INIDP-0008 (23) Waste Management Procedure

1.0 PURPOSE

The purpose of this document is to ensure that all waste generated in VISTAKON® Ireland is stored, and disposed of or recycled so as to prevent harm to human health and the environment and is managed in Compliance with all requirements and in particular the Waste Management Act 1996 to 2005, the Litter Pollution Acts 1997 to 2003 and the EC Regulations EC No 1013/2006 on shipments of waste and the Vistakon IPPC Licence.

2.0 SCOPE

This procedure outlines the way hazardous waste and non-hazardous waste is generated in VISTAKON® Ireland is stored and handled to ensure compliance with the VISTAKON® Ireland environmental management System and Johnson & Johnson Worldwide EHS Standards Environmental Sustainability Practices and the Vistakon IPPC Licence.
All employees, contractors and Vendors are expected to comply with this Procedure.

3.0 DEFINITIONS

3.1 **Waste Stream Inventories:** these reports detailing the origin, the hazard characteristics, the quantity generated and the disposal method used for all Hazardous, Biological and non-hazardous waste generated in VISTAKON® Ireland. The reports are reviewed and updated annually by the EHS Manager and filed in a central location controlled by the EHS Specialist.

3.2 **Hazardous Waste:** Waste materials that when improperly managed may cause or significantly contribute to serious illness or death or that may pose a substantial threat to human health or the environment. This includes hazardous chemical waste including waste IPA, biological waste, waste oils and used ultra violet and fluorescent bulbs. The handling of waste Senofilcon, Narafilcon and Galfilcon Monomer is also covered under Hazardous waste.

3.3 Biohazardous waste shall consist of the following :

a) Sharps from Microbiology Lab.
b) Bandages, Dressings and Sharps from the Medical room
c) All other biological waste generated in the Microbiology Lab.
d) Product/Material from any part of the facility that may become contaminated by bodily fluid (particularly blood) as a result of cuts. (Contact First Aider for disposal)

3.4 **Non-Hazardous Waste**: This includes all waste which is not included in the hazard waste list

3.5 **Trade effluent**: All liquid waste entering the process drains at Vistakon Ireland and finally discharged to public sewer

3.6 **IWA** (Ireland Work Aid) Graphic drawing depicting waste streams

3.7 **Waste Rooms** : There are two waste rooms in the facility, one in Phase II and the other in Phase III both room are dedicated to segregation, disposal and recycling of waste of hazardous and non-hazardous waste.

3.8 **Chemical Storage Area** : Purpose Built bunded storage area located in Warehouse which stores chemicals and some raw materials. It is a storage area for one waste stream and that is Galyfilcon which is stored in a segregated flame-proof metal cabinet .

3.9 **Waste Management Accumulation Area**: External Waste Area at rear of Phase III dedicated to diposal and recycling of hazardous and non hazardous waste which is picked up from the Waste Rooms. This area is managed by the Waste Management Contractor.

3.10 **Oasys Waste Management area**: Used IPA, activated charcoal and waste propylene glycol resulting from the Oasys process is managed within the tank compound on the of the Plant outside Phase II by a Waste Management Contractor.

3.11 **Waste Transfer Form (WTF/Trans Frontier Shipments TFS Form):** This form issued from the TFS Office specifically for the shipments of Hazardous waste exclusively within Ireland and replaces the C1 Form as per regulations issued by the Dublin City Council.

3.12 Waste Food Regulations 2009

To comply with these regulations we must ensure that all our canteen waste is segregated properly in accordance with our obligation to Waste Management Act in relation to the Food Waste Regulations.

Obligations are placed on the Canteen as a generator of food waste to segregate food waste at source and to make available specific waste steams for food which Vistakon sends for Composting. The Waste Management Canteen Recycling System complies with this stipulation .

4.0 PROCESS

4.1 The origin of waste report is a detailed Waste Stream Inventory for Hazardous and Non Hazardous Waste VISTAKON® Ireland and is maintained by the EHS Department. This report will include the following:

a) Waste description
b) Disposal method
c) EWC Codes
d) Hazardous characteristics/and or classification
e) Origin of Waste i.e. the process that created the waste
f) Company in receipt of waste
g) Amount of waste generated per waste stream
h) Total Waste Generated

4.2 All waste streams are clearly documented and all waste containers clearly labeled. Signage is posted on the walls over the bins/drum s to ensure that waste is not disposed of incorrectly.

4.3 The Waste Management Contractor will provide the EHS Department a detailed monthly report of all Hazardous and Non-Hazardous Waste moved from Site.

4.4 The following practices are prohibited in the treatment and disposal of waste:

(1) On-site open burning of waste
(2) On-site Landfilling of waste
(3) Intercontinental transport of waste for disposal
(4) Ocean dumping of waste

4.5 The EU Waste policy is as follows:-

(1) Prevention
(2) Minimimisation
(3) Re-use
(4) Recycling
(5) Energy Recovery
(6) Disposal

4.6 **Auditing Waste Disposal Companies**

All waste disposal companies shall be audited in compliance with J&J Standards. A program will be developed by the EHS Team to audit and approve each facility used in the disposal of waste. The audit frequency shall be in compliance with Johnson & Johnson World Wide Standards and is documented in the current revision of **INIDP-0011**.

Emergency Plan and Preparedness/Business Continuity Plan (BCP)

VISTAKON® Ireland shall have documented procedures for responding to spills, releases, explosions or fires involving hazardous waste. The procedures shall be contained within the Emergency Response Procedure and the Business Continuity Plan (BCP).

5.0 HAZARDOUS WASTE

5.1 Hazardous Waste Material streams are depicted on Form Control No. **IWA-0072**.
IWA-0072 is available on the VISTAKON® on Qumas and is displayed in the Waste Rooms and other walls and other walls throughout the facility.

5.2 Special conditions apply to the safe handling and disposal of the following Hazardous Waste:

- Paintainers,
- **WEEE** Waste Oil
- Oily Rags and used Filters
- Hazardous Chemical Waste and contaminated rags.
- Used Ultra Violet and Fluorescent bulbs
- Lead Acid Batteries (will be returned to supplier where possible)
- Biohazardous Waste
- Colourant Electrical Devices including VDU's (Need to take this out of here
- Light Ballasts
- Waste IPA from Oasys Process
- Waste Carbon Filters from abatement for Oasys process
- Waste etafilcon, senofilcon, galyfilcon and narafilcon (A&B) Monomers
- Waste DBE 821
- Waste propylene glycol(PG)
- Waste Process Effluent containing PG

6.0 LABELLING

6.1 All containers storing hazardous waste shall have durable labels that clearly identify:

a). VISTAKON® Ireland
b). The date waste was first placed into container
c). Chemical Identification of waste and hazardous characteristics.
d). Number on the Container/Barrel/Drum
e). Hazard symbol that indicates the characteristics of the contents
f). Infectious component where applicable.

6.2 The above labels must be removed prior to shipment off site to hazardous waste Facility. Reference 12.2 for requirements for off site labeling.

7.0 STORAGE

7.1 All hazardous waste shall be securely packaged in strong, tight packages or containers. These containers shall be maintained in good condition and shall be kept covered during storage. All hazardous waste will be classified and segregated. Containers holding hazardous waste shall be compatible with the material being stored in them. Incompatible waste containers shall be stored separately so that in case of a spill incompatible materials do not mix. Hazardous waste containers shall be handled and stored in a manner that will not cause rupture or leak.

7.2 Hazardous Waste should not be stored in excess of twelve months.

7.3 Hazardous Chemical Waste including oil, oily rags, filters etc shall be stored in labeled containers in the Waste Room in Phase II and Phase III. Waste monomers are stored in monomer rooms and the chemical lock-up in the warehouse.

7.4 Hazardous waste IPA from 3GT processes shall be stored in tanks within a secured bunded chemical store Waste carbon media shall be stored in closed labeled drums in the IPA tank farm. Waste PG wil be stored in IBC's in a bunded area.

7.5 Used Ultra Violet and Fluorescent bulbs shall be stored in the Waste Room in Phase II.

7.6 Biohazardous Waste from Micro Lab and Medical Room shall be stored in Micro Lab and Medical Room in purpose designated bins.

7.7 Colourant Paintainers, empty and part filled will be stored in a drum in the Waste Room Phase III and is transported to the Waste Management Accumlation area when full.

7.8 All electronic devices including VDU's Ballasts etc. shall be stored in the Waste Management Accumulation Area.

7.9 Lab Pack waste (small quantities of waste chemicals that are unidentified, un approved, or are no longer needed) must be provided to the Chemistry group who will arrange for their disposal.

7.10 A 200L clear drum is provided by the Waste Management Supervisor and is used for the collection and disposal of narafilcon A and etafilcon and Senofilcon monomers on site. A 25L clear drum is provided by the Waste Management Supervisor and is used for the collection and disposal of galyfilcon and narafilcon B monomer on site. All drums must be labeled and inspected by the Waste Management Supervisor prior to use. The narafilcon A disposal drum is located in the Phase 4 Staging Room and is and is depicted as hazardous waste as per current revision of **IOIDP-0159.** The senofilcon disposal drum is located in the 3GT Staging Room and is depicted as hazardous waste as per current revision of **IOIDP-0136**. The Etafilcon disposal drum is located in the Phase 1 Staging Room and is depicted as hazardous waste as per current revision of **IOIDP-0060.** The galyfilcon disposal drum is located in the Chemical Lock-up in the warehouse in a small flame-proof metal cabinet and is depicted as hazardous and flammable waste as per current revision of **IOIDP-0186.**

7.10.1 Prior to preparing for the disposal of the monomer waste the Waste Management Supervisor must don PPE, gloves and glasses and add a stabilizing agent to the drum.

7.10.2 The waste drums must contain an inhibitor material for safe storage of monomer and if used without a stabilizing agent there is an explosion risk.

7.10.3 The stabilising agent (100g of MEHQ(4-Methoxyphenol) must be added to the drum by the Waste Management Contractor prior to use.

7.10.4 This substance is available from the Chemistry Laboratory and is weighed in 100g batches per requirement of this procedure and placed in a labeled sterilin container by the Chemistry Technician/Manager.

7.10.5 The 100g of MEHQ must be added to clear plastic drum by the Waste Management Supervisor prior to disposing of any waste narafilcon, senofilcon, and galfilcon monomers in the waste drums.

7.10.6 The drum should not be filled to more than three quarters of its capacity before disposal.

7.10.7 The transportation and disposal and tracking of waste monomer drums is managed by our on-site Waste Management Supervisor and is treated as Hazardous waste.

7.11 Full containers of Hazardous waste must only be transferred by competent personnel.

7.12 The practice of giving used containers to employees or the community is strictly prohibited.

7.13 Waste Propylene glycol (PG) IBC's will be stored in the bunded Temporary PG area"

7.14 Waste propylene glycol process effluent will be diverted to the a dedicated effluent holding tank in the PG tank farm area. Once sufficient volume has been generated, this effluent will be shipped offsite in a bulk vacuum tanker or Isotainer.

8.0 INSPECTION PROGRAM

8.1. The waste and chemical storage areas and containers will be visually inspected using the EHS Monthly Inspection formfor the designated area.

8.2. Carbon Beds/filters - The use of the carbon beds is controlled on the HMI by recording the number of hours used before saturation is reached and depending on the operating time evolved, the carbon is replaced.

9.0 WASTE LOG

A log book, Form Control No. **ICF-425** for tracking hazardous chemical waste collected from the Waste Rooms is completed by the Waste Management Contractor on receipt of the Waste in to their area.

The log book is located in the Waste Accumulation Contractors Office. It is the responsibility of the Waste Management Contractor to complete the hazardous waste log when hazardsous waste enters the Waste Accumulation Area. The hazardous log book will also track details of hazardous waste shipments off site and this is documented on the TFS Form.

For further information on the waste tracking log, Form Control No. **ICF-425** reference the current revision of **INIDP-0032**.

10.0 WASTE ROOMS II & III FOR HAZARDOUS WASTE

Two waste rooms have been dedicated to taking hazardous waste in the facility, one is in Phase II and the other is in Phase III.

Signage with pictograms have been placed over Barrells for disposal of the hazardous waste to ensure that waste is not disposed of incorrectly or contaimindated with other waste of a volatile nature. Hazardous and non hazardous waste are stored in separate locations in the waste rooms.

10.1 **Waste Room Phase II**
Hazardous Waste
- Spill Kit Waste
- IPA Wipes & Oily Rags
- Flourecent Tubes

10.2 **Waste Rooms Phase III**
Hazardous Waste
- Spill Kit Waste
- IPA Wipes & Oily Rags
- Paintainers from the Colurs Lab

11.0 ALL RECORDS /DOCUMENTATION FOR BIOHAZARDOUS SHARPS AND MEDICAL WASTE SHALL BE MAINTAINED IN THE MICRO LABORATORY/WASTE MANAGEMENT CONTRACTOR.

11.1 All other Biohazardous waste generated in the Microbiology laboratory shall be stored in autoclavable bags contained in covered bins. This shall be rendered non hazardous by a validated sterilization cycle and disposed of as general waste. The treated bags shall be handed over to the waste management contractor for disposal**.** The treated bags are placed in the into the general waste bins by the Microbiology Technicians and the waste contractors dispose of this waste in Landfill**.**

11.2 Details of the sterilisation of all autoclavable microbiological waste shall be recorded on Form Control No **ICF-298**. This contains details of sterilization cycle number, bag number date of disposal and run record and date sterilized. This log shall be maintained in the QA Microbiology Laboratory.

12.0 TRANSPORTATION

12.1 The relevant documentation shall accompany all hazardous waste shipments, this includes:
- Transport Emergency card (TREM card) - This is supplied by the licensed disposal company and comes prior to every collection.
- TFS Forms are submitted to the Waste Management Supervisor by the Hazardous Waste Recipient Company. The Supervisor must verify that form is completed correctly on the form as per waste types and quantities on the load. Verification of EWC Codes used must be in compliance with Ireland Work Aid, Form Control No. **IWA-0471** Checking Hazardous Waste Documentation prior to Shipment off site. The quantities of Hazardous Waste being removed off site must also be cheched with the TFS Annex and verified for accuracy. The TFS form number must match the number on the Annex. Once verification is complete the Waste Management Supervisor must sign that the information is correct to the best of their knowledge.

- Waste shipments/hauliers are inspected using Form Control No. **ICF-593**. This document is completed by the Waste Management Supervisor , records of inspections are retained in a Waste folder in Facilities Department in the control of the Waste Management Supervisor.

12.2 All waste containers will be correctly labeled for transportation. These labels will contain the following information:
- Description of waste
- Hazardous characteristics
- UN classification number (where applicable)
- VISTAKON® Ireland

12.3 All hazardous waste will be transferred off-site by an approved waste disposal company. Written confirmation will be given on receipt of this waste and a certificate of disposal will be issued to Vistakon when the waste has been disposed. These will be filed with the TFS waste disposal form in the Facilities Department in the control of the Waste Management Supervisor

13.0 NON-HAZARDOUS WASTE

13.1 Non-Hazardous **Waste Streams for Canteen** are depicted by graphics on the wall over the disposal units to ensure compliance to the waste management of food regulations which are designed to promote segregation.
Obligations are placed on commercial generators of food waste at source and make sure that there is a three bin system in place.

13.1.1 **Recycling** includes all clean, dry recyclable material, plastics, cardboard and cans
13.1.2 **Composting** – left over food, fruit including soiled serviettes
13.1.3 **Landfill** - non recyclable material, butter wrappers, jam containers and foil wrappers

13.2 Non-Hazardous Waste Streams for Manufacturing, Warehouse, Offices and Support Area's are depicted on Form Control No. **IWA-0069** and **IWA-0070**.

13.3 Non-Hazardous Waste Streams for Admin/Engineering and Support Areas are segregated in various Bins. Waste is accumulated in a Green Recycling and Disposal Tray on employees desks, when the recycling tray is full the employees empty the bin into the correct waste stream for example:-

- **Paper Bin – (Blue Lid)**
  This bin takes white paper and envelopes for recycling.
- **Dry Mixed Recyclables (Green Lid)**
  This bin takes newspapers/magazines/empty bottles/cans/cardboard Boxes cups /waste plastic and juice containers for recycling.
- **General Waste – (Grey Lid)**
  This bin takes tayto bags/chocolate wrappers/breakfast and sandwich wrappers/yogurt pots and contaminated napkins which are sent to landfill.

13.4 Form Control No. **IWA-0069** and **IWA-0070** are available on the VISTAKON® Intranet and are displayed in on various walls through out the Facility.

13.5 Liquid waste: Liquid Waste (Propylene Glycol ,Monomer,Tween, Span,Concentrated Peg solution(4%),Conc MEC) Solution (4800ppm), etc) and materials contaminated with same shall be placed in a leak proof container that shall be kept closed and labeled accordingly. All liquid waste shall be provided with adequate 2nd containment and protected from precipitation. All of these liquid wastes are to be sent off site for disposal using the on-site management group.

13.6 Green Dye is a food colourant used in the QC Labs in the ARO chambers to test the integrity of the primary package. To dispose of the green dye the QC technician drains the liquid down the sink. If the green dye is past its expiration date it is poured into a drum labeled Green dye and placed on the counter of the QC Labs. The waste management contractor will collect the green dye container from the QC Labs and stores in the Waste Accumulation area.

13.7 Waste Product for Destruction which originates from production and other areas must is desposed of in a blue bag and labeled accordingly. The bag is placed in the Locked Product for Destruction Bins in Waste Room II or III. This procedure is supported by current revision of **IOIDP-0031** and forms associated with the destruction of Waste Product.

13.8 Contaminated water from the Chemical bunds, Interceptors and Fire water retention pond must be treated as waste for managed removal if the conc of OFG or IPA(measured as COD) exceeds permitted levels.

13.9 VISTAKON® employees and contractors who wish to remove materials from the facility must first seek authorisation from their Departmental Manager and Facilities Director by completing Form Control No. **ICF-651**. All waste and completed forms must be presented to security for inspection and security will maintain the forms.

14.0 WASTE ROOMS II & III FOR NON HAZARDOUS WASTE

Two waste rooms have been dedicated to taking waste in the facility, one is in Phase II and the other is in Phase III. The Waste Rooms are dedicated to taking non hazardous waste. Signage with pictograms are placed over the Wheelie bins/Gayloards for disposal of the waste to ensure that waste is not disposed of incorrectly.

14.1 **Waste Room II**
Non Hazardous

- Product for Destruction – locked blue wheelie bin
- Paper
- Cardboard
- Cartons
- Plastic Waste
- PP/PS
- Cardboard Rungs
- Metal Waste
- Foil
- General Waste
- Batteries
- Toner Cartriges

14.2 Waste Rooms III is dedicated to taking the folloing waste steams of hazardous and non hazardous nature.
Non Hazardous

- Product for Destruction – locked blue wheelie bin
- Paper
- Cardboard
- Cartons
- Plastic Waste
- Plastic Container Waste
- PP/PS
- Cardboard Rungs
- Metal Waste
- Foil
- General Waste
- Batteries
- Toner Cartriges

15.0 RESPONSIBILITY:

15.1 The EHS Manager/Specialist is responsible for this procedure.

15.2 Department Managers are responsible for ensuring that all employees in his/her area have been trained in and are complying with the requirements of this procedure.

15.3 Inspections and audits are conducted periodically by EHS and members of the Operations Support Team to ensure that employees are segregating waste correctly.

16.0 RECORDS/DOCUMENTATION

All records/documentation relating to hazardous/ chemical & Biohazardous waste will be retained in the Facilities Department and under the direct supervision of the Waste Management Supervisor. Monthly reports of all waste transaction are provided by the Waste Management Supervisor to the EHS Specialist.

17.0 TRAINING

17.1 The training requirements for this document are "Read Only." This document is supported by waste labeling and signage throughout the facility and also by Waste Signage in the Waste Rooms in Phase II and Phase III.

17.2 All personnel responsible for generating, handling and managing waste shall be provided with training on the safe handling of waste during normal and emergency conditions. This training is incorporated in the Awareness Training and is also provided at Induction Training. An overview of this training is available with the EHS Team.

17.3 Chemical and waste handling training is provided at induction as part of the EHS Induction Training Programme for all employees. Refresher and practical training Training sessions are provided as required by the EHS Team for personnel who handle chemical and hazardous waste as part of their job.

18.0 RELATED CONTROLLED DOCUMENTS

INIDP-0032
IWA-0069
IWA-0070
IWA-0072
QA-0037
ICF-425
ICF-593
ICF-651
IOIDP-0031
IWA-0471
IOIDP-0186
IOIDP-0159
IOIDP-0136
IOIDP-0060
INIDP-0011