

INEOS Oligomers

March 2009

Panalane Regulatory Bulletin

FOREWORD

This bulletin summarizes regulatory information for Panalane® Polybutenes including chemical inventory status and clearances for applications such as, cosmetics/personal care use, and others.

COSMETICS/PERSONAL CARE PRODUCTS

Panalane ® Polybutenes are used in various cosmetic and personal care applications.

Panalane is a hydrogenated polybutene and is used as versatile cosmetic base oil. The Personal Care Products Council Ingredient Dictionary lists Panalane as hydrogenated polyisobutene.

Panalanes can also be used as an ingredient in cosmetics for sale in Japan. Panalane L -14E meets the requirement as specified in Japanese Standards of Cosmetic Ingredients (JSCI) Ingredient Code 500576, 'Liquid Isoparaffin'. It can, therefore, be used in cosmetic applications specified for this component, categories 1 through 11 inclusive.

Panalane H-300E meets the requirement as specified in JSCI Ingredient Code 502171, 'Heavy Liquid Isoparaffin' Standard Code 42. It can be used in cosmetic applications specified for this component, categories 1 through 11 inclusive.

FOOD CONTACT APPLICATIONS

Europe:

Panalane® Polybutenes are not listed in the European Directive 2002/72/EC or its amendments.

U.S.A.:

Panalane® Polybutenes meet the composition requirements of the following paragraphs of Title 21 of the Code of Federal Regulations of the U.S. Food and Drug Administration and other applicable regulations. Clearances of specific grades have to be determined on the basis of limitations or specifications on use mentioned below.

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Table 2- Specifications

21 CFR	Title of Regulation
175.105	Component of adhesives
175.125	Pressure sensitive adhesives
175.300	Resinous and polymeric coatings
175.380	Resin component
175.390	Coating component
176.170	Paper and paperboard in contact with aqueous and fatty foods
176.180	Components of paper and paperboard in contact with dry food
176.210	Defoaming agents used in the manufacture of paper and paperboard
177.1210	Closures with sealing gaskets for food containers
177.1350	Ethylene vinyl acetate copolymers
177.1520	Plasticizer in polyethylene and/or polypropylene
177.1640	Plasticizer in polystyrene
177.2260(d)(2)	Resin-bonded filters; substances employed in fiber finishes
177.2800	Textiles and textile fibers
178.3570	Lubricants with incidental food contact (provided that the addition of polybutene to food does not exceed 10 ppm)
178.3740(b)	Plasticizer in polymeric substances
178.3860	Release agent in petroleum wax complying with 178.3710, and polymeric resins
178.3910	Surface lubricant in the manufacture of metallic articles

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CHEMICAL INVENTORY INFORMATION

Many countries have chemical control legislation in place including a comprehensive list of existing chemicals which may be marketed, manufactured or imported. These lists are known as chemical inventories. Panalane® Polybutenes have been evaluated to determine compliance with the following chemical inventories:

Table 2 - Summary of Chemical Inventory Status

Country	Panalane L-14E and H-300E
USA (TSCA)	Listed
EC (EINECS)	Listed
Canada (DSL)	Listed
Japan (ENCS)	Not Listed
Australia (AICS)	Not Listed
Korea (ECL)	Listed
Philippines (PICCS)	Listed
China (IECS)	Listed

MANUFACTURING ORIGIN AND PURITY

Panalane® Polybutenes are additives and solvent free products.

KOSHER CERTIFICATION

Panalane® Polybutenes produced in the U.S. are kosher certified, as manufactured, under the supervision of the Chicago Rabbinical Council. Special shipping arrangements are required in order to maintain kosher status during transport.

BOVINE SPONGIFORM ENCEPHALOPATHY (BSE) – TRANSMISSIBLE SPONGIFORM ENCEPHALOPATHY (TSE)

Panalane® Polybutenes are produced entirely by a petrochemical process, with all feedstocks coming from oil refinery streams. No vegetable material, animal fats, oils, milk products or other animal products are used as components of, or in the manufacture of these products.

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GENETICALLY MODIFIED ORGANISM (GMO)

No genetically modified substances are used as raw materials in the manufacture of Panalane® Polybutenes.

“N” SUBSTANCES

None of the raw materials used in the manufacture of Panalane® Polybutenes are classified as dangerous to the environment (carcinogenic, mutagenic or toxic for the reproduction substance) with the symbol “N” in Annex 1 of the Directive 67/548/EEC (adapted to technical progress for the 28th time by Directive 2001/59/EC).

CALIFORNIA PROPOSITION 65

Panalane® Polybutenes do not contain any substances listed under California Proposition 65.

HEAVY METALS, WEEE, WASTE PACKAGING, CONEG

Panalane® Polybutenes meet the relevant requirements of the following Directives or Regulations:

- 2003/11/EC
- 2002/96/EC (WEEE)

Cadmium, lead, mercury, and hexavalent chromium or compounds of these metals are not used as raw materials in the manufacture of Panalane® Polybutenes. Therefore, the incidental total level of these metals in these products is far below the limit of 100 ppm as set up in the two following legislations.

- 94/62/EC (Packaging Waste Directive)
- USA CONEG Regulation

END-OF LIFE VEHICLES

Panalane® Polybutenes meet the relevant requirements of Directive 2000/53/EC.

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RESTRICTION OF THE USE OF CERTAIN HAZARDOUS SUBSTANCES IN ELECTRICAL AND ELECTRONIC EQUIPMENT (RoHS)

Lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls (PBB) or polybrominated diphenyl ethers (PBDE), listed in Directive 2002/95/EC of the European Parliament and of the Council of 27 January 2003 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS) are not used as raw materials in the manufacture of Panalane® Polybutenes.

PHTHALATES

Phthalates are not used as raw materials in the manufacture of Panalane® Polybutenes.

DIOXINS AND FURANS

Dioxins and furans are not used as raw materials in the manufacture of Panalane® Polybutenes. These substances will not be generated and released during the manufacture and processing of these grades.

OZONE LAYER-DEPLETING AGENTS

Chlorofluorocarbons (CFC's) and substances related to ozone depleting substances (as defined by the MONTREAL PROTOCOL and listed as class I & II substances by the US Clean Air Act) are not used as raw materials in the manufacture of Panalane® Polybutenes.

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ABSENCE OF SUBSTANCES AND CHEMICALS

None of the following substances are used as raw materials in the manufacture of Panalane® Polybutenes:

- Allergens (as defined in Directive 2000/13/EC, as amended)
- Aromatic amines and colorants
- Azodicarbonamide or semi-carbazide compounds
- Asbestos
- Brominated flame retardants
- Bisphenol-A
- Di(ethylhexyl) adipate
- Epoxidised Soya Bean Oil (ESBO)
- Formaldehyde (formol)
- Latexes
- Nonylphenol and its derivatives
- Tert-butyl-4-hydroxyanisole (BHA) and 2,6-di-tert-butyl-p-cresol (BHT)
- Tributyl-tin (TBT), dibutyl-tin (DBT), monobutyl-tin (MBT) or any other organo-tin compounds
- Poly(aromatic hydrocarbons) according to US Environmental Protection Agency Method 610 (EPA 610)
- Vinyl chloride monomer and its polymers or copolymers.

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MATERIAL SAFETY DATA SHEETS / SAFETY DATA SHEETS

Material Safety Data Sheets (MSDS/SDS) are available for all Panalane ® Polybutenes, and describe the health, safety and environmental characteristics of these products as well as advice on handling precautions and emergency procedures.

MSDS should be consulted and fully understood before handling, storage or use of Panalane ® Polybutenes.

To request a copy of a Panalane ® Polybutene Material Safety Data Sheet, phone 1-866-363-2454 Toll Free – (North America), +32 (0)67 875 980 (Europe), +86 21 6103 5970 (Asia)
Or send an e-mail to oligomersmsds@ineos.com.

INEOS CARES

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