

# Product Information

## EX-CELL™ CD Hydrolysate Fusion Chemically Defined, Animal-Component Free

CATALOG NO. 24700C

### Description

EX-CELL™ CD Hydrolysate Fusion is a synthetic option to undefined hydrolysates used in cell culture processes, including both Batch and Fed-Batch modes. It is formulated to have minimal pH and OSMO impact upon addition. EX-CELL CD Hydrolysate Fusion is optimized for Chinese Hamster Ovary (CHO) cell lines but has also been shown to work well with other cell types (e.g. NS0 and Sp2/O).

EX-CELL CD Hydrolysate Fusion is comprised only of animal-free, chemically defined components that were identified to be in hydrolysates or are commonly found in cell culture media. In order to have broad applications, EX-CELL CD Hydrolysate Fusion was based on data generated from four hydrolysate types (soy, wheat gluten, yeast extract, meat).

### Formulation

The formula for EX-CELL CD Hydrolysate Fusion is proprietary to SAFC Biosciences®. For additional information please call our Technical Services department.

### Precautions

Use aseptic technique when handling or supplementing this medium. This product is for research or for further manufacturing use. THIS PRODUCT IS NOT INTENDED FOR HUMAN OR THERAPEUTIC USE.

### Storage

Store dry powder at 2 to 8 C. Do not use after the expiration date.

### Indications of Deterioration

Product should be a white, free-flowing powder. Do not use if product is clumpy or appears to have been exposed to high humidity. Other evidence of deterioration may include color change or degradation of physical or performance characteristics.

### Preparation Instructions

EX-CELL CD Hydrolysate Fusion is formulated as a one-part, readily soluble dry powder. It can be added to a medium in dry powder form or made into a concentrated supplement. If application-specific hydrolysate utilization contributes significantly to the final OSMO of the medium/feed, a slight adjustment with salt addition (e.g. NaCl) may be required when using EX-CELL CD Hydrolysate Fusion. It is suggested that OSMO be checked and compared to a control process currently utilizing hydrolysates prior to use.

#### *Dry Powder Use*

EX-CELL CD Hydrolysate Fusion dry powder can be used in the same fashion as traditional hydrolysates are used. Addition to medium/feed prior to bringing to final volume is ideal, however the addition can occur when at final volume (requires sterile filtration) with only minor impact on pH and OSMO.

#### *Liquid Use*

The dry powder can also be formulated into a concentrated liquid supplement. A 20X (34.736 g/L) supplement is recommended for increased stability, however, more concentrated solutions can be made if needed (i.e. 60X).

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## General Liquid Supplement Preparation

1. Begin with 80% of the final volume of water.
2. Add desired amount of dry powder.
  - a. 20X = 34.736 g/L
3. Mix until fully dissolved.
4. Using concentrated sodium hydroxide, bring the pH to 7.0 (+/- 0.2).
5. Sterile filter product and store at 2 to 8 C.

Supplements, such as antibiotics, can be added to the product using aseptic technique. Shelf life of the product may be affected by the nature of the supplements.

## Methods for Use

### General Use

The standard suggested amount for use is a 1X level (1.74 g/L). A titration is strongly suggested to determine the optimal concentration for the specific process because individual cell lines can require different amounts, especially in systems where high levels (>5 g/L) of hydrolysates are being replaced. The titration should start in the 0.5X (0.87 g/L) to 3X (5.21 g/L) range and expand if necessary. An estimation of the centerpoint for the titration can be calculated with the assumption that 1X of EX-CELL CD Hydrolysate Fusion is roughly equivalent to 3 g/L of an undefined hydrolysate. Please call our Technical Services department for details.

### *Batch Mode (addition to basal medium)*

1. To incorporate EX-CELL CD Hydrolysate Fusion into a batch medium no changes are needed other than creating a lot of basal medium without hydrolysates. Addition of the product (liquid or dry powder) can be accomplished by addition during the formulation process, prior to bringing the medium to final volume.
2. Adaptation to EX-CELL CD Hydrolysate Fusion is usually not necessary. However, if adaptation is needed a simple weaning protocol should be sufficient. For example:
  - a. Start with 75% Non-CD medium/25% medium with EX-CELL CD Hydrolysate Fusion. Once viability and cell growth recover to desired levels proceed to a 50%/50% mix, then 25%/75% and finally 100% medium with EX-CELL CD Hydrolysate Fusion.

### *Fed-Batch Mode (addition to feeding protocol)*

1. Existing Fed-Batch Procedure

- a. Simply substitute the EX-CELL CD Hydrolysate Fusion for the hydrolysate addition.

- b. If the hydrolysate is part of a multi-component single feed, EX-CELL CD Hydrolysate Fusion may be able to be incorporated into the single feed. A check for compatibility will be needed. If the solutions are not compatible, they will need to be added as separate parts.

## 2. New Fed-Batch Procedure - Suggested Protocol

- a. A glucose and L-glutamine feeding protocol is suggested and should be optimized for the specific process. A recommended starting point is to feed additional glucose and glutamine when they reach 2 g/L and 2 mM respectively.

- b. Determine the proper time and amount of addition of the EX-CELL CD Hydrolysate Fusion. Multiple time-points and concentrations should be tested to obtain optimal performance. A recommended starting point would be 1X (1.74 g/L) added when the cultures reach densities around  $1.0 \times 10^6$  viable cells/mL.

## Characteristics

### Appearance

White, free-flowing powder

### Product Profile

EX-CELL CD Hydrolysate Fusion was compared to hydrolysates in a fed-batch system with rIgG producing CHO cells (Charts 1 & 2).

Note: The cell line was adapted to a proprietary chemically defined formulation before evaluating growth and productivity. All conditions were fed on Day 2 with the respective feed and 6 g/L additional glucose.

Chart 1

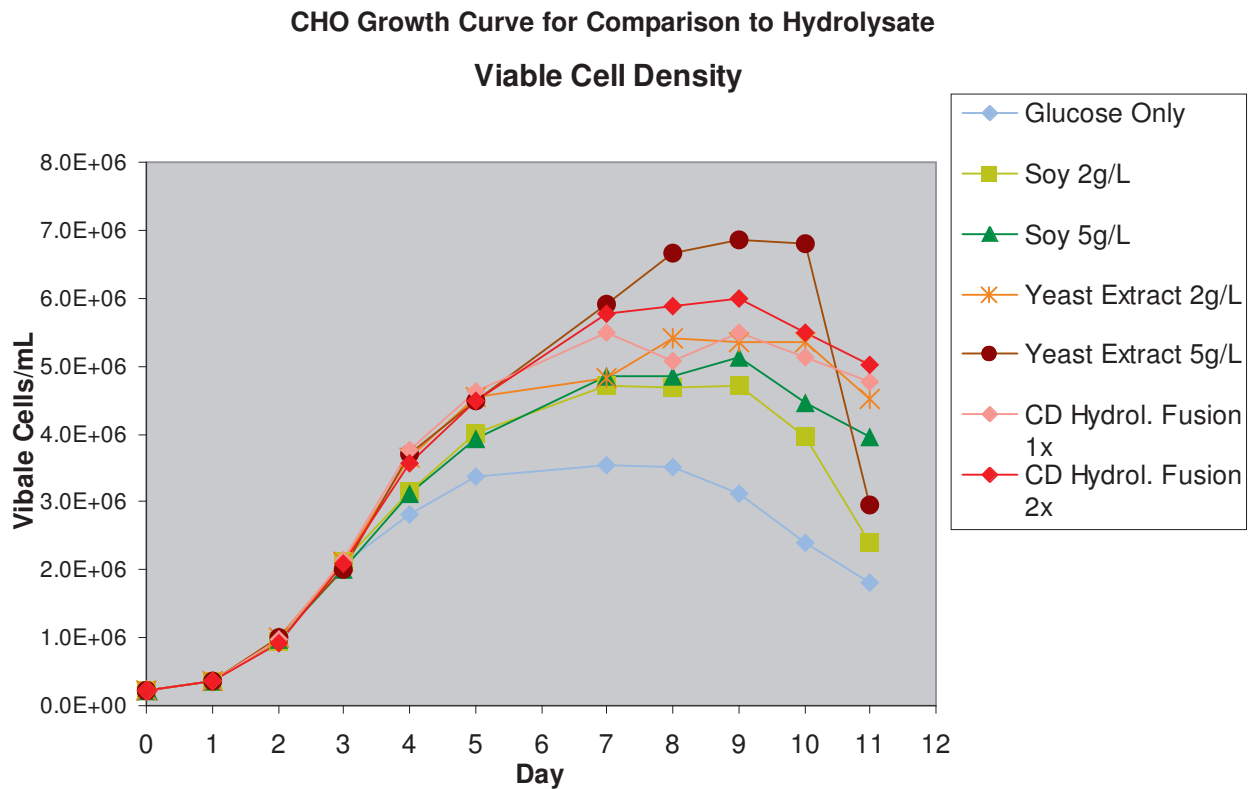
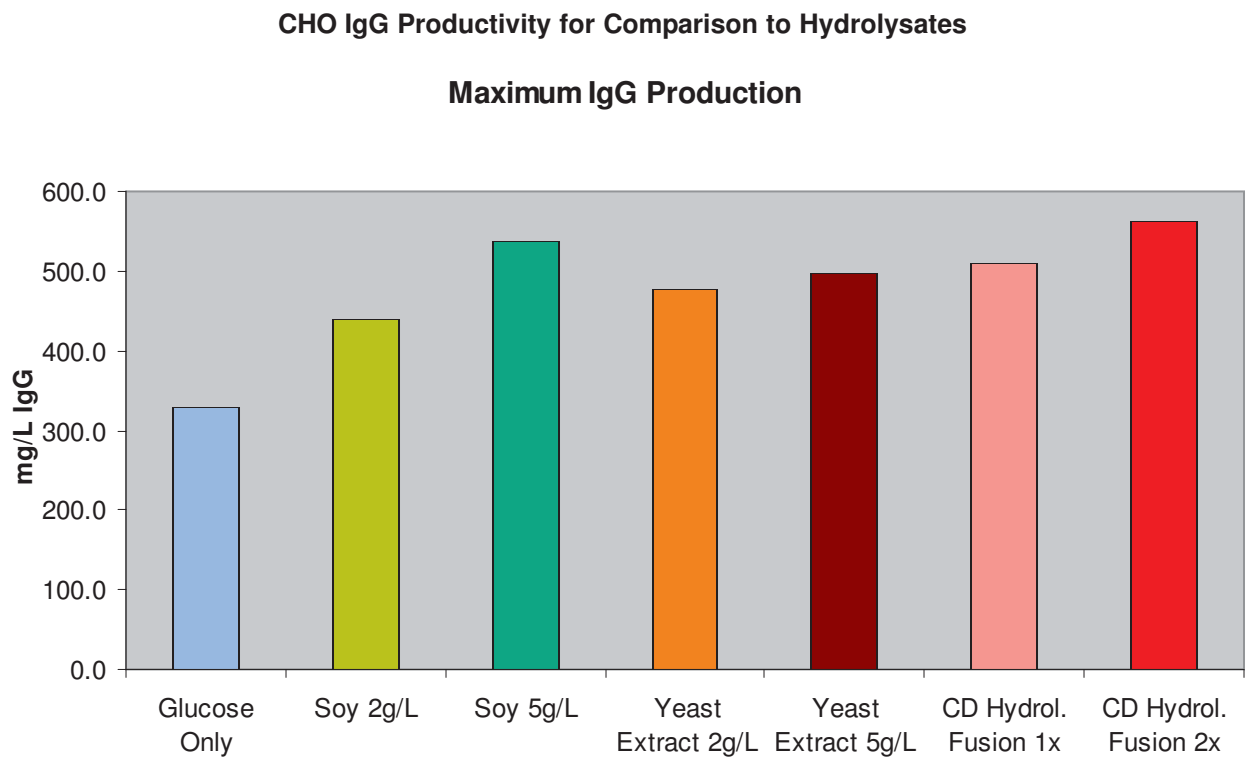


Chart 2



#### Warranty, Limitation of Remedies

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