

Project details	Environmental Permit Variation Application – EPR/XP3602PF Sharpsmart Limited – Normanton Waste Transfer and Treatment Facility
Applicant details	Sharpsmart Limited Unit 1 Enterprise City Meadowfield Avenue Spennymoor County Durham DL16 6JF
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1 Introduction

1.1 General

Sharpsmart Ltd (the ‘applicant’) has requested that Reva Environmental Ltd (the ‘agent’) prepares an Environmental Permit (EP) variation application, for its Normanton Waste Transfer and Treatment Facility at Unit 1 Loscoe Close, Normanton Industrial Estate, Normanton, WF6 1TW.

The site currently houses two autoclave units that thermally treat (by steam sterilisation) the incoming soft clinical waste.

The EP allows the pre-shredding, autoclaving, and compaction of waste and the associated temporary storage of waste pending that process. The EP includes two directly associated activities (DAAs) which are the operation of a steam boiler and the washing of bins. Additionally, the EP allows the storage and repackaging of non-hazardous and hazardous waste as a Waste Operation.

The facility is currently authorised by EP ref. EPR/XP3602PF which was originally granted in April 2011 to HES; the most recent variation being the transfer in full to the application in August 2019.

The current EP allows the following listed activities to be carried out at the facility (explicitly stated in V005):

- A1 – Section 5.3 A(1)(a)(ii) Disposal or recovery of hazardous waste by physico-chemical treatment (shredding, autoclaving and compaction) with a capacity exceeding 10 tonnes per day (D9); and
- A2 – Section 5.6 A(1)(a) Temporary storage of hazardous waste with a total capacity exceeding 50 tonnes. This activity includes the storage of hazardous and non-hazardous waste prior to treatment via the autoclaves (D15).

The following directly associated activities (DAAs) and Waste Operation are included in the EP:

- DAA A3 – Operation of a dual fuel steam raising boiler with a net rated thermal input of 3.9 MW, to be run on natural gas during standard operation;
- DAA A4 – Sharps bin washing. This activity comprises the steam cleaning of bins used for the storage of treatable waste; and
- Waste Operation A5 – Waste Transfer Station. Storage of hazardous and non-hazardous waste pending transfer off site for disposal, repackaging of waste pending treatment on site or disposal of site, and storage of waste pending recovery off site (D14, D15 and R13).

The EP currently limits the acceptance of waste to 20,000 tonnes per annum (of which treatment of hazardous waste is limited to less than 72 tonnes per day), storage of hazardous waste pending treatment is limited to 144 tonnes at any one time whilst post treatment (floc) is limited to 40 tonnes, and storage of waste pending transfer off site for disposal is limited to 70 tonnes at any one time.

The objective of this application is to obtain a varied EP which enables the applicant to:

- Treat decanted sharps waste through the existing autoclave plants. This waste stream would be subject to pre-treatment shredding and subsequent compaction. The proposed acceptance of sharps waste for treatment in the autoclave will not affect the existing Listed Activity (A1) and the addition of the sharps waste code 18 01 03* (with or without 18 01 09) can be achieved through the amendment of Table S2.2 of the permit. **Variation of the existing autoclaving installation activity to add the additional waste stream is considered to represent a normal variation.**

- Operate a larger natural gas fuelled steam-raising boiler. The existing EP specifies the operation of the existing boiler as DAA A3. The applicant intends to install a new boiler to better meet the steam demand of the two autoclaves running in parallel. Whilst the input capacity of the boiler (2.5 MW) is below the threshold for a listed activity the applicant does recognise that as the input capacity will exceed 1 MWth the Medium Combustion Plant Directive (MCPD) is applicable and that emission limits will be imposed on this exhaust via permit conditions. **Variation of the existing DAA A3 to reflect the new boiler is considered to represent a minor variation.**
- Treat offensive waste (18 01 04) in two ways as follows:
 - Shredding through the existing shredders. For this short to medium term option, the waste stream would not be subject to autoclaving but would be subject to compaction. The shredded offensive waste can be compacted and can be transferred off site as RDF under EWC 19 12 10 / 19 12 12. It is proposed that this is achieved through the addition of a new Waste Operation (A6) for D9/R12 shredding of these non-hazardous wastes (<50 tonnes per day). **It is considered that the shredding of offensive waste in the existing plant would add a new waste operation (A6) to the EP so represents a normal variation.**
 - Shredding and autoclaving. For this medium to long term option, the waste stream would be shredded and autoclaved (not compacted) in order enable the recovery of plastic film from the waste. The uncompacted treated floc would be transferred off site via a national contractor under EWC 19 02 codes or suitable 19 12 codes. It is very unlikely that the autoclaving of offensive waste in the existing plant would exceed 50 tonnes per day (the threshold for 5.4 Part A(1)(a); it is therefore proposed that this is achieved through the addition of a new Waste Operation (A7) for D9/R5. **It is considered that the autoclaving of offensive waste in the existing plant would represent a normal variation.**
- Increase the storage capacity of floc (treated waste) from 40 tonnes to 80 tonnes to provide operational flexibility. **It is considered that an increase to the storage capacity of this non-hazardous waste represents a minor variation.**

The application supports the existing market for healthcare waste in the following ways:

- It supports the current market for reusable sharps containers (which can be used up to 500 times) and also promotes the future market for them. This is a more sustainable option and in turn removes a large quantity of plastic (burn bins) from autoclaving and incineration plants, a waste that can cause difficulties for such plants in relation to damage/maintenance and emissions; and
- It will reduce the burden on an ageing infrastructure across the UK for clinical waste incineration (there are few plants that can accept sharps repackaged in volume); and
- It frees up capacity in the small network of clinical waste incinerators in the UK by diverting sharps waste to the autoclaves.

The applicant can confirm that, other than the storage of floc, the existing storage limits in the EP remain applicable; this is constrained by the capacity of the building. These are as follows:

- Storage of hazardous waste pending treatment is limited to 144 tonnes;
- Storage of waste pending transfer off site (no treatment) is limited to 70 tonnes; and
- Total acceptance of waste is 20,000 tonnes per year of which treatment of hazardous waste is limited to <72 tonnes per day.

The maximum storage period for any load of waste is 2 weeks; this provides allowance for the operational contingency plan to be implemented.

The steam required for the autoclave process will be delivered by a new natural gas-fired steam raising boiler. The input capacity of the boiler is below the threshold for a listed activity under Section 1.1 of the EP Regulations and will therefore remain a DAA as per the current EP. The applicant does however recognise that as the input capacity exceeds 1 MWth the Medium Combustion Plant Directive (MCPD) is applicable and that emission limits will be imposed on this exhaust via EP conditions.

1.2 Assessment of BAT

As required by Question 6 in Appendix 4 of EA Application Form Part C3, a description of the treatment activities must also be provided which covers the standards set out in the relevant best available techniques (BAT) document. In terms of this proposal, justification is also required where alternative treatment is proposed for a waste not included in the table in Section 1.4 of the appropriate measures guidance.

The variation does not inherently change the existing repackaging and transfer activities; nor the existing permitted treatment approach. This assessment is therefore limited to the key changes which are demonstrating that the shredding, autoclaving and compaction of sharps waste the standalone shredding of offensive waste is BAT.

The proposals have been assessed against indicative BAT, in accordance with the following EA guidance:

- Sector Guidance Note EPR S5.06 “Recovery and disposal of hazardous and non-hazardous waste”, version 5 dated May 2013; and
- “Healthcare waste: appropriate measures for permitted facilities” version 1.13 dated 8 December 2021 (supersedes EPR 5.07).

The BAT assessment has been written on the basis of information provided to the agent by the applicant.

2 Managing the Activities

2.1 General Management

The applicant recognises that an effective management system is a key technique for ensuring that pollution prevention and control techniques are implemented and support compliance with BAT. Sector guidance EPR S5.06 recommends certification to a recognised standard such as ISO 14001 or EMAS.

The healthcare waste guidance requires appropriate measures to be in place and implemented, in relation to management of shutdown as a result of maintenance, incidents and non-conformances. A malfunction or shutdown can lead to permit conditions being breached.

2.1.1 Procedures

The applicant operates the current facility in accordance with a certified environmental management system (EMS). The EMS is certified by The British Assessment Bureau and was last audited in March 2022 against the requirements of ISO 14001: 2015. The EMS is a live system which is subject to regular review, including when there are any significant changes to the operations; a review will therefore be prompted by the proposals set out in this variation application.

The EMS includes a process of internal auditing, raising of non-conformances, reporting and investigation of incidents, maintenance and routine servicing. It also includes an Accident Management Plan which covers existing waste transfer and repackaging operations at the site. This

has been updated to reflect additional measures or considerations that are pertinent to the proposed activities. A copy of the Accident Management Plan (AMP) is provided in **Appendix I**.

2.1.2 Plant Design

This section is written in the context of the autoclave plants being used to treat sharps waste in addition to the existing permitted soft waste. For this application, the review also includes the treatment (shredding and compaction only) of offensive waste.

At the time of this variation application, the applicant is operating both autoclave plants. A procedure is therefore already in place, within the existing certified EMS, that identifies the items of plant that should be prioritised for planned preventative maintenance (PPM). It is not anticipated that the processing of offensive waste through the shredders or the treatment of sharps waste in the shredders, autoclaves and compactors should impact the existing provision however the HAZOP and risk assessments will be revisited and any changes identified will be reflected in an updated procedure and PPM as required. This will ensure that any known or predictable malfunctions are identified up front and appropriate measures can be put in place to avoid and manage them.

Part of the procedure includes the production of an inventory of equipment whose failure could directly or indirectly lead to an impact on the environment. This includes (but is not limited to) the effluent storage tanks, pipework (effluent management), waste containers, the shredders, autoclaves and the LEV systems.

The design of the existing treatment plant is such that the three parts (shredding, autoclaving, and compaction) can each operate in isolation. This enables the operator to carry out maintenance or repair works on any one part of the plant whilst the other parts can continue to operate. For example, if there is a breakdown of the shredder this can be repaired whilst a treatment cycle is underway. This system reduces the impact of failure or shutdown on the overall plant operation.

The treatment plant and ancillary equipment is in wide use within the UK, including by the applicant at its other sites. As a result the availability of spare parts is good. The operator retains a stock of key spare parts at the facility. An inventory of these spare parts is maintained, and stock replaced upon use to ensure that a sufficient level of parts is always available at the facility. Scheduled maintenance and service is carried out by the manufacturer (or manufacturer's contracted provider); the tools and expertise required for this is therefore assured.

2.1.3 Contingency

When either or both treatment plants are not available, as a result of planned shutdown or unplanned failure, the contingency plan will be activated. The contingency plan also addresses the need to manage materials if the third party recovery facilities are unavailable due to their own planned shutdown or unplanned failure. The contingency plan addresses the need to manage the following streams:

- Incoming offensive and/or sharps waste;
- Flocculent from sharps treatment; and
- Liquid effluent from sharps treatment.

In the event of unavailability of capacity in the autoclave treatment plants, the incoming offensive and sharps waste can continue to be accepted via the permitted transfer activity at the facility as is currently the case. Processed waste is transferred off-site for treatment at a third party permitted plant with which the applicant has a contractual relationship. This will ensure that waste storage and throughput limits set by the EP will not be exceeded. If required, the operator would cease accepting orange bagged waste into the facility and transport this directly to alternative treatment from its customer sites. There are 15 alternative treatment facilities that are able to accept this waste in the

UK. The acceptance of sharps would continue through the transfer facility, but the capacity would be optimised in this approach.

The floc from the site is classified as 19 12 10 / 19 12 12 (non-hazardous) and is transferred to a waste to energy plant with R1 status. The classification of the floc is unchanged by the proposed changes to the site activities. Therefore, should the primary contracted recovery facility for the floc be unavailable, there are three other R1 rated energy from waste plants in the UK that are able to take the waste as well as a number of R1 status energy from waste plants in Europe.

The liquid effluent (from treatment cycles processing sharps waste) is classified under 16 10 02 (non-hazardous) and will be transferred to a plant that is permitted to take this waste. Should the primary contracted facility for the effluent be unavailable, there are two other incinerators in the UK that are permitted to take this waste, and additional plants across Europe including one in Holland that is a recovery operation as steam is used for district heating. The use of facilities outside of the UK would be dependent on successful grant of transfrontier shipment approval.

The contracted, and contingency, plants themselves carry out planned shutdowns; details of these are provided to the applicant so that the contingency plan reflects actual availability. Waste producers/customers are also provided with information regarding the applicant's contingency plan.

The applicant will always seek to honour its waste collection contracts and not cease accepting waste from its customers if there is a viable outlet for treatment that would enable continued operation of the facility within the EP storage limits. This is irrespective of the location of the contingency facility and cost of recovery/disposal.

2.2 Energy Efficiency

The inclusion of the ability to shred offensive waste (in isolation), and to shred, autoclave and compact sharps waste is not likely to have a significant impact on the overall energy use at the facility.

The existing site steam demand is met by a natural gas fired boiler. The variation includes the replacement of this with a new boiler. This will also be a natural gas fired boiler but will be more efficient than the existing boiler. As part of the EMS, efficiency measures are reviewed and implemented as appropriate. When purchasing new equipment, its energy needs are assessed as part of the technology selection process. The gas supply will be limited to the operation of the boiler so the energy consumption of this combustion activity once the new boiler has been installed can be identified.

The proportion of waste that will be diverted to the treatment plant would currently be transferred off site for incineration (with no energy recovery). When the sharps waste and offensive waste can be treated on site, the floc and effluent generated from this waste stream will be going to an R1 rated energy from waste facility. The generation of energy from that receiver plant therefore serves to offset any minor increase in the energy used.

Energy is monitored at the facility at a single meter on the mains supply into the building. As part of the EMS, efficiency measures are reviewed and implemented as appropriate. When purchasing new equipment, its energy needs are assessed as part of the technology selection process.

2.3 Efficient Use of Raw Materials and Water

In accordance with the standard requirements in the EP, a review of raw material use will be carried out at least every four years. This will seek to identify if there are suitable alternative materials that could reduce the environmental impact, or identify opportunities to improve the efficiency of the raw material and water use.

The condenser on the autoclave unit is an air to air type (a heat exchanger with a blast cooler – a closed loop system) which minimises water use.

2.3.1 Chemicals & Reagents

The current operations at the facility use a disinfecting chemical ('Pine Disinfectant' and/or 'Apple Fresh' from CIS) to clean the 770 litre skip containers. The wash plant uses 'Pep Active' from Ecolab. This is a general purpose surface cleaner. There will be no change in the type of detergents used, nor the quantity required. Safety Data Sheets for these are provided in Annex BAT1.

The application introduces two new abated air extraction systems – points A7 (bin-to-bin tipper) and A9 (sharps floc compactor). The filter types are the same as currently in use but the addition of these systems will increase the quantity used by the facility overall.

The quantity of chemicals, filters and reagents used at the facility is recorded and tracked during the lifetime of the EP and assessed at regular intervals.

2.3.2 Water

Water is currently used at the facility for the purposes of cleaning the incoming waste containers, for steam generation, and for general cleaning of the building area, and for welfare facilities (kitchen, toilets, sinks etc.). There will be no change in how water is used at the site following the variation, however the quantity used may change.

The current boiler at the site uses 174 litres per autoclave cycle (524,000 litres per year). The new boiler will present an improvement in efficiency so is likely to result in a reduction in water used.

Consideration has been taken of the potential to re-use condensate from the autoclave process however this has been determined to be inappropriate due to the likely composition of the condensate. The boiler will be sensitive to the quality of the feed water and the use of condensate rather than mains water would lead to scale and sedimentation, and potentially corrosion, of the unit. The reuse of the condensate would therefore not represent BAT.

2.4 Avoidance, Recovery and Disposal of Wastes

The inherent purpose of the existing autoclaving activity is to render the incoming hazardous waste (hazardous by virtue of its infectious nature) non-hazardous, and to treat it to produce residues from which energy can be recovered. There are a number of reasons that highlight the benefit of autoclaving the proposed waste stream, including the following:

- This supports the current market for reusable sharps containers (which can be used up to 500 times) and also promotes the market for them. It is a more sustainable option and in turn removes a large quantity of plastic (burn bins) from autoclaving and incineration plants, a waste that can cause difficulties for such plants in relation to damage/maintenance and emissions;
- It reduces the burden on an ageing infrastructure across the UK for clinical waste incineration (there are 20 plants of which only 5 can accept bulk sharps waste). It provides a level of futureproofing given that some of the existing infrastructure is nearing the end of its operational life;
- The use of the autoclave to sterilise electrical medical instruments which can then be recycled via an appropriate WEEE route rather than being incinerated.

The shredding of offensive waste as a standalone activity will allow the shredded waste to be compacted and transferred off site as RDF.

With respect to waste generation, the autoclave plant currently generates two primary residues:

- Floc – the shredded and treated clinical waste which is compacted (post autoclave); and
- Liquid effluent – the condensed steam from the autoclave plants and the wash water from cleaning the shredder plant. The condensed steam enters a sealed tank. It is then pumped to drain for discharge under Yorkshire Water consent.

The key difference resulting from the proposals is as follows:

- If the liquid effluent generated relates to the autoclaving of sharps bin waste, then it is considered potentially pharmaceutically contaminated and is not discharged to sewer. Instead it is collected in an engineered sump and pumped into a storage tank (20,000 litre) for transfer to a permitted energy from waste facility for disposal (and heat recovery). The same applies if the effluent contains wash water from cleaning the shredder after it has been used for this waste stream.

The floc is classified as 19 02 10 / 19 12 12 and is transferred to a national outlet where the waste is further processed and blended to produce a fossil fuel replacement pellet fuel for use in power plants, energy from waste and cement kilns. The shredding of the waste prior to autoclaving enables the recovery of the floc as it meets the requirement of the R1 status for RDF which is that the waste cannot be recognisable as healthcare waste.

The existing treatment activity generates the following, ancillary residues/wastes:

- Spent HEPA filters; and
- Spent carbon from the carbon filters.

The HEPA filters can become blinded with particulate over time, increasing the resistance to air flow through them, reducing the flow and potentially resulting in a reduction in air quality. Filters usually last anything from 1 – 5 years depending on the loading. When they require replacement, the spent filters are disposed of at an appropriate facility, suitable for the waste type.

The carbon filters can become saturated and their absorptive capacity reduces over time. When they require replacement, the spent filters are disposed of at an appropriate facility, suitable for the waste type.

3 Operations

3.1 Permitted Wastes

3.1.1 Sharps – Repackaging, Shredding, Autoclaving and Compaction

Sector guidance sets out the wastes that are considered suitable for alternative treatment and that it limits this to infectious waste, suggesting that wastes that contain other chemical, pharmaceutical or anatomical characteristics may not be suitable for alternative treatment. The reasons for treating such waste therefore need to be fully justified.

The variation application does not seek to add any new waste codes to the permitted list but does request the inclusion of the following wastes for the treatment process:

- 18 01 03* – wastes whose collection and disposal is subject to special requirements in order to prevent infection (from human source); and
- 18 01 03*/09 – dual coded medicinally contaminated sharps.

The proposed additional waste types for treatment are already permitted for receipt and transfer at the site.

No offensive waste, cytotoxic or cytostatic, non-hazardous, pharmaceutical, or anatomical waste will be processed in the autoclave treatment plant. All other incoming waste types will continue to be processed in the transfer facility as is currently permitted.

The applicant has successfully added the autoclaving of sharps to its Stoke and Rainham facility EPs. Prior to those applications, the applicant had extensive pre-application discussions with the EA. These identified that an early concern of the regulator was the potential for sharps to have a level of

pharmaceutical contamination which could lead to undesirable emissions to air and/or water. In response to this, it is confirmed that pure pharmaceuticals will not be processed through the treatment plants; these will continue to be transferred off site via the current transfer activity. Whilst there is the potential for pharmaceutical contamination in the infectious waste types proposed, this is likely to be <5%. The types of trace pharmaceutical contamination present in wastes generated at the customer sites will vary significantly, depending on the type of care being given. It is however noted that any contamination is limited to a residual level on packaging which is arguably negligible.

Sharpsmart will carry out pre-acceptance audits on its customers for the sharps waste going to the treatment plants, this will be a spot check but will identify typical waste types and confirm that pure pharmaceutical waste will be segregated so not go through the treatment process.

UK hospitals use many thousands of types of pharmaceuticals annually; specific information is difficult to obtain. For the purposes of this application, Sharpsmart has used details from the *NHSBS audit of prescribed medications*, (Annex D). Five of the most commonly used are considered below in Table BAT1. The materials collected in the yellow lidded sharps bins and clinical containers under 18 01 03*/09 are primarily the syringe bodies, needles, IV bags, giving sets used with some of these pharmaceuticals and will contain only residues at most and are therefore contaminated with rather than contain quantities of pharmaceuticals. This is an important distinction.

Table BAT1: Typical Pharmaceuticals

Drug	Form	Typical method of administration	Typical waste received	Melting point (°C)	Decomposition temperature (°C)	Likely capture point	Control / capture
Paracetamol	Liquid	Intravenous, giving sets/drip syringe	Residues in tubing and syringes	170	201 – 230	Floc	Floc retention and disposal via EfW incineration
Morphine				>250		Effluent / floc	Captured in the effluent system and floc Disposal via EfW incineration
Amoxicillin	Liquid	Oral or IV	Residues in tubing and syringes	-	216-218	Effluent	Liquid capture disposal via incineration
Diazepam	Liquid	Injection	Syringe residues	132	204-330	Effluent	Liquid capture disposal via incineration
Tramadol	Liquid	Intravenous, giving sets/drip syringe	Residues in tubing and syringes	180	275-290	Effluent	Liquid capture disposal via incineration

To confirm, Sharpsmart will not be treating the product pharmaceuticals; these are collected separately using the blue lid container system, also hazardous wastes (cytotoxic/cytostatic) medicines will not be accepted for treatment. The vast majority of pharmaceuticals used within the UK have boiling/melting and decomposition points much higher than those that will be achieved in the autoclave process; the pharmaceutical compounds therefore will not change form/characteristics and will be found within the floc and from the autoclave liquid effluent, rather than within the steam.

Irrespective of what types of pharmaceutical products are present in the waste, the waste stream is still disposed of in a similar process to that which it currently is, i.e. incineration. Ascertaining the exact contents does not change the process to which is subjected therefore it is considered that this

would not add value or any other benefit. It is also considered impractical to expect the waste producer to provide an inventory with every individual bin, at ward/clinic level.

Whilst Sharpsmart is aware of tests having been carried out to confirm the achievement of pharmaceutical destruction by another waste operator, that was for a plant that served to destroy pharmaceuticals. Such tests would be redundant for the proposed treatment of sharps activity at Normanton as it is not intended to destroy pharmaceuticals; the outputs are transferred to a disposal site for incineration, a proven technology for pharmaceutical destruction in its own right.

The resultant non-hazardous floc generated by the treatment process is classified as 19 02 10 / 19 12 12 and will be transferred to a national outlet where the waste is further processed and blended to produce a fossil fuel replacement pellet fuel for use in power plants, energy from waste and cement kilns. The shredding of the waste prior to autoclaving enables the recovery of the floc as it meets the requirement of the R1 status for RDF which is that the waste cannot be recognisable as healthcare waste. Sharpsmart has an agreement in place with a number of outlets for the floc, as follows:

- Floc produced from the processing of orange bagged waste 18 01 03* (shredding, autoclave and compaction) and offensive waste 18 01 04 (shredding and compaction) will be combined and transferred off site as RDF/SRF. It is blended at the receiver site to achieve the desired calorific value. A longer term objective for this floc is to implement plastic film recovery which is likely to reduce the stream by a further 60% in volume, the residual of which will be transferred off site as RDF/SRF; and
- Floc produced from the treatment of sharps 18 01 03*/09 (shedding, autoclave and compaction) will be transferred off site as RDF/SRF. A longer term objective for this floc is for it to be 'washed' enabling the recycling of the material. This will result in an increase in process effluent.

Any new facility considering receiving the floc will have a specification which will need to be met to enable it to be accepted. An example is given below, which has been provided by the facility receiving the RDF from the applicant's Stoke facility.

Table BAT2: RDF Specification

Parameter	As received basis		
	Minimum Limit	Maximum Limit	Unit
Net Calorific Value	9	12.5	MJ/kg
Moisture Content	10	40	% w/w
Ash Content	N/A	24	% w/w
Sulphur Content	N/A	0.7	% w/w
Chloride Content	N/A	1	% w/w
Sizing	N/A	300	mm
Metals	N/A	1	% w/w

With respect to air emissions, there is an emergency vent (emission points A2 and A3) from the autoclave but that will only release to atmosphere under abnormal operating conditions so is not an active release to air. Instead, during normal operations, venting is performed through a condenser unit to produce a small volume of liquid effluent, approximately 220 litres per cycle. The post-vacuum cycle removes residual steam from the autoclave and flashes residual liquids, drying the waste. This also controls odour.

The condensate is collected in a sump under each of the autoclaves; there is no direct connection of the effluent system to the point of discharge to sewer.

The condensate from the autoclave will be either non-hazardous and can be discharged to sewer under consent (current permit position), or potentially contaminated when sharps waste is treated.

The two liquid effluent streams are managed in one of two ways, depending on the composition, as follows:

- If the effluent generated is from the autoclaving of sharps bin waste, then it is considered potentially pharmaceutically contaminated and is not discharged to sewer. Instead it is collected in an engineered sump and pumped into a storage tank (20,000 litre) for transfer to a permitted energy from waste facility for recovery.
- If the effluent generated is from the autoclaving of a batch of solely orange bagged waste (or offensive), then it is considered that there is no pharmaceutical contamination and the effluent is no different to that produced by the transfer facility and can be discharged to sewer under the existing consent.

For the liquid effluent, the proposed disposal contractor has provided Sharpsmart with a specification that will need to be met in order for them to accept it. It will be used as a quench water at the disposal facility so will be a benefit to them in terms of combustion control. A copy of the specification is provided in **Annex BAT2** of this BAT Assessment. The Normanton application reflects the activities already permitted and underway at Rainham.

Once operational, it will be possible to quantify the effluent produced per tonne of waste processed. This will enable Sharpsmart to demonstrate that all contaminated effluent has been transferred off site for appropriate disposal.

To summarise, whilst there is the potential for pharmaceutical content to be carried over in the floc and the effluent, this is acceptable for disposal at the designated R1 energy from waste facilities as it will be subject to sufficient incineration temperatures for the destruction of pharmaceutical content. The use of alternative treatment for this waste stream is therefore considered to be appropriate.

3.1.2 Offensive Waste – Shredding and Compaction

As described in Section 1.1 of this BAT Assessment, the presence of the standalone shredding unit will also provide the ability to shred offensive (non-hazardous) waste in isolation. It is proposed that a new Waste Operation (A6) is included for D9/R12 compaction of non-hazardous wastes (<50 tonnes per day), and that a new Permitted Waste Table (wastes accepted for treatment by shredding and compaction only) is added to allow the following:

- 18 01 04 – wastes whose collection and disposal is not subject to special requirements in order to prevent infection; this is limited to non-clinical human offensive/hygiene waste and autoclaved waste from laboratories only.

With respect to air emissions, there is an existing emission point (A4 from the shredder LEV system. This LEV has a carbon filter and a HEPA filter (for VOCs and particulates control respectively). This represents an appropriate level of emissions control for the shredding of offensive waste.

In order to ‘clean’ the shredders following their use for sharps wastes and prior to the shredding of any non-hazardous waste, it is proposed that a sacrificial load will be processed in it. The autoclaves fit 9 carts for treatment. For each batch of sharps waste, the first 8 carts will be sharps waste and the 9th will be orange bag/other non-hazardous waste). This will serve to clean the shredders in order to prevent any cross contamination of this waste from preceding hazardous waste loads.

This means that it is in a state that it can be used as RDF at the designated recovery facility. The treated waste from the existing clinical waste treatment process is compacted and sent as RDF to the designated recovery facility, and the latter has confirmed that it can accept both non-hazardous waste streams as RDF. The use of the compactor for both waste streams is therefore considered to be appropriate, practical, and efficient in terms of onward transfer.

3.1.3 Offensive Waste – Shredding and Autoclaving

As described in Section 1.1 of this BAT Assessment, the proposal is also to shred and autoclave (no compaction) offensive waste (non-hazardous). It is proposed that a new Waste Operation (A7) is included for treatment of non-hazardous wastes (<50 tonnes per day).

With respect to air emissions, there are existing emission points (A4 and A5) from the shredder LEV system and emission point (A8) at the autoclave doors. These LEVs have a carbon filter and a HEPA filter (for VOCs and particulates control respectively). This represents an appropriate level of emissions control for the shredding and autoclaving of offensive waste.

The treated offensive waste will be transferred off site via national contractor, under suitable EWC 19 02 or 19 12 codes to enable the recovery of plastic film from the waste stream.

3.2 Waste Acceptance

Waste acceptance is split into two stages, pre-acceptance and acceptance. For sites accepting waste, the requirements for containment engineering are set out in EPR 5.06 and the healthcare waste appropriate measures guidance. The site has already been set up to conform to this, and has been assessed by the EA in order to obtain the current waste installation permit.

The existing EMS includes a pre-acceptance procedure. BAT requirements, as set out in Section 2.1.1 of EPR 5.06 are fully implemented via this procedure. The existing certified EMS includes a waste acceptance procedure and this remains unchanged and unaffected as a result of the variation. The existing rejection procedure also remains applicable.

3.3 Validation of Treatment

The EA healthcare waste appropriate measures guidance sets out the mandatory standards and measures for clinical waste treatment activities. It confirms that the applicant must demonstrate that the treatment process is able to render the waste safe, by way of efficacy testing. It is understood that the varied EP will include a pre-operational condition requiring the applicant to submit a written site commissioning validation report to the EA for approval.

Autoclaving is a proven technology in the UK with a number of facilities operating successfully in relation to the treatment of healthcare waste. Sharpsmart already operates two facilities in the UK that treat sharps waste through autoclaves and have demonstrated through validation that the waste can be rendered safe.

The floc from the treatment will be sent as RDF as the applicant has an agreement in place with a UK waste disposal company to send this to its energy from waste plants; the applicant is also putting in place contingencies to send the RDF to an exporter with contracts in Europe.

4 Emissions and Monitoring

4.1 Waste storage, handling and dispatch

In relation to waste handling, this is carried out in accordance with the facility waste acceptance procedure and remains relevant and applicable to the facility with the inclusion of the treatment of sharps via the autoclaves. The waste will continue to arrive at the facility in its current form, in proprietary and appropriate containment. Details regarding the tracking processes for the incoming waste are provided in the Supporting Statement.

Manual handling is minimised at the treatment plant by way of the use of an automated bin tipper to raise up and empty the contents of a bin into the shredder unit. Shredded waste is automatically fed into the wheeled autoclave cart which is moved to the autoclave by forklift truck. The feeding of the treated waste from the autoclave cart into the compactor is also by means of forklift which will move

the cart to the bin tipper on the compactor. The area of the building in which the treatment plant, and associated storage activities, benefits from an impermeable flooring with a sealed drainage system. This is commensurate with the existing transfer activity.

Waste pending treatment is stored in a dedicated area and segregated from other types of waste. There is a clearly defined route for the movement of waste depending on its journey (transfer or treatment). This aids the implementation of good waste segregation. All waste storage is within the confines of the building; no untreated waste is stored outside.

Existing measures in place to ensure that containers are cleaned, inspected and repaired or replaced remain relevant. The existing procedures also ensure that waste is processed quickly such that no problems with odour, litter, vermin or pests occur. The contingency plan has been implemented to ensure that storage of waste pending transfer or treatment does not exceed 2 weeks. After 2 weeks, the waste will be transferred off site for incineration or alternative treatment elsewhere.

Dispatch of waste (untreated and residues from treatment) from the facility is covered by existing procedures.

There is a fixed designated quarantine area at the site, in the north-western corner of the building, adjacent to the anatomical fridge. However, under normal operations, receipt of non-conforming waste or that which would require quarantining is rare as waste is collected from serviced customers, in the applicants own (sealed) containers. As the site operates as (and will continue to operate as) a waste transfer facility, should waste arrive that can't be processed, this would be transferred immediately to a treatment facility.

All waste storage infrastructure is subject to regular inspection and any issues recorded and actioned. If damage, deterioration or leakage is found then waste will be removed from the area until repairs are completed.

4.2 Emissions Monitoring

EPR S5.06 recognises that the level of detail relating to fugitive emissions e.g. odour and noise should be in keeping with the risk of causing annoyance at sensitive receptors.

With regards to odour, it is noted that the proposed variation does not alter the types of waste that will be accepted at the site from those which already are and have been under the existing EP. Of the three stages of the proposed treatment activity, the latter two are fully enclosed when in operation (the autoclaves and the compactors). There is therefore very low potential for the release of odours from these. The first stage, the shredders, are fully enclosed and the air extracted from the area and filtered via HEPA and carbon filters (emission points A4 and A5). There is also air extraction around the autoclave unit doors (emission point A8) and this is filtered in the same way. The pathway to receptors is through building openings only as no untreated waste is stored outside it nor is any waste treated outside, and all doors are kept closed when there is no delivery or collection taking place.

EA guidance does specifically require the implementation of an odour management plan (OMP) for applications relating to clinical waste. A copy of the OMP for the site is provided in **Appendix G** of this variation application.

With regards to noise, the potential noise sources, the pathway for propagation, and the sensitivity of the receptors have been considered in the qualitative risk assessment and deemed not to warrant a full noise assessment or management plan. The information provided in the qualitative environmental risk assessment is considered sufficient.

The EA healthcare waste appropriate measures guidance identifies the key potential emission sources from clinical waste sites as being: pathogenic micro-organisms; chemicals and pharmaceuticals; and bodily fluids. The proposed additional activities do not inherently change the types of waste that are permitted to be accepted at the site, albeit two of them (18 01 03*/09 and 18 01 04) are proposed to

be subject to processes that they are not currently permitted for. As such, no new odour emission sources are introduced as a result of the variation application.

Potential pathways leading to an emission include a breach of packaging during manual handling, treatment processes in particular the shredding of untreated waste, and cleaning and disinfection of mobile rigid containers.

Across the variation application documents, details have been provided for control measures that are already in place and new ones to be put in place for the proposed activities. These are confirmed as follows:

- Waste is never manually handled directly. Waste is received in wheeled 770 litre carts that are lidded and locked. Shredded waste is moved to the treatment plant in lined and covered wheeled autoclave carts for safe handling. All containers are subject to regular checks to ensure their integrity and fitness for use.
- Waste is tipped into the shredders using an automated bin lifter. The shredders are fully enclosed to prevent waste spillage from this activity; they will not operate with the doors open. The shredders also have active air extraction which draws air away from the hopper entrance and which is served by both a HEPA filter and a carbon filter (emission points A4 and A5). Both filters are subject to maintenance in accordance with the manufacturer's guidelines to ensure removal efficiency is retained, and pressure differentials measured across the filter to identify when exchange is required.
- Cleaning (disinfection) of the shredders is only when required, for example prior to access to carry out maintenance, repair or service. Effluent generated through the cleaning process is collected in the sealed tank and pumped into an above ground storage tank for transfer to a recovery facility. The tank is in a dedicated area which is clearly marked with the quantity and hazardous characteristics of the effluent stored there. This area is within the building and on hardstanding which is impermeable to the contents. It will be subject to regular inspection.
- The floc from the treatment of sharps and soft waste will be transferred to an intermediate facility that will further treat it and blend it so that it can be sent for recovery at an R1 status energy from waste plant, or use as a fuel in power plants or cement kilns, ensuring that any scant pharmaceutical contamination is destroyed by the combustion process.
- The effluent (condensate from autoclave cycles treating sharps waste) will be transferred to an incinerator plant (either in the UK or in Europe), ensuring that any small pharmaceutical contamination is destroyed by the combustion process.
- Discharge to sewer (of condensate from non-hazardous or offensive waste treatment cycles) is regulated under the existing discharge consent which sets a number of limits.
- Monitoring will be undertaken of emissions of bio-aerosols from the treatment process, specifically around the shredder plants where the waste will be physically treated prior to sterilisation.
- Waste classified as pharmaceutical waste is not processed in the treatment plant. Pre-acceptance processes will identify if there is the potential for significant pharmaceutical contamination in any of the permitted waste streams for treatment and will enable the operator to divert this from the treatment plant.

5 Conclusion

On the basis of the assessment above, which addresses compliance with sector guidance as well as considering the chosen technology against the other available options, it is deemed that the proposed activities appropriately fulfil the definition of BAT.

In relation to the autoclaving of waste, the autoclaving process offers the requisite level of sterilisation, utilises a waste feed system that presents a very low health and safety risk for maintenance, is in use across the UK for healthcare waste so is proven and parts are available, and the resultant solid residues can be used to generate energy in waste to energy facilities.

Annex BAT1

Safety Data Sheets

Pep Active**Section: 1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING****1.1 Product identifier**

Product name : Pep Active
Product code : 109774E
Use of the Substance/Mixture : Surface cleaner
Substance type: : Mixture

For professional users only.

Product dilution information : No dilution information provided.

1.2 Relevant identified uses of the substance or mixture and uses advised against

Identified uses : General purpose cleaner. Spray and wipe manual process
Floor cleaner. Spray and wipe manual process
Recommended restrictions on use : Reserved for industrial and professional use.

1.3 Details of the supplier of the safety data sheet

Company : Ecolab Ltd.
PO Box 11; Winnington Avenue
Northwich, Cheshire, United Kingdom CW8 4DX
+ 44 (0)1606 74488
ccs@ecolab.com

1.4 Emergency telephone number

Emergency telephone number : +441618841235
+32-(0)3-575-5555 Trans-European
Poison Information Centre telephone number : Not Available

Date of Compilation/Revision : 17.08.2017
Version : 1.0

Section: 2. HAZARDS IDENTIFICATION**2.1 Classification of the substance or mixture****Classification (REGULATION (EC) No 1272/2008)**

Skin corrosion, Category 1A H314
Serious eye damage, Category 1 H318

The classification of this product is based only on its extreme pH value (in accordance with current European legislation).

Pep Active

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms :



Signal Word : Danger

Hazard Statements : H314 Causes severe skin burns and eye damage.

Precautionary Statements : **Prevention:**
 P280 Wear protective gloves/ eye protection/ face protection.
Response:
 P303 + P361 + P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.
 P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
 P310 Immediately call a POISON CENTER/doctor.

Hazardous components which must be listed on the label:
 Alcoholsulphates

2.3 Other hazards

None known.

Section: 3. COMPOSITION/INFORMATION ON INGREDIENTS

3.2 Mixtures

Hazardous components

Chemical Name	CAS-No. EC-No. REACH No.	ClassificationREGULATION (EC) No 1272/2008	Concentration: [%]
propan-2-ol	67-63-0 200-661-7 01-2119457558-25	Flammable liquids Category 2; H225 Eye irritation Category 2; H319 Specific target organ toxicity - single exposure Category 3; H336	>= 10 - < 20
2-butoxyethanol	111-76-2 203-905-0 01-2119475108-36	Acute toxicity Category 4; H302 Acute toxicity Category 4; H332 Acute toxicity Category 4; H312 Skin irritation Category 2; H315 Eye irritation Category 2; H319	>= 5 - < 10
Alcoholsulphates	90583-19-0 292-217-4	Skin irritation Category 2; H315 Serious eye damage Category 1; H318	>= 3 - < 5
Benzyl alcohol	100-51-6 202-859-9 01-2119492630-38	Acute toxicity Category 4; H302 Acute toxicity Category 4; H332	>= 2.5 - < 5

For the full text of the H-Statements mentioned in this Section, see Section 16.

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Section: 4. FIRST AID MEASURES

4.1 Description of first aid measures

- In case of eye contact : Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Get medical attention immediately.
- In case of skin contact : Wash off immediately with plenty of water for at least 15 minutes. Use a mild soap if available. Wash clothing before reuse. Thoroughly clean shoes before reuse. Get medical attention immediately.
- If swallowed : Rinse mouth with water. Do NOT induce vomiting. Never give anything by mouth to an unconscious person. Get medical attention immediately.
- If inhaled : Remove to fresh air. Treat symptomatically. Get medical attention if symptoms occur.

4.2 Most important symptoms and effects, both acute and delayed

See Section 11 for more detailed information on health effects and symptoms.

4.3 Indication of immediate medical attention and special treatment needed

- Treatment : Treat symptomatically.

Section: 5. FIREFIGHTING MEASURES

5.1 Extinguishing media

- Suitable extinguishing media : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
- Unsuitable extinguishing media : None known.

5.2 Special hazards arising from the substance or mixture

- Specific hazards during firefighting : Fire Hazard
Keep away from heat and sources of ignition.
Flash back possible over considerable distance.
Beware of vapours accumulating to form explosive concentrations.
Vapours can accumulate in low areas.
- Hazardous combustion products : Decomposition products may include the following materials:
Carbon oxides
nitrogen oxides (NOx)
Sulphur oxides
Oxides of phosphorus

5.3 Advice for firefighters

- Special protective equipment for firefighters : Use personal protective equipment.
- Further information : Fire residues and contaminated fire extinguishing water must be

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disposed of in accordance with local regulations. In the event of fire and/or explosion do not breathe fumes.

Section: 6. ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Advice for non-emergency personnel : Ensure adequate ventilation. Remove all sources of ignition. Keep people away from and upwind of spill/leak. Avoid inhalation, ingestion and contact with skin and eyes. When workers are facing concentrations above the exposure limit they must use appropriate certified respirators. Ensure clean-up is conducted by trained personnel only. Refer to protective measures listed in sections 7 and 8.

Advice for emergency responders : If specialised clothing is required to deal with the spillage, take note of any information in Section 8 on suitable and unsuitable materials.

6.2 Environmental precautions

Environmental precautions : Do not allow contact with soil, surface or ground water.

6.3 Methods and materials for containment and cleaning up

Methods for cleaning up : Eliminate all ignition sources if safe to do so. Stop leak if safe to do so. Contain spillage, and then collect with non-combustible absorbent material, (e.g. sand, earth, diatomaceous earth, vermiculite) and place in container for disposal according to local / national regulations (see section 13). Flush away traces with water. For large spills, dike spilled material or otherwise contain material to ensure runoff does not reach a waterway.

6.4 Reference to other sections

See Section 1 for emergency contact information.
For personal protection see section 8.
See Section 13 for additional waste treatment information.

Section: 7. HANDLING AND STORAGE

7.1 Precautions for safe handling

Advice on safe handling : Do not ingest. Do not get in eyes, on skin, or on clothing. Do not breathe dust/fume/gas/mist/vapours/spray. Use only with adequate ventilation. Keep away from fire, sparks and heated surfaces. Take necessary action to avoid static electricity discharge (which might cause ignition of organic vapours). Wash hands thoroughly after handling.

Hygiene measures : Handle in accordance with good industrial hygiene and safety practice. Remove and wash contaminated clothing before re-use. Wash face, hands and any exposed skin thoroughly after handling. Provide suitable facilities for quick drenching or flushing of the eyes and body in case of contact or splash hazard.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage : Keep away from heat and sources of ignition. Keep away from

SAFETY DATA SHEET according to Regulation (EC) No. 1907/2006

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areas and containers oxidizing agents. Keep out of reach of children. Keep container tightly closed. Store in suitable labeled containers.

Storage temperature : -5 °C to 40 °C

7.3 Specific end uses

Specific use(s) : General purpose cleaner. Spray and wipe manual process
Floor cleaner. Spray and wipe manual process

Section: 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
propan-2-ol	67-63-0	TWA	400 ppm 999 mg/m ³	UKCOSSTD
		STEL	500 ppm 1,250 mg/m ³	UKCOSSTD
2-butoxyethanol	111-76-2	TWA	25 ppm	UKCOSSTD
Further information	Sk	Can be absorbed through skin. The assigned substances are those for which there are concerns that dermal absorption will lead to systemic toxicity.		
		STEL	50 ppm	UKCOSSTD
Further information	Sk	Can be absorbed through skin. The assigned substances are those for which there are concerns that dermal absorption will lead to systemic toxicity.		

Biological occupational exposure limits

Substance name	CAS-No.	Control parameters	Sampling time	Basis
2-butoxyethanol	111-76-2	butoxyacetic acid: 240 mmol/mol creatinine (Urine)	After shift	GB EH40 BAT

DNEL

propan-2-ol	:	End Use: Workers Exposure routes: Dermal Potential health effects: Long-term systemic effects Value: 888 mg/cm ²
		End Use: Workers Exposure routes: Inhalation Potential health effects: Long-term systemic effects Value: 500 mg/m ³
		End Use: Consumers Exposure routes: Dermal Potential health effects: Long-term systemic effects Value: 319 mg/cm ²
		End Use: Consumers Exposure routes: Inhalation Potential health effects: Long-term systemic effects Value: 89 mg/m ³
		End Use: Consumers Exposure routes: Ingestion Potential health effects: Long-term systemic effects Value: 26 ppm

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2-butoxyethanol	:	End Use: Consumers Exposure routes: Ingestion Potential health effects: Long-term systemic effects Value: 3.2 ppm
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PNEC

propan-2-ol	:	Fresh water Value: 140.9 mg/l
		Marine water Value: 140.9 mg/l
		Intermittent use/release Value: 140.9 mg/l
		Fresh water Value: 552 mg/kg
		Marine sediment Value: 552 mg/kg
		Soil Value: 28 mg/kg
		Sewage treatment plant Value: 2251 mg/l
		Oral Value: 160 mg/kg
2-butoxyethanol	:	Fresh water Value: 8.8 mg/l
		Marine water Value: 0.88 mg/l
		Water Value: 9.1 mg/l
		Fresh water sediment Value: 8.14 mg/kg
		Water Value: 463 mg/l
		Soil Value: 2.8 mg/kg
		Value: 20 mg/kg Other conditions

8.2 Exposure controls

Appropriate engineering controls

Engineering measures : Effective exhaust ventilation system. Maintain air concentrations

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below occupational exposure standards.

Individual protection measures

- Hygiene measures : Handle in accordance with good industrial hygiene and safety practice. Remove and wash contaminated clothing before re-use. Wash face, hands and any exposed skin thoroughly after handling. Provide suitable facilities for quick drenching or flushing of the eyes and body in case of contact or splash hazard.
- Eye/face protection (EN 166) : Safety goggles
Face-shield
- Hand protection (EN 374) : Recommended preventive skin protection
Gloves
Nitrile rubber
butyl-rubber
Breakthrough time: 1 – 4 hours
Minimum thickness for butyl-rubber 0.7 mm for nitrile rubber 0.4 mm or equivalent (please refer to the gloves manufacturer/distributor for advise).
Gloves should be discarded and replaced if there is any indication of degradation or chemical breakthrough.
- Skin and body protection (EN 14605) : Personal protective equipment comprising: suitable protective gloves, safety goggles and protective clothing
- Respiratory protection (EN 143, 14387) : None required if airborne concentrations are maintained below the exposure limit listed in Exposure Limit Information. Use certified respiratory protection equipment meeting EU requirements(89/656/EEC, 89/686/EEC), or equivalent, when respiratory risks cannot be avoided or sufficiently limited by technical means of collective protection or by measures, methods or procedures of work organization.

Environmental exposure controls

- General advice : Consider the provision of containment around storage vessels.

Section: 9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

- Appearance : liquid
- Colour : light yellow
- Odour : alcohol-like
- pH : 11.5 - 12.5, 100 %
- Flash point : 40 °C closed cup, Does not sustain combustion.
- Odour Threshold : Not applicable and/or not determined for the mixture
- Melting point/freezing point : Not applicable and/or not determined for the mixture
- Initial boiling point and boiling range : Not applicable and/or not determined for the mixture
- Evaporation rate : Not applicable and/or not determined for the mixture

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Flammability (solid, gas)	: Not applicable and/or not determined for the mixture
Upper explosion limit	: Not applicable and/or not determined for the mixture
Lower explosion limit	: Not applicable and/or not determined for the mixture
Vapour pressure	: Not applicable and/or not determined for the mixture
Relative vapour density	: Not applicable and/or not determined for the mixture
Relative density	: 0.97 - 0.98
Water solubility	: soluble
Solubility in other solvents	: Not applicable and/or not determined for the mixture
Partition coefficient: n-octanol/water	: Not applicable and/or not determined for the mixture
Auto-ignition temperature	: Not applicable and/or not determined for the mixture
Thermal decomposition	: Not applicable and/or not determined for the mixture
Viscosity, kinematic	: Not applicable and/or not determined for the mixture
Explosive properties	: Not applicable and/or not determined for the mixture
Oxidizing properties	: The substance or mixture is not classified as oxidizing.

9.2 Other information

Not applicable and/or not determined for the mixture

Section: 10. STABILITY AND REACTIVITY

10.1 Reactivity

No dangerous reaction known under conditions of normal use.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

No dangerous reaction known under conditions of normal use.

10.4 Conditions to avoid

Heat, flames and sparks.

10.5 Incompatible materials

None known.

10.6 Hazardous decomposition products

Decomposition products may include the following materials:
Carbon oxides
nitrogen oxides (NO_x)
Sulphur oxides
Oxides of phosphorus

Section: 11. TOXICOLOGICAL INFORMATION

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11.1 Information on toxicological effects

Information on likely routes of exposure : Inhalation, Eye contact, Skin contact

Product

Acute oral toxicity : Acute toxicity estimate : > 2,000 mg/kg
Acute inhalation toxicity : 4 h Acute toxicity estimate : > 5 mg/l
Acute dermal toxicity : Acute toxicity estimate : > 2,000 mg/kg
Skin corrosion/irritation : There is no data available for this product.
Serious eye damage/eye irritation : There is no data available for this product.
Respiratory or skin sensitization : There is no data available for this product.
Carcinogenicity : There is no data available for this product.
Reproductive effects : There is no data available for this product.
Germ cell mutagenicity : There is no data available for this product.
Teratogenicity : There is no data available for this product.
STOT - single exposure : There is no data available for this product.
STOT - repeated exposure : There is no data available for this product.
Aspiration toxicity : There is no data available for this product.

Components

Acute oral toxicity : propan-2-ol
LD50 rat: 5,840 mg/kg

2-butoxyethanol
LD50 rat: 1,500 mg/kg

Alcoholsulphates
LD50 rat: 2,175 mg/kg

Benzyl alcohol
LD50 rat: 1,620 mg/kg

Components

Acute inhalation toxicity : propan-2-ol
4 h LC50 rat: 30 mg/l

Benzyl alcohol
4 h LC50 rat: 4.178 mg/l

Components

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Acute dermal toxicity : propan-2-ol
LD50 rabbit: 12,870 mg/kg

Benzyl alcohol
LD50 rabbit: 2,000 mg/kg

Potential Health Effects

Eyes : Causes serious eye damage.

Skin : Causes severe skin burns.

Ingestion : Causes digestive tract burns.

Inhalation : May cause nose, throat, and lung irritation.

Chronic Exposure : Health injuries are not known or expected under normal use.

Experience with human exposure

Eye contact : Redness, Pain, Corrosion

Skin contact : Redness, Pain, Corrosion

Ingestion : Corrosion, Abdominal pain

Inhalation : Respiratory irritation, Cough

Section: 12. ECOLOGICAL INFORMATION

12.1 Ecotoxicity

Environmental Effects : This product has no known ecotoxicological effects.

Product

Toxicity to fish : no data available

Toxicity to daphnia and other aquatic invertebrates : no data available

Toxicity to algae : no data available

Components

Toxicity to fish : propan-2-ol
96 h LC50 Pimephales promelas (fathead minnow): 9,640 mg/l

2-butoxyethanol
96 h LC50: 1,474 mg/l

Benzyl alcohol
96 h LC50 Fish: > 100 mg/l

Components

Toxicity to daphnia and other aquatic invertebrates : propan-2-ol
LC50 Daphnia magna (Water flea): > 10,000 mg/l

2-butoxyethanol

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48 h EC50: 690 mg/l

Alcoholsulphates
48 h EC50: 31 mg/l

Components

Toxicity to algae : 2-butoxyethanol
72 h EC50: 911 mg/l

12.2 Persistence and degradability

Product

Biodegradability : The surfactants contained in the product are biodegradable according to the requirements of the detergent regulation 648/2004/EC

Components

Biodegradability : propan-2-ol
Result: Readily biodegradable.

2-butoxyethanol
Result: Readily biodegradable.

Alcoholsulphates
Result: Readily biodegradable.

Benzyl alcohol
Result: Readily biodegradable.

12.3 Bioaccumulative potential

no data available

12.4 Mobility in soil

no data available

12.5 Results of PBT and vPvB assessment

Product

Assessment : This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

12.6 Other adverse effects

no data available

Section: 13. DISPOSAL CONSIDERATIONS

Dispose of in accordance with the European Directives on waste and hazardous waste. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.

13.1 Waste treatment methods

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- Product : Where possible recycling is preferred to disposal or incineration. If recycling is not practicable, dispose of in compliance with local regulations. Dispose of wastes in an approved waste disposal facility.
- Contaminated packaging : Dispose of as unused product. Empty containers should be taken to an approved waste handling site for recycling or disposal. Do not re-use empty containers. Dispose of in accordance with local, state, and federal regulations.
- Guidance for Waste Code selection : Organic wastes containing dangerous substances. If this product is used in any further processes, the final user must redefine and assign the most appropriate European Waste Catalogue Code. It is the responsibility of the waste generator to determine the toxicity and physical properties of the material generated to determine the proper waste identification and disposal methods in compliance with applicable European (EU Directive 2008/98/EC) and local regulations.

Section: 14. TRANSPORT INFORMATION

The shipper/consignor/sender is responsible to ensure that the packaging, labeling, and markings are in compliance with the selected mode of transport.

Land transport (ADR/ADN/RID)

- 14.1 UN number : Not dangerous goods
14.2 UN proper shipping name : Not dangerous goods
14.3 Transport hazard class(es) : Not dangerous goods
14.4 Packing group : Not dangerous goods
14.5 Environmental hazards : Not dangerous goods
14.6 Special precautions for user : Not dangerous goods

Air transport (IATA)

- 14.1 UN number : Not dangerous goods
14.2 UN proper shipping name : Not dangerous goods
14.3 Transport hazard class(es) : Not dangerous goods
14.4 Packing group : Not dangerous goods
14.5 Environmental hazards : Not dangerous goods
14.6 Special precautions for user : Not dangerous goods

Sea transport (IMDG/IMO)

- 14.1 UN number : Not dangerous goods
14.2 UN proper shipping name : Not dangerous goods
14.3 Transport hazard class(es) : Not dangerous goods
14.4 Packing group : Not dangerous goods
14.5 Environmental hazards : Not dangerous goods

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14.6 Special precautions for user : Not dangerous goods
 14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code : Not dangerous goods

Section: 15. REGULATORY INFORMATION

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

according to Detergents Regulation EC 648/2004 : less than 5 %: Anionic surfactants
 Other constituents: Perfumes
 Allergens:
 Benzyl alcohol

National Regulations

Take note of Dir 94/33/EC on the protection of young people at work.

Other regulations : The Chemicals (Hazard Information and Packaging for Supply) Regulations.
 The Control of Substances Hazardous to Health Regulations.
 Health and Safety at Work Act.

15.2 Chemical Safety Assessment

This product contains substances for which Chemical Safety Assessments are still required.

Section: 16. OTHER INFORMATION

Procedure used to derive the classification according to REGULATION (EC) No 1272/2008

Classification	Justification
Skin corrosion 1A, H314	Based on product data or assessment
Serious eye damage 1, H318	Based on product data or assessment

Full text of H-Statements

H225 Highly flammable liquid and vapour.
 H302 Harmful if swallowed.
 H312 Harmful in contact with skin.
 H315 Causes skin irritation.
 H318 Causes serious eye damage.
 H319 Causes serious eye irritation.
 H332 Harmful if inhaled.
 H336 May cause drowsiness or dizziness.

Full text of other abbreviations

ADN – European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR – European Agreement concerning the International Carriage of Dangerous Goods by Road; AICS – Australian Inventory of Chemical Substances; ASTM – American Society for the Testing of Materials; bw – Body weight; CLP – Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR – Carcinogen, Mutagen or

Pep Active

Reproductive Toxicant; DIN – Standard of the German Institute for Standardisation; DSL – Domestic Substances List (Canada); ECHA – European Chemicals Agency; EC-Number – European Community number; ECx – Concentration associated with x% response; ELx – Loading rate associated with x% response; EmS – Emergency Schedule; ENCS – Existing and New Chemical Substances (Japan); ErCx – Concentration associated with x% growth rate response; GHS – Globally Harmonized System; GLP – Good Laboratory Practice; IARC – International Agency for Research on Cancer; IATA – International Air Transport Association; IBC – International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 – Half maximal inhibitory concentration; ICAO – International Civil Aviation Organization; IECSC – Inventory of Existing Chemical Substances in China; IMDG – International Maritime Dangerous Goods; IMO – International Maritime Organization; ISHL – Industrial Safety and Health Law (Japan); ISO – International Organisation for Standardization; KECI – Korea Existing Chemicals Inventory; LC50 – Lethal Concentration to 50 % of a test population; LD50 – Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL – International Convention for the Prevention of Pollution from Ships; n.o.s. – Not Otherwise Specified; NO(A)EC – No Observed (Adverse) Effect Concentration; NO(A)EL – No Observed (Adverse) Effect Level; NOELR – No Observable Effect Loading Rate; NZIoC – New Zealand Inventory of Chemicals; OECD – Organization for Economic Co-operation and Development; OPPTS – Office of Chemical Safety and Pollution Prevention; PBT – Persistent, Bioaccumulative and Toxic substance; PICCS – Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR – (Quantitative) Structure Activity Relationship; REACH – Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RID – Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT – Self-Accelerating Decomposition Temperature; SDS – Safety Data Sheet; TCSI – Taiwan Chemical Substance Inventory; TRGS – Technical Rule for Hazardous Substances; TSCA – Toxic Substances Control Act (United States); UN – United Nations; vPvB – Very Persistent and Very Bioaccumulative

Prepared by : Regulatory Affairs

Numbers quoted in the MSDS are given in the format: 1,000,000 = 1 million and 1,000 = 1 thousand. 0.1 = 1 tenth and 0.001 = 1 thousandth

REVISED INFORMATION: Significant changes to regulatory or health information for this revision is indicated by a bar in the left-hand margin of the SDS.

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

ANNEX: EXPOSURE SCENARIOS

DPD+ Substances:

The following substances are the lead substances that contribute to the mixture Exposure Scenario according to the DPD+ Rule:

Route	Substance	CAS-No.	EINECS-No.
Ingestion	2-butoxyethanol	111-76-2	203-905-0
Inhalation	propan-2-ol	67-63-0	200-661-7

SAFETY DATA SHEET according to Regulation (EC) No. 1907/2006**Pep Active**

Dermal	2-butoxyethanol	111-76-2	203-905-0
Eyes	propan-2-ol 2-butoxyethanol	67-63-0 111-76-2	200-661-7 203-905-0
aquatic environment	No lead substance		

Physical properties DPD+ Substances:

Substance	Vapour pressure	Water solubility	Pow	Molar Mass
2-butoxyethanol	117 Pa		0.81	118 g/mol
propan-2-ol	6,020 Pa			60.10 g/mol

To calculate if your downstream Operating Conditions and Risk management Measures are safe, please calculate your risk factor at the website below:

www.ecetoc.org/tra

Short title of Exposure Scenario : **General purpose cleaner. Spray and wipe manual process**

Use descriptors

Main User Groups : Professional uses: Public domain (administration, education, entertainment, services, craftsmen)

Sectors of end-use : **SU22:** Professional uses: Public domain (administration, education, entertainment, services, craftsmen)

Process categories : **PROC10:** Roller application or brushing
PROC11: Non industrial spraying
PROC8a: Transfer of substance or preparation (charging/ discharging) from/ to vessels/ large containers at non-dedicated facilities

Product categories : **PC35:** Washing and cleaning products (including solvent based products)

Environmental Release Categories : **ERC8a:** Wide dispersive indoor use of processing aids in open systems

Short title of Exposure Scenario : **Floor cleaner. Spray and wipe manual process**

Use descriptors

Main User Groups : Professional uses: Public domain (administration, education, entertainment, services, craftsmen)

Sectors of end-use : **SU22:** Professional uses: Public domain (administration, education, entertainment, services, craftsmen)

Pep Active

- Process categories : **PROC10:** Roller application or brushing
PROC11: Non industrial spraying
PROC8a: Transfer of substance or preparation (charging/
discharging) from/ to vessels/ large containers at non-dedicated
facilities
- Product categories : **PC35:** Washing and cleaning products (including solvent based
products)
- Environmental Release
Categories : **ERC8a:** Wide dispersive indoor use of processing aids in open
systems

Annex BAT2

Example Effluent Specification

General Specification applicable to All Wastes considered for treatment

State	Liquid, single phase (Note 5)
Viscosity	Less than 10 cP
Total Solids	Less than 1% w/w, in suspension (Note 1)
Solids over 1mm in size	Less than 0.01% w/w in suspension(Note 1)
Organic Halide	Up to 3% w/w, expressed as Chlorine (Note 2)
Phosphorous	Less than 0.1% (Note 3)
Sulphur	Less than 1% w/w (Note 4)
Restricted Content	None (Note 7)

Special Provisions for Aqueous Waste

pH	>5
Water content	>65% by mass (Note 6)
Calorific Value	<8 MJ/kg (Note 6)

Special Provisions for Organic Waste

pH	>5
Water content	<10% by mass (Note 6)
Calorific Value	>18 MJ/kg (Note 6)

Special Provisions for Acidic Waste

pH	<6
Water content	>50% by mass (Note 6)
Calorific Value	<12 MJ/kg (Note 6)

Notes : General Provisions Applicable to all Wastes

1. Solids not in suspension will be considered a separate phase and a unique waste stream with a unique disposal fee
2. Additional charges apply for halide content over 3% (expressed by mass as Chlorine)
3. Charges may apply for additional Phosphorous content
4. Charges may apply for additional Sulphur content
5. Separate layers will be considered separate waste streams with unique disposal prices
6. Charges may apply for wastes with properties out of specified parameters
7. Includes monomers, polymers, adhesives, peroxides, persulphates, resins, sludge, tars, epoxy, all Class 1 explosives and Class 7 radioactive material, Class 4.1 Water-Reactives and Class 4.2 pyrophorics as classed by ADR

Charges will Apply for wastes which do not meet specification.

Table M

0.2	ppm	Hg
0.5	ppm	Cd
0.5	ppm	Tl
2.0	ppm	Cr
3.0	ppm	Cu
5.0	ppm	Ni
1.5	ppm	As
2.0	ppm	Mn
2.0	ppm	V
5.0	ppm	Zn
1.0	ppm	Pb

*Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on industrial emissions (integrated pollution prevention and control)

Emission limits for air set out in Annex VI, part 3, paragraph (table) 1.3 of the above referenced Directive.

FES detection method:

Energy Dispersive X-Ray Fluorescence Spectrophotometry (EDXRF)

Limits are rigid and non-negotiable for all elements listed in Table M