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Our Ref: JNSH/AB

17 June 2004

To: Captain H Snaith, Intertanko

Dear Howard

SUBMISSION OF DATA TO THE EUROPEAN COMMISSION

You will recall that when the EC introduced Directive 2004/4/EC of 15 January 2004, a statement was included in the 'Whereas:' preamble that certain substances continued to be considered as 'provisionally acceptable':

(5) In the case of iso-decanol, iso-nonanol, iso-octanol, montan wax, paraffin wax and white mineral oils the information available was inadequate to carry out a complete valuation. However, according to the opinion of the Scientific Committee on Food, these substances may be considered as provisionally acceptable as previous cargoes considering their unlikely genotoxic potential, their easy removal by tank cleaning procedures and the very low residues expected as a result of these factors and their likely dilution.

(6) These provisionally acceptable substances should be reassessed on the basis of new scientific data and the Annex reviewed as appropriate within an adequate period of time. The data needed for the above evaluation should be provided, in particular, by relevant food business operators.

The Commission has stated that it plans to update the List after a three year period, i.e. in early 2007. This means that any new data to support the continuation of these products on the EU Acceptable List must be submitted to the SCF by early 2006. If no further relevant data is submitted, then it is probable that these substances will be removed from the EU List of Acceptable Previous Cargoes.

Originally, very limited data on these substances, and indeed, all of the substances, was submitted to the EU prior to the issuing of the directive in 1996. The detailed data which was available, much from the NIOP files, was submitted by FOSFA in November 2001 (an example of this for Iso-decanol is attached). Some further information and an explanation of how the physical and chemical properties could be interpreted with respect to the processing steps within our industry was submitted in 2002. It was explained that a high solubility in water meant that any residues would be removed in the washing process, and that even low saturated vapour pressure materials would be removed during the deodorisation process. This further information is also attached. In their latest opinion, the SCF have stated that the information that was provided was 'inadequate to reconsider SCF's opinion'. During the submission procedure, the SCF Secretariat stressed that what was required was essentially biological and toxicological data. A thorough search of the standard references and the Internet revealed very little data in this area. It is suggested that this is the area where further investigation is required.

Unfortunately, as you know, FOSFA does not have any expertise in-house in this area. Thus, I am writing to you, as FOSFA Members within the shipping industry, to firstly remind you of the EC requirement for further data, but mainly to request your help in approaching companies which are producing these substances to provide you/us with any biological or toxicological data which they may have. A description of type of data that is required to allow a toxicological evaluation to be made is attached. I hope that the manufacturers will readily provide you with this data in the interests of maintaining the current level of flexibility, beneficial to both the shipping industry and the trade.

My previous dealings with the Commission indicate that a re-submission of data which has already been submitted would be of little value, and indeed, would only irritate the SCF. The members of the SCF are experts from both academia and industry. They will not be 'blinded by science' or the weight of the submissions. This is the second time they have asked for new data. I feel that without the submission of new toxicological data, the EU Acceptable List will be further reduced with the removal of these substances. We feel that data should be supplied by the Members whose best interests are served by these substances remaining on the List.

Yours sincerely

A handwritten signature in cursive script that reads "JNS Hancock".

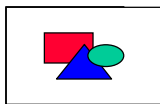
John Hancock
Technical Manager

ISODECYL ALCOHOL (MIXED ISOMERS)		ICSC: 0495
		October 1999
	Isodecanol (mixed isomers)	
CAS #	25339-17-7	C ₁₀ H ₂₁ OH
RTECS #	NR0960000	Molecular mass: 158.3
UN #		
EC #		

TYPES OF HAZARD / EXPOSURE	ACUTE HAZARDS / SYMPTOMS	PREVENTION	FIRST AID / FIRE FIGHTING
FIRE	Combustible.	NO open flames.	Powder, AFFF, foam, carbon dioxide (Note: Water may be ineffective).
EXPLOSION			

EXPOSURE			
Inhalation	Cough. Dizziness. Dullness. Headache. Nausea. Sore throat.	Ventilation.	Fresh air, rest. Refer for medical attention.
Skin	Dry skin. Redness.	Protective gloves.	Remove contaminated clothes. Rinse and then wash skin with water and soap. Refer for medical attention
Eyes	Redness. Pain.	Safety goggles.	First rinse with plenty of water for several minutes (remove contact lenses if easily possible), then take to a doctor.
Ingestion	Diarrhoea. Vomiting. (Further see Inhalation).	Do not eat, drink, or smoke during work.	Rinse mouth. Rest. Refer for medical attention.

SPILLAGE DISPOSAL	PACKAGING & LABELLING
Collect leaking and spilled liquid in sealable containers as far as possible. Absorb remaining liquid in sand or inert absorbent and remove to safe place.	EU Classification UN Classification
EMERGENCY RESPONSE	STORAGE
NFPA Code: H 0; F 1; R 0;	Separated from strong oxidants.



IPCS International Programme on Chemical Safety	Prepared in the context of cooperation between the International Programme on Chemical Safety and the Commission of the European Communities © IPCS, CEC 1999 SEE IMPORTANT INFORMATION ON BACK
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ISODECYL ALCOHOL (MIXED ISOMERS)	ICSC: 0495
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IMPORTANT DATA	
PHYSICAL STATE; APPEARANCE: SLIGHTLY VISCOUS LIQUID , WITH CHARACTERISTIC ODOUR.	ROUTES OF EXPOSURE: The substance can be absorbed into the body by inhalation and through the skin, and by ingestion.
CHEMICAL DANGERS: Reacts with strong oxidants.	INHALATION RISK: No indication can be given about the rate in which a harmful concentration in the air is reached on evaporation of this substance at 20°C.
OCCUPATIONAL EXPOSURE LIMITS: TLV not established.	EFFECTS OF SHORT-TERM EXPOSURE: The substance irritates the eyes, the skin and the respiratory tract. Exposure could cause central nervous system depression.
	EFFECTS OF LONG-TERM OR REPEATED EXPOSURE: The liquid defats the skin.
PHYSICAL PROPERTIES	
Boiling point: 220°C Melting point: 7°C Relative density (water = 1): 0.84 Solubility in water, g/100 ml: 2.5 Vapour pressure, kPa at 70°C: 0.13 Relative vapour density (air = 1): 5.5	Relative density of the vapour/air-mixture at 20°C (air = 1): 1.00 Flash point: 104°C o.c. Auto-ignition temperature: 266°C Explosive limits, vol% in air: 0.8-4.5
ENVIRONMENTAL DATA	
This substance may be hazardous to the environment; special attention should be given to fish.	
NOTES	
ADDITIONAL INFORMATION	

FURTHER INFORMATION SUBMITTED TO SCF OF EC, NOVEMBER 2001

Iso decyl alcohol, iso nonyl alcohol and iso octyl alcohol

These products were accepted provisionally on the EU List. These products are used as anti-foaming agents in textile processing, plasticisers and intermediates in detergents and surfactants. In their pure form, they are considered to be moderately toxic by ingestion. However, their boiling points are such that any trace would be easily removed during the deodorisation stage of processing.

Montan wax

This substance is a defoaming agent and is permitted by the FDA in the manufacture of paper and paper to and intended for use in packaging, transporting, or holding food. It is a substitute for Carnauba wax and beeswax.

Petroleum wax (food grade)

This substance is a mixture of solid hydrocarbons, paraffinic in nature, derived from petroleum and refined to meet specifications found in the Code of Federal Regulations. It meets the FDA requirements set forth in 21 CFR, 178.3710 for use in non-food articles in contact with food, in 21 CFR, 172.886 for use in food.

White mineral oil

This product has been used as a food additive for glazing dried fruit and in chewing. JECFA has published a report which documents an ADI for mineral oil with a viscosity of ISO 100 (Ref. 3). The ADI established by JECFA is similar to the daily intake that FDA considered acceptable when it approved an increased level of use of mineral oil as a dust control agent for rice.

**Updated opinion
of the Scientific Committee on Food
on the potential risk to human health arising from
the transport in ships' tanks of oils and fats from
substances proposed as acceptable previous cargoes
(expressed on 4 April 2003)**

Substance	CAS No.	Previous Evaluation (SCF 1996)	Present Evaluation (this opinion)
iso-Decanol (isodecyl alcohol)	25339-17-7	PROVISIONALLY ACCEPTABLE	PROVISIONALLY ACCEPTABLE
iso-Nonanol (iso-nonyl alcohol)	27458-94-2	No toxicological data, mixtures of isomers of uncertain composition.	Information provided was inadequate to reconsider SCF's opinion.
iso-Octanol	26952-21-6	Easily removed by the oil refining process.	
Montan wax	8002-53-7	PROVISIONALLY ACCEPTABLE Regarded as temporarily acceptable by the SCF as a food additive, highly insoluble	PROVISIONALLY ACCEPTABLE Information provided was inadequate to reconsider SCF's opinion.
Paraffin wax	8002-74-2 & 63231-60-7	PROVISIONALLY ACCEPTABLE only for those types which are considered temporarily acceptable as food additives by the Committee pending further data	PROVISIONALLY ACCEPTABLE Information provided was inadequate to reconsider SCF's opinion.
White mineral oils	8042-47-5	PROVISIONALLY ACCEPTABLE only for those types which are considered temporarily acceptable as food additives by the Committee pending further data	PROVISIONALLY ACCEPTABLE Information provided was inadequate to reconsider SCF's opinion.

Toxicological Properties

Route of Entry

A chemical can enter the body by several routes:

- Inhalation (breathing)
- Contact with skin or eyes (localized irritation)
- Absorption through the skin and eyes (systemic)
- Ingestion
- Injection with a needle or cuts from contaminated glassware

All routes of entry must be shown, for example methanol is absorbed by inhalation, through the skin and it can be ingested.

Effects of Acute Exposure

Acute exposures are short term exposures, usually either a single exposure or multiple exposures occurring within a short time, typically 24 hours or less. The health effects of over-exposure are normally seen quickly, but can occur for an extended period of time depending on the exposure.

Effects of Chronic Exposure

Chronic exposures are long term and occur repeatedly over months or years. Some examples are cancer, asbestosis and silicosis. Sometimes the health effects may result from a single exposure, but the symptoms may take a long period of time to develop.

Exposure Limits

These are the legislated or recommended limits of an airborne substance to which a worker is allowed to be exposed. These limits generally represent conditions in which it is believed that nearly all workers may be repeatedly exposed day after day without adverse effect.

Because exposure limits may vary from one jurisdiction to another, it is appropriate for suppliers to specify the agency responsible for the limit cited on the supplier MSDS and to include a statement advising employers to check with the local regulatory agency for the limit in effect in their area.

There are three types of limits in common use:

1. Exposure Limit – TWA
This is the time-weighted average concentration for a normal 8-hour work day or 40-hour work week to which nearly all workers can be repeatedly exposed without adverse effect.
2. Exposure Limit – STEL
This is the short-term exposure limit, i.e. the maximum concentration to which workers can be periodically exposed for a period up to 15 minutes without suffering from irritation, chronic or irreversible tissue change, or narcosis of sufficient degree to increase risk of accidental injury, or impair ability for self-rescue.
3. Exposure Limit – C
This is the ceiling concentration of an airborne substance that must not be exceeded at any time. This limit is applied to substances that are primarily irritant or fast-acting and for which the TWA is inappropriate.

Irritancy of Product

This section provides information on the primary irritant qualities of the material, i.e. its capability to cause localized effects such as irritation, erythema, burn or swelling at the site of contact on the skin, eyes, or mucosal areas.

Sensitizing Capability of Product

A sensitizer is a substance which on first exposure likely causes little or no reaction in persons or test animals, but which on repeated exposure may cause a marked response not necessarily limited to the contact site.

Carcinogenicity

This section indicates if a chemical is a suspected carcinogen, or a cancer causing agent. Repeated exposure to the chemical may cause cancer.

Teratogenicity and Embryotoxicity

This section indicates if a product is a teratogen. These chemicals can induce birth defects if a pregnant woman is exposed to them. The embryonic stage of development of the fetus (2 to 8 weeks) is particularly at risk of injury to such products.

Reproductive Toxicity

This section indicates if the chemical is a reproductive toxin. These chemicals can cause sterility or adverse effect on reproductive capability.

Mutagenicity

This section indicates if a product is a mutagen. These substances produce changes in the genetic material (RNA/DNA) of living cells. Changes to reproductive (germ) cells may result in heritable genetic effects. Changes to non-reproductive (body) cells may be associated with increased risk of other effects such as cancer.

Synergistic Materials

This section identifies any material which interacts with the controlled product to produce a toxic effect greater than the sum of the effects of the material and the controlled product acting separately. Example: asbestos and cigarette smoke

Optional Information Items

If the LD₅₀ or LC₅₀ has not been determined for a product as a whole where the product is a mixture, the supplier may report an estimated LD₅₀ or LC₅₀ for the whole product that is calculated on the basis of the lethality of the ingredients.