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Toxicological Assessment of Tartrazine as a Synthetic Food Colorant: Regulatory Status, Metabolic Activation, and Adverse Health Effects

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Abstract:

Tartrazine, a synthetic azo dye, is widely used in the food, pharmaceutical, cosmetic, and textile industries to provide a stable yellow color. Its industrial prevalence is attributed to its superior cost-effectiveness, solubility, and stability compared to natural alternatives. This review consolidates current toxicological literature on tartrazine, addressing its chemical identity, global market trends, and regulatory framework. Also focus on the biochemical mechanisms responsible for its toxicity, including metabolic activation through azoreductase-mediated cleavage, induction of oxidative stress, and organ-specific damage. The analysis concludes that although tartrazine remains commercially essential, its potential health risks, such as hypersensitivity, hepatorenal toxicity, and genotoxicity, necessitate stringent regulation, ongoing toxicological research, and the development of safer alternatives.

Keywords: Tartrazine, Azo Dye, Food Additive, Oxidative Stress, Hepatotoxicity, Regulatory Toxicology

Introduction:

Food colorants are essential sensory additives that play a significant role in enhancing product appeal and consumer acceptance. These colorants are generally classified into two categories: natural, which are derived from biological sources, and synthetic, which are produced through chemical synthesis. Synthetic dyes, particularly azo dyes such as tartrazine, are prevalent in industrial applications due to their superior stability against heat and light, vibrant colours, and cost-effectiveness, qualities in which natural colorants often lack. Tartrazine, designated as E102 in the European Union, is among the most extensively used synthetic colorants worldwide. Its application is governed by a complex regulatory framework that requires thorough safety assessments and the determination of acceptable daily intake (ADI) limits. This

review offers a comprehensive toxicological analysis of tartrazine, covering its chemical properties, various applications, market trends, and scientific evidence concerning its physiological effects (Silva, 2021).

Chemical Profile and Structural Characteristics:

Tartrazine is a trisodium salt of a pyrazolone-based azo dye, characterized by the molecular formula $C_{16}H_9N_4Na_3O_9S_2$ and a molecular weight of 534.37 g/mol. Its systematic IUPAC designation is trisodium (4E)-5-oxo-1-(4-sulfonatophenyl)-4-[(4-sulfonatophenyl) hydrazono]-3-pyrazole carboxylate. The azo bond (–N=N–) connecting two aromatic rings is a defining structural feature, categorizing it within the azo dye family. The presence of sulfonate ($–SO_3^-$) groups imparts high water solubility and an anionic nature. This molecular structure is crucial for its dye functionality and influences its metabolic fate and potential toxicity. The azo bond is prone to reductive cleavage by bacterial azoreductase in the gastrointestinal tract, leading to the formation of aromatic amine metabolites, primarily sulfanilic acid and aminopyrazolone, which are associated with subsequent adverse biological effects (El-Hakam 2021).

Industrial Applications and Global Market Analysis:

Tartrazine's functional properties have established its significance across various sectors. In the food and beverage industry, it is commonly found in soft drinks, powdered drink mixes, ice cream, candies, confectionery, flavoured yogurts, snacks, and processed foods. The pharmaceutical sector utilizes it to color syrups, tablets, and capsules, facilitating brand identification and enhancing patient acceptability. Additionally, its application extends to cosmetics, such as soaps and shampoos, as well as textiles. Market analysis reveals significant growth, with projections from Dataintelo (2024) forecasting consistent global market expansion from 2022 to 2033, driven by its entrenched use in expanding consumer markets. Powdered tartrazine maintains a dominant market share due to its formulation ease and stability, while granular forms exhibit high growth potential for large-scale industrial food processing. This sustained growth trajectory continues despite increasing regulatory scrutiny and consumer awareness regarding synthetic dyes.

Regulatory Framework and Acceptable Intake Limits:

The use of tartrazine is subject to rigorous international and national regulations that define permissible levels to reduce health risks. The Joint FAO/WHO Expert Committee on Food Additives (JECFA) has established an Acceptable Daily Intake (ADI) of 0–7.5 mg/kg of body weight. Regulatory authorities implement this ADI by setting maximum permitted levels (MPLs) for specific food categories (Golli, 2016).

Mechanisms of Toxicity and Health Implications:

When ingested, tartrazine undergoes reductive metabolism in the colon, facilitated by azo reductase enzymes produced by intestinal microflora. This process results in the cleavage of tartrazine

into primary aromatic amine metabolites, specifically sulfanilic acid and 1-aminopyrazolone, which are biologically reactive. In the acidic environment of the stomach, the free amino groups of these metabolites can react with dietary nitrites and nitrates, leading to the formation of N-nitroso derivatives. These compounds are known for their cytotoxic and genotoxic properties and have the ability to diffuse across cellular membranes, thereby entering systemic circulation (Ibrahim, 2024).

Induction of Oxidative Stress and Cellular Damage:

The primary mechanism underlying tartrazine-induced toxicity involves the generation of oxidative stress. Aromatic amine metabolites and their nitroso derivatives lead to an overproduction of reactive oxygen species (ROS), thereby disrupting cellular redox homeostasis.

- **Lipid Peroxidation:** ROS target polyunsaturated fatty acids within cell membranes, compromising membrane integrity, fluidity, and function, which may result in cell lysis or apoptosis.
- **Protein Oxidation:** ROS oxidize amino acid side chains, such as cysteine and methionine, causing protein carbonylation, loss of enzymatic activity, and disruption of cellular signalling pathways.
- **DNA Damage:** Oxidative attacks on DNA result in base modifications, strand breaks, and adduct formation. If unrepaired, such damage can lead to mutations, chromosomal instability, and altered gene expression, which constitute the molecular basis for mutagenic and carcinogenic potential (Shakoor, 2020).
- **Organ-Specific Toxicity:** Chronic exposure to elevated levels of tartrazine has been associated with both functional and structural damage in critical organs (Golli, 2016).
- **Hepatotoxicity:** The liver, as the primary organ for xenobiotic metabolism, is particularly susceptible. Research indicates that tartrazine induces hepatic inflammation, hepatocellular degeneration, elevated liver enzyme levels, and fatty changes, all of which suggest impaired metabolic and detoxification functions (Silva, 2021).
- **Nephrotoxicity:** The kidneys, which are essential for filtration and excretion, also experience damage. Pathological alterations include glomerular congestion, tubular necrosis, and interstitial inflammation, which compromise renal clearance (Shakoor, 2020).

Neurotoxicity and Behavioural Effects:

Tartrazine is capable of crossing the blood-brain barrier. Evidence links its consumption to neuroinflammation, oxidative damage in neural tissue, and behavioural changes. Clinical studies have associated synthetic food colours with increased hyperactivity, irritability, and sleep disturbances in susceptible children (Obeid, 2020).

Immunological Reactions:

Tartrazine can provoke pseudo-allergic reactions (non-IgE mediated) in certain individuals, presenting as urticaria, asthma, angioedema, and rhinitis (Obeid, 2020).

Carcinogenic and Mutagenic Potential:

Although definitive human evidence is lacking, in vitro and animal studies provide supportive data. Genotoxic metabolites and sustained oxidative stress contribute to a pro-carcinogenic environment, necessitating a precautionary classification (Ibrahim, 2024).

Conclusion:

Tartrazine presents a paradox as an additive; it is economically valuable for its colouring efficacy, yet it is scientifically contentious due to its toxicological profile. This review confirms that its potential health risks, which include hypersensitivity, organ toxicity, and potential genotoxicity, are biologically plausible. These risks are rooted in metabolic conversion and the provocation of oxidative stress. Current regulatory [ADI] levels are intended to mitigate these risks for the general population; however, individual susceptibility and cumulative exposure from multiple sources remain concerns. Therefore, while tartrazine continues to hold significant industrial importance, a precautionary principle guided by robust science is essential. Balancing economic benefits with a steadfast commitment to public health safety requires concerted efforts from researchers, regulators, and industry.

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