

Initial Risk-Based Prioritization of High Production Volume Chemicals

Chemical/Category: *n*-Butyric Acid/Anhydride Category

CAS No. 107-92-6 *n*-Butyric acid

CAS No. 106-31-0 *n*-Butyric anhydride

Metabolic precursors: CAS No. 123-86-4 *n*-Butyl acetate

CAS No. 71-36-3 *n*-Butanol

Additional analogs: CAS No. 79-09-4 Propionic acid

CAS No. 79-31-2 Isobutyric acid

CAS No. 109-52-4 Pentanoic acid

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 Program¹ and the 2006 Inventory Update Reporting (IUR)², and data publicly available through other selected sources³. 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 America⁴.

Human Health and Environmental Hazard Summary:

- Available data indicate the potential acute toxicity of the butyric acid/anhydride category members is low via the oral, dermal and inhalation routes. The category members also show low toxicity in repeated-dose studies, developmental and reproductive toxicity studies, and mutagenicity studies.
- *n*-Butyric acid is a moderate skin and severe eye irritant, while *n*-butyric anhydride is corrosive. Both category members should be considered respiratory irritants.
- Available aquatic toxicity data for fish, aquatic invertebrates and aquatic plants indicates that the potential acute aquatic hazard of the members of this category may be partly due to pH effects, but it is considered low overall.

Persistence and Bioaccumulation Summary:

- Both category members are ranked low for the potential to persist. *n*-Butyric anhydride is expected to hydrolyze rapidly to *n*-butyric acid, and *n*-butyric acid is expected to biodegrade rapidly.
- Both category members are also ranked low for the potential to bioaccumulate.

¹ US EPA, HPV Challenge Program information: <http://www.epa.gov/hpv/>.

² US EPA, IUR Reporting 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>.

Exposure Summary:

- Both IUR Confidential Business Information (CBI) and non-CBI information from IUR and other sources were used in this initial prioritization.
- **Production volume:** Both *n*-butyric acid and *n*-butyric anhydride are HPV chemicals that were manufactured (including imported) in the United States in amounts ranging from 100 million to 500 million pounds in 2005.
- **Uses:** *n*-Butyric acid is used as an intermediate, food additive, and ingredient in varnish, cosmetics and detergents. *n*-Butyric anhydride is used primarily as an intermediate in the production of other chemicals.
- **General Population and Environment:** Neither category member is listed on the Toxics Release Inventory (TRI), so no release data from this source are available. Environmental sources of *n*-butyric acid include fugitive emissions during its production and use and its presence in motor vehicle exhaust. It naturally occurs in vegetable oils and animal fluids and also natural metabolic and fermentative processes and can be a food additive. It has been detected in air, water and sediment/soil. IUR-based ranking for the general population and the environment is to *n*-butyric anhydride is low because it will quickly degrade to *n*-butyric acid for which the ranking is high due to the assumption that there will be exposure, although the degree of exposure that can be attributed to TSCA uses cannot be determined from the references examined.
- **Workers:** The National Occupational Exposure Survey (NOES), conducted between 1981 and 1983, reported 4,817 and 11,600 as the possible number of workers exposed to *n*-butyric acid and *n*-butyric anhydride respectively. The 2005 IUR data submitted indicate that between 1,000 and 10,000 workers may be exposed to both category members. (Differences between numbers of workers estimated by IUR submitters and by the NOES are attributable to many factors, including time, scope, and method of the estimates. For example, NOES estimates are for all workplaces while IUR are for industrial workplaces only, and NOES used a survey and extrapolation method while IUR submitters simply provide their best estimates based on available information for the specific reporting year.) Both chemicals' vapor pressure could result in significant worker exposures to vapors if workers are near the liquid. There is no OSHA permissible exposure limit (PEL) for either chemical. Based on IUR data, specifically the number of potentially exposed workers and use codes, the potential for worker exposure is considered high for *n*-butyric acid and medium to high for *n*-butyric anhydride.
- **Commercial workers and consumers:** Although commercial workers and consumers may use TSCA-regulated products made with *n*-butyric acid or *n*-butyric anhydride, the IUR data indicate that exposure to butyric acid in these products is not expected because all (100%) of the production volume for both chemicals is reported to be used as an intermediate.
- **Children:** Although children may use or be exposed to TSCA-regulated products made with *n*-butyric acid or *n*-butyric anhydride, the IUR data indicate that exposure to butyric acid in these products is not expected because all (100%) of the production volume for both chemicals is reported to be used as an intermediate.

Assumptions and Uncertainties:

- Minor uses are not reported under the IUR, and are thus unknown.

Risk Characterization Summary:

- *Potential Risk to Aquatic Organisms from Environmental Releases (LOW CONCERN):* Although *n*-butyric acid and *n*-butyric anhydride may be present in environmental media from a variety of sources, data indicate a low potential for exposure to aquatic organisms from environmental releases during production of TSCA-regulated products, because both *n*-butyric acid and *n*-butyric anhydride are used as chemical intermediates. The low acute aquatic hazard and the overall environmental fate characteristics (e.g., not persistent or bioaccumulative) suggest a low concern for potential risk to aquatic organisms from environmental releases.
- *Potential Risk to General Population from Environmental Releases (LOW CONCERN):* Although *n*-butyric acid and *n*-butyric anhydride may be present in environmental media from a variety of sources, data indicate a low potential for exposure to the general population from environmental releases during the production of TSCA-regulated products, because both *n*-butyric acid and *n*-butyric anhydride are used as chemical intermediates. The low overall human health hazard profile and the environmental fate characteristics suggest a low concern for potential risk to the general population from environmental releases.
- *Potential Risk to Workers (LOW CONCERN):* There is the potential for worker exposure from the production and use of both chemicals in TSCA-regulated products or in the event of accidental release. However, because both *n*-butyric anhydride and *n*-butyric acid are eye, skin and respiratory irritants, it is presumed that potentially exposed workers will follow standard hazard communication/industrial hygiene practices and wear personal protective equipment that will likely be sufficient to address this concern. Thus, although there is a potential human health hazard, the exposure issues (use as an intermediate, corrosive and thus self-limiting in terms of personal protective equipment) suggest a low concern for potential risk to workers.
- *Potential Risk to Commercial Workers and Consumers from Known Uses (LOW CONCERN):* It is assumed from the available IUR-based information that *n*-butyric acid and *n*-butyric anhydride are not present in TSCA-regulated commercial and consumer products. Coupled with the low hazard profile, the information suggests a low concern for potential risk to commercial workers and consumers.
- *Potential Risk to Children (LOW CONCERN):* It is assumed from the available IUR-based information that *n*-butyric acid and *n*-butyric anhydride are not present in TSCA-regulated products intended for use by children. Coupled with the low hazard profile, the information suggests a low concern for potential risk to children.

Rationale Leading To Prioritization Decision:

- Both *n*-butyric acid and *n*-butyric anhydride present low hazard profiles. Although they do have the potential to be skin, eye and respiratory irritants, this potential is expected to be mitigated by certain chemical properties and the use of the chemicals as intermediates in the production of TSCA-regulated products.
- The use of both chemicals as intermediates in the production of TSCA-regulated products and the low potential to persist or bioaccumulate suggest that effects of environmental release from industrial facilities would be limited. In occupational settings, it is presumed that personal protective equipment will be used.

- *n*-Butyric acid has been detected in river water, drinking water, and sediments. It is regulated as a hazardous substance under CERCLA (under which its reportable quantity when there is an environmental release is 2270 kg), the Federal Water Pollution Control Act, and the Clean Water Act and as a volatile organic chemical under the Clean Air Act. Professional judgment suggests that the presence of *n*-butyric acid in other natural and artificial sources is expected to be insufficient to cause eye, skin or respiratory irritation in the general population, consumers, and children.
- Information specifically addressing releases to the environment and potential uses in consumer and children's products could replace default exposure assumptions with more accurate data. Additional information clarifying existing controls on potential occupational exposures and whether there are any environmental releases could be useful to better characterize potential risks. However, such information would not be likely to change the indication that the concern for risks presented by use of these chemicals in TSCA-regulated products does not appear to be significant.

Prioritization Decision:

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

Supporting Documentation:

Screening-Level Risk Characterization: 3/13/2008

Screening-Level Hazard Characterization: OECD SIDS Initial Assessment Profile, 5/27-30/2003, <http://cs3-hq.oecd.org/scripts/hpv/Index2.asp?CASNUM=107926>

Note: OECD SIDS Initial Assessment Profiles (SIAPs) are publicly available through the United Nations Environmental Programme website. These documents are presented in an international forum that involves review and endorsement by governmental authorities around the world. The U.S. EPA is an active participant in these meetings and accepts these documents as reliable screening-level hazard assessments for the purpose of the U.S. HPV Challenge qualitative risk characterization process.

Screening-Level Exposure Characterizations: 3/14/2008

Screening-Level Fate Characterization: 3/14/2008