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Regulatory Data Set

SABOSTAT® DELA

Polymer Additives

CHEMICAL IDENTITY	
Chemical name (REACH)	N,N-Bis(2-hydroxyethyl)dodecanamide
Chemical name (TSCA)	Dodecanamide, N,N-bis(2-hydroxyethyl) hydroxyethyl)-
Common name	Lauryl diethanolamide
CAS number	120-40-1
EC number	204-393-1
REACH number	01-2119962187-30-0002

CHEMICAL INVENTORY STATUS		
Australia	AICS	Listed
Canada	DSL	Listed
China	IECSC	Listed
Europe	REACH	Registered
Japan	ENCS	Listed (No. 2-827X)
Korea	ECL	Listed (No. KE-03194)
Philippines	PICCS	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.e.* 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:	
• Directive 2002/95/EU (RoHS), Directive 2011/65/EU (RoHS2), Directive 2015/863/EU (RoHS 3) and Directive 2012/19/EU ?	YES
• 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
• 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
• 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
• 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 the product contain any components subject to SARA Title III Section 313 reporting?	NO
Has this product or its components been listed under California Proposition 65 as a carcinogen or reproductive toxin?	YES
Does the 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 contain animal derived substances (refer to 2001/2/EC regulations)?	NO
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	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). Regulation (EU) No. 10/2011 Ref. No: 39150 SML: 5 mg/kg food Authorized to be used as additive or polymer production aid, not as monomer. The residual amount of diethanolamine in plastics, as an impurity or decomposition product of the substance, shall not result in a migration of diethanolamine higher than 0.3 mg/kg food. There is a risk that the SML could be exceeded from low-density polyethylene. 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.
USA (FDA)	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. 21 CFR §175.105: Adhesives No limitations 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: • 0.5 percent by weight of molded or extruded polyethylene containers intended for contact with honey, chocolate syrup, liquid sweeteners, condiments, flavor extracts and liquid flavor concentrates, grated cheese, light and heavy cream, yogurt, and foods of Type VIII as described in table 1 of 21 CFR §176.170(c). • 0.2 percent by weight in polypropylene films complying with 21 CFR §177.1520, and used in contact with food of Types I, II, III, IV, V, VI-B, VII, VIII, and IX described in table 1 of 21 CFR §176.170(c), and under conditions of use B through H described in table 2 of 21 CFR §176.170(c). The average thickness of such polypropylene film shall not exceed 0.001 inches (30 micrometers).
SOUTH AMERICA	MERCOSUR/GMC/RES. Nº 39/19 MCA: 923; Ref. No.: 39150; LME = 5 mg/kg Dietanolamina: LME = 0.3 mg/kg. La dietanolamina puede estar presente como un producto de descomposición de sustancias y / o impurezas. Existe el riesgo de que se supere el LME desde el polietileno de baja densidad. Brazil regulación RDC 326/2019 MCA: 923; Ref. No.: 39150; LME = 5 mg/kg Dietanolamina LME = 0.3 mg/kg. A dietanolamina pode estar presente como um produto da decomposição de substâncias e / ou impurezas. Há o risco de que o LME seja superado do polietileno de baixa densidade.
CHINA	GB9685 - Permitted Additives in Food Contact Plastics FCA0537 Plastic: PE, PP, PS, AS, ABS Dosage: max. 0.8% (PE, PP); max. 1.5% (PS, AS); max 2.5% (ABS) Total specific migration limit [SML(T)]: 5 mg/kg

PHARMACOPEIA STATUS	
Ph.Eur	Listed in European Pharmacopeia Concentration max 0,5% in final polyolefin articles
USP	Listed in US Pharmacopeia In accordance with the FDA food packaging requirements

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