

Product Compliance Data Sheet

January 2015

CYROLITE® acrylic and acrylic-based multipolymer compounds
000 and 001 color Grades Only Unless Otherwise Indicated

Evonik Cyro LLC

Manufacturer

This product is manufactured by:
Evonik Cyro LLC, based in Parsippany, NJ

Performance Polymers Molding Compounds

528 South Cherry Street
Building #4
Wallingford, CT 06492

www.cyrolite.com
Phone +1 203-303 3431

Chemical Inventories

TSCA	USA	All components listed
DSL	Canada	All 001 color grades listed
EINECS	Europe	All 001 color grades listed
AICS	Australia	Yes
KECL	Korea	Not yet determined
PICCS	Philippines	Not yet determined
IECSC/SEPA	China	Yes

These products have no special requirements under TSCA (e.g. consent orders, test rules, 12(b) requirements, etc.)

REACH Regulations

CYROLITE® all grades comply with REACH regulations and Substances of very high concern (SVHC December 2014 Listing), are **not** present in concentrations of 0.1% or higher.

Food Law

North America

CYROLITE® compounds are regulated for food contact under FDA regulation 21CFR177.1010. Our natural color materials (color 000 & 001) meet the requirements of this regulation for all food types except those containing more than 8% alcohol. CYROLITE® Grades in color 000 & 001 meet the requirements for all use conditions up to and including room temperature filled. When used for water-based products or for solids containing no free fats or oil, CYROLITE® compounds meet the extractive requirements of Condition C – hot filled or pasteurized above 150° F (21CFR176.170, Table2).

Europe

CYROLITE® G20-100 and G20-300 compounds in 001 tint and L40 002 MD and H12-003 MD in 000 tint comply with

- EU Regulation 1935/2004 (replaces 89/109/EEC) materials and articles intended to come into contact with food
- EU Plastics directive 2002/72/EC, 2002/16/EC Plastic materials and articles intended to come into contact with foodstuffs
- EC-positive list (“Synoptic 7”) Draft of provisional list of monomers and additives used in the manufacture of plastics and coatings intended to come into contact with foodstuffs,
- Council of Europe AP (89) I “on the use of colorants in plastic materials coming into contact with food”

California Proposition 65

CYROLITE® compounds may be used as intended in contact with food in full compliance with Proposition 65 (California Safe Drinking Water and Toxic Enforcement Act of 1986) without providing a warning to customers. CYROLITE® compounds G20-100, G20-300, GS-90, CG 97, Med 2, and VuStat compounds contain chemicals known to the state of California to cause cancer and birth defects or other reproductive harm. The chemicals are present in trace amounts or less than the maximum potential exposure is calculated to be well below ADIL or NSRL established values.

USP Class VI

CYROLITE® L40-002-000 MD, H12-003-000 MD, G20 (G20-100-001), CYROLITE® G20 HIFLO (G20-300-001), CYROLITE® G20 color 8038 white (G20-100-8038), CYROLITE® GS 90 (G90-200-001), CYROLITE® CG 97 (G97-100-001), CYROLITE® Med 2, CYROLITE® Vu-Stat Y20; have all been found to meet the requirements for United States Pharmacopeia Class VI tests for determining suitability of a plastic material intended for use in fabricating containers or accessories (24 hours, 70 C, 4g/20ml extraction) for parenteral preparations.

ISO 10993-1

CYROLITE® L40 -002-000 MD, H12-003-000 MD, G20 (G20-100-001), CYROLITE® G20 HIFLO (G20-300-001), CYROLITE® G20 color 8038 white (G20-100-8038), CYROLITE® GS 90 (G90-200-001), CYROLITE® CG 97 (G97-100-001), CYROLITE® Med 2, CYROLITE® Vu-Stat Y20; be non-hemolytic, non-cytotoxic, non-pyrogenic, non-sensitizing and non-mutagenic in short term in vitro and in vivo biological testing following ISO 10993 and Tripartite protocols. The Tripartite protocols for these tests are technically identical to the ISO 10993 protocols.

Underwriters Laboratories – Certifications

File number: QMFZ2.E54671 Plastics Component

Material Dsg	Color	Min. Thk. mm	Flame Class	H W I	H A I	R T I			H V T R	D 4 9 5	C T I
						Elec	Mech				
							Imp	Str			
L40 MD	NC	1.5	HB	-	-	50	50	50	-	-	-
H12 MD	All	1.5	HB	-	-	90	90	90	-	-	-
G20-100 & 300	All	1.5	HB	-	-	50	50	50			
		3.0	HB	-	-	50	50	50			
GS-90	NC	1.5	HB	-	-	50	50	50			
CG-97	CL	1.5	HB	-	-	50	50	50			
Med 2	CL	1.5	HB	-	-	50	50	50			
HP2	CL	1.5	HB	-	-	50	50	50			
P06	NC	1.5	HB	-	-	50	50	50			
P07	All	1.5	HB	-	-	50	50	50			
		3.0	HB	-	-	50	50	50			

Bovine Spongiform Encephalopathy (BSE) / Transmissible spongiform Encephalopathy (TSE) / “Mad Cow”

The United States Food and Drug Administration has issued a strong recommendation to manufacturers of FDA-Regulated Drug/Biologic/Device products intended for administration to humans, to avoid the use of materials that have come from cattle born, raised, or slaughtered in countries where bovine spongiform encephalopathy (BSE) is known to exist. Stearic acid and its derivatives such as metallic or alkyl stearates which might in some cases be derived from animal sources are sometimes used as additives in plastics as mold release agents, plasticizers, or dispersing aids for colorants. As such they are included in FDA's strong recommendation.

CYROLITE® in colors 001 and 003 do not contain any fatty acids tallow/Stearic acid or its derivatives or any other animal derived substances.

While some other products including L40 MD and H12 MD and some other colors of these materials contain stearic acid or its derivatives, all suppliers have certified that their products meet the strong recommendation from FDA. In most cases they have certified that only tallow derivatives are used or if animal sources were used as starting materials they have been processed at conditions to preclude the transmission of BSE.

Natural Rubber Latex

Be advised that no natural rubber latex is used in the manufacture of any of these products. CYROLITE® L40 MD and H12 MD do not contain any impact modifiers. The impact modifier used in all other grades is butadiene polymer with methyl methacrylate and styrene. Its CAS number is 25053-09-2.

Kosher

We do not certify our resins to be Kosher or in compliance with Kosher Requirements.

Drug Master File

Information on CYROLITE® G20-100-001 and G20-300-001 is listed in file number BB-MF-2138. Contact Evonik Cyro for an authorization letter to be sent to FDA

ROHS

CYROLITE® compounds are manufactured without using substances named in the European Directive 2011/65/EC (replace 2002/95/EC, the amendment 2008/35 EC inclusive decision of commission 2009/443/EC) on the Restriction of the use of certain Hazardous Substances in electrical and electronic equipment (ROHS)

Furthermore, in our natural and most other colors, with regard to cadmium, hexavalent chromium, lead and mercury, be assured that the total incidental level of these elements in virgin product is significantly less than 75 ppm.

WEEE

CYROLITE® compounds are manufactured without using substances named in the European Directive 2002/96/EC Directive on the disposal of Waste Electrical and Electronic Equipment. (WEEE)

Coneg (Coalition of Northeastern Governors)

CYROLITE® compounds are manufactured without using cadmium, chromium, lead, and mercury named in model legislation regulating heavy metals in packaging. CYROLITE® compounds meet the CONEG requirements of less than 100 ppm for total incidental cadmium, chromium, lead and mercury.

Greenpeace

CYROLITE® compounds are manufactured without using substances named by Greenpeace as targeted for investigations: ozone depleting substances, PCBs and related compounds, and asbestos.

Ozone Depleting Chemicals

CYROLITE® compounds are not manufactured with and do not contain any Class I nor Class II ozone depleting substances as defined in Title VI of the Clean Air Act of 1990 and as defined by the final rule published in the Federal Register on February 11, 1993 (58 FR 8136). (CFCs, HCFCs, CHCs) (short chain chlorinated parafins or SCCPs).

Perfluorooctane sulfonate PFOS and Perfluorooctanoic Acid

Neither Perfluorooctane sulfonate and its salts (PFOS CAS #45298-90-6) nor Perfluorooctanoic Acid (PFOA CAS #1763-23-1 (acid)) are added to or used in the manufacture of CYROLITE® compounds. We have not tested these materials for trace impurities but expect the levels to be well below the part per million level.

HCB (Hexachlorobenzene)

Due to information received from the Canadian and Japanese governments, importing, exporting and manufacturing of HCB-containing products is prohibited in these two countries.

Certain colorants which are produced from Tetrachlorophthalic Anhydride (TCPA) are suspected of containing traces of HCB (hexachlorobenzene) as a minor contaminant, by-product or reaction product.

Neither TCPA nor HCB are used in the production of CYROLITE® compounds. These substances are neither added in the production process nor are they added to the manufactured molding compound products.

Our colorant suppliers informed us that the colorants used for CYROLITE® compounds are not manufactured on basis of TCPA. They further informed us that they do not use HCB in their manufacturing processes for these dyes. Colorant suppliers therefore assume that no HCB is formed in their production processes. For this reason they did not analyze their products specifically for HCB.

In conclusion, we assume that CYROLITE® compounds do not contain traces of HCB exceeding the volumes that are omnipresent in the environment.

Ethylene Glycol

There is no ethylene glycol nor materials known to contain ethylene glycol as an impurity, intentionally added to our CYROLITE® L40 MD, H12 MD, G-20 and CYROLITE® G-20 HIFLO® acrylic-based multipolymer compounds. The total incidental amount would be below 10 ppm or 0.001%. The extractable levels would be much lower.

Although we do manufacture certain CYROLITE® Grades with polyethylene glycol, CYROLITE® L40 MD, H12 MD, G-20, and CYROLITE® G-20 HIFLO® acrylic-based multipolymer compounds are not manufactured with this material. The level of ethylene glycol in those other compounds with polyethylene glycol is limited to less than 0.01% or 100 ppm.

Bis-phenol A (BPA)

Bis-phenol A (BPA) is not added to or used in the manufacture of CYROLITE® acrylic-based multipolymer compounds.

Chemicals not used in the formulation or manufacture of CYROLITE® compounds but not tested for trace impurities.

Be assured that the total incidental level of these elements in virgin natural color material (color 000 and 001) is significantly less than 75 ppm. CYROLITE® compounds have not been tested for these chemical substances.

<p>Asbestos Bisphenol A or nonyl phenol, BHA Chlorofluorocarbons Formaldehyde Isocyanate PCB PCT PCP Polyurethane</p>	<p>Polybrominated or polychlorinated biphenyls, Polybrominated biphenyl ethers (PBBs), Polybrominated diphenyl ethers (PBDEs), polychlorinated terphenyls, pentachlorophenol, nonyl phenols, octyl phenols nor brominated flame retardants.</p>	<p>Pentabromodiphenyl ether, and octabromo-diphenyl ether, phthalate esters, nor organotin compounds.</p> <p>Phthalate Plasticizers: di-2-ethylhexyl phthalate (diethylhexyl phthalate DEHP). This is sometimes also referred to as Diocetyl Phthalate (DOP), diisononyl Phthalate (DINP), Dibutyl Phthalate (DBP), butyl benzyl phthalate (BBP), di-<i>n</i>-butyl phthalate (DBP), · di-<i>n</i>-hexyl phthalate (DnHP) · di-isodecyl phthalate (DIDP) · di-<i>n</i>-octyl phthalate (DNOP)</p>
<p><u>Heavy Metals</u> Lead Hexavalent Chromium, Cadmium, Mercury, Selenium, silver, and compounds of these elements.</p>	<p>C6H4 (NH2) 2p-Phenylenediamine (PPD), 1,4-Benzenediamine nor compounds containing PPD.</p>	<p>Phosphorous and phosphorous containing compounds</p> <p>Silicone</p>

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Americas Evonik CYRO LLC An Evonik Degussa Corporation group company 379 Interpace Parkway Parsippany, NJ 07054 USA PHONE: 800-631-5384 EMAIL: cyro.polymer@evonik.com www.cyrolite.com	Europe and Asia Pacific Evonik Röhm GmbH Molding Compounds Business line Kischenalle 64293 Darmstadt Germany PHONE: +49 (0) 6151-18 4595 EMAIL: Plexiglas.polymers@evonik.com www.plexiglas.de
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Evonik Cyro LLC 299 Jefferson Road, Parsippany, NJ 07054-0677 USA
 Phone: 800-631-5384; Email: cyro.polymer@evonik.com; Website: <http://www.cyrolite.com>