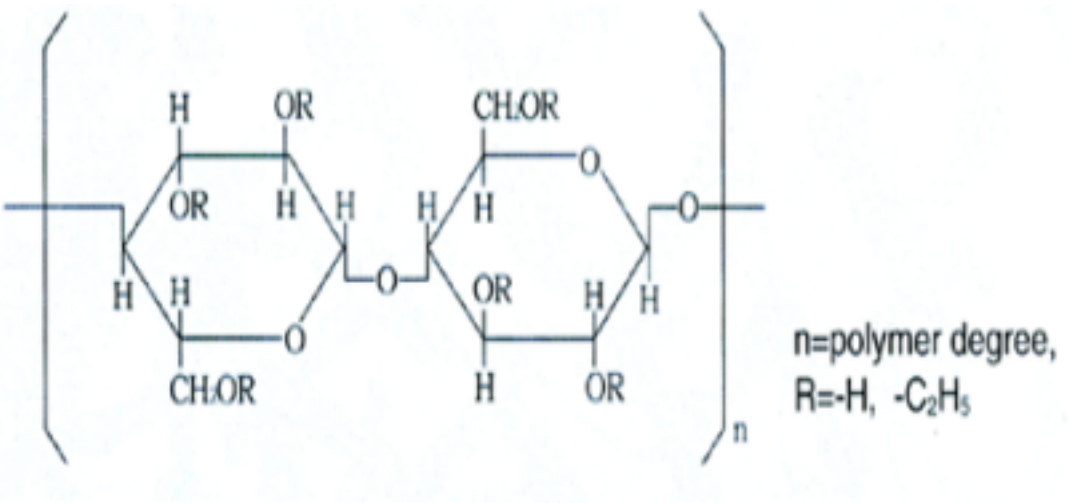
ETHYL CELLULOSE

SYNONYMS

Ampacet E/C, Aquacoat, Aquacoat ECD 30, Aquacoat ECD 30FMC, Cellulose ethyl, Cellulose ethyl ether , Cellulose ethylate , Cellulose, ethyl ester , Cellulose, triethyl ether , ET 100 (cellulose derivative) , ETs, ETs (Polysaccharide), Ethocel, Ethocel 150, Ethocel 890, Ethocel E50, Ethocel E7, Ethocel MED, Ethocel N10,
Ethocel N200 , Ethocel N7 , Ethocel STD , Ethylcellulose, G 200 , G 200 (polysaccharide), G 50, G 50 (Polysaccharide), 5; Nixon E/C, SPT 50CPS, T 100, T 100 (Polysaccharide), Triethyl cellulose.

CHEMICAL STRUCTURE



CHEMICAL FORMULA

Unspecified

IDENTIFIER DETAILS

CAS Number	:	9004-57-3
CoE Number	:	-
FEMA	:	-
EINECS Number	:	-
E Number	:	-

SPECIFICATIONS

Melting Point: 240^{o}C

Boiling point: Not known

STATUS IN FOOD AND DRUG LAWS

CoE limits:

Beverages (mg/kg)	Food (mg/kg)	Exceptions (mg/kg)
-	-	-

Acceptable Daily Intake:

ADI (mg/kg)	ADI Set by	Date Set	Comments
Not specified	JECFA	1989	Group ADI for modified celluloses: ethyl cellulose, ethyl hydroxyethyl cellulose, hydroxypropyl cellulose, hydroxypropylmethyl cellulose, methyl cellulose, methyl ethyl cellulose, and sodium carboxymethyl cellulose

FDA Status: CFR 21

Section Number	Comments
73.1	Listing of colour additives exempt from certification
172.868	Food additives permitted for direct addition to food for human consumption
182.90	GRAS: Substances migrating to food from paper and paperboard products
573.420	Food additives permitted in feed and drinking water of animals

HUMAN EXPOSURE

Natural Occurrence: Not reported to occur in nature.

Reported Uses: Ethyl cellulose is used as a microcapsule material, binder and filler [FDA, 01/04/09]. This compound is also used as a food additive, rubber substitute, adhesive, lacquer and coating [FDA, 01/04/09]. It is also a key component of printing inks, and paper food packaging materials [FDA, 01/04/09].

TOXICITY DATA

Species	Test Type	Route	Reported Dosage
Rat	LD_{50}	Oral	5g/kg BW
Rabbit	LD_{50}	Skin	5g/kg BW

[ChemIDplus viewed 07/09/09]

***In Vivo* Toxicity Status**

Kotkoskie and Freeman (1998) studied the effects of dosing Sprague-Dawley rats with Aquacoat ECD ethyl cellulose aqueous dispersion via oral gavage at doses of 903, 2709 or 4515 mg/kg BW for 90 days. When compared with control rats no statistically significant changes in body weight, food consumption, organ weight or haematology were observed. However, in male rats receiving more than 2709 mg/kg; there was an elevation of ALT and AST levels and a reduction in total protein and globulin levels. Histopathology revealed no adverse effects. The NOAEL was deemed to be greater than 4.5 g/kg BW in female rats and 903 mg/kg BW in male rats [Kotkoskie and Freeman, 1998].

Another study exposed groups of 80 rats orally to 1.2% Ethyl cellulose for 8 months; this is equivalent to 182 mg/rat/day. No changes in appearance, behaviour or growth occurred in any of the animals. Gross pathology and histology revealed no adverse effects [Patty's Industrial Hygiene and Toxicology 3rd Ed].

DeMerlis *et al*. (2005) administered an aqueous Ethyl Cellulose dispersion orally to Sprague-Dawley CD rats (20/sex/group) at doses of 0, 2000, 3500, and 5000 mg/kg/day for a minimum of 3 months. None of the exposed animals died during the dosing stage. At 3 months the rats were euthanized; had specific organs weighed and complete macroscopic and histopathological examinations. No statistically significant adverse changes were observed in either the organ weights, macroscopic or histopathological analyses. The highest dose tested was therefore deemed to be the NOAEL (5000 mg/kg/day) [DeMerlis *et al.,* 2005].

Reproductive and Developmental toxicity

The development toxicity of Aquacoat ECD ethylcellulose aqueous dispersion was assessed by Freeman *et al*. (2000) in sets of 25 Charles River Sprague-Dawley CD rats. These rats were presumed to be pregnant and were exposed by oral gavage to doses of 0, 903, 2709 and 4515 mg/kg/day of Aquacoat ECD once a day on days 6-15 of gestation. On day 20 of gestation the surviving foetuses were removed by caesarean section, weighed, and killed. Gross and microscopic examination of the dams revealed no toxic effects, with foetal sex ratios and body weights being similar to controls. Skeletal examination of the foetuses revealed ossified or waxy ribs in foetuses receiving 4514 mg/kg/day; also an increase in incidence of thickened ribs was observed at doses of 2709 mg/kg/day and higher. These findings were deemed statistically significant. No statistically significant changes were observed in any of the mothers [Freeman *et al*., 2000].

Behavioural data

DeMerlis *et al.* (2005) performed neurobehavioural tests on equal numbers of rats from each dose group that had been exposed to an aqueous Ethyl Cellulose dispersion in the subchronic test. Over four different staggered sessions the following evaluations were implemented: home cage evaluations,

handling evaluations, open field evaluations, reflex assessments, grip strength, landing foot splay, proprioception, air righting ability and body weight. None of these evaluations revealed any adverse effects.

Carcinogenicity and Mutagenicity

DeMerlis *et al .* (2005) assessed the genotoxicity of an aqueous Ethyl Cellulose dispersion using the Ames and Mouse Lymphoma tests. *Salmonella Typhimurium* stains TA1535, TA1537, TA98 and TA100 and an *Escherichia Coli* strain WP2uvrA/Pkm101 were exposed to 5000 µg/plate of the dispersion, in the presence or absence of S9. No mutagenic activity was observed at the concentration tested. For the mouse lymphoma assay a subline of 3.7.2.c of mouse lymphoma L5178Y cells was exposed to 250 µg/ml for 3 (plus or minus S9) or 24 hours (minus S9). From the results it was concluded that the ethyl cellulose dispersion did not display mutagenicity.

Other relevant studies

The pyrolysis products of ethyl cellulose and of cigarette paper treated with ethyl cellulose was examined by Forehand *et al.* (1995) using two different pyrolysis methods. The first technique involved pyrolysing the sample at 600^{o}C then analysing the products given off using GC/MS with a polar chromatographic column. The other technique also involved pyrolysin g the sample at 600^{o}C but this time used off line derivatization with BSTFA followed by GC/MS . Pyrolysis of ethyl cellulose on it 's own yielded the following products: Acetaldehyde, 1,3-Cyclopentadiene, Propanal, Ethoxyethene, Ethanol, Propenal, Furan, Ethoxypropene, Ethanol and Ethoxypropanal. Some of the products generated from pyrolysis of an ethyl cellulose treated paper include: Acetaldehyde, 1,3-Cyclopentadiene, Propanal, Furan, 2-Propanone, 5-methyl-1,3-Cycloptentadiene, 2,3-Dihydrofuran, 2-Propenal, 2-methyl-Furan and Butanal .

Trace metal analysis of ethyl cellulose ash revealed the following heavy metal concentrations: nickel 31ppm, iron 16ppm and copper 5ppm [Communication from General Cigar and Tobacco Co. 1977]. Traces of lead, cadmium and zinc were also detected at concentrations less than 3ppm.

REFERENCES

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