Product Stewardship Summary  Fumaric Acid

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Introduction

We Thirumalai Chemicals Limited, have continually committed to protecting our society and the environment by safe with care operational manufacturing base capable and are delivering quality products with excellent logistics and technical support.

Fumaric Acid can replace traditional acidulants in the preparation of fruit juice drinks at substantial material and cost savings.

In Pharmaceutical industry, Fumaric Acid finds a major use for Ferrous Fumarate.

Industrial use as intermediate and monomer for production of resins.
Appreciable quantities of Fumaric acid are used in fruit-juice drinks, gelatin desserts, pie fillings, refrigerated biscuit dough, maraschino cherries and wines. Fumaric acid increases the strength of gelatin gels and acts as a calcium liberator when incorporated in alginate preparations. It is also a valuable chemical reactant for preparing various edible coatings for candy, water-in-oil emulsifying agents, reconstituted fats and dough conditioners.

Fumaric acid displays good antioxidant properties when used to prevent rancidity from developing in lard, butter, cheese, powdered milk, sausage, bacon, frankfurters, nuts and potato chips. It can be used in preservation green foods and fish to supply the acidity required when sodium benzoate is used as a preservative. It has been suggested also as an ingredient in combination with magnesium carbonate in baking powder. It may also be used for improving the whipping properties of gelatin and egg white and products containing them.

Fumaric acid increases the strength of gelatin gels and acts as a calcium liberator when incorporated in alginate preparations.
**Description and properties**

The chemical structure of a Fumaric acid contains two critical parts:

1) Ethylene group
2) Carboxyl group

Fumaric Acid is found abundantly in nature. Fumaric Acid has a slight acid taste. It is free flowing, stable and non-hygrosopic. Fumaric acid is non flammable, not flammable in contact with water.

Oxidising properties based on the fact that fumaric acid is incapable of reacting exothermically with combustible materials.

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The chemical structure of a Fumaric acid contains two critical parts.

1) Ethylene group
2) Carboxyl group
Fumaric acid contains only ethylene and carboxyl groups, and no moieties that would lead to potential for explosion.

Fumaric acid (trans-1,2-ethylenedicarboxylic acid) is manufactured through the catalysed isomerisation of Maleic acid (cis-1,2-ethylenedicarboxylic acid), Maleic acid is manufactured mainly by the hydrolysis of Maleic anhydride (MA). MA is hydrolysed to Maleic acid with water at room temperature.

Maleic acid is isomerised to Fumaric acid either under heat or using a variety of catalysts.
Health Information

Studies of Fumaric acid by the dermal, oral and inhalation routes of exposure indicate that these substances are relatively low in acute toxicity by all the three routes of exposure. Exposure via inhalation to the highest vapor concentration attainable did not cause any deaths or signs of systemic toxicity. (Since the particle size is largely non-respirable, no significant exposure can be predicted.)

Studies indicate that these substances are not irritating to the skin but moderately irritating to the eyes. Studies have not shown any evidence of skin sensitization.

Repeated dose toxicity studies with Fumaric acid demonstrated that none of the tested substances caused systemic toxicity. Toxicity studies conducted by oral exposure demonstrate that fumaric acid do not cause developmental malformations.

Fumaric acid plays an essential role in metabolism and is a naturally occurring compound that has been used in human therapy since ancient times. Based on the available information, no further testing is necessary for hazard identification or risk assessment purposes. Over the past 30 years, fumaric acid esters have been used in the treatment of psoriasis, both topically and orally.
Dietary exposure also results from the large volumes of fumaric acid used as a food acidulant in applications such as beverages, baking powders, and fruit drinks. The major route of exposure of the general population to exogenous fumaric acid is through consumption of food and beverages.

Based on the evidence from mutagenicity assays and carcinogenesis investigations there are no indications of any human tumorigenic potential for fumaric acid.

Fumaric acid occurs naturally in mammals and plays an essential role in metabolism, and the lack of reproductive effects in a study with the fumaric acid metabolite, maleic acid, provide sufficient information to determine that fumaric acid has a low toxicity profile and is not considered to be a reproductive toxicant.

Based on the evidence from mutagenicity assays and carcinogenesis investigations there are no indications of any human tumorigenic potential for fumaric acid.
Environmental Information:

Fumaric acid is readily biodegradable. Fumaric acid can be expected to have a low potential for bioaccumulation and soil adsorption. Fumaric acid not toxic to aquatic organism.
Regulatory Information

Requirements may exist that govern the manufacture, importation, sale, transportation, use, and/or disposal of Fumaric acid or products containing them. These requirements may vary by jurisdiction. For more information, consult the relevant Material Safety Data Sheet (MSDS) or contact us.

Fumaric Acid has been approved by the Food and Drug Administration of India for use in the food products under Prevention of Food Adulteration act, Government Gazette Notification 1972.

Fumaric Acid has been accorded Generally Recognised As Safe (GRAS) status by Food & Drug Administration of USA.

Joint Expert Committee on Food Additives of FAO, Rome and WHO, Geneva has given approval for use of Fumaric acid in Food Products.

Various tests conducted by different health bodies have cleared Fumaric acid as being safe for human beings.
Exposure Potential

Fumaric acid is manufactured in a closed batch reactor where opportunity for exposure can arise, e.g. during charging, sampling or discharge of the material. There is also potential exposure to workers during transfer of fumaric acid when filling the trucks with final product or when transferring the material into drums for further use.

The use of fumaric acid as a laboratory reagent is performed indoors with general ventilation. Exposure to fumaric acid is likely during charging, sampling or discharge of the material. Workers involved in the production, handling, sampling and transfer of materials are well-trained in these procedures and they use eye goggles, plastic gloves (no specific requirements but for example neoprene and coated neoprene / rubber / nitrile rubber gloves) and clothing with long sleeves and long legs, in order to minimise exposure.

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