

## **GAMMA BUTYROLACTONE AND 1-4 BUTANEDIOL QUESTION AND ANSWER DOCUMENT**

### ***Introduction***

The Gamma Butyrolactone (GBL) and 1-4 Butanediol (BDO) Panel of the American Chemistry Council (ACC) prepared these materials to provide useful background information concerning GBL and BDO. The Panel is composed of companies that domestically produce and/or use GBL and BDO and their precursors in the manufacturing process.<sup>1</sup>

### ***What are the Physical and Toxicological Characteristics of GBL and BDO?***

GBL and BDO generally appear as oily, tasteless liquids. GBL has a melting point of -44 C, a boiling point of 206 C, and is a liquid under normally encountered environmental conditions. BDO has a melting point of 20 C, a boiling point of 229 C, and, under some environmental conditions, is a solid. In the liquid state, BDO is a heavy clear liquid with a consistency similar to corn syrup. Both GBL and BDO are soluble in water.

In occupational settings, the chemicals have relatively low toxicity and exposures may be controlled through conventional industrial safeguards. Routes of exposure that may present a concern include eye and skin contact, ingestion and inhalation. Contact with skin or eyes can result in irritation. Normal precautions (including personal protective equipment and hazard training) relevant to occupational exposure and chemical handling are required. The autoignition temperature for the chemicals is high – approximately 370 C for BDO and 455 C for GBL.

Both chemicals are rapidly metabolized to Gamma Hydroxybutyrate (GHB) when ingested. GHB is often called the “date rape drug.” Ingestion of GBL, BDO or GHB causes central nervous system effects and respiratory depression. Human deaths have also been reported in situations of overexposure.

### ***Why are GBL and BDO Important Industrial Chemicals?***

GBL and BDO have many industrial uses and represent critical ingredients in several widely used industrial and commercial products. GBL is used significantly as an intermediate to manufacture industrial chemicals such as N-methylpyrrolidone. However, because of its strong solvency properties, GBL is also used for circuit board cleaning in the electronics and high technology industries, and in paint stripping applications. Other uses of GBL include the production of herbicides and as a processing aid in the production of pharmaceuticals.

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<sup>1</sup> The Panel is composed of the following companies: BASF Corporation, International Specialty Products, Lyondell, and PPG Industries.

BDO is used as an intermediate in common industrial and commercial products such as polyether diols, urethane polymers and polyester polymers. Many of the polyester polymers end up as automotive components such as car bumpers. BDO is also used as a plasticizer, a carrier solvent in printing inks, and a cleaning agent.

### ***Have Some Individuals Misused GBL and BDO for Illegal Purposes?***

Unfortunately, the proliferation of illegal drug use has long been an issue of national importance. Despite their many beneficial purposes, GBL and BDO have been misused. These chemicals have been identified as potential “club drugs.” They have been formulated into illicit dietary supplements sold as libido enhancers, muscle builders, and sleep inducers. The chemicals have also helped serve as a mechanism for “date rape.” GBL and BDO have been diverted from lawful industrial applications to produce GHB in illegal drug laboratories.

### ***What Is Industry’s Position on Such Drug Abuse?***

The Panel members strongly support laws that punish individuals who divert GBL or BDO for human consumption. The producers of GBL and BDO formed the Panel in 2000 as a means of enhancing and coordinating industry efforts to help provide that these chemicals are used solely for their intended commercial and/or industrial uses. Panel members support vigorous enforcement of existing drug laws and the prevention of drug abuse of any kind. Panel members have shared their expertise concerning the manufacture and distribution of GBL and BDO with Federal and state regulators and have assisted law enforcement personnel in their efforts to help prevent and investigate abuse of these chemicals. The Panel believes strongly that its products should remain in the industrial stream and should only be used for lawful purposes.

### ***Are Existing Laws Adequate?***

The Panel believes that when applied properly, existing laws can provide a satisfactory framework for controlling illicit activities. Notwithstanding, the Panel continues to work cooperatively with Federal and state government authorities to assist in crafting effective and workable regulations where new regulations are being prepared.

### ***What Actions Has the Federal Government Taken?***

There are a variety of Federal laws, state laws, and associated governmental authorities helping to control and prevent the misuse of GBL, BDO and GHB. For example, in 2000, Congress regulated GHB as a Schedule I Controlled Substance. To help prevent diversion of GBL, yet allow for legitimate industrial use, Congress placed GBL in the regulatory scheme for “Listed Chemicals.” Requirements for listed chemicals, enforced by the Drug Enforcement Administration (DEA), include an annual registration requirement for persons who manufacture GBL for distribution, or who distribute, import, or export the chemical. There are also extensive reporting, record keeping, and security requirements applicable to registered companies. DEA has investigation and suspension authorities and may impose a variety of penalties to ensure registrants comply with these requirements.

The U.S. Food and Drug Administration (FDA) has taken several actions to help prevent misuse of these chemicals as drugs and dietary supplements. In 1990, FDA banned the consumer use of GHB. In 1999, FDA issued warnings on GBL noting its status as an unapproved new drug that failed to meet safety requirements for a dietary supplement. FDA warned consumers not to purchase or consume products containing GBL and asked companies that manufacture such products to voluntarily recall them. In that same year, FDA issued health warnings about BDO and classified BDO as "Class I Health Hazard." FDA worked with US Attorneys Offices around the country to arrest, indict, and convict individuals involved with illegal marketing and distribution of these chemicals. Panel members have provided assistance to FDA in such government activities.

### ***What Product Stewardship Activities Have Companies Taken to Mitigate Diversion?***

In addition to activities taken to meet Federal requirements, the Panel member companies have independently and voluntarily adopted measures to help preclude diversion of their chemicals and to help their customers to do likewise. The members' product stewardship efforts help to educate and coordinate with Federal and state regulators, law enforcement, and other interested parties. As part of their efforts to be good product stewards for the industry, Panel member companies support the following practices:

- Communicating regulatory requirements internally and externally to customers and chemical distributors to help assist in maintaining product security. The Panel developed a guide specifically designed for industrial users as a means of helping to facilitate compliance with relevant requirements. Customer contact on regulatory requirements is a common part of this effort.
- Requesting written confirmation of GBL and BDO use from customers to help verify compliance with applicable requirements. As part of these efforts, customers provide information and commercial verification about the specific use of the chemical. When considered appropriate by the member company, a follow-up investigation is conducted to help assess the veracity of customer responses.
- Reporting suspicious or unusual activity, including product orders and sample requests, to appropriate legal authorities. Panel members look to DEA's established criteria to identify suspicious activities for reporting purposes.
- Promoting proper safety and handling procedures. Panel members conduct training programs within their own companies and engage customers to foster similar programs.
- Monitoring regulatory developments and work with regulators. Panel members have worked with several states and government authorities (e.g., DEA, NJ, OH) to help create an effective regulatory system and prevent chemical diversion.

### ***Are There Other Governmental Authorities With Responsibility for Controlling Misuse?***

In addition to the Federal government's responsibilities, many state and local agencies or boards regulate GBL and BDO. Although many states concluded the Federal requirements applicable to chemical producers and distributors are adequate in and of themselves, some states have adopted controls different from their Federal counterparts. The Panel has, and remains committed, to work with states developing regulations governing the legitimate industrial use and reporting of GBL and BDO. Of course, in addition to requirements applicable to legitimate chemical manufacturers and distributors of GBL and BDO, state and local law enforcement agencies have adopted a variety of criminal penalties to punish individuals who divert or misuse GBL and BDO for human consumption.

***What Are Industry's Future Plans Regarding Potential Misuse?***

Panel members will continue to work with government authorities to help prevent diversion of GBL and BDO and to help ensure that sound and appropriate requirements are established. The Panel will also maintain its commitment to product stewardship. Future Panel activities include information sharing and communication efforts.

***Who Should I Contact For Further Information?***

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