

Product information

Crodamide E Crodamide ER Incroslip C

Regulatory Information

Non-warranty

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Croda Oleochemicals is a trading name of Croda Chemicals Ltd, Croda Leek Ltd and Croda Universal Ltd

Crodamide E, ER & Incroslip C

Identity

Crodamides E, ER & Incroslip C are Erucamide [IUPAC name: (Z)-docos-13-enamide] and are assigned CAS number 112-84-5.

Origin

Crodamides E, ER & Incroslip C are manufactured using raw materials of vegetable and synthetic origin. The vegetable source used has not been genetically modified.

Inventory Status

<u>Country</u>	<u>Status</u>	<u>Inventory number</u>
Europe (EINECS)	Listed	204-009-2
Austria	See EINECS	
Switzerland	See EINECS	
USA (TSCA)	Listed	112-84-5
Canada (DSL)	Listed	112-84-5
Australia (AICS)	Listed	112-84-5
New Zealand	Listed	112-84-5
Japan (MITI/ENCS)	Listed	[2]-981
Korea (MEO/ECL)	Listed	2-83
Phillipines (PICCS)	Listed	112-84-5
China (NEPA)	Listed	112-84-5

Toys

The European Standard EN71 Safety of Toys Part-3: Migration of Certain Elements is concerned with the migration of Antimony, Arsenic, Barium, Cadmium, Chromium, Lead, Mercury and Selenium. The Standard lays down migration limits, ranging from 25 - 500 mg/kg, and test methods for determining migration levels from toys. No migration limits are specified for ingredients used in the manufacture of toys. However, it is advisable to ensure that ingredients do not contain high levels of these heavy metals. Crodamides E, ER & Incroslip C have a total heavy metals limit of 10ppm maximum and a limit of 1ppm maximum for any individual metal.

Packaging & Packaging Waste

European Parliament and Council Directive 94/62/EC of 20 December 1994 requires that the sum of concentration levels of lead, cadmium, mercury and hexavalent chromium present in packaging or packaging components shall not exceed 100ppm. Crodamides E, ER & Incroslip C have a total heavy metals limit of 10ppm maximum and a limit of 1ppm maximum for any individual metal.

Pharmaceutical Plastics

The European Pharmacopoeia contains a number of monographs for plastic containers and closures for pharmaceutical use. Acceptable additives are indicated in the type specification for each material described in the European Pharmacopoeia. Crodamides E, ER & Incroslip C are listed under the following General Chapters:

3.1.3 Polyolefines

Alkenamides (not more than 0.5% per cent)

3.1.5 Polyethylene with additives for containers for preparations for parenteral use and for ophthalmic preparation

Alkenamides (not more than 0.5% per cent)

3.1.6 Polypropylene for containers and closures for preparations for parenteral and ophthalmic use

Alkenamides (not more than 0.5% per cent)

3.1.7 Poly(ethylene-vinyl acetate) copolymer for containers and tubing for total parenteral nutrition preparations

Erucamide (not more than 0.5% per cent)

Food Contact Approvals in Europe

Specific European directives on materials and articles intended to come into contact with foodstuffs are currently limited to regenerated cellulose, ceramics and plastics.

Regulations relating to regenerated cellulose are laid down in commission directive 93/10/EEC as amended. The directive lists substances authorised for use in the manufacture of regenerated cellulose film together with conditions and restrictions on use. Crodamides E, ER & Incroslip C are not included on the list of permitted substances.

Regulations relating to plastics are laid down in commission directive 2002/72/EC as amended. The directive includes an incomplete list of additives together with conditions and restrictions on use. Crodamides E, ER & Incroslip C are listed as Erucamide (PM/Ref No 52720).

Food Contact Approvals in the USA

Code of Federal Regulations Title 21 – Food and Drugs	
Part 175 – Indirect Food Additives: Adhesives and Components of Coatings	
175.105 Adhesives	
Crodamide E, ER & Incroslip C	- Erucamide (erucylamide)
175.300 Resinous and polymeric coatings	
- b) 3) xxxi) Can end cements (sealing compounds used for sealing can ends only):	
Crodamide E, ER & Incroslip C	- Substances listed in paragraph (b) of this section and those listed in §177.1210 (b)(5) of this chapter
175.320 Resinous and polymeric coatings for polyolefin films	
- b) 3) iii) Adjuvants (release agents, waxes and dispersants):	
Crodamide E, ER & Incroslip C	- Amides (unsubstituted) of fatty acids from vegetable or animal fats
175.390 Zinc-silicon dioxide matrix Coatings	
Crodamide E, ER & Incroslip C	- Substances for which safe conditions of use have been prescribed in 175.300

Part 176 - Indirect Food Additives : Paper and Paperboard Components	
176.180 Components of paper and paperboard in contact with dry food	
Crodamide E, ER & Incroslip C	- Erucamide (erucylamide)
176.210 Defoaming agents used in the manufacture of paper and paperboard	
Crodamide E, ER & Incroslip C	- (d)(2) Fatty triglycerides and marine oils and the fatty acids and alcohols derived therefrom (paragraph (d)(1) of this section) reacted with one or more of the following, with or without dehydration, to form chemicals of the category indicated in parentheses. ...Ammonia (amides)
Part 177 - Indirect Food Additives : Polymers	
177.1200 Cellophane	
Crodamide E, ER & Incroslip C	- Erucamide
177.1210 Closures with sealing gaskets for food containers	
Crodamide E, ER & Incroslip C	- Erucylamide ¹
177.1350 Ethylene-vinyl acetate copolymers	
Crodamide E, ER & Incroslip C	- Erucamide as identified in 178.3860 of this chapter
177.1390 Laminate structures for use at temperatures of 250°F and above - c) 2) Adhesives:	
Crodamide E, ER & Incroslip C	- Substances complying with 175.105 of this chapter may be used in these constructions provided they are separated from the interior (food-contact) layer(s) by a functional barrier as discussed under paragraph (a) of this section
177.1395 Laminate structures for use at Temperatures between 120°F & 250°F	
Crodamide E, ER & Incroslip C	- 1) Polymers and adjuvants complying with part 177.1390 of this chapter
177.1400 Hydroxyethyl cellulose film, water-insoluble	
Crodamide E, ER & Incroslip C	- Substances identified in and used in compliance with 177.1200(c).
177.2210 Ethylene polymer, chlorosulphonated	
Crodamide E, ER & Incroslip C	- d) Substances permitted by 177.2600 may be employed in the preparation of ethylene polymers, chlorosulphonated subject to any limitations prescribed therein
177.2600 Rubber articles intended for repeated use - c) 4) ix) Miscellaneous:	
Crodamide E, ER & Incroslip C	- Animal glue as described in §178.3120 of this chapter ²

Part 178 - Indirect Food Additives, Production Aids and Sanitizers	
178.3120 Animal Glue	
Crodamide E, ER & Incroslip C	- d) 3) Defoaming agents as provided in 176.210 of this chapter
178.3860 Release Agents	
Crodamide E, ER & Incroslip C	- Erucamide (erucylamide)
Part 179 - Irradiation in the Production, Processing and Handling of Food	
179.45 Packaging material for use during the irradiation of prepackaged foods	
Crodamide E, ER & Incroslip C	- Amides of erucic, linoleic, oleic, palmitic and stearic acids ³

¹ Up to 5% by weight of closure sealing gasket composition

² Not to exceed 5% by weight of rubber product

³ Not to exceed 1% by weight of the polymer