RUM

SYNONYMS

Jamaica rum
White rum
Dark rum
Rum Martinique
Rum Extract (absolute)

CHEMICAL STRUCTURE

Undefined (mixture of components)

CHEMICAL FORMULA

Undefined (mixture of components)

IDENTIFIER DETAILS

CAS Number	:	90604-30-1, 91450-09-8 (Rum ether 8030-89-5)
CoE Number	:	-
FEMA	:	-
EINECS Number	:	292-323-0
E Number	:	-

SPECIFICATIONS

Melting Point: -

Boiling point: -

PURPOSE

Flavouring substance.

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
-	-	-	

FDA Status:

Section Number	Comments
172.515	Food additives permitted for direct addition to food for human consumption - Synthetic flavouring substances and

	adjuvants (as rum ether)

HUMAN EXPOSURE

Natural Occurrence: Rum does not occur in nature but is derived from natural ingredients.

Reported Uses: After distillation, rums are about 94.5% alcohol (ethanol) by volume but diluted to about 80% before aging. Ethanol is present as an endogenous substance in the blood of man, being produced probably in the intestinal tract, at an average level of 1.5 mg/l [Baselt, 1988].

TOXICITY DATA

Carmines *et al*., (2002), Rustemeier *et al*., (2002), Roemer *et al*., (2002) and Vanscheeuwijck *et al.,* (2002) reported on a testing program designed to evaluate the potential effects of 333 ingredients added to typical commercial blended test cigarettes on selected biological and chemical endpoints. The studies performed included a bacterial mutagenicity screen (Ames assay) a mammalian cell cytotoxicity assay (neutral red uptake), determination of smoke chemical constituents and a 90-day rat inhalation study. Based on the findings of these studies, the authors concluded that the addition of the combined ingredients, including rum at levels up to 261 ppm, "did not increase the overall toxicity of cigarette smoke" [Carmines *et al*., 2002].

In Vivo Toxicity Status

Carcinogenicity and mutagenicity

Huang *et al.,* (2003) investigated the association between alcohol concentration and the risk of oral cancer (mouth and pharynx) in Puerto Rico by comparing alcohol intake between 286 male cases (age 21-79 years old) and 417 p opulation based male controls (frequency matched by age). Elevated risks associated with home made rum were similar to other types of liquor. For example heavy consumers of liquor (>/=43 drinks per week) had an increased risk of developing oral cancer (od ds ration = 6.4, 95% confidence interval: 2.4, 16.8) and the risks were considerably greater for liquor drinkers who drank undiluted liquor compared to those who diluted the liquor with a mixer (odds ration = 4.0, 95% confidence interval: 2.4, 6.7). This s tudy also reported that risks associated with combined exposure to tobacco and liq uor were increased when straight liquor was consumed [Huang *et al.,* 2003].

Similarly, a recent mouse skin painting study investigated the carcinogenicity of condensate prep ared from cigarettes containing a number of additives in combination, including rum ether at 0.1 ppm. The authors concluded that the study "did not indicate any substantive effect of these ingredients on the tumorigenicity of cigarette smoke condensate " (Gaworski *et al.* , 1999) (It should be noted that the cigarettes contained a typical American blend humectant and sugar component (*i.e.* glycerine 20,000 ppm, propylene

glycol at 24,000 ppm, and brown invert sugar at 24,000 ppm)) (Gaworski *et al.*, 1999).

Inhalation toxicity

When tested at 22046 ppm in cigarettes, in a 13-week inhalation study, the presence of rum "…had no discernible effect on the character of extent of the biologic responses normally associated with inhalation of mainstream cigarette smoke in rats."[Gaworski *et al.*, 1998]. (However, it should be noted that the cigarettes had been spiked with a number of flavour ingredients in combination prior to smoking, and they contained a typical American blend humectant and sugar component (*i.e.* glycerine 20,000 ppm, propylene glycol at 24,000 ppm, and brown invert sugar at 24,000 ppm).

A recent study investigated the effect of cigarettes, containing various additives in three combinations, in a 90-day nose-only smoke inhalation study in rats. These ingredients included rum at 261 ppm, a level described as a multiple of its typical use in a US cigarette. The data from this study, along with that from a number of other biological and chemical studies indicate that the addition of the combined ingredients "did not increase the inhalation toxicity of the smoke, even at the exaggerated levels used" [Vanscheeuwijck *et al.*, 2002].

The addition of white rum at 5850 ppm to reference cigarettes, used in a 90 day-sub-chronic inhalation exposure in rats, led to a series of pathological changes to smoke exposure that were indistinguishable from those changes caused by the control cigarettes. This indicated that addition of white rum to a reference cigarette had no discernable effect upon the type or severity of the treatment related pathological changes associated with tobacco smoke exposure [Baker *et al.,* 2004]

A total of 31 ingredients were tested in 90-day nose-only rat inhalation studies using mainstream cigarette smoke. Studies were designed following conventional toxicity testing methods employed for food additives and other consumer products. The authors concluded that these added ingredients, which included Rum at levels up to 15,000 ppm produced minimal changes in the overall toxicity profile of mainstream cigarette smoke, and in some cases, the addition of high levels of an ingredient caused a small reduction in toxicity findings, probably due to displacement of burning tobacco [Gaworski *et al*., 2011].

The addition of rum extract (absolute) at 12 ppm or dark rum at 2340 ppm to reference cigarettes, used in a 90 day-sub-chronic inhalation exposure in rats, led to a series of pathological changes to smoke exposure that were indistinguishable from those changes caused by the control cigarettes. This indicated that addition of rum extract (absolute) to a reference cigarette had no discernable effect upon the type or severity of the treatment related pathological changes associated with tobacco smoke exposure [Baker *et al.,* 2004].

Behavioural data

No data identified

In Vitro Toxicity Status

Carcinogenicity and mutagenicity

Additional information concerning the *in vitro* mutagenicity of this material may be found in "An Interim report on data originating from Imperial Tobacco Limited's Genotoxicity testing programme September 2003" or "An updated report on data originating from Imperial Tobacco Limited's external Genotoxicity testing programme – Round 2 August 2007".

Roemer *et al.,* (2002) reported on a study in which cigarettes containing various additives in three different combinations were produced. Smoke condensates prepared from these cigarettes were then tested in two different *in vitro* assays. The mutagenicity of the smoke condensate was assayed in the *Salmonella* plate incorporation (Ames) assay with tester strains TA98, TA100, TA102, TA1535 and TA1537 in the presence and absence of an S9 metabolic activation system. The cytotoxicity of the gas/vapour phase and the particulate phase was determined in the neutral red uptake assay with mouse embryo BALB/c 3T3 cells. The authors concluded that the *in vitro* mutagenicity and cytotoxicity of the cigarette smoke was not increased by the addition of the ingredients which included rum at levels up to 261 ppm (a multiple of its typical use in a US cigarette) [Roemer *et al.,* 2000].

Baker *et al.,* [2004]; examined the effects of the addition of 482 tobacco ingredients upon the biological activity and chemistry of mainstream smoke. The ingredients, essentially different groups of flavourings and casings, were added in different combinations to reference cigarettes. The addition of white rum at 5850 ppm was determined not to have affected the mutagenicity of the total particulate matter (TPM) of the smoke in either the Ames, *in vitro* micronucleus assay or the neutral red assay when compared with that of the control cigarettes [Baker *et al.,* 2004].

In Vitro Toxicity Status

Carcinogenicity and mutagenIcity

Ariza *et al*., (1992) reported on the mutagenicity of evaporated residues of brandy in the Ara *Salmonella typhimurium* forward mutation assay. In this study it was revealed that five brands of French brandy were mutagenic without activation and on the inclusion of S-9 mutagenic activity was either reduced or abolished. The authors reported that the phenolic beverage component could lead to the production of active oxygen intermediates through an autooxidative process. The authors also reported that non-matured distilled beverages such as gin or non-matured rum were not mutagenic in this test, (Ariza *et al*., 1992).

Baker *et al.,* [2004]; examined the effects of the addition of 482 tobacco ingredients upon the biological activity and chemistry of mainstream smoke.

The ingredients, essentially different groups of flavourings and casings, were added in di fferent combinations to reference cigarettes. The addition of rum extract (absolute) at 12 ppm or dark rum at 2340 ppm was determined not to have affected the mutagenicity of the total particulate matter (TPM) of the smoke in either the Ames, *in vitro* micronucleus assay or the neutral red assay when compared with that of the control cigarettes [Baker *et al.,* 2004].

A total of 95 ingredients were tested individually through addition at different concentrations to the tobacco of experimental cigarettes. Mainstream cigarette smoke chemistry analysis, bacterial mutagenicity testing, and cytotoxicity testing were conducted. The authors concluded that these added ingredients, which included Rum at levels up to 15,000 ppm produced minimal changes in the overall toxicity profile of mainstream cigarette smoke, and in some cases, the addition of high levels of an ingredient caused a small reduction in toxicity findings, probably due to displacement of burning tobacco [Gaworski *et al*., 2011].

REFERENCES

Ariza *et al*., (1992). Study on the mutagenicity of brandy with the Ara test. *Mutagenisis* **7**: 77.

Baker RR, *et al.,* (2004) An overview of the effects of tobacco ingredients on smoke chemistry and toxicity. *Food Chem Toxicol*. **42** Suppl: S53-83.

Baselt (1988). Biological Monitoring Methods for Industrial Chemicals. 2nd ed. Littleton, MA: PSG Publishing Co., Inc. 1988. 140.

Carmines E. L. (2002). Evaluation of the potential effects of ingredients added to cigarettes. Part 1: Cigarette design, testing approach, and review of results. *Food and Chemical Toxicology* **40**: 77-91.

Gaworski *et al.*, (1998). Toxicologic evaluation of flavor ingredients added to cigarette tobacco: 13-week inhalation exposure in rats. *Inhalation Toxicology*. **10**: 357-381.

Gaworski *et al.*, (1999). Toxicologic evaluation of flavor ingredients added to cigarette tobacco: skin painting bioassay of cigarette smoke condensate in SENCAR mice. *Toxicology* **139**: 1-17.

Gaworski *et al*., (2011). An evaluation of the toxicity of 95 ingredients added individually to experimental cigarettes: approach and methods. Inhalation Toxicology: 1-12

Huang WY, Winn DM, Brown LM, Gridley G, Bravo-Otero E, Diehl SR, Fraumeni JF Jr & Hayes RB (2003). Alcohol concentration and risk of oral cancer in Puerto Rico. *American Journal of Epidemiology.* **157(10):** 881-887.

Roemer *et al.,* (2002). Evaluation of the potential effects of ingredients added to cigarettes. Part 3: *In vitro* genotoxicity and cytotoxicity. *Food and Chemical Toxicology* **40**: 105-111.

Rustemeier *et al.,* (2002). Ev aluation of the potential effects of ingredients added to cigarettes. Part 2: Chemical composition of mainstream smoke. *Food and Chemical Toxicology* **40**: 93-104.

Vanscheeuwijck *et al.,* (2002). Evaluation of the potential effects of ingredients added to cigarettes. Part 4: Subchronic inhalation toxicity. *Food and Chemical Toxicology* **40**: 113-131.