INEOS Oligomers

Isododecane in the production of polymer films - Food contact approval status.

Isododecane is used extensively around the World in the production of Low Density Polyethylene (LDPE), both as a catalyst phlegmating agent, and as a catalyst carrier in the polymerization reactor. A major use of LDPE film is in food packaging applications, and the status of isododecane with respect to food contact regulations is a frequently asked question

Europe.

In Europe, the principle legislation is Commission Regulation (EU) No 10/2011 (relating to plastic materials and articles intended to come into contact with foodstuffs) and it's subsequent amendments. The directive considers four classes of compounds used in polymer production, only the first two of which are currently covered by the directive

- Monomers (e.g. ethylene, propylene)
- Polymer additives (intended to modify the end polymer properties, e.g. colourings)
- Polymerisation aids (e.g. catalysts/initiators and chain transfer agents)
- Polymerisation production aids (e.g. buffers and pH regulators)

Isododecane has been classed as a polymerisation aid, and as such falls outside of the scope of the overall directive. It is not currently possible, therefore, for isododecane to be 'approved' under EU 10/2011.

INEOS recognises that this may place film manufacturers in a difficult position with the food packaging industry, who demand reassurance on behalf of the consumer. We have, therefore, undertaken our own risk analysis, based on protocols developed within the polyethylene technical community. Using an EU approved model to estimate isododecane migration, industry data on residual isododecane concentrations in finished film, and experimental toxicity values, we have calculated a 'safety factor'. A safety factor of 1 would indicate that with long term continuous exposure it might be possible for an adult to absorb enough isododecane to show some effects.

Film thickness	**Predicted specific migration (1)** mg/kg food	**Estimated human exposure** µg/kg body wt./day	**Safety factor (2)**
1mm	2.0	33	10000
50µ	0.11	1.8	183000

1) Olive oil food simulant, 10 days, 40C, concentration of isododecane in finished film = 30ppm

2) Based on a Non Observable Effect Level (NOAEL) of 330 mg/kg body weight/day, 3 month sub chronic toxicology study in rats (ref. IUCLID database)

Based on above risk assessment, and the huge margin of safety between the NOAEL and the estimated human exposure, we believe that isododecane is safe for food contact and does not represent any human health concern when applied to LDPE film manufacture.

Kosher and Halal compliance

Isododecane is Kosher approved (see our technical website for a current certificate).
Isododecane is completely free of all materials of biological origin, in compliance with Halal requirements

Isododecane purity

Isododecane is completely free of aromatic residues (< 1ppm specification, typically <0.2ppm LOD), and sulphur containing molecules, making it odour free.
One of the benefits of the very high single isomer purity of isododecane (c.a. 83% 2,2,4,6,6-pentamethylheptane) is that residues in polymer films are easy to quantify accurately by conventional techniques.

SALES SPECIFICATION

Parameter	Units	Value	Test Method
Sum of C_{12} hydrocarbons	% by wt.	98 min	3002-0202103-98D (GC method)
Sum of C_8 and C_{16} hydrocarbons	% by wt.	2 max	3002-0202103-98D (GC method)
Aromatics	mg/kg	1 max	3002-0600203-97D (UV method)
Carbonyls	mg/kg	5 max	3002-0300303-98D (titration)
Bromine index	mg Br_2/ 100g	15 max	3002-0300502-98D (potentiometric titration)
Sulphur	mg/kg	1 max	3002-0302802-00D (coulometric)
Peroxides (calculated as H_2O_2)	mg/kg	1 max	3002-0300502-98D (potentiometric titration)
Water	mg/kg	50 max	3002-0300101-95D (Karl Fischer titration)
Evaporation residue	mg/100ml	1 max	3002-0100201-95D (ASTM-D 381-80)
Neutralisation number	mg KOH/ g	0.01 max	3002-0300303-98D (titration)

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