

CP97-2-29

LAW OFFICES

KELLER AND HECKMAN LLP

1001 G STREET, N.W.
SUITE 500 WEST
WASHINGTON, D.C. 20001
TELEPHONE (202) 434-4100
FACSIMILE (202) 434-4648
—
BOULEVARD LOUIS SCHMIDT 87
B-1040 BRUSSELS
TELEPHONE 32(2) 732 52 80
FACSIMILE 32(2) 732 53 92
—
WWW.KHLAW.COM

JOSEPH E. KELLER (907-1994)
JEROME N. HECKMAN
WILLIAM H. BORGHEANSI, JR.
MALCOLM D. MACARTHUR
WAYNE V. BLACK
TERRENCE D. JONES
MARTIN W. BERGOVICI
JOHN S. ELBRED
RICHARD J. LEIGHTON
ALFRED S. BISHERY
WILLIAM L. HOWES
DOUGLAS J. BEMR
RAYMOND A. KOWALSKI*
SHIRLEY A. COFFIELD
MICHAEL F. MORRONE
JOHN S. RICHARDS
JEAN SAVIGNY**
JOHN E. DUBECK
PETER L. DE LA CRUZ
MELVIN S. DROZEN
LAWRENCE P. HALPRIN
RALPH A. SIMMONS
RICHARD F. MAHN

C. DOUGLAS JARRETT
SHEILA A. MILLAR
GEORGE S. WISKO
SARIN E. DODD
PATRICK J. MURD
MARK A. SEEVERS
CATHERINE R. NIELSEN
JEAN-PHILIPPE MONTFORT**
JUSTIN C. POWELL
DAVID G. SARVADI
JONATHAN R. SPENCER
SUSAN M. MAPLE*
AMY M. RODGERS
ELLIOT BELILOS
MARK L. ITZKOFF
ROSEMARIE A. KELLEY
BRIAN T. ASHBY
ARTHUR S. GARRETT III
ELIZABETH W. HARRISON
ROBERT H.G. LOCKWOOD
CAROL MOORE TOTH
JOAN C. STLVAIN
MARTHA E. MARRAPESE

DONALD T. WURTH
DAVID B. BERRY
NICOLE E. DONATH
DEBORAH ROSEN WHITE
DAVID R. JOY
FREDERICK A. STEARNS
TONY RUSSELL EPPS
THOMAS C. BERGER
JOHN F. FOLEY
JENNIFER A. BONANNO
JOHN REARDON
PATRICK W. RATKOWSKI
JOHN F.C. LUEDKE*
PAULA DEZA*
JOHN W. HOPKINS, JR.*
MICHAEL C. HOCHMAN*
JOHN B. O'LOUGHLIN, JR.*
DAWN M. RAMES*
DEVON WH. HILL*
DANIEL QUINTART**
MICHAEL A. PETRUZZI*

*NOT ADMITTED IN D.C.
OR RESIDENT BRUSSELS

SCIENTIFIC STAFF
DANIEL S. DIXLER, Ph. D.
CHARLES V. BREDER, Ph. D.
ROBERT A. MATHEWS, Ph. D., D.A.B.T.
JOHN P. MODDERMAN, Ph. D.
HOLLY NUTHIRE FOLEY
JANETTE HOUK, Ph. D.
LESTER BORODINSKY, Ph. D.
THOMAS C. BROWN*
MICHAEL T. FLOOD, Ph. D.
ANDREW P. JOVANOVIICH, Ph. D.
ANNA GERGELY*
—
TELECOMMUNICATIONS
ENGINEER
RANDALL D. YOUNG
—
WRITER'S DIRECT ACCESS

September 2, 1997

(202) 434-4121
powell@khlaw.com

DATE-STAMPED FILE COPY REQUESTED

Handwritten signatures and notes:
Products Ident...
Comments Process...

BY HAND

Ms. Sadye E. Dunn
Office of the Secretary
Consumer Product Safety Commission
Room 502
4330 East-West Highway
Bethesda, Maryland 20814

Re: ANPR for Petroleum Distillates

Dear Ms. Dunn:

On behalf of our client, the Florida Chemical Company, this letter comments on the Advanced Notice of Proposed Rulemaking (ANPR) for Household Products Containing Petroleum Distillates and Other Hydrocarbons [62 Fed. Reg. 8659 (Feb. 26, 1997)]. We understand that comments will be accepted on September 2, due to the the extended deadline to submit comments falling on a holiday, September 1, 1997.

Among the welter of comments that the Consumer Products Safety Commission (CPSC) receives for a proposed rulemaking, we understand the difficulty by the staff in extracting meaningful inputs from polemics. As one might expect, comments are only likely to be generated by stakeholders. Our client, the Florida Chemical Company produces "limonene," one of the "other hydrocarbons" named in the ANPR. On their behalf, we hope our remarks are perceived

as insights with the intention of enhancing the process of rulemaking. These comments are based on our understanding of the ANPR, literature research, a review of non-confidential comments that have already been received by the CPSC, and on the combined knowledge and experience of our client and ourselves.

As described in more detail below, we believe that "limonene" can be distinguished from hydrocarbons that pose high potential risks if aspirated. While the physical properties of viscosity and surface tension appear to be important factors in assessing the potential for aspiration of liquids, other factors should not be overlooked in assessing the risk of such aspiration. In focusing on petroleum-based hydrocarbons, the other factors are neglected because hydrophobic hydrocarbons with sufficiently low evaporation rates which can be aspirated can be fatal at low doses. The category of substances considered for regulation is based on data for substances that consist predominantly of water insoluble, straight-chain, saturated, aliphatic hydrocarbons. By extending this category to "limonene," which is a cyclic, branched unsaturated hydrocarbon with significantly higher solubility in water, the scope of the category has become too inclusive.

GENERAL COMMENT

This ANPR communicates that the CPSC has perceived a risk due to reported incidents of death and other adverse effects where children have aspirated household products into their lungs. Some of the household products involved in these incidents contained various concentrations of hydrocarbons and other chemical substances, including non-hydrocarbons. The argument seems to be that because of these incidents the CPSC should investigate and determine if something should be done to prevent or to mitigate the occurrence of such incidents. We cannot agree that the data support an across-the-board requirement for child-resistant closures for household products containing "limonene."

The description of the category of substances announced in the ANPR is "household products containing petroleum distillates and other hydrocarbons." The words *petroleum distillates* cast a negative image on the chemical category being considered for regulation. However, some of the substances in the category are perceived as harmless. In particular, "limonene" has a pleasing, fresh aroma, and as a constituent of food it is generally recognized as safe. As a natural product, some people would not regard D-limonene as a "chemical."

Without the florid language in the ANPR or in some of the previous comments, we ask the CPSC staff to assess the perceived risk accurately and in the light of other risks. As tragic as death and harmful incidents are, especially to young children, this rulemaking should proceed on a sound technical, scientific, and economic basis. There will always be some risks of death and other adverse effects that rulemaking cannot reach or should not reach.

Insufficiently supervised children will not be necessarily at less risk due to the aspiration of household liquids by the imposition of packaging requirements. For example, it is not known how

many of the incidents cited in the ANPR involved open vs. closed containers.¹ Please note that we say household liquids, because many, but not all, liquids in and around the home can produce the same effects.

Moreover, the risks being addressed are largely physical, not chemical. It does not serve the purposes of this inquiry to couch the description of the adverse effects as though they are brought about by chemical effects. It appears that the authors of the ANPR, consider all "chemicals" "toxic" as though they are metabolic poisons. This illustrates, perhaps more cogently than any other point, that this risk can be most cost-effectively thwarted by labeling, disseminating information, and other educational approaches.

If people do not know of the risks from consumer products, they should be informed. If they knowingly allow a child to be exposed to substances in and around the home that can harm a child, there is little that the CPSC can meaningfully do to prevent or to mitigate the results. In fact, child-resistant closures often result in at-home repackaging of substances or non-closure of containers.

Obviously, children are often not capable of perceiving risks in their environment, and sometimes their supervisors are uninformed of certain risks. Where information is lacking, it should and must be provided. It can be argued that the CPSC should make efforts, consistent with their resources and the benefits to be derived, to inform people of risks, particularly risks to children and to teach people how to avoid risks and to protect the health and welfare of children. In many cases, it can also be argued that the relative risk of the behavior to be avoided is not sufficiently high or particularly germane to the CPSC's purpose to warrant the cost.²

This ANPR seems to address *behavior*. The behavior, in some cases exacerbated by ignorance, is that people allow children access to hydrophobic liquids that can be aspirated. That behavior is not reckless if people do not know of the risk. The end result of getting such a liquid into one's lungs is not necessarily prevented nor significantly mitigated by a mandated device.

The facts to be communicated are that certain substances and mixtures that are mostly liquids and that have a certain surface tension, solubility parameter, and other physical properties can be self-aspirated into lungs and can cause death and other severely adverse effects. The scope

¹ The effectiveness of a rule depends on whether most aspiration incidents occur because a container was able to be opened or whether the substance was available because the container was left open. In the latter situation, child-resistant closures might be counter-effective.

² Please note that education might reduce the number of aspiration incidents regardless of the type of closures on containers.

of potential regulation is enormous. It is not limited to petroleum distillates. But not all liquids can be aspirated, and of those that can, not all have the same risk. The focus on this particular category serves to illustrate that the emphasis is misplaced. It is as though by using the words, *petroleum distillates and other hydrocarbons*, an insidious, inherent chemical risk like that of a metabolic poison has been identified.

We urge the CPSC staff to reconsider the scope of the category to be regulated as well as the fundamental concepts of relative risk and assumption of risk. The risk in the present matter primarily originates with those who have the responsibility for the care of children. It is undeniable that children might die if they are permitted to have access to some liquids in certain concentrations, forms, and packages. The real issues are (1) precisely what substances cause the risk and (2) can rulemaking make a *significant* difference. If it is to make any difference, a more substantial grounding on facts and scientific supporting rationale must be its basis. Thus far, the CPSC has not established a meaningful link between child-resistant packaging and aspiration, particularly for "limonene."

SPECIFIC COMMENTS

I. Definition of the Category of Substances to be Regulated

The ANPR defines the category of substances to be petroleum distillates and other hydrocarbons that are said not to be petroleum distillates. However, the actual category appears to be hydrophobic hydrocarbons. Apparently, the existing supporting data is specifically for substances such as gasoline, kerosene, and mineral seal oil. These products all consist primarily of straight-chain aliphatic, saturated hydrocarbons known as *n*-alkanes. This type of hydrocarbon is hydrophobic, *i.e.*, essentially insoluble in water.

Petroleum consists of a vast range of hydrocarbons and other classes of substances. Benzene, toluene, and xylene are not "other hydrocarbons." These occur in petroleum and can be derived from petroleum streams, although not necessarily from the distillation of crude oil.

Pine oil is not a hydrocarbon, *per se*, it is principally a combination of terpene alcohols. Because alcohols contain the element oxygen, they are not hydrocarbons. Pine oil, turpentine, and "limonene" are derived primarily from plant sources.

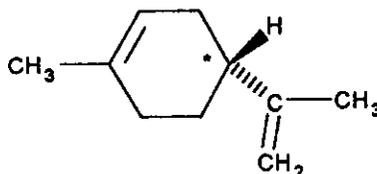
Pine oil, turpentine, and "limonene" are not composed of the *n*-alkanes that make up gasoline, kerosene, and mineral seal oil. As a whole, this ANPR's category of substances does not appear to have sufficiently common attributes.

II. Chemical Identity of Limonene

The ANPR gives notice of potential regulation of terpenes as a class including "limonene" among the "other hydrocarbons" that are not petroleum distillates. This terminology is too vague to give adequate notice of what is the subject of potential regulation.

Terpenes are unsaturated hydrocarbons having the molecular formula $C_{10}H_{16}$. Various terpenes are naturally produced by plants and are constituents of most essential oils. Terpenes that contain one ring are classified as dipentenes. *Limonene* is a dipentene, but that is not a definitive term. *Limonene* is not a chemically specific name.

There are several specific substances that are referred to loosely as "limonene." In the most specific sense, at least to our client, *limonene* means (*R*)-1-methyl-4-(1-methylethenyl)cyclohexene with Chemical Abstract Services Registry Number (CASRN) 5989-27-5. The structure is



R-Limonene

(*R*)-1-methyl-4-(1-methylethenyl)cyclohexene is optically active. The carbon in the ring with an asterisk is asymmetrical. Optically active substances rotate plane-polarized light. This "limonene" is also known as *l*-, *D*-, or (+)-limonene [or -1-methyl-4-(1-methylethenyl)-cyclohexene]. Other interested parties might interpret "limonene" as a wholly different specific substance.

The mirror image of (*R*)-1-methyl-4-(1-methylethenyl)cyclohexene is (*S*)-1-methyl-4-(1-methylethenyl)cyclohexene with CASRN 5989-54-8. This limonene also occurs naturally and is also known as *l*-, *L*-, or (-)-1-methyl-4-(1-methylethenyl)cyclohexene (or -limonene). Except for the direction of the rotation of plane-polarized light, the *R*- and *S*- isomers have essentially identical physical properties. Such isomers are termed *enantiomers*. Enantiomers can interact differently with other asymmetric substances.

A distinction has been made between mixtures of enantiomers and the special case where both an *R*- and *S*- isomer occur together equally. Such a combination of optically active isomers cancels their property to rotate plane-polarized light. This combination of isomers is termed *racemic*. A racemic mixture has been considered to be a single entity in the chemical

nomenclature system of Chemical Abstracts Service (CAS). In this case, racemic limonene is described specifically as (+ -)-1-methyl-4-(1-methylethenyl)cyclohexene with CASRN 7705-14-8. Any other non-equal mixture of these enantiomers would properly be represented by the two separate chemical names and CASRN's. This racemic "limonene" is also known as *dipentene*, but this usage should not be confused with *dipentene* as applied in the context immediately below.

A further distinction is made for optically active substances where the configuration of the asymmetric center is of a substance is unknown, not reasonably ascertainable, or not reasonably anticipated. In such cases, the chemical description of the substance omits any indication of the configuration. That is, the substance is not described as *R*-, *S*-, nor (+ -). In this case, *unspecified* limonene is described specifically as 1-methyl-4-(1-methylethenyl)cyclohexene with CASRN 138-86-3. This "limonene" is also known as *dipentene*. 1-Methyl-4-(1-methylethenyl)-cyclohexene with CASRN 138-86-3 is manufactured by the pyrolysis of α -pinene. This process involves an intermediate in which the asymmetric center is temporarily symmetric. Therefore, both the *R*- and *S*-isomers are probably produced, but not necessarily in equal nor consistent proportions. Hence, the asymmetric center's configuration is unknown, not reasonably ascertainable, or not reasonably anticipated.³

Optically active limonenes are derived from various citrus oils and are considered a by-product of the citrus fruit industry. Racemic limonene or *dipentene* is formed (with other terpenes) in the processing of sulfate liquor from kraft paper manufacture. In the paper industry, *dipentene* is sometimes used to designate a crude distillate fraction from pulp mill liquor.

There are three other descriptions of "limonene" substances which are considered single entities that are believed to be in United States' commerce. These chemical descriptions are based on the perspective of industrial streams being entities that are permitted to be listed on the Chemical Substances Inventory under the Toxic Substances Control Act.

One substance has the CAS Index Name, *Hydrocarbons, terpene processing by-products* and CASRN 68956-56-9. This listing is for a *combination* of substances and has no further

³ Sometimes, chemical descriptions that are less than fully descriptive (as in the omission of the asymmetric configuration) are interpreted incorrectly as "generic." In other words, if the chemical description is not totally specified, such descriptions might be deemed to mean whatever is within the scope of what is specified. We understand that Chemical Abstracts Service considers it incorrect to ascribe more specific chemical identities to less specific chemical descriptions and their associated CASRN's. Omission of a structural feature in the CAS nomenclature system generally does not permit latitude in what is known, reasonably ascertainable, or reasonably anticipated about the omitted structural feature. The *unspecified* chemical name with CASRN 138-86-3 does not comport with either enantiomer or the *racemic* mixture.

information that would permit a better understanding of what is represented. It seems reasonable to think that some "limonene" might be a constituent.

A second substance has the CAS Index Name, *Terpenes and Terpenoids, limonene fraction* and CASRN 65996-98-7*†.⁴ The Chemical Substance Definition that is associated with this listing is

A complex combination of terpenes derived from oil of turpentine or citrus oils by fractionation or isomerization of other terpene fractions. Contains at least 80% limonene, the remainder being other terpene hydrocarbons. May contain trace amounts of alcohols, ethers, aldehydes, or ketones.

Before the TSCA Chemical Substance Inventory (Inventory) was compiled, the Environmental Protection Agency (EPA) proposed a candidate list of chemical substances that were believed to be in U.S. commerce. The candidate list was established as a convenience in reporting substances for the initial TSCA Inventory. In the third addition to that list, a document known as Addendum III, a group of substances is provided in Section IV that is titled Wood and Pulp Chemicals. This list was developed by the EPA in conjunction with the Pulp Chemicals Association (PCA). In Addendum III, the listing with CASRN 65996-98-7 was described as *Terpenes, 80% or greater Limonene Fraction*. This description is currently listed as an alternative description or "synonym." According to PCA records,⁵ one earlier description of this same product was:

Limone

A terpene fraction containing at least 90% limonene, the remainder being other terpene hydrocarbons and trace amounts of alcohols, ethers, aldehydes, or ketones.

According to the early records, this earlier version of the description was designed to cover (1) high purity dipentenes produced by fractionation, (2) high purity dipentenes produced

⁴ The asterisk denotes that Chemical Abstracts Service has only assigned a registry number (RN) to this substance for the purpose of compiling the TSCA Inventory. These RN's are not used by CAS in their Abstracts or Indices. All of the substances that have an asterisk after their RN's appear in the UVCB Index. The UVCB Index is a portion of the printed TSCA Inventory wherein chemical substances of unknown or variable composition, complex reaction products, and biological materials are listed under general headings. The dagger (†) denotes a substance that has a scope note in *Chemical Substance Definitions*, Appendix A of the printed Inventory.

⁵ Letter from Douglas E. Campbell to PCA members of a TOSCA (*sic*) group, August 17, 1977 (re definitions of tall-oil products).

Ms. Sadye E. Dunn
 September 2, 1997
 Page 8

by isomerization of other terpene fractions, (3) dipentene from citrus production, (4) distilled and undistilled products. Another earlier description was identical including the purpose, except that the "limonene" content was 80%.

The listing above should be compared to the third listing that specifies a lower content of limonene: *Terpenes and Terpenoids, turpentine-oil, limonene fraction*, with CASRN 65996-99-8*†. The Chemical Substance Definition that is associated with this listing is

Oil of Turpentine, 50% or greater limonene fraction.

A complex combination of terpenes derived from oil of turpentine. Contains at least 50% limonene, the remainder being phellandrenes, terpinenes, terpinolene, cineoles.

In Addendum III, the listing with Chemical Abstracts Service Registry Number (CASRN) 65996-99-8 was described as *Oil of Turpentine, 50% or greater limonene fraction*. This description is currently listed as an alternative description or "synonym." According to the same PCA records noted above, there were two earlier descriptions of this same product that were identical:

Dipentene

A distilled fraction derived from turpentine containing at least 50% limonene with phellandrene, the terpinenes, terpinolene, and the cineoles as the other major components.

In summary, there are several "limonenes," including at least two "dipentenes" that are described as "limonenes." One should not rely on the name "limonene" alone nor on a single CASRN to designate "limonene."⁶ The CASRN's and Index Names and Chemical Substance Definitions (where they exist) are listed in the table below for the "limonenes" discussed above.

⁶ For example, " ϕ -limonene" or *pseudo*-limonene, better described as 4-methylene-1-(1-methylethenyl)cyclohexane, CASRN 499-97-8, while it is a dipentene, it is not included in this discussion of "limonenes" because it does not have the 1-methyl-4-(1-methylethenyl)-cyclohexene structure. Various other dipentenes are not considered "limonenes" for the same reason.

"LIMONENE" CHEMICAL DESCRIPTIONS⁷

1. 68956-56-9
Hydrocarbons, terpene processing by-products
2. 65996-99-8
Terpenes and Terpenoids, turpentine-oil, limonene fraction
Oil of Turpentine, 50% or greater limonene fraction. A complex combination of terpenes derived from oil of turpentine. Contains at least 50% limonene, the remainder being phellandrenes, terpinenes, terpinolene, cineoles.
3. 65996-98-7
Terpenes and Terpenoids, limonene fraction
Terpenes, 80% or greater Limonene Fraction. A complex combination of terpenes derived from oil of turpentine or citrus oils by fractionation or isomerization of other terpene fractions. Contains at least 80% limonene, the remainder being other terpene hydrocarbons. May contain trace amounts of alcohols, ethers, aldehydes, or ketones.
4. 7705-14-8
Cyclohexene, 1-methyl-4-(1-methylethenyl)-, (+-)-
5. 5989-54-8
Cyclohexene, 1-methyl-4-(1-methylethenyl)-, (S)-
6. 5989-27-5
Cyclohexene, 1-methyl-4-(1-methylethenyl)-, (R)-
7. 138-86-3
Cyclohexene, 1-methyl-4-(1-methylethenyl)-.

III. Properties of "Limonene"

We searched the technical literature for physical properties of the various "limonenes" and as well as for some analogous linear aliphatic hydrocarbons that have the same or nearly the same carbon number. We have enclosed a chart of our findings on physical property data.

⁷ These substances are listed on the Chemical Substance Inventory under the Toxic Substances Control Act (TSCA).

Our searches yielded data that shows that these hydrocarbons have many properties in common *except solubility in water* and octanol-water partition coefficient. In general, various "limonenes" are over 250 times more soluble in water than decane and over 3700 times more soluble than dodecane. Given the decrease in solubility in water from decane to dodecane, it could well be that hydrocarbons such as mineral seal oil which have the greatest propensity to cause death and other adverse effects are of about the same or even less soluble than dodecane in water because they consist of homologs to dodecane with higher molecular weight. It would appear that "limonene" should not be grouped with straight-chain aliphatic, saturated hydrocarbons derived from petroleum on the basis of this physical property. For example, there are many non-hydrocarbon liquids that are less soluble in water than "limonene," and they are not all grouped with hydrocarbons derived from petroleum.

The log of the octanol-water partition coefficient of decane is 5.98 while that for "limonene" is 4.232. This means that decane concentrates in 1-octanol vs. water to a degree that is 45 times more than that for "limonene." In general, for mucus membranes there should be an optimum octanol-water partition coefficient for absorption above which the more hydrophobic a substance becomes the less it is absorbed. It would appear that, aliphatic hydrocarbons cause the adverse effects observed in the lung because they are not absorbed. Usually there is an octanol-water partition coefficient "floor" above which there is no membrane absorption. Because adverse effects are particularly severe for hydrophobic liquids that can be aspirated such as decane, it seems reasonable that this data might mean that the effects for "limonene" are less severe.

While both solubility in water and octanol-water partition coefficients are indicative of the differences in physical properties between "limonene" and non-cyclic, aliphatic hydrocarbons, there might be others, such as various solubility parameters. If these solubility factors are combined with evaporation rates, surface tension, viscosity, and other properties, a model could emerge that will properly focus which products pose the greatest risks.

IV. Origin of the Inclusion of "Limonene"

The ANPR states that "a number of household products contain low-viscosity hydrocarbons other than petroleum distillates" including terpenes. It also states that "terpene hydrocarbons" are in such products as "limonene" and that "limonene" is found in "cleaning products" and "spot removers."

There does not appear to be any other reason for inclusion of "limonene" in this ANPR except that it is a low-viscosity hydrocarbon that is not a petroleum distillate that occurs in certain types of household products that, in some cases, do not require child-resistant packaging. Because "limonene" has significantly different solubility characteristics compared with typical petroleum-derived hydrocarbons and because it has a characteristically pleasant, citrus odor, "limonene" is used at various concentrations. Sometimes the concentrations are quite low,

because "limonene" is used merely as an odorant. However, "limonene" is sometimes used in applications in conjunction with petroleum-derived hydrocarbons and may have been perceived incorrectly as just one of many "other hydrocarbons."

V. Products Containing "Limonene"

"Limonene" is contained in a wide variety of products: food, cosmetics, and cleaning products. Food products and cosmetics constitute smaller uses of "limonene," while cleaning products constitute larger uses.

In food and cosmetics the concentrations of "limonene" are relatively low. In general, food products such as citrus drinks will contain less than one percent "limonene" by volume, because it is added to enhance flavor characteristics. Cosmetic formulations might contain as much as about five to ten percent "limonene." In cosmetic formulations, "limonene" is used as an odorant or as a co-solvent.

Cleaning products vary greatly. They range from general-purpose cleaners to heavy industrial formulations. We discuss six general groups. Group 1 includes products that usually contain less than one percent "limonene" to act as an odorant. Such products rely on surfactants or other non-hydrocarbon ingredients to perform the cleaning function. Group 2 includes a number of general-purpose cleaners that usually contain five to fifteen percent "limonene" in an aqueous formulation. These are to be used as is, or they can be further diluted with water to perform cleaning tasks. A third group of cleaning products consist of "limonene" and surfactant mixtures with the "limonene" concentration close to 90 percent of the formulation. This group of products is used undiluted for heavy duty cleaning, such as removal of greases, and then rinsed with water. These products can also be diluted with water and used for lighter cleaning applications. Group four consists of "limonene" packaged by itself to perform heavy cleaning jobs without water rinsing. There are two miscellaneous groups that combine "limonene" with hydrocarbons derived from petroleum. Group five generally contains 20 to 30 percent "limonene" and are intended for heavy degreasing without water rinsing. In group six, "limonene" is used in hand-cleaner formulations, usually at about 20 weight percent. Hand-cleaner formulations generally are too viscous to have any significant aspiration potential.

VI. Evidence of Relevant Toxicological Endpoint(s) and Mechanism of Toxic Effects

We did not find any actual studies on any form of "limonene" that are relevant to this proceeding. While various forms of "limonene" might be better than hydrocarbons for which there are data, there are thousands of substances in U.S. commerce and many new ones introduced each week that might be better or worse than hydrocarbons for which there are data.

Some liquids do not pose a risk of death or other severe adverse effects if aspirated, or they do not pose as severe a risk as alkanes, such as those in mineral seal oil, even if they have the

viscosity and surface tension that cause them to be susceptible to aspiration. One cannot validly conclude that any or all forms of "limonene" are likely to have the same effects as hydrocarbons derived from petroleum. Given the differences in solubility in water and in octanol-water partition coefficients between "limonene" and alkanes, it appears that more study would be needed to include "limonene" along with petroleum-based products.

The ANPR identified cases of aspiration that were linked with products containing "limonene." However, in no case was a product identified that was labeled as "limonene" or as primarily consisting of "limonene."

The adverse effects of aspirating liquids are not well understood; therefore, it is reasonable to limit current consideration to those substances known to be directly associated with harmful aspirations. The presence of "limonene" as an aroma chemical in a petroleum-based product does not implicate the "limonene" as an ingredient posing an aspiration risk.

VII. Concentration Threshold for "Limonene"

While we have no data on a level of "limonene" that is equivalent to the adverse effects of undiluted petroleum-derived hydrocarbons or their mixtures with other liquids, it would appear that the levels of "limonene" that are equivalent could be much higher than for petroleum-derived hydrocarbons. This is due to the higher solubility of "limonene" in water and its lower octanol-water partition coefficient.

It is evident that the aspiration of mixtures, particularly where water is a component may pose much less risk.⁸ Because "limonene" is often used without hydrocarbons and with water, these mixtures should not be regulated due the *presence* of "limonene" alone.

* * * * *

"Limonene" is not a typical hydrocarbon in that it does not have as low a solubility in water nor as high an octanol-water partition coefficient. "Limonene" should not be classed with petroleum-derived hydrocarbons. "Limonene" itself needs to be more particularly identified. No incidents of death or serious adverse effects have been reported for "limonene," *per se*, and the severe effects including death might only be bought about if a person was essentially drowned in "limonene." In that is indeed the case, child-resistant packaging is not warranted for "limonene."

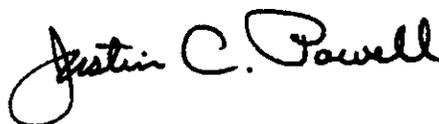
⁸ André G. Craan, "Aspiration hazard and consumer products: a review," *International Journal for Consumer Safety*, vol.3 (3) 153-164 (Mar. 1966) (in comments labeled CP97-2-24).

Ms. Sadye E. Dunn
September 2, 1997
Page 13

KELLER AND HECKMAN LLP

The authors of this ANPR have been too ambitious in determining the scope of the class of substances under consideration. We respectfully ask the CPSC staff to elucidate the role of solubility characteristics among the properties of liquids that can be aspirated to determine their role in these incidents. More than anything else, we hope that sound scientific reasoning and practical knowledge will be invested in these considerations. The only meaningful regulations are those that achieve the desired result. In this case, it might be more meaningful and cost-effective to inform and educate the public.

Sincerely yours,

A handwritten signature in black ink that reads "Justin C. Powell". The signature is written in a cursive style with a large initial 'J'.

Justin C. Powell, Ph.D., J.D.

Enclosure

cc: Ross Gustafson, Florida Chemical Company

SUBSTANCE	CASRN	BP	MP	K _{ow}	BV	DV ¹	KV ²	SLB ³	DM
Hydrocarbons, terpene processing by-products	68956-56-9	-----	-----	-----	-----	-----	-----	-----	-----
Terpenes and Terpenoids, turpentine-oil, limonene fraction	65996-99-8	-----	-----	-----	-----	-----	-----	-----	-----
Terpenes and Terpenoids, limonene fraction	65996-98-7	-----	-----	-----	-----	-----	-----	-----	-----
Cyclohexene, 1-methyl-4-(1-methylethenyl)-, (.+.-.)-	7705-14-8	175.5- 176.5 ⁴	-95.5	4.232	-----	-----	-----	13.8 ⁵	-----
Cyclohexene, 1-methyl-4-(1-methylethenyl)-, (S)-	5989-54-8	177.70 ⁶	-73.95	4.232	-----	-----	-----	-----	-----
Cyclohexene, 1-methyl-4-(1-methylethenyl)-, (R)-	5989-27-5	178.00	-96.60 ⁷	4.232	-----	-----	-----	13.8	.64

1 At 25.0 C. The units are g/cm*s.

2 At 25.0 C. The units are cm²/s.

3 At 25 C in water. Units are in mg/L.

4 At 763 MM HG. Taken from HSDB database citing Budavari, S., *The Merck Index - Encyclopedia of Chemicals, Drugs and Biologicals*, 865 (1989).

5 Lists the same value for 5989-54-8 and 138-86-3.

6 The value is an average of the values listed in BEILSTEIN of 177.60-177.80. Also note that the value is for a pressure of 755 Torr.

7 -74.35 was another value listed. It is dated 1943.

SUBSTANCE	CASRN	BP	MP	K _{ow}	BV	DV ⁸	KV ⁹	SLB	DM
Cyclohexene, 1-methyl-4-(1-methylethenyl) -	138-86-3	175.55	-89.03 ¹⁰	4.232	-----	-----	-----	13.8	.63
Octane	111-65-9	125.67	-56.80 ¹¹	5.18	-----	.005080	.007251	0.7 ¹²	-----
Decane	124-18-5	174.1	-29.7	5.98	-----	.008527	.011610	.052	0.00
1-Decene	872-05-9	170.56	-66.3	-----	-----	-----	.010900	INSOL	-----
Dodecane	112-40-3	216.3	-9.6	-----	-----	.013460	.018040	.0037	-----

KEY:

BP - Boiling Point at 760 Torr (Degrees Celsius)

MP - Melting Point at 760 Torr (Degrees Celsius)

K_{ow} - Octanol Water Partition Coefficient

BV - Bulk Viscosity

DV - Dynamic Viscosity

KV - Kinematic Viscosity

HLB - Hydrophilic Lipophilic Balance

SLB - Solubility in Water (or Other Substances)

SLP - Solubility Parameter

DM - Dipole Moment (via Dielectric Constant in Benzene)

8 At 25.0 C. The units are g/cm*s.

9 At 25.0 C. The units are cm²/s.

10 This is the most recent value from 1954. Another value listed was -95.50C, taken in 1943.

11 One melting point value also listed was -98.20.

12 Units are microgram/milliliter in water.

THOMPSON
HINE & FLORY LLP

Attorneys at Law

CPA: -2-30
CPSA 6 (b)(1) Cleared
No. 1199A
Products Identified
ANPR

December 15, 1998

Ms. Suzanne Barone
U.S. Consumer Product Safety Commission
4330 East-West Highway
Room 600
Bethesda, Maryland 20814-4408

Re: ANPR on Child Resistant Packaging for Products Containing Hydrocarbons

Dear Suzanne:

As you know, this Firm represents the Writing Instrument Manufacturers Association ("WIMA"). On behalf of WIMA, we want to first thank you for the opportunity to attend your November 18, 1998 meeting in the above-referenced proceeding.

After careful thought, WIMA recommends that the Commission simply provide for the same exemptions under the PPPA as are provided for under the FHSA, i.e., 16 C.F.R. Parts 1500.83(a)(7)(9)(12) and (38). See attached. WIMA would not oppose more generic descriptions of writing instruments such as pens and markers. However, ultimately these terms would need to be defined further. Accordingly, WIMA believes that the current definitions in the FHSA exemptions are probably most workable.

Thank you for this opportunity to comment.

Very truly yours,

THOMPSON HINE & FLORY LLP



David H. Baker
Attorney for
Writing Instrument Manufacturers
Association, Inc.

DHB:jkp
Enclosures

§ 1500.83

be expected, to read and heed such directions and warnings, may submit to the Commission a request for exemption under section 2(q)(1)(B)(1) of the act (repeated in proviso (7) under §1500.3(b)(15)(1)), presenting facts in support of his contention. The commission shall determine on the basis of the facts submitted, and all other available information, whether the requested exemption is consistent with the purposes of the act. If the Commission so finds, it shall detail the exemption granted and the reasons therefor by an appropriate order in the FEDERAL REGISTER.

(d) On its own initiative, the Commission may determine on the basis of available facts that a particular banned hazardous substance should be exempted from section 2(q)(1)(A) of the act (repeated in §1500.3(b)(15)(1)(A)), because its functional purpose requires inclusion of a hazardous substance, it bears labeling giving adequate directions and warnings for safe use, and it is intended for use by children who have obtained sufficient maturity, and may reasonably be expected, to read and heed such directions and warnings. If the Commission so finds, it shall detail the exemption granted and the reasons therefor by an appropriate order in the FEDERAL REGISTER.

§1500.83 Exemptions for small packages, minor hazards, and special circumstances.

(a) The following exemptions are granted for the labeling of hazardous substances under the provisions of §1500.82:

(1) When the sole hazard from a substance in a self-pressurized container is that it generates pressure or when the sole hazard from a substance is that it is flammable or extremely flammable, the name of the component which contributes the hazards need not be stated.

(2) Common matches, including book matches, wooden matches, and so-called "safety" matches are exempt from the labeling requirements of section 2(p)(1) of the act (repeated in §1500.3(b)(14)(1)) insofar as they apply to the product being considered hazardous because of being "flammable" or "extremely flammable" as defined in §1500.3(c)(6)(iii) and (iv).

16 CFR Ch. II (1-1-98 Edition)

(3) Paper items such as newspapers, wrapping papers, toilet and cleansing tissues, and paper writing supplies are exempt from the labeling requirements of section 2(p)(1) of the act (repeated in §1500.3(b)(14)(1)) insofar as they apply to the products being considered hazardous because of being "flammable" or "extremely flammable" as defined in §1500.3(c)(6)(iii) and (iv).

(4) Thread, string, twine, rope, cord, and similar materials are exempt from the labeling requirements of section 2(p)(1) of the act (repeated in §1500.3(b)(14)(1)) insofar as they apply to the products being considered hazardous because of being "flammable" or "extremely flammable" as defined in §1500.3(c)(6) (iii) and (iv).

(5) Laboratory chemicals intended only for research or investigational and other laboratory uses (except those in home chemistry sets) are exempt from the requirements of placement provided in §1500.121 if all information required by that section and the act appears with the required prominence on the label panel adjacent to the main panel.

(6) [Reserved]

(7) Rigid or semirigid ballpoint ink cartridges are exempt from the labeling requirements of section 2(p)(1) of the act (repeated in §1500.3(b)(14)(1)), insofar as such requirements would be necessary because the ink contained therein is a "toxic" substance as defined in §1500.3(c)(2)(1), if:

(i) The ballpoint ink cartridge is of such construction that the ink will, under any reasonably foreseeable conditions of manipulation or use, emerge only from the ballpoint end;

(ii) When tested by the method described in §1500.3(c)(2)(1), the ink does not have an LD-50 single oral dose of less than 500 milligrams per kilogram of body weight of the test animal; and

(iii) The cartridge does not have a capacity of more than 2 grams of ink.

(8) Containers of paste shoe waxes, paste auto waxes, and paste furniture and floor waxes containing toluene (also known as toluol), xylene (also known as xylol), petroleum distillates, and/or turpentine in the concentrations described in §1500.14(a)(3) and (5) are exempt from the labeling requirements of §1500.14(b)(3)(ii) and (5) if the

Consumer Product Safety Comm

viscosity of such products is sufficiently high so that they will not flow from their opened containers when inverted for 5 minutes at a temperature of 80 °F., and are exempt from being a flammability warning statement if the flammability of such waxes is solely to the presence of solvents having flashpoints above 80 °F. tested by the method describe §1500.43.

(9) Porous-tip ink-marking devices are exempt from the labeling requirements of section 2(p)(1) of the act (repeated in §1500.3(b)(14)(1)) and from labeling requirements of §1500.14(c)(2), and (3)(ii) and (iii) insofar as requirements would be necessary because the ink contained therein contains a toxic substance as defined in §1500.3(c)(2)(1), and/or because the device contains 10 percent or more by weight of toluene (also known as toluol), xylene (also known as xylol), or petroleum distillates as defined in §1500.14(a)(3), and/or because the device contains 10 percent or more by weight of ethylene glycol; provided that:

(i) The porous-tip ink-marking device is of such construction that:

(A) The ink is held within the device by an absorbent material so that free liquid is within the device; and

(B) Under any reasonably foreseeable conditions of manipulation and use, including reasonably foreseeable abuse by children, the ink will emerge only through the porous writing nib of the device; and

(ii)(A) The device has a capacity of not more than 10 grams of ink and the ink, when tested by methods described in §1500.3(c)(2)(1), has an LD-50 single oral dose of not less than 2.5 grams per kilogram of body weight of the test animal; or

(B) The device has a capacity of not more than 12 grams of ink and the ink, when tested by methods described in §1500.3(c)(2)(1), has an LD-50 single oral dose of not less than 3.8 grams per kilogram of body weight of the test animal.

(10) Viscous nitrocellulose-base adhesives containing more than 4 percent methyl alcohol by weight are exempt from the label statement "Cannot be made nonpoisonous" required by §1500.14(b)(4) if:

Paper items such as newspapers, typing papers, toilet and cleaning paper, and paper writing supplies are exempt from the labeling requirements of section 2(p)(1) of the act (repeated in 1500.3(b)(14)(i)) insofar as they apply to the products being considered hazardous because of being "flammable" or "extremely flammable" as defined in 1500.3(c)(6)(iii) and (iv).

Thread, string, twine, rope, cord, and similar materials are exempt from labeling requirements of section 1) of the act (repeated in 1500.3(b)(14)(i)) insofar as they apply to the products being considered hazardous because of being "flammable" or "extremely flammable" as defined in 1500.3(c)(6)(iii) and (iv).

Laboratory chemicals intended for research or investigational or other laboratory uses (except those in some chemistry sets) are exempt from the requirements of placement of the label as provided in § 1500.121 if all information required by that section and the act is placed with the required prominence on the label panel adjacent to the main panel.

[Reserved]

Rigid or semirigid ballpoint ink cartridges are exempt from the labeling requirements of section 2(p)(1) of the act (repeated in § 1500.3(b)(14)(i)), insofar as such requirements would be necessary because the ink contained therein is a "toxic" substance as defined in § 1500.3(c)(2)(i), if:

The ballpoint ink cartridge is of such construction that the ink will, under any reasonably foreseeable conditions of manipulation or use, emerge from the ballpoint end;

When tested by the method described in § 1500.3(c)(2)(i), the ink does have an LD-50 single oral dose of not less than 500 milligrams per kilogram body weight of the test animal; and

The cartridge does not have a capacity of more than 2 grams of ink.

Containers of paste shoe waxes, auto waxes, and paste furniture floor waxes containing toluene (also known as toluol), xylene (also known as xylol), petroleum distillates, or turpentine in the concentrations described in § 1500.14(a)(3) and (5) are exempt from the labeling requirements of § 1500.14(b)(3)(i) and (5) if the

viscosity of such products is sufficiently high so that they will not flow from their opened containers when inverted for 5 minutes at a temperature of 90 °F., and are exempt from bearing a flammability warning statement if the flammability of such waxes is due solely to the presence of solvents that have flashpoints above 90 °F. when tested by the method described in § 1500.43.

(9) Porous-tip ink-marking devices are exempt from the labeling requirements of section 2(p)(1) of the act (repeated in § 1500.3(b)(14)(i)) and from the labeling requirements of § 1500.14(b)(1), (2), and (3)(i) and (iii) insofar as such requirements would be necessary because the ink contained therein is a toxic substance as defined in § 1500.3(c)(2)(i), and/or because the ink contains 10 percent or more by weight of toluene (also known as toluol), xylene (also known as xylol), or petroleum distillates as defined in § 1500.14(a)(3), and/or because the ink contains 10 percent or more by weight of ethylene glycol; provided that:

(i) The porous-tip ink-marking devices are of such construction that:

(A) The ink is held within the device by an absorbent material so that no free liquid is within the device; and

(B) Under any reasonably foreseeable conditions of manipulation and use, including reasonably foreseeable abuse by children, the ink will emerge only through the porous writing nib of the device; and

(i)(A) The device has a capacity of not more than 10 grams of ink and the ink, when tested by methods described in § 1500.3(c)(2)(i), has an LD-50 single oral dose of not less than 2.5 grams per kilogram of body weight of the test animal; or

(B) The device has a capacity of not more than 15 grams of ink and the ink, when tested by methods described in § 1500.3(c)(2)(i), has an LD-50 single oral dose of not less than 3.0 grams per kilogram of body weight of the test animal.

(10) Viscous nitrocellulose-base adhesives containing more than 4 percent methyl alcohol by weight are exempt from the label statement "Cannot be made nonpoisonous" required by § 1500.14(b)(4) if:

(i) The total amount of methyl alcohol by weight in the product does not exceed 15 percent; and

(ii) The contents of any container does not exceed 2 fluid ounces.

(11) Packages containing polishing or cleaning products which consist of a carrier of solid particulate or fibrous composition and which contain toluene (also known as toluol), xylene (also known as xylol), or petroleum distillates in the concentrations described in § 1500.14(a)(1) and (2) are exempt from the labeling requirements of § 1500.14(b)(3)(ii) if such toluene, xylene, or petroleum distillate is fully absorbed by the solid, semisolid, or fibrous carrier and cannot be expressed therefrom with any reasonably foreseeable conditions of manipulation.

(12) Containers of dry ink intended to be used as a liquid ink after the addition of water are exempt from the labeling requirements of section 2(p)(1) of the act (repeated in § 1500.3(b)(14)(i)) and from the labeling requirements of § 1500.14(b)(1) and (2) insofar as such requirements would be necessary because the dried ink contained therein is a toxic substance as defined in § 1500.3(c)(2)(i) and/or because the ink contains 10 percent or more of ethylene glycol as defined in § 1500.14(a)(3); provided that:

(i) When tested by the method described in § 1500.3(c)(2)(i), the dry ink concentrate does not have an LD-50 (lethal dose, median; lethal for 50 percent or more of test group) single oral dose of less than 1 gram per kilogram of body weight of the test animal.

(ii) The dry ink concentrate enclosed in a single container does not weigh more than 75 milligrams.

(iii) The dry ink concentrate does not contain over 15 percent by weight of ethylene glycol.

(13) Containers of liquid and semisolid substances such as viscous-type paints, varnishes, lacquers, roof coatings, rubber vulcanizing preparations, floor covering adhesives, glazing compounds, and other viscous products containing toluene (also known as toluol), xylene (also known as xylol), or petroleum distillates in concentrations described in § 1500.14(a)(3) are exempt from the labeling requirements of

§ 1500.83

16 CFR Ch. II (1-1-98 Edition)

§1500.14(b)(3)(ii) insofar as that subdivision applies to such toluene, xylene, or petroleum distillates, provided that the viscosity of the substance or of any liquid that may separate or be present in the container is not less than 100 Saybolt universal seconds at 100 °F.

(14) Customer-owned portable containers that are filled by retail vendors with gasoline, kerosene (kerosine), or other petroleum distillates are exempt from the provision of section 2(p)(1)(A) of the act (which requires that the name and place of business of the manufacturer, distributor, packer, or seller appear on the label of such containers) provided that all the other label statements required by section 2(p)(1) of the act and §1500.14(b)(3) appear on the labels of containers of the substances named in this subparagraph.

(15) Cellulose sponges are exempt from the labeling requirements of section 2(p)(1) of the act and §1500.14(b)(1) insofar as such requirements would be necessary because they contain 10 percent or more of diethylene glycol as defined in §1500.14(a)(1), provided that:

(i) The cellulose sponge does not contain over 15 percent by weight of diethylene glycol; and

(ii) The diethylene glycol content is completely held by the absorbent cellulose material so that no free liquid is within the sponge as marketed.

(16) Containers of substances which include salt (sodium chloride) as a component are exempt from the labeling requirements of section 2(p)(1) of the act (repeated in §1500.3(b)(14)(i)) insofar as such requirements would be necessary because the salt contained therein is present in a quantity sufficient to render the article "toxic" as defined in §1500.3(3)(2)(i), provided that the labels of such containers bear a conspicuous statement that the product contains salt.

(17) The labeling of substances containing 10 percent or more of ferrous oxalate is exempt from the requirement of §1500.129(f) that it bear the word "poison" which would be required for such concentration of a salt of oxalic acid.

(18) Packages containing articles intended as single-use spot removers, and which consist of a cotton pad or other absorbent material saturated with a

mixture of drycleaning solvents, are exempt from the labeling requirements of section 2(p)(1) of the act (repeated in §1500.3(b)(14)(i)) insofar as they apply to the "flammable" hazard as defined in §1500.3(c)(5)(iv), provided that:

(i) The article is packaged in a sealed foil envelope;

(ii) The total amount of solvent in each package does not exceed 4.5 milliliters; and

(iii) The article will ignite only when in contact with an open flame, and when so ignited, the article burns with a sooty flame.

(19) Packages containing articles intended as single-use spot removers, and which consist of a cotton pad or other absorbent material containing methyl alcohol, are exempt from the labeling requirements of §1500.14(b)(4), if:

(i) The total amount of cleaning solvent in each package does not exceed 4.5 milliliters of which not more than 25 percent is methyl alcohol; and

(ii) The liquid is completely held by the absorbent materials so that no free liquid is within the packages marketed.

(20) Cigarette lighters containing petroleum distillate fuel are exempt from the labeling requirements of section 2(p)(1) of the act (repeated in §1500.3(b)(14)(i)) and §1500.14(b)(3) insofar as such requirements would be necessary because the petroleum distillate contained therein is flammable and because the substance is named in §1500.14(a)(3) as requiring special labeling, provided that:

(i) Such lighters contain not more than 10 cubic centimeters of fuel at the time of sale; and

(ii) Such fuel is contained in a sealed compartment that cannot be opened without the deliberate removal of the flush-set, screw-type refill plug of the lighter.

(21) Containers of dry granular fertilizers and dry granular plant foods are exempt from the labeling requirements of section 2(p)(1) of the act (repeated in §1500.3(b)(14)(i)) insofar as such requirements would be necessary because the fertilizer or plant food contained therein is a toxic substance as defined in §1500.3(c)(2)(1), provided that:

(i) When tested by the method described in §1500.3(c)(2)(1), the product

Consumer Product Safety Commis

has a single dose LD-50 of not less than 3.0 grams per kilogram of body weight of the test animal;

(ii) The label of any such exempt granular fertilizers discloses the identity of each of the hazardous ingredients;

(iii) The label bears the name and address of the manufacturer, packer, distributor, or seller; and

(iv) The label bears the statement "Keep out of the reach of children" or its practical equivalent.

(22) Small plastic capsules contain a paste composed of powdered metal solder mixed with a liquid flux are exempt from the requirements of section 2(p)(1) of the act (repeated in §1500.3(b)(14)(i)), if:

(i) The capsule holds not more than one-half milliliter of the solder mixture;

(ii) The capsule is sold only as a component of a kit; and

(iii) Adequate caution statements appear on the carton of the kit and any accompanying labeling which bears directions for use.

(23) Chemistry sets and other science education sets intended primarily for use by juveniles, and replacement containers of chemicals for such sets, are exempt from the requirements of section 2(p)(1) of the act (repeated in §1500.3(b)(14)(i)), if:

(i) The immediate container of each chemical that is hazardous as defined in the act and regulations thereunder bears on its main panel the name of such chemical, the appropriate sign word for that chemical, and the additional statement "Read back panel before using" (or "Read side panel before using," if appropriate) and bears on the back (or side) panel of the immediate container the remainder of the appropriate cautionary statement for the specific chemical in the container;

(ii) The experiment manual or other instruction book or booklet accompanying such set bears on the front page thereof, as a preface to any written matter in it (or on the cover, if any there be), the following caution statement within the borders of a rectangle and in the type size specified in §1500.121:

mixture of drycleaning solvents, are exempt from the labeling requirements of section 2(p)(1) of the act (repeated in 1500.3(b)(14)(i)) insofar as they apply to the "flammable" hazard as defined in §1500.3(c)(8)(iv), provided that:

(i) The article is packaged in a sealed envelope;

(ii) The total amount of solvent in each package does not exceed 4.5 milliliters; and

(iii) The article will ignite only when in contact with an open flame, and when so ignited, the article burns with sooty flame.

(19) Packages containing articles intended as single-use spot removers, and which consist of a cotton pad or other absorbent material containing methyl alcohol, are exempt from the labeling requirements of §1500.14(b)(4), if:

(i) The total amount of cleaning solvent in each package does not exceed 5 milliliters of which not more than 3 percent is methyl alcohol; and

(ii) The liquid is completely held by absorbent materials so that no free liquid is within the packages marketed.

(20) Cigarette lighters containing petroleum distillate fuel are exempt from the labeling requirements of section 2(p)(1) of the act (repeated in 1500.3(b)(14)(i)) and §1500.14(b)(3) insofar as such requirements would be necessary because the petroleum distillate contained therein is flammable and because the substance is named in 1500.14(a)(3) as requiring special labeling, provided that:

(i) Such lighters contain not more than 10 cubic centimeters of fuel at the time of sale; and

(ii) Such fuel is contained in a sealed compartment that cannot be opened without the deliberate removal of the tab-set, screw-type refill plug of the lighter.

(21) Containers of dry granular fertilizers and dry granular plant foods are exempt from the labeling requirements of section 2(p)(1) of the act (repeated in §1500.3(b)(14)(i)) insofar as such requirements would be necessary because the fertilizer or plant food contained therein is a toxic substance as defined in §1500.3(c)(2)(i), provided that:

(i) When tested by the method defined in §1500.3(c)(2)(i), the product

has a single dose LD-50 of not less than 3.0 grams per kilogram of body weight of the test animal;

(ii) The label of any such exempt dry granular fertilizers discloses the identity of each of the hazardous ingredients;

(iii) The label bears the name and address of the manufacturer, packer, distributor, or seller; and

(iv) The label bears the statement "Keep out of the reach of children" or its practical equivalent.

(22) Small plastic capsules containing a paste composed of powdered metal solder mixed with a liquid flux are exempt from the requirements of section 2(p)(1) of the act (repeated in §1500.3(b)(14)(i)), if:

(i) The capsule holds not more than one-half milliliter of the solder mixture;

(ii) The capsule is sold only as a component of a kit; and

(iii) Adequate caution statements appear on the carton of the kit and on any accompanying labeling which bears directions for use.

(23) Chemistry sets and other science education sets intended primarily for use by juveniles, and replacement containers of chemicals for such sets, are exempt from the requirements of section 2(p)(1) of the act (repeated in §1500.3(b)(14)(i)), if:

(i) The immediate container of each chemical that is hazardous as defined in the act and regulations thereunder bears on its main panel the name of such chemical, the appropriate signal word for that chemical, and the additional statement "Read back panel before using" (or "Read side panel before using," if appropriate) and bears on the back (or side) panel of the immediate container the remainder of the appropriate cautionary statement for the specific chemical in the container;

(ii) The experiment manual or other instruction book or booklet accompanying such set bears on the front page thereof, as a preface to any written matter in it (or on the cover, if any there be), the following caution statement within the borders of a rectangle and in the type size specified in §1500.121:

WARNING—This set contains chemicals that may be harmful if misused. Read cautions on individual containers carefully. Not to be used by children except under adult supervision

; and

(iii) The outer carton of such set bears on the main display panel within the borders of a rectangle, and in the type size specified in §1500.121, the caution statement specified in paragraph (a)(23)(ii) of this section.

(24) Fire extinguishers containing fire extinguishing agents which are stored under pressure or which develop pressure under normal conditions of use are exempt from the labeling requirements of section 2(p)(1) of the act (repeated in §1500.3(b)(14)(i)) insofar as such requirements apply to the pressure hazard as defined in §1500.3(c)(7)(i), provided that:

(i) If the container is under pressure both during storage and under conditions of use, it shall be designed to withstand a pressure of at least 5 times the charging pressure at 70 °F., except that carbon dioxide extinguishers shall be constructed and tested in accordance with applicable Interstate Commerce Commission specifications; or

(ii) If the container is under pressure only during conditions of use, it shall be designed to withstand a pressure of not less than 5 times the maximum pressure developed under closed nozzle conditions at 70 °F. or 1½ times the maximum pressure developed under closed nozzle conditions at 120 °F., whichever is greater.

(25) Cleaning and spot removing kits intended for use in cleaning carpets, furniture, and other household objects; kits intended for use in coating, painting, antiquing, and similarly processing furniture, furnishings, equipment, sidings, and various other surfaces; and kits intended for use in photographic color processing are exempt from the requirements of section 2(p)(1) of the act (repeated in §1500.3(b)(14)(i)) and from the requirements of §1500.14, provided that:

(i) The immediate container of each hazardous substance in the kit is fully labeled and in conformance with the

§ 1500.83

requirements of the act and regulations thereunder; and

(ii) The carton of the kit bears on the main display panel (or panels) within a borderline, and in the type size specified in §1500.121, the caution statement "(Insert proper signal word as specified in paragraph (a)(25)(iii) of this section). This kit contains the following chemicals that may be harmful if misused: (List hazardous chemical components by name.) Read cautions on individual containers carefully. Keep out of the reach of children."

(iii) If either the word "POISON" or "DANGER" is required on the container of any component of the kit, the same word shall be required to appear as part of the caution statement on the kit carton. If both "POISON" and "DANGER" are required in the labeling of any component or components in the kit, the word "POISON" shall be used. In all other cases the word "WARNING" or "CAUTION" shall be used.

(25) Packages containing articles intended as single-use spot removers and containing methyl alcohol are exempt from the labeling specified in §1500.14(b)(4), if:

(i) The total amount of cleaning solvent in each unit does not exceed 1 milliliter, of which not more than 40 percent is methyl alcohol;

(ii) The liquid is contained in a sealed glass ampoule enclosed in a plastic container with a firmly attached absorbent wick at one end through which the liquid from the crushed ampoule must pass, under the contemplated conditions of use; and

(iii) The labeling of each package of the cleaner bears the statement "WARNING—Keep out of the reach of children." or its practical equivalent, and the name and place of business of the manufacturer, packer, distributor, or seller.

(27) Packaged fireworks assortments intended for retail distribution are exempt from section 2(p)(1) of the act (repeated in §1500.3(b)(14)(1)), if:

(i) The package contains only fireworks devices suitable for use by the public and designed primarily to produce visible effects by combustion, except that small devices designed to produce audible effects may also be in-

16 CFR Ch. II (1-1-98 Edition)

cluded if the audible effect is produced by a charge of not more than 2 grains of pyrotechnic composition;

(ii) Each individual article in the assortment is fully labeled and in conformance with the requirements of the act and regulations thereunder; and

(iii) The outer package bears on the main display panel (or panels), within the borders of a rectangle and in the type size specified in §1500.121, the caution statement "WARNING—This assortment contains items that may be hazardous if misused and should be used only under adult supervision. IMPORTANT—Read cautions on individual items carefully." (See also §1500.14(b)(7); §1500.17(a)(3), (8) and (9); §1500.26(a)(2); and part 1507).

(28) Packages containing felt pads impregnated with ethylene glycol are exempt from the labeling requirements of §1500.14(b)(1), if:

(i) The total amount of ethylene glycol in each pad does not exceed 1 gram; and

(ii) The liquid is held by the felt pad so that no free ethylene glycol is within the package.

(29) Cigarette lighters containing butane and/or isobutane fuel are exempt from the labeling requirements of section 2(p)(1) of the act (repeated in §1500.3(b)(14)(1)) insofar as such requirements would otherwise be necessary because the fuel therein is extremely flammable and under pressure, provided that:

(i) The lighters contain not more than 12 grams of fuel at the time of sale; and

(ii) The fuel reservoir is designed to withstand a pressure of at least 1 1/4 times the maximum pressure which will be developed in the container at 120 °F.

(30) The outer retail containers of solder kits each consisting of a small tube of flux partially surrounded by a winding of wire-type cadmium-free silver solder are exempt from the labeling requirements of section 2(p)(1) of the act (repeated in §1500.3(b)(14)(1)), if:

(i) The metal solder contains no cadmium and is not otherwise hazardous under the provisions of the act;

(ii) The tube of flux in the kit is fully labeled and in conformance with the act and regulations thereunder, and

Consumer Product Safety Comm

any accompanying literature bears directions for use also bears the information required by section 2(p) of the act; and

(iii) The main panel of the outer container bears in type size specified in §1500.121 the following: (A) The signal word; (B) a statement of principal hazard or hazards; (C) the statement "Keep out of the reach of children"; and (D) instructions to read other cautionary instructions on the tube of flux with the solder.

(31) Visual novelty devices consist of sealed units, each of which unit consists of a steel and glass cell containing perchloroethylene (among other things) are exempt from the requirements of §1500.121(a) that would otherwise require a portion of the warning statement to appear on the glass face of the device, provided that:

(i) The device contains not more than 105 milliliters of perchloroethylene; contains no other component that contributes substantially to the hazard; and

(ii) The following cautionary statement appears on the device (other than on the bottom) in the type size specified in §1500.121 (c) and (d):

CAUTION—IF BROKEN, RESULTANT VAPOR MAY BE HARMFUL.

Contains perchloroethylene. Do not expose to extreme heat. If broken indoors, open doors and doors until all odor of chemical is gone.

Keep out of the reach of children.

A practical equivalent may be substituted for the statement "Keep out of the reach of children."

(32) Hollow plastic toys containing mineral oil are exempt from the labeling specified in §1500.14(b)(3)(ii), if:

(i) The article contains no other ingredient that would cause it to pose the aspiration hazard specified in §1500.14(b)(3)(ii);

(ii) The article contains not more than 6 fluid ounces of mineral oil;

(iii) The mineral oil has a viscosity of at least 70 Saybolt universal seconds at 100 °F.;

(iv) The mineral oil meets the specifications in the N.F. for light mineral oil; and

(v) The container bears the statement "CAUTION—Contains light mineral oil."

ided if the audible effect is produced a charge of not more than 2 grains pyrotechnic composition;

(i) Each individual article in the as-
tment is fully labeled and in con-
formance with the requirements of the
and regulations thereunder; and
(ii) The outer package bears on the
display panel (or panels), within
borders of a rectangle and in the
size specified in §1500.121, the cau-
tion statement "WARNING—This as-
tment contains items that may be
hazardous if misused" and should be
used only under adult supervision. IM-
PORTANT—Read cautions on individ-
ual items carefully." (See also
§1500.14(b)(7); §1500.17(a)(3), (8) and (9);
§1500.85(a)(2); and part 1507).

28) Packages containing felt pads
pregnated with ethylene glycol are
exempt from the labeling requirements
§1500.14(b)(1), if:

(i) The total amount of ethylene gly-
col in each pad does not exceed 1 gram;

(ii) The liquid is held by the felt pad
that no free ethylene glycol is with-
the package.

29) Cigarette lighters containing bu-
tane and/or isobutane fuel are exempt
from the labeling requirements of sec-
tion 2(p)(1) of the act (repeated in
§1500.3(b)(14)(i)) insofar as such require-
ments would otherwise be necessary
because the fuel therein is extremely
flammable and under pressure, pro-
vided that:

(i) The lighters contain not more
than 12 grams of fuel at the time of
use; and

(ii) The fuel reservoir is designed to
withstand a pressure of at least 1½
times the maximum pressure which
could be developed in the container at
70°F.

30) The outer retail containers of
solder kits each consisting of a small
tube of flux partially surrounded by a
ring of wire-type cadmium-free sil-
ver solder are exempt from the labeling
requirements of section 2(p)(1) of the
act (repeated in §1500.3(b)(14)(i)), if:

(i) The metal solder contains no cad-
mium and is not otherwise hazardous
under the provisions of the act;

(ii) The tube of flux in the kit is fully
sealed and in conformance with the
and regulations thereunder, and

any accompanying literature that
bears directions for use also bears all
the information required by section
2(p) of the act; and

(iii) The main panel of the outer con-
tainer bears in type size specified in
§1500.121 the following: (A) The signal
word; (B) a statement of principal haz-
ard or hazards; (C) the statement
"Keep out of the reach of children," or
its practical equivalent; and (D) in-
structions to read other cautionary in-
structions on the tube of flux within.

(31) Visual novelty devices consisting
of sealed units, each of which unit is a
steel and glass cell containing per-
chloroethylene (among other things),
are exempt from the requirements of
§1500.121(a) that would otherwise re-
quire a portion of the warning state-
ment to appear on the glass face of the
device, provided that:

(i) The device contains not more than
105 milliliters of perchloroethylene and
contains no other component that con-
tributes substantially to the hazard; and

(ii) The following cautionary state-
ment appears on the device (other than
on the bottom) in the type size speci-
fied in §1500.121 (c) and (d):

CAUTION—IF BROKEN, RESULTANT VAPORS
MAY BE HARMFUL

Contains perchloroethylene. Do not expose
to extreme heat. If broken indoors, open win-
dows and doors until all odor of chemical is
gone.

Keep out of the reach of children.

A practical equivalent may be sub-
stituted for the statement "Keep out of
the reach of children."

(32) Hollow plastic toys containing
mineral oil are exempt from the label-
ing specified in §1500.14(b)(3)(ii), if:

(i) The article contains no other in-
gredient that would cause it to possess
the aspiration hazard specified in
§1500.14(b)(3)(ii);

(ii) The article contains not more
than 6 fluid ounces of mineral oil;

(iii) The mineral oil has a viscosity
of at least 70 Saybolt universal seconds
at 100°F.;

(iv) The mineral oil meets the speci-
fications in the N.F. for light liquid
petrolatum; and

(v) The container bears the state-
ment "CAUTION—Contains light liquid

petrolatum N.F. Discard if broken or
leak develops."

(33) Containers of mineral oil having
a capacity of not more than 1 fluid
ounce and intended for use in produc-
ing a smoke effect for toy trains are
exempt from the labeling specified in
§1500.14(b)(3), if:

(i) The mineral oil meets the speci-
fications in the N.F. for light liquid
petrolatum;

(ii) The mineral oil has a viscosity of
at least 130 Saybolt universal seconds
at 100°F.;

(iii) The article contains no other in-
gredient that contributes to the haz-
ard; and

(iv) The label declares the presence
light liquid petrolatum and the name
and place of business of the manufac-
turer, packer, distributor, or seller.

(34) Viscous products containing
more than 4 percent by weight of meth-
yl alcohol, such as adhesives, asphalt-
base roof and tank coatings, and simi-
lar products, are exempt from bearing
the special labeling required by
§1500.14(b)(4), if:

(i) The product contains not more
than 15 percent by weight of methyl al-
cohol;

(ii) The methyl alcohol does not sepa-
rate from the other ingredients upon
standing or through any foreseeable
use or manipulation;

(iii) The viscosity of the product is
not less than 7,000 centipoises at 77°F.,
unless the product is packaged in a
pressurized container and is dispensed
as a liquid unsuitable for drinking; and

(iv) The labeling bears the statement
"Contains methyl alcohol. Use only in
well-ventilated area. Keep out of the
reach of children."

(35) Individual blasting caps are ex-
empt from bearing the statement
"Keep out of the reach of children," or
its practical equivalent, if:

(i) Each cap bears conspicuously in
the largest type size practicable the
statement "DANGEROUS—BLASTING
CAPS—EXPLOSIVE"; and

(ii) The outer carton and any accom-
panying printed matter bear appro-
priate, complete cautionary labeling.

(36) Individual toy rocket propellant
devices and separate delay train and/or
recovery system activation devices in-
tended for use with premanufactured

§ 1500.83

model rocket engines are exempt from bearing the full labeling required by section 2(p)(1) of the act (repeated in §1500.3(b)(14)(i)) insofar as such requirements would be necessary because the articles are flammable or generate pressure, provided that:

(i) The devices are designed and constructed in accordance with the specifications in §1500.26(a) (8) or (9):

(ii) Each individual device or retail package of devices bears the following:

(A) The statement "WARNING—FLAMMABLE: Read instructions before use";

(B) The common or usual name of the article;

(C) A statement of the type of engine and use classification;

(D) Instructions for safe disposal; and

(E) Name and place of business of manufacturer or distributor; and

(iii) Each individual rocket engine or retail package of rocket engines distributed to users is accompanied by an instruction sheet bearing complete cautionary labeling and instructions for safe use and handling of the individual rocket engines.

(37) Glues with a cyanoacrylate base in packages containing 3 grams or less are exempt from the requirement of §1500.121(d) that labeling which is permitted to appear elsewhere than on the main label panel must be in type size no smaller than 6 point type, provided that:

(i) The main panel of the immediate container bears both the proper signal word and a statement of the principal hazard or hazards associated with this product, as provided by §1500.121 (a) and (c);

(ii) The main panel of the immediate container also bears an instruction to read carefully additional warnings elsewhere on the label and on any outer package, accompanying leaflet, and display card. The instruction to read additional warnings must comply with the size, placement, conspicuousness, and contrast requirements of §1500.121; and

(iii) The remainder of the cautionary labeling required by the act that is not on the main label panel must appear elsewhere on the label in legible type and must appear on any outer package,

16 CFR Ch. II (1-1-98 Edition)

accompanying leaflet, and display card. If there is no outer package, accompanying leaflet, or display card, then the remainder of the required cautionary labeling must be displayed on a tag or other suitable material that is securely affixed to the article so that the labeling will remain attached throughout the conditions of merchandising and distribution to the ultimate consumer. That labeling which must appear on any outer package, accompanying leaflet, tag, or other suitable material must comply with the size, placement, contrast, and conspicuousness requirements of §1500.121(d).

(38) Rigid or semi-rigid writing instruments and ink cartridges having a writing point and an ink reservoir are exempt from the labeling requirements of section 2(p)(1) of the act (repeated in §1500.3(b)(14)(i) of the regulations) and of regulations issued under section 3(b) of the act (§1500.14(b)(1, 2)) insofar as such requirements would be necessary because the ink contained therein is a "toxic" substance as defined in §1500.3(c)(2)(i) and/or because the ink contains 10 percent or more by weight ethylene glycol or diethylene glycol, if all the following conditions are met:

(i) The writing instrument or cartridge is of such construction that the ink will, under any reasonably foreseeable condition of manipulation and use, emerge only from the writing tip.

(ii) When tested by the method described in §1500.3(c)(2)(i), the ink does not have an LD-50 single oral dose of less than 2.5 grams per kilogram of body weight of the test animal.

(iii) If the ink contains ethylene glycol or diethylene glycol, the amount of such substance, either singly or in combination, does not exceed 1 gram per writing instrument or cartridge.

(iv) The amount of ink in the writing instrument or cartridge does not exceed 3 grams.

[38 FR 27012, Sept. 27, 1973; 43 FR 33028, June 29, 1977, as amended at 43 FR 32745, July 28, 1978; 43 FR 47176, Oct. 13, 1978; 44 FR 42878, July 20, 1979; 45 FR 11613, Feb. 9, 1981; 48 FR 16, Jan. 2, 1983]

Consumer Product Safety Co

§1500.85 Exemptions from section as banned hazardous substances.

(a) The term *banned hazardous substances* as used in section 2(p) of the act shall not apply to the articles provided that these articles bear labeling giving adequate instructions and warnings for safe use:

(1) Chemistry sets and other education sets intended primarily for juveniles, and replacement containers for such sets, when labeled in accordance with §1500.26(a)(23).

(2) Firecrackers designed to produce audible effects, if the audible effect is produced by a charge of not more than 50 milligrams (.773 grains) of technical composition. (See §1500.14(b)(7); §1500.17(a) (3), (8) and part 1507).

(3) [Reserved]

(4) Educational materials such as preserved biological specimens, laboratory chemicals, or articles intended and used for educational purposes.

(5) Liquid fuels containing not more than 4 percent by weight of methyl alcohol that are intended and used for the propulsion of miniature engines for airplanes, boats, cars, etc.

(6) Novelties consisting of a mixture of polyvinyl acetate, U.S. Certifiers, and not more than 25 percent by weight of acetone, and intended for use in blowing plastic balloons.

(7) Games containing, as the hazardous component, a self-preserving container of soap solution or foam-generating mixture provided the foam-generating component presents hazards other than being in a pressurized container.

(8) Model rocket propellant containers designed for use in light-weight, reusable, and reusable model rockets provided such devices:

(i) Are designed to be ignited by electrical means.

(ii) Contain no more than 62.5 (2.2 ounces) of propellant material which will produce less than 80 newton-seconds (17.92 pound seconds) of total thrust with thrust duration not less than 0.2 second.

(iii) Are constructed such that the chemical ingredients are protected into a cylindrical paper or air