in the treated leaves compared with that in the untreated leaves. Moreover, the hyphae in the treated leaves exhibited very thin and undeveloped structures compared with the hyphae in the untreated leaves. In addition, a few nongerminated spores could be detected in the treated leaves.

The antifungal activity of C14-KLLK (three consecutive

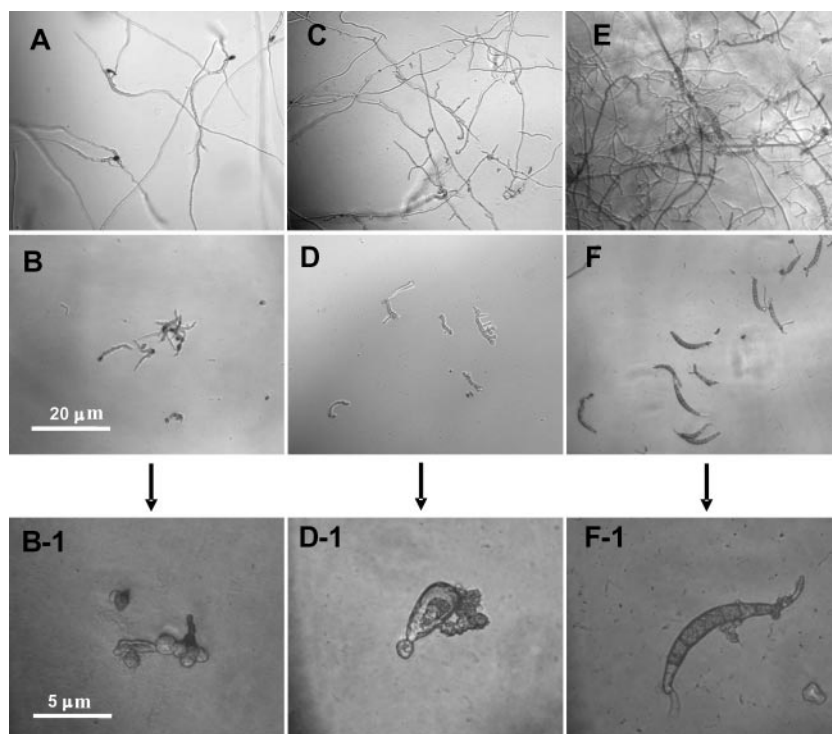


FIG. 1. Microscopic images of fungi 48 h after treatment or without treatment with the lipopeptides. Panel designations are as follows. For *Alternaria alternata*: A, blank; B, with 6 μ M of C14-KLLK. For *Botrytis cinerea*: C, blank; D, with 6 μ M of C14-KLLK. For *Cochliobolus heterostrophus*: E, blank; F, with 6 μ M of C14-KLLK. Panels B-1, D-1, and F-1 are $\times 4$ magnifications of panels B, D, and F, respectively.

treatments) was also tested on cucumber fruits infected with *B. cinerea*. As shown in Fig. 3 (panel 3), the lesion's expansion was fully inhibited. Further examination of slices of the cucumber revealed that the internal part of the untreated cucumber had severe fungal infection, whereas no infection was observed in the internal part of the treated cucumber. A similar in planta antifungal treatment was done on corn seedlings infected with

Cochliobolus heterostrophus (Fig. 3, panel 4), and the lipopeptide prevented the expansion of the necrotic lesions.

Inhibition of *Pseudomonas syringae* growth in vivo by C14-KLLK. The in vivo antibacterial activity of C14-KLLK was investigated in *Arabidopsis* plants that were inoculated by spraying them with the common bacterial phytopathogen *P. syringae*. The *Arabidopsis* leaves were treated by infiltrating the

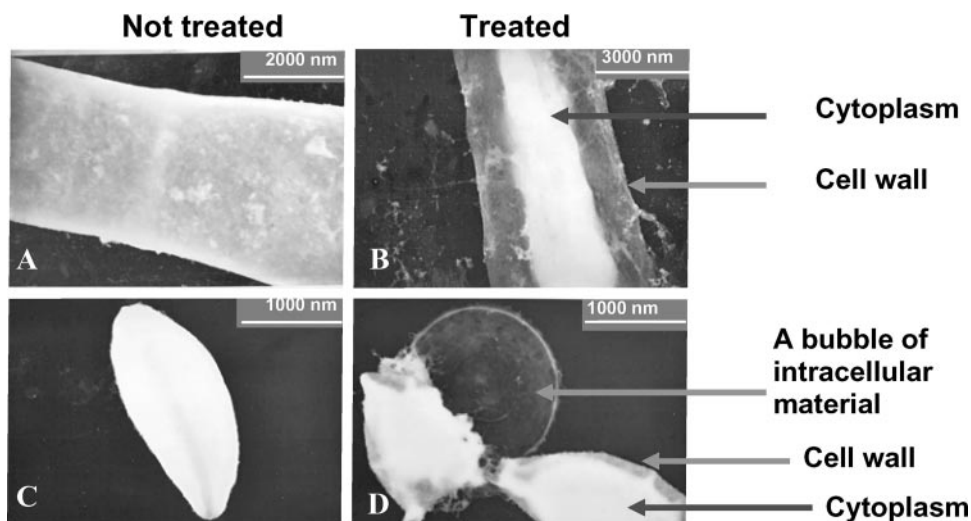


FIG. 2. Electron micrographs of negatively stained *C. heterostrophus* hyphae (A and B) and *B. cinerea* spores (C and D), untreated (A and C) or treated (B and D) with C14-KLLK.

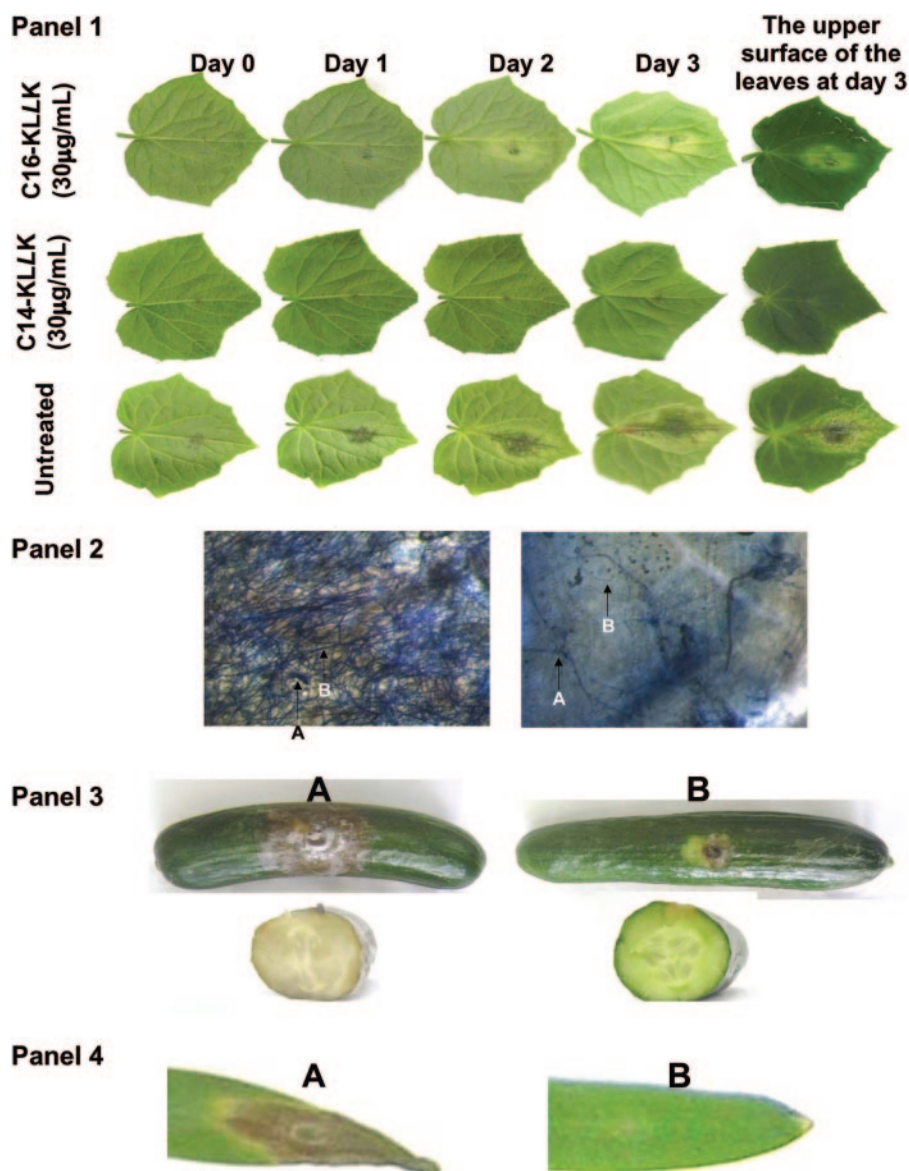


FIG. 3. (Panel 1) Fungicidal activities of the lipopeptides upon artificial infection of gray mold (*Botrytis cinerea*) on cucumber leaves for 4 days after infection and 3 days after treatment. (Panel 2) Effect of C14-KLLK upon *B. cinerea* infection of cucumber leaves stained with methyl blue. Results are shown for untreated leaves (left) and leaves treated with 30 mg/liter C14-KLLK (right). A, spores; B, hyphae. (Panel 3) Cucumber fruits infected with *B. cinerea* conidia 3 days after the last treatment with double-distilled water (A) or 30 mg/liter C14-KLLK (B). (Panel 4) Corn leaves infected with *Cochliobolus heterostrophus*, untreated (A) or treated with 30 mg/liter C14-KLLK (B).

ultrashort lipopeptide into the mesophyll at a concentration of 30 µg/ml 4 h before or 4 h after inoculating the leaves with the bacteria. Both of these treatments with C14-KLLK displaced similar antibacterial activities in vivo, which is manifested by the significant reduction (sixfold) in the number of bacterial cells in the treated leaves compared with the number in the untreated leaves (Fig. 4).

Toxicity of C14-KLLK against plant tissues. The toxicity of C14-KLLK against plant tissues was assessed by infiltrating 120 µg/ml, 60 µg/ml, and 30 µg/ml of the lipopeptide solution into the mesophylls of tobacco leaves (Fig. 5). Melittin, a nonspecific, 26-amino-acid, non-cell-selective peptide, was used as a positive control and caused cell necrosis. In large areas of

leaves, mesophyll, infiltrated by melittin, became progressively clearer, and 12 h after infiltration, this area started to desiccate. The necrotic area then turned brown and was completely desiccated at 24 h postinfiltration. In contrast, no necrosis could be detected in the mesophylls of the leaves that were infiltrated with the lipopeptide C14-KLLK.

DISCUSSION

In the present study, we demonstrated that short, positively charged peptides attached to fatty acids of various lengths are potent inhibitors of plant-pathogenic fungi and bacteria, in vitro and in planta, without harming plant tissues. The most

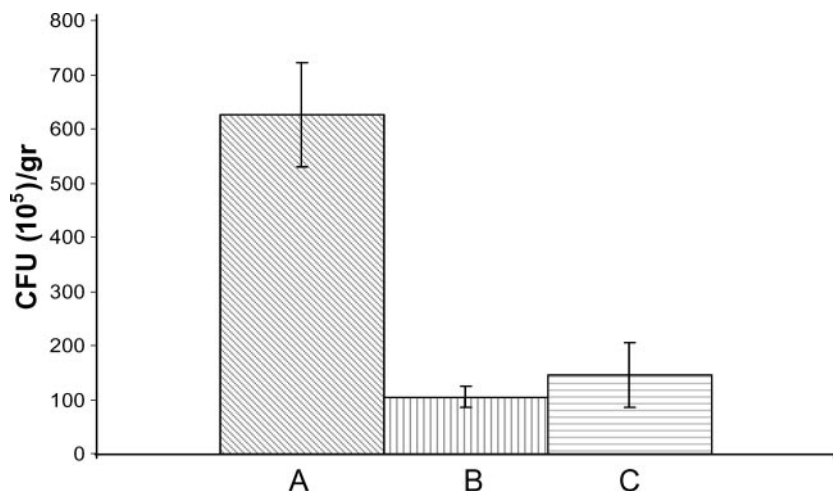


FIG. 4. *Arabidopsis* colonization by *Pseudomonas syringae* pv. tomato. *Arabidopsis* leaves were treated by infiltrating sterile double-distilled water (A) or 30 mg/liter C14-KLLK 4 h before inoculation (B) or 4 h after inoculation (C). Proliferation of bacteria in plant leaves was assayed 2 days after inoculation by monitoring bacterial growth as described in Materials and Methods. Each bar represents the mean for three replicates. Similar results were obtained in a second, independent experiment (data not shown).

active lipopeptides are those with the peptidic moiety KLLK. Interestingly, the lengths of the fatty acids did not have a major effect on the activities of the corresponding lipopeptides C16-KLLK and C14-KLLK against the different pathogens (Table 1). In comparison, previous studies have shown that the lipopeptide C16-KLLK, with a long palmitic acid, is less effective on human-pathogenic gram-negative bacteria than on gram-positive bacteria, whereas the lipopeptide C14-KLLK, with a shorter myristic acid, is equally active on both types of bacteria (29). Note that the bacteria selected are *P. syringae*, which causes disease symptoms ranging from leaf spots to stem cankers (36), and *A. tumefaciens*, which causes crown gall disease (18). Importantly, the MICs of these lipopeptides are similar to or higher than those of many long AMPs, particularly taking into account their relatively low molecular masses (~600 Da). Owing to the superior activities of the C14-KLLK

lipopeptides on the various pathogens, we used these lipopeptides for further in vitro mode-of-action studies as well as for the in planta experiments.

Our data revealed that lipopeptides act via lysis of the pathogen membrane. This was demonstrated by both light microscopy (Fig. 1) and transmission electron microscopy (Fig. 2). At its MIC, C14-KLLK induces severe membrane disruption and lytic activity toward all the examined spores as well as growth inhibition of the fungal hyphae (Fig. 1). Furthermore, in both treated *C. heterostrophus* hyphae and *B. cinerea* spores, membranes and cytoplasm shrank and separated from the rigid cell wall, possibly due to loss of intracellular liquid (Fig. 2). Importantly, the drastic lytic effect is rapid (20-min incubation time), which should make it difficult for the pathogen to develop resistance. Nevertheless, the proposed effects on the membrane may also be partially a result of the cell wall disruption rather than a direct effect of the lipopeptides, due to the thick cell walls of these pathogens.

The lipopeptides are also active in vitro against *Pythium aphanidermatum* (data not shown). This microorganism belongs to the oomycete family, a unique group of diploid, fungus-like organisms related to chromophyte algae and other heterokont protists (4), which do not contain or produce sterols (1). This strong inhibitory activity (data not shown) further supports the notion that the lipopeptides directly act on and disrupt the membranes of the microorganisms without the involvement of sterols and ergosterol, which have been shown to affect the activity of the antifungal polyene family (9, 21).

Many studies were conducted with AMPs against plant pathogens in vitro and in planta, and their advantages and disadvantages are discussed in the introduction (3, 11, 15, 31–35, 40–42). Here, we demonstrated the successful application of the ultrashort lipopeptides as fungicides for treatment of gray mold on different plant tissues. Briefly, we infected cucumber leaves with mycelial agar discs of *B. cinerea*, and after 24 h of incubation, we treated the mycelium with C14-KLLK and C16-KLLK (Fig. 3, panel 1). C14-KLLK efficiently and

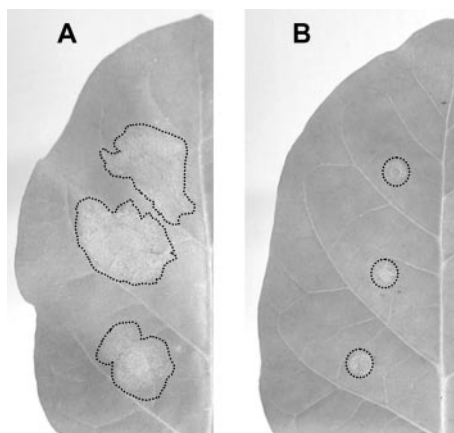


FIG. 5. Infiltration of tobacco leaves with the nonspecific lytic peptide melittin (A) and with C14-KLLK (B). The images were taken at 24 h postinfiltration. Three different concentrations were used: 120 mg/liter (upper infiltration), 60 mg/liter (middle infiltration), and 30 mg/liter (lower infiltration).

completely inhibited the expansion of the fungal mycelium in the cucumber leaves, whereas C16-KLLK did so to a lesser extent, in agreement with the *in vitro* results. Interestingly, treatment with C14-KLLK 24 h prior to infection with fungi also prevented the establishment and expansion of the fungal mycelium on the cucumber leaves. This demonstrates that the lipopeptide can conserve its antifungal activity for at least 24 h after being administered to the plant leaves. Further analysis of the fungal mycelium in leaf tissue stained with methyl blue solution revealed the inhibition of growth of the fungal hyphae as well (Fig. 3, panel 2). Furthermore, the diameter of the hyphal cylinder was also dramatically reduced compared to that in the untreated tissue. Although the *in vitro* and *in planta* studies strongly support the membranolytic mechanism of these lipopeptides, other mechanisms, such as induced systemic resistance, could also contribute to the observed effect (17, 25, 27, 30, 38, 58).

The ability of the lipopeptide to also inhibit the establishment of mycelium in corn leaves infected with *C. heterostrophus* spores emphasizes the universal potent activity of C14-KLLK toward different fungi that infected different plants (Fig. 3, panel 4).

Losses particularly due to fungal invasions are much more significant for highly perishable fresh fruits and vegetables. The characteristics of fruits and vegetables, such as high levels of sugars and other nutrients, high moisture content, and low pHs, make them highly susceptible to attacks by different pathogenic fungi, and they are difficult to treat (6, 22, 55). In this study, we also showed that cucumber fruits infected with *B. cinerea* fully recovered after treatment with C14-KLLK (Fig. 3, panel 3). We further examined the lipopeptides' toxicity by infiltrating high concentrations of the lipopeptides into the mesophylls of fully expanded tobacco leaves (Fig. 5). The effect of the lipopeptides was compared to that of melittin, a non-cell-selective lytic peptide, which induced necrotic and toxic properties in the plant cells (56). Infiltration of melittin resulted in hemolysis of the plant cells and comprehensive and severe damage to the leaf mesophyll tissues. In contrast, infiltration of the lipopeptides did not induce any toxicity in the mesophyll tissue.

Importantly, C14-KLLK was also active *in planta* against plant-pathogenic bacteria. *P. syringae* is a common and aggressive phytopathogen that grows in the intercellular spaces of plant tissues. Treatment with C14-KLLK of living *Arabidopsis* leaves infected with *P. syringae* efficiently and rapidly reduced the number of bacterial cells (Fig. 4).

In summary, we present a strategy for eliminating plant-pathogenic microorganisms by using very short and economically available antimicrobial lipopeptides. These lipopeptides, which are composed of natural building blocks, namely, amino acids and fatty acids, have an efficient and broad spectrum of activity toward both bacteria and fungi and act rapidly on the membranes of the microorganisms via a lytic mechanism by which it should be difficult to confer resistance. Moreover, the lipopeptides are biodegradable to natural proteases such as trypsin. Therefore, we can assume that, similarly to native plant AMPs, they will finally be cleaved by plant proteases and therefore might not cause environmental pollution. Due to the increasing resistance of plant pathogens to the currently available antimicrobial agents and the emerging need to eliminate

toxic chemicals from agricultural use, these new ultrashort lipopeptides could serve as potential candidates to be developed as relatively economical broad-spectrum antifungal and antibacterial agents in agriculture.

ACKNOWLEDGMENT

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second comment period on this action. Any parties interested in commenting must do so at this time.

IV. Statutory and Executive Order Reviews

A. General Requirements

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this action is not a "significant regulatory action" and therefore is not subject to review by the Office of Management and Budget. For this reason, this action is also not subject to Executive Order 13211, "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355, May 22, 2001). This action merely approves state law as meeting Federal requirements and imposes no additional requirements beyond those imposed by state law. Accordingly, the Administrator certifies that this rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). Because this rule approves pre-existing requirements under state law and does not impose any additional enforceable duty beyond that required by state law, it does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Public Law 104-4). This rule also does not have tribal implications because it will not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified by Executive Order 13175 (65 FR 67249, November 9, 2000). This action also does not have Federalism implications because it does not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999). This action merely approves a state rule implementing a Federal standard, and does not alter the relationship or the distribution of power and responsibilities established in the Clean Air Act. This rule also is not subject to Executive Order 13045 "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997),

because it is not economically significant.

In reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the Clean Air Act. In this context, in the absence of a prior existing requirement for the State to use voluntary consensus standards (VCS), EPA has no authority to disapprove a SIP submission for failure to use VCS. It would thus be inconsistent with applicable law for EPA, when it reviews a SIP submission, to use VCS in place of a SIP submission that otherwise satisfies the provisions of the Clean Air Act. Thus, the requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) do not apply. This rule does not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

B. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. Section 804 exempts from section 801 the following types of rules: (1) Rules of particular applicability; (2) rules relating to agency management or personnel; and (3) rules of agency organization, procedure, or practice that do not substantially affect the rights or obligations of non-agency parties. 5 U.S.C. 804(3). EPA is not required to submit a rule report regarding today's action under section 801 because this is a rule of particular applicability establishing source-specific requirements for PPG Industries, Inc., in Marshall County, West Virginia.

C. Petitions for Judicial Review

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by June 28, 2004. Filing a petition for reconsideration by the Administrator of this final rule approving a Consent Order for PPG Industries, Inc., in Marshall County, West Virginia does not affect the finality of this rule for the purposes of judicial

review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Reporting and recordkeeping requirements, Sulfur oxides.

Dated: April 13, 2004.

Richard J. Kampf,

Acting Regional Administrator, Region III.

■ 40 CFR part 52 is amended as follows:

PART 52—[AMENDED]

■ 1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart XX—West Virginia

■ 2. Section 52.2520 is amended by adding paragraph(c)(58) to read as follows:

§ 52.2520 Identification of plan.

* * * * *

(c) * * *

(58) Revision to the West Virginia Regulations to achieve and maintain the sulfur dioxide national ambient air quality standards (NAAQS) in Marshall County consisting of Consent Order, CO-SIP-C-2003-27 for PPG Industries, Inc., submitted on November 17, 2003, by the West Virginia Department of Environmental Protection:

(i) Incorporation by reference.

(A) Letter of November 17, 2003, from the West Virginia Department of Environmental Protection transmitting a revision to the State Implementation Plan (SIP) to achieve and maintain the NAAQS for sulfur dioxide in Marshall County, West Virginia.

(B) Consent Order, CO-SIP-C-2003-27, entered into by and between the West Virginia Department of Environmental Protection, Division of Air Quality, and PPG Industries, Inc., on July 29, 2003. The consent order was effective on July 29, 2003.

(ii) Additional Material.—Remainder of the State submittal pertaining to the revision listed in paragraph (c)(58)(i) of this section.

[FR Doc. 04-9580 Filed 4-27-04; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY**40 CFR Parts 153, 168, and 180**

[OPP-2003-0368; FRL-7335-4]

Pesticides; Tolerance Exemptions for Active and Inert Ingredients for Use in Antimicrobial Formulations (Food-Contact Surface Sanitizing Solutions)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is adding a new section to part 180 to list the pesticide chemicals that are exempt from the requirement of a tolerance when used in food-contact surface sanitizing solutions. This list of exempt pesticide chemicals is duplicated from the Food and Drug Administration's (FDA) regulations in 21 CFR 178.1010. For some of these chemical substances, EPA's list will use naming conventions differing from those used by FDA. Additionally, EPA is redesignating/reorganizing § 180.1001. This section of CFR will be split into five separate sections with no changes in text or content.

DATES: This final rule is effective on April 28, 2004.

ADDRESSES: EPA has established a docket for this action under Docket ID number OPP-2003-0368. All documents in the docket are listed in the EDOCKET index at <http://www.epa.gov/edocket>. Although listed in the index, some information is not publicly available, i.e., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in EDOCKET or in hard copy at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA., Monday through Friday, excluding legal holidays. The Docket telephone number is (703) 305-5805.

FOR FURTHER INFORMATION CONTACT: Kathryn Boyle, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-6304; fax number: (703) 305-0599; e-mail address: boyle.kathryn@epa.gov.

SUPPLEMENTARY INFORMATION:**I. General Information***A. Does This Action Apply to Me?*

You may be potentially affected by this action if you formulate or market pesticide products. Potentially affected categories and entities may include, but are not limited to:

- Food manufacturing (NAICS 311)
- Antimicrobial pesticides (NAICS 32561)

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Access Copies Of this Document and Other Related Information?

In addition to using EDOCKET (<http://www.epa.gov/edocket/>), you may access this **Federal Register** document electronically through the EPA Internet under the "Federal Register" listings at <http://www.epa.gov/fedrgstr/>. A frequently updated electronic version of 40 CFR part 180 is available at E-CFR Beta Site Two at <http://www.gpoaccess.gov/ecfr/>.

II. What is the Agency's Authority for Taking this Action?

This final rule is issued under the Federal Food, Drug and Cosmetic Act (FFDCA) section 408, 21 U.S.C. 346a, as amended by the Food Quality Protection Act (FQPA) (Public Law 104-170), and the Antimicrobial Regulation Technical Correction Act (ARTCA) (Public Law 105-324).

Section 408 of FFDCA authorizes the establishment of tolerances, exemptions from the requirement of a tolerance, modifications in tolerances, and revocation of tolerances for residues of pesticide chemicals in or on raw agricultural commodities and processed foods. Owing to the FQPA and ARTCA amendments to FFDCA, certain chemical substances originally regulated by FDA under FFDCA section 409 as food-contact surface sanitizing solutions are now subject to EPA's authority under FFDCA section 408. Section 408(j)(2) of FFDCA provides that all regulations issued by FDA under FFDCA section 409 that stated conditions for safe use of substances

that are now, post-FQPA, considered pesticide chemical residues in or on processed food or that otherwise stated the conditions under which such pesticide chemicals could be safely used, shall be deemed to be regulations issued under FFDCA section 408.

These pesticide chemical regulations are now subject to modification or revocation at EPA's initiative under FFDCA section 408(e). Today's rule duplicates the substance of FDA's food additive regulations for those chemical substances found in 21 CFR 178.1010 which are now pesticide chemicals, by codifying tolerance exemptions in a format consistent with EPA's authority under section 408 in a new section, 40 CFR 180.940.

Because some solutions described in 21 CFR 178.1010 may still have uses as food additives, FDA is leaving 21 CFR 178.1010 in effect. EPA's rulemaking activity has no effect on any of the FDA-regulated FFDCA section 409 food additive regulations in 21 CFR 178.1010.

III. Impact on Tolerance Reassessment

This rule shifts existing tolerance exemptions from 21 CFR 178.1010 to 40 CFR 180.940. These are duplicated from existing, valid FFDCA section 408 regulations. FDA promulgated the food additive regulations in 21 CFR 178.1010 under the authority of FFDCA section 409 prior to the enactment of FQPA. Those portions of 21 CFR 178.1010 that pertain to chemical substances that are pesticide chemicals post-FQPA and remain as such post-ARTCA were converted by FFDCA section 408(j)(2) into FFDCA section 408 tolerance exemptions. Thus, EPA's duplication of these tolerance exemptions is not "establishing, modifying, or revoking a tolerance" under FFDCA section 408(b). EPA is not, therefore, required to conduct a full reassessment of these tolerance exemptions at this time. However, because the tolerance exemptions duplicated from 21 CFR 178.1010 into 40 CFR 180.940 were in effect prior to the enactment of FQPA, they are subject to the tolerance reassessment deadline of August 2, 2006.

IV. Background

In the **Federal Register** of December 3, 2002 (67 FR 71847) (FRL-6824-2), the Agency published a direct final rule to establish 40 CFR 180.940. Comments were received. In the December 3, 2002 FR final rule, EPA had announced that it would withdraw the direct final rule if it received adverse comment, and proceed with proposed rule as provided by section 553 of the Administrative

Procedure Act, 5 U.S.C. 553. Because some of the comments were of a nature that would warrant a response if made on a proposed rule, they were adverse comments that required withdrawal of the direct final rule. EPA withdrew the direct final rule on March 24, 2003 (68 FR 14165)(FRL-7299-4).

In the **Federal Register** of June 25, 2003 (68 FR 37778) (FRL-7302-2), the Agency issued its proposal to establish 40 CFR 180.940. The comments received as a result of the December 3, 2002, direct final rule were addressed in that proposed rule.

Six comments were received in response to the June 25th proposed rule. There was also a late comment to the direct final rule.

One commenter requested to increase the concentrations of certain chemical ingredients. At this time, EPA is not proposing to change the upper concentration limits as specified by FDA in 21 CFR 178.1010. The purpose of this final rule action is to duplicate FDA's previous clearances in a format consistent with EPA's authority under section 408. To increase the concentration limitations from those specified by FDA, requires the performance of a risk assessment. At this time EPA is merely duplicating the listing of chemicals in 21 CFR 178.1010 to 40 CFR 180.940, albeit in a different format. EPA is required under section 408(q)(1)(C) to complete tolerance reassessment for all pesticide chemicals by 2006, and will consider the commenter's suggestion during tolerance reassessment.

The same commenter requested that all GRAS ingredients listed under 21 CFR part 184 be included in 180.940. Another commenter requested that all chemical substances designated as GRAS in 21 CFR part 582 be included in 40 CFR 180.940 under a catch-all provision. The Agency understands that 21 CFR 178.1010 allows the inclusion of GRAS chemical substances and chemical substances "permitted by prior sanction or approval," that are not expressly identified in 21 CFR 178.1010. It is for this reason that the Agency asked registrants of food-contact surface sanitizing solutions to specifically identify all other ingredients that they believe should be included in 40 CFR 180.940. At a later date, EPA intends to publish its proposal to revise 40 CFR 180.940 by adding chemical substances that were not specified by name in 21 CFR 178.1010 but that are included in a registered food-contact surface sanitizing solution. Today's final rule only considers the chemical substances that were specified by name in 21 CFR 178.1010.

One commenter expressed concern that documenting all of FDA's informal clearances could prove to be difficult. They stated that the existence of a registration should be sufficient proof. The Agency agrees. In fact, several registrants of various food-contact surface sanitizing solutions have already supplied the Agency with a list of chemical substances that were not included in the proposed 40 CFR 180.940, but are part of a registered pesticide product. The claims for inclusion of these chemical substances were documented only by reference to an EPA Registration Number. Where EPA's files clearly demonstrate both that the registered pesticide was subject to section 409 and contained the chemical substance before enactment of the FQPA, EPA will include the chemical substance in the upcoming proposal to revise 40 CFR 180.940. So although identifying a registered pesticide as containing a particular chemical substance may be sufficient to support inclusion in 40 CFR 180.940, registrants can maximize the likelihood of inclusion by providing documentation of FDA's prior sanction or approval.

Two commenters requested confirmation on whether or not chemical substances that are included in an existing, registered food-contact surface sanitizing solution, but are not included by name in 21 CFR 178.1010, are considered under this final rule to be FDA-approved substances. Today's final rule does not address such chemical substances. In the preambles to both the direct final rule and the proposed rule, EPA asked registrants of food-contact surface sanitizing solutions to identify to EPA any chemical substances that they claim have been cleared by FDA for use in sanitizing solutions but not expressly identified in 21 CFR 178.1010. As previously stated, at some time in the near future, EPA intends to publish its proposal to revise 40 CFR 180.940 to add chemical substances that were not specified by name in 21 CFR 178.1010. In order to preserve the use of registered food-contact surface sanitizing solutions whose ingredients were cleared by FDA before FQPA's enactment, EPA will treat all of the component chemicals (whether or not they are specifically identified in 21 CFR 178.1010) of registered food-contact surface sanitizing solutions as exempt from the requirement of a tolerance until EPA has completed its review of the registrants' claims with respect to pesticide chemicals not specifically identified in 21 CFR 178.1010.

The same two commenters also stated that EPA should not distinguish

between the three categories of food-contact surface sanitizing solutions. They believe that these categories have not been rigidly applied. Today's final rule addresses only those use patterns as specifically described in 21 CFR 178.1010. If a registrant supplies information to the Agency to demonstrate that FDA cleared a solution for uses broader than described in § 178.1010, then EPA can include these changes in its upcoming proposal to revise 40 CFR 180.940. However, today's regulation merely duplicates the substance of the existing FDA regulation.

The late comment (to the direct final rule) requested that all of the quaternary sanitizer solutions currently listed under 21 CFR 178.1010 be approved by EPA for end use at a concentration not to exceed 400 ppm of the active quaternary compound. The rationale for such a change included a statement that FDA had intended to make such a change and a discussion of the concerns of public health officials who advocate for solutions with demonstrated efficacy over a wide range of concentrations. Such a range would provide the user "a reasonable margin of error" while preparing safe and effective sanitizing solutions.

In a similar manner, another commenter indicated its belief that the proposed language for the quaternary ammonium compounds was inconsistent with the existing FDA regulations. According to the commenter FDA had established a total limit of 400 ppm for the quaternary ammonium compounds, while EPA's approach could possibly allow up to 750 ppm. EPA discussed this issue with FDA, and concluded that the comments have merit, not only for the quaternary ammonium compounds, but also for other chemicals that were expressed as total or solution limits. This would include the halogens (chloride-, bromide-, and iodide-producing chemicals) and naphthalene sulfonate derivatives. Since the concentration limits for the above chemicals are specified in 21 CFR 178.1010 as total or solution limits, this change has been carried forward to 40 CFR 180.940.

One of the commenters submitted a letter from FDA which seemed to indicate that FDA had raised the maximum at-use concentration of certain chemicals from 200 ppm to 220 ppm. This comment was also discussed with FDA who indicated that while they had "no objection" to 220 ppm as the at-use concentration, they intended that the tolerance for residues in or on food should remain at 200 ppm. FDA would continue to have no objection to use

levels as high as 220 as indicated through field testing.

While not in response to a comment, the Agency is making several changes to the list of chemical substances proposed in the June 25th proposed rule. Several of the chemical substances (citric acid, dextrin, magnesium oxide, sodium bicarbonate, starch and octadecanoic acid, calcium salt) have been recently classified as List 4A minimal risk inert ingredients (see the listings of inert ingredients at <http://www.epa.gov/oppr001/inerts/lists.html>). Tolerance exemptions for certain of these List 4A substances (citric acid, dextrins, and starch (as a food commodity)) have already been established in 40 CFR 180.950, the section of CFR that holds "Tolerance Exemptions for Minimal Risk Active and Inert Ingredients." Because chemical substances with a tolerance exemption identified in 40 CFR 180.950 may be used in any pesticide product, including antimicrobial products, without limitation, having tolerance exemptions in both 40 CFR 180.940 and 180.950 would be redundant. Therefore, duplicative entries for citric acid, dextrin, and starch are not created today in 40 CFR 180.940. Additionally, because the Agency intends that all List 4A substances eventually will be transferred to 40 CFR 180.950 without limitations, the Agency is removing the concentration use limitations for sodium bicarbonate, magnesium oxide and octadecanoic acid, calcium salt.

Based on the reasons set forth in the preamble to the proposed rule, and considering the comments received by the Agency in response to the direct final and proposed rules, EPA is creating a new section 40 CFR 180.940.

Redesignation of 40 CFR 180.1001

In the July 1, 2002 edition of title 40 CFR parts 150 to 189, § 180.1001 occupies pages 508 to 537, a large amount of information for one section of CFR. Today's action shifts and splits 40 CFR 180.1001 with no changes to the text or content. See Table 1 for a redesignation of the paragraphs and the new sections.

TABLE 1.—REDESIGNATION OF 40 CFR 180.1001

Former CFR Designation	New CFR Designation
180.1001(a)	40 CFR 180.900
180.1001(b)	40 CFR 180.905
180.1001(c)	40 CFR 180.910

TABLE 1.—REDESIGNATION OF 40 CFR 180.1001—Continued

Former CFR Designation	New CFR Designation
180.1001(d)	40 CFR 180.920
180.1001(e)	40 CFR 180.930

All references to 40 CFR 180.1001 in other sections of 40 CFR are also being changed to reflect the shift. Additionally two FDA regulations cite to 180.1001: 21 CFR 182.99 and 582.99. FDA is aware that this shift of 40 CFR 180.1001 is occurring.

V. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA of 1996, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) provides essentially the same process for persons to "object" to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d), as was provided in the old FFDCA sections 408 and 409. However, the period for filing objections is now 60 days, rather than 30 days.

A. What Do I Need to Do to File an Objection or Request a Hearing?

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number OPP-2003-0368 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before June 28, 2004.

1. *Filing the request.* Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issues(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). Information submitted in connection with an objection or hearing

request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

Mail your written request to: Office of the Hearing Clerk (1900C), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001. You may also deliver your request to the Office of the Hearing Clerk in Rm.104, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (703) 603-0061.

2. *Tolerance fee payment.* If you file an objection or request a hearing, you must also pay the fee prescribed by 40 CFR 180.33(i) or request a waiver of that fee pursuant to 40 CFR 180.33(m). You must mail the fee to: EPA Headquarters Accounting Operations Branch, Office of Pesticide Programs, P.O. Box 360277M, Pittsburgh, PA 15251. Please identify the fee submission by labeling it "Tolerance Petition Fees."

EPA is authorized to waive any fee requirement "when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection." For additional information regarding the waiver of these fees, you may contact James Tompkins by phone at (703) 305-5697, by e-mail at tompkins.jim@epa.gov, or by mailing a request for information to Mr. Tompkins at Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

If you would like to request a waiver of the tolerance objection fees, you must mail your request for such a waiver to: James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

3. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit V.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in ADDRESSES. Mail your copies, identified by docket ID number OPP-2003-0368, to: Public Information

and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. In person or by courier, bring a copy to the location of the PIRIB described in **ADDRESSES**. You may also send an electronic copy of your request via e-mail to: *opp-docket@epa.gov*. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

B. When Will the Agency Grant a Request for a Hearing?

A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

VI. Statutory and Executive Order Reviews

This final rule reorganizes the existing exemptions in 40 CFR 180.1001, shifting them from one section to another within the same part. The Agency is acting on its own initiative under FFDCA section 408(e) in shifting these existing tolerance exemptions to a new section of part 180. This has no substantive effect, and is not expected to have any adverse impact, or otherwise impose any new requirements.

This final rule also establishes a new section, 40 CFR 180.940, "Tolerance Exemptions for Active and Inert Ingredients for Use in Antimicrobial Formulations (Food-Contact Surface Sanitizing Solutions)." As discussed in Unit II., this new section merely duplicates that portion of the existing FDA regulation 21 CFR 178.1010 that applies to chemical substances that are now subject to EPA's authority under FFDCA section 408.

The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735,

October 4, 1993). Because this rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104-4). Nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note).

Under section 605(b) of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), the Agency hereby certifies that the proposed action to reorganize 40 CFR 180.1001 will not have significant negative economic impact on a substantial number of small entities. Creation of a new section and the reorganization of 40 CFR 180.1001 does not have a substantive effect and hence causes no impact. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure "meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications." "Policies that have federalism implications" is defined in the Executive order to include regulations that have "substantial direct effects on the States, on the relationship between the national government and the States, or on the

distribution of power and responsibilities among the various levels of government." This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). For these same reasons, the Agency has determined that this rule does not have any "tribal implications" as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure "meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications." "Policies that have tribal implications" is defined in the Executive order to include regulations that have "substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes." This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

VII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the Agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This rule is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Parts 153, 168, and 180

Environmental protection, Administrative practice and procedure, Advertising, Agricultural commodities,

Exports, Labeling, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: April 21, 2004.

James Jones,

Director, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 153—[AMENDED]

■ 1. The authority citation for part 153 continues to read as follows:

Authority: 15 U.S.C. 136 *et seq.*

■ 2. Sections 153.155 is amended by revising paragraph (c)(1) to read as follows:

§ 153.155 Seed treatment products.

* * * * *

(c) * * *

(1) Sections 180.910, 180.920, and 180.950 if an exemption from the requirement of a tolerance has been established.

* * * * *

PART 168—[AMENDED]

■ 3. The authority citation for part 168 continues to read as follows:

Authority: 15 U.S.C. 136 *et seq.*

■ 4. Section 168.65 is amended by revising the first sentence of paragraph (b)(1)(iii)(A)(2)(i), and by revising paragraph (b)(1)(iii)(A)(2)(ii) to read as follows:

§ 168.65 Pesticide export label and labeling requirements.

* * * * *

(b) * * *

(1) * * *

(iii) * * *

(A) * * *

(2) * * *

(i) The change in color must result only from the addition of a dye included

on the list of the chemicals exempted from the requirement of a tolerance at 40 CFR 180.910, 180.920, 180.930, and 180.950, and the dye must not be a List 1 inert. * * *

(ii) The change in fragrance must result only from the addition of a chemical included on the list of the chemicals exempted from the requirement of a tolerance at 40 CFR 180.910, 180.920, 180.930, and 180.950, and the chemical must not be a List 1 inert.

* * * * *

■ 5. Section 168.75 is amended by revising the second and fifth sentences of paragraph (b)(4)(iii) to read as follows:

§ 168.75 Procedures for exporting unregistered pesticide-purchase acknowledgment statements.

* * * * *

(b) * * *

(4) * * *

(iii) * * * The change in color must result only from the addition of a dye included on the list of the chemicals exempted from the requirement of a tolerance at 40 CFR 180.910, 180.920, 180.930, and 180.950, and the dye must not be a List 1 inert.

* * * The change in fragrance must result only from the addition of a chemical included on the list of the chemicals exempted from the requirement of a tolerance at 40 CFR 180.910, 180.920, 180.930, and 180.950, and the chemical must not be a List 1 inert.

* * * * *

PART 180—[AMENDED]

■ 6. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 7. Section 180.900 is added to subpart D to read as follows:

§ 180.900 Exemptions from the requirement of a tolerance.

An exemption from a tolerance shall be granted when it appears that the total quantity of the pesticide chemical in or on all raw agricultural commodities for which it is useful under conditions of use currently prevailing or proposed will involve no hazard to the public health.

■ 8. Section 180.905 is added to subpart D to read as follows:

§ 180.905 Pesticide chemicals; exemptions from the requirement of a tolerance.

(a) When applied to growing crops, in accordance with good agricultural practice, the following pesticide chemicals are exempt from the requirement of a tolerance:

- (1) [Reserved]
- (2) *N*-Octylbicyclo(2,2,1)-5-heptene-2,3-dicarboximide.
- (3) Petroleum oils.
- (4) Piperonyl butoxide.
- (5) [Reserved]
- (6) Pyrethrum and pyrethrins.
- (7) Rotenone or derris or cube roots.
- (8) Sabadilla.

(b) These pesticides are not exempted from the requirement of a tolerance when applied to a crop at the time of or after harvest.

■ 9. Section 180.910 is added to subpart D to read as follows:

§ 180.910 Inert ingredients used pre- and post-harvest; exemptions from the requirement of a tolerance.

Residues of the following materials are exempted from the requirement of a tolerance when used in accordance with good agricultural practice as inert (or occasionally active) ingredients in pesticide formulations applied to growing crops or to raw agricultural commodities after harvest:

Inert ingredients	Limits	Uses
Acetic acid		Catalyst
Acetic anhydride		Solvent, cosolvent
Acetone		Do.
Alkanoic and alkenoic acids, mono- and diesters of α -hydro- ω -hydroxypoly (oxyethylene) with molecular weight (in amu) range of 200 to 6,000.		Emulsifiers
Alkyl (C ₈ -C ₂₄) benzenesulfonic acid and its ammonium, calcium, magnesium, potassium, sodium, and zinc salts.		Surfactants, related adjuvants of surfactants
α -Alkyl (C ₉ -C ₁₈ - ω -hydroxypoly(oxyethylene) with poly(oxyethylene) content of 2-30 moles.		Solvent, cosolvent, surfactant, and related adjuvants of surfactants
α -(<i>p</i> -Alkylphenyl)- ω -hydroxypoly(oxyethylene) produced by the condensation of 1 mole of alkylphenol (alkyl is a mixture of propylene tetramer and pentamer isomers and averages C ₁₃) with 6 moles of ethylene oxide.		Surfactants, related adjuvants of surfactants

Inert ingredients	Limits	Uses
α -Alkyl (C ₆ -C ₁₄)- ω -hydroxypoly(oxypropylene) block copolymer with polyoxyethylene; polyoxypropylene content is 1-3 moles; polyoxyethylene content is 4-12 moles; average molecular weight (in amu) is approximately 635.		Do.
α -alkyl (C ₁₂ -C ₁₅)- ω -hydroxypoly (oxypropylene) poly (oxyethylene) copolymers (where the poly (oxypropylene) content is 3-60 moles and the poly (oxyethylene) content is 5-80 moles).	Not more than 20% of pesticide formulations	Surfactant
Alkyl (C ₈ -C ₁₈) sulfate and its ammonium, calcium, isopropylamine, magnesium, potassium, sodium, and zinc salts.		Surfactants.
Aluminum hydroxide		Diluent, carrier
Aluminum oxide		Diluent
Aluminum stearate		Surfactant
Ammonium bicarbonate		Surfactant, suspending agent, dispersing agent
Ammonium carbamate		Synergist in aluminum phosphide formulations
Ammonium chloride		Intensifier when used with ammonium nitrate as a dessicant or defoliant. Fire suppressant in aluminum phosphide and magnesium phosphide formulations
Ammonium hydroxide		Solvent, cosolvent, neutralizer, solubilizing agent
Ammonium stearate		Surfactant
Ammonium sulfate		Solid diluent, carrier
Ammonium thiosulfate		Intensifier when used with ammonium nitrate as dessicant or defoliant
Amyl acetate		Solvent, cosolvent, attractant
Ascorbic acid (CAS Reg. No. 50-81-7)		Stabilizer, preservative
Ascorbyl palmitate		Preservative
Attapulgate-type clay		Solid diluent, carrier, thickener
<i>Bacillus thuringiensis</i> fermentation solids and/or solubles.		Diluent, carrier
Beeswax		Coating agent
Bentonite		Solid diluent, carrier
Benzoic acid		Preservative for formulation
Butane		Propellant
<i>n</i> -Butanol (CAS Reg. No. 71-36-3)		Solvent, cosolvent
Butylated hydroxyanisole		Antioxidant
Butylated hydroxytoluene		Do.
α -(<i>p</i> - <i>tert</i> -Butylphenyl)- ω -hydroxypoly (oxyethylene) mixture of dihydrogen phosphate and monohydrogen phosphate esters and the corresponding ammonium calcium, magnesium, monoethanolamine, potassium, sodium, and zinc salts of the phosphate esters; the poly(oxyethylene) content averages 4-12 moles.		Surfactants related adjuvants of surfactants
Calcareous shale		Solid diluent carrier
Calcite		Do.
Calcium carbonate		Do.
Calcium chloride		Stabilizer
Calcium phosphate		Solid diluent, carrier
Calcium hydroxide		Do.
Calcium hypochlorite		Sanitizing and bleaching agent
Calcium oxide		Solid diluent, carrier
Calcium salt of partially dimerized rosin, conforming to 21 CFR 172.210.		Coating agent
Calcium silicate		Solid diluent, carrier
Calcium stearate		Do.
Carnauba wax		Coating agent
Carrageenan, conforming to 21 CFR 172.620	Minimum molecular weight (in amu): 100,000.	Thickener
Casein	Expires May 24, 2005.	Surfactant, emulsifier, wetting agent
Cetyl alcohol (CAS Reg. No. 36653-82-4)	Not more than 5.0% of pesticide formulation.	Evaporation retardant
Charcoal, activated	Meets specifications in the Food Chemical Codex.	Carrier
Coconut shells		Solid diluent and carrier
Cod liver oil		Solvent, cosolvent
Coumarone-indene resin, conforming to 21 CFR 172.215.	For use on citrus only	Component of coating agent
Croscarmellose sodium (CAS Reg. No. 74811-65-7)		Disintegrant, solid diluent, carrier, and thickener
Diacetyl tartaric acid esters of mono- and diglycerides of edible fatty acids.		Emulsifier

Inert ingredients	Limits	Uses
Dialkyl (C ₈ -C ₁₈) dimethyl ammonium chloride	Not more than 0.2% in silica, hydrated silica.	Flocculating agent in the manufacture of silica, hydrated silica for use as a solid diluent, carrier
Diatomite (diatomaceous earth)		Solid diluent carrier
Dichlorodifluoromethane		Propellant
Dichlorotetrafluoroethane		Do.
Diethylene glycol abietate		Surfactants, related adjuvants of surfactants
1,1-Difluoroethane (CAS Reg. No. 75-37-6)	For aerosol pesticide formulations used for insect control in food- and feed-handling establishments and animals.	Aerosol propellant
1,2-Dihydro-6-ethoxy-2,2,4-trimethylquinolene	Not more than 0.02% of pesticide formulation.	Antioxidant
3,6-Dimethyl-4-octyn-3,6-diol	Not more than 2.5% of pesticide formulation.	Surfactants, related adjuvants of surfactants
α -(<i>o,p</i> -Dinonylphenyl)- ω -hydroxypoly (oxyethylene) mixture of dihydrogen phosphate and monohydrogen phosphate esters and the corresponding ammonium, calcium, magnesium, monoethanolamine, potassium, sodium, and zinc salts of the phosphate esters; the nonyl group is a propylene trimer isomer and the poly(oxyethylene) content averages 4-14 moles.		Surfactants, related adjuvants of surfactants
α -(<i>o,p</i> -Dinonylphenyl)- ω -hydroxypoly (oxyethylene) produced by condensation of 1 mole of dinonylphenol (nonyl group is a propylene trimer isomer) with an average of 4-14 or 140-160 moles of ethylene oxide.		Do.
Dipropylene glycol		Solvent, cosolvent
Disodium phosphate		Anticaking agent, conditioning agent
Disodium zinc ethylenediaminetetraacetate dihydride ..		Sequestrant
Dodecylbenzenesulfonic acid, amine salts		Release rate regulator in pheromone formulation
α -(<i>p</i> -Dodecylphenyl)- ω -hydroxypoly (oxyethylene) produced by the condensation of 1 mole of dodecylphenol (dodecyl group is a propylene tetramer isomer) with an average of 4-14 or 30-70 moles of ethylene oxide; if a blend of products is used, the average number of moles of ethylene oxide reacted to produce any product that is a component of the blend shall be in the range of 4-14 or 30-70.		Surfactants, related, adjuvants of surfactants
Dolomite		Solid diluent, carrier
Epoxidized linseed oil		Surfactants, related adjuvants of surfactants
Epoxidized soybean oil		Do.
Ethoxylated lignosulfonic acid, sodium salt		Surfactant
Ethyl acetate		Solvent, cosolvent
Ethyl alcohol		Do.
Ethyl esters of fatty acids derived from edible fats and oils.		Solvent, cosolvent
Ethylene methylphenylglycidate		Synthetic flavoring
Ethylene oxide adducts of 2,4,7,9-tetramethyl-5-decynediol, the ethylene oxide content averages 3.5, 10, or 30 moles.		Surfactants, related adjuvants of surfactants
Ethylenediaminetetraacetic acid	3% of pesticide formulation	Sequestrant
Ethylenediaminetetraacetic acid, tetrasodium salt	5% of pesticide formulation	Sequestrant
2-Ethyl-1-hexanol	Not more than 2.5% of pesticide formulation.	Solvent, adjuvant of surfactants
Fatty acids, conforming to 21 CFR 172.860		Binder, defoaming agent, lubricant
FD&C Blue No. 1	Not more than 0.2% of pesticide formulation.	Dye
FD&C Red No. 40 (CAS Reg. No. 25956-17-6) conforming to 21 CFR 74.340.	Not to exceed 0.002% by weight of pesticide formulation.	Dye, coloring agent
Ferric sulfate		Solid diluent, carrier
Fish meal	Expires May 24, 2005.	Solid diluent, carrier
Furcelleran		Thickener
Glycerides, edible fats and oils derived from plants and animals, reaction products with sucrose (CAS Reg. Nos. 100403-38-1, 100403-41-6, 100403-39-2, 100403-40-5).		Emulsifier, dispersing agent
Glycerol		Thickener
Glycerol mono-, di-, and triacetate		Solvent, cosolvent
Glyceryl monostearate		Emulsifier
Granite		Do.
Graphite		Solid diluent, carrier

Inert ingredients	Limits	Uses
Gum arabic (acacia)		Surfactant, suspending agent, dispersing agent
Gypsum		Solid diluent, carrier
Hexamethylenetetramine	For use in citrus washing solutions only at not more than 1%.	Preservative
<i>n</i> -Hexyl alcohol (CAS Reg. No. 111-27-3)		Solvent, cosolvent
Humic acid, sodium salt (CAS Reg. No. 68131-04-4)		Adjuvant, UV protectant.
Hydrochloric acid		Solvent, neutralizer
Hydroxyethylidene diphosphonic acid (HEDP) (CAS Reg. No. 2809-21-4).	For use in antimicrobial pesticide formulations at not more than 1 percent.	Stabilizer, chelator
Iron oxide		Solid diluent, carrier
Isopropyl alcohol		Solvent, cosolvent, stabilizer, inhibitor
Isopropyl myristate, CAS Reg. No. 110-27-0		Solvent
Kaolinite-type clay		Solid diluent, carrier
Lactic acid		Solvent
Lauryl alcohol		Surfactant
α -Lauryl- ω -hydroxypoly(oxyethylene), average molecular weight (in amu) of 600.		Emulsifier
α -Lauryl- ω -hydroxypoly(oxyethylene) sulfate, sodium salt; the poly(oxyethylene) content is 3-4 moles.		Surfactants, related adjuvants of surfactants
Lignosulfonate, ammonium, calcium, magnesium, potassium, sodium, and zinc salts.		Surfactants, related adjuvants of surfactants
d-Limonene (CAS Reg. No. 5989-27-5)		Solvent, fragrance
Magnesium carbonate		Anticaking agent, conditioning agent
Magnesium chloride		Safener
Magnesium lime		Solid diluent, carrier
Magnesium oxide		Do.
Magnesium silicate		Do.
Magnesium stearate		Surfactant
Magnesium sulfate		Solid diluent, carrier, safener
Manganous oxide		Solid diluent, carrier
Methyl alcohol		Solvent
Methyl <i>n</i> -amyl ketone (CAS Reg. No. 110-43-0)		Solvent, cosolvent
Methylated silicones		Antifoaming agent
Methyl esters of fatty acids derived from edible fats and oils.		Solvent, cosolvent
Methyl esters of higher fatty acids conforming to 21 CFR 573.640.		Antidusting agent, surfactant
Methyl ester of rosin, partially hydrogenated (as defined in 21 CFR 172.615).		Surfactants, related adjuvants of surfactants
Methyl isobutyl ketone		Solvent
Mica		Solid diluent, carrier
Mineral oil, U.S.P., or conforming to 21 CFR 172.878 or 178.3620(a) (CAS Reg. No. 8012-95-1).		Diluent, carrier, and solvent
Modified polyester resin derived from ethylene glycol, fumaric acid, and rosin.	For use on citrus only	Resinous coating
Monoammonium phosphate	No more than 3.75% by weight in formulation.	Postharvest fumigation in formulation with aluminum phosphide
Mono- and diglycerides of C ₈ -C ₁₈ fatty acids		Surfactants, related adjuvants of surfactants
Montmorillonite-type clay		Solid diluent, carrier
Montmorillonite-type clay treated with polytetrafluoroethylene (PTFE; CAS Reg. No. 9002-84-0).	PTFE content not greater than 0.5% (w/w) of clay.	Carrier
Nonyl, decyl, and undecyl glycoside mixture with a mixture of nonyl, decyl, and undecyl oligosaccharides and related reaction products (primarily decanol and undecanol) produced as an aqueous-based liquid (50 to 65% solids) from the reaction of primary alcohols (containing 15 to 20% secondary alcohol isomers) in a ratio of 20% C ₉ , 40% C ₁₀ , and 40% C ₁₁ with carbohydrates (average glucose to alkyl chain ratio 1.3 to 1.8).		Surfactant.
α -(<i>p</i> -Nonylphenyl)- ω -hydroxypoly(oxyethylene) mixture of dihydrogen phosphate and monohydrogen phosphate esters and the corresponding ammonium, calcium, magnesium, monoethanolamine, potassium, sodium, and zinc salts of the phosphate esters; the nonyl group is a propylene trimer isomer and the poly(oxyethylene) content averages 4-14 moles or 30 moles.		Surfactants, related adjuvants of surfactants

Inert ingredients	Limits	Uses
α -(<i>p</i> -Nonylphenyl)- ω -hydroxypoly(oxyethylene) produced by the condensation of 1 mole of nonylphenol (nonyl group is a propylene trimer isomer) with an average of 4-14 or 30-90 moles of ethylene oxide; if a blend of products is used, the average number of moles of ethylene oxide reacted to produce any product that is a component of the blend shall be in the range of 4-14 or 30-90.		Do.
α -(<i>p</i> -Nonylphenyl)- ω -hydroxypoly(oxyethylene) sulfate, ammonium, calcium, magnesium, potassium, sodium, and zinc salts; the nonyl group is a propylene trimer isomer and the poly(oxyethylene) content averages 4 moles.		Do.
Octyl and decyl glucosides mixture with a mixture of octyl and decyloligosaccharides and related reaction products (primarily <i>n</i> -decanol) produced as an aqueous-based liquid (68-72% solids) from the reaction of straight chain alcohols (C ₈ (45%), C ₁₀ (55%)) with anhydrous glucose.		Do.
Oleic acid		Diluent
Oleic acid diester of α -hydro- ω -hydroxypoly (oxyethylene); the poly(oxyethylene) having average molecular weight (in amu) 400.		Surfactants, related adjuvants of surfactants
α -Oleoyl- ω -hydroxypoly(oxyethylene), average molecular weight (in amu) of 600.		Emulsifier
Oleyl alcohol (CAS Reg. No. 143-28-2)	15%	Cosolvent
Oxalic acid	No more oxalic acid should be used than is necessary to chelate calcium and in no case should more than 2 lb oxalic acid per acre be used.	Calcium chelating hard water inhibitor
Oxidized pine lignin, sodium salt, (CAS Reg. No. 68201-23-0).	Maximum of 2% of formulation	Surfactant, related adjuvant of surfactant
Palmitic acid		Diluent
Pentaerythritol ester of maleic anhydride modified wood rosin.		Plasticizer
Pentaerythritol ester of modified resin		Do.
Pentaerythritol stearates mixture (CAS Reg. No. 85116-93-4) which include pentaerythritol monostearate (CAS Reg. No. 78-23-9), pentaerythritol distearate (CAS Reg. No. 13081-97-5), pentaerythritol tristearate (CAS Reg. No. 28188-24-1) and pentaerythritol tetrastearate (CAS Reg. No. 115-83-3).	No more than 25 ppm in pesticide formulations.	Emulsifier
Petrolatum, conforming to 21 CFR 172.880		Coating agent
Petroleum hydrocarbons, light odorless conforming to 21 CFR 172.884.		Solvent, diluent.
Petroleum hydrocarbons, synthetic isoparaffinic, conforming to 21 CFR 172.882.		Do.
Petroleum naphtha, conforming to 21 CFR 172.250(d)		Component of coating agent
Petroleum wax, conforming to 21 CFR 172.886(d)		Coating agent
Phosphoric acid		Buffer
Phosphorus oxychloride		Catalyst
Pine lignin		Adsorbent
<i>B</i> -Pinene polymers		Surfactants, related adjuvants of surfactants
Polyethylene, conforming to 21 CFR 177.1520(c)		Binder, carrier, and coating agent
Polyethylene glycol[α -hydro- ω -hydroxypoly(oxyethylene)]; mean molecular weight (in amu) 194 to 9,500 conforms to 21 CFR 178.3750.		Surfactants, related adjuvants of surfactants
Polyglycerol esters of fatty acids conforming to 21 CFR 172.854.		Surfactants, related adjuvants of surfactants
Polyglyceryl phthalate ester of coconut oil fatty acids ..		Do.
Poly(methylene- <i>p-tert</i> -butylphenoxy)-poly(oxyethylene) ethanol; the poly(oxyethylene) content averages 4-12 moles.		Coating agent
Poly(methylene- <i>p</i> -nonylphenoxy)poly (oxyethylene) ethanol; the poly(oxyethylene) content averages 4-12 moles.		Coating agent

Inert ingredients	Limits	Uses
Poly(oxy-1,2-ethanediyl), α -(carboxymethyl)- ω -(nonylphenoxy) produced by the condensation of 1 mole of nonylphenol (nonyl group is a propylene trimer isomer) with an average of 4-14 or 30-90 moles of ethylene oxide. The molecular weight (in amu) ranges are 454-894 and 1598-4238.		Surfactant
Polyoxyethylene (20) sorbitan monostearate		Surfactants, related adjuvants of surfactants
[Poly[oxy(methyl-1,2-ethanediyl)], α -[2-bis(2-hydroxy-ethyl)amino]propyl]- ω -hydroxy-ether with α -hydro- ω -hydroxypoly(oxy-1,2-ethanediyl) (1:2), mono-C ₁₂₋₁₆ alkyl ethers, (CAS Reg. No. 176022-82-5).	Not to exceed 15% in the formulated product; only for use with glyphosate.	Surfactant
Polysorbate 65, conforming to 21 CFR 172.838		Emulsifier
Potassium aluminum silicate		Solid diluent, carrier
Potassium hydroxide		Neutralizer
Potassium phosphate		Buffer
Potassium sulfate		Solid diluent
Propane		Propellant
n-Propanol		Solvent, cosolvent
2-Propenoic acid, 2-methyl-, polymer with ethyl 2-propenoate and methyl 2-methyl-2-propenoate, ammonium salt (CAS Registration No. 55989-05-4), minimum number average molecular weight (in amu), 18,900.		Encapsulating agent, dispensers, resins, fibers and beads
Propionic acid		Catalyst
Propylene glycol		Solvent, cosolvent.
Propylene glycol alginate (as defined in 21 CFR 172.858).		Defoaming agent
Propyl gallate		Antioxidant
Propyl p-hydroxybenzoate		Preservative for formulations
Pyrophyllite		Solid diluent, carrier
<i>Rhizobium</i> inoculants (e.g. <i>Sinorhizobium</i> , <i>Bradyrhizobium</i> & <i>Rhizobium</i>).		All leguminous food commodities
Rosin, partially dimerized (as defined in 21 CFR 172.615).		Surfactants, related adjuvants of surfactants
Rosin, partially hydrogenated (as defined in 21 CFR 172.615).		Do.
Rosin, wood		Do.
Salts of fatty acids, conforming to 21 CFR 172.863		Binder, emulsifier, anticaking agent
Sand		Solid diluent, carrier
Secondary alkyl (C ₁₁ -C ₁₅) poly(oxyethylene) acetate, sodium salt; the ethylene oxide content averages 5 moles.		Surfactant
Shellac, bleached; refined, food grade, arsenic and rosin-free.		Coating agent
Soap (sodium or potassium salts of fatty acids)		Surfactant, emulsifier, wetting agent
Soapstone		Solid diluent
Sodium acid pyrophosphate		Surfactant, suspending agent, dispersing agent, buffer
Sodium α -olefinsulfonate (sodium C ₁₄ -C ₁₆) (Olefin sulfonate).		Surfactants, related adjuvants of surfactants
Sodium aluminum silicate		Solid diluent, carrier
Sodium benzoate		Anticaking agent
Sodium bicarbonate		Neutralizer
Sodium diisobutyl naphthalenesulfonate		Surfactants, related adjuvants of surfactants
Sodium dioctylsulfosuccinate		Do.
Sodium dodecylphenoxybenzenedisulfonate		Do.
Sodium hexametaphosphate		Surfactant, emulsifier, wetting agent, suspending agent, dispersing agent, buffer
Sodium hydroxide		Neutralizer
Sodium isopropylisohexyl naphthalenesulfonate		Surfactants, related adjuvants of surfactants
Sodium N-lauroyl-N-methyltaurine		Do.
Sodium lauryl glyceryl ether sulfonate		Do.
Sodium metasilicate		Surfactants, emulsifiers, wetting agents, dispersing agents, buffer
Sodium monoalkyl and dialkyl (C ₈ -C ₁₆) phenoxybenzenedisulfonate mixtures containing not less than 70% of the monoalkylated product.		Surfactants, related adjuvants of surfactants
Sodium mono- and dimethyl naphthalenesulfonates, molecular weight (in amu) 245-260.		Do.
Sodium mono-, di-, and tributyl naphthalenesulfonates		Do.
Sodium mono-, di-, and triisopropyl naphthalenesulfonate.		Do.
Sodium N-oleoyl-N-methyltaurine		Do.
Sodium oleyl sulfate		Do.

Inert ingredients	Limits	Uses
Sodium <i>N</i> -palmitoyl- <i>N</i> -methyltaurine		Do.
Sodium propionate		Preservative for formulation
Sodium salt of sulfated oleic acid		Surfactants, related adjuvants of surfactants
Sodium silicate		Surfactant, emulsifier, wetting agent, stabilizer, inhibitor
Sodium starch glycolate (CAS Reg. No. 9063–38–1) ..	Granular and tableted products only; not to exceed 8% of the formulated product.	Disintegrant
Sodium sulfate		Solid diluent, carrier
Sodium sulfite		Stabilizer
Sodium thiosulfate anhydrous (CAS Reg. No. 7772–98–7 or sodium thiosulfate pentahydrate, CAS Reg. No. 10102–17–7).	Not to exceed 6% of the formulated product.	Dechlorinator, reducing agent
Sodium tripolyphosphate		Buffer, surfactant, suspending agent, dispersing agent, anticaking agent, conditioning agent
Sorbitan fatty acid esters (fatty acids limited to C ₁₂ , C ₁₄ , C ₁₆ , and C ₁₈ containing minor amounts of associated fatty acids) and their derivatives; the poly(oxyethylene) content averages 5-20 moles.		Surfactants, related adjuvants or surfactants.
Sorbic acid (and potassium salt)		Preservative for formulations
Sorbitol		Antidusting agent
Soy protein, isolated	Expires May 24, 2005	Adhesive
Soybean flour	Expires May 24, 2005.	Surfactant
Soybean oil-derived fatty acids		Solvent, cosolvent
Sperm oil conforming to 21 CFR 172.210		Coating agent
Stearic acid		Diluent
α-Stearoyl-ω-hydroxypoly(oxyethylene), average molecular weight (in amu) of 600.		Emulsifier
α-Stearoyl-ω-hydroxypoly(oxyethylene); the poly(oxyethylene) content averages either 8, 9, or 40 moles; if a blend of products is used, the average number of moles ethylene oxide reacted to produce any product that is a component of the blend shall be either 8, 9, or 40.		Surfactants, related adjuvants of surfactants
Sucrose octaacetate		Adhesive
Sulfuric acid (CAS Reg. No. 7664–93–9) that meets the Food Chemicals Codex specifications.	0.1% of pesticide formulation ...	pH control agent
Sulfurous acid		Preservative
Synthetic paraffin and its succinic derivatives conforming to 21 CFR 172.275.		Carrier, binder, and carrying agent
Synthetic petroleum wax, conforming to 21 CFR 172.888.		Binder, carrier, and coating agent
Talc		Solid diluent, carriers
Tall oil; fatty acids not less than 58%, rosin acids not more than 44%, unsaponifiables not more than 8%.		Surfactants, related adjuvants of surfactants
Tartrazine		Dye
1,1,1,2-Tetrafluoroethane, (CAS Reg. No. 811–97–2)		Aerosol propellant
Tetrahydrofurfuryl alcohol		Solvent cosolvent
α-[<i>p</i> -(1,1,3,3-Tetramethylbutyl)phenyl]-ω-hydroxypoly(oxyethylene) produced by the condensation of 1 mole of <i>p</i> -(1,1,3,3-tetramethylbutyl)phenol with a range of 1-14 or 30-70 moles of ethylene oxide: if a blend of products is used, the average range number of moles of ethylene oxide reacted to produce any product that is a component of the blend shall be in the range of 1-14 or 30-70.		Surfactants, related adjuvants of surfactants
α-[<i>p</i> -(1,1,3,3-Tetramethylbutyl)phenyl]-ω-hydroxypoly(oxyethylene) produced by the condensation of 1 mole of <i>p</i> -(1,1,3,3-tetramethylbutyl)phenol with an average of 4-14 or 30-70 moles of ethylene oxide; if a blend of products is used, the average number of moles of ethylene oxide reacted to produce any product that is a component of the blend shall be in the range of 4-14 or 30-70.		Do.
2,4,7,9-Tetramethyl-5-decyn-4, 7-diol	Not more than 2.5% of pesticide formulation.	Surfactants, related adjuvants of surfactants
Tetrasodium pyrophosphate		Anticaking agent, conditioning agent
Tricalcium phosphate		Surfactant, suspending agent, dispersing agent, anticaking agent, conditioning agent
1,1,1-Trichloroethane		Solvent, cosolvent
Trichlorofluoromethane		Propellant
Tridecylpoly(oxyethylene) acetate, sodium salt; where the ethylene oxide content averages 6-7 moles.		Surfactants, related adjuvants of surfactants

Inert ingredients	Limits	Uses
Trisodium phosphate		Surfactant, emulsifier, wetting agent
Vermiculite		Solid diluent, carrier.
Walnut shells		Leaching inhibitor, binder for water-dispersible aggregates, sticker and suspension stabilizer
Wheat, including flour, bran, and starch	Expires May 24, 2005.	Solid diluent carrier, attractant
Wheat bran		Do.
Wintergreen oil		Attractant
Wood flour	Derived from wood free of chemical preservatives.	Solid diluent and carrier
Xanthan gum-modified, produced by the reaction of xanthan gum and glyoxal (maximum 0.3% by weight).	Not more than 0.5% of pesticide formulation.	Surfactant
Xylene meeting the specifications listed in 21 CFR 172.884(b)(4).	In pesticide formulations for grain storage only.	Solvent, cosolvent
Zeolite (hydrated alkali aluminum silicate)		Solid diluent, carrier
Zinc oxide		Coating agent
Zinc sulfate (basic and monohydrate)		Do.
Zinc sulfate (basic and monohydrate)		Solid diluent, carrier

■ 10. Section 180.920 is added to subpart D to read as follows:

§ 180.920 Inert ingredients used pre-harvest; exemptions from the requirement of a tolerance.

The following materials are exempted from the requirement of a tolerance

when used in accordance with good agricultural practice as inert (or occasionally active) ingredients in pesticide formulations applied to growing crops only:

Inert ingredients	Limits	Uses
Acetonitrile	Not more than 0.5% of pesticide formulation.	Solvent for blended emulsifiers in all pesticides used before crop emerges from soil and in herbicides before or after crop emerges
Acetophenone		Attractant
Adenosine (CAS Reg. No. 58–61–7)	Maximum of 0.5% of formulation.	Synergist
Alder bark		Seed germination stimulator
α -Alkyl (C ₁₂ -C ₁₈)- ω -hydroxypoly(oxyethylene) copolymers with poly(oxypropylene); polyoxyethylene content averages 3-12 moles and polyoxypropylene content 2-9 moles.		Surfactants, related adjuvants of surfactants
α -Alkyl (C ₁₀ -C ₁₆)- ω -hydroxypoly(oxyethylene) mixture of dihydrogen phosphate and monohydrogen phosphate esters and the corresponding ammonium, calcium, magnesium, monoethanolamine, potassium, sodium, and zinc salts of the phosphate esters; the poly(oxyethylene) content averages 3-20 moles.		Surfactants, related adjuvants of surfactants
α -Alkyl (C ₁₂ -C ₁₅)- ω -hydroxypoly(oxyethylene) sulfosuccinate, isopropylamine and <i>N</i> -hydroxyethyl isopropylamine salts of; the poly(oxyethylene) content averages 3-12 moles.	Not more than 0.2% in the final solution.	Emulsifiers in pesticide concentrates applied with liquid fertilizer solutions before crop emerges from soil or not later than 4 weeks after planting
α -Alkyl(C ₁₀ -C ₁₂)- ω -hydroxypoly(oxyethylene) poly(oxypropylene) copolymer; poly(oxyethylene) content is 11-15 moles; poly(oxypropylene) content is 1-3 moles.		Surfactants, related adjuvants of surfactants.
α -Alkyl(C ₁₂ -C ₁₈)- ω -hydroxypoly(oxyethylene)/oxypropylene) hetero polymer in which the oxyethylene content averages 13-17 moles and the oxypropylene content averages 2-6 moles.		Do.
α -Alkyl (C ₁₀ -C ₁₆)- ω -hydroxypoly (oxyethylene)poly(oxypropylene) mixture of di- and monohydrogen phosphate esters and the corresponding ammonium, calcium, magnesium, monoethanolamine, potassium, sodium, and zinc salts of the phosphate esters; the combined poly(oxyethylene) poly(oxypropylene) content averages 3-20 moles.		Do.
α -Alkyl (C ₁₂ -C ₁₈)- ω -hydroxypoly(oxyethylene)/oxypropylene) hetero polymer in which the oxyethylene content is 8-12 moles and the oxypropylene content is 3-7 moles.		Do.

Inert ingredients	Limits	Uses
α -Alkyl (C ₁₂ -C ₁₅)- ω -hydroxypoly(oxyethylene/oxypropylene) hetero polymer in which the oxyethylene content is 8-13 moles and the oxypropylene content is 7-30 moles.		Solvent, cosolvent, surfactant, and related adjuvants of surfactants
α -Alkyl (C ₂₁ -C ₇₁)- ω -hydroxypoly (oxyethylene) in which the poly(oxyethylene) content is 2 to 91 moles and molecular weight range from 390 to 5,000.	Not to exceed 10%	Wetting agent or granule coating
<i>n</i> -Alkyl(C ₈ -C ₁₈)amine acetate		Surfactants, related adjuvants of surfactants
Almond, bitter		Attractant
Aluminum 2-ethylhexanoate	Not more than 0.25% of pesticide formulation.	Gelling agent
Aluminum sulfate		Safener adjuvant
Amine salts of alkyl(C ₈ -C ₂₄) benzenesulfonic acid (butylamine, dimethylaminopropylamine, mono- and diisopropylamine, mono-, di-, and triethanolamine).		Surfactants, related adjuvants of surfactants
<i>N</i> -(Aminoethyl) ethanalamine salt of dodecylbenzenesulfonic acid.	For use only in liquid emulsifiable herbicide concentrates.	Do.
Ammonium nitrate (CAS Reg. No. 6484-52-2)		Adjuvant/ intensifier for herbicides
Ammonium polyphosphate (CAS Reg. No. 68333-79-9).		Sequestrant, buffer, or surfactant
Ammonium thiocyanate		Adjuvant/intensifier for defoliation of, and weed control in/on cotton and soybeans
Animal waste material (produced by the thermophilic digestion of cattle and poultry manure).	<i>E. coli</i> and <i>Salmonella</i> free; heavy metal content not to exceed the following: Material/Concentration (ppm): As/12.5; Cd/12.0; Cu/14.0; Pb/17.0; Hg/0.1; Se/0.2.	Carrier
Barium sulfate		Carrier
1,2-Benzisothiazolin-3-one	Not more than 0.1% of formulation. Not more than 0.02 lb to be applied per acre.	Preservative/stabilizer
<i>N,N</i> -Bis[α -ethyl- ω -hydroxypoly(oxyethylene) alkylamine; the poly(oxyethylene) content averages 3 moles; the alkyl groups (C ₁₄ -C ₁₈) are derived from tallow, or from soybean or cottonseed oil acids.		Surfactants for preemergence use with herbicides on sugarcane only
<i>N,N</i> -Bis(2-hydroxyethyl)alkylamine, where the alkyl groups (C ₈ -C ₁₈) are derived from coconut, cottonseed, soya, or tallow acids.		Surfactants, related adjuvants of surfactants
<i>N,N</i> -Bis 2-(ω -hydroxypolyoxyethylene) ethyl) alkylamine; the reaction product of 1 mole <i>N,N</i> -bis(2-hydroxyethyl)alkylamine and 3-60 moles of ethylene oxide, where the alkyl group (C ₈ -C ₁₈) is derived from coconut, cottonseed, soya, or tallow acids.		Do.
<i>N,N</i> -Bis-2-(ω -hydroxypolyoxyethylene/polyoxypropylene) ethyl alkylamine; the reaction product of 1 mole of <i>N,N</i> -bis(2-hydroxyethyl alkylamine) and 3-60 moles of ethylene oxide and propylene oxide, where the alkyl group (C ₈ -C ₁₈) is derived from coconut, cottonseed, soya, or tallow acids.		Surfactant, related adjuvants of surfactants
Boric acid		Sequestrant
Buffalo gourd root powder (<i>Cucurbita foetidissima</i> root powder); or, Zucchini juice (<i>Cucurbita pepo</i> juice) or Hawkesbury melon <i>Citrullus lanatus</i> ..	No more than 2.5 lbs/acre/season (3.4 gm/acre/season of Cucurbitacin).	Gustatory stimulant
Butoxytriethylene glycol phosphate		Surfactants for arsenical herbicide formulations only
1,3-Butylene glycol dimethacrylate	Not more than 0.1% of pesticide formulation.	Stabilizer
Butyl stearate		Defoamer
γ -Butyrolactone		Solvent
C.I. Pigment Blue #15 (CAS Reg. No. 147-14-8; containing no more than 50 ppm polychlorinated biphenyls (PCBs)).	For seed treatment use only	Dye, coloring agent
C.I. Pigment Green #7 (CAS Reg. No. 1328-53-6; containing no more than 50 ppm polychlorinated biphenyls (PCBs)).	For seed treatment use only	Dye, coloring agent
C.I. Pigment Violet #23 (CAS Reg. No. 6358-30-1; containing no more than 20 ppb of polychlorinated dibenzo- <i>p</i> -dioxins and/or polychlorinated dibenzofurans).	For seed treatment use only	Dye, coloring agent

Inert ingredients	Limits	Uses
Calcium and sodium salts of certain sulfonated petroleum fractions (mahogany soaps); calcium salt molecular weight (in amu) 790-1,020, sodium salt molecular weight (in amu) 400-500.		Surfactants, related adjuvants of surfactants
Camphor (CAS Reg. No. 76-22-2)	Not more than 5% weight to weight (w/w) of pesticide formulations.	Deodorant, melting point adjustment
Carous chloride	10 ppm in formulation	Tagging agent
Carrageenan, conforming to 21 CFR 172.260	Not more than 0.15% of pesticide formulation.	Thickener and stabilizer for pesticide formulations applied to seeds before planting
Chlorobenzene	Contains not more than 1% impurities. Not for use after edible parts of plant begin to form. Do not graze livestock in treated areas within 48 hours after application.	Solvent, cosolvent
5-Chloro-2-methyl-4-isothiazolin-3-one (in combination with 2-methyl-4-isothiazolin-3-one).	Not more than 0.0022% (22.5 ppm) in the formulation; 0.00022% (or 2.25 ppm) in the final solution applied to growing crops.	Preservative
Condensation product of orthophenylphenol with 5 moles of ethylene oxide.		Stabilizer.
Copper naphthenate	Not more than 2.5% of formulation; application limited to before edible portions of plants begin to form.	Mercaptan scavenger in technical pesticide
Copper salts of neodecanoic acid and 2-ethylhexanoic acid.	Not more than 1% of formulation; application limited to before edible portions of plants begin to form.	Do.
Cyclohexane		Solvent, cosolvent
Cyclohexanol		Do.
Cyclohexanone		Do.
Cysteine (CAS Reg. No. 52-90-4)	Maximum of 0.5% of formulation.	Synergist
D&C Green No. 6		Dye
D&C Red No. 17, technical grade		Dye
D&C Red No. 33 (CAS Reg. No. 3567-66-6); meeting the specifications listed in 21 CFR 74.1333.		Dye
D&C Violet No. 2, technical grade	Not more than 0.005% of pesticide formulation.	Dye
n-Decyl alcohol		Do.
Diacetone alcohol		Deactivator, solvent for formulations used before crop emerges from soil
Diallyl phthalate	Not more than 0.1% of pesticide formulation.	Stabilizer
Diammonium phosphate (CAS Reg. No. 7783-28-0) ..		Buffer, surfactant
α -(Di-sec-butyl)phenylpoly(oxypropylene) block polymer with poly(oxyethylene); the poly(oxypropylene) content averages 4 moles, the poly(oxyethylene) content averages 5 to 12 moles, the molecular.		Surfactants, related adjuvants of surfactants
Diethanolamine		Stabilizer, inhibitor for formulations used before crop emerges from soil
Diethylene glycol		Deactivator, adjuvant for formulations used before crop emerges from soil
Diethylene glycol and diethylene glycol monobutyl, monoethyl, and monomethyl ethers.		Deactivator for formulations used before crop emerges from soil, stabilizer
3,6-Dimethyl-4-octyn-3,6-diol	In pesticide formulations, for soil prior to planting or to plants before edible parts form.	Surfactants, related adjuvants of surfactants
Dimethyl sulfoxide		Solvent or cosolvent for formulations used before crop emerges from soil or prior to formation of edible parts of food plants
Dipotassium hydrogen phosphate		Buffering agent
Dipropylene glycol dibenzoate	For seed treatment use only	Solvent, cosolvent
Dipropylene glycol monomethyl ether		Stabilizer
Disodium 4-isodecyl sulfosuccinate		Surfactants related adjuvants of surfactants.
Dodecylphenol		Coupling agent in emulsifier

Inert ingredients	Limits	Uses
α -Dodecylphenol- ω -hydroxypoly(oxyethylene/oxypropylene) hetero polymer where ethylene oxide content is 11-13 moles and oxypropylene content is 14-16 moles, molecular weight (in amu) averages 600 to 965.		Surfactants, related adjuvants of surfactants
Douglas-fir bark, ground		Solid diluent, carrier
Dysprosium chloride	10 ppm in formulation	Tagging agent
Ethylene glycol		Antifreeze, deactivator for all pesticides used before crop emerges from soil and in herbicides before or after crop emerges
Ethylene glycol monobutyl ether		Solvent for formulations used before crop emerges from soil
Ethylene glycol monomethyl ether		Cosolvent, defoamer, solvent for all pesticides used before crop emerges from soil and in herbicides before or after crop emerges
2-Ethylhexanol		Surfactants, related adjuvants of surfactants
Ethyl methacrylate		Tagging agent
Europic chloride	10 ppm in formulation	Dye, coloring agent
FD&C Red No. 40 (CAS Reg. No. 25956-17-6)	For seed treatment use only. Not to exceed 2% by weight of the pesticide formulation.	
Ferric chloride		Not greater than 2% of suspending, dispersing agent, pesticide formulation
Fluorapatite		Solid diluent, carrier
Folic acid (CAS Reg. No. 59-30-3)	Maximum of 0.5% of formulation.	Synergist
Furfural byproduct (a granular steam-acid sterilized, lignocellulosic residuum in the extraction of furfural from corn cobs, sugarcane bagasse, cottonseed hulls, oat hulls, and rice hulls).		Solid diluent, carrier
Gluconic acid (and sodium salt)		Sequestrant
L-Glutamic acid (C ₅ H ₉ NO ₄ CAS Reg. No. 56-86-0)	Seed treatment use only	Plant nutrient
Glutamine (CAS Reg. No. 56-85-9)	Maximum of 0.5% of formulation.	Synergist
Glycerol—propylene oxide polymer (CAS Reg. No. 25791-96-2).		Component in water-soluble film
Glyceryl triacetate		Stabilizer
Glyceryl tris-12-hydroxystearate		Flow control agent
Graphite		Treatment aid for seeds
Hexamethylenetetramine		Stabilizer for carriers in solid pesticide formulations
2-Hydroxy-4- <i>n</i> -octoxybenzophenone (CAS Reg. No. 1843-05-6).	Not more than 0.2 pt of pesticide formulation.	Light stabilizer
Hydroxypropyl guar gum		Thickener
Isoamyl acetate	Not more than 0.5% of pesticide formulation.	Odor-masking agent
Isobornyl acetate		Solvent
Isobutyl alcohol		Do.
Isobutylene-butene copolymers	For soil application only	Binder
Isooctadecanol	Not more than 2% of pesticide formulation.	Defoaming agent
Isophorone (CAS Reg. No. 78-59-1)		Solvent, cosolvent
Isopropylbenzene		Solvent, cosolvent
Isopropylbenzenesulfonic acid and its ammonium, calcium, magnesium, potassium, sodium, and zinc salts.		Surfactants and related adjuvants of surfactants
Lanthanum chloride	10 ppm in formulation	Tagging agent.
(3-Lauramidopropyl) trimethylammonium methyl sulfate.	Not more than 2.6% in the formulation. Not to be applied within 7 days of harvest.	Antistatic agent
Linoleic diethanolamide (CAS Reg. No. 56863-02-6)		Surfactant
Magnesium nitrate (in combination with 2-methyl-4-isothiazolin-3-one and 5-chloro-2-methyl-4-isothiazolin-3-one).	None	Preservation
Maleic acid and maleic anhydride	For pesticide formulations applied to apples with a minimum preharvest interval of 21 days.	Stabilizer
Manganese carbonate		Plant nutrient
Mesityl oxide	Not for use after edible parts of plant begin to form. Do not graze livestock in treated areas within 48 hours after application.	Solvent, cosolvent

Inert ingredients	Limits	Uses
Methionine (CAS Reg. No. 59–51–8)	Maximum of 0.5% of formulation.	Synergist
Methyl alcohol		Do.
Methyl bis(2-hydroxyethyl)alkyl ammonium chloride, where the carbon chain (C ₈ -C ₁₈) is derived from coconut, cottonseed, soya, or tallow acids.		Surfactant
α,α' -[Methylenebis]-4-(1,1,3,3-tetramethylbutyl)-o-phenylene bis[ω -hydroxypoly(oxyethylene)] having 6-7.5 moles of ethylene oxide per hydroxyl group.		Solvent, cosolvent, surfactant, and related adjuvants of surfactants
Methylene blue		Dye for formulations used on cotton
Methyl ethyl ketone		Surfactant
Methyl <i>p</i> -hydroxybenzoate		Preservative for formulations
Methyl isoamyl ketone		Solvent, cosolvent
Methyl isobutyl ketone		Do.
2-Methyl-4-isothiazolin-3-one (in combination with 5-chloro-2-methyl-4-isothiazolin-3-one).	Not more than 0.0022% (22.5 ppm) in the formulation; 0.00022% (or 2.25 ppm) in the final solution applied to growing crops.	Preservative
Methyl methacrylate		Surfactants, related adjuvants of surfactants
Methylnaphthalenesulfonic acid—formaldehyde condensate, sodium salt.		Dispersant
Methyl oleate		Surfactant
2-Methyl-2,4-pentanediol		Solvent for formulations used before crop emerges from soil
Methyl poly(oxyethylene) alkyl ammonium chloride, where the poly(oxyethylene) content is 3-15 moles and the alkyl group (C ₈ -C ₁₈) is derived from coconut, cottonseed, soya, or tallow acids.		Surfactant
<i>N</i> -Methylpyrrolidone (CAS Reg. No. 872-504)		Solvent, cosolvent
Methyl violet 2B		Dye
Mixed phytosterols (consisting of campesterol, sitosterol and stigmasterol, with minor amounts of associated plant sterols) derived from edible vegetable oils.		Surfactant.
Mono- and bis-(1 <i>H</i> , 1 <i>H</i> , 2 <i>H</i> , 2 <i>H</i> -perfluoroalkyl) phosphates where the alkyl group is even numbered and in the C ₆ -C ₁₂ range.	Not more than 0.5% of pesticide formulation.	Defoaming agent
Mono- and dialkyl (C ₈ -C ₁₈) methylated ammonium chloride compounds, where the alkyl group(s) (C ₈ -C ₁₈) are derived from coconut, cottonseed, soya, tallow, or hogfat fatty acids.		Surfactants, related adjuvants of surfactants
Morpholine salt of dodecylbenzenesulfonic acid		Do.
Naphthalenesulfonic acid-formaldehyde condensate, ammonium and sodium salts.		Do.
Nicotinamide (CAS Reg. No. 98–92–0)	Maximum of 0.5% of formulation.	Synergist
α -(<i>p</i> -Nonylphenyl)- ω -hydroxypoly(oxyethylene); produced by the condensation of 1 mole of nonylphenol (nonyl group is a propylene trimer isomer) with an average of 4-14 or 30-100 moles of ethylene oxide; if a blend of products is used, the average number of moles of ethylene oxide reacted to produce any product that is a component of the blend shall be in the range 4-14 or 30-100.		Surfactant
X-(<i>p</i> - Nonylphenyl)- ω -hydroxy-poly(oxyethylene) sulfosuccinate isopropylamine and <i>N</i> -hydroxyethyl isopropylamine salts of: the poly(oxyethylene) content averages <i>r</i> moles.	Not more than 0.2% in the final solution.	Emulsifiers in pesticide concentrates applied with liquid fertilizer solutions before crop emerges from soil or not later than 4 weeks after planting
<i>n</i> - Octyl alcohol		Solvent, cosolvent
α -Oleoyl- ω -(oleoyloxy) poly(oxyethylene) derived from α -hydro- ω -hydroxypoly(oxyethylene) (molecular weight 600 amu).		Component of defoamers
Oxo-decyl acetate (CAS reg. No. 108419–33–6)		Solvent
Oxo-heptyl acetate (CAS Reg. No. 90438–79–2)		Solvent
Oxo-hexyl acetate (CAS Reg. No. 88230–35–7)		Solvent
Oxo-nonyl acetate (CAS Reg. No. 108419–34–7)		Solvent
Oxo-octyl acetate (CAS Reg. No. 108419–32–5)		Solvent
Oxo-tridecyl acetate (CAS Reg. No. 108419–35–8)		Solvent
Paraformaldehyde	Not more than 2% of pesticide formulation.	Preservative for formulation
Partial sodium salt of <i>N</i> - lauryl- α -iminodipropionic acid	Not more than 1% of pesticide formulation.	Surfactants, related adjuvants of surfactants
Phenol		Solvent, cosolvent

Inert ingredients	Limits	Uses
Phenolic resins	Soil applications	Binding agent
Phenolsulfonic acid—formaldehyde—urea condensate and its sodium salt.	Applied to growing plants only	Dispersant surfactant
(Phthalocyaninato (2)) copper; (C.I. pigment blue No. 15).	When used as a colorant in low-density plastic films.	Coloring agent, pigment
Pigment red 48	For seed treatment use only	Dye
α -Pinene	Not more than 2% of formulation by weight.	Stabilizer
Poly(methylene- <i>p</i> -nonylphenoxy)poly(oxypropylene) propanol; the poly(oxy-propylene) content averages 4-12 moles.		Encapsulating agent
Poly(oxyethylene) adducts of mixed phytosterols (such sterols to consist of campesterol, stigmasterol and sitosterol with minor amounts of associated plant sterols) derived from edible vegetable oils; polyoxyethylene content averaging 5-26 moles.		Surfactant, related adjuvants
Poly(oxyethylene) (5) sorbitan monooleate		Surfactants, related adjuvants of surfactants
Polysorbate 60, conforming to 21 CFR 172.836		Surfactant
Potassium carbonate		Buffering agent
Potassium dihydrogen phosphate		Do.
Primary <i>n</i> -alkylamines, where the alkyl group (C ₈ -C ₁₈) is derived from coconut, cottonseed, soya, or tallow acids.		Surfactant
Propylene dichloride		Solvent for formulations used before crop emerges from soil
Propylene glycol monomethyl ether		Solvent
Pyridoxine (CAS Reg. No. 65-23-6)	Maximum of 0.5% of formulation.	Synergist
Rosin, dark wood (as defined in 21 CFR 178.3870(a)(1)(v)).		Surfactants, related adjuvants of surfactants
Rosin, gum		Do.
Rosin, tall oil		Do.
Scandium chloride	10 ppm in formulation	Tagging agent
Sodium bisulfate (CAS Reg. No. 7681-38-1)		Acidifying/buffering agent
Sodium butyl naphthalenesulfonate		Surfactants, related adjuvants of surfactants
Sodium caseinate	Expires May 24, 2005.	Suspending agent and binder
Sodium 1,4-dicyclohexyl sulfosuccinate		Surfactants, related adjuvants of surfactants
Sodium 1,4-dihexyl sulfosuccinate		Do.
Sodium dihydrogen phosphate (CAS Reg. No. 7558-80-7) conforming to 21 CFR 182.6778.		Buffering agent
Sodium 1,4-diisobutyl sulfosuccinate		Surfactants, related adjuvants of surfactants
Sodium 1,4-dipentyl sulfosuccinate		Do.
Sodium 1,4-ditridecyl sulfosuccinate		Do.
Sodium fluoride	Not more than 0.25% of pesticide formulation.	Stabilizer carrier for formulations used before crop emerges from soil
Sodium metaborate		Sequestrant
Sodium molybdate		Plant nutrient
Sodium mono- and dimethyl naphthalenesulfonate; molecular weight (in amu) 245-260.		Surfactants, related adjuvants of surfactants
Sodium nitrate		Solid diluent
Sodium nitrite	Not more than 3% of pesticide formulation.	Stabilizer, inhibitor.
Sodium <i>o</i> -phenylphenate	Not more than 0.1% of pesticide formulation.	Preservative for formulation
Sodium salt of the insoluble fraction of rosin		Surfactants, related adjuvants of surfactants
Sodium salt of partially or completely saponified dark wood rosin (as defined in 21 CFR 178.3870(a)(4)).		Surfactants, related adjuvants of surfactants
Sodium tetraborate	Not more than 2% of pesticide formulation.	Buffering agent; corrosion inhibitor
Sulfosuccinic acid ester with <i>N</i> -(2-hydroxy-propyl) oleamide, ammonia and isopropylamine salts of.	Not more than 0.2% in the final solution.	Emulsifiers in pesticide concentrates applied with liquid fertilizer solutions before crop emerges from soil or not later than 4 weeks after planting
Tall oil diesters with polypropylene glycol (CAS Reg. No. 68648-12-4).		Component in water-soluble film
Tannin		Dispersing agent
Tertiary butylhydroquinone		Antioxidant
1-Tetradecanamine, <i>N,N</i> -dimethyl-, <i>N</i> -oxide (CAS Reg. No. 3332-27-2).		Component in water-soluble film
<i>N,N,N',N'</i> -Tetrakis-(2-hydroxypropyl) ethylenediamine		Stabilizer for formulations used before crop emerges from soil

Inert ingredients	Limits	Uses
α -[<i>p</i> -(1,1,3,3-Tetramethylbutyl)phenyl]- ω -hydroxypoly(oxyethylene) mixture of dihydrogen phosphate and monohydrogen phosphate esters and the corresponding sodium salts of the phosphate esters; the poly(oxyethylene) content averages 6 to 10 moles.		Surfactants, related adjuvants of surfactants
2,4,7,9-Tetramethyl-5-decyne 4,7-diol	In pesticide formulations, for application to soil prior to planting or to plants before edible parts form.	Do.
Tetrapotassium pyrophosphate (CAS Reg. No. 7320–345).	Not to exceed 10% of formulation.	Sequestrant, anticaking agent, conditioning agent
Tetrasodium <i>N</i> -(1,2-dicarboxyethyl)- <i>N</i> -octadecyl-sulfosuccinamate.		Do.
[2,2'-(2,5-Thiophenediyl) bis (5- <i>tert</i> -butylbenzoxazole)] (CAS Reg. Number 7128–64–5).	10 ppm in pesticide formulations.	Quality control agent
Titanium dioxide (CAS Reg. No. 13463–67–7)		Pigment/coloring agent in plastic bags used to wrap growing banana (preharvest), colorant on seeds for planting
Toluene		Solvent, cosolvent
Toluenesulfonic acid and its ammonium, calcium, magnesium, potassium, sodium, and zinc salts.		Do.
Tri- <i>tert</i> -butylphenol polyglycol ether (molecular weight (in amu) 746).		Surfactant for formulations used before crop emerges from soil
Triethanolamine		Stabilizer, inhibitor for formulations used before crop emerges from soil
Triethylene glycol		Deactivator
Triethyl phosphate		Stabilizer for formulations used before crop emerges from soil
Trimethylolpropane (CAS Reg. No. 77–66–9)	Not more than 15% of the pesticide formulation.	Component of water-soluble film
Trimethylolpropane (CAS Reg. No. 77–99–6)	Not to exceed 15% by weight of the film.	Component in water-soluble film
α -[2,4,6-Tris[1-(phenyl)ethyl]phenyl]- ω -hydroxy poly(oxyethylene), the poly(oxyethylene) content averages 4-150 moles).	Not more than 15% of the formulation.	Surfactant.
α -[2,4,6-Tris[1-(phenyl)ethyl]phenyl]- ω -hydroxy poly(oxyethylene); mixture of monohydrogen and dihydrogen phosphate esters and the corresponding ammonium, calcium, magnesium, potassium, sodium, and zinc salts, the poly(oxyethylene) content averages 4-150 moles).	Not more than 15% of the formulation.	Do.
α -[2,4,6-Tris[1-(phenyl)ethyl]phenyl]- ω -hydroxy poly(oxyethylene) sulfate, and the corresponding ammonium, calcium, magnesium, potassium, sodium, and zinc salts, the poly(oxyethylene) content averages 4-150 moles.	Not more than 15% of the pesticide formulation.	Do.
Tryptophan (CAS Reg. No. 73–22–3)	Maximum of 0.5% of formulation.	Synergist
Valeric acid, normal	Not more than 2% in pesticide formulations.	Stenching agent or odorant
Vanillin		Attractant
Woolwax alcohols		Safener
Xylene		Solvent, cosolvent
Xylenesulfonic acid its ammonium calcium, magnesium, potassium, sodium, and zinc salts.		Surfactants, related adjuvants of surfactants
Yucca extract from <i>Yucca schidigera</i>		Wetting agent
Ytterbium chloride	10 ppm in formulation	Tagging agent
Yttrium chloride	10 ppm in formulation	Tagging agent
Zinc orthophosphate		Plant nutrient and safener
Zinc stearate, conforming to 21 CFR 182.5994 and 582.5994.		Flow control agent

■ 11. Section 180.930 is added to subpart D to read as follows:

§ 180.930 Inert ingredients applied to animals; exemptions from the requirement of a tolerance.

The following materials are exempted from the requirement of a tolerance

when used in accordance with good agricultural practice as inert (or occasionally active) ingredients in pesticide formulations applied to animals:

Inert ingredients	Limits	Uses
Acetic acid (CAS Reg. No. 64–19–7)	Not more than 0.5% of pesticide formulation.	Catalyst
Acetic anhydride		Solvent, cosolvent, stabilizer
Acetyl tributyl citrate (CAS Reg. No. 77–90–7)		Component of plastic animal tags
Acetylated lanolin alcohol		Moisturizer
Alkanoic and alkenoic acids, mono- and diesters of α -hydro- ω -hydroxypoly(oxyethylene) with molecular weight (in amu) range of 200 to 6,000.		Emulsifiers
Alkyl (C ₈ -C ₂₄) benzenesulfonic acid and its ammonium, calcium, magnesium, potassium, sodium, and zinc salts.		Surfactants, emulsifier, related adjuvants of surfactants
α -Alkyl (C ₉ -C ₁₈)- ω -hydroxy poly(oxyethylene): the poly(oxyethylene) content averages 2-20 moles.		Solvent, cosolvent, surfactant, and related adjuvants of surfactants
α -Alkyl (C ₁₂ -C ₁₅)- ω -hydroxypoly(oxyethylene/oxypropylene) hetero polymer in which the oxyethylene content is 8-13 moles and the oxypropylene content is 7-30 moles.		Solvent, cosolvent, surfactant, and related adjuvants of surfactants
α -Alkyl (C ₈ -C ₁₀) hydroxypoly(oxypropylene) block polymer with polyoxyethylene; polyoxypropylene content averages 3 moles and polyoxyethylene content averages 5-12 moles.		Do.
α -Alkyl (C ₆ -C ₁₄)- ω -hydroxypoly(oxypropylene) block copolymer with polyoxyethylene; polyoxypropylene content is 1-3 moles; polyoxyethylene content is 7-9 moles; average molecular weight (in amu) approximately 635.		Surfactants, related adjuvants of surfactants
α -alkyl (C ₁₂ -C ₁₅)- ω -hydroxypoly (oxypropylene)poly (oxyethylene)copolymers (where the poly(oxypropylene) content is 3-60 moles and the poly(oxyethylene) content is 5-80 moles), the resulting ethoxylated propoxylated (C ₁₂ -C ₁₅) alcohols having a minimum molecular weight (in amu) of 1,500, CAS Reg. No. 68551–13–3.	Not to exceed 20% of pesticide formulations	Surfactant
α -(<i>p</i> - Alkylphenyl)- ω -hydroxypoly (oxyethylene) produced by the condensation of 1 mole of alkylphenol (alkyl is a mixture of propylene tetramer and pentamer isomers and averages C ₁₃) with 6 moles of ethylene oxide.		Do.
Alkyl (C ₈ -C ₁₈) sulfate and its ammonium, calcium, magnesium, potassium, sodium, and zinc salts.		Do.
Amine salts of alkyl (C ₈ -C ₂₄) benzenesulfonic acid (butylamine; dimethylamino propylamine; mono- and diisopropyl- amine; and mono-, di-, and triethanolamine).		Do.
Ascorbyl palmitate		Preservative
Attapulgate-type clay		Solid diluent, carrier
Barium sulfate (CAS Reg. No. 7727–43–7)		Carrier, density control agent
Benzoic acid		Preservative for formulations
Butane		Propellant
<i>n</i> -Butanol (CAS Reg. No. 71–36–3)		Solvent for blended emulsifiers
Butylated hydroxyanisole		Antioxidant
Butylated hydroxytoluene		Do.
α -(<i>p</i> - <i>tert</i> - Butylphenyl)- ω -hydroxypoly (oxyethylene) mixture of dihydrogen phosphate and monohydrogen phosphate esters and the corresponding ammonium, calcium, magnesium, monoethanolamine, potassium, sodium, and zinc salts of the phosphate esters; the poly(oxyethylene) content averages 4-12 moles.		Surfactants, related adjuvants of surfactants
Calcium carbonate		Solid diluent, carrier
Calcium chloride		Stabilizer
Calcium silicate, hydrated calcium silicate		Anticaking agent, solid diluent, carrier
Calcium stearate (CAS Reg. No. 1592–23–0)		Stabilizer, component of plastic animal tag
Calcium sulfate		Solid diluent, carrier
Calcium and sodium salts of certain sulfonated petroleum fractions (mahogany soaps); calcium salt molecular weight (in amu) 790-1,020, sodium salt molecular weight (in amu) 400-500.		Surfactants, related adjuvants of surfactants
Carbon black (CAS Reg. No. 1333–86–4)		Colorant/pigment in animal tag
Carnauba wax (CAS Reg. No. 8015–86–9)		Binder
Carrageenan, conforming to 21 CFR 172.620	Minimum molecular weight (in amu): 100,000.	Thickener
Cumene (isopropylbenzene)		Solvent, cosolvent
Cyclohexanone		Do.

Inert ingredients	Limits	Uses
D&C Green No. 6		Dye, coloring agent
D&C Red No. 17		Do.
D&C Violet No. 2		Do.
Diacetyl tartaric acid esters of mono- and diglycerides of edible fatty acids.		Emulsifier
Dialkyl (C ₈ -C ₁₈) dimethylammonium chloride	Not more than 0.2% in silica hydrated silica.	Flocculating agent in the manufacture of silica hydrated silica for use as a solid diluent, carrier
Diatomite (diatomaceous earth)		Solid diluent, carrier
Dibutyltin dilaurate (CAS Reg. No. 77-58-7)		Component of plastic slow release tag
Dichlorodifluoromethane		Propellant
Diethylphthalate		Solvent, cosolvent
1,1-Difluoroethane (CAS Reg. No. 75-37-6)	For aerosol pesticide formulations used for insect control in food- and feed-handling establishments and animals.	Aerosol propellant
Dimethyl ether (CAS Reg. No. 115-10-6)		Propellant
3,6-Dimethyl-4-octyne-3,6-diol	Not more than 2.5% of pesticide formulation.	Surfactants, related adjuvants of surfactants
Dimethylpolysiloxane (CAS Reg. No. 9016-00-6)		Defoaming agent
α -(<i>o,p</i> -Dinonylphenyl)- ω -hydroxypoly (oxyethylene) mixture of dihydrogen phosphate and monohydrogen phosphate esters and the corresponding ammonium, calcium, magnesium, monoethanolamine, potassium, sodium, and zinc salts of the phosphate esters; the nonyl group is a propylene trimer isomer and the poly(oxyethylene) content averages 4-14 moles.		Surfactants, related adjuvants of surfactants
α -(<i>o,p</i> -Dinonylphenyl)- ω -hydroxypoly (oxyethylene), produced by the condensation of 1 mole of dinonylphenol (nonyl group is a propylene trimer isomer) with an average of 4-14 moles of ethylene oxide.		Do.
Dipropylene glycol monomethyl ether		Do.
Dodecylbenzenesulfonic acid, amine salts		Do.
α -(<i>p</i> -Dodecylphenyl)- ω -hydroxypoly (oxyethylene) produced by the condensation of 1 mole of dodecylphenol (dodecyl group is a propylene tetramer isomer) with an average of 4-14 or 30-70 moles of ethylene oxide; if a blend of products is used, the average number of moles of ethylene oxide reacted to produce any product that is a component of the blend shall be in the range of 4-14 or 30-70 moles.		Surfactants, emulsifier
Epoxidized soybean oil (CAS Reg. No. 8013-07-8)		Stabilizer, plasticizer, component animal tag
Ethyl alcohol		Solvent, cosolvent
Ethylene oxide adducts of 2,4,7,9-tetramethyl-5-decynediol, the ethylene oxide content averages 3.5, 10, or 30 moles.		Surfactants, related adjuvants of surfactants
2-Ethyl-1-hexanol	Not more than 2.5% of pesticide formulation.	Solvent, adjuvant of surfactants
Ethyl vinyl acetate (CAS Reg. No. 24937-78-8)		Component of plastic slow release tag
FD&C Blue No. 1		Dye, coloring agent
FD&C Yellow No. 6 Aluminum Lake (CAS Reg. No. 15790-07-5).	Not more than 2% by weight of pesticide formulation.	Pigment in animal tag and similar slow-release devices
Glycerol (glycerin)	Meets specifications of Food Chemicals Codex.	Solvent and thickener
Glycerol monooleate		Surfactants, related adjuvants of surfactants
Glyceryl monostearate		Emulsifier
Glyceryl tris-12-hydroxystearate		Flow control agent
Graphite		Solid diluent, carrier
<i>n</i> -Hexyl alcohol (CAS Reg. No. 111-27-3)		Solvent, cosolvent
2-(2'-Hydroxy-5'-methylphenyl)benzotriazole (CAS Reg. No. 2440-22-4).	Not more than 0.5% by weight of pesticide formulation.	Ultraviolet light absorber/stabilizer in animal tag and similar slow-release devices
Iron oxide (CAS Reg. No. 1309-37-1)		Colorant in pesticide formulations for animal tags
Isopropyl alcohol		Solvent, cosolvent
4,4'-Isopropylidenediphenol alkyl (C ₁₂ -C ₁₅) phosphites (CAS Reg. No. 92908-32-2).	Not to exceed 1% of polymer ...	Stabilizer, component animal tag
Isopropyl myristate, CAS Reg. No. 110-27-0		Solvent
Kaolinite-type clay		Solid diluent, carrier
Kerosene, U.S.P. reagent		Solvent, cosolvent
Lactic acid		Solvent
α -Lauryl- ω -hydroxypoly(oxyethylene), average molecular weight (in amu) of 600.		Emulsifier

Inert ingredients	Limits	Uses
α -Lauryl- ω -hydroxypoly(oxyethylene) sulfate, sodium salt; the poly(oxyethylene) content is 3-4 moles.		Surfactants, related adjuvants of surfactants
Lignosulfonate: ammonium, calcium, magnesium, potassium, sodium, and zinc salts.		Surfactants, related adjuvants of surfactants
d-Limonene (CAS Reg. No. 5989-27-5)		Solvent, fragrance
Magnesium carbonate		Solid diluent, carrier
Magnesium silicate, hydrated magnesium silicate		Do.
Manganous oxide		Do.
Methyl alcohol		Solvent, cosolvent
Methyl <i>n</i> -amyl ketone (CAS Reg. No. 110-43-0)		Solvent, cosolvent
α -(Methylene (4-(1,1,3,3-tetramethylbutyl)- <i>o</i> -phenylene) bis- ω -hydroxypoly(oxyethylene) having 6-7.5 moles of ethylene oxide per hydroxyl group.		Surfactants, related adjuvants of surfactants
Methyl esters of higher fatty acids conforming to 21 CFR 573.640.		Antidusting agent
Methyl- <i>p</i> -hydroxybenzoate (Methyl paraben)	Meets specifications of Food Chemicals Codex; not to exceed 0.1% in formulations.	Preservative
Methyl isobutyl ketone		Solvent, cosolvent
2-[Methyl [(perfluoroalkyl)alkyl(C ₂ -C ₈)sulfonyl]amino]alkyl(C ₂ -C ₈) acrylate—alkyl(C ₂ -C ₈) methacrylates- <i>N</i> -methylolacrylamide copolymer.		Water repellant agent
Mineral oil, U.S.P., or conforming to 21 CFR 172.878 or 178.3620(a), (b).		Solvent, diluent
Mono-, di-, and trimethylnaphthalenesulfonic acids-formaldehyde condensates, sodium salts.	Not to exceed 0.006% in final formulation.	Dispersing-wetting agent in dip vat operations for large animals, such as cattle
Montmorillonite-type clay		Solid diluent, carrier
Naphthalenesulfonic acid and its sodium salt		Surfactants, related adjuvants of surfactants
Nitrile rubber modified acrylonitrile methylacrylate (CAS Reg. No. 27012-62-0) conforming to 21 CFR 177.1480.		Component of plastic slow release tag
Nonyl, decyl, and undecyl glycoside mixture with a mixture of nonyl, decyl, and undecyl oligosaccharides and related reaction products (primarily decanol and undecanol) produced as an aqueous-based liquid (50 to 65% solids) from the reaction of primary alcohols (containing 15 to 20% secondary alcohol isomers) in a ratio of 20% C ₉ , 40% C ₁₀ , and 40% C ₁₁ with carbohydrates (average glucose to alkyl chain ratio 1.3 to 1.8).		Surfactant
α -(<i>p</i> -Nonylphenyl)- ω -hydroxypoly(oxyethylene) mixture of dihydrogen phosphate and monohydrogen phosphate esters and the corresponding ammonium, calcium, magnesium, monoethanolamine, potassium, sodium, and zinc salts of the phosphate esters; the nonyl group is a propylene trimer isomer and the poly(oxyethylene) content averages 4-14 moles.		Surfactants, related adjuvants of surfactants
α -(<i>p</i> -Nonylphenyl)- ω -hydroxypoly(oxyethylene) produced by the condensation of 1 mole of nonylphenol (nonyl group is a propylene trimer isomer) with an average of 4-15 or 30-90 moles of ethylene oxide; if a blend of products is used, the average number of moles of ethylene oxide reacted to produce any product that is a component of the blend shall be in the range of 4-15 or 30-90 moles.		Surfactants, emulsifier, related adjuvants of surfactants.
α -(<i>p</i> -Nonylphenyl)- ω -hydroxypoly(oxyethylene) sulfate, and its ammonium, calcium, magnesium, potassium, sodium, and zinc salts; the nonyl group is a propylene trimer isomer and the poly(oxyethylene) content averages 4 moles.		Surfactants, related adjuvants of surfactants
α -(<i>p</i> -Nonylphenyl)- ω -hydroxypoly(oxyethylene) sulfate, and its ammonium, calcium, magnesium, monoethanolamine, potassium, sodium, and zinc salts; the nonyl group is a propylene trimer isomer and the poly(oxyethylene) content averages 4-14 or 30-90 moles of ethylene oxide.		Surfactants, related adjuvants of surfactants
Octadecyl 3,5-di- <i>tert</i> -butyl-4-hydroxyhydro cinnamate (CAS Reg. No. 2082-79-3).	Not more than 0.5% by weight of pesticide formulation.	Thermal stabilizer/antioxidant in animal tag and similar slow-release devices
Octyl and decyl glucosides mixture with a mixture of octyl and decyl oligosaccharides and related reaction products (primarily <i>n</i> -decanol) produced as an aqueous-based liquid (68-72% solids) from the reaction of straight chain alcohols (C ₈ (45%), C ₁₀) with anhydrous glucose.		Do.

Inert ingredients	Limits	Uses
Octyl epoxystallate (CAS Reg. No. 61788-72-5)		Plasticizer, component animal tag
Oleic acid, conforming to 21 CFR 172.862 (CAS Reg. No. 112-80-1).		Defoaming agent
α -Oleoyl- ω -hydroxypoly(oxyethylene), average molecular weight (in amu) of 600.		Emulsifier
α -Oleoyl- ω -(oleoyloxy)poly(oxyethylene) derived from α -hydro- ω -hydroxypoly(oxyethylene), molecular weight (in amu) 600.		Emulsifier, defoaming agent
Oxidized pine lignin, sodium salt (CAS Reg. No. 68201-23-0).	Maximum of 2% of formulation	Surfactant, related adjuvant of surfactant
Paraformaldehyde	Not more than 2% of pesticide formulation.	Preservative for formulation
Petroleum hydrocarbons, light, odorless, conforming to 21 CFR 172.884 or 178.3650.		Solvent, diluent
Petroleum hydrocarbons, synthetic isoparaffinic, conforming to 21 CFR 172.882 or 178.3530.		Do.
Phenol		Solvent, cosolvent
Pine lignin		Adsorbent
α -Pinene	Not more than 2% of formulation by weight.	Stabilizer
Polyethylene (CAS Reg. No. 9002-88-4) conforming to 21 CFR 172.615.		Component of plastic slow release tag
Polyethylene esters of fatty acids, conforming to 21 CFR 172.854.		Surfactants, related adjuvants of surfactants
Polyethylene glycol [α -hydro- ω -hydroxypoly(oxyethylene)]; mean molecular weight (in amu) 194 to 9,500 conforms to 21 CFR 178.3750.		Surfactants, related adjuvants of surfactants
Polyglyceryl phthalate esters of coconut oil fatty acids		Do.
Poly(methylene- <i>p</i> - <i>tert</i> -butylphenoxy)poly(oxyethylene) ethanol; the poly(oxyethylene) content averages 4-12 moles.		Do.
Poly(methylene- <i>p</i> -nonylphenoxy)poly(oxyethylene) ethanol; the poly(oxyethylene) content averages 4-12 moles.		Do.
Poly(methylene- <i>p</i> -nonylphenoxy)poly(oxypropylene) propanol; the poly(oxypropylene) content averages 4-12 moles.		Do.
Potassium hydroxide	Meeting Food Chemicals, Codex specifications.	Neutralizer
Propane		Propellant
<i>n</i> -Propanol		Solvent, for blended emulsifiers
2-Propenoic acid, 2-methyl-, polymer with ethyl 2-propenoate and methyl 2-methyl-2-propenoate, ammonium salt (CAS Registration No. 55989-05-4), minimum number average molecular weight (in amu), 18,900.		Encapsulating agent, dispensers, resins, fibers and beads
Propylene glycol		Solvent, cosolvent
Propylene glycol monomethyl ether		Deactivator, emmollient
Propyl gallate		Antioxidant
Propyl <i>p</i> -hydroxybenzoate (Propyl paraben)	Meets specifications of Food Chemicals Codex; not to exceed 0.1% in formulations.	Preservative
Pyrophyllite		Solid diluent, carrier
Rhodamine B	Expires December 27, 2004.	Dye for use in ear tags only
Secondary alkyl (C ₁₁ -C ₁₅) poly(oxyethylene) acetate, sodium salt; the ethylene oxide content averages 5 moles.		Surfactant
Silica, hydrated silica		Anticaking agent, solid diluent, carrier
Silica aerogel (finely powdered microcellular silica foam having a minimum silica content of 89.5%).		Component of antifoaming agent
Soapstone		Solid diluent
Sodium benzoate (CAS Reg. No. 532-32-1)		Anticaking agent/stabilizer/preservative
Sodium butylphenylsulfonate		Not more than 0.5% of pesticide formulation
Sodium diisobutylphenylsulfonate		Surfactants, related adjuvants of surfactants
Sodium dioctylsulfosuccinate		Do.
Sodium hydroxide		Neutralizer
Sodium isopropylisohexylphenylsulfonate		Surfactants, related adjuvants of surfactants
Sodium isopropylphenylsulfonate		Do.
Sodium monoalkyl and dialkyl (C ₈ -C ₁₃) phenoxybenzenedisulfonate mixtures containing not less than 70% of the monoalkylated product.		Do.
Sodium mono- and dimethylphenylsulfonate, molecular weight (in amu) 245-260.		Do.

Inert ingredients	Limits	Uses
Sodium mono-, di-, and tributyl-naphthalenesulfonates		Solvent, cosolvent stabilizer
Sodium <i>N</i> -oleoyl- <i>N</i> -methyl taurine	Not more than 1% of pesticide formulations.	Surfactant
Sodium starch glycolate (CAS Reg. No. 9063–38–1) ..	Granular and tableted products only; not to exceed 8% of the formulated product.	Disintegrant
Sodium sulfate		Solid diluent, carrier
Sorbitan fatty acid esters (fatty acids limited to C ₁₂ , C ₁₄ , C ₁₆ , and C ₁₈ containing minor amounts of associated fatty acids) and poly(oxyethylene) derivatives of sorbitan fatty acid esters; the poly(oxyethylene) content averages 16-20 moles.		Buffering agent; corrosion inhibition
Sorbitol		Antidusting agent.
Soy protein, isolated	Expires May 24, 2005.	Adhesive
Stearic acid (CAS Reg. No. 57–11–4)		Lubricant, component animal tag
α -Stearoyl- ω -hydroxypoly(oxyethylene), average molecular weight (in amu) of 600.		Emulsifier
α -Stearoyl- ω -hydroxypoly(oxyethylene); the poly(oxyethylene) content averages 8, 9, or 40 moles; if a blend of products is used, the average number of moles of ethylene oxide reacted to produce any product that is a component of the blend shall be 8, 9, or 40.		Surfactants; related adjuvants of surfactants
Sulfur (CAS Reg. No. 7704–34–9)		Stabilizer
Talc		Do.
Tall oil; fatty acids not less than 58%, rosin acids not more than 44%, unsaponifiables not more than 8%.		Surfactants, related adjuvants of surfactants
Tartrazine		Dye, coloring agent
α -[<i>p</i> -(1,1,3,3-Tetramethylbutyl)phenyl]- ω -hydroxypoly(oxyethylene) produced by the condensation of 1 mole of <i>p</i> (1,1,3,3-tetramethylbutyl)phenol with a range of 1-14 or 30-70 moles of ethylene oxide: if a blend of products is used, the average range number of moles of ethylene oxide reacted to produce any product that is a component of the blend shall be in the range of 1-14 or 30-70.		Surfactants, related adjuvants of surfactants
α -[<i>p</i> -(1,1,3,3-Tetramethylbutyl)phenyl]- ω -hydroxypoly(oxyethylene) produced by the condensation of 1 mole of <i>p</i> -(1,1,3,3-tetramethylbutyl)phenol with an average of 4-14 or 30-70 moles of ethylene oxide; if a blend of products is used, the average number of moles of ethylene oxide reacted to produce any product that is a component of the blend shall be in the range of 4-14 or 30-70.		Surfactants, related adjuvants of surfactants
2,4,7,9-Tetramethyl-5-decyne-4,7-diol	Not more than 2.5% of pesticide formulation.	Do.
Titanium dioxide (CAS Reg. No. 13463–67–7)		Pigment/colorant in pesticide formulations for animal tag
Toluenesulfonic acid and its ammonium, calcium, magnesium, potassium, sodium, and zinc salts.		Do.
Triacetin (glyceryl triacetate)		Solvent, cosolvent
Tri- <i>tert</i> -butylphenol polyglycol ether (molecular weight (in amu) 746).		Dispersing agent
1,1,1-Trichloroethane		Solvent, cosolvent
Trichlorofluoromethane		Propellant
Tridecylpoly(oxyethylene) acetate sodiums salt; where the ethylene oxide content averages 6-7 moles.		Surfactants, related adjuvants of surfactants
Triethylene glycol diacetate (CAS Reg. No. 111–21–7)	For use on beef cattle only	Solvent
Trisodium phosphate		Precipitant, buffer, filler
Ultramarine blue(CAS Reg. No. 57455–37–5)	Not more than 1.5% of pesticide formulation.	Pigment/colorant in animal tag
Wheat shorts	Expires May 24, 2005.	Solid diluent
Wood rosin acid, potassium salts, conforming to 21 CFR 178.3870.		Surfactants, related adjuvants of surfactants
Xylene		Solvent, cosolvent
Xylenesulfonic acid and its ammonium, calcium, magnesium, potassium, sodium, and zinc salts.		Surfactants, related adjuvants of surfactants
Zinc oxide		Solid diluent, carrier
Zinc stearate, conforming to 21 CFR 182.5994 and 582.5994.		Water repellent, dessicant, and coating agent.
Zinc stearate (CAS Reg. No. 557–05–1)		Water repellent, desiccant, and coating agent; stabilizer, component of plastic animal tag

Inert ingredients	Limits	Uses
Zinc sulfate (basic and monohydrate)		Water repellant, dessicant, and coating agent

■ 12. Section 180.940 is added to subpart D to read as follows:

§ 180.940 Tolerance exemptions for active and inert ingredients for use in antimicrobial formulations (Food-contact surface sanitizing solutions).

Residues of the following chemical substances are exempted from the

requirement of a tolerance when used in accordance with good manufacturing practice as ingredients in an antimicrobial pesticide formulation, provided that the substance is applied on a semi-permanent or permanent food-contact surface (other than being applied on food packaging) with

adequate draining before contact with food.

(a) The following chemical substances when used as ingredients in an antimicrobial pesticide formulation may be applied to: Food-contact surfaces in public eating places, dairy-processing equipment, and food-processing equipment and utensils.

Pesticide Chemical	CAS Reg. No.	Limits
Acetic acid	64–19–7	When ready for use, the end-use concentration is not to exceed 290 ppm
α -Alkyl(C ₁₀ -C ₁₄)- ω -hydroxypoly (oxyethylene) poly(oxypropylene) average molecular weight (in amu), 768 to 837	None	None
α -Alkyl(C ₁₂ -C ₁₈)- ω -hydroxypoly (oxyethylene) poly(oxypropylene) average molecular weight (in amu), 950 to 1120	None	None
Ammonium chloride	12125–02–9	When ready for use, the end-use concentration is not to exceed 48 ppm
Ethanol	64–17–5	None
Ethylenediaminetetraacetic acid (EDTA), tetrasodium salt	64–02–8	None
Hydrogen peroxide	7722–84–1	When ready for use, the end-use concentration is not to exceed 91 ppm
Hypochlorous acid, sodium salt	7681–52–9	When ready for use, the end-use concentration of all hypochlorous acid chemicals in the solution is not to exceed 200 ppm determined as total available chlorine
Iodine	7553–56–2	When ready for use, the total end-use concentration of all iodide-producing chemicals in the solution is not to exceed 25 ppm of titratable iodine
Magnesium oxide	1309–48–4	None
Methylene blue	61–73–4	When ready for use, the end-use concentration is not to exceed 0.4 ppm
α -(p-Nonylphenyl)- ω -hydroxypoly (oxyethylene) average poly(oxyethylene) content 11 moles)	None	None
Octadecanoic acid, calcium salt	1592–23–0	None
1-Octanesulfonic acid, sodium salt	5324–84–5	When ready for use, the end-use concentration is not to exceed 46 ppm
Octanoic acid	124–07–2	When ready for use, the end-use concentration is not to exceed 52 ppm
Oxirane, methyl-, polymer with oxirane, minimum molecular weight (in amu), 1900	9003–11–6	None
Peroxyacetic acid	79–21–0	When ready for use, the end-use concentration is not to exceed 58 ppm
Peroxyoctanoic acid	33734–57–5	When ready for use, the end-use concentration is not to exceed 52 ppm
Phosphonic acid, (1-hydroxyethylidene)bis-	2809–21–4	When ready for use, the end-use concentration is not to exceed 14 ppm
Phosphoric acid, trisodium salt	7601–54–9	When ready for use, the end-use concentration is not to exceed 5916 ppm
Potassium bromide	7758–02–3	When ready for use, the end-use concentration is not to exceed 46 ppm total available halogen
Potassium iodide	7681–11–0	When ready for use, the total end-use concentration of all iodide-producing chemicals in the solution is not to exceed 25 ppm of titratable iodine
Potassium permanganate	7722–64–7	When ready for use, the end-use concentration is not to exceed 0.7 ppm
2-Propanol (isopropanol)	67–63–0	None
Quaternary ammonium compounds, alkyl (C ₁₂ -C ₁₈) benzyl dimethyl, chlorides	8001–54–5	When ready for use, the end-use concentration of all quaternary chemicals in the solution is not to exceed 200 ppm of active quaternary compound
Quaternary ammonium compounds, n-alkyl (C ₁₂ -C ₁₄) dimethyl ethylbenzyl ammonium chloride, average molecular weight (in amu), 377 to 384	None	When ready for use, the end-use concentration of all quaternary chemicals in the solution is not to exceed 200 ppm of active quaternary compound

Pesticide Chemical	CAS Reg. No.	Limits
Quaternary ammonium compounds n-alkyl (C ₁₂ -C ₁₈) dimethyl ethylbenzyl ammonium chloride average molecular weight (in amu) 384	None	When ready for use, the end-use concentration of all quaternary chemicals in the solution is not to exceed 200 ppm of active quaternary compound
Quaternary ammonium compounds di-n-alkyl (C ₈ -C ₁₀) dimethyl ammonium chloride, average molecular weight (in amu), 332 to 361	None	When ready for use, the end-use concentration of this specific quaternary compound is not to exceed 150 ppm of active quaternary compound; the end-use concentration of all quaternary chemicals in the solution is not to exceed 200 ppm of active quaternary compound
Sodium bicarbonate	144-55-8	None
Sulfuric acid monododecyl ester, sodium salt (sodium lauryl sulfate)	151-21-3	When ready for use, the end-use concentration is not to exceed 3 ppm
1,3,5-Triazine-2,4,6-(1H,3H,5H)-trione, 1,3-dichloro-, sodium salt	2893-78-9	When ready for use, the end-use concentration of all di- or trichloroisocyanuric acid chemicals in the solution is not to exceed 100 ppm determined as total available chlorine

(b) The following chemical substances antimicrobial pesticide formulation may equipment, and food-processing when used as ingredients in an be applied to: Dairy processing equipment and utensils.

Pesticide Chemical	CAS Reg. No.	Limits
Acetic acid	64-19-7	When ready for use, the end-use concentration is not to exceed 686 ppm
Acetic acid, chloro-, sodium salt, reaction products with 4,5-dihydro-2-undecyl-1H-imidazole-1-ethanol and sodium hydroxide	68608-66-2	When ready for use, the end-use concentration is not to exceed 42 ppm chloroacetic acid
Benzenesulfonic acid, dodecyl-	27176-87-0	When ready for use, the end-use concentration is not to exceed 5.5 ppm
Butanedioic acid, octenyl-	28805-58-5	When ready for use, the end-use concentration is not to exceed 156 ppm
Butoxy monoether of mixed (ethylene-propylene) polyalkylene glycol, minimum average molecular weight (in amu), 2400	None	None
Calcium chloride	10043-52-4	When ready for use, the end-use concentration is not to exceed 17 ppm
n-Carboxylic acids (C ₆ -C ₁₂), consisting of a mixture of not less than 56% octanoic acid and not less than 40% decanoic acid	None	When ready for use, the end-use concentration is not to exceed 39 ppm
Decanoic acid	334-48-5	When ready for use, the end-use concentration is not to exceed 90 ppm
Ethanesulfonic acid, 2-[cyclohexyl (1-oxohexadecyl) amino]-, sodium salt	132-43-4	When ready for use, the end-use concentration is not to exceed 237 ppm
Ethylenediaminetetraacetic acid (EDTA), disodium salt	139-33-3	When ready for use, the end-use concentration is not to exceed 1400 ppm
FD&C Yellow No. 5 (Tartrazine) (conforming to 21 CFR 74.705)	1934-21-0	None
D-Gluconic acid, monosodium salt	527-07-1	When ready for use, the end-use concentration is not to exceed 760 ppm
Hydriodic acid	10034-85-2	When ready for use, the total end-use concentration of all iodide-producing chemicals is not to exceed 25 ppm of titratable iodine
Hydrogen peroxide	7722-84-1	When ready for use, the end-use concentration is not to exceed 465 ppm
Hypochlorous acid	7790-92-3	When ready for use, the end-use concentration of all hypochlorous acid chemicals in the solution is not to exceed 200 ppm determined as total available chlorine
Iodine	7553-56-2	When ready for use, the total end-use concentration of all iodide-producing chemicals in the solution is not to exceed 25 ppm of titratable iodine
Lactic acid	50-21-5	When ready for use, the end-use concentration is not to exceed 138 ppm
α-Lauroyl-ω-hydroxypoly (oxyethylene) with an average of 8-9 moles ethylene oxide, average molecular weight (in amu), 400	None	None
Nonanoic acid	112-05-0	When ready for use, the end-use concentration is not to exceed 90 ppm
1-Octanamine, N,N-dimethyl-	7378-99-6	When ready for use, the end-use concentration is not to exceed 113 ppm

Pesticide Chemical	CAS Reg. No.	Limits
1,2-Octanedisulfonic acid	113669-58-2	When ready for use, the end-use concentration is not to exceed 102 ppm
1-Octanesulfonic acid	3944-72-7	When ready for use, the end-use concentration is not to exceed 172 ppm
1-Octanesulfonic acid, sodium salt	5324-84-5	When ready for use, the end-use concentration is not to exceed 297 ppm
1-Octanesulfonic acid, 2-sulfino-	113652-56-5	When ready for use, the end-use concentration is not to exceed 102 ppm
Octanoic acid	124-07-2	When ready for use, the end-use concentration is not to exceed 176 ppm
Oxirane, methyl-, polymer with oxirane, ether with (1,2-ethanediyldinitrilo)tetrakis [propanol] (4:1)	11111-34-5	When ready for use, the end-use concentration is not to exceed 20 ppm
Oxychloro species (including chlorine dioxide) generated by acidification of an aqueous solution of sodium chlorite	None	When ready for use, the end-use concentration is not to exceed 200 ppm of chlorine dioxide as determined by the method titled, Iodometric Method for the Determination of Available Chlorine Dioxide (50-250 ppm available chlorine dioxide)
Peroxyacetic acid	79-21-0	When ready for use, the end-use concentration is not to exceed 315 ppm
Peroxyoctanoic acid	33734-57-5	When ready for use, the end-use concentration is not to exceed 122 ppm
Phosphonic acid, (1-hydroxyethylidene)bis-	2809-21-4	When ready for use, the end-use concentration is not to exceed 34 ppm
Phosphoric acid	7664-38-2	None
Phosphoric acid, monosodium salt	7558-80-7	When ready for use, the end-use concentration is not to exceed 350 ppm
Potassium iodide	7681-11-0	When ready for use, the total end-use concentration of all iodide-producing chemicals in the solution is not to exceed 25 ppm of titratable iodine
Propanoic acid	79-09-4	When ready for use, the end-use concentration is not to exceed 297 ppm
2-Propanol (isopropanol)	67-63-0	None
2,6-Pyridinedicarboxylic acid	499-83-2	When ready for use, the end-use concentration is not to exceed 1.2 ppm
Sodium mono-and didodecylphenoxy-benzenedisulfonate	None	When ready for use, the end-use concentration is not to exceed 1920 ppm
Sulfuric acid	7664-93-9	When ready for use, the end-use concentration is not to exceed 288 ppm
Sulfuric acid monododecyl ester, sodium salt (sodium lauryl sulfate)	151-21-3	When ready for use, the end-use concentration is not to exceed 350 ppm

(c) The following chemical substances be applied to: Food-processing equipment and utensils.
when used as ingredients in an
antimicrobial pesticide formulation may

Pesticide Chemical	CAS Reg. No.	Limits
Acetic acid	64-19-7	When ready for use, the end-use concentration is not to exceed 686 ppm
Acetic acid, chloro-, sodium salt, reaction products with 4,5-dihydro-2-undecyl-1H-imidazole-1-ethanol and sodium hydroxide	68608-66-2	When ready for use, the end-use concentration is not to exceed 42 ppm chloroacetic acid
α -Alkyl(C ₁₀ -C ₁₄)- ω -hydroxypoly (oxyethylene) poly (oxypropylene) average molecular weight (in amu), 768 to 837	None	None
α -Alkyl(C ₁₁ -C ₁₅)- ω -hydroxypoly (oxyethylene) with ethylene oxide content 9 to 13 moles	None	None
α -Alkyl(C ₁₂ -C ₁₅)- ω -hydroxypoly (oxyethylene) polyoxypropylene, average molecular weight (in amu), 965	None	None
α -Alkyl(C ₁₂ -C ₁₈)- ω -hydroxypoly (oxyethylene) poly(oxypropylene) average molecular weight (in amu), 950 to 1120	None	None
Alkyl (C ₁₂ -C ₁₅) monoether of mixed (ethylene-propylene) polyalkylene glycol, cloud point of 70 - 77°C in 1% aqueous solution, average molecular weight (in amu), 807	None	None

Pesticide Chemical	CAS Reg. No.	Limits
Ammonium chloride	12125-02-9	When ready for use, the end-use concentration is not to exceed 48 ppm
Benzenesulfonamide, N-chloro-4-methyl, sodium salt	127-65-1	None
Benzenesulfonic acid, dodecyl-	27176-87-0	When ready for use, the end-use concentration is not to exceed 400 ppm
Benzenesulfonic acid, dodecyl-, sodium salt	25155-30-0	When ready for use, the end-use concentration is not to exceed 430 ppm
Benzenesulfonic acid, oxybis[dodecyl-	30260-73-2	When ready for use, the end-use concentration is not to exceed 474 ppm
[1,1'-Biphenyl]-2-ol	90-43-7	When ready for use, the end-use concentration is not to exceed 400 ppm
Boric acid, sodium salt	7775-19-1	None
Butanedioic acid, octenyl-	28805-58-5	When ready for use, the end-use concentration is not to exceed 156 ppm
Butanedioic acid, sulfo-, 1,4-dioctyl ester, sodium salt	1639-66-3	None
Butoxy monoether of mixed (ethylene-propylene) polyalkylene glycol, cloudpoint of 90 - 100°C in 0.5 aqueous solution, average molecular weight (in amu), 3300	None	None
Butoxy monoether of mixed (ethylene-propylene) polyalkylene glycol, minimum average molecular weight (in amu), 2400	None	None
Calcium bromide	7789-41-5	When ready for use, the end-use concentration of all bromide-producing chemicals in the solution is not to exceed 200 ppm total available halogen
Calcium chloride	10043-52-4	When ready for use, the end-use concentration is not to exceed 17 ppm
n-Carboxylic acids (C ₆ -C ₁₂), consisting of a mixture of not less than 56% octanoic acid and not less than 40% decanoic acid	None	When ready for use, the end-use concentration is not to exceed 39 ppm
3-Cyclohexene-1-methanol, $\alpha,\alpha,4$ -trimethyl-	98-55-5	None
1-Decanaminium, N-decyl-N, N-dimethyl-, chloride	7173-51-5	When ready for use, the end-use concentration is not to exceed 200 ppm of active quaternary compound
Decanoic acid	3347-48-5	When ready for use, the end-use concentration is not to exceed 234 ppm
Ethanesulfonic acid, 2-[cyclohexyl (1-oxohexadecyl) amino]-, sodium salt	132-43-4	When ready for use, the end-use concentration is not to exceed 237 ppm
Ethanol	64-17-5	None
Ethanol, 2 butoxy-	111-76-2	None
Ethanol, 2-(2-ethoxyethoxy)-	111-90-0	None
Ethylenediaminetetraacetic acid (EDTA), disodium salt	139-33-3	When ready for use, the end-use concentration is not to exceed 1400 ppm
Ethylenediaminetetraacetic acid (EDTA), tetrasodium salt	64-02-8	None
Fatty acids, coco, potassium salts	61789-30-8	None
Fatty acids, tall-oil, sulfonated, sodium salts	68309-27-3	When ready for use, the end-use concentration is not to exceed 66 ppm
FD&C Yellow No. 5 (Tartrazine) (conforming to 21 CFR 74.705)	1934-21-0	None
D-Gluconic acid, monosodium salt	527-07-1	When ready for use, the end-use concentration is not to exceed 760 ppm
Hydriodic acid	10034-85-2	When ready for use, the total end-use concentration of all iodide-producing chemicals in the solution is not to exceed 25 ppm of titratable iodine
Hydrogen peroxide	7722-84-1	When ready for use, the end-use concentration is not to exceed 1100 ppm
Hypochlorous acid	7790-92-3	When ready for use, the end-use concentration of all hypochlorous acid chemicals in the solution is not to exceed 200 ppm determined as total available chlorine
Hypochlorous acid, calcium salt	7778-54-3	When ready for use, the end-use concentration of all hypochlorous acid chemicals in the solution is not to exceed 200 ppm determined as total available chlorine
Hypochlorous acid, lithium salt	13840-33-0	When ready for use, the end-use concentration of all hypochlorous acid chemicals in the solution is not to exceed 200 ppm determined as total available chlorine and 30 ppm lithium
Hypochlorous acid, potassium salt	7778-66-7	When ready for use, the end-use concentration of all hypochlorous acid chemicals in the solution is not to exceed 200 ppm determined as total available chlorine

Pesticide Chemical	CAS Reg. No.	Limits
Hypochlorous acid, sodium salt	7681-52-9	When ready for use, the end-use concentration of all hypochlorous acid chemicals in the solution is not to exceed 200 ppm determined as total available chlorine
Iodine	7553-56-2	When ready for use, the total end-use concentration of all iodide-producing chemicals in the solution is not to exceed 25 ppm of titratable iodine
Lactic acid	50-21-5	None
α -Lauroyl- ω -hydroxypoly (oxyethylene) with an average of 8-9 moles ethylene oxide, average molecular weight (in amu), 400	None	None
Magnesium oxide	1309-48-4	None
Methylene blue	61-73-4	When ready for use, the end-use concentration is not to exceed 0.4 ppm
Naphthalene sulfonic acid, sodium salt	1321-69-3	When ready for use, the end-use concentration of all naphthalene sulfonate chemicals in the solution is not to exceed 332 ppm naphthalene sulfonates
Naphthalene sulfonic acid sodium salt, and its methyl, dimethyl and trimethyl derivatives	None	When ready for use, the end-use concentration of all naphthalene sulfonate chemicals in the solution is not to exceed 332 ppm naphthalene sulfonates
Naphthalene sulfonic acid sodium salt, and its methyl, dimethyl and trimethyl derivatives alkylated at 3% by weight with C ₆ -C ₉ linear olefins	None	When ready for use, the end-use concentration of naphthalene sulfonate chemicals in the solution is not to exceed 332 ppm naphthalene sulfonates
Neodecanoic acid	26896-20-8	When ready for use, the end-use concentration is not to exceed 174 ppm
Nonanoic acid	112-05-0	When ready for use, the end-use concentration is not to exceed 90 ppm
α -(p-Nonylphenyl)- ω -hydroxypoly (oxyethylene) maximum average molecular weight (in amu), 748	None	None
α -(p-Nonylphenyl)- ω -hydroxypoly (oxyethylene) average poly(oxyethylene) content 11 moles	None	None
α -(p-Nonylphenyl)- ω -hydroxypoly (oxyethylene) produced by the condensation of 1 mole p-nonylphenol with 9 to 12 moles ethylene oxide	None	None
α -(p-Nonylphenyl)- ω -hydroxypoly (oxyethylene), 9 to 13 moles ethylene oxide	None	None
Octadecanoic acid, calcium salt	1592-23-0	None
9-Octadecenoic acid (9Z)-, sulfonated	68988-76-1	When ready for use, the end-use concentration is not to exceed 312 ppm
9-Octadecenoic acid (9Z)-sulfonated, sodium salts	68443-05-0	When ready for use, the end-use concentration is not to exceed 200 ppm
1-Octanamine, N,N-dimethyl-	7378-99-6	When ready for use, the end-use concentration is not to exceed 113 ppm
1,2-Octanedisulfonic acid	113669-58-2	When ready for use, the end-use concentration is not to exceed 102 ppm
1-Octanesulfonic acid	3944-72-7	When ready for use, the end-use concentration is not to exceed 172 ppm
1-Octanesulfonic acid, sodium salt	5324-84-5	When ready for use, the end-use concentration is not to exceed 312 ppm
1-Octanesulfonic acid, 2-sulfino-	113652-56-5	When ready for use, the end-use concentration is not to exceed 102 ppm
Octanoic acid	124-07-2	When ready for use, the end-use concentration is not to exceed 234 ppm
Oxirane, methyl-, polymer with oxirane, minimum molecular weight (in amu), 1900	9003-11-6	None
Oxirane, methyl-, polymer with oxirane, block, average molecular weight (in amu), 1900	106392-12-5	None
Oxirane, methyl-, polymer with oxirane, block, minimum average molecular weight (in amu), 2000	None	None
Oxirane, methyl-, polymer with oxirane, block, 27 to 31 moles of polyoxypropylene, average molecular weight (in amu) 2000	None	None
Oxirane, methyl-, polymer with oxirane, ether with (1,2-ethanediyl)dinitrilo)tetrakis [propanol] (4:1)	11111-34-5	When ready for use, the end-use concentration is not to exceed 20 ppm
Oxychloro species (predominantly chlorite, chlorate and chlorine dioxide in an equilibrium mixture) generated either (i) by directly metering a concentrated chlorine dioxide solution prepared just prior to use, into potable water, or (ii) by acidification of an aqueous alkaline solution of oxychloro species (predominately chlorite and chlorate) followed by dilution with potable water	None	When ready for use, the end-use concentration is not to exceed 200 ppm of chlorine dioxide as determined by the method titled, $\geq$ Iodometric Method for the Determination of Available Chlorine Dioxide (50-250 ppm available chlorine dioxide)

Pesticide Chemical	CAS Reg. No.	Limits
Oxychloro species (including chlorine dioxide) generated by acidification of an aqueous solution of sodium chlorite	None	When ready for use, the end-use concentration is not to exceed 200 ppm of chlorine dioxide as determined by the method titled, $\geq$ Iodometric Method for the Determination of Available Chlorine Dioxide (50-250 ppm available chlorine dioxide)
2,4-Pentanediol, 2-methyl- Peroxyacetic acid	107-41-5 79-21-0	None When ready for use, the end-use concentration is not to exceed 315 ppm
Peroxyoctanoic acid	33734-57-5	When ready for use, the end-use concentration is not to exceed 122 ppm
Phenol, 4-chloro-2-(phenylmethyl)-	120-32-1	When ready for use, the end-use concentration is not to exceed 320 ppm
Phenol, 4-(1,1-dimethylpropyl)-	80-46-6	When ready for use, the end-use concentration is not to exceed 80 ppm
Phosphonic acid, (1-hydroxyethylidene)bis-	2809-21-4	When ready for use, the end-use concentration is not to exceed 34 ppm
Phosphoric acid	7664-38-2	None
Phosphoric acid, monosodium salt	7558-80-7	When ready for use, the end-use concentration is not to exceed 350 ppm
Phosphoric acid, trisodium salt	7601-54-9	When ready for use, the end-use concentration is not to exceed 5916 ppm
Poly(oxy-1,2-ethanediyl), α -[(1,1,3,3-tetramethylbutyl) phenyl]- ω -hydroxy-, produced with one mole of the phenol and 4 to 14 moles ethylene oxide	None	None
Potassium bromide	7758-02-3	When ready for use, the end-use concentration of all bromide-producing chemicals in the solution is not to exceed 200 ppm total available halogen
Potassium iodide	7681-11-0	When ready for use, the total end-use concentration of all iodide-producing chemicals in the solution is not to exceed 25 ppm of titratable iodine
Potassium permanganate	7722-64-7	When ready for use, the end-use concentration is not to exceed 0.7 ppm
Propanoic acid	79-09-4	When ready for use, the end-use concentration is not to exceed 297 ppm
2-Propanol (isopropanol)	67-63-0	None
2,6-Pyridinedicarboxylic acid	499-83-2	When ready for use, the end-use concentration is not to exceed 1.2 ppm
Quaternary ammonium compounds, alkyl (C_{12} - C_{18}) benzyl dimethyl, chlorides	8001-54-5	When ready for use, the end-use concentration of this specific quaternary compound is not to exceed 200 ppm within the end-use total concentration that is not to exceed 400 ppm active quaternary compound
Quaternary ammonium compounds, n-alkyl (C_{12} - C_{14}) dimethyl ethylbenzyl ammonium chloride, average molecular weight (in amu), 377 to 384	None	When ready for use, the end-use concentration of this specific quaternary compound is not to exceed 200 ppm within the end-use total concentration that is not to exceed 400 ppm active quaternary compound
Quaternary ammonium compounds, n-alkyl (C_{12} - C_{18}) dimethyl ethylbenzyl ammonium chloride average molecular weight (in amu) 384	None	When ready for use, the end-use concentration of this specific quaternary compound is not to exceed 200 ppm within the end-use total concentration that is not to exceed 400 ppm active quaternary compound
Quaternary ammonium compounds, di-n-Alkyl (C_8 - C_{10}) dimethyl ammonium chloride, average molecular weight (in amu), 332 to 361	None	When ready for use, the end-use concentration of this specific quaternary compound is not to exceed 240 ppm within the end-use total concentration that is not to exceed 400 ppm active quaternary compound
Sodium- α -alkyl(C_{12} - C_{15})- ω -hydroxypoly (oxyethylene) sulfate with the poly(oxyethylene) content averaging one mole	None	None
Sodium bicarbonate	144-55-8	None
Sodium bromide	7647-15-6	When ready for use, the end-use concentration of all bromide-producing chemicals in the solution is not to exceed 200 ppm total available halogen
Sodium iodide	7681-82-5	When ready for use, the total end-use concentration of all iodide-producing chemicals in the solution is not to exceed 25 ppm of titratable iodine
Sodium mono-and didodecylphenoxy-benzenedisulfonate	None	When ready for use, the end-use concentration is not to exceed 1920 ppm
Sulfuric acid	7664-93-9	When ready for use, the end-use concentration is not to exceed 228 ppm

Pesticide Chemical	CAS Reg. No.	Limits
Sulfuric acid monododecyl ester, sodium salt (sodium lauryl sulfate)	151–21–3	None
1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3-dichloro-	2782–57–2	When ready for use, the end-use concentration of all di- or trichloroisocyanuric acid chemicals in the solution is not to exceed 100 ppm determined as total available chlorine
1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3-dichloro-, potassium salt	2244–21–5	When ready for use, the end-use concentration of all di- or trichloroisocyanuric acid chemicals in the solution is not to exceed 100 ppm determined as total available chlorine
1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3-dichloro-, sodium salt	2893–78–9	When ready for use, the end-use concentration of all di- or trichloroisocyanuric acid chemicals in the solution is not to exceed 100 ppm determined as total available chlorine
1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-trichloro-	87–90–1	When ready for use, the end-use concentration of all di- or trichloroisocyanuric acid chemicals in the solution is not to exceed 100 ppm determined as total available chlorine
1,3,5-Triazine, N,N',N''-trichloro-2,4,6-triamino-	7673–09–8	When ready for use, the end-use concentration of all di- or trichloroisocyanuric acid chemicals in the solution is not to exceed 200 ppm determined as total available chlorine
Xylenesulfonic acid, sodium salt	1300–72–7	When ready for use, the end-use concentration is not to exceed 62 ppm

§ 180.1001 [Removed]

- 13. Section 180.1001 is removed.
- 14. In § 180.1067, paragraph (b) is revised to read as follows:

§ 180.1067 Methyl eugenol and malathion combination; exemption from the requirement of a tolerance.

* * * * *

(b) This combination is to be impregnated on a carrier (cigarette filter tips (cellulose acetate); cotton strings; fiberboard squares) or mixed with a jel cleared under 40 CFR 180.920 or 180.950.

* * * * *

[FR Doc. 04–9578 Filed 4–27–04; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY**40 CFR Part 180**

[OPP–2004–0067; FRL–7351–6]

Citronellol; Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of the citronellol on all food commodity when applied/used to control Tetranychid mites. Natural Plant Protection S.A. submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA),

as amended by the Food Quality Protection Act of 1996 (FQPA), requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of citronellol.

DATES: This regulation is effective April 28, 2004. Objections and requests for hearings, identified by docket ID number OPP–2004–0067, must be received on or before June 28, 2004.

ADDRESSES: To submit a written objection or hearing request follow the detailed instructions as provided in Unit VIII. of the **SUPPLEMENTARY INFORMATION.** EPA has established a docket for this action under docket ID number OPP–2004–0067. All documents in the docket are listed in the EDOCKET index at <http://www.epa.gov/edocket/>. Although listed in the index, some information is not publicly available, i.e., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in EDOCKET or in hard copy at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal

holidays. The docket telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT:

Raderrio Wilkins, Biopesticides and Pollution Prevention Division (7511C), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–1259; e-mail address: Wilkins.Raderrio@epa.gov.

SUPPLEMENTARY INFORMATION:**I. General Information****A. Does this Action Apply to Me?**

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to:

- Crop production (NAICS 111)
- Animal production (NAICS 112)
- Pesticide manufacturing (NAICS 32532)
- Food manufacturing (NAICS 311)

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT.**

Antimicrobial Treatments for Minimally Processed Cantaloupe Melon

G.M. SAPERS, R.L. MILLER, V. PILIZOTA, AND A.M. MATTRAZZO

ABSTRACT: Efficacy of decontamination treatments in reducing endogenous microbial populations on cantaloupe and in extending fresh-cut shelf-life were investigated. Composite rind plug samples were washed with water or solutions of sodium hypochlorite, H_2O_2 , commercial detergent formulations containing dodecylbenzene sulfonic acid and phosphoric acid, or trisodium phosphate, and surviving microbial populations determined. Fresh-cut cubes were prepared aseptically from whole melons given similar treatments, and their visual appearance and bacterial population determined during storage at 4 °C. Population reductions on washed rind plugs were < 1 log with water, 1 to 2 logs with washing and sanitizing agents applied individually, and 3 logs with some sequential treatments with H_2O_2 . H_2O_2 applied at 50 °C was superior to other whole-melon treatments, yielding a fresh-cut shelf-life of > 2 weeks.

Key Words: Cantaloupe, minimally processed, fresh-cut, sanitizers, shelf-life, hydrogen peroxide

Introduction

MINIMALLY PROCESSED (FRESH-CUT) CANTALOUPE MELON is now widely accepted and available year-round throughout the United States. However, this product is highly perishable (O'Connor-Shaw and others 1994, Portela and Cantwell 1999) and, in common with other melons, has been associated with outbreaks of Salmonellosis (CDC 1991, Tاملین 1997). Survival and growth of *Salmonella* spp. and *Escherichia coli* O157:H7 on cantaloupe rind and flesh have been reported (Golden and others 1993, Del Rosario and Beuchat 1995). Efforts to improve the shelf-life and microbiological quality of fresh-cut melons have focused on raw material quality and ripeness (López-Gálvez and others 1996), reduction of microbial populations on the melon rind by treatment with hypochlorite (Ayhan and others 1996) or hydrogen peroxide vapor (Simmons and others 1996), rigorous attention to sanitation during cutting (Ayhan and others 1996), treatment of cut melon with $CaCl_2$ (Luna-Guzman and others 1996) or hypochlorite (Cantwell and others 1996), controlled atmosphere storage (Portela and Cantwell 1998), and storage at low temperatures (Cantwell and others 1996).

Although hypochlorite is widely used to sanitize fresh-cut fruits and vegetables, its effectiveness is limited with some products (Beuchat and Brackett 1990, Wei and others 1995). Preliminary studies in our laboratory indicated that treatment of fresh-cut cantaloupe with 200 ppm Cl_2 reduced aerobic plate counts by less than 1 log and did not appreciably delay visible spoilage (Sapers and Simmons 1998). Furthermore, because Cl_2 may react with food constituents to form potentially carcinogenic or mutagenic products, its safety as a treatment for fruits and vegetables has been questioned, and future regulatory restrictions may require the development of alternatives (Hurst 1995).

We have demonstrated that washing with dilute hydrogen peroxide (H_2O_2) solution is a highly effective sanitizing treatment for fresh mushrooms (Sapers and others 1994) and apples (Sapers and others 1999, 2000). This treatment showed promise with fresh-cut cantaloupe and zucchini, although results were not consistent (Sapers and Simmons 1998). Our

objectives in this study were to improve the efficacy of H_2O_2 treatments for sanitizing external surfaces of uncut cantaloupe and to apply such treatments to the preparation of fresh-cut cantaloupe.

Materials and Methods

Raw materials

Ripe ("full slip") cantaloupes, free of visual defects, were purchased at local food stores in sufficient quantities to meet experimental needs (6 to 25 melons) and briefly refrigerated at 4 °C until needed. Experiments were conducted during the fall and winter of 1996–1997, the summer of 1997, and the summer of 1998, so that the melons were likely to have originated from several growing locations.

Preparation and treatment of cantaloupe rind plugs

Because of anticipated melon-to-melon variability in microbiological quality and the logistical problem of applying replicated washing treatments to large numbers of whole melons, a model system was devised to permit application of treatments to replicate plugs of cantaloupe rind. To avoid cross-contamination during sample preparation and treatment, all knives, cutting boards, and other equipment in contact with melons were sanitized by immersion for 10 min in 1000 ppm Cl_2 (0.21% sodium hypochlorite adjusted to pH 6.5 with citric acid). Disposable gloves, changed between samples, were worn by the investigators during preparation and treatment of melons. Plugs of cantaloupe rind and attached flesh 20 mm in dia, were obtained from 1 or more melons (40 to 60 plugs per melon) with a sanitized stainless steel cork borer, and flesh portions were trimmed off with a sanitized knife and discarded. Washing treatments were applied to sets of 10 plugs (20 plugs in some trials), taken from a composite sample of 70–100 plugs. The plugs were immersed in 500 mL wash solution and stirred under standardized conditions for 1 min. Treatments included washes with water, 5% H_2O_2 , 0.025–0.2% sodium dodecyl sulfate (SDS, Sigma-Aldrich, St. Louis, Mo., U.S.A.), sodium dioctyl sulfosuccinate (Sigma

and sodium 2-ethylhexyl sulfate (Carsonol SHS, Lonza Inc., Fair Lawn, N.J., U.S.A.), 1000 ppm chlorine (sodium hypochlorite solution, adjusted to pH 6.5 with citric acid), 4% trisodium phosphate (TSP, Rhodia Inc., Washington, Pa., U.S.A.), 2 commercial detergent formulations (DECCO APL KLEEN 246, Elf Atochem North America, Inc., Monrovia, Calif., U.S.A., and AFCCO 4344 Fruit and Vegetable Wash, Alex C. Fergusson Inc., Frazer, Pa., U.S.A.) both containing dodecylbenzene sulfonic acid and phosphoric acid at pH 2, combinations of these commercial detergent products with 5% H₂O₂, and sequential treatments with the commercial products followed by 5% H₂O₂. The 5% H₂O₂ solutions were prepared fresh prior to each trial from 30% H₂O₂ (Certified ACS, Fisher, Fair Lawn, N.J., U.S.A.). Previous studies with mushrooms (Sapers and Simmons 1998) and apples (Sapers and others 1999) demonstrated the stability of such solutions over many hours at ambient and elevated temperatures in which the peroxide concentration was monitored with the EM Reflectoquant™ Analysis System (EM Industries, Inc., Gibbstville, N.J., U.S.A.). Washing treatments were carried out at ambient temperature (ca. 20 °C) or 50 °C. Plugs were removed from the wash solution, drained, and rinsed in 500 mL sterile H₂O.

Fresh-cut processing

All processing was carried out with sanitized equipment as described above. For each treatment, replicate ripe melons were placed in plastic tubs containing water or the sanitizing solution, and immersed with vigorous scrubbing with a stiff scrub brush for 1 min. After treatment and rinsing, the melons were cut in half and the seeds removed. Melon halves were then cut into 8ths and the edible portion removed from the rind and cut into cubes using separate cutting boards, knives, and gloves to minimize cross-contamination. A composite sample of cubes from the treated melons was dipped in water (control) or 50 ppm Cl₂ (sodium hypochlorite solution adjusted to pH 6.5 with citric acid). The treated and rinsed melon cubes were dewatered in a salad spinner (Triumpher Model M83, Fouineteau USA Inc., Indianapolis, Ind., U.S.A.) for 15 sec. The cubes were weighed (about 200g) into sanitized plastic boxes, which were then heat-sealed within modified atmosphere packaging bags (laminated polyethylene film; Cypress Packaging, Rochester, N.Y., U.S.A.) having a specified oxygen transmission rate value of 1,395 cc/m²/d. Treatments were carried out in duplicate. For each of the duplicate trials, 6 replicate boxes of cut melon cubes were prepared for storage at 4 °C and were examined at D 4, 7 or 8, 14 or 15, and 17 or 18 for visual indications of spoilage (presence of colonies, slime, turbidity in juice drained from cut cubes) and off-odors. At the same time, samples were taken for microbiological evaluation.

Microbiological methods

Rind plug samples and 250 mL of sterile 0.1% peptone (Difco Labs., Detroit, Mich., U.S.A.) water were homogenized for 1 min in a 1,250 mL glass jar with a Waring single-speed drive unit (Waring Products Division, Dynamics Corp. of America, New Hartford, Conn., U.S.A.) operated at half-speed by means of a variable transformer. Homogenates were sampled, diluted with 1% peptone, spread-plated on Tryptic Soy Agar (Difco), and incubated for 18 to 24 h at 37 °C for enumeration of the surviving microflora. Counts were expressed as CFU/cm² of surface area, based on the surface area of the 10 or 20 plugs (31.4 or 62.8 cm², respec-

Table 1—Variability in microbial load on external surface of cantaloupe melon

Date of Purchase	Sample treatment ^a	n ^b	Log ₁₀ CFU/cm ^{2c}		
			Mean	Stand dev.	Range
10/13/96-11/4/96	Washed control	3	5.24	1.69	4.04-7.18
1/10/97-2/26/97	Dry control	6	6.04	1.82	3.90-8.38
	Washed control	9	5.82	1.74	3.32-8.15
7/14/97-9/2/97	Dry control	9	4.09	1.09	2.50-5.53
7/27/98-8/6/98	Dry control	10	4.41	0.58	3.53-5.43
Summer	All samples	19	4.26 ^e	0.85	2.50-5.53
Fall/Winter	All samples	18	5.79 ^d	1.68	3.32-8.38
All samples	Dry control	25	4.68 ^e	1.36	2.50-8.38
	Washed control	12	5.67 ^d	1.67	3.32-8.15

^aPlugs immersed in 500 mL sterile H₂O for 5 min and drained (washed control) or sampled without washing (dry control).

^bSamples from 10/13/96-7/24/97 consisted of 10 plugs each; samples obtained thereafter contained 20 plugs each.

^cAerobic plate count per cm² of external surface of 10 or 20 rind plugs.

^{d-e}Within the comparisons of summer compared with fall/winter and dry compared with washed controls, means with no letter in common are significantly different ($p < 0.05$) by Duncan's Multiple Range Test.

tively).

Preweighed fresh-cut melon cube samples were blended with 250 mL sterile 0.1% peptone (Difco) water, diluted, plated and incubated, as described above. Counts were expressed as CFU/g.

Statistical analyses

Microbiological data were analyzed for differences in response to treatments by ANOVA and Duncan's Multiple Range Test to separate means. All statistical analyses were performed with SAS/STAT software (SAS Institute Inc., Cary, N.C., U.S.A.).

Results and Discussion

Variability in microbial load

To estimate variability in the microbial load on external surfaces of cantaloupes, aerobic plate count data for replicate rind plugs representing samples, obtained over several seasons, were examined (Table 1). Samples obtained during the late fall and winter were more variable and of lower microbiological quality than samples obtained during the summer. This may be a reflection of cantaloupe-handling conditions at the point of origin or during distribution and marketing. The small difference between washed (with water in the laboratory) and unwashed melons is a reflection of the absence of washed samples during the summer months and is of no practical significance. The considerable variability in microbial load, even within the same year and season, requires that rind decontamination studies be designed so that all trials within an individual experiment employ replicate rind plugs taken from a sufficiently large pool of similar-appearing melons to compensate for variability.

Effect of washing on microbial load of rind

Washing trials were carried out with the rind plug model system to determine the efficacy of various cleaning and sanitizing agents in reducing the microbial load. Washing with ambient or warm (50 °C) water was ineffective in reducing the microbial load on rind plugs (Table 2). Addition of 0.1 to 0.2% surfactants such as sodium dioctyl sulfosuccinate, sodium 2-ethylhexyl sulfate, or sodium dodecyl sulfate (data not shown) did not improve the efficacy of water as a decontaminating agent, even when the solutions were applied at 50 °C

Table 2—Effect of washing with water and surfactant solutions on microbial load on cantaloupe rind plugs

Wash treatment ^a	Temperature (°C)	n	Log ₁₀ CFU/cm ² reduction ^{b,c}
H ₂ O	20	6	0.45 ± 0.50
	50	11	0.55 ± 0.61
0.1% sodium dioctyl sulfosuccinate	20	2	-0.15 ± 0.28
0.2% sodium 2-ethylhexyl sulfate	20	3	0.38 ± 0.44

^aPlugs immersed in 500 mL sterile H₂O or surfactant solution for 5 min, rinsed and drained.

^bBased on total plate count for washed sample and corresponding dry control.

^cLog reduction values not significantly different ($p < 0.05$) by Duncan's Multiple Range Test.

Table 3—Effect of washing with sanitizing agents at 50°C on microbial load on cantaloupe rind plugs

Wash treatment ^a	n	Log ₁₀ CFU/cm ² reduction ^c
1000 ppm Cl ₂ (pH 6.5)	10	0.63 ^f
1% APL KLEEN 246	3	1.32 ^{ef}
4% trisodium phosphate	3	1.33 ^{ef}
8% trisodium phosphate	2	1.13 ^{ef}
5% H ₂ O ₂	7	1.65 ^e
1% APL KLEEN 246; 5% H ₂ O ₂ ^b	3	1.60 ^e
2% APL KLEEN 246; 5% H ₂ O ₂ (no final rinse) ^b	2	3.08 ^d
5% trisodium phosphate; 5% H ₂ O ₂	3	1.81 ^e

^aPlugs immersed in 500 mL wash solution for 1 min, rinsed in 500 mL sterile H₂O and drained.

^bDetergent treatments applied, sample rinsed, and then H₂O₂ applied.

^cBased on total plate count for washed sample and corresponding dry control.

^{d-f}Means with no letter in common are significantly different ($p < 0.05$) by Duncan's Multiple Range Test.

(data not shown).

Sanitizers are widely used in produce-washing operations. In this study, a series of conventional and experimental products was tested at 50 °C. Application of 1,000 ppm Cl₂ (pH adjusted to 6.5) reduced the microbial load on cantaloupe rind plugs by less than 1 log (Table 3).

A commercial detergent formulation (DECCO APL KLEEN 246) achieved log reductions in excess of 1 when applied at concentrations of 1 and 2%. TSP, applied at concentrations of 4 and 8%, also yielded log reductions in excess of 1. However, log reductions attained by an experimental sanitizing agent, 5% H₂O₂, exceeded 2 in some trials. Results could be improved further by applying the detergent product or TSP first, rinsing it off, and then applying the H₂O₂ wash. Previously, we reported favorable results in decontaminating apples, artificially inoculated with a nonpathogenic *E. coli*, by washing with 5% H₂O₂, alone or in sequence with a detergent wash (Sapers and others 1999, 2000). However, it is evident with both apples and cantaloupe rind plugs that washing by itself cannot achieve a level of decontamination consistently exceeding a 3-log (99.9%) population reduction. Whether this is sufficient to control spoilage and preclude survival of contaminating human pathogens is the subject of continuing studies.

Effect of cantaloupe decontamination on fresh-cut shelf-life

Our previous attempts to improve the microbiological quality and shelf-life of fresh-cut cantaloupe entailed wash-

Table 4—Effect of melon decontamination treatments with Cl₂ and H₂O₂ on shelf-life of fresh-cut cantaloupe at 4 °C

Expt.	Treatment	Log ₁₀ CFU/g ^b Day				Appearance ^d	
		0	7	15/14 ^c	18/17 ^c	D15/14 ^c	D18/17 ^c
A	Control	1.88 ^e	6.51 ^e	9.17 ^e	7.71 ^e	Spoiled	Spoiled
	1000 ppm Cl ₂ (pH 6.5) ^a	1.49 ^e	7.04 ^e	8.67 ^e	9.44 ^e	Spoiled	Spoiled
	5% H ₂ O ₂ at 50 °C ^a	1.44 ^e	3.62 ^f	5.24 ^e	5.94 ^e	Not spoiled	Not spoiled
B	Control	1.94 ^e	4.95 ^e	7.24 ^e	8.69 ^e	Spoiled	Spoiled
	1000 ppm Cl ₂ (pH 6.5) ^a	1.50	4.72 ^e	8.17 ^e	8.11 ^e	Spoiled	Spoiled
	5% H ₂ O ₂ at 50 °C ^a	1.03 ^e	2.35 ^e	6.02 ^e	6.21 ^f	Not spoiled	Not spoiled

^aMelons scrubbed in solution for 1 min; residual Cl₂ but not H₂O₂ removed by rinsing; fresh-cut cubes rinsed with 50 ppm Cl₂ and de-watered.

^bTotal aerobic plate count.

^cExpt. A samples examined on D 15 and 18, and Expt. B samples examined on D 14 and 17.

^dSpoilage indicated by presence of mold, white colonies, cloudy liquid, or off-odor.

^{e-f}Within the same experiment and column, means with no letter in common are significantly different ($p < 0.05$) by Duncan's Multiple Range Test.

ing the intact melons with 1,000 ppm chlorine (pH 6.5), rind removal and preparation of melon cubes, treatment of the fresh-cut cubes with various antimicrobial washes, dewatering, and packaging with a modified atmosphere. While this process resulted in some shelf-life extension (Sapers and Simmons 1998), the results were erratic and the benefits small (data not shown). In addition, we were concerned about chemical changes induced by sanitizers in the melon flesh prior to dissipation or removal of sanitizer residues. Residual H₂O₂ levels in excess of 25 ppm were detected in melon cubes after direct exposure to 5% H₂O₂ solution (Sapers and Simmons 1998). Therefore, in the present study we concentrated our efforts on more effective decontamination of whole melons rather than the cut flesh, based on the rind plug results, and avoidance of cross-contamination during rind removal, preparation and handling of the cut melon cubes, and packaging. A rigorous protocol to avoid cross-contamination was developed after a number of unsuccessful trials in which fresh-cut samples spoiled prematurely (data not shown). Essential elements of the protocol were physical isolation of rind-removal steps from cube-preparation steps (separate work stations and technicians, use of separate knives and cutting boards); sanitizing of latex gloves, knives and cutting boards between processing of replicate melons given the same treatment; and sanitizing of the work area and replacement of latex gloves between treatments.

Comparisons of fresh-cut cantaloupe cubes, prepared from control (unwashed), Cl₂-washed, and H₂O₂-washed melons indicated minimal differences in total aerobic plate count at D 0 of storage (Table 4). However, during storage at 4 °C, the total aerobic plate counts of melon cubes were consistently lower (although significantly lower in only 2 comparisons because of sample variability) after H₂O₂ treatment than in controls or after Cl₂ treatment. Examination of samples on D 7 revealed no evidence of spoilage. On D 15 and 18, evidence of spoilage was seen in the controls and with Cl₂-treatment, but not with the H₂O₂-treatment. This effect is not likely to be due to residual peroxide transferred from the cantaloupe rind to the flesh during flesh-cut preparation. Residual H₂O₂ levels in cubes immediately after preparation were only 2 to 5 ppm when the whole melons were not rinsed after treatment, and 0.5 to 2 ppm when the melons

Table 5—Effect of two-stage melon decontamination treatments with a commercial acidic detergent or trisodium phosphate (TSP) followed by H₂O₂ on shelf-life of fresh-cut cantaloupe at 4 °C

Expt.	Treatment ^a	Log ₁₀ CFU/g ^b Day				Appearance ^c	
		0	7	15/14 ^c	18/17 ^c	D 15/14 ^c	D 18/17 ^c
C	Control	1.72 ^e	3.83 ^e	7.80 ^e	8.31 ^e	Spoiled	Spoiled
	1% APL KLEEN 246 at 50 °C	2.04 ^e	2.13 ^f	4.43 ^e	5.65 ^e	Not spoiled	Not spoiled
	5% H ₂ O ₂ at 50 °C	1.51 ^e	1.54 ^f	4.43 ^e	4.04 ^e	Not spoiled	Not spoiled
	1% APL KLEEN 246 at 50 °C; rinse;	2.12 ^e	1.50 ^f	3.14 ^e	6.73 ^e	Not spoiled	Not spoiled
	5% H ₂ O ₂ at 50 °C						
D	Control	3.75 ^{ef}	8.18 ^e	9.16 ^e	10.46 ^e	Spoiled	Spoiled
	4% TSP at 50 °C	4.28 ^e	6.70 ^{ef}	8.70 ^{ef}	9.50 ^e	Spoiled(±)	Spoiled
	5% H ₂ O ₂ at 50 °C	1.50 ^f	4.78 ^f	7.59 ^f	8.31 ^e	Not spoiled	Spoiled
	4% TSP at 50 °C; rinse; 5% H ₂ O ₂ at 50 °C	2.96 ^{ef}	5.91 ^f	7.98 ^{ef}	8.80 ^e	Not spoiled(±)	Spoiled

^aMelons scrubbed in solution for 1 min; residual detergent and TSP but not H₂O₂ removed by rinsing; fresh-cut cubes rinsed with 50 ppm Cl₂ and de-watered.

^bTotal aerobic plate count.

^cExpt. C samples examined on D 7, 14, and 17, and Expt. D samples examined on D 8, 14, and 17.

^dSpoilage indicated by presence of mold, white colonies, cloudy liquid, or off-odor; lack of uniformity among replicates indicated by "±."

^{e-f}Within the same experiment and column, means with no letter in common are significantly different ($p < 0.05$) by Duncan's Multiple Range Test.

were rinsed with water. After only 20 min, no H₂O₂ could be detected in either case. These results suggest that treatment of the melons with H₂O₂ resulted in injury to the surviving bacteria on the cantaloupe external surface that were transferred onto the flesh surface during cutting. The injured bacterial cells apparently did not grow as well as bacteria on controls or the survivors of Cl₂ treatment, resulting in lower counts during storage following fresh-cut processing and consequently, in shelf-life extension.

Attempts to improve the efficacy of H₂O₂ treatments in decontaminating cantaloupes by means of a two-stage wash, in which the H₂O₂ wash was preceded by an acidic detergent (DECCO APL KLEEN 246) or TSP wash and water rinse, were not successful (Table 5). A single wash with H₂O₂ was at least as good if not more effective than the two-stage washes, based on the total aerobic plate counts and visual appearance of fresh-cut melon cubes. In these trials, the fresh-cut controls failed as early as D 7, while fresh-cut cubes from cantaloupes given the H₂O₂ treatment showed no evidence of spoilage even after 14 d. We had anticipated some improvement in microbial detachment or disruption of biofilms with the two-stage treatments, based on our rind plug results and the TSP results reported by Somers and others (1994). However, it is possible that the putative cantaloupe biofilms, if present, were resistant to the detergent and TSP treatments. It is also possible that the surviving bacteria were embedded within inaccessible sites on the melon surface and were never exposed to the wash solutions.

In other trials with whole melons, a two-stage application of 2% AFCCO 4344 at 60 °C, followed by a water rinse and application of a 5% H₂O₂ dip at 60 °C, was less effective than 1,000 ppm Cl₂ in suppressing bacterial growth and visible spoilage in fresh-cut cantaloupe, but both treatments were superior to untreated controls (data not shown). A two-stage treatment with the combination of 2% AFCCO 4344, followed by a dip in 2,000 ppm Cl₂, was more effective than treatment with the detergent/H₂O₂ combination or Cl₂, applied separately, in suppressing bacterial growth in the fresh-cut product (Table 6).

Variability in the response of bacterial contaminants of

Table 6—Effect of two-stage melon decontamination treatments with a commercial acidic detergent/H₂O₂ combination followed by Cl₂ on shelf-life of fresh-cut cantaloupe at 4°C

Treatment ^a	Log ₁₀ CFU/g ^b Day				Appearance ^c	
	0	7	14	17	Day 14	Day 17
Control	3.60 ^d	4.86 ^d	8.64 ^d	8.77 ^d	Not spoiled	Spoiled
2000 ppm Cl ₂	2.31 ^f	4.62 ^d	7.66 ^e	8.43 ^d	Not spoiled	Not spoiled
5% H ₂ O ₂ + 2% AFCCO4344 at 60°C	3.83 ^d	4.29 ^d	7.56 ^e	8.20 ^d	Not spoiled	Spoiled
2000 ppm Cl ₂ ; H ₂ O ₂ + 2% AFCCO 4344 at 60°C	3.41 ^{de}	4.46 ^d	7.71 ^e	8.11 ^d	Not spoiled	Spoiled (±)
2% AFCCO 4344 at 60 °C; 2000 ppm Cl ₂	2.56 ^{ef}	3.16 ^e	5.83 ^f	6.45 ^e	Not spoiled	Not spoiled (±)

^aMelons scrubbed in solution for 1 min; residual detergent and H₂O₂ removed by rinsing.

^bTotal aerobic plate count.

^cSpoilage indicated by presence of mold, white colonies, cloudy liquid, or off-odor; lack of uniformity among replicates indicated by "±."

^{d-f}Within the same column, means with no letter in common are significantly different ($p < 0.05$) by Duncan's Multiple Range Test.

cantaloupes to antimicrobial treatments is a continuing problem. We suspect that such variability is related to the melon surface condition, make-up and population size of the microflora, and presence of bacteria within biofilms. Further improvements in treatment efficacy are required to overcome this problem. However, we must also consider the potential risk of making melons "too clean" so that competition against human pathogens that survive the wash or are introduced after fresh-cut processing is not eliminated. Greater growth of *Listeria monocytogenes* on endive following reductions in background microflora by chemical disinfection were reported by Carlin and others (1996). Studies in these areas are continuing.

Conclusions

Washing with 5% H₂O₂ or with a commercial detergent formulation followed by 5% H₂O₂ at 50 °C was more effective than washing with water, surfactant solutions, 1000 ppm Cl₂, trisodium phosphate, or the commercial detergent formulation in reducing the microbial load on cantaloupe rind. A H₂O₂ wash, applied to melons prior to cutting, shows promise in improving the microbiological quality and shelf-life of fresh-cut cantaloupe.

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