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Regulatory Compliance Letter

Product Name: Hydrogenated Castor Oil (HCO)

To Whom It May Concern

Subject: HCO (castor oil, hydrogenated or also called Hydrogenated Castor Oil)

I. Regulation EU 10-2011

The HCO may be considered as substance falling under S.No.44 (glycerol, esters with 12-hydroxystearic acid) which are to be used for EEC packaging material numbers 56495. The HCO may also be considered as substance falling under S.No.37 (fats & oils, hydrogenated) which are to be used for EEC packaging material numbers 54480. These substances are authorized to be used as additives or as polymer production aids (PPAs) without any restrictions.

HCO complies with the requirement of Annex II (residual metals & aromatic amines) viz.

Barium	< 1mg / kg
Cobalt	< 0.05mg / kg
Copper	< 5mg / kg
Iron	< 48mg / kg
Lithium	< 0.6mg/kg
Manganese	< 0.6mg / kg
Zinc	<25mg/kg

Under German Legislation, it is listed at ID 250 in the Database BfR Recommendations on Food Contact Materials.

Also HCO produced by us is free of aromatic amines It is not a Dual Use additive nor a Colorant.

II. HCO is listed under US FDA 21CFR - Indirect Food additives as follows:

178.3280 Adjuvants, Production Aids & Sanitizers

177.1200 Polymers - Cellophanes

177.2800 Textile & Textile fibres

176.210 Defoaming agents used in the manufacture of paper & paperboard

176.180 Paper & Paperboard in contact with dry food

176.170 - Components of paper & paperboard in contact with aqueous and fatty foods

175.300 - Components of resinous & polymeric coatings

175.105 - Components of adhesives

Our HCO product can comply with the pharma grade specifications, without labelling as pharma grade as no official licence. Also HCO is used as an intermediate to convert to products like ethoxylates, which are covered under specifications of Pharmacopoeia and to function as emulsifiers/solubilizers for pharmaceutical ingredients e.g. vitamins and some other drugs.

Regarding food or feed grade:

As such, HCO is not a food (to the best of our knowledge), but it can be used for applications related to processing of food packaging materials, food contact lubricants, paper coatings in contact with dry food. HCO is listed in EU 10-2011 & various sections of US FDA 21CFR (as mentioned above).

Regarding feed, which we understand is for animals, HCO is very likely used as an intermediate to convert to products like ethoxylates to function as solubilizers/ emulsifiers for improving the digestibility of feed ingredients e.g. vitamins, oils, etc. There is some unofficial information that HCO is used to help in the floatation of the fish baits.

