

White Paper

Parker NITROSource range Nitrogen gas generators
Compliance with European Food Grade Gas specifications

By Phil Green - Industrial Gas Generation Applications Manager

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www.parker.com/gsfe

In this white paper, Phil Green- Applications Manager Industrial Gas Generation, considers food and beverage specifications and requirements pertinent to nitrogen gas produced from on-site gas generation as opposed to cryogenic separation; and demonstrates that Parker NITROSource range nitrogen gas generators fully comply with regards to both gas quality and materials of construction.

Additionally, compressed air pre-treatment is considered along with compressed air sources, installation requirements and food safety risk assessment through HACCP, (Hazard and Critical Control Point), analysis.

Nitrogen gas used for food applications

European Union

Within the European Union the specification for food grade gases and associated equipment can be found within in-depth legislative documentation from the European Parliament such as (EC) 231/2012.

Publications produced by the "European Industrial Gases Association", (EIGA), in conjunction with the "Joint Expert Committee on Food Additives, (JECFA), provide helpful, focused, easy to understand information, explaining the European legislature and they are referenced throughout this white paper.

What is EIGA?

"EIGA: European Industrial Gases Association - AISBL

The European Industrial Gases Association, EIGA, is a safety and technically oriented organization representing the vast majority of European and a number of non-European companies producing and distributing industrial, medical and food gases.

EIGA is an International Non-Profit Organization (AISBL).

The member companies closely co-operate in safety and technical matters concerning production, transport, storage and application to achieve the highest level of safety and environmental care in the handling of gases. EIGA also initiates the development of appropriate standards and provides standardization bodies with technological expertise.

EIGA fully co-operates with all National Industrial Gas Associations and Regional Industrial Gas Associations around the world such as AIGA (Singapore), ANZIGA (Australia/New Zealand), CGA (USA), JIMGA (Japan), SACGA (South Africa), which are all associated members to EIGA."

When associate members of EIGA do not have a local specification for a specific gas and application, for example food grade nitrogen, they generally adopt the European specification.

Nitrogen Gas

With specific regards to nitrogen, (N_2), three descriptions apply to food grade gas.

As a **Processing Aid**; as a **Food Additive**; as a **Food Ingredient**.

EIGA states with regards to on-site nitrogen generation -

"Nitrogen produced from an on-site generator is used in many food applications as a **processing aid (without purity limit)** *or* **additive** *(E941 Commission Regulation 231/2012/EC of March 9th 2012, laying down* **specific purity criteria** *on food additives other than colours and sweeteners). Typical applications include: atmosphere protection of liquid and solid foodstuffs; tank blanketing; liquids mixing; liquid pressure transfer; modified atmosphere packaging; injection in liquid for container pressurization, de-carbonation, deoxygenation, beverage dispensing; aerosol propulsion".*

EIGA state for Food Ingredient gas -

"A gas is described as an ingredient when it is used in the preparation of a food and is still present in the final product, even in an altered form, for example in the carbonation of beverages: Although food law requirements are generally applicable, ***no specific purity criteria*** *are set under EU law for use of gases as an ingredient. Though any food additive criteria set for the gas could be relevant together with general food safety and hygiene legislation."*

Therefore, in summary of the three food gas descriptions -

1. "Processing aid" is **without purity limit**
2. "Food additive" has **specific purity criteria** that must comply with European Commission Regulations.
3. "Food Ingredient" has "**no specific purity criteria**"

Nitrogen Gas used as a Food Ingredient:

Parker's interpretation of "food ingredient" applications for nitrogen gas –

For generated nitrogen gas, consideration of typical applications for nitrogenation, (a similar process to carbonation), would be for use in "cream flow" type beers "nitro-coffee and associated nitro-soda beverages for example, where the nitrogen gas is dissolved into the liquid and is designed to alter the texture and mouth feel of the product; being consumed as an ingredient in the process.

This could also apply to creams, desserts and any other food product where high or low pressure nitrogenation again alters the density and hence the texture and mouthfeel of the food stuff and by being encapsulated within the product, can be considered as an ingredient designed to be consumed.

Although no purity criteria are specified, Parker believe it would be prudent for safety reasons to adopt the purity specification for nitrogen as a food additive E941, when selecting nitrogen generation equipment, when the product gas is to be used as a food ingredient.

This is because invariably the gas will be ingested and must not contain any harmful contaminants that could affect or pose a risk to human health.

What is the difference between a processing aid and food additive?

Processing Aid

EIGA states Food Processing Aids are legally defined as -

"Any substance not consumed as a food by itself, intentionally used in the processing of raw materials, foods or their ingredients to fulfil a certain technological purpose during treatment or processing, and which may result in the unintentional but technically unavoidable presence of residues of the substance or its derivatives in the final product, provided that these residues do not present any health risk and do not have any technological effect on the finished product" (Directive 1333/2008/EC)."

Food Additive

EIGA states –

"Any substance not normally consumed as a food in itself and not normally used as a characteristic ingredient of food, whether or not it has nutritive value, the intentional addition of which to food for a technological purpose in the manufacture, processing, preparation, treatment, packaging, transport or storage of such food results, or may reasonably be expected to result, in it or its by-products becoming directly or indirectly a component of such foods" (Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives)."

The two statements for processing aid and food additive appear very similar but the key difference is-

"Processing aid" the gas might **un-intentionally** be present in the food product.

"Food additive" the gas is **reasonably expected** to be an indirect or direct component of the food product.

Although there isn't any purity* criteria specified for gas used as a processing aid, the directive states –

EIGA -

The gas must *"not present any health risk and not have any technological effect on the finished product"*

In the case where on-site generated nitrogen is used as a processing aid, in accordance with the user's specifications, the on-site generator can be designed to produce different nitrogen assay values (typically between 90% and 99% nitrogen, with the balance predominantly noble gases and oxygen).

With the caveat –

" NOTE No purity criteria are set under European Union (EU) law for the use of gas as a processing aid. However, national legislation can require a purity alignment with those criteria applied to food additives."*

EIGA does not appear to differentiate, specifically detailing precise **processing** and food **additive** applications but have this statement within document 126/18 –

"Gases are processing aids when used during the processing of a food, for example liquid nitrogen or carbon dioxide for freezing, chilling and temperature control or inerting of bulk materials during processing but they are not themselves consumed as part of the food. In this case the only legal requirement is that the gas should not leave residues in the product that would present a risk to health".

Whilst EIGA provide an outline description, to compile an exhaustive list of applications and processes clearing defining either or, would be impractical. Parker's conclusion is that it is invariably the responsibility of the end user to determine whether "unintentional" or "reasonably expected" inclusion of nitrogen gas within the final product is possible.

In consideration of this , if it is uncertain as to the exact application description that applies, it would be sensible to select nitrogen generation equipment to produce gas to the highest specification, E941, for use as a food additive. This would ensure compliance for all eventualites, leaving the end user free from any ambiguity in application description.

Interpretation of the gas uses based on Parkers' application experience might include -

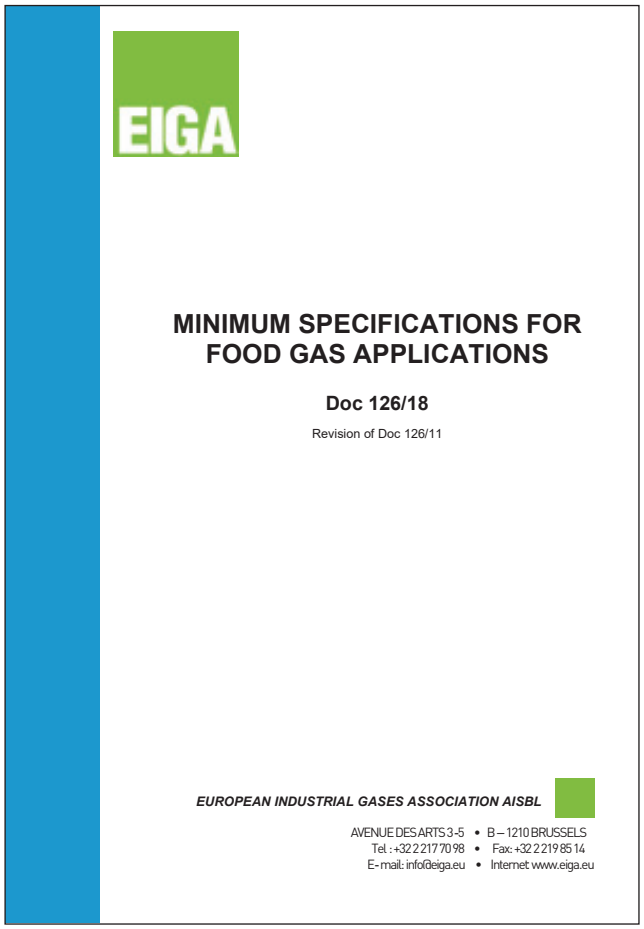
Processing aid – Blanketing bulk storage, blending, (where the gas is only used as a blanket and not the motive force of mixing), of food products to limit microbial spoilage, oxidization or flammability. Including discharging product through pipe-work or from tankers, storage vessels and purging of equipment to remove food remnants or cleaning residues, receptacle blowing, gas knives and counter pressure filling beverages for example.

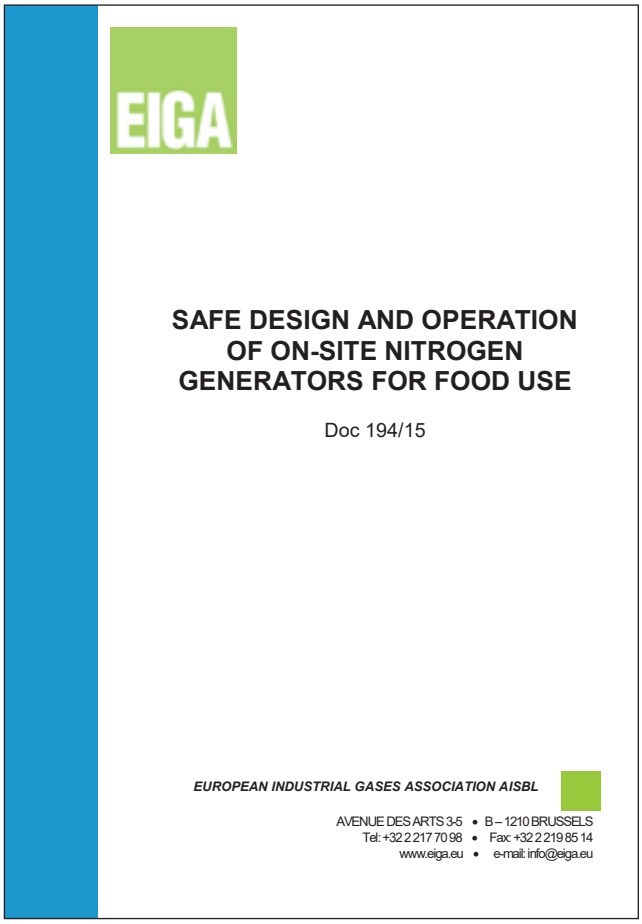
Food additive – EIGA is quite clear that in the case of Modified Atmosphere Packaging

> *"Where on-site generated nitrogen is used as a food additive, such as in the modified atmosphere packaging (MAP) application, nitrogen should comply with minimum purity criteria for E941"*

Additionally, applications such as "sparging" where micro bubbles of nitrogen are used for de-oxygenation or homogenization it can be reasonably expected that dissolved or encapsulated nitrogen gas could be consumed as a component of the food product and it is therefore a food additive.

EIGA have produced the following - document 126/18 defines the purity specification for food grade gas used as a food additive.





The specification for nitrogen used as a food additive produced from on-site generation is detailed in Doc 194/15 "Safe design and operation of on-site nitrogen generators for food use" –

EIGA

Food Additive E941 specification purity limits –

Commission Regulation (EU) No 231/2012 of 9th March 2012

Laying down specifications for food additives listed in Annexes II & III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council

*Nitrogen**	*≥ 99% v*
Oxygen	*≤ 1% v*
Water	*≤ 0.05% v (500ppmV)*

*99% including other inert gases such as noble gases (argon mainly)

Impurities:

Carbon monoxide	*≤10 ppmV*
Methane and other hydrocarbons (as methane)	*≤100 ppmV*
Nitrogen monoxide and nitrogen dioxide	*≤ 10 ppmV*

Important to note that the nitrogen assay includes other inert gases such as noble gases and argon.

The reason for this is - argon comprises 0.934% v of the earths' atmosphere at mean sea level, (and is also technically more inert than nitrogen and completely harmless in the context of MAP). Argon will pass through a nitrogen gas generator, untouched, and into the output nitrogen gas stream. The difference in output gas volume ratios by removal of the oxygen may also mean, that if measured, the volume of argon contained within the total inert gas assay could be in excess of 1%.

Industrial gas companies also acknowledge that argon is present in cryogenically produced liquid and compressed gas cylinders derived from cryogenically produced liquid.

It is usual to observe statements on cryogenic liquid or gas vessels such as –
"99.998% Minimum Nitrogen (Specification includes argon)".

The determination of argon content and other noble gases within the nitrogen assay is not a prerequisite of European law.

The nitrogen assay calculation should be a function of
Nitrogen Assay % = 100% - (Oxygen % +Total Impurities %)

While generated nitrogen gas used for "processing" is not required to meet the purity criteria with regards to the nitrogen assay for E941, (with limits advised from 99% to 90%), it could be reasonably expected that the maximum impurity levels would be a requirement so as not to present any health risk, from for example – aerobic microbes, oxidative rancidity and other oxygen supported spoilage mechanisms.

Parker NITROSource PSA range compliance with EC 231/2012 and EIGA documents 194/15 & 126/18

Parker NITROSource range have been tested by a 3rd party independent analytical laboratory to demonstrate full compliance with the nitrogen gas purity and contamination specifications as detailed in EC 231/2012 and EIGA Documents 194/15 and 126/18 for use to the highest specification as a "food additive" E941.



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School Lane, Newton Aycliffe, Co. Durham, DL5 6EA
T: +44 1325 311263 E: enquiries@edwards-analytical.com

Project Number: 19/EA/04/11
Date received: Samples Collected 07 May 2019
Sample Details: Nitrogen gas product

Analysis Certificate

Version:V04

Client: Parker Hannifin Manufacturing Ltd

Subject: Compliance testing of Nitrogen gas purity generated by NITROSource PSA Nitrogen Generator

Introduction:

Analysis of product gas, (Nitrogen N_2), produced by Parker NITROSource PSA range of Nitrogen gas generators to demonstrate full compliance with food grade Nitrogen and "Food Additive – E941" purity criteria as detailed within:-

Commission Regulation (EU) N° 231/2012 of 09th March 2012 laying down specifications for food additives listed in Annexes II and III to regulation (EC) N° 1333/2008 of the European Parliament.
Additional references:

- EIGA Document 126/18 Minimum Specification for Food Gas Applications.
- EIGA Document 194/15 Safe Design and Operations of On-Site Nitrogen generators for Food Use.

Regulation (EC) N°178/2002 of European Parliament of of The Council of 28th January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety authority laying down procedures in matters of food safety.

Component Impurity	EC 231/2012 - E941 N_2 Specification
Assay (v/v)	>99%
Moisture	<0.05% vol.
CO	<10 ppmV
NO/NO_2 (combined)	<10 ppmV
Total Hydrocarbon inc. Methane CH_4	<100 ppmV
Residual gases (O_2)	<1% vol.

- EIGA Doc.194/15 :-

In the case where on-site generated Nitrogen is used as a food additive, such as in the Modified Atmosphere Packaging (MAP) application, Nitrogen should comply with the minimum purity criteria for E941 additive as described in EIGA Doc. 126/18.
Nitrogen* ≥ 99% vol
Oxygen ≤1% vol
Water ≤0.05% vol
*99% including other inert gases (Argon mainly)
Impurities:
Carbon Monoxide ≤10ppmV
Methane and other hydrocarbons (as Methane) ≤100ppmV
Nitrogen monoxide and nitrogen dioxide ≤10ppmv

Methods of Analysis:

- EU 231/2012 of 09th March 2012
- EIGA Docs. 194/15 and 126/18

Results:

Results are detailed over page 2 of this report

Conclusion:

The NITROSource PSA product's Nitrogen gas, as tested was found to meet the assay and minimum purity specification requirements as laid out in EU 231/2012 of 09th March 2012 and EIGA Docs. 194/15 and 126/18.

Certificate Author W S Cullen, Business Manager — **20 June 2019**

Certificate Authorized: JH Edwards, Quality Manager — **20 June 2019**

Page: 1 of 2

Edwards' Analytical contract laboratory is considered to comply with the principles of Good Manufacturing Practice as detailed in Directive 2003/94/EC.

EDWARDS ANALYTICAL - MATERIAL ANALYSIS CERTIFICATE

CONTINUATION SHEET

Subject: Compliance testing of Nitrogen gas purity generated by NITROSource PSA Nitrogen Generator

EA Project No.: 19/EA/04/11 **Version:** V04

Results:

TEST	REGULATION AND SPECIFICATION		RESULT	PASS/FAIL
	231/2012	EIGA 194/15		
Assay (Including trace inert gas, Argon mainly)	>99%	>99%	N2 (98.67%) Ar (1.07%) 99.74 % (combined)	PASS
Moisture	<0.05% vol.	<0.05% vol.	0.0006% Vol.	PASS
CO	<10 ppmV	<10 ppmV	ND (<1ppm)	PASS
NO/NO_2 (combined)	<10 ppmV	<10 ppmV	ND (<0.6ppm)	PASS
Total Hydrocarbon including Methane	<100 ppmV	<100 ppmV	11 ppmV	PASS
Residual gases (O_2)	<1% vol.	<1% vol.	0.75% vol.	PASS

ND = Not Detected



Safety Risk Assessment. Nitrogen Generation HACCP (Hazard and Critical Control Points)

EIGA -

"On-site generators shall be designed and operated to produce gases suitable for the intended food applications.
This hazard analysis should be structured to systematically examine all relevant parts of the equipment design and operation including both normal and malfunctioning conditions, and interaction of the generator with its surroundings."

Potential Hazards

Biological contamination

TYPE OF CONTAMINANT	POSSIBLE CONTAMINANT	REASON FOR TAKING INTO ACCOUNT OR NOT THESE CONTAMINANTS
Bacteria	Bacillus (sporulated bacteria) Clostridium (sporulated bacteria) Erypsipelothrix rhusiopathiae Corynebacterium Staphylococcus aureus Micrococcus Listeria monocytogenes Legionella Enteric bacteria (Klebsellia) Pseudomonas Brevibacillus	Bacteria which can be found in the environment (air, water or soil), and responsible for human pathology
Moulds	Aspergillus Fusarium	Moulds produce mycotoxins and are present in the atmosphere
Yeasts	Candida albicans	Main yeast presenting risks for humans and present in the atmosphere
Viruses	Not applicable	Does not present a food safety hazard
Parasites	Not applicable	Cannot survive without host organism

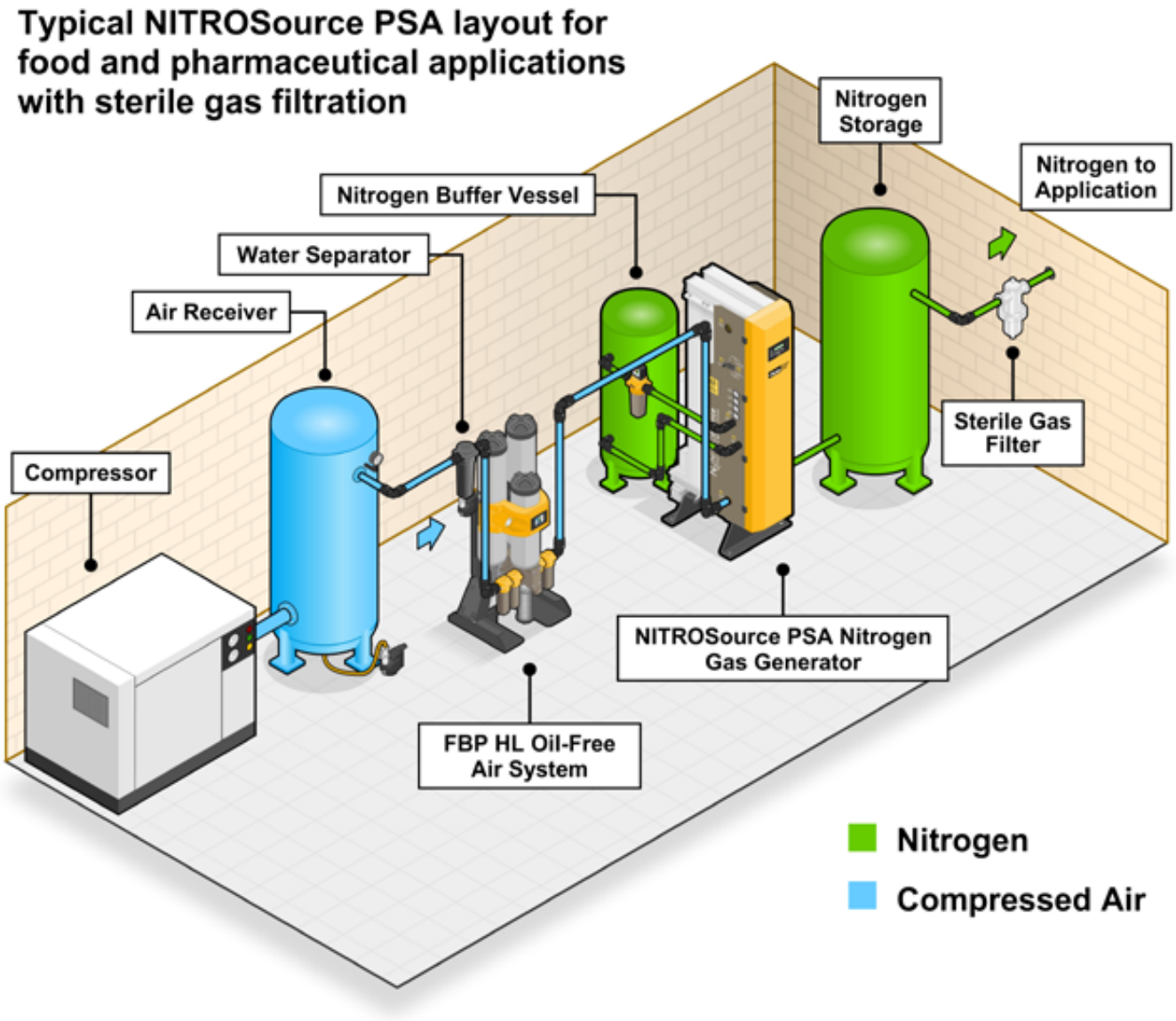
Physical Contamination

TYPE OF CONTAMINANT	POSSIBLE CONTAMINANT	REASON FOR TAKING INTO ACCOUNT OR NOT THESE CONTAMINANTS
Solids > x micron	Carbon molecular sieve or other particulates	Could present a hazard without correct downstream filtration
Radioactive elements	Not applicable in normal conditions	No radiation source in the process and control of radioactivity of the air by governmental bodies
Others	Solid (metals, plastics) carried over	Will be present in the gas lines of the installation. Could present a hazard without correct downstream filtration

Chemical Contamination

TYPE OF CONTAMINANT	POSSIBLE CONTAMINANT	REASON FOR TAKING INTO ACCOUNT OR NOT THESE CONTAMINANTS
Residues in distribution system	Cleaning agents (i.e. solvents)	Hydrocarbons shall not be present in food products above 1 ppm (0.02 ppm for $C_2H_2F_4$ and $C_2H_2Cl_2$)
Impurities from air gas manufacturing process	Volatle compounds such as VOC, oxygen, water, compressor oil and atmospheric borne hydrocarbons	Applicable for on-site generators depending on their location and malfunction of the on-site generator
Nitrogen product reactions	Products resulting of polymer degradation	Specific release limits (SRL) according to the "Metals and alloys practical quide for manufacturers and regulators" EDQM 2013 edition [11] See EC 1881/2006 [12] and EC 22/2001 [13]
Metal contaminants and impurities	Arsenic, Lead, Mercury, Cadmium, aluminium, nickel, silver, cobalt	Specific release limits (SRL) according to the
Others	Dioxins and Dioxin-like PCBs	Applicable for on-site generators depending on their location See EC 1881/2006 [12] and EC 22/2001 [13

Parker nitrogen gas generation solutions and EIGA HACCP analysis.



The diagram above details a typical Parker NITROSource installation.
When considering the potential hazards, the function of the Parker system and individual components along with analysis of the risk and safety controls is detailed below. This demonstrates how a correctly specified, installed, operated and maintained Parker nitrogen gas generation system eliminates the hazards identified by EIGA.

Biological Contamination Risk

Bacteria, Moulds & Yeasts

Compressed air source – Nitrogen gas generation equipment generally uses compressed air as the feed stock to produce nitrogen. Careful consideration concerning the positioning of the compressor and the ambient air intake should be undertaken to ensure that the risk of biological contamination is minimized or eliminated.

The compressed air source intake should not be located adjacent to an obvious potential source of pollution (proximity to boiler combustion exhaust, solvents or chemicals venting, cooling air towers, aerosols, open or vented sewage systems, parking areas, main roads, etc.).

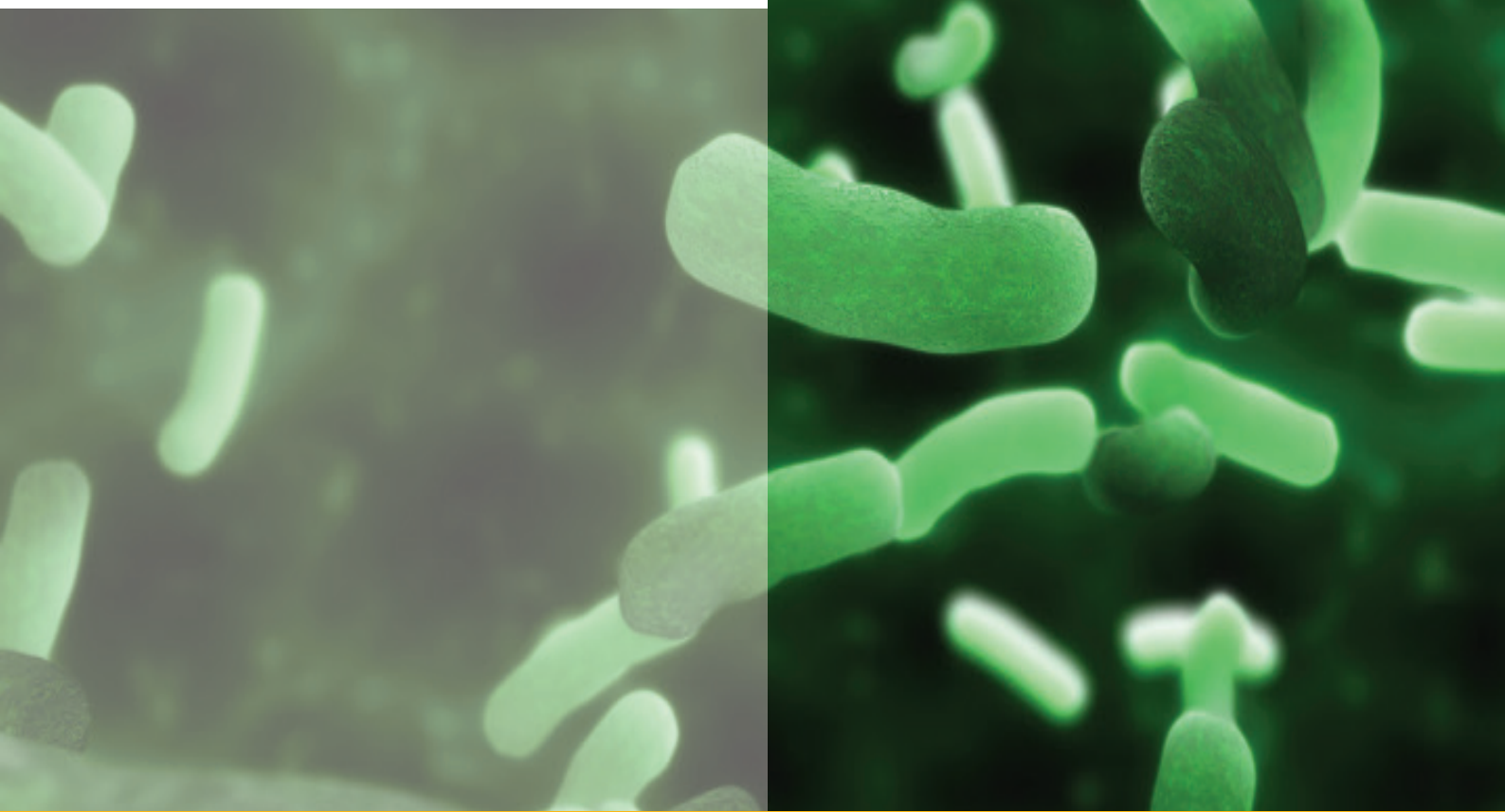
Compressed air pre-treatment – Parker FBP, (Food Beverage & Pharmaceutical Oil-Free Air System), compressed air pre-treatment desiccant dryer package – Bacteria, moulds and yeasts fall within the size range of 0.2 to 10 microns. Bacteria cannot survive below -26°C dew point.

The FBP pre-treatment package produces food grade compressed air that is dry to at least -40°C dew point and provides filtration to 0.01microns. This demonstrates that it is almost impossible for any bacteria, moulds or yeasts to survive past the outlet of the FBP pre-treatment package.

The NITROSource range nitrogen gas generators – In addition to removing oxygen, the carbon molecular sieve contained within, also removes water vapour. At 5 barg nitrogen outlet pressure the moisture content will be less than 1ppm equating to a pressure dew point of -74°C.The buffer vessel return filter provides a particulate removal level of 0.1 microns.

The output gas stream from a Parker nitrogen gas generator can be considered commercially sterile.

Sterile Gas Filter – Installed centralized or point of use, this component consists of a crevice free, electro-polished stainless steel housing containing a “Bio-X” replaceable filter cartridge to remove particulate 100% to 0.01 microns, providing total process security.



Physical Contamination

Solids & Others

Filtration is included at critical stages within the air and gas flow paths to protect both the equipment and the output gas stream. The particulate filtration level is to 0.01 microns.

There does not appear to be any limits for particulate contamination within the gas specification for any of the three food gas descriptions - Additive, processing aid and ingredient.

The British Retail Consortium in conjunction with the British Compressed Air Society have produced guidelines for "Food Grade Compressed Air". The full details can be found in their document "Best Practice Guideline 102"

This document specifies particulate levels for different "indirect contact" and "direct contact" situations.

The majority of food grade nitrogen application would fall under the direct food contact category. The details are shown in the table adjacent –

Table 1 - Compressed Air Purity Designation - Direct contact with food

Class	Maximum number of particles per m^3 **for particle sizes, d (µm) (at reference conditions see 7.3.1)**		
	0,1 < d ≤ 0,5	0,5 < d ≤ 1,0	1,0 < d ≤ 5,0
2	≤ 400 000	≤ 6000	≤ 100

	Pressure Dew-point (°C)
2	≤ -40

	Concentration total oil (liquid, aerosol, and vapour) (mg/m^3)(at reference conditions)
1	≤ 0,01

It would be sensible to conclude that this specification should be applied to all three food gas descriptions, as a processing aid, additive and ingredient.



Chemical Contamination

EIGA

Residues in distribution system –

"The distribution systems materials selected should be suitable for food grade use and constructed using defined methods suitable for food grade installations."

The Parker compressed air pre-treatment package, nitrogen generator and filtration are constructed from materials that have been independently tested to demonstrate that they are food and pharmaceutical safe.

EIGA

Impurities from air and gas manufacturing process –

"The compressed air source intake should not be located adjacent to an obvious potential source of pollution (proximity to boiler combustion exhaust, solvents or chemicals venting, cooling air towers, aerosols, open or vented sewage systems, parking areas, main roads, etc.)."

Parkers' FBP compressed air pre-treatment package ensures contamination from moisture and oil vapour is eliminated regardless of compressor type, (oil-free or oil lubricated).

ISO8573-1
CLASS ZERO
OIL FREE AIR
AT THE POINT OF USE

Oil odour and vapour is beyond the limit of organoleptic detection generally at 0.003ppm, with moisture removal to -40°C pressure dew point. The FBP is equipped with pressure dew point read out and local/remote alarm indication capability.

VOC's would be absorbed by the integral granular activated carbon stage.



NITROSource PSA range nitrogen gas generators are manufactured with an integral oxygen analyser providing a digital read out of the maximum remaining oxygen content. This data can be monitored locally or remotely through proprietary data logging or BMS equipment using the integral 4-20mA or MODBUS outputs.

Local or remote high oxygen condition alarms can be configured as required with user definable limits. The generator can be programmed to stop gas output during an alarm condition enabling a self-cleaning purity rectification procedure.

Suitability of materials

EIGA -

"Materials and equipment that come in contact with the nitrogen stream shall not contribute an additional food safety hazard. Where available, certificates of food compatibility for components, consumable materials or materials of construction will contribute to the overall food safety validation of the system.

In practice this means that the compatibility of the seals, lubricants, metals and plastics with foodstuffs shall be individually checked.

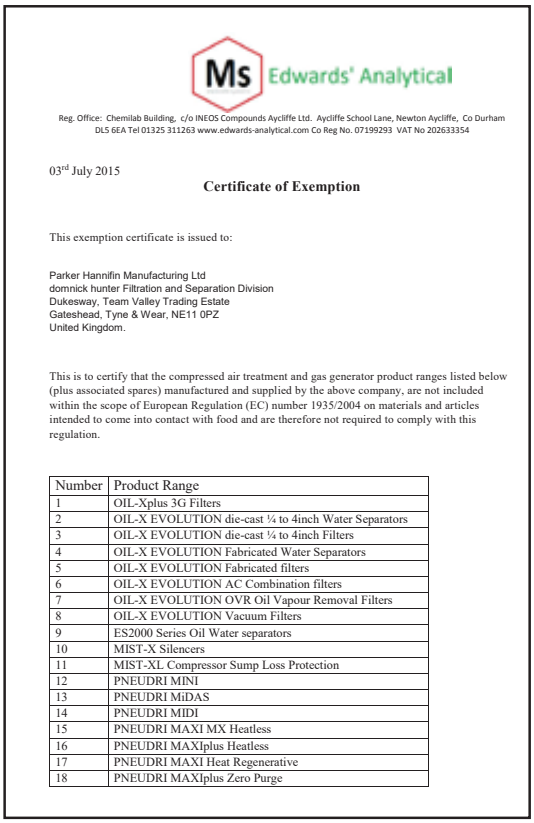
Consideration should be given to Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food."

Parker NITROSource range Nitrogen gas generators have been independently assessed by a 3rd party compliance laboratory, Edwards Analytical*, to ascertain suitability for food applications.

Considering that the entire nitrogen generation system produced by Parker, including the compressed air pre-treatment and filtration package are not designed or intended to come into direct contact with food stuffs, generally the equipment comprising a nitrogen gas generation system is exempt from Regulation (EC) No. 1935/2004. The exemption certification detailing the equipment concerned is produced below, however to comply with United States Federal Drugs Administration requirements additionally all the components that contact the produced Nitrogen gas were compared or analysed to reference standards for materials of construction covering food use, under one of the most stringent of global standards – the United States of America Food and Drug Administration "Article 21(FDA Article 21)".

Results of this testing demonstrate full compliance with FDA Article 21.
Document: "14/EA/08/19" refers to the full details of this analysis

** Edwards' Analytical is licensed by the Medicines Control Agency (MHRA) as an approved Contract Quality Control Laboratory and in general compliance with the principles and guidelines of good laboratory practice.*



Ms Edwards' Analytical

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03rd July 2015

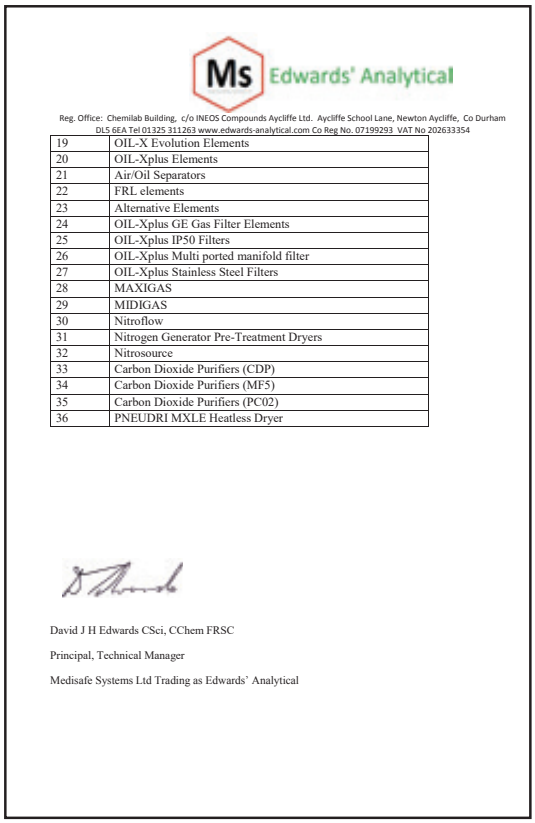
Certificate of Exemption

This exemption certificate is issued to:

Parker Hannifin Manufacturing Ltd
domnick hunter Filtration and Separation Division
Dukesway, Team Valley Trading Estate
Gateshead, Tyne & Wear, NE11 0PZ
United Kingdom.

This is to certify that the compressed air treatment and gas generator product ranges listed below (plus associated spares) manufactured and supplied by the above company, are not included within the scope of European Regulation (EC) number 1935/2004 on materials and articles intended to come into contact with food and are therefore not required to comply with this regulation.

Number	Product Range
1	OIL-Xplus 3G Filters
2	OIL-X EVOLUTION die-cast ¼ to 4inch Water Separators
3	OIL-X EVOLUTION die-cast ¼ to 4inch Filters
4	OIL-X EVOLUTION Fabricated Water Separators
5	OIL-X EVOLUTION Fabricated filters
6	OIL-X EVOLUTION AC Combination filters
7	OIL-X EVOLUTION OVR Oil Vapour Removal Filters
8	OIL-X EVOLUTION Vacuum Filters
9	ES2000 Series Oil Water separators
10	MIST-X Silencers
11	MIST-XL Compressor Sump Loss Protection
12	PNEUDRI MINI
13	PNEUDRI MiDAS
14	PNEUDRI MIDI
15	PNEUDRI MAXI MX Heatless
16	PNEUDRI MAXIplus Heatless
17	PNEUDRI MAXI Heat Regenerative
18	PNEUDRI MAXIplus Zero Purge



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19	OIL-X Evolution Elements
20	OIL-Xplus Elements
21	Air/Oil Separators
22	FRL elements
23	Alternative Elements
24	OIL-Xplus GE Gas Filter Elements
25	OIL-Xplus IP50 Filters
26	OIL-Xplus Multi ported manifold filter
27	OIL-Xplus Stainless Steel Filters
28	MAXIGAS
29	MIDIGAS
30	Nitroflow
31	Nitrogen Generator Pre-Treatment Dryers
32	Nitrosource
33	Carbon Dioxide Purifiers (CDP)
34	Carbon Dioxide Purifiers (MF5)
35	Carbon Dioxide Purifiers (PC02)
36	PNEUDRI MXLE Heatless Dryer

David J H Edwards CSci, CChem FRSC

Principal, Technical Manager

Medisafe Systems Ltd Trading as Edwards' Analytical

Edwards Analytical
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School Lane, Newton Aycliffe, Co. Durham, DL5 6EA
T: +44 1325 311263 E: enquiries@edwards-analytical.com

Project Number: 14/EA/08/19
Date Samples Received: August & September 2014

Executive Summary Report
Version:V003

Client: Parker Hannifin Manufacturing Ltd
Subject: Compliance test report of NITROSource PSA Nitrogen Gas Generator to the FDA and European Pharmacopeia regulations for use as medical gas generator.

Introduction:

Outline:
NitroSource PSA Nitrogen Gas Generator is a redesign of the MAXIGAS Nitrogen Generator. The components tested in this exercise are additional components that come into contact with the product gas.

Specification:

1. The gas product generated is to be compliant in purity to the European Pharmacopeia for medical grade gasses (Nitrogen) and EIGA Minimum Specifications for Food gas applications.
2. The additional component product contact materials (polymeric) are to be compliant in stability from extractable and leachability to the FDA CFR food contact regulation; EC Food contact regulations and European Pharmacopia for polymeric materials designed to come into contact with pharmaceutical products.

Methods of Analysis:

Analysis monographs:

- FDA 21 CFR Part 177.2600 Nitrile Rubbers
- FDA 21 CFR Part 177.1520 Polyolefins
- EC 10/2011 "Plastics in contact with food"
- European Pharmacopeia: EP 3.2.9 Rubber Closures
- European Pharmacopeia: EP 3.1.3 Polyolefins
- European Pharmacopeia: EP 1247 Nitrogen gas
- EIGA Minimum Specifications for food gas applications IGC Doc 126/11/E

Results and Comments

- All product contact polymeric components comply for Extractable and leachable stability.
- Nitrogen Gas generated and tested met the minimum requirements for gas purity to the United States and European Pharmacopeia's and EIGA regulations.

Certificate Author & Authorisor: JH Edwards — **09th Feb 2017**

Edwards' Analytical contract laboratory is considered to comply with the principles of Good Manufacturing Practice as detailed in Directive 2003/94/EC.

Traceability and batch definition for on-site nitrogen production

EIGA -

"The principal purpose of food traceability is to enable efficient and rapid withdrawal from the market of any food that may be injurious to consumer's health".

A food grade gas's primary function is to preserve the product by eliminating or retarding food spoilage mechanisms.

If the gas is out of specification then it could reduce the advised shelf-life, resulting in a product not fit for human consumption.

EIGA –

"At least one continuously on-line residual oxygen analyser shall be installed in the generated nitrogen gas stream to ensure end user's product quality and traceability requirements."

Parker's NITROSource range nitrogen generators are fitted with an integral oxygen analyser as standard. This measures the oxygen content in the output gas stream so is fully compliant with the EIGA's recommendations.

EIGA -

"In the event that the on-line instrumentation detects the produced nitrogen stream to be out of specification range for oxygen, this nitrogen stream shall be vented to a safe location"

Parker's NITROSource range nitrogen generators are fitted with an integral "off-gas by-pass" control system as standard. This vents off specification gas exactly as the EIGA recommendation.

EIGA -

"An alarm for off-specification gas should be routed to the operator so that corrective action can be initiated"

Parker's NITROSource range nitrogen generators are fitted with a local alarm indication light as well as integral volt free alarm contacts that can be used to communicate with a remote alarm beacon/ siren as required. Fully compliant with EIGA's recommendation.

EIGA -

"An indication of oxygen concentration shall be present on the front panel of the gas generator and ideally be transmitted to the user"

Parker's NITROSource range nitrogen generators are fitted with an integral oxygen analyser that produces a numerical display of the maximum remaining oxygen content in the output gas stream as either a percentage by volume or parts per million level by volume depending on the generator purity level specification.

Additionally, 4-20 milli Amp output or MODBUS integral to the generator facilitate the remote monitoring and data logging of oxygen content.

Exactly in compliance with EIGA's recommendations.



EIGA -

"Consideration should be given to the installation of an on-line residual moisture analyser"

Parker's CDAS/OFAS/FBP compressed air pre-treatment packages include an integral hygrometer to continually monitor the compressed air dew point. As the compressed air entering the nitrogen generator already exceeds the specification for the nitrogen moisture content, the output nitrogen gas is even dryer. This negates the need for an additional hygrometer in the nitrogen gas stream.

The specification for food grade nitrogen is 0.05% vol. moisture content, (or 500ppm vol.).

The compressed air outlet from an OFAS dryer at -40°C pressure dew point @ 7 barg is 1.6 ppm vol. or 0.0016%



Oxygen readout available on generator screen and or via remote connection.

NITROSource PSA - Average Moisture Content in Nitrogen Gas Output Flow with standard desiccant dried inlet air

Nitrogen Outlet Pressure	Pressure Dew Point 0C	ppm(V)	ppm(W)	Absolute Humidity g/m3	Relative Humidity % @ 200C
1bara	-85.0	0.535	0.344	0.0004	0.0023
1barg	-80.9	0.517	0.332	0.0008	0.0044
2barg	-78.5	0.500	0.322	0.0011	0.0064
3barg	-76.7	0.492	0.317	0.0015	0.0084
4barg	-75.3	0.485	0.312	0.0018	0.0104
5barg	-74.1	0.482	0.310	0.0021	0.0124
6barg	-73.1	0.478	0.307	0.0025	0.0142
7barg	-72.2	0.475	0.306	0.0028	0.0163
8barg	-71.5	0.467	0.300	0.0031	0.0179
9barg	-70.8	0.463	0.298	0.0034	0.0198
10barg	-70.1	0.465	0.299	0.0038	0.0219
11barg	-69.5	0.463	0.298	0.0041	0.0238
12barg	-69.0	0.458	0.295	0.0044	0.0255



Batch definition –

EIGA –

"Any raw material in the food chain requires traceability in compliance with Regulation (EC) 178/2002, (European Food Act) Article 18"

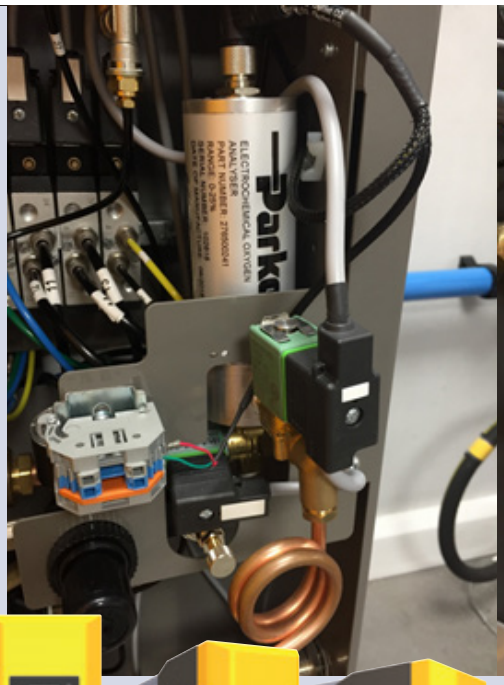
"Since on-site generators are usually supplying only one gas to only one customer, a set of control parameters and quality critical criteria should be mutually defined and recorded in a process trail."

"The production of nitrogen can be divided into batches, according to a "period of production," defined by the operator. A batch definition may not be necessary if a permanent trail recording the defined intervals of analysis is available"

"The food business operator shall, for instance, define the parameters that are to be recorded and traced during each production batch"

Parker's NITROSource range nitrogen generators are fitted with an integral oxygen analyser and off-gas by-pass. By design, therefore, out of specification gas cannot reach the application.

If a record of gas output purity is necessary then this can be detailed from reading the gas generator display at defined intervals or by using the remote oxygen outputs to data log or display, for example, at point of use or a quality analysis station.







Labelling of equipment –

Labelling "E941 Nitrogen For Food Use" or "E941 N2 For Food Use", shall be applied to the nitrogen gas generator and the buffer tank, (and sensibly any other appropriate nitrogen storage vessels).

Maintenance –

EIGA –

"A rigorous preventive maintenance program is a crucial element of any food safety program designed to maintain the nitrogen food grade compliance."

"Particular care shall be taken in the areas where food grade nitrogen is produced in order to avoid contamination of the system during maintenance operations".

"Maintenance personnel shall be familiar with all safety regulations and be made aware of all potential hazards."

"With regard to procedures relating to the hazard analysis and critical control points (HACCP), factors affecting food hygiene shall be identified and suitably controlled during the maintenance. These factors will be broadly associated with the people working within the workplace and the materials which can be in contact with the food grade quality nitrogen during the maintenance operation.

The following is a non-exhaustive list of pre-requisite factors that shall be considered and controlled to manage the food safety risk:

1. *For maintenance a check list of control points and operations shall be issued.*
2. *Materials and spare parts in contact with the produced food grade quality nitrogen shall be suitable for use in food applications;*
3. *Washing and cleaning products for the components in contact with the produced food grade quality nitrogen shall be suitable for food (potable water, ethanol, etc.).*
4. *Hygiene of the operator and protection of the equipment in the area where food grade quality nitrogen is produced;*
5. *Specific food safety training for the operator involved in the maintenance shall comply with the operation manual of the on-site nitrogen generator;*
6. *Periodic calibration of the installed analysis instruments.*
7. *Periodic maintenance of the dust filter(s) of carbon molecular sieves*
8. *Upon completion of the maintenance, the purity of the nitrogen flow shall be checked to confirm it meets the product specification.*

Parker authorized service agents have to undergo pre-defined and rigorous training programs to enable them to service the nitrogen generator and compressed air pre-treatment equipment.

This training also requires regular re-training and refresher courses every three years.

Specific attention is paid to the criteria identified by EIGA with regards to the points above concerning food grade nitrogen service training.

Only completion of the official or approved Parker service training course receives the relevant certification.

In summary

Parker NITROSource range nitrogen gas generators when installed with the appropriate Parker dryer and filtration compressed air pre-treatment packages and are operated and maintained as per Parker's recommendations by authorized trained and certified personnel

A) *Produce food grade nitrogen gas suitable for use as a food additive - E941.*

B) *Although technically exempt under EU regulations, have been independently tested and demonstrated they are constructed from materials in the compressed air and gas flow paths approved for contact with food products.*

C) *Compliant with USA FDA Article 21. Materials of construction.*

D) *Protect and provide safe conditions against, Biological, Chemical and Physical risks identified by HACPP analysis*

E) *Have integral quality control features that fully comply with EIGA recommendations to ensure gas purity, food safety and traceability.*

F) *Are independently 3rd Party tested and validated.*

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References

Commission Regulation 2012/231/EC of March 9th 2012 laying down specific purity criteria on food additives other than colours and sweeteners

Commission Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety Directive 1333/2008/EC

Commission Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives

United States Code of Federal Regulations; http://www.gpo.gov/

EIGA Doc 125 Guide to the Use of Gases in Foods; www.eiga.eu

EIGA Doc 126/18 Minimum Specifications for Food Gas Applications; www.eiga.eu

EIGA Doc 194/15 Safe design and operation of on-site nitrogen generators for food use; www.eiga.eu

EIGA Doc 149 Safe Installation and Operation of PSA and Membrane Oxygen and Nitrogen Generators www.eiga.eu

Commission Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food

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