

Regulatory Data Set

SABOSTAT® ASE 3

Polymer Additives

CHEMICAL IDENTITY

Chemical name	Ethanol, 2,2'-iminobis-, N-tallow alkyl derivs.
Common name	Tallow amine 2EO
CAS number	61791-44-4 / 1218787-32-6
EC number	263-177-5 / 620-540-6
REACH number	01-2119510877-33-0012

CHEMICAL INVENTORY STATUS

Australia	AICS	Listed
New Zealand	NZIoC	Listed
Canada	DSL	Listed
China	IECSC	Listed
Europe	REACH	Listed
Japan	ENCS	Listed
Korea	ECL	Listed (No. KE-20967)
Philippines	PICCS	Listed
Taiwan	TCSI	Listed
USA	TSCA	Listed (Active)

HEAVY METALS LEGISLATION

Does this product have the heavy metals lead, mercury, cadmium, or hexavalent chromium intentionally added?	NO
Does this product comply with Directive 94/62/EC (Packaging and Packaging Waste) and its amendments?	YES
Does this product comply with Directive 2000/53/EC (End-of Life Vehicles) and its amendments?	YES
Does this product meet the CONEG 1994 standard, <i>i.e.</i> is the total of the heavy metals lead, mercury, cadmium, and hexavalent chromium less than 100 ppm?	YES
Are Conflict Minerals (gold, tantalum, tin, tungsten) used in the manufacturing of this product or intentionally added?	NO

EU REGULATIONS

Does this product comply with:

<ul style="list-style-type: none"> • Directive 2002/95/EU (RoHS), Directive 2011/65/EU (RoHS2), Directive 2015/863/EU (RoHS 3) and Directive 2012/19/EU ? 	YES
<ul style="list-style-type: none"> • Directive 2003/11/EC of the European Parliament and of the Council of 6 February 2003 amending for the 24th time Council Directive 76/769/EEC relating to restrictions on the marketing and use of certain dangerous substances and preparations (pentabromodiphenyl ether, octabromodiphenyl ether)? 	YES
<ul style="list-style-type: none"> • Commission Regulation (EC) No. 1895/2005 of 18 November 2005 prohibiting certain epoxy derivatives in materials and articles intended to come into contact with food and setting migration limits for 2,2-bis (4-hydroxyphenyl) propane bis (2,3-epoxypropyl) ether and Commission Directive 2004/13/EC of 29 January 2004 amending Directive 2002/16/EC on the use of certain epoxy derivatives in materials and articles intended to come into contact with foodstuffs? 	YES
<ul style="list-style-type: none"> • Commission Directive 2004/21/EC of 24 February 2004 relating to restrictions on the marketing and use of "azo colorants" (thirteenth adaptation to technical progress of Council Directive 76/769/EEC)? 	YES
<ul style="list-style-type: none"> • Council Directive 78/142/EEC of 30 January 1978 on the approximation of the laws of the Member States relating to materials and articles which contain vinyl chloride monomer and are intended to come into contact with foodstuffs? 	YES
Is this product acceptable for use in toys according to EN71-3:2013 with the incorporation of amendment A1:2000 Safety of toys-Part 3: migration of certain elements, and Directive 2009/48/CE?	YES

USA FEDERAL AND STATE REGULATIONS

Are any components of this product currently subject to any rules or orders under TSCA Section 4, 5, 6, 8, or 12b export notification?	NO
Does this product contain any components regulated under SARA Title III Section 302 (EPCRA Extremely Hazardous Substances)?	NO
Does this product contain any components regulated under SARA Title III Section 304 (CERCLA Hazardous Substances)?	NO
Does this product contain any components subject to SARA Title III Section 313 reporting?	NO
Does this product contain any components listed under California Proposition 65 as a carcinogen or reproductive toxin?	YES
Does this product contain any components currently listed in a Right-to-Know List of hazardous substances in the States of Massachusetts, New Jersey, or Pennsylvania?	NO
Does this product comply with the requirements of ASTM F963-11 "Standard Consumer Safety Specification for Toy Safety"?	YES

INFORMATION ABOUT REGULATED COMPONENTS

Does the product comply with USDA/APHIS regulations (e.g.: 9 CFR 94.18) and/or international regulations (e.g.: European Commission Directives) governing exposures to transmissible spongiform encephalopathy (TSE) / bovine spongiform encephalopathy (BSE)?	YES
Does the product contain substances derived from genetically modified organisms (GMO) (refer to 2001/18/EC)?	NO
Does the product contain allergens latex, natural rubber, peanuts and peanut by-products, milk or milk products, eggs, crustaceans (except mollusks) and fish, refined or unrefined oils, soy, wheat (gluten), cereals (oats, barley, rye, triticale, spelt), sesame, seeds, sulfites, food colors, celery, nuts (almonds, walnuts, hazelnuts, pistachios, brazil nuts, macadamia nuts, pecans, cashews, pine kernels) (refer to Directive 2000/13/EC as amended by 2003/89/EC and the USA Food Allergen Labeling and Consumer Protection Act (FALCPA)?	NO
Is the product produced under Rabbinic supervision (Letter of Kosher Certification)?	NO
Is the product certified as Halal?	NO
Does this product contain any regulated compounds such as PBB's, PBDE's, PCB's, PCT's, PCN's, CFC's or other halogenated hydrocarbons, formaldehyde, alkylphenol or alkylphenol ethoxylates, phthalates, Bisphenol A, organotin compounds, trisnonylphenyl phosphite (TNPP), radioactive substances, dioxins, furans, or flame retardants?	NO
Does this product contain any of the following materials or their compounds: cadmium, lead, mercury, chromium, asbestos, antimony, arsenic, beryllium, bismuth, or nickel?	NO
Are Noxious Substances (EN 13428) excluded?	YES
Does the product comply with EU Recovery Standards, including Material Recovery (EN 13430), Energy Recovery (EN 13431) and Organic Recovery (EN 13432)?	YES
Does this product contain, or does its manufacturing process utilize any Class I or Class II ozone depleting chemicals as regulated by the Clean Air Act of 1990, the Montreal Protocol, or USA EPA regulation 40 CFR Part 82?	NO
Are organotin compounds contained in or used to synthesize or process this product?	NO
Does this product contain substance(s) listed under SVHC Candidate list in a concentration above 0.1% weight by weight?	NO
Does this product contain substance(s) listed under Annex XVII (REACH)?	NO
Does this product contain substance(s) listed under GADSL list?	NO
Does this product contain any Mineral oil hydrocarbons (MOH), mineral oil saturated hydrocarbons (MOSH) and mineral oil aromatic hydrocarbons (MOAH) according to the Scientific Opinion on Mineral Oil Hydrocarbons in Food (EFSA)?	NO
Does this product contain any PAHs (polycyclic aromatic hydrocarbons) listed in the REACH Annex XVII or AfPS GS 2014:01 PAK?	NO
Does this product contain any biocide regulated under Regulation (EU) No. 528/2012?	NO
Are nanomaterials, as defined by the European Commission's Recommendation 2011/696/EU, used in the manufacturing of this product or intentionally added?	NO

FOOD CONTACT STATUS

EU	<p>This product is in accordance with the relevant requirements defined in Regulation (EC) No. 1935/2004 (as amended) and Regulation (EU) No. 10/2011 (as amended).</p> <p>Regulation (EU) No. 10/2011 Ref. No: 39090 SML: 1.2 mg/kg (expressed as tertiary amine) Authorized to be used as additive or polymer production aid, not as monomer</p> <p>This product may contain impurities relevant for further risk assessments and/or subject to restrictions / specifications defined in Regulation (EU) No. 10/2011; a detailed EU food contact declaration can be requested through the mailbox polymeradditives@sabo.com or your usual SABO business contact.</p>
USA (FDA)	<p>This product is deemed suitable for use as an indirect food additive in the FDA regulation(s) listed below, in accordance with 21 CFR §174.5.</p> <p>21 CFR §178.3130 Antistatic and/or antifogging agents in food-packaging materials For use only as an antistatic agent at levels not to exceed:</p> <ul style="list-style-type: none"> • 0.15 pct by weight in molded or extruded polyethylene containers that contact food only of the types identified in 21 CFR §176.170(c), table 1, under Types I, IV-B, VI-B, VII-B, and VIII, under the conditions of use E through G described in table 2 of 21 CFR §176.170(c) provided such foods have a pH above 5.0. • 0.10 mg per square inch of food-contact surface in vinylidene chloride copolymer coatings complying with 21 CFR §175.320, 21 CFR §177.1200, or 21 CFR §177.1630, provided that such coatings contact food only of the types identified in 21 CFR §176.170(c), table 1, under Types I, IV, VII, VIII, and IX under the conditions of use E through G described in table 2 of 21 CFR §176.170(c). The finished copolymers shall contain at least 70 weight pct of polymer units derived from vinylidene chloride; and shall contain not more than 5 weight pct of total polymer units derived from acrylamide, acrylic acid, fumaric acid, itaconic acid, methacrylic acid, octadecyl methacrylate, and vinyl sulfonic acid.
SOUTH AMERICA	<p>MERCOSUR/GMC/RES. N° 39/19 MCA: 19; Ref. No.: 39090; LME: 1,2 mg/kg (expressed as tertiary amine) LME is referred to the sum of substances with MCA 19 and 20</p> <p>Brazil regulación RDC 326/2019 MCA: 19; Ref. No.: 39090; LME: 1,2 mg/kg (expressed as tertiary amine) LME is referred to the sum of substances with MCA 19 and 20</p>
CHINA	<p>GB9685 - Permitted Additives in Food Contact Plastics FCA0543 Plastic: PE, PP Dosage: max 0.15% (PE); max. 0.1% (PP)</p>

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