Isoparaffinic Hydrocarbon

Crop Production

Identification of Petitioned Substance

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Chemical Name: Distillates, petroleum (naphtha), hydrotreated light

CAS Number: 64742-47-8

Other Codes: EU EINECS/ELINCS 265-149-8
EC 649-422-00-2
US EPA PC Code 505200
CA DPR Chem. Code 001641

Other Names: Synthetic Isoparaffinic Hydrocarbon
Light Aliphatic Hydrocarbon
Low odor paraffinic solvent

Trade Names: Isopar™ M Solvent

Characterization of Petitioned Substance

Composition of the Substance: Isoparaffinic hydrocarbon is not a naturally occurring compound, but it is synthesized as a complex mixture of hydrocarbons (ExxonMobil Chemical Isopar™ M solvent) obtained by a light hydrogenation treatment of a petroleum distillate (naptha) fraction in the presence of a catalyst. Product consists of hydrocarbons having carbon numbers in range C11 to C16 and boiling range 218°C (424°F) to 257°C (495°F). Composition of Isopar™ M is listed (Carter et al, 2000, p. 14) by constituent type weight percent (%) as follows:

Constituent Types	Weight Percent (%)
n-Undecane	0.001%
n-Dodecane	0.02%
n-Tridecane	0.04%
n-Tetradecane	0.10%
n-Pentadecane	0.03%
n- Hexadecane	0.01%
Branched C11 Alkanes	0.42%
Branched C12 Alkanes	6.38%
Branched C13 Alkanes	18.63%
Branched C14 Alkanes	41.53%
Branched C15 Alkanes	13.59%
Branched C16 Alkanes	3.36%
Cyclic C11 Alkanes	0.08%
Cyclic C12 Alkanes	1.21%
Cyclic C13 Alkanes	3.53%
Cyclic C14 Alkanes	7.87%
Cyclic C15 Alkanes	2.58%
Cyclic C16 Alkanes	0.64%

The Isopar-M® is a synthetic product of the ExxonMobil Chemical Company and it is characterized as a lightly hydrotreated isoparffinic hydrocarbon solvent with a relatively high boiling point. Isopar-M® is characterized as an isoparaffinic hydrocarbon because it consists mostly (≈84%) of branched alkanes (isoparaffins). Aromatic content is 0.95% maximum.

Properties of the Substance (Ref. ExxonMobil, 2003, 2007, 2008 and Esso Imperial Oil, 2004):

Physical State: Liquid
Color: Clear, Colorless (30 Saybolt units)
Odor: Odorless
Relative Density at 15.6°C: 0.791 g/m³
Flash Point: 80.5°C (177°F)
Boiling Point Range: 218°C (424°F) to 257°C (495°F)
Solubility in Water: Negligible
Viscosity at 40°C: 2.7 cSt
Vapor Density (Air = 1): 6.5 at 101 kPa
Auto Flammability: 254°C (489°F)
Molecular Weight: 191 (Average)
Freezing Point: -77°C (-107°F)
Evaporation Rate (n-butyl acetate = 1): < 0.01

Specific Uses of the Substance:

Isopar-M® is a synthetic isoparaffinic hydrocarbon solvent or fluid (CAS # 64742-47-8) that commonly is used as an inert component of commercially available insecticide formulations of Pyrethrins containing products like Diatect International Diatect® Insecticide V (EPA Reg. No. 42850-5). The Diatect® V product contains as the active ingredients 0.5% Pyrethrins by weight and 82.45 % Silicon Dioxide from Diatomaceous Earth. The Diatect® V insecticide (Diatect International, Heber City, UT) was EPA approved for use on May 18, 1995. Pyrethrin is derived from the African daisy and its extraction is caused by an osmosis type reaction to Isopar-M®. Thus Isopar-M® is used as both a solvent and extractant for the naturally occurring Pyrethrin in the Diatect® Insecticide V. Diatect® V product can be applied as both a powder and as a wettable powder. Diatect® V's label provides the specific uses of this insecticide as follows:

ON HARVESTED TOMATOES AND FRUIT (including grapes): To control Fruit Flies and Vinegar Flies.

VEGETABLE CROPS: For the control of insects such as Aphids, 12-Spotted Cucumber Beetle, Armyworms, Beet Webworms, Blister Beetle, Cabbage Looper, Cabbage Worms, Caterpillars, Celery Leaftiers, Colorado Potato Beetle, Corn Earworm, Cucumber Beetles, Diamondback Moth Larva, European Corn Borer, Flea Beetles, Garden Fleahoppers, Harlequin Bugs, Imported Cabbage Worms, Japanese Beetles, Leafhoppers, Leaf Miners, Leaftiers, Loopers, Lygus Bugs, Mexican Bean Beetle, Mites, Oblique-Banded Leafrollers, Plant Bugs, Stink Bugs, Squash Vine Borers, Thrips, Vegetable Weevils, Webworms and White Flies. GROWING CROPS (outdoors and greenhouses): Root and Tuber Vegetables including Arracacha, Arrowroot, Purple Arrowroot, Japanese Artichoke, Jerusalem Artichoke, Beets, Sugar Beets, Edible Burdock, Carrots, Cassava (Bitter & Sweet), Cerarlac (Celery Root), Chervil (Turnip Root), Chicory, Chotia, Dasheen, Ginger, Ginseng, Horseradish, Laren, Parsley (turnip rooted), Parsnip, Potato, Radish, Japanese Radish, Rutabaga, Salsify, Black Salsify, Sweet Potato, Tanier, Tarrow Root, Turmeric, Turnip, Yam, Yam Bean. Leaves of Root and Tuber Vegetables including Beet, Sugar Beet, Edible Burdock, Carrot, Cassava (Bitter & Sweet), Celery, Chervil, Chicory, Dasheen, Parsnip, Radish, Japanese Radish, Rutabaga, Black Salsify, Sweet Potato, Tanier, Turnip, and Yam (True). BulbVegetables including Garlic, Leek, Onion (Bulb & Green) and Shallot. Leafy Vegetables including Amaranth, Leafy Amaranth, Chinese Spinach, Tompala, Arugula, Celery, Celluce, Chervil, Cilantro, Corn Salad, Chrysanthemum (edible leaves), Chrysanthemum garland, Cress (garden), Upland Cress (yellow rocket, winter cress), Dandelion, Dock, Endive, Fennel, Lettuce (Head & Leafy), Orach, Parsley, Purslane (garden & winter), Rhubarb, Spinach, Fine Spinach (Metabar, Ceylon), Spinach (New Zealand), Swiss Chard. Brassica (Cole) Leafy Vegetables including Broccoli, Chinese Broccoli, Broccoli Raab, Brussels Sprouts, Cabbage, Chinese Cabbage (Bok Choy & Napa), Chinese Mustard Cabbage (Gai Choy), Cauliflower, Collards, Kale,

Kohlrabi, Mustard Greens and Rape Greens. Legume Vegetables (succulent or dried) including Adzuki Beans, Field Beans, French Beans, Kidney Beans, Lima Beans, Moth Beans, Mung Beans, Navy Beans, Pinto Beans, Runner Beans, Snap Beans, Tepary Beans, Urd Beans, Wax Beans, Asparagus Beans, Black-eyed Peas, Catjang, Chinese Longbeans, Cowpeas, Chowder Peas, Southern Peas, Yard-Longbeans, Broad Beans (Fava Beans), Chick Peas (Garbanzo Beans), Guar, Jack Beans (Sword Beans), Lablab Beans (Hycacinth Beans), Lentils, Peas (garden, field, sugar), Pigeon Peas and Soybeans. Foliage of Legume Vegetables including plant parts of any legume vegetable included in the Legume Vegetables group that will be used as animal feed including any variety of Beans, Field Peas and Soybeans. Fruiting Vegetables including Eggplant, Ground Cherry, Okra, Pepinos, Peppers (Bell, Chili, Cooking and Sweet Peppers and Pimentos), Tomatillo, and Tomatoes. Cucurbit Vegetables including Balsam Pear (Bitter Melon), Chinese Waxgourd, Citron Melon, Cucumber, Gherkin, Edible Gourds, Melons (including hybrids, Cantaloupe, Casaba, Crenshaw, Honeydew, Honey Balls, Mango, Muskmelon and Persian Melons), Pumpkin, Squash (summer & winter) and Watermelon (including hybrids).

ORNAMENTALS: For the control of insects such as Aphids, Armyworms, Caterpillars, Chinch Bugs, Flea Beetles, Fleahoppers, Flies, Fruit Flies, Japanese Beetles, Leafhoppers, Leafminers, Leafrollers, Loopers, Lygus Bugs, Mealy Bugs, Mites, Plant Bugs, Thrips and White Flies. Ornamentals such as African Violets, Aster, Azalea, Begonia, Calceolaria, Calendula, Calia, Camelia, Carnation, Cineraria, Chrysanthemum, Cypress, Daffodil, Dahlia, Dogwood, Elm, Eucalyptus, Fern, Ficus, Geranium, Gladiolus, Gypsophila, Holly, Juniper, Lily, Marigold, Oak, Palm, Peony, Petunia, Philodendron, Pine, Roses, Snapdragons, Sweetpeas, Tulips, Viburnum, Wandering Jew, Yew and Zinnia.

HERBS, SPICES AND SPECIALTY CROPS: For the control of such insects as Aphids, Loopers, Mites, Plant Bugs, Thrips and White Flies. Herbs and Spices including Anise, Balm, Basil, Burnel, Borage, Chamomile, Caraway, Catnip, Chives, Clary, Coriander, Costmary, Cumin, Curry Leaf, Dill, Fennel (Italian & Sweet), Fenugreek, Horehound, Hyssop, Marigold, Marjoram (Sweet & Wild), Mint, Nasturtium, Oregano, Pennyroyal, Rosemary, Rue, Sage, Savory (Winter & Summer), Sweet Bay (Bay Leaf), Tansy, Tarragon, Thyme, Wintergreen, Woodruff, Wormwood. Specialty Crops such as Artichoke, Chayote, Asparagus, Coffee, Cotton, Hops, Jojoba, Ornamental Turf Grass, Sesame, Sunflower (leaves & seed) and Tea.

FIELD GRAIN CROPS: For the control of insects such as Aphids, Armyworms, Chinch Bugs, Boll Weevil, Bollworm, Budworm, Caterpillars, Corn Earworms, Fleabeetles, Fleahoppers, Flies, Horn Worms, Loopers, Lygus Bugs, Midges, Mites, Pear Cucurlia, Pink Bollworms, Thrips and White Flies. Cereal Grains including Barley, Buckwheat, Corn, Millet (Proso & Pearl), Oats, Popcorn, Rice, Rye, Sorghum (Milo), Teosinte, Triticale, Wheat and Wild Rice. Grass Forage, Fodder and Hay including Bermuda Grass, Blue Grass, Bromegrass, Fescue and any type grass, Gramineae Family (green or cured), Barley, Buckwheat, Corn, Millet (Proso & Pearl), Oats, Popcorn, Rice, Rye, Sorghum (Milo), Teosinte, Triticale, Wheat and Wild Rice, that will be fed to or grazed by livestock, all pasture and range grasses and grasses grown for hay or silage. Non-Grass Animal Feeds including Alfalfa, Velvet Bean, Clover, Kudzu, Lespedeza, Lupine, Saintoin, Trefoil, Vetch, Crown Vetch and Milk Vetch.

FRUIT, NUT, VINE CROPS AND ORIENTAL VEGETABLES: For the control of such insects as Aphids, Armyworms, Blueberry Maggots, Cabbage Loopers, Caterpillars, Cherry Fruit Flies, Cutworms, Fireworms, Fruit Flies, Fuller Rose Beetle, Gooseberry Fruit Worms, Imported Currant Worms, Japanese Beetles, Leafhoppers, Mites, Peach Borers, Pecan Weevil, Red-Necked Borers, Raspberry Fruit Worms, Rose Chafers, Stink bugs, Strawberry Leaf Rollers, Thrips, Weevils and White Flies. Citrus Fruits including Calamondin, Citrus Citron, Citrus Hybrids, Grapefruit, Kumquats, Lemons, Limes, Mandarin (Tangerine), Orange (sweet & sour), Pummelo, and Satsuma Mandarin. Pome Fruits including Apple, Crabapple, Loquat, Pear, Oriental Pear and Quince. Stone Fruits

including Apricot, Cherry (sweet & sour), Nectarines, Peaches, Plums, Prunes, Chickasaw Plum, Damson Plum, and Japanese Plum. Small Fruits and Berries including Blackberry, Blueberry, Boysenberry, Cranberry, Currants, Dewberry, Elderberry, Gooseberry, Grape, Huckleberry, Loganberry, Ollie Berry, Raspberry (Black & Red), Strawberry, and Youngberry. Subtropical Fruits including Avocado, Banana, Carob, Barbados Cherry, Cherimoya, Dates, Feijoa, Figs (Adriatic, Calimyrna, Kadota, Black Mission, California Brown Turkey and Brunswick), Guava, Kiwifruit, Lychee, Mango, Papaya, Passion Fruit, Persimmon, Pineapple and Pomegranate. Tree Nuts including Almond, Beech Nut, Brazil Nut, Butter Nut, Cashews, Chestnut, Chinquapin, Filbert (Hazelnut), Hickory Nut, Japanese Horsechestnut, Macadamia Nut (Bushnut), Pecan, Pistachio and Walnut (Black & English). Oriental Vegetables including Japanese Artichoke, Chinese Broccoli (Gai Lon), Chinese Cabbage (Bok Choy & Napa), Chinese Mustard Cabbage (Gai Choy), Cilantro, Dasheen, Ginger, Ginseng, Chinese Longbeans, Mung Beans, Citron Melon, Balsam Bear (Bitter Melon), Japanese Radish (Daikon), Chinese Spinach and Chinese Waxgourd.

Approved Legal Uses of the Substance:

Table 1. Summary of Approved Legal Uses of the Substance

Food Product	Application	ASC Solution	
		CAS 64742-47-8	
Vegetables (ref: 21 CFR 172, § 172.882)	Froth-flotation cleaning.	1-10 Wt. Percent	
Processed Foods (ref: 21 CFR 172, § 172.882)	Inert component of insecticide (e.g., Pyrethrins) formulations.	0.5-10 Wt. Percent	
Processed Foods (ref: 40 CFR 180, § 180.526)	Inert component of herbicide (e.g., 2,4-D Ester) formulations.	1-5 Wt. Percent	
Fruits and Vegetables (ref: 21 CFR 172, § 172.882)	As a component of coatings.		
Vinegar and Wine (ref: 21 CFR 172, § 172.882)	Float on fermentation in the manufacture of.		
Pickles (ref: 21 CFR 172, § 172.882)	On brine used in curing to prevent or retard access of air, evaporation, and contamination with wild organisms during fermentation.		
Shell Eggs (ref: 21 CFR 172, § 172.882)	As a component of coatings.		
Animal Feed (ref: 40 CFR 180, § 180.526)	As a component of insecticide formulations.		

Action of the Substance:

The inert ingredient of Isopar-M® is isoparaffinic hydrocarbon (CAS 64742-47-8). Isoparaffinic hydrocarbon serves as a solvent and diluent for the active ingredients of an insecticide or pesticide formulation. Natural pyrethrin insecticide is extracted from the African daisy by an osmosis type reaction to isoparaffinic hydrocarbon of the Isopar-M® fluid that is used as the extractant.

Status

International:

There are no CODEX Alimentarius Commission Maximum Residue Levels (MRLs) for residues of isoparaffinic hydrocarbon solvent or fluid.

Evaluation Questions for Substances to be used in Organic Handling

Evaluation Question #1: Is the petitioned substance formulated or manufactured by a chemical process? (From 7 U.S.C. § 6502 (21).)

Isopar-M® is a synthetic isoparaffinic hydrocarbon solvent or fluid product (CAS # 64742-47-8) that is manufactured by a chemical process. The predominantly branched alkanes (isoparaffins) formed are synthetically derived from isobutene and propane gases that combine with n-butane in the presence of a catalyst containing noble metals such as platinum or rhenium in a batch reactor at temperatures of 65-150°C and a pressure of 2MPa. The mixture of mainly isoparaffins formed (reaction product) undergoes a hydrotreatment whereby hydrogen at a partial pressure of 1.5-2.5 MPa is added or saturation occurs in the presence of a catalyst at elevated temperature of 260-370°C (CCOHS, 2007; Tagiev et al, 2008). Atmospheric distillation then occurs to provide the appropriate boiling range of 218°C (424°F) to 257°C (495°F) for the M grade of Isopar fluid product.

Evaluation Question #2: Is the petitioned substance formulated or manufactured by a process that chemically changes the substance extracted from naturally occurring plant, animal, or mineral sources? (From 7 U.S.C. § 6502 (21).)

As described in question #1 above, Isopar-M® Fluid, which consists predominantly of isoparaffins, is synthetically manufactured from light gases which are treated then with hydrogen in the presence of a catalyst. It involves no extraction from natural material sources.

Evaluation Question #3: Is the petitioned substance created by naturally occurring biological processes? (From 7 U.S.C. § 6502 (21).)

Isopar-M® Fluid which consists mainly of an isoparaffinic hydrocarbon (CAS 64742-47-8) is created only by artificial means. It involves no biological processes.

Evaluation Question #4: Is there a natural source of the petitioned substance? (From 7 CFR § 205.600 (b) (1).)

A natural source for this petitioned inert and synthesized ingredient substance does not exist.

Evaluation Question #5: Is there an organic agricultural product that could be substituted for the petitioned substance? (From 7 CFR § 205.600 (b) (1).)

An organic alternative for this petitioned substance does not exist.

Evaluation Question #6: Are there adverse effects on the environment from the petitioned substance's manufacture, use, or disposal? (From 7 CFR § 205.600 (b) (2).)

Isopar-M® Fluid which consists mainly of an isoparaffinic hydrocarbon (CAS 64742-47-8) biodegrades at a rapid rate. According to U.S. EPA (2008) study data, the chemical substance exhibited a range 7 to 29% biodegradation by microorganisms as a source of energy and carbon after 28 days. The chemical substance undergoes some photolysis after 1 to 53 hours (U.S. EPA, 2008) but undergoes rapid degradation by atmospheric oxidation in the air so that it will not persist in the environment (ExxonMobil. 2008). It is not expected to cause acute harm to fish or other aquatic organisms. Because

of its low water solubility and volatility (tendency to move from water to air), chronic aquatic toxicity is not anticipated (ExxonMobil, 2008). The ExxonMobil (2008) recommended occupational exposure limit of this petitioned chemical substance for personnel in the manufacturing facilities is 165 parts per million (ppm) per an 8-hour work day. This chemical is Toxic Substances Control Act (TSCA) partially exempt from U.S. EPA reporting under 40 CFR §710.46(b)(1), so use and disposal of this petitioned substance is of minimal concern.

Evaluation Question #7: Does the petitioned substance have an adverse effect on human health as defined by applicable Federal regulations? (From 7 CFR § 205.600 (b) (3).)

According to Mullin et al (1990) studies, the petitioned substance (isoparaffinic hydrocarbon, CAS #64742-47-8) has little or no adverse effect on human health. Isoparaffinic hydrocarbon is considered to be almost a non-toxic substance in humans by means of oral, dermal and inhalation routes. However, aspiration of liquid isoparaffinic hydrocarbon into the lungs during oral ingestion could result in severe pulmonary injury (Mullin et al, 1990). The substance can produce slight skin irritation in humans that can be avoided by wearing chemical resistant gloves during handling. Any skin irritation can be readily overcome by washing hands with soap and water. The petitioned substance is not considered to be a mutagen, a human carcinogen, a teratagen, a reproductive toxin or developmental toxin, and it has no toxic effects on the nervous system (Mullin et al., 1990).

Evaluation Question #8: Is the nutritional quality of the food maintained when the petitioned substance is used? (From 7 CFR § 205.600 (b) (3).)

The nutritional quality of the food is never affected when the petitioned substance is used. According to FDA regulations in 21 CFR 178, § 178.3530, isoparaffinic hydrocarbons may be safely used in the production of nonfood articles intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food.

Evaluation Question #9: Is the petitioned substance to be used primarily as a preservative? (From 7 CFR § 205.600 (b) (4).)

According to FDA regulations in 21 CFR 178, § 178.3530, isoparaffinic hydrocarbons may contain antioxidants authorized for use in food in an amount not to exceed that reasonably required to accomplish the intended technical effect. According to 21 CFR 172, § 172.882 the substance may be used on brine used in curing pickles to prevent or retard access of air, evaporation, and contamination with wild organisms during fermentation.

Evaluation Question #10: Is the petitioned substance to be used primarily to recreate or improve flavors, colors, textures, or nutritive values lost in processing (except when required by law, e.g., vitamin D in milk)? (From 7 CFR § 205.600 (b) (4).)

The petitioned substance (CAS 64742-47-8) has little effects or serves as an inert component when used in processing. According to FDA regulations in 21 CFR 178, § 178.3530, isoparaffinic hydrocarbons may be safely used in the production of nonfood articles intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food.

Evaluation Question #11: Is the petitioned substance generally recognized as safe (GRAS) when used according to FDA's good manufacturing practices? (From 7 CFR § 205.600 (b) (5).)

21 CFR 172, § 172.882 states the petitioned substance may be safely used in foods, in accordance with FDA's good manufacturing practices and such safe substances do not need to be cited in a regulation as Generally Recognized as Safe (GRAS). More information about GRAS substances can be found at FDA, 2004 "Guidance for Industry Frequently Asked Questions About GRAS." FDA has defined "safe" (21 CFR 170.3(i)) as a reasonable certainty in the minds of competent scientists that the substance is not harmful under its intended conditions of use. Isoparaffinic hydrocarbon (CAS #64742-47-8) meets this FDA definition of safe in 21 CFR §170.3(i).

Evaluation Question #12: Does the petitioned substance contain residues of heavy metals or other contaminants in excess of FDA tolerances? (From 7 CFR § 205.600 (b) (5).)47

The petitioned substance (CAS 64742-47-8) does not contain detectable levels of heavy metals. According to 40 CFR Part 63, Table 3 to Subpart MMMM, isoparaffinic hydrocarbon contains just 0.001 mass fraction of toluene as hazardous air pollutant (HAP) in the solvent. According to ExxonMobil Chemical (2008), the petitioned substance contains also typical toxic chemical concentrations of < 0.4 ppm of benzene, < 1 ppm naphthalene, and < 1 ppm ethylbenzene. Thus the benzene content in the petitioned substance is negligible. This is significant since benzene is linked to increased incidence of leukemia in humans. According to Linda S. Mullin et al. (1990), isoparaffinic hydrocarbons are not listed in 'chemicals known to the State (California) to cause cancer or reproductive effects' (California proposition 65).

References

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Supplemental information on whether Isoparaffininc hydrocarbon is allowed under EU or other international regulations on organic production.

Synthetic Isoparaffinic Hydrocarbon (CAS 64742-47-8) is under UN # 1268, EC # 649-422-00-2, and ICSC # 1379.

It has EU Classification for Packaging & Labeling as follows (IPCS, 2001): Symbol, Xn; R, 65; S, (2-)23-24-62; Note, H; UN Hazard Class, Class 3.

Use of Isoparaffinic hydrocarbon may cause inhalation dizziness, headache, drowsiness, nausea, and unconsciousness. Prevention methods include adequate ventilation, local exhaust, or breathing protection with filter respirator for organic vapors of low boiling compounds. Tissue exposure may result in dry skin, de-fatting of skin, and short-term vapor exposure may result in redness and irritation to eyes. Protective gloves and safety eye ware are needed when handling this chemical. The substance is considered to be harmful to aquatic organisms.

According to CCOHS (2007) the International agency for Research on Cancer (IARC) has concluded that there is limited evidence for carcinogenicity of chemical compound (CAS 64742-47-8) in experimental animals. Male mice at average body weight of 0.3 kg were dosed twice weekly by application of 50 mg of the chemical until a papilloma greater than 1 mm appeared. After 79 weeks, 24/38 mice exhibited skin tumors. It is thought that the skin tumors may be secondary to severe skin irritation.

The IARC concluded that this substance is not classifiable as to its carcinogenicity to humans (Group 3).

There are no international regulations allowing this substance on organic production.

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