Announcement

Cosmetic Ingredient Review Expert Panel
124th Meeting (September 10-11, 2012) - Findings

September 14, 2012

● **Final Safety Assessments**

- **α-amino acids – 34 ingredients**
- **bis-diglyceryl polyacyladipate-1 and bis-diglyceryl polyacyladipate-2 – 2 ingredients**
- **borosilicate glasses – 5 ingredients**
- **chlorphenesin – 1 ingredient**
- **dialkyl malates – 6 ingredients**
- **dimethicone crosspolymers – 62 ingredients**
- **microbial polysaccharide gums – 34 ingredients**
- ***Panax* spp. root extract – 13 ingredients**
- **polyether lanolins – 39 ingredients**
- ***Vitis vinifera* (grape)-derived ingredients – 24 ingredients**

● **Tentative and Tentative Amended Safety Assessments**

- **PEGylated oils – 130 ingredients**
- **tin (IV) oxide – 1 ingredient**

● **Insufficient Data Announcement**

- **methyl glucose polyethers and esters – 25 ingredients**

● **Re-review and New Data**

- **retinol and retinyl palmitate - reopened - 9 ingredients**
- **parabens – conclusion reaffirmed**
- **triclosan – conclusion reaffirmed**

● **124th Meeting Notes**

- **Director's report**
- **Reports tabled**
  - **fatty acid amidopropyl dimethylamines**
  - **alkyl esters**
- **2013 review priorities**
- **Scientific literature reviews posted on the CIR website**
  - **for ingredients that may be considered at the next Panel meeting**
    - 6-hydroxyindole
    - modified terephthalate polymers
    - palmitoyl oligopeptides
    - talc
- **Next CIR Expert Panel Meeting – Monday and Tuesday, December 10-11, 2012**

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Final Safety Assessments

Any interested person who believes that a final safety assessment or final amended safety assessment is incorrect may petition the CIR Expert Panel to amend the safety assessment. Unpublished data cited as references in CIR safety assessments are posted on the CIR website and available for review at the CIR office. Final safety assessments and final amended safety assessments will be posted on the CIR website at www.cir-safety.org.

α-Amino Acids

The following 34 α-amino acids and their salts were found safe in the present practices of use and concentration in cosmetics:

alanine
arginine
arginine HCl
asparagine
aspartic acid
sodium aspartate*
potassium aspartate
dipotassium aspartate*
calcium aspartate*
magnesium aspartate
cysteine
cysteine HCl
cystine
glutamic acid
sodium glutamate
glutamine
glycine
sodium glycinate
calcium glycinate
magnesium glycinate*
histidine
histidine HCl
isoleucine
leucine
lysine
lysine HCl
methionine
phenylalanine
proline
serine
threonine
tryptophan
tyrosine
valine

*Not reported to be in current use. Were the ingredients not reported to be in current use to be used in the future, the expectation is that they would be used in product categories and at concentrations comparable to others in the group.

The CIR Expert Panel noted that glycine (no stereocenter) and the L-amino acids are listed by FDA as Generally Recognized As Safe (GRAS) direct food additives. These ingredients function as hair and skin conditioning agents. The *International Cosmetic Dictionary and Handbook* does not distinguish among the α-amino acids used in cosmetics that are L-sterioisomers from those that are D-stereoisomers (or are mixtures of L- and D-stereoisomers). Amino acids with a mixture of the 2 stereoisomers (DL-) have approved uses as food additives according to the USP Food Chemicals Codex. The FDA Voluntary Cosmetic Registration Program (VCRP) has registered reported uses of the DL-mixtures in addition to L-amino acids in cosmetics. However, no cosmetic uses were reported for α-amino acids ingredients that are specifically the D-stereoisomers, the α-D-amino acids most probably are not used because their production is more costly compared to the forms that are used in cosmetics. The Expert Panel does not anticipate that there are significant toxicological differences in cosmetic applications between the 2 stereoisomers.

The Expert Panel considered comments that were provided by the International Glutamate Technical Committee on monosodium glutamate (MSG). The Panel reiterated that while some individuals may have MSG symptom complex after ingestion of large amounts of MSG in some foods, the low concentrations of MSG in cosmetic products would not be significantly absorbed through topical application or incidental ingestion, and thus, would not cause systemic reactions even in these individuals.

Bis-Diglyceryl Polyacyladipate-1 and Bis-Diglyceryl Polyacyladipate-2

Bis-diglyceryl polyacyladipate-1 and bis-diglyceryl polyacyladipate-2 were found safe in the present practices of use and concentration in cosmetics.

These ingredients are mixed fatty acid esters and different structural configurations are possible within each bis-diglyceryl polyacyladipate ingredient. They are used in cosmetics as lanolin substitutes. The Panel primarily relied on unpublished data submitted by industry. Although gaps remained regarding toxicokinetics and carcinogenicity data, both ingredients are large, highly lipid-soluble compounds that are not expected to efficiently pass through the stratum corneum of the skin. In addition, the fatty acids that comprise these mixed fatty acid esters have separately been determined to be safe for use in cosmetics, which supports the Panel's findings.

Borosilicate Glasses

The following 5 borosilicate glasses were found safe in the present practices of use and concentration in cosmetics:

calcium sodium borosilicate
calcium aluminum borosilicate
calcium titanium borosilicate
silver borosilicate*
zinc borosilicate*

*Not reported to be in current use. Were silver borosilicate and zinc borosilicate to be used in the future, the expectation is that they would be used in product categories and at use concentrations comparable to others in the group.

These ingredients function as bulking agents in cosmetics and are used at concentrations up to 97%. While there is a lack of data on toxicokinetics and repeated dose toxicity, these ingredients are large, stable molecules that are not water soluble, would not penetrate the skin, and, therefore, would not be associated with systemic toxicity. They are not dermal irritants or sensitizers.

Chlorphenesin

Chlorphenesin was found safe in the present practices of use and concentration in cosmetics.

This ingredient is a widely used cosmetic biocide. Some confusion is apparent because a drug, chlorphenesin carbamate (CAS No. 886-754-8) is also frequently called "chlorphenesin." The drug chlorphenesin carbamate has muscle relaxant activity, can depress the CNS and should not be used in cosmetics. The cosmetic ingredient, chlorphenesin (CAS No. 104-29-0), does not have similar activity, based upon published studies. The Panel agreed that the possible confusion of chlorphenesin with chlorphenesin carbamate should be emphasized to help clearly convey that muscle relaxant effects do not appear to be associated with the cosmetic ingredient, chlorphenesin.

Dialkyl Malates

The following 6 dialkyl malates were found safe in the current practices of use and concentration in cosmetics:

dibutyloctyl malate*
di-C12-13 alkyl malate
diethylhexyl malate
diisoamyl malate*
diisostearyl malate
dioctyldodecyl malate*

*Not reported to be in current use. Were the ingredients not reported to be in current use to be used in the future, the expectation is that they would be used in product categories and at concentrations comparable to others in the group.

These ingredients have general functionality in cosmetics as skin conditioning agents and are used at concentrations up to 82%. While complete toxicological data were not available for each of the ingredients, the data that were available indicated that dialkyl malates were not systemic toxicants and were not genotoxic, irritating, nor sensitizing in mammalian and/or human studies. These data could be extrapolated to support the safety of the entire group.

Dimethicone Crosspolymers

The following 62 dimethicone crosspolymers were found safe in the current practices of use and concentration in cosmetics:

acrylates/bis-hydroxypropyl dimethicone crosspolymer*
behenyl dimethicone/bis-vinyldimethicone crosspolymer
bis-phenylisopropyl phenylisopropyl dimethicone/vinyl dimethicone crosspolymer*
bis-vinyldimethicone/bis-isobutyl PPG-20 crosspolymer*
bis-vinyldimethicone crosspolymer*
bis-vinyldimethicone/ PEG-10 dimethicone crosspolymer*
bis-vinyldimethicone/PPG-20 crosspolymer*
butyldimethicone methacrylate/methyl methacrylate crosspolymer*
C30-45 alkyl cetearyl dimethicone crosspolymer
C4-24 alkyl dimethicone/ divinyldimethicone crosspolymer
C30-45 alkyl dimethicone/ polycyclohexene oxide crosspolymer
cetearyl dimethicone crosspolymer
cetearyl dimethicone/vinyl dimethicone crosspolymer
cetyl dimethicone/bis-vinyldimethicone crosspolymer
cetyl hexacosyl dimethicone/bis-vinyldimethicone crosspolymer*
crotonic acid/vinyl C8-12 isoalkyl esters/VA/bis-vinyldimethicone crosspolymer*
dimethicone/bis-isobutyl PPG-20 crosspolymer
dimethicone/bis-vinyldimethicone/silsesquioxane crosspolymer*
dimethicone crosspolymer
dimethicone crosspolymer-3
dimethicone/divinyldimethicone/silsesquioxane crosspolymer
dimethicone/lauryl dimethicone/bis-vinyldimethicone crosspolymer*
dimethicone/PEG-10 crosspolymer
dimethicone/PEG-10/15 crosspolymer
dimethicone/PEG-15 crosspolymer*
dimethicone/phenyl vinyl dimethicone crosspolymer
dimethicone/polyglycerin-3 crosspolymer
dimethicone/PPG-20 crosspolymer
dimethicone/titanate crosspolymer*
dimethicone/vinyl dimethicone crosspolymer
dimethicone/vinyltrimethylsiloxysilicate crosspolymer
diphenyl dimethicone crosspolymer*
diphenyl dimethicone/vinyl diphenyl dimethicone/silsesquioxane crosspolymer
divinyldimethicone/dimethicone crosspolymer
hydroxypropyl dimethicone/polysorbate 20 crosspolymer*
isopropyl titanium triisostearate/triethoxysilylethyl polydimethylsiloxyethyl dimethicone crosspolymer
lauryl dimethicone PEG-15 crosspolymer*
lauryl dimethicone/polyglycerin-3 crosspolymer*
lauryl polydimethylsiloxyethyl dimethicone/bis-vinyldimethicone crosspolymer*
PEG-10 dimethicone crosspolymer
PEG-12 dimethicone crosspolymer
PEG-8 dimethicone/polysorbate 20 crosspolymer*
PEG-12 dimethicone/bis-isobutyl PPG-20 crosspolymer*
PEG-12 dimethicone/PPG-20 crosspolymer*
PEG-10 dimethicone/vinyl dimethicone crosspolymer
PEG-10/lauryl dimethicone crosspolymer
PEG-15/lauryl dimethicone crosspolymer
PEG-15/lauryl polydimethylsiloxyethyl dimethicone crosspolymer*
perfluorononyl dimethicone/methicone/amodimethicone crosspolymer
polydimethylsiloxyethyl dimethicone/bis-vinyldimethicone crosspolymer*
polyglyceryl-3/lauryl polydimethylsiloxyethyl dimethicone crosspolymer*
silicone quaternium-16/glycidoxy dimethicone crosspolymer
styrene/acrylates/dimethicone acrylate crosspolymer
trifluoropropyl dimethicone/PEG-10 crosspolymer*
trifluoropropyl dimethicone/trifluoropropyl divinyldimethicone crosspolymer*
trifluoropropyl dimethicone/vinyl trifluoropropyl dimethicone/silsesquioxane crosspolymer*
trimethylsiloxysilicate/ dimethicone crosspolymer*
vinyl dimethicone/lauryl/behenyl dimethicone crosspolymer*
vinyl dimethicone/lauryl dimethicone crosspolymer
vinyl dimethicone/methicone silsesquioxane crosspolymer
vinyldimethyl/trimethylsiloxysilicate/dimethicone crosspolymer*
vinyldimethyl/trimethylsiloxysilicate stearyl dimethicone crosspolymer*

*Not reported to be in current use. Were the dimethicone crosspolymers not reported to be in current use to be used in the future, the expectation is that they would be used in product categories and at concentrations comparable to others in the group.

These large, stable, insoluble molecules are used in cosmetics for functions such as bulking and non-aqueous viscosity-increasing agents at concentrations up to 46%. These cosmetic ingredients will not penetrate the skin and cannot cause systemic toxicity. They are neither toxicants in acute toxicity studies, nor are they dermal irritants or sensitizers. A lack of data on possible residual monomer content was noted. For the crosspolymers for which impurities data were available, monomers levels were below the detection limits of the analytical methods used. This suggested to the Panel that steps are taken to remove residual monomers or that residual monomers are contained within the cross-linked structure of these large crosspolymers. The Panel noted that manufacturers should continue to take steps to ensure that monomers and catalysts are at levels as low as reasonably achievable, which would, in turn, suggest that such levels are below the level of toxicological concern.

Microbial Polysaccharide Gums

The following 34 microbial polysaccharide gums were found safe in the present practices of use and concentration in cosmetics:

xanthan gum;
hydroxypropyl xanthan gum;*
undecylenoyl xanthan gum;*
dehydroxanthan gum;
xanthan gum crosspolymer;
xanthan hydroxypropyltrimonium chloride;*
gellan gum;
welan gum;*
biosaccharide gum-1;
biosaccharide gum-2;
biosaccharide gum-3;*
biosaccharide gum-4;
biosaccharide gum-5;*
pseudoalteromonas exopolysaccharides;*
dextran;
carboxymethyl dextran;*
dextran hydroxypropyltrimonium chloride;*
sodium carboxymethyl dextran;
dextran sulfate;
sodium dextran sulfate;
sclerotium gum;
hydrolyzed sclerotium gum;
beta-glucan;
beta-glucan hydroxypropyltrimonium chloride;*
beta-glucan palmitate;*
hydrolyzed beta-glucan;*
oxidized beta-glucan;*
sodium carboxymethyl beta-glucan;
pullulan;
myristoyl pullulan;*
levan;*
rhizobian gum;

hydrolyzed rhizobian gum; and

alcaligenes polysaccharides.

*Not reported to be in current use. Were the ingredients not reported to be in current use to be used in the future, the expectation is that they would be used in product categories and at concentrations comparable to others in the group.

The Panel noted that although there are some data gaps, the data that are available may be extrapolated to support the safety of the entire group. While there were no specific data on the hydroxypropyltrimonium chloride compounds, data on trimonium ingredients that are included in the existing safety assessment on trimoniums are applicable for determining the safety of the three hydroxypropyltrimonium chloride compounds included in the present report. The Panel noted that parenterally administered polysaccharides appear to be biotransformed to a limited, though variable, extent in animal and human studies. However, these very large compounds appear not to be significantly absorbed through the skin and, thus, would have negligible bioavailability. Coupled with a lack of significant toxicity associated with other routes of exposure, the CIR Expert Panel determined that systemic effects were unlikely to result from topical application of cosmetics containing these ingredients.

Panax spp. Root-Derived Ingredients

The following 13 *Panax* spp. root-derived ingredients were found safe in the present practices of use and concentration in cosmetics:

hydrolyzed ginseng root*
hydrolyzed ginseng root extract
hydrolyzed ginseng saponins*
panax ginseng root
panax ginseng root extract*
panax ginseng root oil*
panax ginseng root powder
panax ginseng root protoplast*
panax ginseng root water*
panax japonicus root extract*
panax notoginseng root
panax notoginseng root powder*
panax quinquefolium root extract

*Not reported to be in current use. Were the ginseng root-derived ingredients not reported to be in current use to be used in the future, the expectation is that they would be used in product categories and at concentrations comparable to others in the group.

These ingredients function in cosmetics mostly as skin conditioning agents at concentrations up to 0.5%. As with many botanical extracts in cosmetics, the potential exists for plant phytosterols to be a constituent. An extensive discussion of the potential estrogenic activity of plant phytosterols has been developed by the Panel in its safety assessment of PEGs soy sterol ingredients. Although no dermal absorption data were available, in the Panel's judgment, plant phytosterols and phytosterol esters are not significantly absorbed. Extensive data show that these constituents are not estrogenic, are not reproductive toxicants, are not genotoxic, and are not carcinogenic.

The Panel was aware of a report of pulegone in *Panax quinquefolim* root oil. While the root oil is not a cosmetic ingredient, pulegone toxicity is a concern. Because the extract of other *Panax* spp. root materials may be prepared using a variety of solvents, the Panel considered the possible presence of pulegone in these extracts should be addressed. Accordingly, the Expert Panel alerted finished product manufacturers that pulegone content in any ingredient should be < 1%. If these ingredients are used in combination with peppermint oil or any other ingredient that also contains pulegone, the use concentrations for those ingredients should not contribute to a total pulegone level that could produce toxicity through the use of the finished product.

Polyether Lanolins

The following 39 polyether lanolins were found safe in the present practices of use and concentration in cosmetics:

PPG-5 lanolin wax
PPG-5 lanolin wax glyceride
PEG-75 lanolin wax*
PEG-5 hydrogenated lanolin*
PEG-10 hydrogenated lanolin*
PEG-15 hydrogenated lanolin*
PEG-20 hydrogenated lanolin
PEG-24 hydrogenated lanolin
PEG-30 hydrogenated lanolin*
PEG-40 hydrogenated lanolin*
PEG-70 hydrogenated lanolin*
PEG-5 lanolin
PEG-10 lanolin*
PEG-20 lanolin*
PEG-24 lanolin*
PEG-25 lanolin*
PEG-27 lanolin*
PEG-30 lanolin
PEG-35 lanolin*
PEG-40 lanolin
PEG-50 lanolin
PEG-55 lanolin*
PEG-60 lanolin
PEG-70 lanolin*
PEG-75 lanolin
PEG-85 lanolin
PEG-100 lanolin*
PEG-150 lanolin
PEG-75 lanolin oil*
polyglyceryl-2 lanolin alcohol ether*
PPG-2 lanolin alcohol ether*
PPG-5 lanolin alcohol ether*
PPG-10 lanolin alcohol ether*
PPG-20 lanolin alcohol ether*
PPG-30 lanolin alcohol ether*
PPG-20-PEG-20 hydrogenated lanolin*
PPG-12-PEG-50 Lanolin
PPG-12-PEG-65 lanolin oil
PPG-40-PEG-60 lanolin oil*

*Not reported to be in current use. Were the polyether lanolins not reported to be in current use to be used in the future, the expectation is that they would be used in product categories and at concentrations comparable to others in the group.

This is an amended safety assessment. Polyether lanolins are used as hair and skin conditioning agents and can function as surfactants/emulsifiers. Data regarding the safety of lanolin itself, acetylated lanolin alcohols, PEGs lanolin, alkyl PEG ethers, propylene glycols, and PEGs were combined with the data previously available for PPG-5 lanolin wax and PPG-5 lanolin wax glyceride to support the safety of the larger group of polyether lanolins.

Vitis Vinifera (Grape)-Derived Ingredients

The following 24 *Vitis vinifera* (grape)-derived ingredients were found safe in the present practices of use and concentration in cosmetics:

vitis vinifera (grape);
vitis vinifera (grape) bud extract;
vitis vinifera (grape) flower extract;*
vitis vinifera (grape) fruit extract;
vitis vinifera (grape) fruit powder;
vitis vinifera (grape) fruit water;
vitis vinifera (grape) juice;
vitis vinifera (grape) juice extract;
vitis vinifera (grape) leaf extract;
vitis vinifera (grape) leaf oil;*
vitis vinifera (grape) leaf/seed/skin extract;*
vitis vinifera (grape) leaf water;*
vitis vinifera (grape) leaf wax;*
vitis vinifera (grape) root extract;*
vitis vinifera (grape) seed;
vitis vinifera (grape) seed extract;
vitis vinifera (grape) seed powder;
vitis vinifera (grape) shoot extract;*
vitis vinifera (grape) skin extract;*
vitis vinifera (grape) skin powder;*

vitis vinifera (grape) vine extract;
vitis vinifera (grape) vine sap;*
hydrolyzed grape fruit;*
hydrolyzed grape skin.*

*Not reported to be in current use. Were the ingredients not reported to be in current use to be used in the future, the expectation is that they would be used in product categories and at concentrations comparable to others in the group.

Some of the constituents of *Vitis vinifera* plant parts , such as ascorbic acid, biotin, and malic acid, are cosmetic ingredients for which a CIR safety assessment is available. Others are compounds that have been discussed in previous CIR assessments. For example, whole *Vitis vinifera* contains a variety of phytosterols at low concentrations. In previous CIR safety assessments, the Panel has addressed the potential estrogenic and other effects of phytosterols. Although no dermal absorption data were available, in the Panel's judgment, phytosterols and phytosterol esters are not significantly absorbed and do not result in systemic exposure. Additionally, these constituents are not estrogenic, are not reproductive toxicants, are not genotoxic, and are not carcinogenic.

The Panel also noted that the leaf extract, which is used at up to 3% in perfumes, is a highly colored component and could be photoactive. The dermatologists on the Panel remarked that phototoxicity issues have not been reported in vineyard workers, and the Panel relied on this clinical expertise to alleviate the concern of possible phototoxic effects of vitis vinifera (grape) leaf extract. The Panel also noted that that low levels of quercetin are present in some components of *Vitis vinifera*. However, because the *Vitis vinifera*-derived ingredients are used at very low concentrations in cosmetics, and because the concentrations of quercetin in the plant parts are low, the presence of quercetin was below the level of toxicological concern.

Tentative Safety Assessments

These tentative safety assessments will be posted on the CIR website at www.cir-safety.org on or before September 21, 2012. Interested persons are given 60 days to comment, provide information and/or request an oral hearing before the CIR Expert Panel. Information may be submitted without identifying the source or the trade name of the cosmetic product containing the ingredient. All unpublished data submitted to CIR will be discussed in open meetings, posted on the CIR website, and are available at the CIR office for review by any interested party. ***Please submit data and/or comments to CIR by November 21, 2012, or sooner if possible.*** *These reports may be scheduled for review by the CIR Expert Panel at its* ***December 10-11, 2012 meeting****.*

PEGylated Oils

The CIR Expert Panel issued a tentative amended safety assessment for public comment with the conclusion that PEGylated Oils are safe in the present practices of use and concentration in cosmetics when formulated to be non-irritating. This conclusion supersedes the earlier conclusion issued by the Expert Panel in 1997 for PEGs castor oils.

The 130 ingredients included in this safety assessment are:

PEG-2 castor oil*
PEG-3 castor oil*
PEG-4 castor oil*
PEG-5 castor oil*
PEG-8 castor oil*
PEG-9 castor oil
PEG-10 castor oil*
PEG-11 castor oil*
PEG-15 castor oil*
PEG-16 castor oil*
PEG-20 castor oil*
PEG-25 castor oil
PEG-26 castor oil*
PEG-29 castor oil*
PEG-30 castor oil
PEG-33 castor oil
PEG-35 castor oil
PEG-36 castor oil
PEG-40 castor oil
PEG-44 castor oil*
PEG-50 castor oil
PEG-54 castor oil*
PEG-55 castor oil*
PEG-60 castor oil
PEG-75 castor oil*
PEG-80 castor oil*
PEG-100 castor oil*
PEG-200 castor oil*
PEG-18 castor oil dioleate*
PEG-60 castor oil isostearate*
PEG-2 hydrogenated castor oil
PEG-5 hydrogenated castor oil*
PEG-6 hydrogenated castor oil*
PEG-7 hydrogenated castor oil
PEG-8 hydrogenated castor oil*
hydrogenated castor oil PEG-8 esters*
PEG-10 hydrogenated castor oil
PEG-16 hydrogenated castor oil
PEG-20 hydrogenated castor oil
PEG-25 hydrogenated castor oil
PEG-30 hydrogenated castor oil
PEG-35 hydrogenated castor oil
PEG-40 hydrogenated castor oil
PEG-45 hydrogenated castor oil
PEG-50 hydrogenated castor oil
PEG-54 hydrogenated castor oil*
PEG-55 hydrogenated castor oil*
PEG-60 hydrogenated castor oil
PEG-65 hydrogenated castor oil*
PEG-80 hydrogenated castor oil
PEG-100 hydrogenated castor oil
PEG-200 hydrogenated castor oil*
PEG-5 hydrogenated castor oil isostearate*
PEG-10 hydrogenated castor oil isostearate*
PEG-15 hydrogenated castor oil isostearate*
PEG-20 hydrogenated castor oil isostearate*
PEG-30 hydrogenated castor oil isostearate*
PEG-40 hydrogenated castor oil isostearate*
PEG-50 hydrogenated castor oil isostearate*
PEG-58 hydrogenated castor oil isostearate*
PEG-20 hydrogenated castor oil laurate*
PEG-30 hydrogenated castor oil laurate*
PEG-40 hydrogenated castor oil laurate*
PEG-50 hydrogenated castor oil laurate*
PEG-60 hydrogenated castor oil laurate*
PEG-20 hydrogenated castor oil pca isostearate*
PEG-30 hydrogenated castor oil pca isostearate*
PEG-40 hydrogenated castor oil pca isostearate
PEG-60 hydrogenated castor oil pca isostearate*
PEG-50 hydrogenated castor oil succinate
potassium PEG-50 hydrogenated castor oil succinate*
sodium PEG-50 hydrogenated castor oil succinate*
PEG-5 hydrogenated castor oil triisostearate*
PEG-10 hydrogenated castor oil triisostearate*
PEG-15 hydrogenated castor oil triisostearate*
PEG-20 hydrogenated castor oil triisostearate
PEG-30 hydrogenated castor oil triisostearate*
PEG-40 hydrogenated castor oil triisostearate
PEG-50 hydrogenated castor oil triisostearate*
PEG-60 hydrogenated castor oil triisostearate*
adansonia digitata seed oil PEG-8 esters*
almond oil PEG-6 esters*

almond oil PEG-8 esters *
apricot kernel oil PEG-6 esters
apricot kernel oil PEG-8 esters*
apricot kernel oil PEG-40 esters*
argan oil PEG-8 esters*
avocado oil PEG-8 esters*
avocado oil PEG-11 esters
bertholletia excelsa seed oil PEG-8 esters*
borage seed oil PEG-8 esters*
coconut oil PEG-10 esters
corn oil PEG-6 esters*
corn oil PEG-8 esters*
grape seed oil PEG-8 esters
hazel seed oil PEG-8 esters*
hydrogenated palm/palm kernel oil PEG-6 esters
jojoba oil PEG-8 esters
jojoba oil PEG-150 esters*
linseed oil PEG-8 esters*
macadamia ternifolia seed oil PEG-8 esters*
mango seed oil PEG-70 esters*
mink oil PEG-13 esters*
olive oil PEG-6 esters*
olive oil PEG-7 esters
olive oil PEG-8 esters*
olive oil PEG-10 esters
orbignya oleifera seed oil PEG-8 esters*
palm oil PEG-8 esters*
passiflora edulis seed oils PEG-8 esters*
peanut oil PEG-6 esters*
PEG-75 crambe abyssinica seed oil*
PEG-75 meadowfoam oil
pumpkin seed oil PEG-8 esters*
rapeseed oil PEG-3 esters*
rapeseed oil PEG-20 esters*
raspberry seed oil PEG-8 esters*
safflower seed oil PEG-8 esters*
schinziophyton rautanenii kernel oil PEG-8 esters*
sclerocarya birrea seed oil PEG-8 esters*
sesame seed oil PEG-8 esters*
soybean oil PEG-8 esters*
soybean oil PEG-20 esters*
soybean oil PEG-36 esters*
sunflower seed oil PEG-8 esters*
sunflower seed oil PEG-32 esters*
sweet almond oil PEG-8 esters*
watermelon seed oil PEG-8 esters*
wheat germ oil PEG-40 butyloctanol esters*
wheat germ oil PEG-8 esters*

*Not reported to be in current use. Were ingredients in this group not reported to be in current use to be used in the future, the expectation is that they would be used in product categories and at concentrations comparable to others in this group.

PEGylated Oils is the name CIR devised to describe this large group of cosmetic ingredients. These ingredients are mixtures of the etherification and transesterification products of fatty acid glycerides and fatty acids from plant sources and equivalents of ethylene oxide to produce the desired PEG length. Because of the nature of the process by which these ingredients are produced, PEG compounds unattached to glycerides or fatty acid groups will be present,. Overall, PEGylated oils are complex mixtures of structurally related molecules. The Panel determined that the available data in previous safety assessments of PEGs and of plant-derived fatty acids strongly supported the safety of PEGylated oils. In addition, the Panel considered that the available data on PEGs castor oils and PEGs hydrogenated castor oils could be "read across" to support the safety of the entire group.

The Expert Panel recognized that these ingredients can enhance the penetration of other ingredients through the skin. The Panel cautioned that care should be taken in formulating cosmetic products that may contain these ingredients in combination with any ingredients whose safety was based on their lack of dermal absorption, or when dermal absorption was a concern.

The Expert Panel noted that the earlier safety assessment of PEG castor oils specified safe up to a 50% use concentration. As PEGs castor oils and the rest of the PEGylated oils now are used at concentrations below 50% in leave-on products, the Panel determined that a concentration limit need no longer be specified. Products using these ingredients should be formulated to be non-irritating.

Tin(IV) Oxide

The CIR Expert Panel issued a tentative report for public comment with the conclusion that tin(IV) oxide is safe in the present practices of use and concentration in cosmetics.

This ingredient is a widely used cosmetic abrasive, bulking, and opacifying agent. Throughout the report, the valence of tin oxide used in studies will be specified and, if not available, the absence of this information will be noted. The Panel asserted that, while there are no carcinogenicity or reproductive and developmental toxicity data, these endpoints are not of concern because this ingredient is insoluble and would not be percutaneously absorbed.

Insufficient Data Announcement

For insufficient data announcements, interested persons are given an opportunity to comment, provide information and/or request an oral hearing before the CIR Expert Panel. Information may be submitted without identifying the source or the trade name of the cosmetic product containing the ingredient. All unpublished data submitted to CIR will be discussed in open meetings, posted on the CIR website, and are available at the CIR office for review by any interested party. ***Please submit data and/or comments to CIR by November 14, 2012, or sooner if possible.*** *These ingredient reports may be scheduled for review by the CIR Expert Panel at its* ***December 10-11, 2012*** *meeting.*

Methyl Glucose Polyethers and Esters

The CIR Expert Panel requested additional data to support the safety of methyl glucose polyethers and esters.

The additional data needed are: (1) skin penetration data on the polyethers; if dermal absorption occurs, then reproductive and developmental toxicity data may be needed; 2) genotoxicity data on the polyethers and esters; (3) repeated insult patch test (RIPT) data on methyl glucose dioleate to confirm safety at the maximum use concentration of 2%; and (4) study details for the RIPT on methyl glucose sesquistearate included in the safety assessment.

The 25 methyl glucose polyethers and esters in this safety assessment are:

Esters	*Polyethers*	*Esters and polyethers*
methyl glucose caprylate/caprate	PPG-10 methyl glucose ether	PEG-120 methyl glucose dioleate
methyl glucose dioleate	PPG-20 methyl glucose ether	PEG-20 methyl glucose distearate
methyl glucose isostearate	PPG-25 methyl glucose ether	PEG-80 methyl glucose laurate
methyl glucose laurate	methyl gluceth-10	PEG-20 methyl glucose sesquicaprylate/ sesquicaprate
methyl glucose sesquicaprylate/ sesquicaprate	methyl gluceth-20	PEG-20 methyl glucose sesquilaurate
methyl glucose sesquicocoate		PEG-20 methyl glucose sesquistearate
methyl glucose sesquiisostearate		PEG-120 methyl glucose triisostearate
methyl glucose sesquilaurate		PEG-120 methyl glucose trioleate
methyl glucose sesquioleate		PPG-20 methyl glucose ether acetate
methyl glucose sesquistearate		PPG-20 methyl glucose ether distearate

Methyl glucose polyethers are widely used skin and hair conditioning agents. Methyl glucose esters are used only as skin conditioning agents in cosmetic products.

Because either methyl glucose or methyl glucoside is the backbone of these methyl glucose polyether and ester chemical structures and would likely be released by the hydrolysis of these ingredients in the skin, the Panel requested literature searches on methyl glucose and methyl glucoside to identify data that may be pertinent to this safety assessment. Industry is alerted that any available unpublished data on methyl glucose and methyl glucoside should be submitted to CIR.

Re-review

Retinol and Retinyl Palmitate - reopened

The CIR Expert Panel determined that there were sufficient new data to warrant reopening this safety assessment and, in particular, to develop a robust review of the available photo co-mutagenicity and photo co-carcinogenicity data. Notable among the available information was a photocarcinogenesis study of retinoic acid and retinyl palmitate conducted by FDA's National Center for Toxicological Research under the auspices of the National Toxicology Program.

CIR will add an additional 7 related ingredients and search for published studies relating to evaluating their safety as cosmetic ingredients. These additional ingredients include retinyl acetate, retinyl linoleate, retinyl oleate, retinyl propionate, retinyl rice branate, retinyl soyate, and retinyl tallate. Industry is alerted that any available unpublished data on these 7 additional ingredients should be submitted to CIR. Both retinyl palmitate and retinol are widely used cosmetic skin conditioning agents. Retinyl acetate has 27 uses reported to the FDA's Voluntary Cosmetic Registration Program (VCRP), retinyl linoleate has 30 reported uses, and retinyl propionate has 9 reported uses, but the other retinol esters are not reported to be in current use. It will also be important to have current use concentration information for all 9 ingredients.

New Data

Parabens

The CIR Expert Panel determined to not reopen the safety assessment of methylparaben, ethylparaben, propylparaben, isopropylparaben, butylparaben, isobutylparaben and benzylparaben. One new study suggesting that the preservative function of parabens might be linked to allergic sensitization, while other potential endocrine disrupting chemicals were not linked to this condition, was considered by the CIR Expert Panel. The Panel also reviewed a study that measured paraben concentrations as a function of location in breast tissue. In addition, an in vitro study of immortalized but untransformed human breast epithelial cells in culture reported cell transformation at concentrations that were considered to be comparable to the concentrations measured in some of the breast tissue studied. The Panel determined that these data are not relevant to the assessment of the safety of parabens in cosmetics. The Panel reaffirmed that parabens are safe in the present practices of use and concentration. The Panel suggested that their extensive discussion about these data would be important to communicate to the public and to the scientific community and that a detailed discussion should be prepared for posting on the CIR website, for a press release, and for a letter to the editor of an appropriate scientific journal.

Barr L et al. 2012. Measurement of paraben concentrations in human breast tissue at serial locations across the breast from axilla to sternum. J. Appl. Toxicol. 32: 219-232.

Khanna S and Darbre PD. 2012. Parabens enable suspension growth of MCF-10A immortalized, non-transformed human breast epithelial cells. J. Appl. Toxicol. [Epub ahead of print].

Savage JH et al. 2012. Urinary levels of triclosan and parabens are associated with aeroallergen and food sensitization. J Allergy Clin Immunol 130(2): 453-460.

Triclosan

The CIR Expert Panel determined to not reopen the safety assessment of triclosan. One new study suggesting that the biocide function of triclosan might be linked to allergic sensitization, while other potential endocrine disrupting chemicals were not linked to this condition, was considered by the CIR Expert Panel. In addition, the Panel reviewed a study of the effects of triclosan on muscle excitation-contraction coupling and divalent calcium dynamics in vitro and in vivo tests. The data from these studies was not considered relevant to the assessment of the safety of triclosan in cosmetics. The Panel reaffirmed that triclosan is safe for use in cosmetics in the present practices of use and concentration. The Panel suggested that their extensive discussion about these data would be important to communicate to the public and to the scientific community and that a detailed discussion should be prepared for posting on the CIR website, for a press release, and for a letter to the editor of an appropriate scientific journal.

Cherednichenko G et al. 2012. Triclosan impairs excitation-contraction coupling and Ca2+ dynamics in striated muscle. Proceedings of the National Academy of Sciences 109(35): 14158-14163.

Savage JH et al. 2012. Urinary levels of triclosan and parabens are associated with aeroallergen and food sensitization. J Allergy Clin Immunol 130(2): 453-460.

124th Meeting Notes

Director's Report

Dr. Andersen noted that the planned visit by the Chairman of the Personal Care Products Council's Board of Directors has been postponed. That the Board Chair wanted to see the Panel in action is a first that we should applaud. CIR will work with the Council to try and reschedule.

Dr. Andersen reported that CIR has had some functionality issues with the website. The part that CIR uses to post material for the Panel meetings is working as designed and implemented, but CIR needs to ensure that users can find all posted safety assessments. This will be a work in progress, but the plan all along has been to continuously improve the website, expand content, and develop other elements of the site on an ongoing basis.

For the December meeting Dr. Andersen two items were highlighted. Because the Expert Panel will be reviewing a hair dye ingredient, CIR will also have to address the concerns raised in Europe regarding the risks potentially associated with directions to consumers to test such products on a small patch of skin before use. In addition, there are new studies about phthalates that CIR will need to examine, as done for parabens and triclosan at this meeting.

Note: re-reviews to be considered at the December meeting include 2-amino-6-chloro-4-nitrophenol and m-phenylenediamines.

Finally, Dr. Andersen indicated that CIR may receive information from the Professional Keratin Smoothing Council on the impact of their programs to improve the use conditions under which hair smoothing products containing formaldehyde and/or methylene glycol are used. PKSC has made a major effort to develop a plan of action to help address the Panel's concerns, but CIR has repeatedly emphasized that PKSCs plan, alone, will not be sufficient to change the Panel's findings. The Panel agreed that CIR will need to see evidence of the impact of the implementation of the plan.

Reports tabled – alkyl esters and fatty acid amidopropyl dimethylamines

Alkyl Esters - The CIR Expert Panel tabled further discussion of the alkyl esters report.

This re-review includes more than 50 ingredients that have been reviewed previously by the CIR. During its discussion of this ingredient group, the Panel noted that the current use concentration of a number of these previously reviewed ingredients is greater than the use concentration reported at the time of the original safety assessment. While data may be available to support the current, higher use concentrations, the Panel wanted to more closely examine the existing data to ensure that the safety of use at the higher concentrations is supported. Interested parties are encouraged to submit any available unpublished data supporting the safety of such higher use concentrations.

Prior to tabling the report, the Panel removed the 16 ethylhexanoate ingredients that were included in the group because of concern for the reproductive risk of exposure to 2-ethylhexanoic acid, which is a possible metabolite of these ingredients.

The remaining 238 alkyl esters included in this group are listed below, and those that were reviewed previously are indicated by †.

arachidyl behenate
arachidyl erucate
arachidyl propionate†
batyl isostearate
batyl stearate
behenyl beeswax
behenyl behenate
behenyl erucate
behenyl isostearate
behenyl olivate
behenyl/isostearyl beeswax
butyl avocadate
butyl babassuate
butyl isostearate
butyl myristate†
butyl oleate
butyl stearate†
butyloctyl beeswax
butyloctyl behenate
butyloctyl candelillate
butyloctyl cetearate
butyloctyl oleate
butyloctyl palmitate
C10-40 isoalkyl acid octyldodecanol esters
C14-30 alkyl beeswax
C16-36 alkyl stearate
C18-38 alkyl beeswax
C18-38 alkyl c24-54 acid ester
C20-40 alkyl behenate
C20-40 alkyl stearate
C30-50 alkyl beeswax
C30-50 alkyl stearate
C32-36 isoalkyl stearate
C40-60 alkyl stearate
C4-5 isoalkyl cocoate
caprylyl butyrate
caprylyl caprylate
caprylyl eicosenoate
cetearyl behenate
cetearyl candelillate
cetearyl isononanoate†
cetearyl nonanoate†
cetearyl olivate
cetearyl palmate
cetearyl palmitate
cetearyl rice branate
cetearyl stearate
cetyl babassuate
cetyl behenate
cetyl caprate
cetyl caprylate
cetyl dimethyloctanoate
cetyl esters
cetyl isononanoate†
cetyl laurate
cetyl myristate†
cetyl oleate
cetyl palmitate†
cetyl ricinoleate†
cetyl stearate†
cetyl tallowate
chimyl isostearate
chimyl stearate
coco-caprylate
coco-caprylate/caprate
coco-rapeseedate
decyl castorate
decyl cocoate†
decyl isostearate
decyl jojobate
decyl laurate
decyl myristate†
decyl oleate†
decyl olivate
decyl palmitate
decyltetradecyl cetearate
erucyl arachidate
erucyl erucate
erucyl oleate
ethylhexyl adipate/palmitate/stearate
ethylhexyl C10-40 isoalkyl acidate
ethylhexyl cocoate†
ethylhexyl hydroxystearate
ethylhexyl isononanoate†
ethylhexyl isopalmitate
ethylhexyl isostearate
ethylhexyl laurate
ethylhexyl myristate†
ethylhexyl neopentanoate
ethylhexyl oleate
ethylhexyl olivate
ethylhexyl palmitate†
ethylhexyl pelargonate†
ethylhexyl stearate†
heptyl undecylenate
heptylundecyl hydroxystearate
hexyl isostearate
hexyl laurate
hexyldecyl hexyldecanoate

hexyldecyl isostearate
hexyldecyl laurate
hexyldecyl oleate
hexyldecyl palmitate
hexyldecyl stearate
hexyldodecyl/octyldecyl hydroxystearate
hydrogenated castor oil behenyl esters
hydrogenated castor oil cetyl esters
hydrogenated castor oil stearyl esters
hydrogenated ethylhexyl olivate
hydrogenated ethylhexyl sesamate
hydrogenated isocetyl olivate
hydrogenated isopropyl jojobate
hydroxycetyl isostearate
hydroxyoctacosanyl hydroxystearate
isoamyl laurate
isobutyl myristate†
isobutyl palmitate
isobutyl perlargonate†
isobutyl stearate†
isobutyl tallowate
isocetyl behenate
isocetyl isodecanoate
isocetyl isostearate
isocetyl laurate
isocetyl myristate
isocetyl palmitate
isocetyl stearate†
isodecyl cocoate†
isodecyl hydroxystearate
isodecyl isononanoate†
isodecyl laurate
isodecyl myristate†
isodecyl neopentanoate
isodecyl oleate†
isodecyl palmitate
isodecyl stearate
isohexyl caprate
isohexyl laurate
isohexyl neopentanoate
isohexyl palmitate
isolauryl behenate
isononyl isononanoate†
isooctyl caprylate/caprate
isooctyl tallate
isopropyl isostearate
isopropyl arachidate
isopropyl avocadate
isopropyl babassuate
isopropyl behenate
isopropyl hydroxystearate
isopropyl isostearate†
isopropyl jojobate
isopropyl laurate
isopropyl linoleate
isopropyl myristate†
isopropyl oleate
isopropyl palmitate†
isopropyl ricinoleate†
isopropyl sorbate
isopropyl stearate†
isopropyl tallowate
isostearyl avocadate
isostearyl behenate
isostearyl erucate
isostearyl hydroxystearate
isostearyl isononanoate†
isostearyl isostearate
isostearyl laurate
isostearyl linoleate
isostearyl myristate†
isostearyl neopentanoate†
isostearyl palmitate
isotridecyl isononanoate†
isotridecyl laurate
isotridecyl myristate†
isotridecyl stearate
lauryl behenate
lauryl cocoate†
lauryl isostearate
lauryl laurate
lauryl myristate†
lauryl oleate
lauryl palmitate
lauryl stearate
lignoceryl erucate
myristyl isostearate
myristyl laurate
myristyl myristate†
myristyl neopentanoate
myristyl stearate†
octyldecyl oleate
octyldodecyl avocadoate
octyldodecyl beeswax
octyldodecyl behenate
octyldodecyl cocoate†
octyldodecyl erucate
octyldodecyl hydroxystearate
octyldodecyl isostearate
octyldodecyl meadowfoamate
octyldodecyl myristate†
octyldodecyl neodecanoate
octyldodecyl neopentanoate
octyldodecyl octyldodecanoate
octyldodecyl oleate
octyldodecyl olivate
octyldodecyl ricinoleate†
octyldodecyl safflowerate
octyldodecyl stearate
oleyl arachidate
oleyl erucate
oleyl linoleate
oleyl myristate†
oleyl oleate
oleyl stearate
propylheptyl caprylate
stearyl beeswax
stearyl behenate†
stearyl caprylate†
stearyl erucate
stearyl heptanoate†
stearyl linoleate
stearyl olivate†
stearyl palmitate†
stearyl stearate†
tetradecyleicosyl stearate
tetradecyloctadecyl behenate
tetradecyloctadecyl hexyldecanoate
tetradecyloctadecyl myristate†
tetradecyloctadecyl stearate
tetradecylpropionates
tridecyl behenate
tridecyl cocoate†
tridecyl erucate
tridecyl isononanoate†
tridecyl laurate
tridecyl myristate†
tridecyl neopentanoate
tridecyl stearate

Fatty Acid Amidopropyl Dimethylamines – further discussion of the fatty acid amidopropyl dimethylamines group report was tabled.

The Panel was informed that a dossier including data from additional studies on stearamidopropyl dimethylamine is being prepared under the auspices of the REACH program in Europe. The Panel anticipates that it will receive the data mid-2013 and determined that this safety assessment should include such data.

While awaiting these data, the CIR Expert Panel is alerting the public that the data in the current safety assessment are insufficient to support the safety of the fatty acid amidopropyl dimethylamine ingredients. The additional data needed include: (1) percutaneous absorption data on cocamidopropyl dimethylamine, and if it is absorbed; (2) reproduction and developmental toxicity data; and (3) sensitization and irritation data on oleamidopropyl dimethylamine at use concentration. The 24 fatty acid amidopropyl dimethylamines in this safety assessment are:

almondamidopropyl dimethylamine*
avocadamidopropyl dimethylamine*
babassuamidopropyl dimethylamine*
behenamidopropyl dimethylamine
brassicamidopropyl dimethylamine
cocamidopropyl dimethylamine
dilinoleamidopropyl dimethylamine*
isostearamidopropyl dimethylamine
lauramidopropyl dimethylamine
linoleamidopropyl dimethylamine
minkamidopropyl dimethylamine
myristamidopropyl dimethylamine*
oatamidopropyl dimethylamine*
oleamidopropyl dimethylamine
olivamidopropyl dimethylamine*
palmitamidopropyl dimethylamine
ricinoleamidopropyl dimethylamine*
sesamidopropyl dimethylamine*
soyamidopropyl dimethylamine*
stearamidopropyl dimethylamine
sunflowerseedamidopropyl dimethylamine*
tallamidopropyl dimethylamine*
tallowamidopropyl dimethylamine*
wheat germamidopropyl dimethylamine*

*Not reported to be in current use.

2013 Review Priorities

The 2013 Priority list was approved by the CIR Expert Panel. The 15 reports on the list are:

- camellia sinensis leaf extract – 1701 uses
- rosmarinus officinalis (rosemary) leaf extract – 634 uses
- alumina – 612 uses
- pentaerythrityl tetra-di-*t*-butyl hydroxyhydrocinnamate – 475 uses
- hydrogenated polydecene – 455 uses
- maltodextrin – 442 uses
- trehalose & glucose - 440 & 350 uses, respectively
- betaine – 439 uses
- tocotrienols – 436 uses
- citrus medica limonum (lemon) fruit extract – 421 uses
- PPG-5-ceteth-20 – 414 uses
- phytosterols – 408 uses
- magnesium sulfate – 393 uses
- ceramide 3 – 377 uses
- hydroxypropyl bis(*n*-hydroxyethyl-*p*-phenylenediamine) HCl – 75 uses

The list was based on use data from FDA's Voluntary Cosmetic Registration Program (VCRP), received from FDA in May, 2012. Comments were provided by the Personal Care Products Council's CIR Science and Support Committee. The list includes only the lead ingredients. These lead ingredients, in many cases, will form the nidus for a group. For example, PPG-5 ceteth-20 may be expanded to a group of 160 alkyl PEG/PPG ethers. Magnesium Sulfate may include other inorganic sulfates. As literature reviews and draft reports are prepared for these ingredients, groups may be revised based on the available scientific information. For example certain inorganic sulfates may present different toxicity profiles and be eliminated on that basis. The full list of 2013 priorities will be posted at http://www.cir-safety.org/about .

CIR will also re-review safety assessments in 2013. These will include:

- cetearyl ethylhexanoate
- dioctyl sodium sulfosuccinate
- glycolic acid, ammonium, calcium, potassium, and sodium glycolates, methyl, ethyl, propyl, and butyl glycolates, and lactic acid, ammonium, calcium, potassium, sodium, and tea-lactates, methyl, ethyl, isopropyl, and butyl lactates, and lauryl, myristyl, and cetyl lactates
- hc yellow no. 4
- hc orange no. 1
- iodopropynyl butylcarbamate (IPBC)
- polyvinyl alcohol
- polyvinylpyrrolidone (PVP)
- sodium alpha-olefin sulfonates

Scientific Literature Reviews

- **These literature reviews are currently posted on the CIR website at http://www.cir-safety.org/ingredients/glossary/all**
  - 6-hydroxyindole
  - hydrolyzed proteins
  - modified terephthalate polymers
  - palmitoyl oligopeptides
  - source amino acids
  - talc

Draft reports for these ingredients, along with any unpublished data submitted by interested parties may be presented to the Panel at its meeting on December 10-11, 2012.

- **These literature reviews are currently in preparation**
  - amino acid alkyl amines
  - boron nitride
  - chamomile ingredients
  - nitrocellulose
  - tromethamine

Next CIR Expert Panel Meeting - Monday and Tuesday, December 10-11, 2012 at the Madison Hotel, 1177 Fifteenth Street, NW, Washington, DC 20005 --- Please contact Carla Jackson (jacksonc@cir-safety.org) at CIR before the meeting if you plan to attend.

►►IMPORTANT CHANGE◄◄

CIR no longer includes an order form listing CIR safety assessments available for sale. Because all CIR documents from this meeting will be posted on the web site, they will be freely available.