

**TO:** Ms. Mary Paron-Boswell, Sr. Planner, City of Coppel, TX.

**C.C.:** Mr. Allen Hager, DPR, Mr. Jerome Doyle, AstraZeneca

**SUBJECT:** Project Summary

**PREPARED BY:** Aidan Coleman, Project Manager, DPS

## 1. SITE OVERVIEW

The AstraZeneca (AZ) site located at 508 Wrangler Drive, Coppel, TX (Lot 3R-1, Block 8 Park West Commerce Center / Building 3 / West Facility ) is a single product manufacturing site and the only AZ site that produces Lokelma. Lokelma is a prescription medicine that is used to treat adults with Hyperkalemia. Hyperkalemia occurs when the potassium levels in a patient's blood are too high. It is a condition that can lead to serious and potentially life-threatening health issues. Patients with Chronic Kidney Disease (CKD) are at a higher risk for Hyperkalemia. CKD affects an estimated 200 million people worldwide. AstraZeneca's vision is to ensure every patient across the globe has access to the life-saving Lokelma.

The AstraZeneca Coppel Site is approximately 118,185 square feet. The Coppel Site currently includes 6 manufacturing lines (Process Trains 1 - 6), Warehousing, Starting Material Storage (Tank Farm), Utility Space, Quality Control Lab and Administrative Areas. The Coppel Site operates 24 / 7 and the existing manufacturing capacity is one-hundred percent utilized to meet the current patient demand for Lokelma. The Lokelma demand is forecasted to more than double by 2026. Therefore, AstraZeneca needs to increase the Coppel Site's manufacturing capacity to be able to meet that demand. AstraZeneca's strategic plan includes the addition of 2 manufacturing lines (Process Trains 7 and 8), the associated utilities and a separate starting material storage building (Tank Farm) to the Coppel Manufacturing Site. The additional manufacturing lines will provide the capacity needed to meet the forecasted global demand for Lokelma.

## 2. SITE HISTORY

2015 - AstraZeneca acquired Lokelma from ZS Pharma and Coppel Site lease transferred to AstraZeneca

2018 – Received FDA and European Medicines Agency (EMA) regulatory approval for Lokelma

2019 – Launched commercial distribution of Lokelma

2023 – Lokelma approved in 55 Markets Worldwide

2023 – Tank Farm Design Initiated

2025- Tank Farm in Operation

2026- Q1 Train 7 Commercial Production

2026- Q3 Train 8 Commercial Production (TBD)

### 3. TANK FARM ADDITION

The Aqueous Chemical Tank Farm addition to the site will be used to support the existing and new manufacturing lines (Process Trains 7 and 8).

The overall facility footprint of the new Tank Farm is approximately 9,500 sf, including both floors. The building equates to 19,000 sf, including the Truck Unloading Area, the Tank Farm, and the supporting utilities on the first and second floors.

The project is expected to have a land disturbance area of approximately 2.5 acres, which will require ground clearing, excavation, and levelling to allow a first-floor elevation to match the existing cGMP Building. Pacheco Koch, a Westwood company proposed approach to excavation/grading, site equipment location and will be the site civil engineering firm of record. Site work also includes utility infrastructure for water mains, sanitary sewer, storm water and electrical routing.

The Tank Farm portion of the building, which will house the tanks and aqueous chemicals, requires the addition of nine tanks, eight of which are 17,000 Gallons intended to be fabricated from stainless steel, and one 10,000-gallon tank which will be Fiberglass Reinforced Polyester (FRP) to store the raw materials listed below:

- Sodium Hydroxide (NaOH)
- Zirconium Acetate (ZrAc)
- Colloidal Silica
- Hydrochloric Acid (HCl)

It is important to note that the existing Tank Farm already in operation within the site holds the same chemicals. Thus, no new chemicals are being introduced to the site with the addition of the new and separate Tank Farm building. The additional starting material storage capacity of the new Tank Farm is required to support the increased manufacturing capacity with the addition of Process Trains 7 and 8.

### 4. City's review comments (received on July 28,2023) and DPS Responses

- is there any release of fumes, etc. into the atmosphere?

DPS Response: No, All Hydrochloric Acid vents will be scrubbed prior to venting to atmosphere. Scrubber design will be managed in Detailed Design phase. All other vents are non-hazardous vent services.

- Still needing information relating to chemicals and proximity to other buildings and property lines. As this may affect setback or construction material/rating of this building.

DPS Response: The Tank Farm Building is considered an H-4 Occupancy Group. Section 307.6

High-hazard Group H-4 defines the tank farm building as containing materials that are health hazards that includes but not limited to Corrosives. The raw materials stored within the tank farm building are considered corrosives.

1: Tank Farm Building to Existing AZ Manufacturing Facility: Based on the attached civil site plan, the existing AstraZeneca manufacturing facility is 97.5 Feet off of the tank farm building. As listed in the 2015 IBC – Table 602 FIRE-RESISTANCE RATING REQUIREMENTS FOR EXTERIOR WALLS BASED ON FIRE SEPARATION DISTANCE there is a greater than 30 foot distance between buildings so we would need a 0 Hr fire rating on the exterior wall of the tank farm building.

2: There is a 10 foot side yard setback on the existing property line. The Tank Farm building is located 14.6 feet off the side yard property line as shown on the attached civil site plan. As mentioned above, sine we are greater than 30 feet to any building based on the side yard property line, the exterior wall of the tank farm would be at 0 hours. As a precaution, and should the adjacent side yard property be developed, we are providing a 4-hour rated interior wall along the entire length of the tank farm building along the side yard property line. This will protect AZ from ever having to go back and install a fire rated wall in the future should the adjacent property ever be developed.

Table 602

FIRE-RESISTANCE RATING REQUIREMENTS FOR EXTERIOR WALLS BASED ON FIRE SEPARATION DISTANCE

FIRE SEPARATION DISTANCE = X (feet)	TYPE OF CONSTRUCTION	OCCUPANCY GROUP H (e)	OCCUPANCY GROUP F-1, M, S-1 (f)	OCCUPANCY GROUP A,B,E,F-2,I,R,S-2,U(h)
X ≥ 30	All	0	0	0

(e) For special requirements for Group H occupancies, see Section 415.6

Section 415.6 – Fire Separation Distance: Building must comply with requirements outlined within this section, which we do.