Initial Risk-Based Prioritization of High Production Volume Chemicals

Carboxylic Food Acids and Salts Category

Acetic acid **(CASRN 64-19-7)**

Acetic acid, ammonium salt **(CASRN 631-61-8)**
(CA Index Name: Acetic acid, ammonium salt (1:1))

Acetic acid, potassium salt **(CASRN 127-08-2)**
(CA Index Name: Acetic acid, potassium salt (1:1))

Acetic acid, sodium salt **(CASRN 127-09-3)**
(CA Index Name: Acetic acid, sodium salt (1:1))

Acetic acid, calcium salt **(CASRN 62-54-4)**
(CA Index Name: Acetic acid, calcium salt (2:1))

Acetic acid, magnesium salt **(CASRN 142-72-3)**
(CA Index Name: Acetic acid, magnesium salt (2:1))

Acetic acid, manganese salt **(CASRN 638-38-0)**
(CA Index Name: Acetic acid, manganese(2+) salt (2:1)

Fumaric Acid **(CASRN 110-17-8)**
(CA Index Name: 2-Butenedioic acid (2E)-)

Malic Acid **(CASRN 6915-15-7)**
(CA Index Name: Butanedioic acid, 2-hydroxy-)

Citric Acid **(CASRN 77-92-9)**
(CA Index Name: 1,2,3-Propanetricarboxylic acid, 2-hydroxy-)

Citric acid, sodium salt (unspecified number of sodium atoms) **(CASRN 994-36-5)**
(CA Index Name: 1,2,3-Propanetricarboxylic acid, 2-hydroxy-, sodium salt (1:?))

Citric acid, trisodium salt **(CASRN 68-04-2)**
(CA Index Name: 1,2,3-Propanetricarboxylic acid, 2-hydroxy-, sodium salt (1:3))

Citric acid, tripotassium salt **(CASRN 866-84-2)**
(CA Index Name: 1,2,3-Propanetricarboxylic acid, 2-hydroxy-, potassium salt (1:3))

This document is based on screening-level characterizations done by EPA on the environmental fate, hazard, and exposure of the listed chemicals. The information used by EPA includes data submitted under the HPV Challenge Program[1] and the 2006 Inventory Update Reporting (IUR)[2], and data publicly available through other selected sources[3]. This screening-level prioritization presents EPA's initial thinking regarding the potential risks presented by these chemicals and future possible actions that may be needed. These initial characterization and prioritization documents do not constitute a final Agency determination as to risk, nor do they determine whether sufficient data are available to characterize risk. Rather, they are interim evaluations. Recommended actions may be considered by EPA in the future based on a relative judgment regarding this chemical in comparison with others evaluated under this program, and in light of the uncertainties presented by gaps in the available data that may be determined to exist. These evaluations contribute to meeting U.S. commitments under the chemicals cooperation work being done in North America[4] through the EPA Chemical Assessment and Management Program (ChAMP)[5].

Hazard and Fate Summary:

Human Health:

- Acute and chronic toxicity of chemicals in this category is low. A repeated oral exposure to CASRN 64-19-7 in rats induced irritation at the point of contact and an acute skin irritation study in rabbits exposed to a solution containing CASRN 77-92-9 caused redness and swelling.
- Environment: Available data indicate that the potential acute hazard of all the chemicals in the category is low to aquatic organisms.
- Persistence and Bioaccumulation:
  - Available data indicate that CASRNs 64-19-7, 77-92-9, and 110-17-8 are all readily biodegradable, therefore the persistence potential for the compounds in this category is judged to be low.
  - Available data indicate that all the chemicals in this category are judged to have low bioaccumulation potential.

Exposure Summary:

- Both Confidential Business Information (CBI) and non-confidential information from IUR and other sources were used in developing this initial prioritization.
- Production Volume: The ranges reported below are based on 2006 IUR submissions.
  - Eleven category members are HPV chemicals:
    - CASRN 64-19-7: > 1 billion lbs.
    - CASRN 77-92-9: ≥ 50 million and < 100 million lbs.
    - CASRNs 127-08-2, 127-09-3, 68-04-2: ≥ 10 million and < 50 million lbs.
    - CASRNs110-17-8, 142-72-3, 62-54-4, 631-61-8, 638-38-0, 6915-15-7: ≥ 1 million and < 10 million lbs.

[1] US EPA, HPV Challenge Program information: http://epa.gov/hpv/.
[2] US EPA, IUR information: http://www.epa.gov/oppt/iur/index.htm.
[3] US EPA, Information on additional public databases used: http://www.epa.gov/hpvis/pubdtsum.htm.
[4] US EPA, U.S. Commitments to North American Chemicals Cooperation: http://www.epa.gov/hpv/pubs/general/sppframework.htm.
[5] US EPA, ChAMP information: http://www.epa.gov/champ/.

  - Two category members are moderate production volume (MPV) chemicals:
    - CASRN 866-84-2: ≥ 500,000 lbs. and < 1 million lbs.
    - CASRN 994-36-5: < 500,000 lbs.
- Uses: Non-confidential information in the IUR for many of the chemicals in this category indicates that these chemicals are used as intermediates, solvents, coloring agents, pH-regulating agents, and functional fluids in a variety of industries. Information in the Hazardous Substances Data Bank (HSDB) indicates uses in food preservation, pharmaceuticals, textile dyeing, anticoagulants for blood, buffers for photography, and the manufacturing of other chemicals. All chemicals in this category have IUR submissions that indicate uses in commercial settings or consumer uses.
- General Population and Environment: Public data sources indicate that some of the chemicals in this category occur naturally in plants and organisms. They can also be released through waste streams from various industrial applications. Based on the information considered, including chemical presence in monitoring data and known uses, EPA identifies a high potential that the general population and the environment may be exposed.
- Workers: EPA identifies a high relative ranking for potential worker exposure based on the large number of industrial processing sites and uses, potential for dermal and inhalation exposure to liquids and solids, substantially high production volume, and a high number of potentially exposed workers (>1,000 workers for most members of the category). Only one chemical in this category, CASRN 64-19-7, has an OSHA Permissible Exposure Limit (PEL) of 10 ppm 8-hour time weighted average (TWA).
- Consumers: EPA identifies a high potential that consumers may be exposed based on the use of manufactured and natural products containing these chemicals. All chemicals in this category have IUR submissions that indicate uses in commercial settings or consumer uses. Some non-confidential IUR commercial and consumer uses are in rubber and plastic products, soaps and detergents, photographic supplies, paints and coatings, as well as paper products.
- Children: EPA identifies a high potential that children may be exposed to manufactured and natural products containing these chemicals. Seven of the IUR submissions reported uses in products intended to be used by children, and six submissions reported that such information was Not Readily Obtainable. HSDB also indicates that chemicals in this category are added in foods and beverages that may be consumed by children.

Risk Characterization Summary:

- Potential Risk to Aquatic Organisms from Environmental Releases: *LOW CONCERN*. EPA identifies a high potential that aquatic organisms might be exposed from environmental releases. Chemicals in this category have low persistence and low bioaccumulation. These characteristics in combination with the low toxicity to aquatic organisms for chemicals in the category indicate a low concern for potential risk to fish, aquatic invertebrates, and aquatic plants.
- Potential Risk to the General Population from Environmental Releases: *LOW CONCERN*. EPA identifies a high potential that the general population might be exposed from environmental releases. The potential human health hazard is expected to be low due to the lack of specific toxicity to animals following exposure to high doses. The low hazard and the environmental fate characteristics of low persistence and low

bioaccumulation suggest a low concern for potential risk to the general population from environmental releases.

- Potential Risk to Workers: *LOW CONCERN*. EPA identifies a high relative ranking for potential worker exposure. The potential human health hazard is expected to be low due to the lack of specific toxicity to animals following exposure to high doses. However, there is potential for irritation at point of contact following prolonged exposures. Adherence to standard industrial hygiene practices (gloves, respirators, goggles, and other protective clothing) to prevent irritation would limit the exposure of workers. Therefore, the available information suggests a low concern for potential risk to workers.
- Potential Risk to Consumers from Known Uses: *LOW CONCERN*. EPA identifies a high potential that consumers may be exposed. The potential human health hazard is expected to be low due to the lack of specific toxicity to animals following exposure to high doses. Some members of the category have the potential for irritation at point of contact following prolonged exposures; however, EPA assumes it is unlikely that concentrations in consumer products would be high enough to warrant concern. The available information suggests a low concern for potential risk to consumers.
- Potential Risk to Children: *LOW CONCERN*. EPA identifies a high potential that children may be exposed to manufactured and natural products containing these chemicals. Exposures to children may also be expected to occur through the household use of some consumer products. Data that specifically addresses toxicity to children do not exist; however, the overall toxicity profile is low. The available information suggests a low concern for potential risk to children.

Regulatory and Related Information Summary:

- With the exception of CASRNs 638-38-0, 994-36-5, and 866-84-2, all 3 of which appear only on the TSCA Inventory and are not otherwise regulated, the remaining 10 chemicals in this category appear in a number of other regulatory and related sources:
    - CASRNs 64-19-7, 631-61-8, 127-08-2, 127-09-3, 62-54-4, 110-17-8, 6915-15-7, 77-92-9, and 68-04-2 are considered as inert ingredients permitted for use in nonfood use pesticide products under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA).
    - EPA regulates, with a reportable quantity of 5,000 pounds, CASRNs 64-19-7, 631-61-8, and 110-17-8 under the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA).
    - EPA identifies CASRNs 64-19-7, 631-61-8, and 110-17-8 as hazardous substances under section 311 of the Clean Water Act.
    - EPA regulates CASRNs 64-19-7, 127-09-3, 142-72-3, 110-17-8, 6915-15-7, and 77-92-9 as air pollutants in new sources under section 111 of the Clean Air Act.
    - EPA regulates CASRNs 64-19-7, 110-17-8, and 6915-15-7 as hazardous air pollutants under section 112(b) of the Clean Air Act.
- Exposure limits of 10 ppm (8-hour TWA) have been set as an OSHA PEL, a NIOSH REL and an ACGIH TLV for CASRN 64-19-7.
- The National Institute of Occupational Safety and Health (NIOSH), an institute of the U.S. Centers for Disease Control and Prevention (CDC), includes safe handling recommendations for industrial concentrations of CASRNs 64-19-7, 127-08-2, 127-09-3, 77-92-9, and 68-04-2 on International Chemical Safety Cards.

- CASRN 77-92-9 has been assessed under the Organization for Economic Cooperation and Development's HPV Chemicals Programme.

Assumptions and Uncertainties:

- EPA has no information on releases of these chemicals, and assumes potential exposures based on reported uses and on the natural occurrence of these chemicals in the environment.

Rationale Leading To Prioritization Decision:

- Chemicals in this category are naturally occurring in many fruits and vegetables, and are critical for basic metabolic processes.
- Available data suggest a low hazard to all potential exposure groups.
- Professional judgment suggests that the presence of the chemicals in this category in natural and artificial sources is expected to be insufficient to cause irritation at the point of contact in the general population, consumers, and children.

Prioritization Decision:

- LOW PRIORITY - Follow-up action not suggested at this time.

Supporting Documentation:

Screening-Level Risk Characterization: August 2008
Screening-Level Hazard Characterization: August 2008
Screening-Level Exposure Characterization: August 2008