

1st May 2025

Office of Environmental Enforcement,
Environmental Protection Agency,
PO Box 3000,
Johnstown Castle,
Wexford,
Co. Wexford,
Y35 W821

MOR Ref: E2363

IEL: P0638-02

Via EDEN

Re: Priority Substances Wastewater Assessment, Zoetis Belgium S.A., Tullamore

To Whom it May Concern,

1.1 Background

Zoetis Belgium S.A. ('Zoetis') are required under Condition 6.18 of Industrial Emissions Licence P0638-02 to undertake a desktop assessment and subsequent screening Of Priority Substances, Priority Hazardous Substances and Watchlist Substances as listed in the European Communities Environmental Objectives (Surface Waters) Regulations 2009 (S.I. No. 272/2009); Tables 11 to 13 inclusive.

1.2 Context

Zoetis operate a biopharmaceutical manufacturing facility which began operations in 2002 as a single-site development under the ownership of GeneMedix plc. under Industrial Emissions License ('IEL') P0638-01, located at the IDA-owned Srah Business Park, Tullamore. The facility was transferred to BioNua Ireland in 2016. Zoetis took ownership of the facility in 2018, and the IEL was transferred without any amendment to this discharge.

The original facility (termed Building 100) had one drainage point to foul sewer (SE2), which discharged trade effluent to the IDA-owned foul sewer. This trade effluent consists of boiler blowdown, wastewater from the Water Treatment Plant, and utilities condensate.

Zoetis decided to expand the facility through the creation of a separate, purpose-built expansion built on neighbouring land. Zoetis applied for a review of the IEL in 2022, and the reviewed licence Reg. No. P0638-02 was granted on 5th June 2024.

The new building is termed Building 200 and has a separate foul drainage system and a separate foul discharge point (SE3), which discharges into the same IDA-owned foul sewer as discharge point SE2.

Laboratory chemicals do not discharge to foul sewer from either Building 100 or Building 200. This waste stream is collected separately and disposed of off-site as hazardous waste.

In Building 100, process wastewater (which included chemically inactivated GMO liquid waste) passes through the on-site Wastewater Pre-Treatment Plant (WWPTP), where it is adjusted for pH and temperature. This treated wastewater is then directed through emission point SE2.

In Building 200, process wastewater (which includes GMO liquid waste heat-treated through the on-site biowaste system) passes through the on-site WWPTP, where it is adjusted for pH and temperature. This treated wastewater is then directed through emission point SE3.

All emissions from SE2 and SE3 ultimately discharge via foul sewer to the Tullamore Urban Wastewater Treatment Plant (UWWTP).

1.3 Relevant Substances

1.3.1 Condition 6.18.1

Condition 6.18.1 of the licence requires the completion of a desktop assessment and screening of the trade effluent.

Zoetis provided an updated Raw Materials list, which was checked against Tables 11, 12 and 13 from S.I.272/2009.

One substance from Table 11 was found to be present on the Raw Materials list:

- **Dichloromethane** (CAS Number 75-09-02) is listed in Table 11.

Dichloromethane is used at the Zoetis complex as a laboratory chemical. Total usage is calculated at 5 litres per annum. Dichloromethane is disposed of as a laboratory chemical and is therefore not discharged to wastewater.

No substances from Tables 12 or 13 were found to be present on the Raw Materials list.

1.3.2 Condition 6.18.2

Condition 6.18.2 requires the submission of a report on the desktop assessment to be submitted to Uisce Éireann. This report is attached to this letter as Appendix A.

1.4 Conclusion

One substance (dichloromethane) in use at the IEL facility is listed as a priority substance. This substance is disposed of as a laboratory chemical and is not disposed of to wastewater. It will therefore not be found in the trade effluent or enter the public sewer.

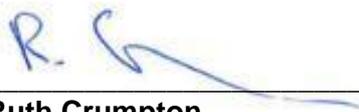
As no Priority Substance, no Priority Hazardous Substance and no Watchlist Substance is discharged as trade effluent, IEL Conditions 6.18.3 to 6.18.5 inclusive do not apply.

If new products or processes are introduced at the facility, the above screening exercise should be repeated to determine if such changes result in the introduction of any Priority Substance, Priority Hazardous Substance or Watchlist Substance. This should be included as a Standard Operational Procedure in Zoetis's Environmental Management System to ensure compliance with Condition 6.18.6 of the IEL.

Please note that VOC testing will take place annually.

Yours sincerely,

for Malone O'Regan Environmental


Ruth Crumpton

ATTACHMENTS



**Priority Substances Wastewater
Desktop Assessment of Trade
Effluent**

Zoetis Belgium S.A.

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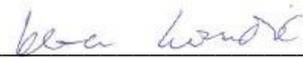
Title: Priority Substances Wastewater, Desktop Assessment of Trade Effluent, Zoetis Belgium S.A., Sragh Technology Park, Rahan Road, Tullamore, Co. Offaly

Job Number: E2363

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Signed: 

Revision Record

Issue No.	Date	Description	Remark	Prepared	Checked	Approved
01	01/05/25	Report	Final	RC	KK	KK

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**Priority Substances Wastewater
Desktop Assessment of Trade Effluent
Zoetis Belgium S.A.
Sragh Technology Park, Rahan Road, Tullamore, Co. Offaly**

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1 INTRODUCTION

1.1 Background Information

Malone O'Regan Environmental ('MOR Environmental') have been contracted by Zoetis Belgium S.A. ('Zoetis') to complete works arising from the review of the Industrial Emissions Licence ('IEL') Ref. P0638-02 granted by the Environmental Protection Agency ('EPA') for operations at Zoetis's biopharmaceutical production facility ('the Facility') at Tullamore, Co. Offaly.

The Facility consists of two buildings (designated as B100 and B200) located respectively on the eastern and western sides of the Route 100 road within the IDA Business Park. Under agreement with Uisce Éireann ('UÉ'), trade effluent from the Facility discharges into the IDA-owned sewer system within the Business Park via emission points SE2 (B100) and SE3 (B200).

Laboratory chemicals are not disposed of as trade effluent to either point SE2 or SE3 but are collected separately for disposal off-site as hazardous waste.

Process wastewater from B100 (which includes chemically inactivated GMO liquid waste) passes through the on-site Wastewater Pre-Treatment Plant (WWPTP), where it is adjusted for pH and temperature. This treated wastewater is then directed through emission point SE2.

Process wastewater from B200 (which includes GMO liquid waste heat-treated through the on-site biowaste system) passes through the on-site WWPTP, where it is adjusted for pH and temperature. This treated wastewater is then directed through emission point SE3.

All emissions from SE2 and SE3 are treated at Tullamore Urban Wastewater Treatment Plant (UWWTP).

1.2 Purpose of Report

Condition 6.18.2 of the IEL requires Zoetis to:

“undertake a desktop assessment and subsequent screening of trade effluent generated as a result of onsite activities for priority substances, priority hazardous substances and watchlist substances as listed in Tables 11, 12 and 13 of S.I. No 272/2009 – EC Environmental Objectives (Surface Waters) Regulations 2009, as amended.”

Condition 6.18.2 states:

“A report on the assessment and screening shall be submitted to Uisce Éireann within twelve months of the date of grant of this licence”.

The following report complies with Condition 6.18.2.

2 DESKTOP ASSESSMENT AND SCREENING

Zoetis provided an updated Raw Materials list to MOR Environmental. The listed substances were assessed against Tables 11 (Priority Substances), 12 (Priority Hazardous Substances) and 13 (Watchlist Substances) of S.I. 272/2009 as per the IEL Conditions – see Table 2-1 below.

Table 2-1: Substances Discharged to Wastewater At Zoetis Tullamore

Substance	CAS No.	Priority Substance	Priority Substance	Hazardous	Watchlist Substance	Discharged as Trade Effluent
2-Mercaptoethanol	60-24-2	No	No	No	No	No
2M Hydrochloric Acid	7648-01-0	No	No	No	No	Yes
2,3,4,-5 Tetramethylbenzidine	54827-17-7	No	No	No	No	No
8M Guanidine HCl solution	Mixture	N/A	N/A	N/A	N/A	No
ABTS Microwell Substrate	N/A	N/A	N/A	N/A	N/A	No
Acetic Acid	64-19-7	No	No	No	No	Yes
Acetone	67-64-1	No	No	No	No	No
Acetonitrile	75-05-8	No	No	No	No	No
Ammonia	7336-21-6	No	No	No	No	No
Ammonium Bicarbonate	1066-33-7	No	No	No	No	No
Ammonium Formate	540-69-02	No	No	No	No	No
Ammonium Hydroxide	1336-1-6	No	No	No	No	No
Ammonium Thiocyanate	1762-95-4	No	No	No	No	No
Antifoam Solution	8050-81-5	No	No	No	No	Yes
Bovine Serum Albumin	9048-46-8	No	No	No	No	No
Buffer Solution pH 5	55965-84-9	No	No	No	No	No
Carrier Ampholytes	N/A	N/A	N/A	N/A	N/A	No
Casein Sodium salt	9005-46-3	No	No	No	No	No
CE-SDS 25	Mixture	N/A	N/A	N/A	N/A	No
CHO Cell ELIZA Kit	Mixture	N/A	N/A	N/A	N/A	No
CHO HCP ELIZA Kit	Mixture	N/A	N/A	N/A	N/A	No
cIEF pI Marker	N/A	N/A	N/A	N/A	N/A	No
Citric Acid Monohydrate	5949-29-1	No	No	No	No	No
Cleaklens 70% IPA	67-63-0	No	No	No	No	No

Substance	CAS No.	Priority Substance	Priority Substance	Hazardous	Watchlist Substance	Discharged as Trade Effluent
Clearklens Bi-Spore VH26 Activator	Mixture	N/A	N/A	N/A	N/A	No
Clearklens Bi-Spore VH26 Base	77-92-8 7681-11-0	No	No	No	No	No
Clearklens Cleansinald SS VH9	68424-85-1 64-02-8 68439-46-3 2372-82-9	No	No	No	No	No
Cobalt (III) Nitrate Hexahydrate	10026-22-9	No	No	No	No	No
Colour Reference Solution B	Mixture	N/A	N/A	N/A	N/A	No
D-Sorbitol	50-70-4	No	No	No	No	Yes
Diesel	68334-30-5	No	No	No	No	No
Dextrose Anydrous	50-99-7	No	No	No	No	Yes
Dextrose Monohydrate/D-glucose	14431-43-7	No	No	No	No	Yes
Dichloromethane	75-09-2	YES	No	No	No	No
Diphenylamine solution	122-39-4	No	No	No	No	No
Di-Sodium Hydrogen Phosphate Dihydrate	10028-24-7	No	No	No	No	Yes
Disodium Edetate	6381-92-6	No	No	No	No	Yes
Dithiothreitol	3483-12-3	No	No	No	No	No
Dynamis agt media	N/A	N/A	N/A	N/A	N/A	Yes
Eco Surf EH-9 solution	Mixture	N/A	N/A	N/A	N/A	No
Ethanol	64-17-5	No	No	No	No	No
Ethanolamine	141-43-5	No	No	No	No	No
Extran AP17 Labwash	1310-73-2	No	No	No	No	No

Substance	CAS No.	Priority Substance	Priority Substance	Hazardous	Watchlist Substance	Discharged as Trade Effluent
Feed A	N/A	N/A	N/A	N/A	N/A	Yes
Feed B	N/A	N/A	N/A	N/A	N/A	Yes
Foam away anti-foam	N/A	N/A	N/A	N/A	N/A	No
Foam Doctor	N/A	N/A	N/A	N/A	N/A	No
Formic acid	64-18-6	No	No	No	No	No
Glacial Acetic Acid	64-196-7	No	No	No	No	Yes
Glycine	56-40-6	No	No	No	No	No
Glyco Works N,N,-dimethylformamide	68-12-2	No	No	No	No	No
Glyco Works Rapid PNGase F Enzyme	Mixture	N/A	N/A	N/A	N/A	No
Glyco Works Rapid Buffer	Mixture	N/A	N/A	N/A	N/A	No
Glyco Works RapiGest Surfactant	Mixture	N/A	N/A	N/A	N/A	No
Glyco Works Elution Buffer	Mixture	N/A	N/A	N/A	N/A	No
Glyco Works Sample Diluent	Mixture	N/A	N/A	N/A	N/A	No
Glyco Works RapiFluor-MS	1429047-69-7	No	No	No	No	No
Hellmanex III	Mixture	N/A	N/A	N/A	N/A	No
HEPES	7365-45-9	No	No	No	No	No
HRP Conjugate	N/A	N/A	N/A	N/A	N/A	No
Hydrex 1259	10124-56-8	No	No	No	No	Yes
Hydrex 1568	1310-73-2	No	No	No	No	Yes
Hydrex 1940	Mixture	N/A	N/A	N/A	N/A	Yes
Hydrex 7310	26172-55-4 2682-20-4	No	No	No	No	Yes
Hydrex 7902	7681-52-9	No	No	No	No	Yes

Substance	CAS No.	Priority Substance	Priority Substance	Hazardous	Watchlist Substance	Discharged as Trade Effluent
Hydrochloric acid	7647-01-0	No	No	No	No	Yes
Intact mAB Mass Check	N/A	N/A	N/A	N/A	N/A	No
Iodacetamide	144-48-9	No	No	No	No	No
IPA 70%	67-63-0	No	No	No	No	No
L-Cysteine	52-90-4	No	No	No	No	Yes
L-Histidine	71-00-1	No	No	No	No	Yes
L-Histidine Mono-hydrochloride	5934-29-2	No	No	No	No	Yes
L-Methionine	63-68-3	No	No	No	No	Yes
L-Methionine Sulfoximine	15985-39-4	No	No	No	No	Yes
Lonza CHO Feed Base	N/A	N/A	N/A	N/A	N/A	Yes
Lonza Feed Medium Base	1004-52-4 53-90-4	N/A	N/A	N/A	N/A	Yes
LTEM1	N/A	N/A	N/A	N/A	N/A	No
LTEM2	N/A	N/A	N/A	N/A	N/A	No
LTEM3	N/A	N/A	N/A	N/A	N/A	No
L-Tryptophan	73-22-3	No	No	No	No	No
Maurice CD-SDS Application	Mixture	N/A	N/A	N/A	N/A	No
Maurice cIEF Chemical Test Kit	Mixture	N/A	N/A	N/A	N/A	No
Methanol	67-56-1	No	No	No	No	No
N-Ethylmaleimide	128-53-0	No	No	No	No	No
Nerve Growth Factor	Mixture	N/A	N/A	N/A	N/A	No
Nitrate Solution	7732-18-5	No	No	No	No	No
Nitric Acid	7697-37-2	No	No	No	No	No
N'N'diphenyl-benzidine	531-91-9	No	No	No	No	No

Substance	CAS No.	Priority Substance	Priority Substance	Hazardous	Watchlist Substance	Discharged as Trade Effluent
Orthophosphoric acid	7664-38-2	No	No	No	No	No
pH calibration Buffers	Mixture	N/A	N/A	N/A	N/A	No
Phosphate Buffered Saline tablets	Mixture	N/A	N/A	N/A	N/A	No
Pierce TCEP HCl	Mixture	N/A	N/A	N/A	N/A	No
Poloxamer-P188	9003-11-6	No	No	No	No	Yes
Polysorbate 20	9005-64-5	No	No	No	No	Yes
Polysorbate 20/Tween-20	9005-64-5	No	No	No	No	Yes
Potassium Phosphate Monobasic	7778-77-0	No	No	No	No	Yes
Primary Opalescent suspension	Mixture	N/A	N/A	N/A	N/A	No
Protein A Antigen	Mixture	N/A	N/A	N/A	N/A	No
Protein A Mix	Mixture	N/A	N/A	N/A	N/A	No
Protein Simple CE-SDS Reagent	Mixture	N/A	N/A	N/A	N/A	No
Protein Simple cIEF Reagent	Mixture	N/A	N/A	N/A	N/A	No
Rapid Digest Kit	9002-07-7	No	No	No	No	No
Rapigest SF Surfactant	Mixture	N/A	N/A	N/A	N/A	No
Rely on Virkon Powder/Tablets	70693-62-8 68411-30-3 6915-15-7 5329-14-6 12068-03-0 7727-21-1 138-86-3	No	No	No	No	Yes
Servalyt 3-10	Mixture	N/A	N/A	N/A	N/A	No
Servalyt 4-7	Mixture	N/A	N/A	N/A	N/A	No

Substance	CAS No.	Priority Substance	Priority Substance	Hazardous	Watchlist Substance	Discharged as Trade Effluent
Silver nitrate	7761-88-8	No	No	No	No	No
Sodium acetate trihydrate	6131-90-4	No	No	No	No	No
Sodium Azide solution	N/A	N/A	N/A	N/A	N/A	No
Sodium Bicarbonate	144-55-8	No	No	No	No	No
Sodium Carbonate	497-19-8	No	No	No	No	No
Sodium Chloride	7647-14-5	No	No	No	No	Yes
Sodium Dihydrogen Phosphate	13473-35-0	No	No	No	No	Yes
Sodium Dodecyl Sulfate solution	151-21-3	No	No	No	No	No
Sodium Formate	141-53-7	No	No	No	No	No
Sodium Hydrogen phosphate anhydrous	7558-79-4	No	No	No	No	No
Sodium hypochlorite solution	7681-52-9	No	No	No	No	No
Sodium Hydroxide	1310-73-2	No	No	No	No	Yes
Sodium Hydroxide pellets	1310-73-2	No	No	No	No	Yes
Sodium Phosphate 7 Hydrate	7782-85-6	No	No	No	No	Yes
Sodium Phosphate Monobasic	7558-80-7	No	No	No	No	Yes
Sodium Phosphate Monohydrate	10049-21-5	No	No	No	No	Yes
SP6	Proprietary	N/A	N/A	N/A	N/A	Yes
SP7	Proprietary	N/A	N/A	N/A	N/A	Yes
SP8	Proprietary	N/A	N/A	N/A	N/A	Yes
SP9	Proprietary	N/A	N/A	N/A	N/A	Yes
Sulphuric acid	7664-93-9	No	No	No	No	No
Terg-a-zyme enzyme detergent	Mixture	N/A	N/A	N/A	N/A	No
Tergitol 15-5-9	Mixture	N/A	N/A	N/A	N/A	No

Substance	CAS No.	Priority Substance	Priority Substance	Hazardous	Watchlist Substance	Discharged as Trade Effluent
Tert-butyl hydroperoxide	75-91-2	No	No	No	No	No
Trace element mix	N/A	N/A	N/A	N/A	N/A	No
Tregalose di-hydrate	6138-23-4	No	No	No	No	No
Trifluoroacetic acid	76-05-01	No	No	No	No	No
Trifluoroacetic acid	75-91-2	No	No	No	No	No
Tris-hydroxymethylaminomethane	77-86-7	No	No	No	No	No
Triton X-100	9002-93-1	No	No	No	No	No
Tropolone	533-75-5	No	No	No	No	No
Trypsin Protease	9002-07-7	No	No	No	No	No
Urea	53-13-6	No	No	No	No	No
Vi-Cell Meta Flex	Mixture	N/A	N/A	N/A	N/A	No
Vi-Cell Solution	Mixture	N/A	N/A	N/A	N/A	No
Waters Ammonium Formate solution	540-69-2	No	No	No	No	No

3 CONCLUSION

The only substance listed as a Priority Substance, Hazardous Propriety Substance or Watchlist Substance in use at the Zoetis facility is dichloromethane, which is listed in Table 11. This substance is used as a laboratory chemical and is disposed of as hazardous waste. It does not enter the wastewater system and is therefore not present in trade effluent.

No substance discharged to wastewater or entering the public sewer from the Zoetis facility is, or contains a substance which is, listed in Tables 11, 12 or 13 of the EC Environmental Objectives (Surface Waters) Regulations 2009 (as amended).