16139\_Orca® 20 Quart Cooler

## **Regulatory Data Sheet**

## **Global Chemical Inventory Compliance**

All components of this product are compliant with the country/region Chemical Inventories as per the following table or are exempt:

Country/Region	Inventory	Status
Australia	AICS	Yes
Canada	DSL	Yes
Japan	ENCS	Yes
China	IECSC	Yes
Korea	KECI	Yes
Canada	NDSL	Not applicable
New Zealand	NZIoC	Yes
Philippines	PICCS	Yes
Europe	REACH	This product has not been evaluated
United States	TSCA	Yes

## **Food Regulations**

## **Allergens (Food)**

To the best of our knowledge, there are no raw materials, including additives, that have their origin in peanuts, soybeans, milk, eggs, fish, shellfish (mollusks), crustaceans, tree nuts, mustard, celery, sesame, sunflowers, lupine, animal or vegetable proteins, caffeine, monosodium glutamate (MSG), colorants (including carmine and cochineal), corn, wheat, barley, rye, triticale, gluten, mushrooms, yams, and/or phenylalanine and its derivatives. No sulfates, sulfites, or sulfur dioxide are used in the synthesis of this material. This evaluation is based on information provided by our raw material and additive suppliers for the presence of the allergen-stimulating substances shown above. Therefore, although we believe this product to be free of the specified known allergy stimulating food substances, we cannot quarantee this.

## **Animal Derived Components (BSE/TSE)**

To the best of our knowledge, this product is not manufactured or formulated with ingredients of animal origin.

## **Brazil ANVISA Food Contact Status**

The composition of this product has not been assessed for use in contact with food according to ANVISA RDC Resolution 105/1999, Resolution No. 326/2019, Resolution No. 51/2010, Resolution No. 52/2010 and Resolution No. 56/2012.

## **Canadian Food Contact (HPFB or CFIA)**

The composition of this product has not been assessed for use in contact with food according to the Canadian Health Products and Food Branch (HPFB).

## **China Food Contact Compliance**

The composition of this resin has not been assessed for use in contact with food according to GB4806.6-2016 Food Safety National Standard: Food-contact Use Plastic Resins and GB9685-2016 Food Safety National Standard: Use of Additives for Food contact Materials and Articles and GB 4806.1-2016 Food Safety National Standard: General Safety Requirements for Food-Contact Materials and Articles.

#### **Colombia INVIMA Food Contact Status**

The composition of this product has not been assessed for use in contact with food according to Resolution 4143/2012, of Instituto Nacional de Vigilancia de Medicamentos y Alimentos.

## European Commission Regulation (EU) No 10/2011 (Food Contact)

The composition of this product has not been assessed for use in contact with food according to European Commission Regulation (EU) No 10/2011.

#### <u>Halal</u>

This product has not been manufactured or formulated with animal fats or ingredients derived from animal or fermentation products.

## India Standard for Contact with Food, Pharmaceuticals, or Drinking Water

The composition of this product has not been assessed for use in contact with foodstuff, pharmaceutical, or drinking water applications under the Indian Standards.

## Japan Hygienic Olefin and Styrene Plastics Association (IHOSPA)

This product is not currently registered under the Japan Hygienic Olefin and Styrene Plastics Association (JHOSPA) for use in food contact packaging applications.

## Kosher

The raw materials used in the manufacture of this product are derived from non-animal sources. There is no animal fat, no animal derived materials, grain derived, or fermentation products used in this product. The product is not certified as kosher but will comply with the kosher dietary laws. Therefore, this product can be used with kosher products without compromising the status of the products.

#### **Latin America MERCOSUR Food Contact Status**

The composition of this product has not been assessed for use in contact with food according to MERCOSUR GMC Resolution No. 56/92, Resolution No. 39/19 and/or Resolution No. 02/12.

## **US FDA Food Contact Status**

When used unmodified and processed in accordance with Good Manufacturing Practices (GMP) for food contact applications, this product will comply with the U.S. Food and Drug Administration's food additive regulation 21 CFR 177.1520(c), paragraph 3.1a, under the Federal Food, Drug, and Cosmetic Act, with restrictions. An additive present in this product limits use in finished articles having a volume of at least 18.9 liters (5 gallons). Conditions of Use are limited to D-G described in Table 2 of U.S. FDA's regulation 21 CFR § 176.170(c). The preceding statement refers to regulatory requirements only, not to the product's physical utility. It is the responsibility of the article producer or food packager to determine that the article is suitable for its intended use.

## **General/Global Regulations**

#### Alkylphenols and Alkylphenol Ethoxylates

This product is not manufactured or formulated with alkylphenols, which belong to the group of potential estrogen mimics (nonylphenol, octylphenol, butylphenol, dodecylphenol) or their associated ethoxylates; however, we do not analyze for these specific substances.

## Butylated Hydroxytoluene (BHT) (CAS# 128-37-0)

This product is not manufactured or formulated with Butylated Hydroxytoluene (BHT - CAS # 128-37-0); however, we do not analyze for this specific substance.

## Heavy Metals, EU 94/62/EC and Coalition of Northeastern Governors (CONEG)

This product conforms to the Coalition of Northeastern Governors (CONEG) and the European Directive 94/62/EC, as amended, on Packaging and Packaging Waste, Article 11. Any incidental levels of lead, cadmium, hexavalent chromium, and mercury do not exceed 100 ppm total.

## **Materials from Genetically Modified Organisms**

To the best of our knowledge, there are no raw materials, including additives, that have been derived from genetically modified organisms (GMO). This is based on information from our additive suppliers. Therefore, although we believe this product to be GMO free, we cannot guarantee it at this time.

#### **Palm Oil Derived Components**

Palm oil, as such, is not used in the manufacturing of this product; however, palm oil derivatives are used in the manufacturing of one or more raw materials utilized in the production of this product. These palm oil derivatives are only purchased from suppliers which are members of the "Roundtable on Sustainable Palm Oil" (RSPO).

## **Plant Derived Components**

This product may contain one or more substances(s) synthesized from plant extracts, i.e. hydrolysis of plant oils into fatty acids and/or their derivatives, as per information from our raw material suppliers.

#### Toy Safety - ASTM F963 / EN 71-3

This product is not formulated with antimony, arsenic, barium, boron, cadmium, chromium, cobalt, copper, mercury, lead, nickel, selenium, strontium or tin. To the best of our knowledge, it does not contain these substances above the limits set in ASTM F 963-11, Section 4.3.5.2. This product complies with the requirements of EN 71 Safety of Toys - Part 3, Migration of Certain Elements.

## <u>Tris(nonylphenyl)phosphite (TNPP)</u>

This product is not manufactured or formulated with tris(nonylphenyl)phosphite (TNPP) (CAS# 26523-78-4); however, we do not analyze for this specific substance.

## **Zinc and Zinc Compounds**

This product contains one or more zinc compounds that have been incorporated during the manufacturing process. These compounds are encapsulated in the polymer and no exposure would be expected under normal handling conditions.

## **Europe Middle East Africa and India Regulations**

## EU Directive 2011/65/EU (RoHS)

This product complies with the requirements of Article 4.1 of EU Directive 2011/65/EU (RoHS 2), as amended (Directive (EU) 2015/863 inclusive) (RoHS 3). It is not intentionally manufactured or formulated with cadmium, hexavalent chromium, lead, mercury, polybrominated biphenyls (PBB), polybrominated diphenyl ethers (PBDE), Bis(2-ethylhexyl) phthalate (DEHP), Butyl benzyl phthalate (BBP), Dibutyl phthalate (DBP), or Diisobutyl phthalate (DIBP).

## **EU Directive 2012/19/EU on Waste Electrical and Electronic Equipment (WEEE)**

EU Directive 2012/19/EU on WEEE: Selective treatment of the waste (Annex VII). None of the substances listed in Annex VII are intentionally added or used in the formulation of this product with the following exception. This product is a hydrocarbon; however, liquid hydrocarbons are not present in this product.

## **REACH**

For information on Dow and the European Union regulation for Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), visit our website, https://reach.dow.com/.

This product is not manufactured or formulated with any of the Substances of Very High Concern (SVHC) as per the candidate list that was current as of the effective date of this regulatory datasheet that would require reporting under this regulation. Current information can be found at the ECHA website. https://echa.europa.eu/candidate-list-table. Please contact Dow's Customer Information Group for more information (http://www.Dow.com/en-us/contact-us-cig).

## **North America Regulations**

## California Proposition 65 (Safe Drinking Water and Toxic Enforcement Act of 1986)

This product contains no listed substances known to the State of California to cause cancer, birth defects or other reproductive harm, at levels which would require a warning under the statute as of the effective date of this regulatory datasheet.

#### **Canadian Environmental Protection Act Challenge Substances**

This product is not intentionally manufactured or formulated with the Batch Lists of Canadian Environmental Protection Agency (CEPA) Challenge Substances released as of the effective date of this document. However, we do not analyze for these specific substances.

(http://www.chemicalsubstanceschimiques.gc.ca/challenge-defi/index-eng.php)

#### **Clean Air Act**

This product is not manufactured or formulated with Class I or II substances as defined under 40 CFR part 82 of the Clean Air Act of 1990, as amended (58 FR 8136).

## Conflict Minerals (Dodd-Frank Wall Street Reform and Consumer Protection Act)

This product is not intentionally manufactured or formulated with the listed conflict minerals as per Section 1502 of the Dodd-Frank Wall Street Reform and Consumer Protection Act; however, we do not analyze for these specific substances or compounds.

- Columbite-Tantalite refined into Tantalum (Ta) (CAS # 7440-25-7)
- Cassiterite refined into Tin (Sn) (CAS # 7440-31-5)
- Wolframite refined into Tungsten (W) (CAS # 7440-33-7)
- Gold (Au) (CAS # 7440-57-5)

For more information please visit Dows Corporate Website - https://corporate.dow.com/en-us/about/codes-of-conduct

## **Consumer Product Safety Improvement Act of 2008 (CPSIA)**

This product is not manufactured or formulated with lead, di-(2-ethylhexyl)phthalate (DEHP), dibutyl phthalate (DBP), or benzyl butyl phthalate (BBP). To the best of our knowledge, it does not contain these materials above the limits set in the Consumer Product Safety Improvement Act of 2008, Title 1, Sections 101 and 108.

## **US FDA Drug Master File (DMF)**

This product is not currently listed under a FDA Drug Master File. Please contact Dow's Customer Information Group if you require more information (http://www.Dow.com/en-us/contact-us-cig).

## US Pharmacopoeia (USP)

This product has not been assessed under U.S. Pharmacopoeia. Please contact Dow's Customer Information Group if you require further information (http://www.Dow.com/en-us/contact-us-cig).

## **Substances and Chemicals**

This product is not intentionally manufactured or formulated with the following substances or compounds; however, we do not analyze for these substances or compounds.

1,4 - Dioxane

Acrylamide

**Adipates** 

Antimony and Antimony compounds

Aromatic amines

Arsenic and Arsenic compounds

**Asbestos** 

Azo compounds

Beryllium and Beryllium compounds

**Biocides** 

Bis(2-ethylhexyl) adipate (DEHA)

Bisphenol compounds, including but not limited to: BPA, BPB, BPC, BPE, BPF, BPS, and BPZ

Butylated Hydroxyanisole (BHA)

Cadmium and Cadmium compounds

Chlorinated paraffins

Chlorofluorocarbons (CFCs) or Hydrochlorofluorocarbons (HCFCs)

Colophony

Colorants or pigments

Copper and Copper compounds

Dimethylfumarate (DMF)

Dioxins or furans

Endocrine disruptors (proven by the industry)

Epoxy derivatives listed in EU Regulation (EC) No 1895/2005

- Bisphenol A diglycidyl ether (BADGE) (CAS # 1675-54-3)
- Bisphenol F diglycidyl ether (BFDGE) (CAS # 39817-09-9)
- Novolac Glycidyl Ethers (NOGE)

**Fiberglass** 

Flavorings or Fragrances

Fluorotelomers

Formaldehyde

Fungicides, pesticides, preservatives, or fumigants

Halogenated (Brominated or chlorinated) or phosphorous based flame retardants

Halogenated organic compounds

Hexachlorobenzene

**Human Derived substances** 

Isocyanates

Materials derived from the Jatropha Plant

Melamine

Mercury and Mercury compounds

Mineral Oil Hydrocarbons - Aromatic (MOAH), Saturated (MOSH)

Nano materials

Natural rubber latex, dry natural rubber, or synthetic latex

Nickel and nickel compounds

Nitroso compounds

Organotin compounds

Ozone-depleting chemicals (includes lists under the Montreal Protocol & Regulation (EC) No 1005/2009)

**Parabens** 

Pentachlorophenol

Perchlorates

Perfluoroctanoic acid (PFOA), perfluoroctane sulfonate (PFOS) or perfluoroalkyls

Photoinitiators, including: benzophenone, hydroxybenzophenone, and 4-methylbenzophenone, and

Isopropylthioxanthone (ITX)

Phthalates / Phthalate esters

**Plasticizers** 

Polybrominated Diphenyl Ethers (PBDEs)

Polychlorinated and Polybrominated Biphenyls (PCBs and PBBs)

Polychlorinated and Polybrominated Naphthalenes

Polychlorinated and Polybrominated Terphenyls (PCTs and PBTs)

Polycyclic Aromatic Hydrocarbons (PAHs)

Polyvinyl Chloride (PVC)

Polyvinylidene Chloride (PVDC)

Radioactive Substances

Recycled materials

Silicone

Silver and silver compounds

Styrene

Sulfonamides

Tertiary butylhydroquinone (TBHQ) CAS# 1948-33-0

Triclosan (2,4,4'-trichloro-2'-hydroxydiphenylether)

Tris(2-chloroethyl)phosphate (TCEP) CAS# 115-96-8

Vinyl Chloride Monomer (VCM)

Xylene

#### **Product Stewardship**

The Dow Chemical Company and its subsidiaries ("Dow" have a fundamental concern for all who make, distribute, and use its products, and for the environment in which we live. This concern is the basis for our Product Stewardship philosophy by which we assess the safety, health, and environmental information on our products and then take the appropriate steps to protect employee and public health and our environment. The success of our product stewardship program rests with each and every individual involved with Dow products—from the initial concept and research, to manufacture, use, sale, disposal and recycle of each product.

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#### **Medical Applications Policy**

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- a. long-term or permanent contact with internal bodily fluids or tissues. "long-term" is contact which exceeds 72 continuous hours;
- b. use in cardiac prosthetic devices regardless of the length of time involved ("cardiac prosthetic devices" include, but are not limited to, pacemaker leads and devices, artificial hearts, heart valves, intra-aortic balloons and control systems, and ventricular bypass-assisted devices);
- c. use as a critical component in medical devices that support or sustain human life; or
- d. use specifically by pregnant women or in applications designed specifically to promote or interfere with human reproduction.

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