SAFC®
Pharma & Biopharma Raw Material Solutions

Cellvento® ModiFeed Prime COMP

Chemically defined cell culture feed

Product Description

Cellvento® ModiFeed Prime COMP is a chemically defined feed formulation containing only components of non-animal origin. It does not contain hydrolysates, phenol red, 2-mercaptoethanol, or glucose ensuring batch-to-batch consistency. The product is intended for use in the development and manufacturing of monoclonal antibodies and next-generation biopharmaceuticals in Chinese Hamster Ovary (CHO) cell-based expression systems.

Cellvento® ModiFeed Prime COMP is a highly concentrated, one-part, pH neutral feed added to replenish depleted nutrients required for cellular function and to extend the production phase in fed-batch mode. This single feed is highly concentrated, at more than 131 g/L, allowing for a reduction in volume of feed added to the medium thereby increasing product yield.

The formulation has been specifically designed to provide increased process control and decreased complexity. Exclusion of glucose from the formulation allows for fed-batch process dictated regulation of this critical parameter. As a one-part feed, containing modified amino acids and amino acid derivatives, the complexity of hydration, storage, and feeding is drastically reduced. The option to store hydrated feed protected from light either at 2–8 °C for up to 90 days or room temperature for up to 30 days provides unparalleled flexibility. The feed is supplied as a compacted dry powder, a convenient to handle and hydration friendly format.

Application

Cellvento® ModiFeed Prime COMP has been developed as a feed supplement to be used in combination with the production media, Cellvento® 4CHO COMP and EX-CELL® Advanced CHO, during fed-batch manufacturing processes. It has been designed to support optimal cell growth and high productivity of suspension CHO cell lines such as CHO-K1, CHO-DG44, CHO-S and CHO-GS, including cell lines derived using the CHOZN® platform. Careful attention has been paid to multiple protein quality metrics.

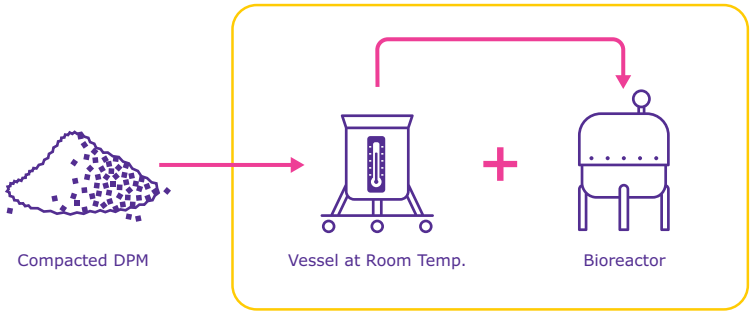
This product is intended for research or further manufacturing but not for human or therapeutic use.

Cellvento® ModiFeed Prime COMP

Compacted DPM
- Reduced bulk volume
- Easier handling
- Reduced dust formation
- Improved flowability

Hydration
- Single-part feed
- Six steps
- No pH adjustment
- 100 min mixing

Feed
- Highly concentrated
- Neutral final pH
- Low total % added
- High starting bioreactor volume



Straightfoward Hydration
Ease of use by applying innovative approaches

MERCK

Reconstitution method - Cellvento® ModiFeed Prime COMP

1. Slowly add 131.6 g/L of compacted powder to 85% of final volume Milli-Q® or similar cell culture grade room temperature (18–25 °C) water in an appropriately sized container
2. Rinse weighing vessel as necessary to remove remaining compacted powder
3. Vigorously mix for at least 10 min until all compacted powder is dissolved, solution will still be slightly turbid
4. Using a calibrated vessel adjust to 100% volume (QS) with Milli-Q® or similar cell culture grade room temperature (18–25 °C) water
5. Vigorously mix for at least 90 min until solution is clear
6. Measure final pH: Expected pH 6.7 ± 0.3
7. Measure final osmolality: Expected osmolality 1245 ± 70 mOsmol/kg
8. Immediately filter using a sterilizing-grade filter (≤0.22 µm). Filter recommendations provided.
9. Store reconstituted Cellvento® ModiFeed Prime protected from light at 2–8 °C for up to 90 days or at room temperature for up to 30 days

Storage

Cellvento® ModiFeed Prime COMP should be stored in original packaging at 2-8 °C protected from light.

Do not use after expiration date.

Recommended feeding strategy

Cellvento® ModiFeed Prime COMP has been developed for use as a feed supplement in combination with either the production media Cellvento® 4CHO COMP or EX-CELL® Advanced CHO. As with most upstream bioprocesses, optimization of feed volumes and timing of feed administration should be empirically determined on a process- and cell line-specific basis to maximize performance.

Cellvento® ModiFeed Prime COMP, used in conjunction with Cellvento® 4CHO COMP or EX-CELL® Advanced CHO, is recommended to be fed at between 15% and 27.5% total depending on the demands of the clone(s) tested.

Parameter	Recommended range for evaluation
Cellvento® ModiFeed Prime COMP	2.5% – 7.5% (v/v) per feed
Frequency	48-72 hour feed intervals
Glucose	4 – 8 g/L monitor, maintain and adjust daily

Suggested initial feeding evaluation

Initiate feeding only when viable cell density is ≥2 x 10^6 cells/mL and no earlier than day 3 (to avoid over-feeding). Maintain supplementation with feed supplement and glucose until culture viability is less than 80%. Terminate and harvest cultures when viability drops below 70%.

In order to center in on the optimum approach for the clone(s) being tested, initial evaluation should consist of 17.5% and 22.5% total feed. A low percentage has the potential to under feed while a high percentage has the potential to over feed. Unless the general demands of the clone(s) are already known, during initial evaluation it is suggested to test both a low and high total feed percentage.

Culture Day	Total Feed	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	Total Feed
Cellvento® ModiFeed Prime COMP (% v/v)	Low				3		3		5.5			3		3			17.5
Cellvento® ModiFeed Prime COMP (% v/v)	High				4		4		6.5			4		4			22.5

If preferred the schedule can be adjusted to support a more regular feed interval

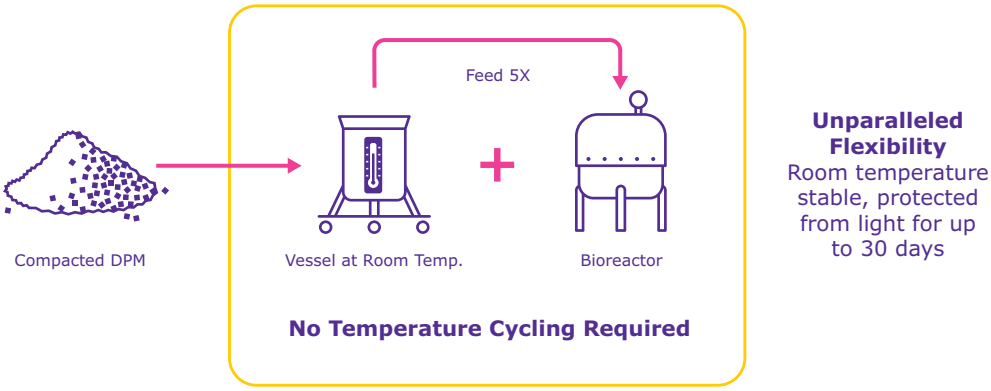
Culture Day	Total Feed	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	Total Feed
Cellvento® ModiFeed Prime COMP (% v/v)	Low				3.5		3.5		3.5		3.5		3.5				17.5
Cellvento® ModiFeed Prime COMP (% v/v)	High				4.5		4.5		4.5		4.5		4.5				22.5

Once a preference for a lower or higher total feed percentage is established optimization through further increasing or decreasing the total feed can be evaluated.

The suggested initial feeding evaluation is designed to support a low seed (2–5 x10^5 cells/mL) 14 day fed-batch process. If viability is still high late in culture longer fed-batches can be supported. Additional feeding may be required. Continue with similar feeding frequency and percentages until viability drops below 80%.

A high seed fed-batch (2–5 x10^6 cells/mL) may require adjustment in feeding schedule to support higher biomass earlier in culture and provide more total feed. Feeding can be initiated as early as day 2 to support higher biomass early in culture. High seed may offer an option for shortening the duration of longer fed-batches or for achieving increased production over the same 14 days.

Cellvento® ModiFeed Prime COMP



Unparalleled Flexibility
Room temperature stable, protected from light for up to 30 days

Ordering Information

Catalog Number	Description	Application	Pkg. Size	Equivalent
1.04132.0001	Cellvento® ModiFeed Prime COMP	Fed-batch feed	131.6 g	1 liter
1.04132.0005	Cellvento® ModiFeed Prime COMP	Fed-batch feed	0.658 kg	5 liters
1.04132.0050	Cellvento® ModiFeed Prime COMP	Fed-batch feed	6.580 kg	50 liters
Recommended Media				
1.03795	Cellvento® 4CHO COMP	Fed-batch medium	Multiple	1/10/100 L
24366C	EX-CELL® Advanced CHO Fed-batch medium	Fed-batch medium	Multiple	1/10/100 L
14366C-1000mL	EX-CELL® Advanced CHO Fed-batch medium	Fed-batch medium		1 liter

Filters

The following sterilizing-grade filters are recommended for use with Cellvento® ModiFeed Prime COMP

Organism Removal	Bacteria Removal	Mycoplasma & Bacteria Removal
Volume (L)	**Millipore Express® SHC**	**Millipore Express® SHR with Prefilter**
1L	**KGHES015FF3**	**KHVES015FF3**
5L	**KHGES015FF3**	**KHVES015FF3**
50L	**KHGES015FF3**	**KHVES015FF3**
500L	**KHGES03TT3**	**KHVES05TT1**

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