

04 April 2014

Project No: 2014-020-001

## Part B Permit Application Support

Prepared for:



### Nagor Limited

Unit 11 Tournament Way  
Ivanhoe Industrial Estate  
Ashby-de-la-Zouch  
Leicestershire  
LE65 2UU

#### Contents Amendment Record

This report has been issued and amended as follows:

Revision	Description	Date	Signed
1.0	Final	04 April 2014	Neil Sullivan



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## Acknowledgement

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Mabbett & Associates Ltd (Mabbett) have prepared this Part B Permit Application report in accordance with a scope of work presented in Mabbett Letter-Agreement dated 18 March 2014 (Ref.: 151-2014/LA/NS/pb). This report is based on information and data provided by Nagor Limited (Nagor) and data generated/collected by Mabbett. Should any of the information be incorrect, incomplete or subject to change, Mabbett may wish to revise the report accordingly.

The following Mabbett personnel completed this Part B Permit Application report:

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The following Mabbett personnel reviewed and approved this Part B Permit Application report:

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Senior Environmental Engineer &  
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## Section 1.0 Introduction

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### 1.1 Background

Nagor Limited (Nagor) provides this report for the purposes of the application to North West Leicestershire District Council (NWLDC) for a Part B Permit under the Environmental Permitting (England and Wales) (Amendment) Regulations 2013. This is to comply with the need to regulate the coating process activities under Part B Section 6.4 (a) (iv) of the Environmental Permitting Regulations, described as 'any process (other than for the re-painting or re-spraying of or of parts of aircraft or road or railway vehicles) for applying to a substrate, or drying or curing after such application, printing ink or paint or any other coating material as, or in the course of, a manufacturing activity, where the process may result in the release into the air of particulate matter or of any volatile organic compound and is likely to involve the use in any twelve month period of five or more tonnes of organic solvents'.

The entire site operated by Nagor has been referred to in this report as the "Site". The part of the Site where the process to be permitted under PPC is proposed to take place has been referred to as the "Installation". For the purposes of this report the Installation forms a portion of the overall Site area (Dipping Room) and is the specific area to be assessed.

This report is provided to describe the proposed Installation activities and the proposed techniques and measures to prevent and reduce waste arising and emissions of substances and/or energy (including leak or malfunction) to air.

At present the Stationary Technical Unit at the Nagor, Ashby-de-la-Zouch facility comprises the following operations:

- Curing Process (involves numerous dispersion and curing stages).

In addition, the following Directly Associated Activities are also carried out on Site:

- Delivery, storage and handling of raw materials;
- Rinsing;
- Post-treatment (including closure patching and gel filling); and
- Cleaning.

## Section 2.0 Process Description

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### 2.1 Non-technical Summary

Nagor Limited manufactures medical devices for the aesthetic and reconstructive market. The product consists of three main components:

- Shell;
- Closure Patch; and
- Gel.

Solvents are used within the manufacturing process to enable the product to be chemically cross-linked by a catalyst enabled reaction to a vulcanised elastomer. Further, solvents are also utilised for general cleaning of equipment, cleanroom furniture and the cleanroom.

The shell and the closure patch (the latter of which is made up of three individual components, two of which are made from the same principle process detailed below but with different tooling) both utilise solvents. The production of the shell utilises the largest quantity. The gel component does not utilise any solvents.

The manufacturing of the shell component is a moulding process, whereby a two part mixture of dispersed polymers are chemically cross linked in the presence of a catalyst at high temperatures. A plastic mandrel is introduced into a bowl of dispersion (mixture of unreacted silicon elastomer and solvent). The plastic mandrel is then placed into a heating oven to remove the solvents from the elastomer (process of devolatilisation). This process is repeated up to six times for each mandrel until the shell has achieved the desired design. This is a manual process. The tool is then placed in the heating curing oven to fully chemically cross link/vulcanise the shell prior to its removal from the tool using a manual stripping process. The product is now available for use in the product.

### 2.2 Technical Process Description

Nagor Limited produce two main products (shell and gel) on site and also cut barrier sheets (produced in the companies Cumbernauld facility) into the required sizes for the three components of the closure patch. These products are medical devices for the aesthetic and reconstruction market.

The manufacturing processes associated with these three products (shell, closure patch and gel) are discussed individually below.

#### 2.2.1 Shell

The shell manufacturing process (shells are predominantly utilised as aesthetic or reconstructive breast implants) is a moulding process which cross links dispersed polymers at high temperatures. Fundamentally, the shells are composed of four to six layers of dispersion (depending on the required specification). The dispersion layers comprise two main mixtures:

- Dimethyl Dispersion Base, a crosslinker and xylene (a thinner); and
- Fluorosilicone Dispersion Base, a crosslinker and either tetrachloroethylene or nButyl Acetate (thinners).

Typically there is only one fluorosilicone layer (classed as a barrier layer) and usually this is the second layer. These chemicals (205 litre drums) are stored out with the main production area on an appropriately sized bund and are vacuum pumped into the mixing area via plastic tubing (minimises manual movement of chemicals). The appropriate mixture (by weight) for the product being produced are then manually mixed (via taps controlled by foot pumps) and sealed in plastic containers. These plastic containers are then shaken for 20 minutes until the desired viscosity is met. The mixture is then transferred into metal buckets which are covered in foil until usage.

The shells (predominantly utilised for breast implants) produced by Nagor are manufactured in two main shapes:

- Round; and
- Tear Drop.

Thirty eight shells can be processed at any one time and once the mandrels have been sorted they are manually cleaned with Isopropanol Acetate prior to the initial dispersion stage (manual process). Once dispersed, the mandrels are removed and placed in an oven for 20 minutes to dry. This occurs up to six times and at least one of the dispersions is in the flurosilicone dispersion.

Following the final dispersion stage, the mandrels are removed from the ovens and undergo a two stage curing process (ovens set at 55° C and 165° C). Once this is complete the shells are removed from the ovens and allowed to stabilise.

The plastic mandrels are then submerged in Dimethyl dispersion again prior to undergoing a texturing process (small grade sodium chloride is blasted at the mandrels for up to 40 minutes). This texturing process is believed to reduce the potential for the body to react to the implant. The mandrels are then moved back to the ovens prior to the shells being stripped off the mandrels and washed. The shells are then quality tested (water pressure, tensile strength and appearance) and stored until required.

### **2.2.2 Closure Patch**

As the plastic mandrels leave a circular hole in the shell, a closure patch is required to fully seal it so that once the gel is inserted no leakages can occur. Barrier sheets are prepared at Nagors Cumbernauld Site utilising the same method as that used when producing the shell and the sheets are transported to the Ashby-de-la-Zouch facility for cutting.

Following cutting of the barrier sheets, the three closure patch components are utilised on site and also transported to the Cumbernauld facility for use on the shells produced there.

### **2.2.3 Gel**

As with the dispersion for the shell production, the gel comprises of two a gel base and a gel crosslinker. Different specifications of gel can be requested based on the desired firmness required for the implant. However, the usual ratio is 1:3. Once the desired density of gel has been mixed, the shells are injected by machine with the gel. The implants are then weighed and additional gel injected manually with a needle if required until the optimum weight is reached. The injection point is then sealed so that no leakages can occur.

The product then goes through de-airing and sealing before a final visual QA/QC inspection and packaging.

## **2.3 Best Available Techniques**

Where practicable, Best Available Techniques (BAT) will be used, within the boundaries of incremental environmental benefit against expenditure to be assigned. It is however noted that some gaps currently exists and an **Action Item** has been raised by Nagor to identify and implement BAT for all aspects of the permitted process undertaken at the Ashby-de-la-Zouch facility.

## **2.4 Site Plans**

The Nagor facility (central grid reference 318000N, 435090E) is located within the Ivanhoe Industrial Estate approximately 1.5 km north west of Ashby-de-la-Zouch town centre. The site is an L-Shaped warehouse building with a small car park and external chemical storage area and is bound immediately to the south by Tournament Way, which is located off to the east of the B6006 (Simsby Road).

The Site is predominantly surrounded by industrial and commercial properties, although an area of rough grassland is located to the north of the site. Residential properties are located approximately 250 m to the south of the site.

A Site and Installation Boundary diagram (Drawing L-1) is included as Appendix A to this Permit Application Report.

## Section 3.0 Raw Materials Inventory

The Installation utilises a variety of chemicals and as such, consideration regarding the purchase, storage and safe handling of these raw materials throughout the life of the Permit should be given.

Raw material data based on 2012-2013 consumption has been provided by Nagor and quantities are presented in the table below:

### Raw Material Consumption Data 2012-2013

Chemical	Usage (kg/unit)	Container Size & Type
Xylene	6,200	200 litre plastic drum
Tetrachloroethylene	1,303	25 litre plastic drum
nButyl Acetate	82.6	2.5 litre glass bottle
Isopropanol Alcohol	4,108	200 litre plastic drum
Sodium Chloride	2,800	25 kg bags

This data is actual data based on consumption during the detailed time period. The volume of material held on Site at any one time will depend on the requirements of production planning. Nagor are committed to the optimisation of the process operations and work to minimise chemical raw materials usage on an ongoing basis.

In order to quantify usage more accurately, Nagor maintain a raw materials inventory for the Installation. A modified version of this inventory is presented for reference in Appendix C to this Permit Application and contains the following information on each of the raw materials:

- Chemical trade name and supplier;
- Principal use and Description of process utilising chemical;
- Chemical constituents;
- Annual usage;
- Annual usage of individual chemical constituents;
- Packaging type and size;
- ID (CAS Number);
- Details of associated hazards;
- Chemical risk phrases;
- Health & Safety risk phrases; and
- Fate/disposal method.

Additional process or chemical specific information shall be included as required.

Production demands require that Nagor maintain a sufficient on-site chemical inventory to allow the process to continue without major interruptions in the event of a delay in delivery. The stock of chemicals held on site is adequate for the infrastructure and management procedures that are in place in order to comply with all relevant material handling requirements. Nagor confirmed that the chemical storage areas are located within impervious bunds for the stored chemicals and that the capacity is 110 % of the largest storage container or 25 % of the total storage volume etc.

The following table provides details of the indicative Best Available Technique requirements for the selection of chemical raw materials.

Indicative BAT Requirements	Nagor Response	Action Plan	Target Date
The Operator should create and maintain a full chemical raw material inventory.	A draft chemical raw material inventory has been prepared to accompany this Permit Application and is presented in Appendix C.	Ongoing.	Ongoing.
The Operator should have procedures for the regular review of new developments in raw materials and the implementation of any suitable ones that are less hazardous.	Nagor acknowledge that selection of raw materials represents an opportunity to control emissions at source. As part of their commitment to continual process improvement Nagor will review advances in chemical raw material selection on a regular basis in order to ensure that cost effective options for substituting existing chemicals raw materials for less hazardous options are fully investigated and where applicable implemented.	Ongoing.	Ongoing.
The Operator should have quality-assurance procedures for controlling the content of raw materials.	Nagor operates dedicated procedures for the control of raw materials. The company will develop and implement bespoke procedures for the checking and controlling the content of chemical raw materials related to Installation.	Ongoing.	Ongoing.
The Operator should complete any longer-term studies needed into the less polluting options and should make any material substitutes identified.	Nagor are committed to continuous improvement and shall review options for substitution and implement alternative where economically and technically feasible.	Ongoing.	Ongoing.

**Note:** Due to the medical nature of the products being manufactured, any changes in the products being utilised require authority from the appropriate regulators. Therefore, it is unlikely that substitutions to the current chemicals utilised would be undertaken in the short term. Material Safety Data Sheets for all materials currently utilised are included as Appendix B to this Permit Application report.

## Section 4.0 Environmental Management Systems

### 4.1 Environmental Management Systems

While Nagor have a number of procedures in place these have not yet been formalised into an internal Environmental Management System. It has been confirmed that a longer term project is underway to investigate the benefits of achieving formal registration to ISO 14001. It is therefore considered likely that Nagor will look to produce an internal Environmental Management Systems (including an Environmental Policy) with the longer term potential to register under ISO 14001. An **Action Item** has been raised to track the development and implementation of a potential Environmental Management System for the site and the processes undertaken.

### 4.2 Quality Management Systems

As a producer of medical devices, Nagor manage all aspects of the operations undertaken at Ashby-de-la-Zouch with a high level of quality control. While the systems in place are not formalised to ISO9001 standard, they do cover all requirements of the various medical devices requirements. Nagor have confirmed to Mabbett that they are currently investigating the creation and implementation of an internal Quality Management System registered to ISO 9001. An **Action Item** has been raised to track the development and implementation of a potential Quality Management System for the site and the processes undertaken.

The following table provides details of the indicative Best Available Technique requirements for effective process management.

Indicative BAT Requirements	Nagor Response	Action Plan	Target Date
<p>Effective operational and maintenance systems should be employed on all aspects of the process whose failure could impact on the environment, in particular there should be:</p> <ul style="list-style-type: none"> <li>▪ documented procedures to control operations that may have an adverse impact on the environment;</li> <li>▪ a defined procedure for identifying, reviewing and prioritising items of plant for which a preventative maintenance regime is appropriate;</li> <li>▪ documented procedures for monitoring emissions or impacts; and</li> <li>▪ preventative maintenance programme covering all plant, whose failure could lead to impact on the environment, including regular inspection of major 'non productive' items such as tanks, pipework, retaining walls, bunds ducts and filters</li> </ul>	<p>Nagor has in place documented procedures to assist minimise their impact on the environment.</p>	<p>Ongoing.</p>	<p>Ongoing.</p>
<p>The maintenance system should include auditing of performance against requirements arising from the above and reporting the result of audits to top management.</p>	<p>Planned preventative and reactive maintenance is undertaken on all key plant and equipment that could result in a change to the facility's impact on the environment.</p>	<p>Ongoing.</p>	<p>Ongoing.</p>
<p>Training systems, covering the following items, should be in place for all relevant staff which Cover:</p> <ul style="list-style-type: none"> <li>▪ awareness of the regulatory implications of the Permit for the activity and their work activities;</li> <li>▪ awareness of all potential environmental effects from operation under normal and abnormal circumstances;</li> <li>▪ awareness of the need to report deviation from the Permit; and</li> <li>▪ prevention of accidental emissions and action to be taken when accidental emissions occur.</li> </ul>	<p>Induction training systems are in place for all new starts and ad-hoc training is also provided on an as required basis.</p>	<p>Ongoing.</p>	<p>Ongoing.</p>
<p>The skills and competencies necessary for key posts should be documented and records of training needs and training received for these post maintained.</p>	<p>Job descriptions contain details of skills and competencies necessary for each post.</p>	<p>Ongoing.</p>	<p>Ongoing.</p>

The key posts should include contractors and those purchasing equipment and materials.	Contractors and those purchasing equipment and materials are also covered.	Ongoing.	Ongoing.
The potential environmental risks posed by the work of contractors should be assessed and instructions provided to contractors about protecting the environment while working on site.	Controls are in place to minimise the impact of all work undertaken by third party contractors.	Ongoing.	Ongoing.
Where industry standards or codes of practice for training exist (e.g. WAMITAB) they should be complied with.	Where appropriate, all industry codes and standards are adhered to.	Ongoing.	Ongoing.
There should be written procedures for handling, investigating, communicating and reporting actual or potential non-compliance with operating procedures or emission limits.	Actual and potential non-compliances or near misses are documented and where appropriate action is taken to rectify any issues.	Ongoing.	Ongoing.
There should be written procedures for handling, investigating, communicating and reporting environmental complaints and implementation of appropriate actions.	Environmental complaints are documented and where appropriate action is taken to rectify any issues.	Ongoing.	Ongoing.
There should be written procedures for investigating incidents, (and near misses) including identifying suitable corrective action and following up	Actual and potential non-compliances or near misses are documented and where appropriate action is taken to rectify any issues.	Ongoing.	Ongoing.
The company should preferably adopt an environmental policy and programme which: <ul style="list-style-type: none"> <li>▪ includes a commitment to continual improvement and prevention of pollution;</li> <li>▪ includes a commitment to comply with relevant legislation, and with other requirements to which the organisation subscribes; and</li> <li>▪ identifies, sets, monitors and reviews environmental objectives and key performance indicators independently of the Permit.</li> </ul>	No formal EMS exists although internal procedures cover all activities that could result in a change to the facility's impact on the environment.	Ongoing.	Ongoing.
The company should preferably have procedures which incorporate environmental issues into the following areas (as supported by demonstrable evidence e.g. written procedures): <ul style="list-style-type: none"> <li>▪ the control of process change on the installation;</li> <li>▪ design and review of new facilities (including provision for their decommissioning), engineering and other capital projects;</li> <li>▪ capital approval; and</li> <li>▪ purchasing policy.</li> </ul>	No formal EMS exists although internal procedures cover all activities that could result in a change to the facility's impact on the environment.	Ongoing.	Ongoing.
The company should preferably have audits, at least annually, to check that all activities are being carried out in conformity with the above requirements. These should preferably be independent.	Annual, internal audits are undertaken by Nagor and all findings documented and actioned as appropriate.	Ongoing.	Ongoing.
The company should preferably report annually on environmental performance, objectives and targets, and future planned improvements. This should preferably be a public environmental statement.	Internal reporting is undertaken on an annual basis.	Ongoing.	Ongoing.
The company should preferably have a registered or certified EMAS/ISO 14001 system (by an accredited certification body).	No formal EMS exists although internal procedures cover all activities that could result in a change to the facility's impact on the environment.	Ongoing.	Ongoing.
The company should preferably have a clear, logical and recorded system for keeping records of: <ul style="list-style-type: none"> <li>▪ Policies;</li> <li>▪ roles and responsibilities;</li> <li>▪ targets;</li> <li>▪ procedures;</li> <li>▪ results of audits; and</li> <li>▪ results of reviews.</li> </ul>	Internal reporting is undertaken on an annual basis.	Ongoing.	Ongoing.

## Section 5.0 Monitoring

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No historic emission monitoring has been undertaken for the Ashby-de-la-Zouch facility. An **Action Item** has been raised to track the completion of quantitative stack testing in order to speciate and quantify the concentration of emissions of solvents from the various manufacturing activities undertaken. Details of the emissions monitoring exercise will be submitted to NWLDC upon completion.

## Section 6.0 Emissions Inventory

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No historic emission monitoring has been undertaken for the Ashby-de-la-Zouch facility. An **Action Item** has been raised to track the completion of quantitative stack testing in order to speciate and quantify the concentration of emissions of solvents from the various manufacturing activities undertaken. Details of the emissions monitoring exercise will be submitted to NWLDC upon completion.

In addition, once data is available for the emission to atmosphere, a mass balance exercise will be undertaken to quantify fugitive emissions arising from the Ashby-de-la-Zouch facility.

## Section 7.0 Impact Assessment

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No historic emission monitoring has been undertaken for the Ashby-de-la-Zouch facility. An **Action Item** has been raised to track the completion of quantitative stack testing in order to speciate and quantify the concentration of emissions of solvents from the various manufacturing activities undertaken. Details of the emissions monitoring exercise will be submitted to NWLDC upon completion.

In addition, once data is available for the emission to atmosphere, a mass balance exercise will be undertaken to quantify fugitive emissions arising from the Ashby-de-la-Zouch facility.

Furthermore, once emission concentration data is available the impact of the facility will be quantified by direct comparison against the relevant BAT emissions limit values. Where required, it is anticipated that further work will be undertaken to optimise the site impact through improved/modified management procedures, production processes and/or engineering controls.

## **Section 8.0 Statutory Consultees**

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### **8.1 Local Authority**

The Nagor facility falls within the North West Leicestershire District Council located at:

North West Leicestershire District Council  
Environmental Health  
Council Offices  
Coalville  
Leicestershire  
LE67 3FJ

### **8.2 Health Board**

**TBC**

### **8.3 SSSI/European Conservation Sites**

There are no known SSSI within 2 km radius of the Nagor facility boundary. Information on the SSSI locations within this area was obtained from the DEFRA website:

<http://magic.defra.gov.uk/MagicMap>

### **8.4 COMAH**

It is not anticipated that the Ashby-de-la-Zouch facility will fall under the COMAH regulations at this time. Consideration will however, be given to any future changes in the regulations and/or activities undertaken at the facility and where appropriate this classification will be revised.