Assessment Plan for Corn Steep Liquor (CAS #66071-94-1) in Accordance with the USEPA High Production Volume Chemical Challenge Program

Prepared for:

The Corn Refiners Association

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EXECUTIVE SUMMARY

The Corn Refiners Association (CRA) is sponsoring Corn Steep Liquor (CSL) in the US High Production Volume (HPV) Challenge program. The primary use of CSL is as a nutrient for ruminant animals. CSL provides proteins, amino acids, minerals, vitamins, reducing sugars (such as dextrose), organic acids (in particular, lactic acid), enzymes, and elemental nutrients (such as nitrogen). CRA assembled and reviewed the available public and private toxicological data, and developed an assessment plan for the sponsored chemical.

CSL is a viscous liquid mixture consisting entirely of the water soluble components of corn steeped in water. All constituents are naturally occurring nutritive materials such as crude proteins, amino acids, vitamins, reducing sugars (e.g., dextrose), organic acids (e.g., lactic acid), minerals, and other elemental nutrients. CSL will transport mainly in the water, and its constituents are easily assimilated into normal cell metabolism. No ecological, mammalian or human toxicity would be expected from these natural nutritive materials.

Worker exposure to CSL during its manufacturing is limited by the automation of the steeping process, use of standard personal protective equipment, and other engineering controls. Exposure during consumer use could occur when giving animals pre-mixed feeds or supplements containing CSL, or during pouring of liquid feed supplements into feed mixers for subsequent distribution to animals. Adequate protective equipment is recommended during these uses. In any case, exposure is not likely result in adverse effects since all CSL components are natural to the corn except for the small amount of sulfur dioxide. Sources of aqueous sodium dioxide (e.g., sulfur dioxide, sodium bisulfite) are approved preservatives for food and are unlikely to cause any adverse effects. Other user exposures could occur when CSL is used in the manufacturing of chemicals and drugs. Exposure during these uses would be mitigated by automation and normal laboratory personal protective equipment.

Based on the long and established history of safe use as a nutrition source in animal feed, the Corn Refiners Association is not proposing to conduct additional testing on this natural water soluble extract of corn.

INTRODUCTION

The High Production Volume (HPV) Challenge Program is a voluntary initiative of the US chemical industry to complete hazard data profiles for approximately 2800 HPV chemicals as identified on the US Environmental Protection Agency's (USEPA) 1990 Toxic Substances Control Act (TSCA) Inventory Update Rule (IUR). In the US, HPV chemicals are those that are manufactured or imported in quantities greater than 1 million pounds per year. The hazard data to be provided in the program are those that meet the requirements of the Screening Information Data Set (SIDS) Program (OECD 1997). SIDS, which has been internationally agreed to by member countries of the Organization for Economic Cooperation and Development (OECD), provides the basic screening data needed for an initial assessment of the physical-chemical properties, environmental fate, and adverse human and environmental effects of chemicals. The information for completing the SIDS can come from existing data or may be generated as part of the HPV Challenge Program. Once the available studies are identified or conducted, "robust summaries" are prepared.

The USEPA, industry, and non-governmental organizations (NGOs) are unified in their commitment to minimize the numbers of animals tested in the HPV Challenge Program whenever it is scientifically justifiable (USEPA 1999a, 2000). Therefore, this test plan evaluates all of the existing data for the sponsored chemical in an effort to adequately characterize the health and environmental hazard while reducing the number of animals required for testing.

The Corn Refiners Association (CRA) has agreed to assemble and review available public and private toxicological data, develop and provide an assessment plan for the sponsored chemical and conduct additional research, including testing when necessary, for corn steep liquor (CSL). CSL is primarily used as a nutrient in animal feed. The participating member companies of the Corn Refiners Association are:

Archer Daniels Midland Company
Cargill, Inc.
Corn Products International, Inc.
National Starch and Chemical Company
Penford Products Company
Roquette America, Inc.
Tate & Lyle Ingredients Americas, Inc.

This assessment plan is the result of the CRA's efforts and provides a summary and analysis of the available data, and identifies any data gaps in the SIDS data profile. The first section of this assessment plan provides an identification of the sponsored chemical, including its structure, production process, and use pattern. Following that are sections on the process used to collect the unpublished and published data, and how those data were evaluated for quality and acceptability. This is followed by a discussion of the physical-chemical properties, environmental fate and transport, ecotoxicity, and mammalian toxicity data as summarized in the accompanying robust summary document. Finally, conclusions regarding data availability and identification of data gaps in the SIDS profiles for the sponsored chemical are presented.

IDENTIFICATION OF SPONSORED CHEMICAL

A. Chemical Structure

The chemical being sponsored is corn steep liquor (CAS #66071-94-1). Corn steep liquor (CSL) is also known by several synonyms including corn steepwater, light steepwater, and heavy steepwater. CSL is a mixture consisting of the water soluble extracts of corn soaked (steeped) in water. In fact, approximately 50% of CSL is water, with the remainder composed entirely of natural nutritive "building blocks" such as crude proteins, amino acids, minerals, vitamins, reducing sugars, organic acids, enzymes and other elemental nutrients. While the actual percent composition varies slightly between member companies, Table 1 lists the average composition of the major constituents of CSL (White and Johnson 2003).

Table 1. Corn Steep Liquor Composition

Major Component	Percent Composition
Ash (oxide)	17
Crude Protein	47
Fat	0.4
Lactic Acid	26
Nitrogen	7.5
Phytic Acid	7.8
Reducing Sugars (as dextrose)	2.5
Water	46

CSL is very low in fat and fiber, which makes it an excellent nutritive source for animal feed. Constituents of ash include magnesium, phosphorus, potassium, calcium, chlorine, sodium and sulfur. CSL is also a good source for all amino acids, important vitamins and nitrogen compounds, and essential trace elements such as iron, manganese, boron, copper, and zinc. All of these constituents provide natural nutrition for normal cell metabolism and are not a cause for concern.

B. Production Process

Corn steep liquor is a byproduct of the initial stages of wet milling of corn. Steeping of corn (i.e., soaking in water) aids in the separation the various components of corn such as starch and nutrients. Corn is normally steeped in stainless steel drums holding from 3,000-25,000 bushels of corn (CRA 2002; White and Johnson 2003). Approximately 5-9 gallons of water per bushel of corn is added to the tank (Liggett and Koffler 1948; White and Johnson 2003). The water originates elsewhere in the wet milling process where it has already obtained some soluble corn matter. The temperature of the water is maintained at 45-54˚C by heating the water as it is recirculated or by using a heat exchanger (Liggett and Koffler 1948; CRA 2006a; White and Johnson 2003). Immediately before adding the water to drums, an aqueous source of sodium dioxide is added to the water to a concentration of 0.1-0.2% (Liggett and Koffler 1948; White and Johnson 2003). In water, these sources of sodium dioxide form sulfurous acid, which

controls fermentation and softens the corn kernel to aid in the separation of the corn products. Most of the sulfurous acid is absorbed by the corn kernels so that after ten hours the concentration of sulfurous acid in the steepwater is lowered to 0.01% (Liggett and Koffler 1948).

The corn is steeped for anywhere between 22-50 hours, while the CSL is moved through six to twelve successive steeping tanks. The CSL is initially added to the tank with the oldest corn so that it is in contact with the highest concentration of the sulfurous acid. The water is then moved to fresher corn so that the oldest CSL is in contact with the freshest corn. Approximately one-third of the water is absorbed by the corn during the steeping, and the other two-thirds is withdrawn from the steeping system as light steepwater that contains between 6-9% solids by weight. The light steepwater is then evaporated until it contains 40-60% solids. The resulting CSL may be further processed by downstream users to meet their own specifications (White and Johnson 2003; Budavari 1996).

C. Use Patterns and Exposure Potential

The primary use of CSL is as a nutrient for ruminant animals. CSL provides proteins, amino acids, minerals, vitamins, reducing sugars (such as dextrose), organic acids (in particular lactic acid), enzymes, and elemental nutrients such as nitrogen. The majority of CSL produced is immediately added to corn gluten and fibrous materials for use as animal feed. The remaining CSL has several uses. It is mostly used as a liquid feed supplement for cattle, dairy cows, sheep, goats, and swine (White and Johnson 2003; Liggett and Koffler 1948; CRA 2006b). In the chemical industry, corn steep liquor is used in the production of acetic acid, food acids, and in fermentation processes. CSL is also used by the pharmaceuticals industry in the production of intravenous solutions and drugs, most notably antibiotics (CRA 2006b). In fact, CSL was instrumental to the large-scale production of penicillin in the 1940s (USDA 2006). In 2005, a total of 1,282,614,000 lbs of CSL was shipped in the United States, representing 2.3% of wet milled corn products (CRA 2006c).

Worker exposure to CSL during its manufacturing is limited by the automation of the steeping process. The water is piped into the steeping tanks and from one tank to another. While small amounts of inhalation are possible during the evaporation of water from the CSL, the vapor would contain mostly water as the solid fraction of the CSL would remain in the evaporation tanks. The low amount of sulfurous acid (0.01% or less) would not be a concern. Local exhaust ventilation is used to control mists. Further exposure to CSL could occur during the mixing of the CSL with corn gluten to make animal feed, and during the packaging of corn steep liquor for uses. Exposure during the mixing or packaging of CSL is mitigated by automation, and the resulting animal feed may, in fact, be introduced directly into trucks for delivery to farms where it may be fed to animals immediately or placed in storage (Linton and Hussar 1989; Westburg 2006). Exposure might also be possible during the cleaning of equipment used in the manufacturing process.

Exposure during consumer use could occur when giving animals pre-mixed feeds or supplements containing CSL, or during pouring of liquid feed supplements into feed mixers for subsequent distribution to animals (Linton and Hussar 1989). Exposure is not likely to cause adverse

effects, since all components of corn steep liquor are natural to the corn except for the small amount of sulfurous acid. This small amount is unlikely to cause any adverse effects as it is an approved preservative for food (FDA 2002). Other user exposures could occur when corn steep liquor is used in the manufacturing of chemicals and drugs. Exposure during these uses would be mitigated by automation and normal laboratory personal protective equipment, such as gloves and safety glasses, and good industrial hygiene practices (MSDS sheets).

COLLECTION OF UNPUBLISHED AND PUBLISHED DATA

Corn Refiners Association member companies contributed available in-house information related to physical-chemical properties, environmental fate and transport, ecotoxicity, and mammalian toxicity for CSL. CRA member companies also provided information related to the use patterns and composition of the CSL mixture. To supplement the industry data, literature searches were conducted of on-line databases (*e.g.*, Hazardous Substances Databank [HSDB], Registry of Toxic Effects of Chemical Substances [RTECS], and the USEPA's ECOTOX database), standard scientific data compendia (*e.g.*, *CRC Handbook of Chemistry and Physics* and *The Merck Index*), and other published sources (*e.g.*, International Uniform Chemical Information Database [IUCLID]). A summary of the literature and database sources searched can be found in Appendix A.

EVALUATION OF DATA FOR QUALITY AND ACCEPTABILITY

The collected data were reviewed for quality and acceptability following the USEPA and OECD SIDS guidance (USEPA 1999b; OECD 1997) and the systematic approach described by Klimisch et al. (1997). These methods include consideration of the reliability, relevance, and adequacy of the data in evaluating their usefulness for hazard assessment purposes. The Klimisch et al. (1997) approach specifies four categories of reliability for describing data adequacy. These are:

1. **Reliable without Restriction:** Includes studies or data complying with Good Laboratory Practice (GLP) procedures, or with valid and/or internationally accepted testing guidelines, or in which the test parameters are documented and comparable to these guidelines.

2. **Reliable with Restrictions:** Includes studies or data in which test parameters are documented but vary slightly from testing guidelines.

3. **Not Reliable:** Includes studies or data in which there are interferences, or that use non-relevant organisms or exposure routes, or which were carried out using unacceptable methods, or where documentation is insufficient.

4. **Not Assignable:** Includes studies or data in which insufficient detail is reported to assign a rating, *e.g.*, listed in abstracts or secondary literature.

Common practice is that only those studies which are deemed reliable for the current HPV Challenge Program purposes are included in the data set. In general, reliable studies include both categories rated 1 (reliable without restriction) and 2 (reliable with restrictions). Studies rated 3 (not reliable) were not used. Studies rated 4 (not assignable) were used when professional judgment deemed it appropriate as part of a weight-of-evidence approach.

Because CSL is a mixture consisting of the water soluble crude proteins, amino acids, reducing sugars and other natural nutrients used in animal feed, and therefore, is of very low concern, formal guideline-based toxicity studies are not available. Therefore, the robust summary dossier (IUCLID Data Set) for CSL primarily summarizes information related to the long history of safe nutritional supplement use of CSL. A previous IUCLID Data Set for CSL was prepared by one of the member companies in 2000; this data set was updated and additional information added for the current HPV Challenge submission. The robust summary dossier for corn steep liquor is attached as Appendix B and should be used in conjunction with this assessment plan.

SUMMARY OF AVAILABLE DATA

The following discussion reviews the available data identified for each of the four major data areas: physical-chemical properties, environmental fate and transport, ecotoxicity, and mammalian toxicity.

Physical-Chemical Properties

Physical-chemical property data are available primarily from the IUCLID 2000 data set for CSL and from member company MSDS and other technical data sheets. Data were collected from all six member companies and the ranges are summarized in Table 2. All physical-chemical properties have a reliability of 4 (not assignable) because the original reports were not available for review.

Table 2. Physical-Chemical Properties

Endpoint	Value	Comment
Form	Liquid	Viscous
Color	Tan to brown	
Odor	Sharp	
Melting Point	Not applicable	Liquid at room temperature
Boiling Point	100-101°C	
Conductivity	2.5 µmoh	
Specific Gravity	1.15-1.25	
Density	1.2-1.4 g/cm^3	
Vapor Pressure	17.5 mm Hg at 25°C	Equal to 23.3 hPa
Partition Coefficient (Log K_{ow})	Not available	
Water Solubility	Soluble	

CSL is a viscous liquid with a boiling point essentially that of water. Because CSL results from the steeping (soaking) of corn in water, all of the individual constituents of the mixture are highly water soluble nutrients. Because of this high solubility, no bioaccumulation is expected, though CSL does provide valuable nutrients that are naturally used by organisms for normal cellular subsistence and metabolism.

Environmental Fate and Transport

Traditional environmental fate data are important for demonstrating the primary mechanism or mechanisms of degradation and how a material's properties affect its transport in the environment. For organic chemicals, fate is generally a function of the breakdown of compounds into smaller constituents by biological degradation. Other breakdown mechanisms that may be important are photolysis and hydrolysis. These breakdown mechanisms are necessarily dependent on what environmental compartment (air, water, soil, sediment) to which the chemicals are distributed. Fugacity modeling is normally used to estimate the relative percentage of chemicals that will partition to various compartments at steady state. However, because CSL consists only of water soluble nutrients, it would be expected that it would be present largely in the water compartment. In addition, the individual components of the mixture are natural nutrients, so would rapidly be assimilated as an energy source in normal cellular processes. No additional environmental fate studies are warranted.

Ecotoxicity

Because of the natural derivation of CSL, specific guideline ecotoxicity studies are not available, nor are they necessary. CSL is not expected to exhibit toxicity to fish or other aquatic organisms. CSL consists of the water soluble components of corn that has been soaked in water. These all-natural constituents are primarily crude proteins, amino acids, vitamins, reducing sugars, organic acids (e.g., lactic acid), and other trace elemental nutrients. The primary use of CSL is as a nutrient source additive in animal feeds, and has a long history of safe use. It should be noted that the available data for one component (lactic acid, which may make up 10-25% of the CSL) have been summarized for the HPV Challenge program. These data indicate very low aquatic toxicity for this component, and provide supporting evidence for the overall toxicity of the CSL mixture.

In addition, CSL is used in the production of acetic acid, other food acids, and in fermentation processes. Therefore, the material would not inhibit microorganism growth, and in fact, would serve as a nutrient source.

No further ecological toxicity studies are being proposed.

Toxicity

While standard guideline mammalian toxicity studies are not available, many nutrition-related studies have been conducted over the years to show the safety of CSL in animals. CSL is used as a nutritive additive in a wide range of animal feeds for cattle, sheep, swine, dairy cows, and

poultry. CSL has also been used to supplement feed used for pets, catfish farming, and honey bee production (Pressick 1985). No adverse effects have been observed in any of these studies. No further mammalian toxicity studies are necessary.

Evaluation of Data Completeness

CSL has a long history (over 100 years) of safe use as a nutrient additive in animal feed and as a nutrient source in fermentation processes. Because of the lack of toxicity concerns and the nutritional benefits of CSL, standard guideline studies have not been completed. The safe use of CSL has been adequately established and therefore the CRA is not proposing to conduct additional guideline studies at this time.

SUMMARY OF CORN STEEP LIQUOR PROPERTIES

Corn steep liquor is a viscous liquid mixture consisting entirely of the water soluble components of corn steeped in water, along with a small amount of sulfurous acid (<0.01%). All constituents are naturally occurring nutritive materials such as crude proteins, amino acids, vitamins, reducing sugars (e.g., dextrose), organic acids (e.g., lactic acid), minerals, and other elemental nutrients. CSL will transport mainly in the water, and its constituents are easily assimilated into normal cell metabolism. No ecological, mammalian, or human toxicity would be expected from these natural nutritive materials.

CONCLUSIONS

CSL has a long history of safe use as an added source of nutrition in animal feed, in fermentation processes, and in antibiotic production. Because CSL consists of natural nutritive materials, there is very low toxicity concern. The CRA is not proposing to conduct additional testing on this natural water soluble extract of corn.

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Appendix A: Summary of Literature and Database Searches

Sites Searched:

1. STN
    a. CAPLUS
        i. "corn steep liquor" – over 4295 hits
        ii. "corn steep liquor" and "composition" – 57 hits, several good, however, these were in foreign languages. Some abstracts of studies of using corn steep liquor to grow antibiotics.
        iii. "corn steep liquor" and "environment" – 44 hits, a few references to using corn steep liquor in environmentally benign de-icing formulas.
        iv. "corn steep liquor" and "human health" – 0 hits
        v. "corn steep liquor" and "toxic?" – 70 hits, no relevant information
    b. ToxCenter – 3 records retrieved. No relevant information.
    c. Registry – Registry entry for corn steep liquor provides no useful property data.

2. PUBMED
    a. "corn steep liquor" – 171 hits. 13 useful articles mostly pertaining to studies of feeding corn steep liquor to lactating cows, or use of CSL to biodegrade TNT, or as a medium to grow antibiotics.
    b. "condensed fermented corn extractives" – 0 hits.

3. FDA GRAS – FDA GRAS Notice GRN 000065 – Corn steep liquor used as a fermentation medium to make nisin which is used in food.

4. Toxnet – Includes CCRIS, DART, GENE-TOX, HSDB, IRIS, TOXLINE, LacMed. No relevant results. CSL is used as a medium for introducing chemicals into lab animals for oral toxicity studies. Results for "corn steep liquor" in Toxnet link to toxicity studies for other chemicals, not actual toxicity studies of corn steep liquor. Results for "condensed fermented corn extractives" gives 2 hits for nutritional value and chemical component of condensed fermented corn extractives.

5. Canadian Feed Act – Condensed fermented corn extractives is an approved feed additive in Canada.

6. HPV – High Production Volume – No relevant information.

7. NTP – National Toxicology Program – No relevant information.

8. SIDS – Screening Information Data Set - A SIDS is available for corn steep liquor, however, it contains limited useful information.

9. IARC – International Agency for Research on Cancer – No relevant information.

Appendix B (cont.)

10. MHLW – Chemical Toxicity Database (Japan) – No relevant information.

11. SIRI MSDS – MSDSs available for corn steep liquor.

12. SRC – Syracuse Research Corporation – Includes TSCATS, EFDB, Ozone Depletion/Global Warming, Kow, PhysProp, ISE Model – No relevant information.

13. TRACE – BIBRA – No BIBRA document on corn steep liquor.

14. CANCERLINE – No relevant information.

15. NICNAS – National Industrial Chemicals Notification and Assessment Scheme (Australia) – No relevant information.

16. US Agency for Toxic Substances and Disease Registry – No relevant information.

17. ECETOC JACC – Reports and inventories of critical reviews – No relevant information.

18. ECB – European Chemicals Bureau – No relevant information.

19. IPCS – Includes CICAD, EHC, HSG, ICSC, IPCS/CEC, JECFA, JMPR, PD, PIM, SIDS – No relevant information.

20. The Carcinogenic Potency Project – No relevant information.

21. Ecotox – No relevant information.

22. ChemFinder – No entry for corn steep liquor.

23. NCEA – US National Center for Environmental Assessment – No relevant information

24. RIVM – Netherlands – No relevant information

25. FERA – Fate, Exposure and Risk Analysis – No relevant information

26. EFAST – No relevant information

27. Merck Index – Entry for corn steep liquor obtained.

28. Modeling – Modeling (ChemSTEER, EPISUITE) cannot be done on CSL because it is not a discreet chemical substance.

Appendix B: 2006 IUCLID Data Set