



ACS DOBFAR HEALTH & SAFETY



ACS DOBFAR

- ❏ **ACS DOBFAR IS A PRIVATE ITALIAN COMPANY THAT SUPPLIES ACTIVE INGREDIENTS TO THE BIGGEST PHARMACEUTICAL COMPANIES IN THE WORLD.**
- ❏ **ACS DOBFAR HAS BEEN PRODUCING β - LACTAM ANTIBIOTICS (in BULK) FOR OVER 40 YEARS.**



ACSD Italian API's Facilities



ACSD 1

Via Rossini



ACSD 2

Viale Addetta



ACSD 3

Via Paullo



ACSD 4

Vimercate



ACSD 5

Albano S. Alessandro



DPHAR 6

ACSD 8

Sesto Uteriano



ACS DOBFAR IN THE WORLD

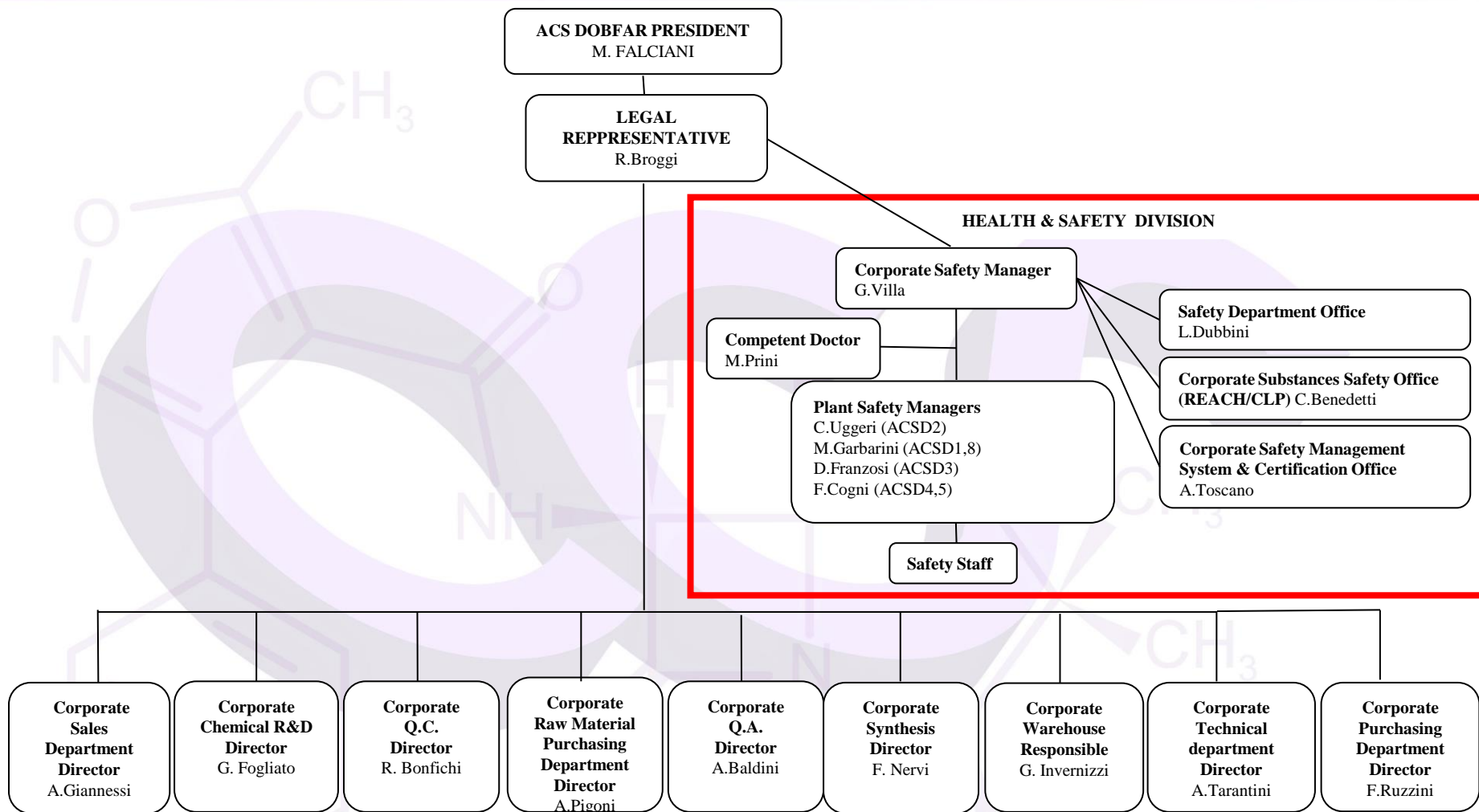
API

FDF

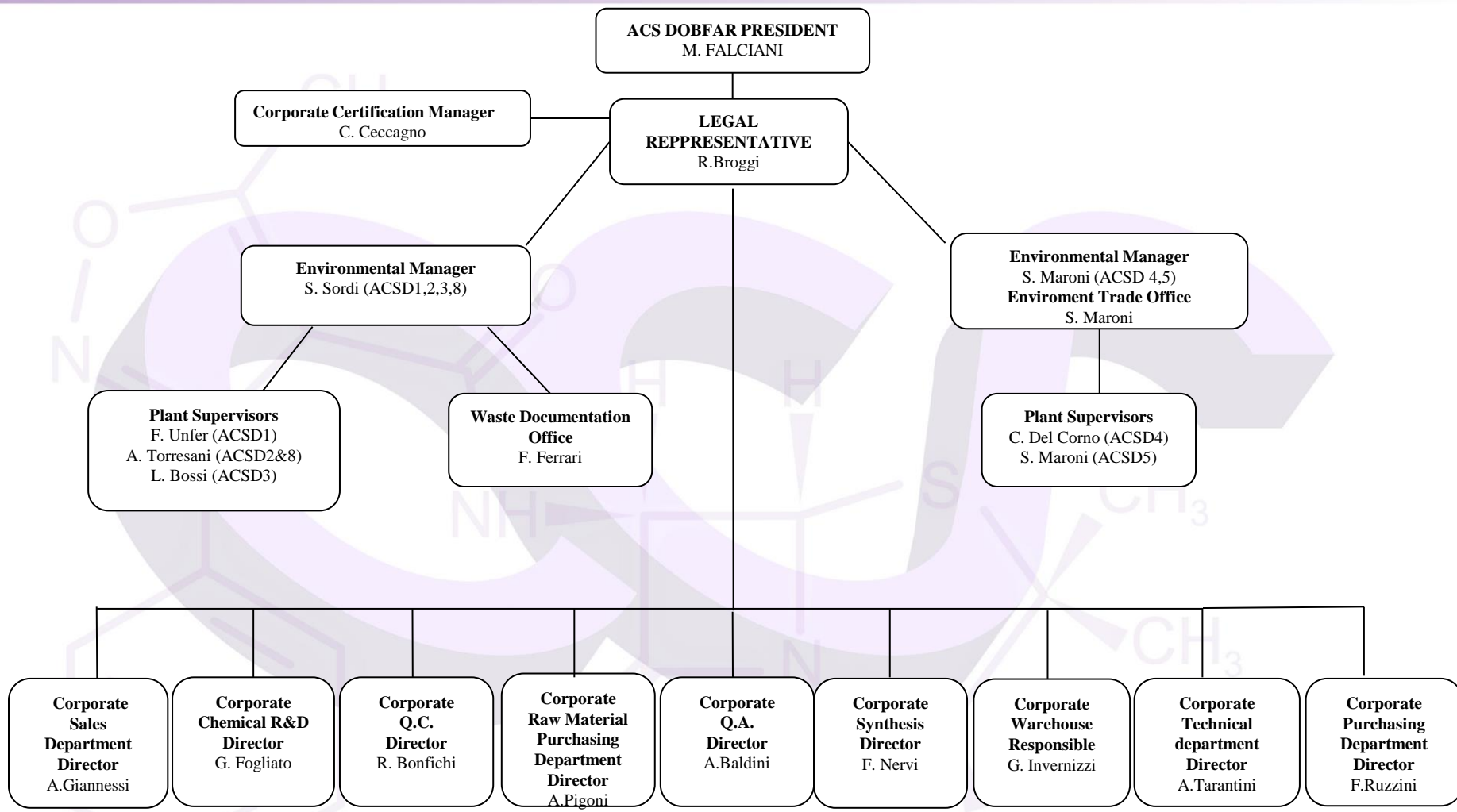
API
&
FDF



ACSD Health & Safety Organization



ACSD Environmental Organization



ACS DOBFAR – Health & Safety Activities

SAFETY:

- Seveso Law (2012/18/UE, 4th July 2012) → Relevant Accident Risk Company
- Safety Management System
(Policy Document, Safety Procedures, Safety Manual “Risk Evaluation Document” or “DVR”)
- “DVR document”
(National Legislative Decree N°81/2008 for Safety in the Workplaces”)

Main Risks evaluated:

- Safety and industrial hygiene (SOV, Dust)
- Noise
- Workplace Microclimate
- Biological
- ATEX
- Fire prevention
- Load Handling



ACS DOBFAR – Health & Safety Activities

SECURITY:

Management of anti intrusion systems.

Eu Regulations:

Substance Safety Office for REACH (EC N.1907/2006) and CLP (EC N.1272/2008) regulations accomplishment.

It is in charge for the REACH registration submissions and manages the preparation and updates of MSDS.

TRAINING:

Health & Safety Division provides for and carries out the permanent information-schooling and training programme of the company workers and also of the contractors' workers and visitors.



ACS DOBFAR - Health & Safety

DECLARATION OF AUTHORITY - (POLICY)

ACS DOBFAR S.P.A.

- The company's progress, which is essential for the smooth running of the company, should only ever be achieved in respect of the Safety and Health of workers, citizens and the environment by taking every necessary resource to the prevention and management of risks.
- With the purpose of the achievement of these objectives the ACSD group undertakes to make adequate resources available and keep an adequate organization and management structure aimed at the minimization of the relevant accident risks of all the ACSD production sites.



ACS DOBFAR - Health & Safety

Safety Management System (SGS)

- Plant RSPP (Prevention and Protection Safety Responsibles) have been trained on Safety Management System:
 - Adverse events reporting,
 - Incidents & near misses reporting
 - “Management of Change” procedure, that addresses the safety impact of proposed changes to hazardous processes.
- Health & Safety division carries out Sites Internal Audits and Self-Assessments to evaluate the effectiveness of the HS management programmes.
- Health & Safety division prepares the “Annual State SGS Report”
- Health & Safety division communicates HS performance and reports the activities done to employees and any other interested parties during the annual meetings



ACS DOBFAR - Health & Safety

PTWs

- The confined space entry programme is periodically assessed for effectiveness, fully comprehensive for each activity. PTWs are used and filled according to SGS procedures. The Technical Office is in charge of the correct use of PTWs by both Acs Dobfar personnel and contractors. The technical office trains both Acs Dobfar personnel and contractors on the PTWs procedures.
- Within the facility Contractor Safety program, Contractors attend the training required by Seveso law with Acs Dobfar's personnel. They are trained in the use of PTWs by the technical office and are given full information on Acs Dobfar hazardous materials, productions, health information and emergency plan by the HS Manager.



SAFETY MEASURES AND FIRST AID ON SITE

- The emergency situations are defined in the Internal Emergency Plan.

The facility has identified potential accidents, emergency situations and other significant events that might plausibly occur and are incorporated into the Emergency Response Plan.

This plan includes two practical exercises that are done, each year, by the Emergency Teams. Also employees are expected to respond during the practical exercise; they have been informed on how to respond.

The Emergency Teams are periodical trained, they are fully equipped and they are always ready for an intervention in case of need.

- Presence of an Infirmary with all the necessary things to help injured people and some first-aid kit in different points on the plant.



PLANTS ACTIVITIES

➤ Chemical R&D Laboratory:

It develops chemical synthesis methods and effective technologies for this manufacturing plant, with the aim of optimizing the scaling-up of the production processes.

➤ Synthesis Department:

Where Synthesis processes takes place. There is a Batch production method; Raw Materials are loaded into the reactor/s, then reactions take place and the products obtained, after being centrifuged, are then crystallized, filtered and dried, so as to obtain the Finished Products.

➤ Chemical Quality Control :

Our Finished Products and Raw Materials are analysed from a quality point of view.

➤ Warehouse:

Storage of Raw Materials and Finished Products.

- at room temperature;
- at controlled temperature: Cold store ($T = +5^{\circ}\text{C} - 20^{\circ}\text{C}$).



Environmental Management System

- Each plant is certified according to UNI EN ISO 14001:2015
- ACS Dobfar has a proper Environmental Policy
- Strong control and incidents report guaranteed by Internal Audits and Self Assessments conducted to evaluate the system application

Environmental Laboratory

- Environmental laboratory personnel conducts analysis on air emissions, wastewaters, solid and liquid wastes, exhausted solvents and soils.
- The monitoring plan of each plant's permit gives the frequency of the analysis and the parameters to be determined



ACSD2 ADDETTA PLANT



ACSD2 Geographical Area



The productive site ACSD2 is located in Viale Addetta n.4/12 in Tribiano.



The ACSD2 area is assessed in the municipal land register of Tribiano and it is included in D1 productive/industrial area.

Within a distance of 5 Km from factory there are:

- towns of Paullo, Pantigliate, Colturano, Dresano, Peschiera, Settala, Zelo Buonpersico
- some provincial roads:
- other chemical productive sites



PLANT EQUIPMENT

Reactors:

- 28 reactors, steel and enameled,
- minimum capacity: 3000 liters
- max capacity: 25000 liters.

The reactors have the following services:

Warm and Cold water, vapor, Liquid nitrogen, liquids for cooling, nitrogen gas.

There are probes for the control of temperature, pressure and pH.

Some reactors can work in a range of temperatures between -60°C and $+40^{\circ}\text{C}$.



PLANT EQUIPMENT

Centrifuges:

They are used to isolate the finish solid products.

They are steel centrifuges:

6 with vertical axis.

Dryers:

2 static rotating dryer

2 rotating dryer



PLANT EQUIPMENT

➤ Sterile Department:

Equipment:

- 15 dissolutor steel
- 6 crystalizzer steel

This equipment have the following services:

Warm and Cold water, vapor, liquids for cooling, nitrogen gas.

Dryers:

6 Filter dryer



PLANT EQUIPMENT

SAFETY EQUIPMENT

- Automatic extinguishing system with water supply is present.
- Water Reserve for sprinkler system (1800 m³)
- The automatic system is actioned by :
 - 2 Diesel motor pump with a capacity of 570 m³/h for each.
- Sprinkler Systems:
 - 2 Dry systems (Cold Stores Raw Material & Finished Product Warehouses)
 - 3 Water deluge systems
(Two inside vapors abatement pipes on synthesis roof,
One runs along the outer perimeter of synthesis dep.)
 - 1 Foam deluge system (roof vacuum pumps)
 - 1 Foam system (Sterile 3 department)
 - 10 water systems (Thermal power plant, Synthesis dep., Raw Mat Warehouse, Finished product Warehouse, Ster.2 Drying Dep., Cri 1 Syntesis dep & Warehouse)
- Fire Foam Pourer in Tank Farm containment basins



PLANT EQUIPMENT

SAFETY EQUIPMENT

- 24 column hydrants (UNI 70)
- 76 wall hydrants (UNI 45)
- Smoke Detectors (Flammables Depository, Electrical Cabins, QA Archive, Technical Warehouse, Raw Material & Finished Products Warehouses, Sterile 3 Dep., IT dep., Tools Rooms n° 1-5)
- Gas Detectors (Thermal Power plant, Canteen)
- Dedicated track with pump and equipment
- Extinguishers (n° 289)
- Fire Foam (2 Tanks of 2000Lt each, 1 Tank of 3000Lt and other 2500 Lt)
- Generator
- Inergen System (Server Room – IT dep.)
- Central Control Room in Drying dep.



PLANT EQUIPMENT

ENVIRONMENTAL EQUIPMENT

AIR EMISSIONS

- 2 WET SCRUBBERS
- CRYOGENIC SYSTEM
- COGENERATION PLANT

WASTEWATERS

- TANK FARM
- COLLECTION PIPES AND TANKS FOR RAINWATER

SOIL SPILL PREVENTION

- CONTAINMENT BASIN

SOLID WASTES

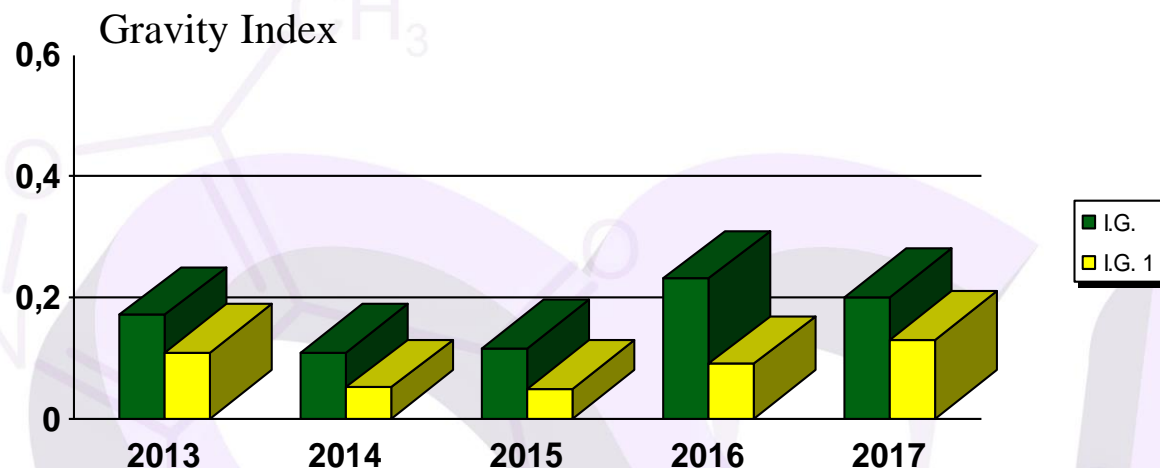
- WASTE COLLECTION ZONE



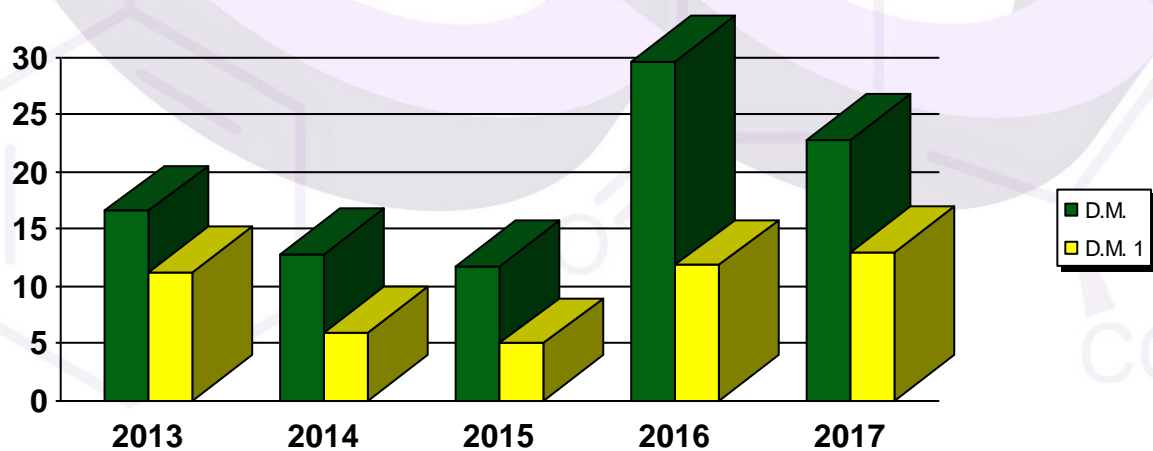
ACS DOBFAR - Health & Safety

INJURY REPORT

G.I. = Days of Injuriy/total worked hours



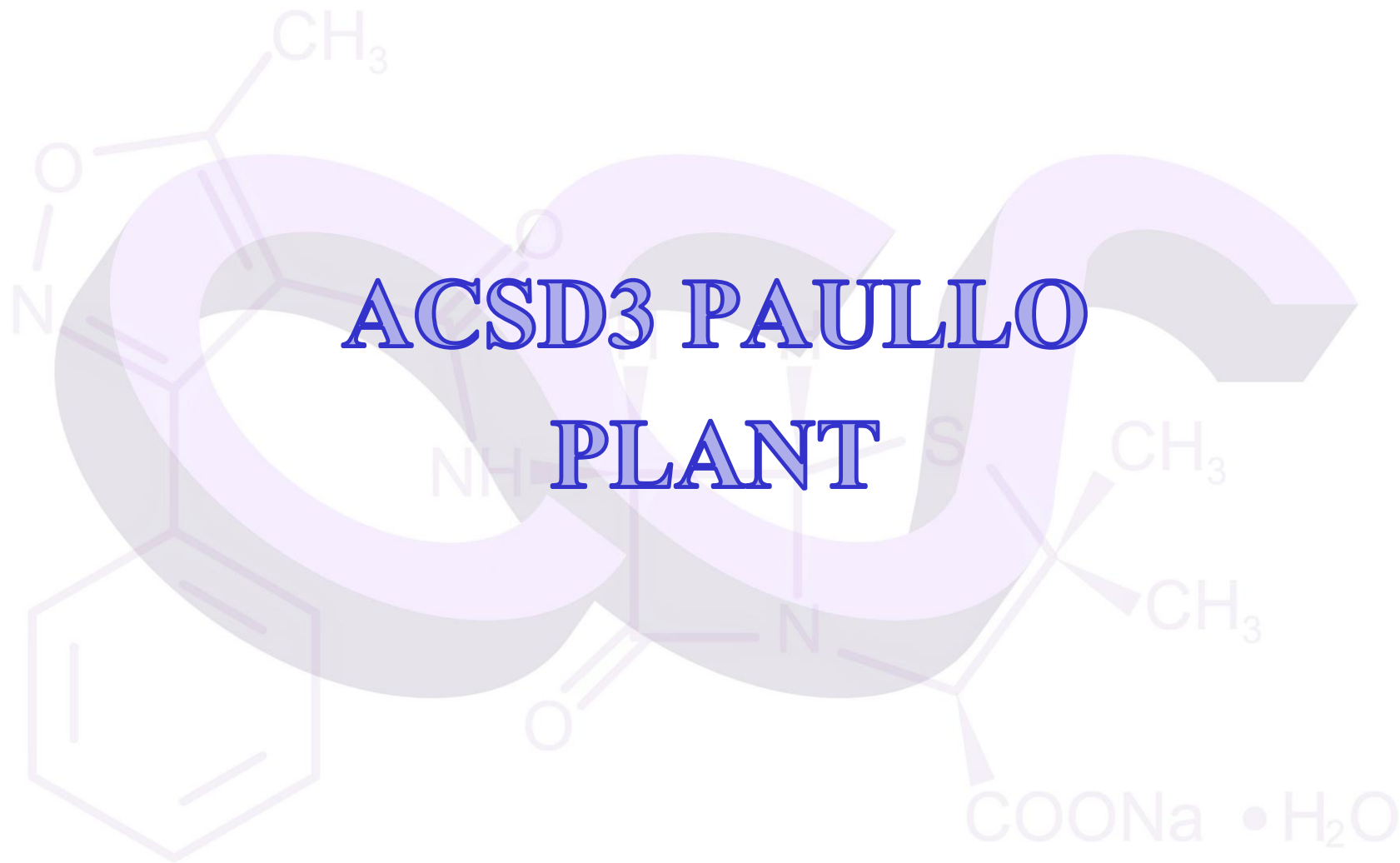
Average Duration



A.D. = Days of Injuries/N° of Injuries



ACSD3 PAULLO PLANT

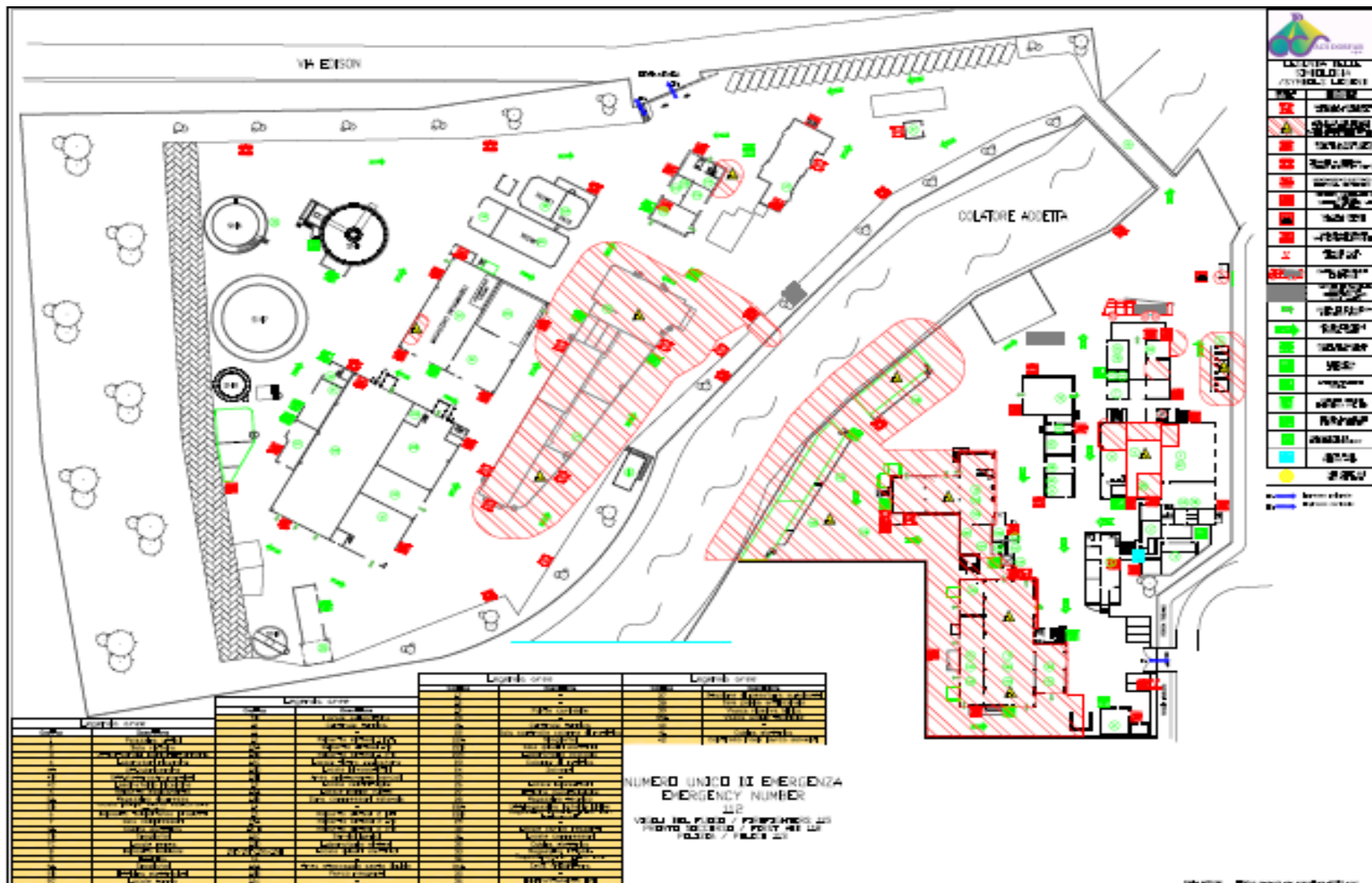


GEOGRAPHIC AREA



SITE MAP

Total Covered Area: 29500 m² - The plant is classified according to ATEX Standards.



GEOGRAPHICAL AREA



ACSD3 production plant is situated in Via Paullo no.9, also accessible from the entrance of Via Edison no. 9, in the town of Tribiano.

Geographical Coordinates:

Latitude: 45°24'58" N

Longitude: 09°23'06" E

Gauss-Boaga Coordinates : X(E) = 1 530 030; Y(N) = 5 029 260

The land, in the Southern part of Milan lowlands, is flat, slightly degrading towards the South.



The area is registered in the cadastral register of Tribiano (sheet 2 map 75-100), included in the production area D1 suitable for building and to be completed (PRG roading zoning – Town of Tribiano, January 2004).

Within a distance of 5 km from the plant:

- Towns: Tribiano, Paullo, Settala, Mediglia
- Roads: SP158, SP39, SS45
- Other production plants of chemical nature



PLANT EQUIPMENT

Reactors:

37 reactors, both in steel and enamel-coated, are operated. Their capacity range is between 150 and 17000 litres.

The utilities supplied to reactors are: cold and hot water, steam, brine, liquid nitrogen (only to some reactors), gas nitrogen.

Probes for the temperature, pressure and pH control are installed.

Some reactors operate at a temperature range between -90°C (liquid nitrogen) and 130°C (steam at 3 bar).

Centrifugal spinners:

They are used to isolate finished solid products.

Centrifugal spinners are in steel: 4 with vertical axis and removable bag and one with horizontal axis and automatic discharge.



PLANT EQUIPMENT

Filter dryers:

Three filter dryers in steel are installed; they have the double function of filtering and drying.

Dissolving filters:

Three dissolving filters are installed; they have the double function of filtering and dissolving.

Dryers:

One double-cone rotary dryer is installed to dry the solids.



PLANT EQUIPMENT

SAFETY EQUIPMENT

- Automatic extinguishing system with water supply is present.
 - Water Reserve for sprinkler system (300 m³)
The automatic system is actioned by
 - 1 Diesel motor pump with a capacity of 900 m³/h.
 - .
 - 5 Sprinkler System (Flammable Depository, Synthesis Dep., Raw Material Warehouse, Thermal Power Plant)
 - Foam Pourer System (manual valve) (Distillation Columns containment basin)
 - Water Deluge System (Distillation Columns C01, C02, C03; Abatement systems)
- 15 Column hydrants (UNI 70)
- 30 wall hydrants (UNI 45)
- 2 Foam Monitors
- Smoke Detectors (Control Room, Electrical Cabins, Thermal Power plant, Archive)
- Gas Detectors (Thermal Power plant)
- Hydrogen detector (QC Lab.)
- Extinguishers (n° 93)
- Fire Foam (1 Tank of 6000Lt, 1 Tank of 1600Lt and other 500Lt)
- Generator



PLANT EQUIPMENT

ENVIRONMENTAL EQUIPMENT

AIR EMISSIONS

- 4 WET SCRUBBERS
- CRYOGENIC SYSTEM
- COGENERATION PLANT

SOIL SPILL PREVENTION

- CONTAINMENT BASIN

SOLID WASTES

- WASTE COLLECTION ZONE



PLANT EQUIPMENT

ENVIRONMENTAL EQUIPMENT

WASTEWATER

- WASTE WATER TREATMENT PLANT
 1. 2 OXYDATION TANKS (2720 m³)
 2. 1 CLARIFIER
 3. 2 WASTEWATER STORAGE TANKS
 4. 2 LIQUID OXYGEN STORAGE TANKS
- TANK FARM
- COLLECTION PIPES AND TANKS FOR RAINWATER

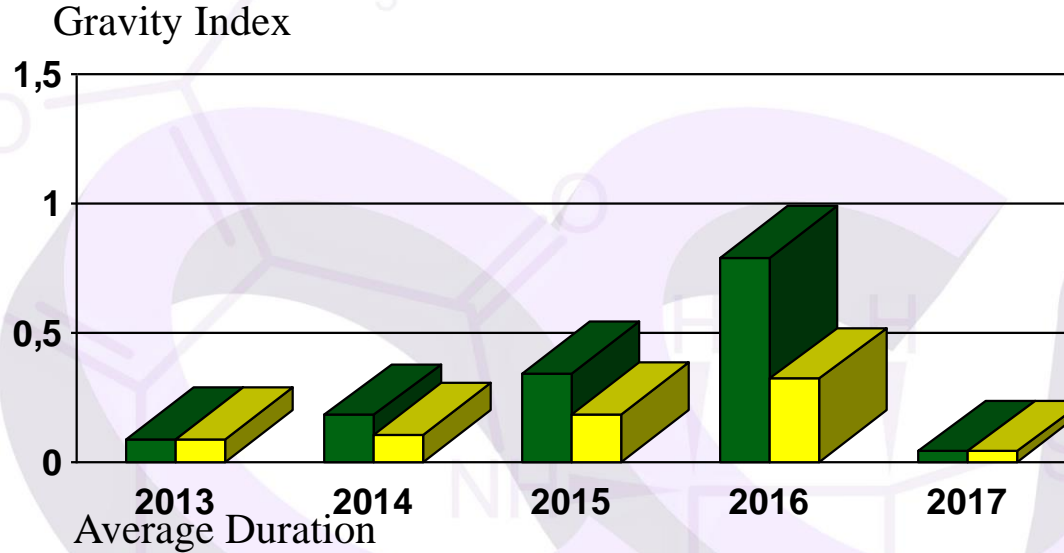
DISTILLATION PLANT

- 3 DISTILLATION TOWERS FOR SOLVENT RECOVERY

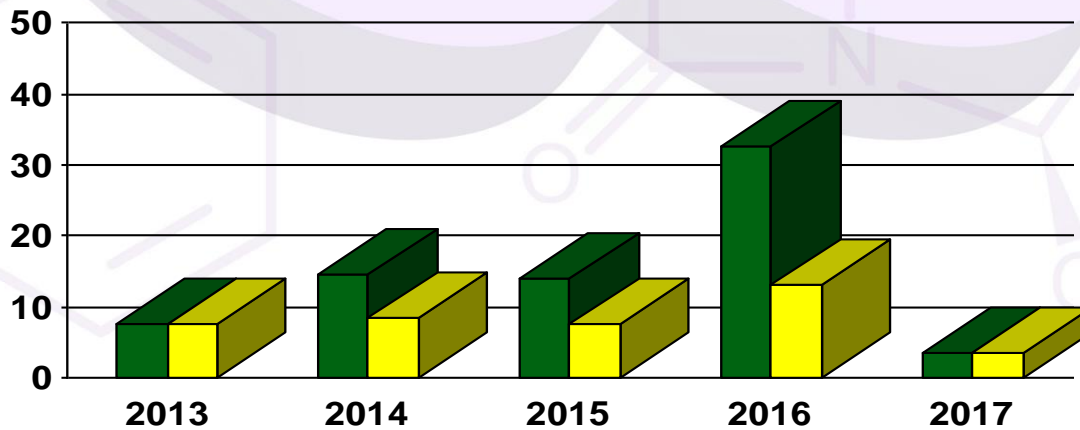


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INJURY REPORT



G.I. = Days of Injuriy/total worked hours



ACSD4 VIMERCATE PLANT



GEOGRAPHIC AREA



SITE MAP

Total Covered Area: 30060 m²

The plant is classified according to ATEX Standards.



PLAN GENERAL D'AMENAGEMENT

DES FACILITES D'ACCES ET DE SECURITE

NO. DE LA FACILITE	DESCRIPTION	TYPE	STATUT	REMARQUES
1	ACCES PRINCIPAL	ROUTE	PROPRIETE	
2	ACCES SECONDAIRE	ROUTE	PROPRIETE	
3	ACCES TERTIAIRE	ROUTE	PROPRIETE	
4	ACCES QUATRIEME	ROUTE	PROPRIETE	
5	ACCES CINQUIEME	ROUTE	PROPRIETE	
6	ACCES SIXIEME	ROUTE	PROPRIETE	
7	ACCES SEPTIEME	ROUTE	PROPRIETE	
8	ACCES HUITIEME	ROUTE	PROPRIETE	
9	ACCES NEUFIEME	ROUTE	PROPRIETE	
10	ACCES DIXIEME	ROUTE	PROPRIETE	
11	ACCES ONZIEME	ROUTE	PROPRIETE	
12	ACCES DOUZIEME	ROUTE	PROPRIETE	
13	ACCES TREIZIEME	ROUTE	PROPRIETE	
14	ACCES QUATORZIEME	ROUTE	PROPRIETE	
15	ACCES QUINZIEME	ROUTE	PROPRIETE	
16	ACCES SEIZIEME	ROUTE	PROPRIETE	
17	ACCES DIX-SEPTIEME	ROUTE	PROPRIETE	
18	ACCES DIX-HUITIEME	ROUTE	PROPRIETE	
19	ACCES DIX-NEUFIEME	ROUTE	PROPRIETE	
20	ACCES VINGTIEME	ROUTE	PROPRIETE	

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GEOGRAPHICAL AREA



ACSD4 production plant is located in Via Marzabotto 7/9 of Vimercate Town. On this side there is the main entrance with the reception; a secondary access is also present on the opposite side of the main entrance in Via Trento.

Geographical Coordinates:

Latitude:

45°35'32" N

Longitude:

09°21'25" E

Gauss-Boaga Coordinates : X(E) = 1 527 970 ; Y(N) = 5 049 040

The land in the Northern part of Milan , is initially flat and then going north becomes hilly.



Within a distance of 2,5 km from the plant:

- Towns: Vimercate, Agrate Brianza, Concorrezzo
- Roads: A51 Est Highway;
- Other: Few little companies.



PLANT EQUIPMENT

Reactors:

- 25 reactors, steel and enameled,
- minimum capacity: 3950 liters
- max capacity: 16000 liters.

The reactors have the following services:

Warm and Cold water, vapor, Liquid nitrogen, liquids for cooling, (only for some reactors), nitrogen gas.

There are probes for the control of temperature, pressure and pH.

Some reactors can work in a range of temperatures between -60°C and $+40^{\circ}\text{C}$.



PLANT EQUIPMENT

Centrifuges:

They are used to isolate the finish solid products.

They are steel centrifuges:

7 with vertical axis and 2 with extractable bag.

Dryers:

Four static rotating dryers

One Comber dryer

One Filtromix dryer

One fluid flow dryer

One rotating dryer



PLANT EQUIPMENT

SAFETY EQUIPMENT

- Automatic extinguishing system with water supply is present.
- Water Reserve for sprinkler system (400 m³)
- The automatic system is actioned by :
 - 1 Diesel motor pump with a capacity of 454 m³/h.
 - 1 Electric pump with a capacity of 455 m³/h.
- 5 Sprinkler System (Synthesis Dep. Ext Area C; Synthesis Dep. Ceiling Area C; Azo Area B; Synthesis Dep. New part Area C; Cold Store Area A)
- Water Deluge system (Flammable Box Area E, Box HCL Area D)
- Foam Deluge system (Tank Farm Area E)
- Water Blade System (Warehouse Area A)
- 10 Wall Hydrants UNI 45
- 14 Column Hydrants UNI 70
- 1 Foam Monitor
- Smoke Detectors (Control Room, Elettrical Cabins, Thermal Power plant, QA Archive)
- 5 Smoke evacuators (Synthesis Dep., Raw Material Warehouse entrance)
- Gas Detectors – (HMDS, TMCS Flammable Deposit Area M)
- Gas Detectors – (Methane - Thermal Power plant Area H)
- Extinguishers (n°113)
- Fire Foam Drums (n° 11 - 200 Litres Drums)



PLANT EQUIPMENT

ENVIRONMENTAL EQUIPMENT

AIR EMISSIONS

- 2 WET SCRUBBERS
- CRYOGENIC SYSTEM MADE OF:
 - 2 CRYOGENIC COLUMN UNITS
 - 2 CARBON UNITS
 - 2 WET SCRUBBERS
- 1 COGENERATION PLANT





PLANT EQUIPMENT

ENVIRONMENTAL EQUIPMENT

WASTEWATERS

- WASTE WATER TREATMENT PLANT MADE OF:
1 BIOLOGICAL AEROBIC PLANT MADE.
- COLLECTION PIPES AND TANKS FOR WASTE WATER.





PLANT EQUIPMENT

ENVIRONMENTAL EQUIPMENT

SOLID WASTES

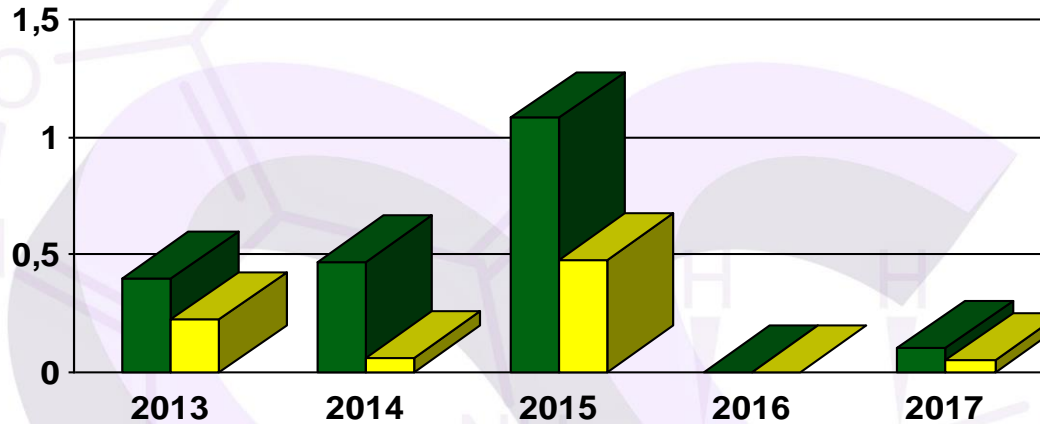
➤ WASTE COLLECTION ZONE



ACS DOBFAR - HEALTH & SAFETY

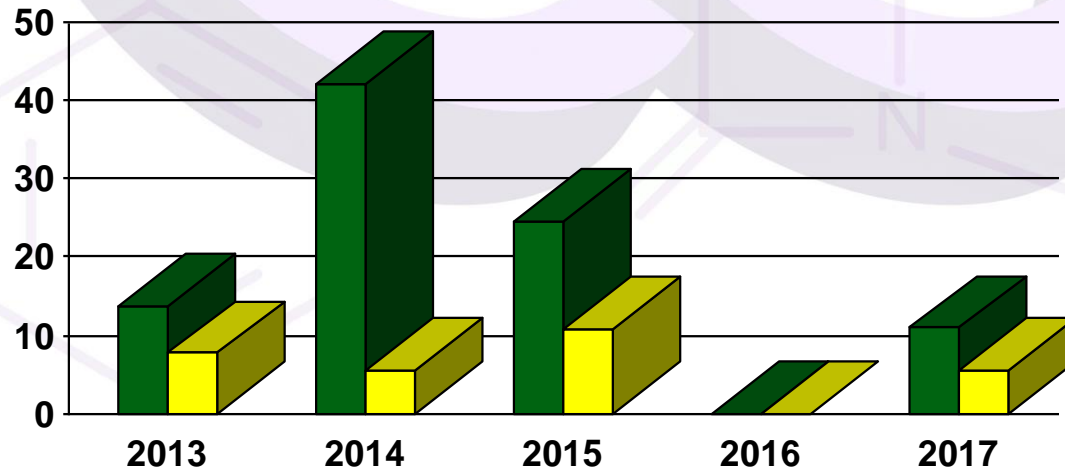
INJURY REPORT

Gravity Index



G.I. = Days of Injuriy/total worked hours

Average Duration



A.D. = Days of Injuries/N° of Injuries



ACSD5 ALBANO SANT'ALESSANDRO PLANT



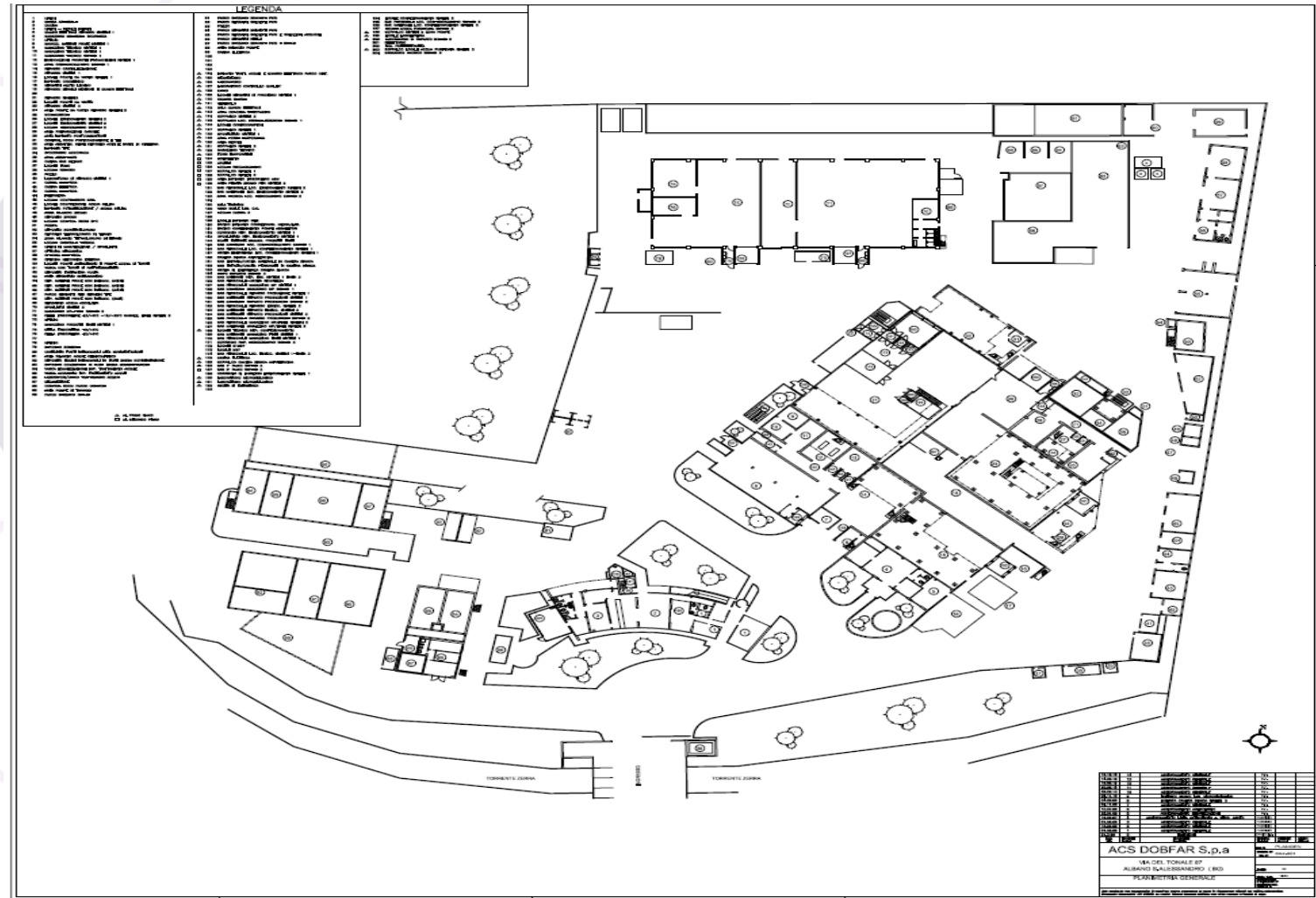
GEOGRAPHIC AREA



SITE MAP

Total Covered Area: 29.770 m²

The plant is classified according to ATEX Standards.



ACSD5 Geographical Area



The productive site ACSD5 is located in Via Tonale, 87 Albano Sant'Alessandro.



Geographical coordinates:

Gauss-Boaga: X(E)= 1.560.910

Y(N)= 5.059.130

Within a distance of 2 Km from factory there are:

- towns of San Paolo d'Argon, Bagnatica;
- some provincial roads;
- other chemical productive sites.



PLANT EQUIPMENT

Reactors:

- 37 reactors, steel and enameled;
- minimum capacity: 1400 liters;
- max capacity: 18000 liters.

The reactors have the following services:

Warm and Cold water, vapor, Liquid nitrogen, liquids for cooling, nitrogen gas.

There are probes for the control of temperature, pressure and pH. Some reactors can work in a range of temperatures between -60°C and $+60^{\circ}\text{C}$.



PLANT EQUIPMENT

Centrifuges:

They are used to isolate the finish solid products.

They are steel centrifuges:

4 with vertical axis.

Dryers:

3 static rotating dryer

1 rotating dryer

2 tilting dryer



PLANT EQUIPMENT

SAFETY EQUIPMENT

- Automatic extinguishing system with water supply is present.
- Water Reserve for sprinkler system (350 m³)
- The automatic system is actioned by :
 - 2 Diesel motor pump with a capacity of 420 m³/h for each.
- Sprinkler Systems:
 - 2 Dry systems (Raw Material Tanks)
 - 3 Water deluge systems with foam (Synthesis Department)



PLANT EQUIPMENT

SAFETY EQUIPMENT

- 16 column hydrants (UNI 70)
- 10 wall hydrants (UNI 45)
- Smoke Detectors (Flammables Depository, Electrical Cabins, Steam Generator, Raw Material Warehouses, Fridge Container)
- Gas Detectors (Synthesis 1-2, Laboratory)
- Dedicated track with pump and equipment
- Extinguishers (n° 107)
- Fire Foam (1 Tanks of 5000Lt and other 2600 Lt)
- Generator
- Central Control Room



PLANT EQUIPMENT

ENVIRONMENTAL EQUIPMENT

AIR EMISSIONS

- 2 WET SCRUBBERS
- POST BURNER

WASTEWATERS

SOIL SPILL PREVENTION

- CONTAINMENT BASIN

SOLID WASTES

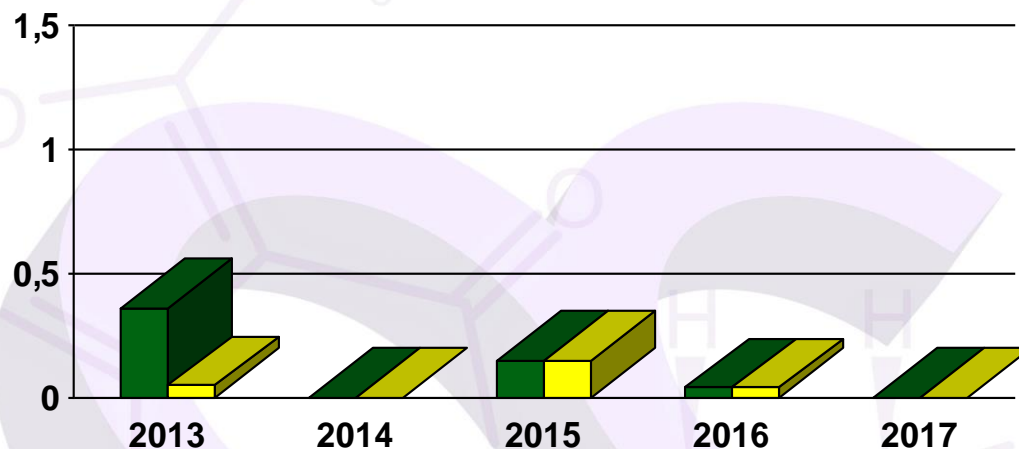
- WASTE COLLECTION ZONE



ACS DOBFAR - HEALTH & SAFETY

INJURY REPORT

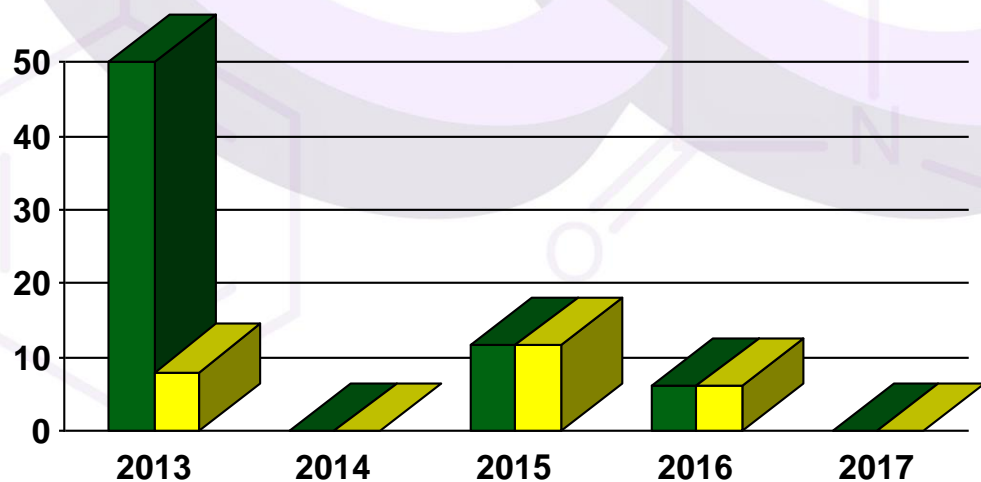
Gravity index



G.I. = Days of Injuriy/total worked hours

I.G.
I.G. 1

Average duration

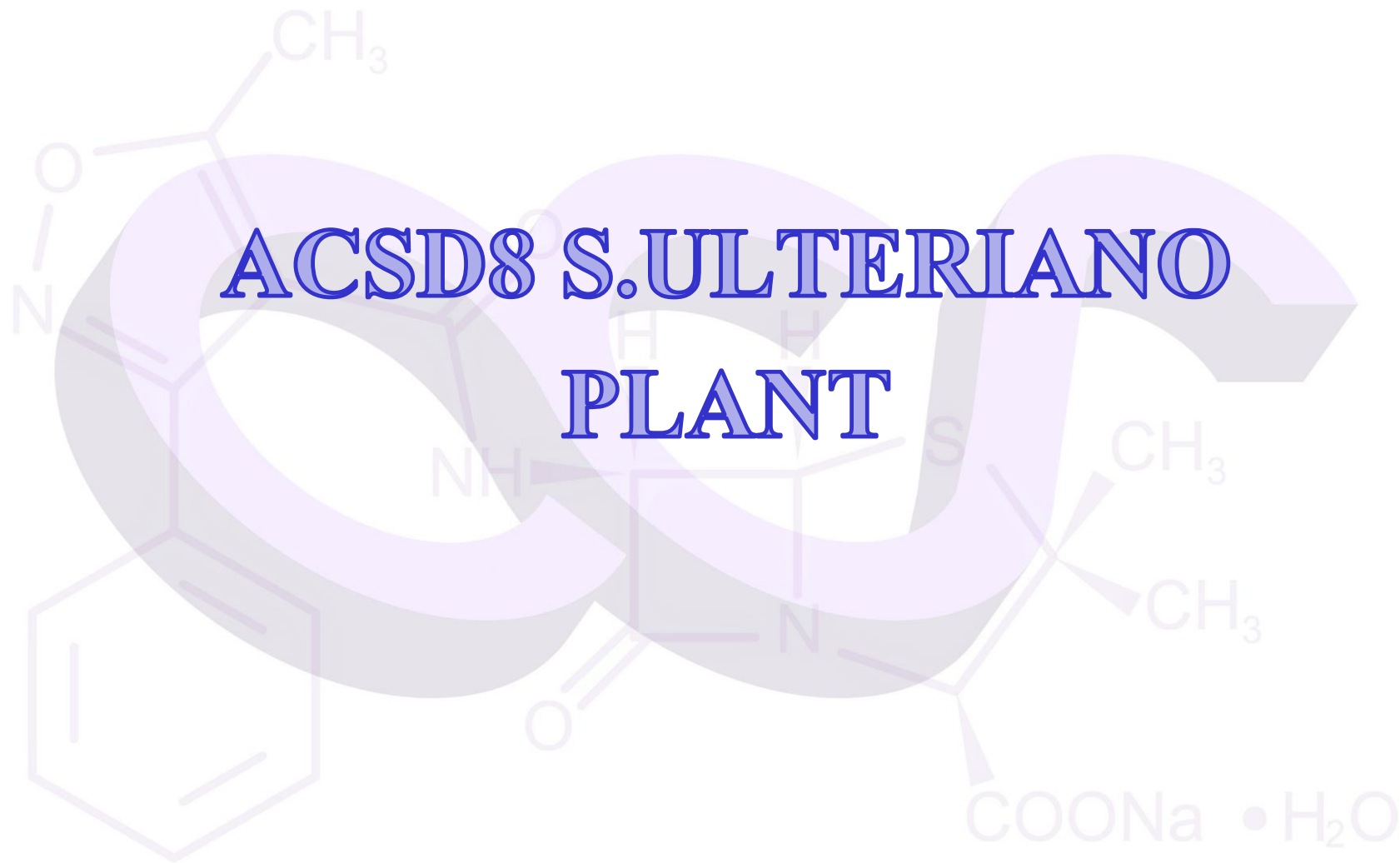


A.D. = Days of Injuries/N° of Injuries

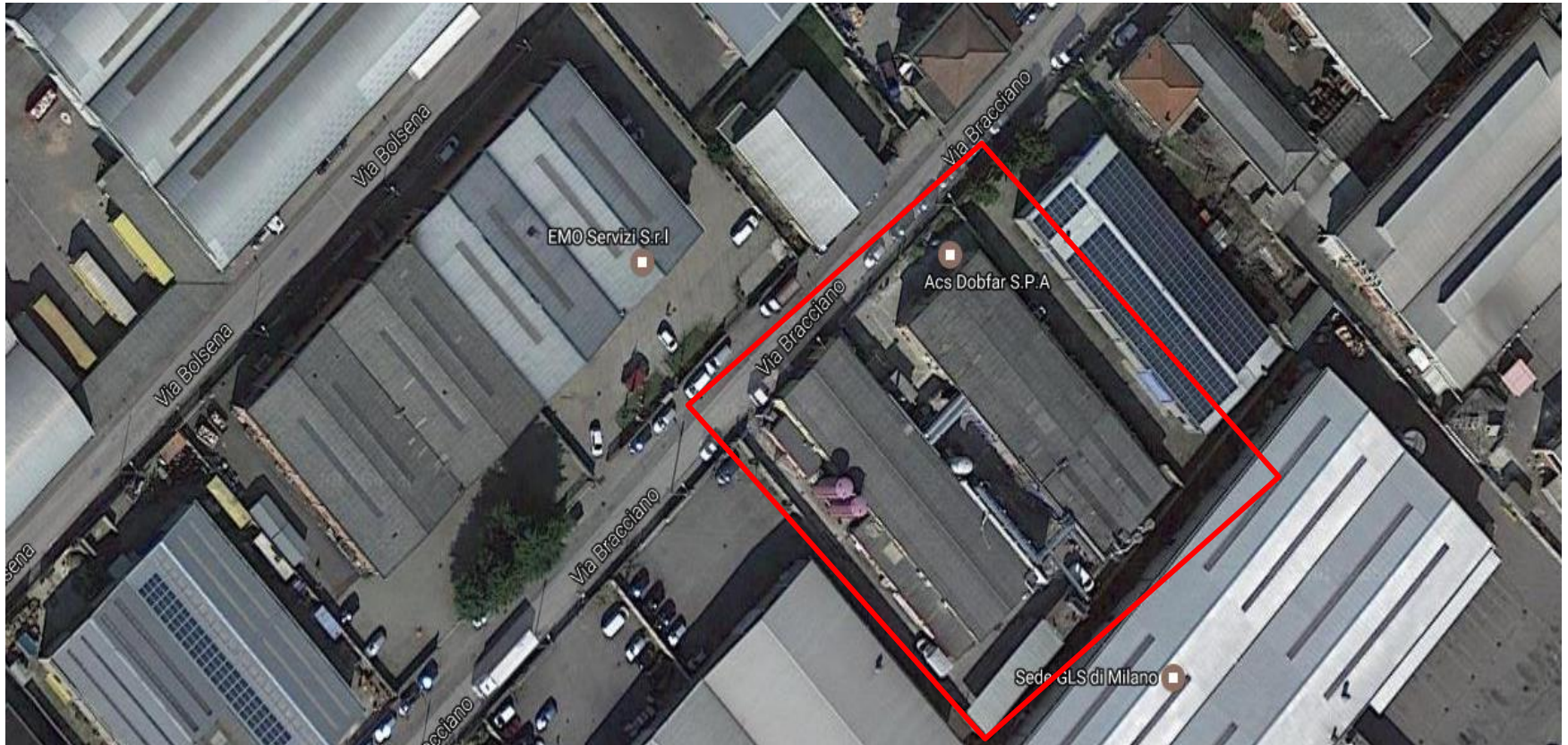
D.M.
D.M. 1



ACSD8 S. ULTERIANO PLANT

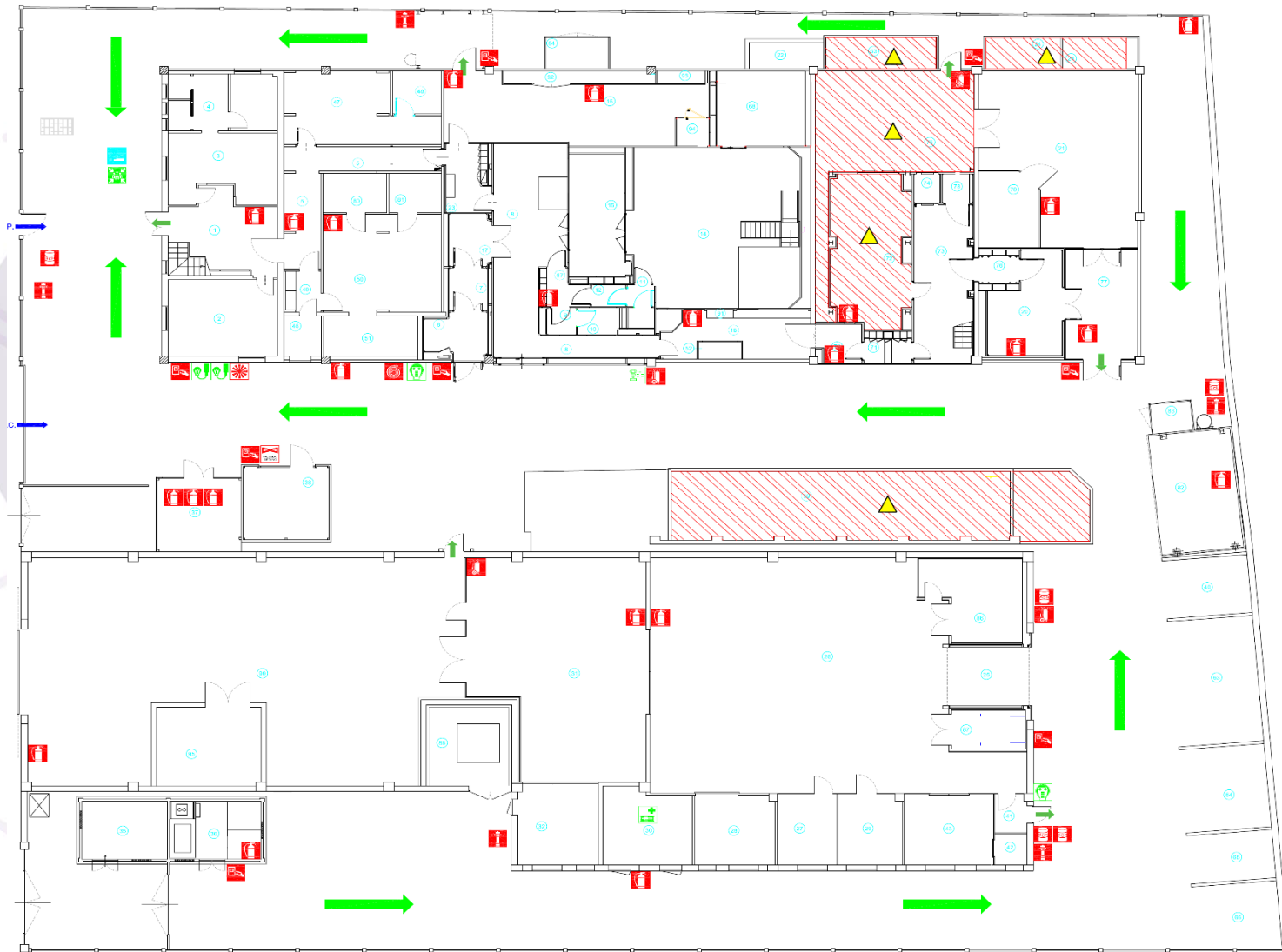


GEOGRAPHIC AREA



SITE MAP

Total Covered Area.....m² - The plant is classified according to ATEX Standards.



GEOGRAPHICAL AREA



ACSD4 production plant is located in Via Marzabotto 7/9 of Vimercate Town. On this side there is the main entrance with the reception; a secondary access is also present on the opposite side of the main entrance in Via Trento.

Geographical Coordinates:

Latitude:

45°35'32" N

Longitude:

09°21'25" E

Gauss-Boaga Coordinates : X(E) = 1 527 970 ; Y(N) = 5 049 040

The land in the Northern part of Milan , is initially flat and then going north becomes hilly.



Within a distance of 2,5 km from the plant:

- Towns: Vimercate, Agrate Brianza, Concorrezzo
- Roads: A51 Est Highway;
- Other: Few little companies.



PLANT EQUIPMENT

- 1 Reactor (R8) with cart steel and enameled?
- minimum capacity:liters
- max capacity:liters.
- 1 Reactor/Crystallizator (R7) steel and enameled?
- minimum capacity:liters
- max capacity:liters.
- 2 Reactors/Dissolutors (R5,6) steel and enameled?
- minimum capacity:liters
- max capacity:liters

The reactors have the following services:

Warm and Cold water, vapor, Liquid nitrogen, liquids for cooling, nitrogen gas.

There are probes for the control of temperature, pressure and pH.

Some reactors can work in a range of temperatures between -60°C and $+40^{\circ}\text{C}$.



PLANT EQUIPMENT

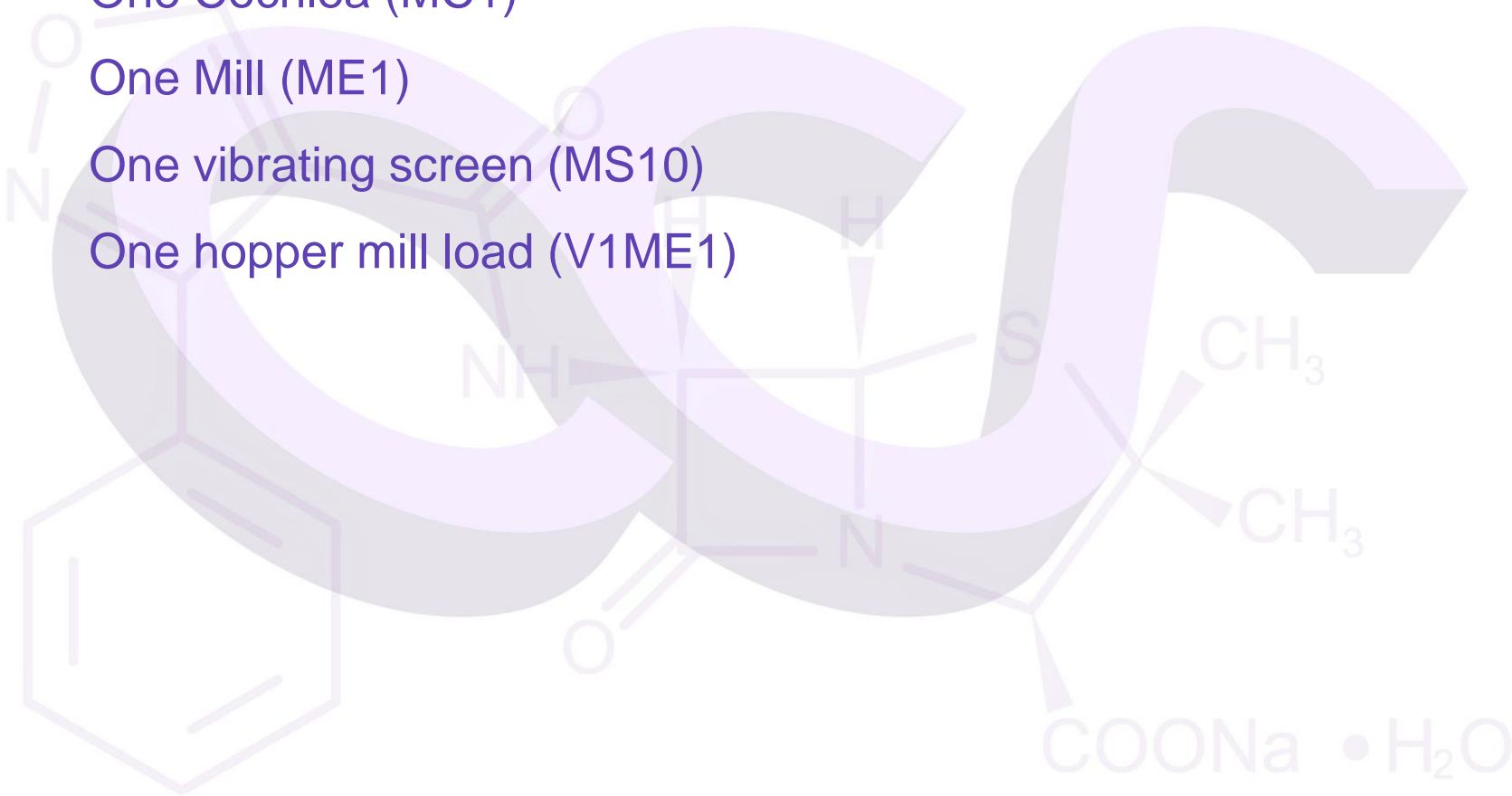
Two rotating filter dryers (MD1, MD2)

One Cochlea (MC1)

One Mill (ME1)

One vibrating screen (MS10)

One hopper mill load (V1ME1)



PLANT EQUIPMENT

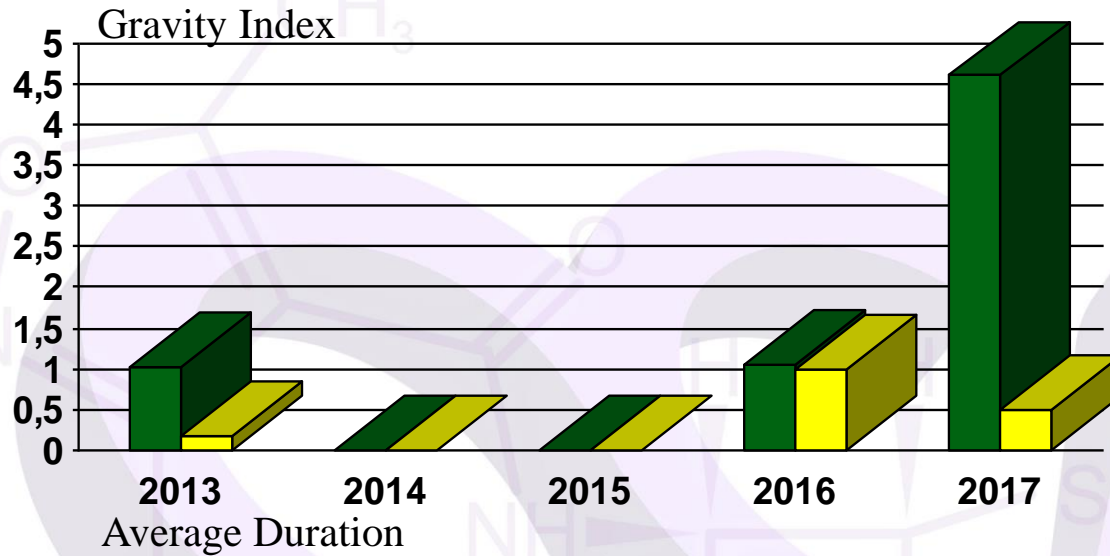
SAFETY EQUIPMENT

- Automatic extinguishing system with water supply is present.
- Water Reserve (144 m³)
 - The automatic system is actioned by :
 - 1 Diesel motor pump with a capacity of 1200 Lt/min.
 - 1 Electric pump with a capacity of 1200 Lt/min..
- 5 Hydrants UNI 45
- 4 Hydrants UNI 70
- 2 Hose reels
- 1 connection UNI 70 for Fire Brigade
- Extinguishers (n°26)
- Fire Foam Drums (n° 4 - 200 Litres Drums)
- QC Labs:
 - 1 Hydrogen detector
 - 1 Oxygen detector
- Thermal Power Plant : 1 methane detector

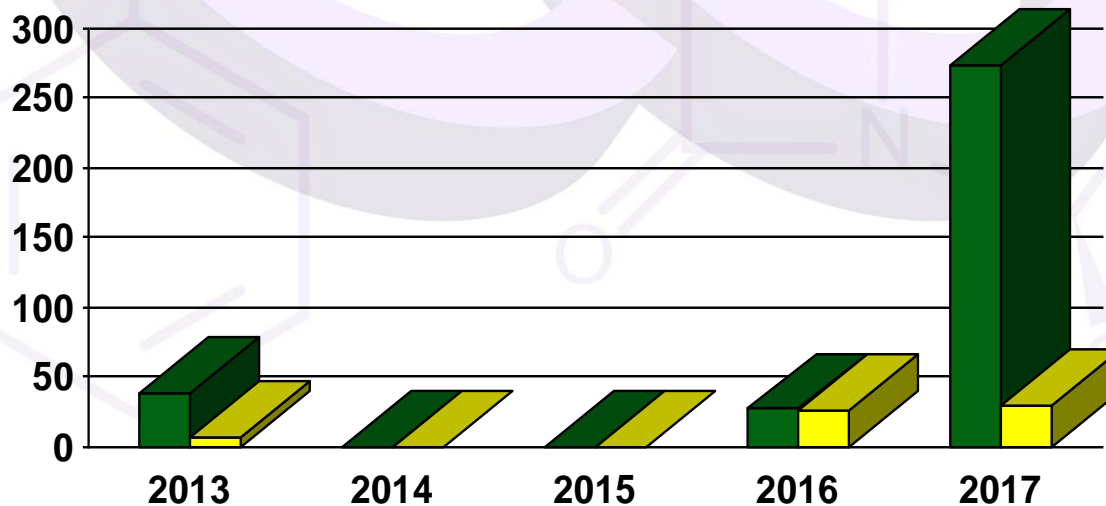
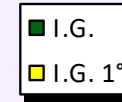


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INJURY REPORT



G.I. = Days of Injuriy/total worked hours



A.D. = Days of Injuries/N° of Injuries

