
Safety Assessment of *Pyrus malus* (Apple)-derived Ingredients as Used in Cosmetics

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All interested persons are provided 60 days from the above date to comment on this safety assessment and to identify additional published data that should be included or provide unpublished data which can be made public and included. 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 All unpublished data submitted to CIR will be discussed in open meetings, will be available at the CIR office for review by any interested party and may be cited in a peer-reviewed scientific journal. Please submit data, comments, or requests to the CIR Director, Dr. Lillian J. Gill.

The 2015 Cosmetic Ingredient Review Expert Panel members are: Chair, Wilma F. Bergfeld, M.D., F.A.C.P.; Donald V. Belsito, M.D.; Curtis D. Klaassen, Ph.D.; Daniel C. Liebler, Ph.D.; Ronald A. Hill, Ph.D.; James G. Marks, Jr., M.D.; Ronald C. Shank, Ph.D.; Thomas J. Slaga, Ph.D.; and Paul W. Snyder, D.V.M., Ph.D. The CIR Director is Lillian J. Gill, D.P.A. This report was prepared by Wilbur Johnson, Jr., M.S., Senior Scientific Analyst.

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INTRODUCTION

The safety of the following 19 ingredients in cosmetics is reviewed in this Scientific Literature Review:

- Pyrus Malus (Apple) Fruit Extract
- Pyrus Malus (Apple) Bark Extract
- Pyrus Malus (Apple) Carpel Powder
- Pyrus Malus (Apple) Fiber
- Pyrus Malus (Apple) Flower Extract
- Pyrus Malus (Apple) Fruit
- Pyrus Malus (Apple) Fruit Water
- Pyrus Malus (Apple) Juice
- Pyrus Malus (Apple) Leaf Extract
- Pyrus Malus (Apple) Pectin Extract
- Pyrus Malus (Apple) Peel Extract
- Pyrus Malus (Apple) Peel Powder
- Pyrus Malus (Apple) Peel Wax
- Pyrus Malus (Apple) Pulp Extract
- Pyrus Malus (Apple) Root Bark Powder
- Pyrus Malus (Apple) Root Extract
- Pyrus Malus (Apple) Seed Extract
- Pyrus Malus (Apple) Seed Oil
- Pyrus Malus (Apple) Stem Extract

These ingredient names and associated definitions are included in the 2014 *International Cosmetic Ingredient Dictionary and Handbook*.¹ Though the ingredients reviewed in this safety assessments are *Pyrus malus* (apple)-derived ingredients and *pyrus malus* is part of each ingredient name, the Cosmetic Ingredient Review (CIR) has been informed that *Pyrus malus* is a genus and species name for apple that is not in current use, and that the ingredients listed above are under consideration by the cosmetics industry for new name assignments.² On the subject of other names for *Pyrus malus*, the name *Malus sylvestris* is identified as the botanical name for *pyrus malus* (apple) fruit extract in data on trade name mixtures provided by industry and included in this safety assessment.^{3,4}

Some of the ingredients (e.g., fruit/fruit-derived) reviewed in this safety assessment may be consumed as food, and daily exposure from food use would result in much larger systemic exposures than those from use in cosmetic products. Thus, the systemic toxicity potential of some *Pyrus malus* (apple)-derived ingredients via oral exposure is not addressed further in this report. The primary focus of the safety assessment of these ingredients as used in cosmetics is on the potential for irritation and sensitization from dermal exposure.

CHEMISTRY

Definition and Structure

Pyrus Malus

Pyrus malus (Fam. Rosaceae) is a medium-sized tree that grows abundantly in the Northwestern Himalayan region.⁵ The definitions and functions of *Pyrus malus* (apple)-derived cosmetic ingredients reviewed in this safety assessment are presented in Table 1.¹

Chemical and Physical Properties

Pyrus Malus (Apple) Fruit Extract

Properties of 2 trade name mixtures containing 10-25% *pyrus malus* (apple) fruit extract are presented in Table 2.^{3,4} Composition data on both mixtures are provided in the section on Composition/Impurities – *Pyrus Malus* (Apple) Fruit Extract.

Method of Manufacture

Pyrus Malus (Apple) Bark Extract

In one study, the air-dried, powdered bark of *Pyrus malus* was extracted with petroleum, chloroform, or 90% ethanol.⁵ The petroleum extract yielded a faintly yellow crystalline mass, the chloroform extract yielded a dark yellow solid, and the ethanolic fraction yielded a very small amount of a brown alkali-soluble residue.

Pyrus Malus (Apple) Fiber

Pyrus malus (apple) fiber is made from residue formed during apple juice production. The residue is dried and mechanically ground and sieved.⁶

Pyrus Malus (Apple) Fruit Extract

Pyrus malus fruit extract has been prepared according to the following procedure:⁷ Pyrus malus fruit was peeled manually and the pericarp (part of fruit enclosing the seeds) was separated, dried at room temperature (26-28°C), and powdered. The powder was extracted with 95% ethanol. The ethanol was evaporated using a rotary evaporator, and the fruit extract was stored at -20°C prior to use.

According to another source, pyrus malus (apple) fruit extract is made by extracting apples with a 50% vol% 1,3-butylene glycol solution (the extraction solution is 50% butylene glycol and 50% water).⁸ The extract is then treated as follows: filtration, sedimentation, filtration, adjustment of the concentration with additional 50% butylene glycol and 50% water solution, and packaging.

The method of manufacture of a trade name material containing 10-25% pyrus malus (apple) fruit extract has been described as follows:³ The plant material is extracted with 1,2-propylene glycol at “considerate” temperatures during a fixed time, and is sterile-filtered at the end of the fabrication. Lactic acid (0.1-1%) is used for pH regulation, and the product contains 0.6% Bactiphen 250G (phenoxyethanol [75-100%], methylparaben [10-25%], ethylparaben [1-5%], propylparaben [1-5%], and butylparaben [1-5%]) as the preservative.

Another trade name material containing 10-25% pyrus malus (apple) fruit extract is manufactured using the same procedure, except that glycerin (vegetable origin) is the extraction solvent. Again, lactic acid (0.1-1%) is used for pH regulation, but the product contains potassium sorbate (0.35%) and sodium benzoate (0.35%) as preservatives.³

Apple Fruit Water

Apple fruit water (*malus domestica* fruit water) is prepared by dehydrating the fruit under vacuum at low temperature.⁹

Apple Juice

Apple juice (from Fuji and Gala varieties; genus and species not stated) was obtained by mechanical pressure, depectinized in a water bath (2 h at 45°C), filtered through paper, bottled, closed, and stabilized by freezing.¹⁰

Pyrus Malus (Apple) Pectin Extract

A simple procedure for the extraction of pectin has been described as follows:¹¹ Approximately 40 g of fruit were washed with N-saline, after which the fruit sample was crushed and homogenized in a blender. The resulting materials were allowed to dry in a hot air (60°C) oven for approximately 2h, i.e., until the pectin extracted turned into powder. To obtain sterilized pectin, the powdered pectin was sterilized with N-saline.

Apple Peel Extract

Prior to analysis for anthocyanin content, apples (*Malus domestica*) were peeled and the peel was extracted with methanol containing 0.1% HCl.¹²

Pyrus Malus (Apple) Root Bark Powder

Pyrus malus (apple) root bark powder is extracted with carbon dioxide, and is purified to contain 95 to 98% phloridzin¹³, a dihydrochalcone.

Pyrus Malus (Apple) Seed Extract

Pyrus malus seed extract has been prepared according to the following procedure:¹⁴ After 3 months of stratification (steady exposure to moist environment before germination becomes possible), the seeds (not dehydrated) were extracted. The extraction procedure was performed using chilled 80% redistilled methanol, to which butylated hydroxytoluene (BHT, 10 mg) was added as an antioxidant. Extraction was followed by homogenization in a chilled blender for 10 minutes. The homogenate was allowed to stand overnight (at 4°C) in the dark, filtered, and the residue was reextracted. The filtrate was evaporated (at 35°C) in a rotary evaporator, avoiding direct sunlight, and an aqueous extract remained.

Pyrus Malus (Apple) Seed Oil

Crude oil from the ground seeds (~ 5 g) has been extracted over a 6 h period using n-hexane.¹⁵ The solvent was removed using a rotary evaporator under reduced pressure, and the oil was flushed with a stream of nitrogen and stored at -20°C in sealed tubes.

Composition/Impurities

Pyrus Malus (Apple) Fruit

Composition data on different varieties of *Pyrus malus* are included in Tables 3 and 4.¹⁶

A number of sweet and sour varieties of apples from the hilly parts of Northwest India have been found to contain malvidin monoglycoside.¹⁷ Additionally, the skin of Grimes Golden, Jonathon, and Stayman wine sap apples have been reported to contain idaein (3-β-galactosidyl cyanidin), and the related yellow varieties yielded quercetin-3-galactoside.

The following 3 predominant hydroxycinnamic derivatives in the apple (*Pyrus malus* L., var. Calville blanc) have been reported:¹⁸ *p*-coumarylquinic acid, *p*-coumarylglucose, and chlorogenic acid. The concentration of each derivative, some weeks after blossoming, is highest in young fruits. The amount per fruit increases during approximately 1 month and 2 months for *p*-coumarylquinic acid and chlorogenic acid, respectively. During this period, a relative accumulation of the *o*-diphenolic compound is observed, in comparison with *p*-coumaric derivatives.

Assay results for the presence of amino acids in *Pyrus malus* were as follows:¹⁹ alanine, γ-amino butyric acid, asparagine, cysteine or cystine, and glutamic acid. Quantitative data were not reported. The presence of an unidentified substance that reacted with ninhydrin was also reported. The following sugars were detected in the nectar of *Pyrus malus* using gas chromatography:²⁰ fructose, glucose, and sucrose. Quantitative data were not reported.

Apple Fruit

Data on the average content of phenolic compounds in fruit from apple trees (genus and species not stated) grown in Lithuania are as follows:²¹

- Chlorogenic acid (729-1047 μg/g dry weight)
- Phloridzin (83.7-122 μg/g dry weight)
- Procyanidin B1 (33.5-81.5 μg/g dry weight)
- Procyanidin B2 (504-920 μg/g dry weight)
- Σ Procyanidins (558-1001 μg/g dry weight)
- (+)-Catechin (35.6-77.3 μg/g dry weight)
- (-)-Epicatechin (217-329 μg/g dry weight)
- Σ Catechins (254-406 μg/g dry weight)
- Hyperoside (87-147 μg/g dry weight)
- Isoquercitrin (15.4-23.3 μg/g dry weight)
- Rutin (15.1-21.6 μg/g dry weight)
- Avicularin (59.9-94 μg/g dry weight)
- Quercitrin (86.1-130 μg/g dry weight)
- Σ Quercitrin glycosides (264-416 μg/g dry weight)
- Σ Phenolic compounds (1976-2943 μg/g dry weight)

Pyrus Malus (Apple) Fruit Extract

Using paper chromatography, the extracts of fruits of *Pyrus malus* have been found to contain chlorogenic and isochlorogenic acids, in combination with their related substances.⁵ Some glycosides of quercetin were also detected. The total polyphenols (~ 200 mg/100 g dry weight) and total flavonoids (~ 25 mg/100 g dry weight) content of pyrus malus fruit extract have also been reported.⁷ According to a supplier of pyrus malus (apple) fruit extract, it contains sugar and organic acids.⁸

The name *Malus sylvestris* has been identified as the botanical name for pyrus malus (apple) fruit extract in 2 pyrus malus (apple) fruit extract trade name mixtures containing 10-25% pyrus malus (apple) fruit extract.^{3,4} Composition data on *Malus sylvestris* include (quantitative data not reported):

- Quercetin
- Mineral substances
- Essential oil
- Enzymes
- Fruit acids
- Amino acids
- Vitamins
- Arabane
- Galactane
- Tannins
- Pectin
- Sugars
- Wax

One trade name mixture contains pyrus malus (apple) fruit extract (10-25%) and propylene glycol (75-100%),³ and the other contains the following: pyrus malus (apple) fruit extract (10-25%), glycerin (75-100%), and aqua (water) (10-25%).⁴

Pyrus Malus (Apple) Fiber

Composition data on pyrus malus (apple) fiber are included in Table 5.^{22,23}

Pyrus Malus (Apple) Bark Extract

The air-dried, powdered bark of *Pyrus malus* was extracted with petroleum, chloroform, or 90% ethanol. The petroleum extract yielded a faintly yellow crystalline mass, the chloroform extract yielded a dark yellow solid, and the ethanolic fraction provided a very small amount of a brown alkali-soluble residue. The following 3 compounds were isolated from the bark of *Pyrus malus* extracted with different solvents (petroleum, chloroform, or 90% ethanol): β -sitoserol, friedelin, and epi-friedelinol.⁵

Pyrus Malus (Apple) Juice

Juice from the Fuji and Gala apple varieties (genus and species not stated) in Brazil has the following composition:¹⁰ malic acid (0.18 to 0.389 g/100 mL), total reducing sugar (8.65 to 15.18 g/100 mL), and total phenolic compounds (100 to 400 mg/L). In comparison, apple juice from the Golden delicious variety contains: malic acid (0.312 g/100 mL), total reducing sugar (10.533 g/100 mL), and total phenolic compounds (535.082 mg/L).

Pyrus Malus Leaf and Pyrus Malus Leaf Extract

The partition of nitrogen in various parts of *Pyrus malus* throughout a one-year cycle has been studied.²⁴ The study involved seedling apple trees that received heavy applications of sodium nitrate at regular intervals throughout the vegetative period. Positive tests for nitrates (or nitrites) were reported for one tissue only, the leaf buds, just as they were opening. Flavone glycosides have also been detected in the leaves of *Pyrus malus*.⁵ The sugar alcohol sorbitol has been detected in *Pyrus malus* leaves at a concentration of 0.45%.²⁵

Although data on the composition of pyrus malus leaf extract were not found, composition data on the volatile oil obtained from fresh leaves of the *Malus domestica* tree are available. This oil is a complex mixture of mono-, sesqui-, and di-terpenes, phenolics, and aliphatic hydrocarbons, and has been classified as cytotoxic to animal and human cancer cell lines.²⁶ The major compounds of this oil have been characterized as: eucalyptol, (43.7%), phytol (11.5%), α -farnesene (9.6%), and pentacosane (7.6%).

Apple Peel Extract

The total phenolic and anthocyanin content of apple peels from 6 apple (*Malus domestica*) cultivars grown in southern Brazil was studied.¹² Total phenolic content varied from 105.4 to 269.7 mg gallic acid equivalents (GAE)/100 g of fresh mass (FM). The differences in phenolic content among the apple cultivars were statistically significant ($p < 0.05$). Similarly, the differences in anthocyanin composition (in apple peels) among the apple cultivars were statistically significant, and values ranged from 4.79 to 41.96 mg cyanidin-3-galactoside (cy-3-gal)/100 g of FM. Cy-3-gal is the major anthocyanin that is present in red or partially red genotype apples.

In another study, variations in the content of phenolics, antioxidant activity, and minerals in the peel and pulp of 5 apple (*Malus domestica* Borkh.) cultivars from Pakistan were studied.²⁷ The mean extract yield of antioxidant components obtained with 80:20 methanol-water (v/v) was determined to be 22.1 g/100 g for the peel and 14.2 g/100 g for pulp on a dry weight (DW) basis. Ranges of total phenolics (1,907.5-2,587.9 mg GAE/100 g DW) and total flavonoids (1,214.3-1,816.4 mg catechin equivalent (CE)/100 g DW) have been reported for the peel of different cultivars of apple. Similarly, ranges of total phenolics (1,185.2-1,475.5 mg GAE/100 g DW) and total flavonoids (711.8-999.3 mg CE/100 g DW) have been reported for the pulp of different cultivars of apple. An analysis for minerals content was also performed. In both the peel and pulp, K containing minerals content was highest, followed by minerals containing Mg, Ca, Fe, Na, and Zn.

Pyrus Malus (Apple) Seed Extract

Endogenous levels of both cis and trans isomers of free and bound abscisic acid were studied in dormant and after-ripened *Pyrus malus* embryos.¹⁴ In bioassays, the level of free abscisic acid was very high in dormant embryos, mainly in cotyledons (4800 ng), but became very low after 3 months of stratification. A considerable increase in bound abscisic acid (1450 ng) was noted, and bound abscisic acid became dormant in after-ripened embryos. Bound trans-abscisic acid was detected only in the cotyledons (100 pg) of after-ripened embryos.

The extracts prepared from dry, dormant *Pyrus malus* L. seed (120 g) were found to contain gibberellins (GAs, growth promoting hormones).²⁸ These extracts contained GA₄ (3.080 mg total; 26 µg/g dry seed) and GA₇ (0.960 mg total; 8 µg/g dry seed). The ratio of GA₄ to GA₇ was 76:24. The ratios for seeds stratified for 35 days and 90 days were 81:19 and 64:36, respectively. Another study was performed to identify free GAs in dormant embryos of *Pyrus malus* L. cv Golden delicious using different extraction procedures.²⁹ Using an ethanolic extraction procedure, minute quantities of free gibberellins (traces to 50 pg/embryo) were detected. Extraction with Tris buffer (pH 7.2) yielded slightly higher quantities of gibberellins (traces to 134 pg). Very large amounts of gibberellins, especially GA₁ and GA₄ (560 and 1560 pg/embryo, respectively), were detected when the embryos were crushed in Tris buffer and treated with Triton X 100.

Apple Seed Extract

Royal Gala apple seeds (genus and species not stated) were collected from apple pomace.³⁰ The methylated hexane extract of the seeds consisted mainly of fatty acids (80.9%) in its volatile fraction and benzaldehyde (< 0.2%) was also detected. Of the fatty acids identified, linoleic acid content was highest (51.2%), followed by palmitic acid (10.5%), linolenic acid (5.6%), stearic acid (4.3%), and oleic acid (4.1%). Fatty acid composition data are included in Table 6.

Further extraction of the seed with 70% aqueous acetone yielded the following 2 major compounds: [(6-*O*-β-D-glucopyranosyl)oxy]benzeneacetonitrile (amygdalin) and phloretin-2'-β-D-glucopyraide (phloridzin). The following minor polyphenols were also identified: chlorogenic acid, *p*-coumarylquinic acid, 3-hydroxyphloridzin, phloretin-2'-xyloglucoside, and quercetin glycosides.³⁰

Pyrus Malus (Apple) Pectin Extract

In the absence of data on the extract, it should be noted that pectin is a complex mixture of polysaccharides that comprises approximately one third of the cell wall dry substance of higher plants.¹¹ The highest concentrations of pectin are found in the middle lamella of the cell wall, with concentrations gradually decreasing from the primary wall toward the plasma membrane.

Pyrus Malus (Apple) Seed Oil

Data on the composition of pyrus malus seed oil are included in Table 7.¹⁵ The fatty acid profile of the seed oil, based on gas chromatography-mass spectrometry (GC-MS) analysis, was actually the fatty acid methyl ester (prepared with

methanol in the presence of KOH) profile. GC-MS analysis of the unsaponifiable fraction of the seed oil for bioactive constituents, such as sterols, tocopherols, hydrocarbons and other components, was also performed.

USE

Cosmetic

The *Pyrus malus* (apple)-derived ingredients have the following functions in cosmetic products: skin conditioning agents, binders, emulsion stabilizers, viscosity increasing agents, astringents, fragrance ingredients, antioxidants, exfoliants, and skin bleaching agents. According to information supplied to the Food and Drug Administration (FDA) by industry as part of the Voluntary Cosmetic Registration Program (VCRP), and the results from a survey of ingredient use concentrations conducted by the Personal Care Products Council (Council) in 2014, the following 10 *Pyrus malus* (apple)-derived ingredients are being used in cosmetic products, and pyrus malus (apple) fruit extract has the highest reported use frequency (89 products).^{31,32}

- Pyrus malus (apple) fruit extract
- Pyrus malus (apple) flower extract
- Pyrus malus (apple) fruit
- Pyrus malus (apple) water
- Pyrus malus (apple) juice
- Pyrus malus (apple) pectin extract
- Pyrus malus (apple) peel powder
- Pyrus malus (apple) root extract
- Pyrus malus (apple) seed extract
- Pyrus malus (apple) seed oil

The Council survey data also indicate that *Pyrus malus* (apple)-derived ingredients are being used in leave-on cosmetic products at maximum ingredient use concentrations up to 9% (i.e., for pyrus malus (apple) fruit water in face and neck products [not sprays]), and in rinse-off cosmetic products at maximum ingredient use concentrations up to 0.75% (i.e., for pyrus malus (apple) fruit extract in hair conditioners).³² Frequency of use/use concentration data for *Pyrus malus* (apple)-derived ingredients are summarized in Table 8.

Cosmetic products containing *Pyrus malus* (apple)-derived ingredients may be applied to the skin and hair or, incidentally, may come in contact with the eyes and mucous membranes. Products containing these ingredients may be applied as frequently as several times per day and may come in contact with the skin or hair for variable periods following application. Daily or occasional use may extend over many years.

Pyrus malus (apple) fruit extract is used in colognes and toilet water at a maximum concentration of 0.00083%, in perfume at a maximum concentration of 0.1%, and in body and hand products (sprays) at maximum concentrations up to 0.1%. *Pyrus malus* (apple) flower extract is used in body and hand products (sprays) at a maximum concentration of 0.0005%. Regarding use in powders, pyrus malus (apple) fruit is used in dusting and talcum powders at a maximum concentration of 0.00005%, and pyrus malus (apple) seed oil is used in face powder at a maximum concentration of 0.001%. Because *Pyrus malus* (apple)-derived ingredients are used in products that are sprayed, they could possibly be inhaled. In practice, 95% to 99% of the droplets/particles released from cosmetic sprays have aerodynamic equivalent diameters >10 µm, with propellant sprays yielding a greater fraction of droplets/particles below 10 µm, compared with pump sprays.^{33,34,35,36} Therefore, most droplets/particles incidentally inhaled from cosmetic sprays would be deposited in the nasopharyngeal and bronchial regions and would not be respirable (i.e., they would not enter the lungs) to any appreciable amount.^{33,34} There is some evidence indicating that deodorant spray products can release substantially larger fractions of particulates having aerodynamic equivalent diameters in the range considered to be respirable.³⁴ However, the information is not sufficient to determine whether significantly greater lung exposures result from the use of deodorant sprays, compared to other cosmetic sprays. The use of *Pyrus malus* (apple)-derived ingredients in deodorant sprays was not reported in the use concentration survey.

Noncosmetic

Apples are among the 20 most frequently consumed raw fruits in the United States.³⁷

TOXICOKINETICS

Data on the toxicokinetics of *Pyrus malus* (apple)-derived ingredients were neither found nor provided.

TOXICOLOGY

Except for data on antimicrobial activity, toxicity data on the *Pyrus malus* (apple)-derived ingredients reviewed in this safety assessment were not found. However, as noted earlier, some of the ingredients (e.g., fruit/fruit-derived) reviewed in this safety assessment may be consumed as food, and daily exposure from food use would result in much larger systemic exposures than those from use in cosmetic products. Therefore, the systemic toxicity potential of some *Pyrus malus* (apple)-derived ingredients via oral exposure is not addressed further in this report. The primary focus of the safety assessment of these ingredients as used in cosmetics is on the potential for irritation and sensitization from dermal exposure.

Data on a polyphenol extract produced from unripe apples, were identified in the published literature.^{38,39} Polyphenols are localized in the peel and seeds of apples, and accumulate as a by-product or pomace in the production of apple juice. In acute oral and repeated dose toxicity tests involving rats, this extract did not cause any significant hematological, clinical, chemical, histopathological, or urinary effects at a dose of 2000 mg/kg. In the Ames test without metabolic activation, the extract was slightly genotoxic when tested at a high concentration of 2500 µg/plate, but significant genotoxic activity was not found in the chromosomal aberration test or the micronucleus test. Efforts to obtain this publication are underway.

Furthermore, toxicity data on procyanidin B-2 (epicatechin-(4β→8)-epicatechin, found in apple fruit) were also identified.³⁹ Procyanidins are members of the procyanidin or condensed tannins class of flavonoids. The subcutaneous injection of procyanidin B-2 into rats did not produce signs of significant injury, and a lethal dose of > 2,000 mg/kg was reported. In primary ocular irritation tests involving rabbits, both a preparation containing procyanidin B-2 and the vehicle induced slight conjunctival irritation; ethanol was presumed to have been the causative agent. The same preparation did not cause skin irritation in rabbits. Additionally, procyanidin B-2 did not induce skin sensitization in guinea pigs in the maximization test. Efforts to obtain this publication are also underway.

Acute Toxicity

Data on the acute toxicity of *Pyrus malus* (apple)-derived ingredients were neither found nor provided.

Repeated Dose Toxicity

Data on the repeated dose toxicity of *Pyrus malus* (apple)-derived ingredients were neither found nor provided.

Antimicrobial Activity

Pyrus Malus (Apple) Pectin Extract

Pectin was extracted from several varieties of apple, i.e., American, Delicious, and Maharaj-ji (all obtained from Kashmir).¹¹ Pectin content was found to be maximum in Maharaj-ji (20.60%), followed by Delicious (14.4%) and American (11.60%). The pectin extracted was evaluated for *in vitro* antibacterial activity against different pathogenic bacterial cultures and antifungal activity. Pectin extracted from the Delicious variety had potent antibacterial activity against *Klebsiella pneumonia* (mean inhibitory concentration [MIC] = 0.8 mg/ml), followed by *Streptococcus pyogenes* (MIC = 0.3 mg/ml), *E. coli* (MIC = 0.7 mg/ml), and *Lactococcus* sp. (MIC = 0.7 mg/ml). There was no evidence of antibacterial activity in any of the bacterial strains tested with pectin extracted from the other varieties. Regardless of the variety from which pectin was extracted, there was no evidence of antifungal activity against the following fungal strains: *Aspergillus niger*, *Candida albicans*, or *Saccharomyces cerevisiae*.

SKIN IRRITATION AND SENSITIZATION

Data on the skin irritation or skin sensitization potential of *Pyrus malus* (apple)-derived ingredients were neither found nor provided.

REPRODUCTIVE AND DEVELOPMENTAL TOXICITY

Data on the reproductive and developmental toxicity of *Pyrus malus* (apple)-derived ingredients were neither found nor provided.

GENOTOXICITY

Data on the genotoxicity of *Pyrus malus* (apple)-derived ingredients were neither found nor provided.

CARCINOGENICITY

Data on the carcinogenicity of *Pyrus malus* (apple)-derived ingredients were neither found nor provided.

SUMMARY

Though the ingredients reviewed in this safety assessments are *Pyrus malus* (apple)-derived ingredients and *pyrus malus* is part of each ingredient name, the Cosmetic Ingredient Review (CIR) has been informed that *Pyrus malus* is a genus and species name for apple that is not in current use, and that the ingredients reviewed in this safety assessment are under consideration by the cosmetics industry for new name assignments.

Pyrus malus (apple)-derived ingredients have the following functions in cosmetic products: skin conditioning agents, binders, emulsion stabilizers, viscosity increasing agents, astringents, fragrance ingredients, antioxidants, exfoliants, and skin bleaching agents. According to information supplied to FDA by industry as part of the VCRP, and the results from a survey of ingredient use concentrations conducted by the Personal Care Products Council, the following 10 *Pyrus malus* (apple)-derived ingredients are being used in cosmetic products, and *pyrus malus* (apple) fruit extract has the highest reported use frequency (89 products):

Pyrus malus (apple) fruit extract	Pyrus malus (apple) pectin extract
Pyrus malus (apple) flower extract	Pyrus malus (apple) peel powder
Pyrus malus (apple) fruit	Pyrus malus (apple) root extract
Pyrus malus (apple) water	Pyrus malus (apple) seed extract
Pyrus malus (apple) juice	Pyrus malus (apple) seed oil

Pyrus malus (apple)-derived ingredients are being used in leave-on cosmetic products at maximum ingredient use concentrations up to 9% (i.e., for *pyrus malus* (apple) fruit water in face and neck products [not sprays]), and in rinse-off cosmetic products at maximum ingredient use concentrations up to 0.75% (i.e., for *pyrus malus* (apple) fruit extract in hair conditioners).

Except for data showing the antimicrobial activity of *pyrus malus* (apple) pectin extract, toxicity data on the *Pyrus malus* (apple)-derived ingredients reviewed in this safety assessment were not found. The available information on the composition of *Pyrus malus* indicates that phenolic compounds are present in the fruit, juice, leaves, peel, and seeds. Toxicity data on a polyphenol extract (produced from unripe apples) were found in the published literature. In acute oral and repeated dose toxicity tests involving rats, this extract did not cause any significant hematological, clinical, chemical, histopathological, or urinary effects at a dose of 2000 mg/kg. In the Ames test without metabolic activation, the extract was slightly genotoxic when tested at a high concentration of 2500 µg/plate, but significant genotoxic activity was not found in the chromosomal aberration test or the micronucleus test.

Toxicity data on another phenolic compound found in *Pyrus malus* fruit, procyanidin B-2 (epicatechin-(4β→8)-epicatechin), were also identified. The subcutaneous injection of procyanidin B-2 into rats did not produce signs of significant injury, and a lethal dose of > 2,000 mg/kg was reported. In primary ocular irritation tests involving rabbits, both a preparation containing procyanidin B-2 and the vehicle induced slight conjunctival irritation; however, ethanol was presumed to have been the causative agent. The same preparation did not cause skin irritation in rabbits. Additionally, procyanidin B-2 did not induce skin sensitization in guinea pigs in the maximization test.

Table 1. Definitions and functions of the ingredients in this safety assessment.¹

Ingredient/CAS No.	Definition	Function
Pyrus malus (apple) fruit extract	Pyrus malus (apple) fruit extract is the extract of the fruit of <i>Pyrus malus</i> .	Skin-Conditioning Agents - Miscellaneous
Pyrus malus (apple) bark extract	Pyrus malus (apple) bark extract is the extract of the bark of <i>Pyrus malus</i> .	Cosmetic Astringents
Pyrus malus (apple) carpel powder	Pyrus malus (apple) carpel powder is the powder obtained from the dried, ground carpels of <i>Pyrus malus</i> .	Skin-Conditioning Agents - Miscellaneous
Pyrus malus (apple) fiber	Pyrus malus (apple) fiber is the finely ground fiber obtained from the dried fruit of <i>Pyrus malus</i> .	Binders; Emulsion Stabilizers; Viscosity Increasing Agents - Aqueous
Pyrus malus (apple) flower extract	Pyrus malus (apple) flower extract is the extract of the flowers of <i>Pyrus malus</i> .	Skin-Conditioning Agents - Miscellaneous
Pyrus malus (apple) fruit	Pyrus malus (apple) fruit is the fruit of the apple, <i>Pyrus malus</i> .	Cosmetic Astringents
Pyrus malus (apple) fruit water	Pyrus malus (apple) fruit water is an aqueous solution of the steam distillate obtained from the fruit of <i>Pyrus malus</i> .	Fragrance Ingredients
Pyrus malus (apple) juice	Pyrus malus (apple) juice is the liquid expressed from the fresh pulp of the apple, <i>Pyrus malus</i> .	Skin-Conditioning Agents - Miscellaneous
Pyrus malus (apple) leaf extract	Pyrus malus (apple) leaf extract is the extract of the leaves of <i>Pyrus malus</i> .	Skin-Conditioning Agents - Miscellaneous
Pyrus malus (apple) pectin extract	Pyrus malus (apple) pectin extract is the extract of the pectin of <i>Pyrus malus</i> .	Skin-Conditioning Agents - Miscellaneous
Pyrus malus (apple) peel extract	Pyrus malus (apple) peel extract is the extract of the peel of <i>Pyrus malus</i> .	Antioxidants
Pyrus malus (apple) peel powder	Pyrus malus (apple) peel powder is the powder obtained from the dried, ground peel of <i>Pyrus malus</i> .	Exfoliants
Pyrus malus (apple) peel wax	Pyrus malus (apple) peel wax is a wax obtained from the peel of the apple, <i>Pyrus malus</i> .	Not Reported
Pyrus malus (apple) pulp extract	Pyrus malus (apple) pulp extract is the extract of the pulp of <i>Pyrus malus</i> .	Skin-Conditioning Agents - Miscellaneous
Pyrus malus (apple) root bark powder	Pyrus malus (apple) root bark powder is the powder obtained from the dried, ground root bark of <i>Pyrus malus</i> .	Skin Bleaching Agents
Pyrus malus (apple) root extract	Pyrus malus (apple) root extract is the extract of the roots of <i>Pyrus malus</i> .	Skin-Conditioning Agents - Miscellaneous
Pyrus malus (apple) seed extract	Pyrus malus (apple) seed extract is the extract of the seeds of <i>Pyrus malus</i> .	Skin-Conditioning Agents - Miscellaneous
Pyrus malus (apple) seed oil	Pyrus malus (apple) seed oil is the oil expressed from the seeds of <i>Pyrus malus</i> .	Skin-Conditioning Agents - Emollient
Pyrus malus (apple) stem extract	Pyrus Malus (Apple) Stem Extract is the extract of the stems of <i>Pyrus malus</i> .	Skin-Conditioning Agents - Miscellaneous

Table 2. Properties of *Pyrus Malus* (Apple) Fruit Extract Trade Name Mixtures.^{3,4}

Trade Name Mixture	Trade Name Mixture
Clear, brownish yellow colored liquid	Clear, brownish yellow colored liquid
Color number of 5 maximum	Color number of 7 maximum
Faint fruity odor	Faint fruity odor
Refractive index of 1.430-1.440 (@ 20°C)	Refractive index of 1.446-1.465 (@ 20°C)
Density of 1.040-1.060 (@ 20°C)	Density of 1.220-1.240 (@ 20°C)
Soluble in water	Soluble in water
pH value of 4.5-5.5	pH value of 4.0-5.0

Table 3. Nutritional Value of Different Varieties of *Pyrus malus*.¹⁶

Variety	Fat (%)	Fiber (%)	Protein (%)	Pectin (%)	Reducing Sugar	Non-reducing Sugar	Total Sugar
Amri	0.22	5.89	0.47	0.58	10.34	3.87	14.21
Bluish Golden	5.15	3.61	0.29	1.29	9.71	2.58	11.83
Bonza	0.21	4.41	0.74	1.63	11.18	4.28	15.46
Discovery	0.66	8.6	0.44	1.6	10.59	6.16	16.75
Elster	0.25	7.46	0.36	0.88	9.51	7.88	16.59
Florina	0.24	4.17	0.48	0.62	11.84	5.93	17.77
Gala	0.26	4.35	0.27	0.53	11.95	5.78	17.73
Gloster 69	3.38	4.03	0.17	1.07	10.76	3.75	14.51
Golden Delicious	0.23	5.06	0.44	0.51	11.29	4.41	15.7
Granny Smith	0.28	3.8	0.48	0.99	11.14	4.32	15.46
Green Sleeves	0.24	6.14	0.37	1.05	11.37	7.92	19.29
Ida Red	0.21	1.91	0.36	0.69	9.95	3.57	13.52
Kaja	0.08	1.13	0.38	0.43	7.1	0.57	7.67
Kids Orange	0.21	1.16	0.35	1.07	11.37	7.51	18.88
Mushadi	0.23	5.55	0.45	0.52	8.69	3.75	12.44
Red Delicious	0.07	2.56	0.47	0.58	10.74	4.09	14.83
Samootree	0.02	3.92	0.34	1.29	13.14	6.99	20.13
Summer Red	0.13	5.26	0.46	0.69	12.88	6.28	19.16
Tyees Men Early	0.23	2.94	0.38	0.5	11.66	6.47	18.13
Spartan	0.28	3.8	0.48	0.99	10.28	1.97	12.25

Table 4. Mineral Composition/Chemistry Data on Different Varieties of *Pyrus malus*.¹⁶

Variety	Sodium (mg/100 g)	Potassium (mg/100 g)	Phosphorus (mg/100 g)	Calcium (mg/100 g)	Magnesium (mg/100 g)	Iron (mg/100 g)	Vitamin A (mg/100 g)	Ascorbic Acid (mg/100 g)	Moisture (%)	Ash (%)	pH Value
Amri	8.69	82.52	15.09	15.31	8.11	5.63	0.94	3.44	80.5	1.29	4.07
Bluish Golden	8.31	75.19	8.34	16.29	14.88	7.47	0.89	3.78	83.39	3.07	3.78
Bonza	14.27	127.34	4.2	13.99	10.97	4.2	0.91	3.91	71.46	1.84	3.76
Discovery	11.01	109.36	16.34	20.79	14.62	7.23	0.95	4.2	75.91	1.14	3.87
Elster	10.14	96.94	11.25	19.89	11.7	7.09	0.99	5.93	79.72	1.51	3.75
Florina	12.8	114.63	16.98	17.85	12.19	2.46	0.8	4.28	75.4	1.71	4.19
Gala	11.4	82.27	13.31	21.99	15.58	7.6	0.79	3.22	81	1.29	4.22
Gloster 69 Golden	11.84	93.76	16.75	17.04	14.82	10.86	0.92	3.29	80.26	1.53	3.79
Delicious	7.75	63.43	8.2	15.51	13.69	3.88	0.84	3.51	84.49	1.06	4.03
Granny Smith	10.37	73.82	13.1	14.55	11.73	10.73	0.87	3.91	82.71	1.73	3.94
Green Sleeves	9.12	75.19	13.59	7.87	4.44	10.92	0.92	2.74	81.75	1.61	3.79
Ida Red	7.7	65.76	9.44	9.06	6.26	3.08	0.94	3.32	84.6	1.63	3.78
Kaja	9.79	102.87	15.25	14.74	10.26	1.57	0.96	3.33	83.67	1.82	3.74
Kids Orange	8.2	72.98	11.97	16.41	14.4	1.25	0.99	7.38	83	1.26	4.44
Mushadi	11.2	64.89	9.58	13.28	7.12	7.08	0.9	5.33	84.25	2.01	4.08
Red Delicious	12.49	73.01	4.56	16.11	7.72	4.46	0.97	4.32	82.15	1.69	4.59
Samootree	10.49	84.69	16.66	13.74	11.63	1.96	0.79	3.95	78.12	1.45	3.93
Summer Red Tyees Men Early	6.4	79.72	12.24	17.21	10.74	5.16	0.88	1.38	87.1	2.6	3.89
Spartan	9.01	76.44	13.95	17.33	9.07	1.8	0.76	3.66	81.5	1.63	3.57
Mean Values	10.37	73.82	13.14	14.55	11.73	10.73	0.81	2.99	82.71	1.73	4.07
Median Values	10.06	84.43	12.19	15.67	11.08	5.78	0.89	3.8	81.95	1.63	3.91

Table 5. Composition Data on *Pyrus Malus* (Apple) Fiber.^{22,23}

Nutritional Value	Impurities
Water (1.5%)	Ash (1.3%)
Fat (1.9%)	Not dioxin-like polychlorinated biphenyls (PCBs, 3 µg/kg; not detected)
Saturated fatty acids (0.3%, calculated as triglyceride)	Lead (0.36 mg/kg)
Monounsaturated fatty acids (0.6%, calculated as triglyceride)	Cadmium (< 0.01 mg/kg)
Polyunsaturated fatty acids (1%, calculated as triglyceride)	Mercury (< 0.30 mg/kg)
Total protein content (4.5%)	Arsenic (0.02 mg/kg)
Carbohydrate (25.5%, calculated)	Ochratoxin A (< 0.5 µg/kg)
Sucrose (enzymatical, 1609 mg/100 g)	Patulin (< 20 µg/kg)
Glucose (enzymatical, 2989 mg/100 g)	Aflatoxin B1 (< 0.7 µg/kg)
Fructose (enzymatical, 7406 mg/100 g)	Aflatoxin B1 (< 0.2 µg/kg)
Sodium (< 50 mg/kg)	Aflatoxin G1 (< 0.7 µg/kg)
Dietary fibers (65.3 g/100 g)	Aflatoxin G2 (< 0.2 µg/kg)
	Total aflatoxin (B1, B2, G1, and G2, not detected)
	Nitrite (as Na-nitrite, <3 mg/kg)
	Nitrate (as Na-nitrate, 29 mg/kg)
	Total nitrite/nitrate (as NaNO ₂ , 23.5 mg/kg)
	Total nitrite/nitrate (as NaNO ₃ , 29 mg/kg)
	Pesticide Residues
	Boscalid (0.164 mg/kg)
	Chlorantraniliprole (0.024 mg/kg)
	Chlorpyrifos (0.072 mg/kg)
	Cyprodinil (0.032 mg/kg)
	Etofenprox (0.020 mg/kg)
	Fenoxycarb (0.032 mg/kg)
	Fludioxonil (0.028 mg/kg)
	Hexythiazox (0.020 mg/kg)
	Indoxacarb (0.020 mg/kg)
	Methoxyfenozide (0.052 mg/kg)
	Myclobutanil (0.028 mg/kg)
	Pendimethalin (0.020 mg/kg)
	Phosalon (0.020 mg/kg)
	Primicarb (0.032 mg/kg)
	Propargite (0.080 mg/kg)
	Pyraclostrobin (0.116 mg/kg)
	Tebufenpyrad (0.024 mg/kg)
	Trifloxystrobin (0.160 mg/kg)
	Captan (0.628 mg/kg)
	Iprodion (0.036 mg/kg)

Table 6. Fatty Acid Composition Data on Apple Seed Extract.³⁰

Fatty Acids	% Composition
Butyl linoleate	1.50%
2-Dodecenal	< 0.2%
Deca-2,4-dienal	0.49%
Ethyl linoleate	4.31%
Ethyl oleate	< 0.2%
Ethyl palmitate	0.56%
Ethyl stearate	< 0.2%
Hexyl hexanoate	0.54%
Hexyl linoleate	3.30%
Hexyl octanoate	0.49%
Hexyl palmitate	0.61%
Linoleic acid	51.15%
Linolenic acid	5.60%
Methyl docosanoate	0.72%
Methyl eicosanoate	2.18%
Methyl eicosenoate	1.05%
Methyl heneicosanoate	< 0.2%
Methyl heptadecanoate	0.28%
Methyl linoleate	37.71%
Methyl linolenate	5.60%
Methyl nonodecanoate	< 0.2%
Methyl nonanoate	< 0.2%
Methyl octanoate	< 0.2%
Methyl oleate	4.12%
Methyl palmitate	9.93%
Methyl palmitoleate	< 0.2%
Methyl pentadecanoate	< 0.2%
Methyl pentanoate	< 0.2%
Methyl stearate	4.33%
Methyl tetracosanoate	< 0.2%
Methyl tricosanoate	< 0.2%
Myristyl myristate	< 0.2%
Nonacosane	3.59%
Oleic acid	4.12%
Palmitic acid	10.49%
Squalene	3.40%
Stearic acid	4.33%
Tricosene	4.29%
Total fatty acids	80.91%

Table 7. Composition Data on *Pyrus Malus* (Apple) Seed Oil.¹⁵

Seed Oil and Fatty Acids*	Unsaponifiables**
Seed Oil: 28.9 ± 0.9%	Hexadecanoic Acid, Ethyl Ester: 6.6 ± 0.3%
Palmitic Acid (C16:0): 6.1 ± 0.4%	Phytol: 0.6 ± 1.1%
Palmitoleic Acid (C16:1): 0.2%	Ethyl Oleate: 34.6 ± 3.1%
Heptadecanoic Acid (C17:0): Not detected	9-Hexadecenal: 0.7 ± 0.4%
Stearic Acid (C18:0): 2.0 ± 0.4%	3-Eicosene: 0.8 ± 0.2%
Oleic Acid (C18:1): 38.7 ± 1.7%	Octadecanoic Acid, Ethyl Ester: 2.9 ± 1.1%
Linoleic Acid (C18:2): 49.6 ± 2.2%	1-Docosene: 2.4 ± 0.3%
Linolenic Acid (C18:3): 0.4%	Docosane: 0.9 ± 0.5%
Eicosanoic Acid (C20:0): 0.9 ± 0.1%	1-Hexacosene: 1.2 ± 1.2%
11-Eicosanoic Acid (C20:1): 0.6%	Octacosane: 0.8 ± 0.4%
Docosanoic Acid (C22:0): 0.7%	Squalene: 5.8 ± 0.8%
	Nonacosane: 0.9 ± 0.3%
	β-Tocopherol: 1.7 ± 0.5%
	α-Tocopherol: 6.1 ± 0.6%
	Campesterol: 0.7 ± 0.2%
	Avenasterol: 0.6 ± 0.1%
	β-Sitosterol: 13.6 ± 1.4%
	9,19-Cyclolanost-24-en-3-ol: 3.6 ± 1.1%
	Stigmast-4-en-3-one: 3.8 ± 0.5%

*Fatty acid profile of the seed oil obtained as fatty acid methyl esters; **Unsaponifiable fraction of *pyrus malus* (apple) seed oil

Table 8. Current Frequency and Concentration of Use According to Duration and Type of Exposure.^{31,32}

	Pyrus Malus (Apple) Fruit Extract		Pyrus Malus (Apple) Flower Extract		Pyrus Malus (Apple) Fruit	
	# of Uses	Conc. (%)	# of Uses	Conc. (%)	# of Uses	Conc. (%)
Totals/Conc. Range	89	0.000002-0.00007	NR	0.0005	NR	0.00005-0.03
Duration of Use						
<i>Leave-On</i>	81	0.000002-0.00007	NR	0.0005	NR	0.00005
<i>Rinse off</i>	7	0.000075-0.75	NR	NR	NR	0.0018-0.03
<i>Diluted for (bath) Use</i>	NR	0.1	NR	NR	NR	NR
Exposure Type						
<i>Eye Area</i>	2	0.018-0.29	NR	NR	NR	NR
<i>Incidental Ingestion</i>	3	0.001-0.0036	NR	NR	NR	NR
<i>Incidental Inhalation- Sprays</i>	74	0.00083-0.1	NR	0.0005	NR	NR
<i>Incidental Inhalation- Powders</i>	74	0.00003-0.12**	NR	NR	NR	0.00005
<i>Dermal Contact</i>	85	0.00003-0.35	NR	0.0005	NR	0.00005
<i>Deodorant (underarm)</i>	1*	NR	NR	NR	NR	NR
<i>Hair - Non-Coloring</i>	NR	0.0002-0.75	NR	NR	NR	0.0018-0.03
<i>Hair-Coloring</i>	NR	0.1	NR	NR	NR	NR
<i>Nail</i>	NR	0.000002-0.00007	NR	NR	NR	NR
<i>Mucous Membrane</i>	5	0.001-0.1	NR	NR	NR	NR
<i>Baby Products</i>	NR	NR	NR	NR	NR	NR
	Pyrus Malus (Apple) Water		Pyrus Malus (Apple) Juice		Pyrus Malus (Apple) Pectin Extract	
	# of Uses	Conc. (%)	# of Uses	Conc. (%)	# of Uses	Conc. (%)
Totals/Conc. Range	NR	0.008-9	NR	0.0003-0.7	4	NR
Duration of Use						
<i>Leave-On</i>	NR	0.008-9	NR	0.07	2	NR
<i>Rinse off</i>	NR	0.008-0.5	NR	0.0003-0.7	2	NR
<i>Diluted for (bath) Use</i>	NR	NR	NR	0.007	NR	NR
Exposure Type						
<i>Eye Area</i>	NR	0.2	NR	NR	NR	NR
<i>Incidental Ingestion</i>	NR	0.008	NR	NR	NR	NR
<i>Incidental Inhalation- Sprays</i>	NR	NR	NR	NR	1*	NR
<i>Incidental Inhalation- Powders</i>	NR	0.76-9**	NR	0.07**	2	NR
<i>Dermal Contact</i>	NR	0.008-9	NR	0.0025-0.07	4	NR
<i>Deodorant (underarm)</i>	NR	NR	NR	NR	NR	NR
<i>Hair - Non-Coloring</i>	NR	NR	NR	0.0003-0.07	NR	NR
<i>Hair-Coloring</i>	NR	NR	NR	NR	NR	NR
<i>Nail</i>	NR	NR	NR	NR	NR	NR
<i>Mucous Membrane</i>	NR	0.008	NR	0.0025-0.007	NR	NR
<i>Baby Products</i>	NR	NR	NR	NR	NR	NR
	Pyrus Malus (Apple) Peel Powder		Pyrus Malus (Apple) Root Extract		Pyrus Malus (Apple) Seed Extract	
	# of Uses	Conc. (%)	# of Uses	Conc. (%)	# of Uses	Conc. (%)
Totals/Conc. Range	1	NR	4	NR	10	0.001-0.6
Duration of Use						
<i>Leave-On</i>	1	NR	2	NR	8	0.001-0.6
<i>Rinse off</i>	NR	NR	NR	NR	2	NR
<i>Diluted for (bath) Use</i>	NR	NR	2	NR	NR	NR
Exposure Type						
<i>Eye Area</i>	NR	NR	NR	NR	3	0.6
<i>Incidental Ingestion</i>	NR	NR	NR	NR	1	0.001
<i>Incidental Inhalation- Sprays</i>	1***	NR	2***	NR	4*	NR
<i>Incidental Inhalation- Powders</i>	1***	NR	2***	NR	NR	NR
<i>Dermal Contact</i>	1	NR	4	NR	8	0.0015-0.6
<i>Deodorant (underarm)</i>	NR	NR	NR	NR	NR	NR
<i>Hair - Non-Coloring</i>	NR	NR	NR	NR	1	NR
<i>Hair-Coloring</i>	NR	NR	NR	NR	NR	NR
<i>Nail</i>	NR	NR	NR	NR	NR	NR
<i>Mucous Membrane</i>	NR	NR	2	NR	1	0.001
<i>Baby Products</i>	NR	NR	NR	NR	NR	NR

Table 8. Current Frequency and Concentration of Use According to Duration and Type of Exposure.

	Pyrus malus (Apple) Seed Oil			
	# of Uses	Conc. (%)		
Totals/Conc. Range	NR	0.001-0.01		
Duration of Use				
<i>Leave-On</i>	NR	0.001-0.1		
<i>Rinse off</i>	NR	NR		
<i>Diluted for (bath) Use</i>	NR	NR		
Exposure Type				
<i>Eye Area</i>	NR	NR		
<i>Incidental Ingestion</i>	NR	NR		
<i>Incidental Inhalation- Sprays</i>	NR	NR		
<i>Incidental Inhalation- Powders</i>	NR	0.001		
<i>Dermal Contact</i>	NR	0.001-0.01		
<i>Deodorant (underarm)</i>	NR	NR		
<i>Hair - Non-Coloring</i>	NR	NR		
<i>Hair-Coloring</i>	NR	NR		
<i>Nail</i>	NR	NR		
<i>Mucous Membrane</i>	NR	NR		
<i>Baby Products</i>	NR	NR		

Pyrus malus (apple) fruit extract is used in colognes and toilet water at a max. concentration of 0.00083%.

Pyrus malus (apple) fruit extract is used in perfume at a max. concentration of 0.1%.

Pyrus malus (apple) fruit extract is used in body and hand products (sprays) at max. concentrations up to 0.1%.

Pyrus malus (apple) flower extract is used in body and hand products (sprays) at a max. concentration of 0.0005%.

Pyrus malus (apple) fruit is used in powders (dusting and talcum) at a max. concentration of 0.00005%.

Pyrus malus (apple) seed oil is used in face powder at a max. concentration of 0.001%.

NR = Not Reported; Totals = Rinse-off + Leave-on Product Uses.

*It is possible that these products may be sprays, but it is not specified whether the reported uses are sprays.

**It is possible that these products may be powders, but it is not specified whether the reported uses are powders.

***Not specified whether a powder or spray, so this information is captured for both categories of incidental inhalation.

Note: Because each ingredient may be used in cosmetics with multiple exposure types, the sum of all exposure type uses may not equal the sum total uses.

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