CHEMNOVATIC

E-LIQUID INDUSTRY REGULATIONS GUIDE

CHEMNOVATIC Sp. z o.o. Sp. k.
Dobrzanskiego 3/BS002, 20-262 Lublin, POLAND

+48 81 475 44 42 | +48 81 745 17 33
office@chemnovatic.com

www.chemnovatic.com

CHEMNOVATIC
360° E-LIQUID INDUSTRY SOLUTIONS

Who we are

Chemnovatic is a chemical company that provides 360° e-liquid industry solutions: raw materials, recipe creation, private label, brand development and regulatory services.

Chemnovatic's main business is to provide top quality raw materials for e-liquids producers worldwide. We are a manufacturer of pure nicotine, nicotine salts, nicotine bases, flavours and additives. Our pride and a flagship product is PureNic 99+ - pure nicotine liquid, which received global recognition. If you produce e-liquids, we aspire to be your core e-liquids raw materials supplier.

Apart from raw materials, Chemnovatic offers private label e-liquids production and all services needed to introduce new e-liquid brand to the markets: recipe and brand creation, packaging design, laboratory tests, TPD registration, MSDS preparation, TPD, REACH, CLP, UFI and ADR consultations. If you have access to distribution channels and you want to start your own brand – we will be your best business partner.

Marcin Ławecki
CEO

TÜVRheinland CERTIFIED Management System ISO 9001:2015 www.tuv.com ID 9108641488

TÜVRheinland CERTIFIED Management System HACCP www.tuv.com ID 9108641488

GMP SAFE & CONSISTENT GOOD MANUFACTURING PRACTICES

E-liquid industry regulations and quality requirements

INTRODUCTION

This vaping industry guide has been created with the intention of providing detailed and useful information for e-liquid manufacturers, wholesalers, retailers and end-users. Topics covered here contain practical information on e-liquid industry law regulations in the European Union, but also USA and non-EU countries. Moreover, we have addressed the subject of quality requirements as e-liquids are products that come into direct contact with the human organism. In other words, these products should be manufactured with the highest quality and safety precautions. Keeping in mind our business partners and all e-liquid consumers' welfare, we have gathered our experience in the field of vape regulation and quality into this guide. We hope that it will serve as a practical source of knowledge and substantive support for your business.

Sections:

- Chemical industry regulations: REACH & CLP
- E-liquid industry regulations: TPD
- Transport regulations
- Packaging
- Quality requirements
- Manufacturing quality requirements
- Private label & regulatory requirements

Chemical industry regulations

REACH AND CLP

In order to enter any industry (including the world of e-liquid industry) it is inevitable to adapt to the current legislative rules. In this place, we should mention two of the most important regulations concerning the chemical industry in general – REACH and CLP. As e-liquids are part of the chemical industry, they also fall under REACH and CLP. Let's take a closer look at them, as they are among the most important e-liquid industry regulations.

REACH

WHAT IS REACH?

REACH is one of the most important regulations of the European Union. It concerns a lot of chemical substances and affects many producers, importers, and downstream users. REACH has also an impact on our everyday life even if we don't know about it. In what way? Let's find out.

As a general rule, REACH applies to chemicals, but with some exceptions. Naturally occurring substances are not subject to registration REACH, unless they are dangerous, or have been chemically modified. REACH not only applies to chemicals of industrial processes but also to substances that occur in our daily lives. For example cleaning agents or paints, as well as components of many products such as clothing or furniture. This is why the regulation applies to most companies in the European Union. The regulatory body that is responsible for REACH is the European Chemical Agency (ECHA).

Companies handling chemicals in the amount above 1 ton annually must register chemicals at the European Chemicals Agency (ECHA).

MAIN ASSUMPTIONS OF REACH

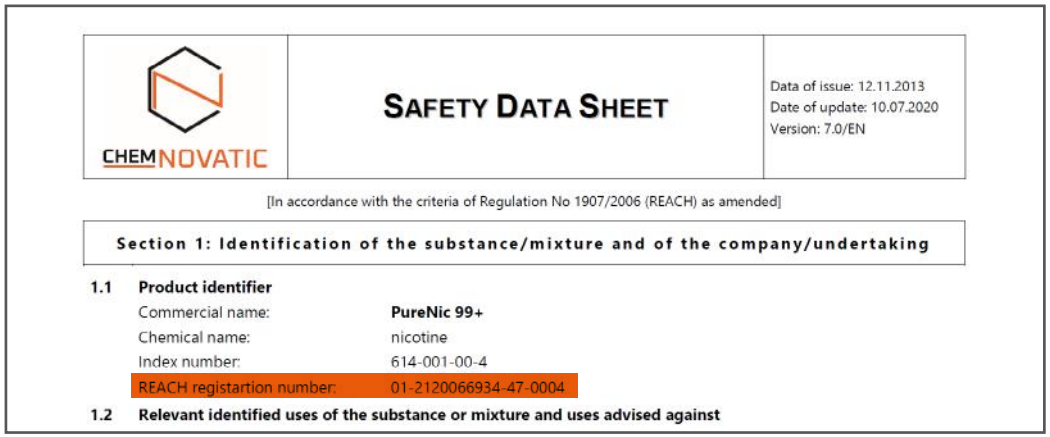
REACH is one of the most important regulations of the European Union. It concerns a lot of chemical substances and affects many producers, importers, and downstream users. REACH has also an impact on our everyday life even if we don't know about it. In what way? Let's find out.

As a general rule, REACH applies to chemicals, but with some exceptions. Naturally occurring substances are not subject to registration REACH, unless they are dangerous, or have been chemically modified. REACH not only applies to chemicals of industrial processes but also to substances that occur in our daily lives. For example cleaning agents or paints, as well as components of many products such as clothing or furniture. This is why the regulation applies to most companies in the European Union. The regulatory body that is responsible for REACH is the European Chemical Agency (ECHA).

WHY IS REACH REGULATION SO IMPORTANT FOR THE E-LIQUID INDUSTRY?

Vaping companies must comply with REACH regulation in the sense that pure nicotine is a substance that falls under REACH.

Currently, companies that produce or import pure nicotine in quantities of more than 1 ton per year have to undergo a registration process. Sales of pure nicotine, which have not been pre-registered or registered, to the European market, is illegal. For this reason, it is a good idea to buy pure nicotine with the REACH registration number. Thanks to this, you will have a guarantee that it comes from a fully legal and reliable source.



CHEMNOVATIC

SAFETY DATA SHEET

Data of issue: 12.11.2013
Date of update: 10.07.2020
Version: 7.0/EN

[In accordance with the criteria of Regulation No 1907/2006 (REACH) as amended]

Section 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Commercial name:	**PureNic 99+**
Chemical name:	nicotine
Index number:	614-001-00-4
REACH registartion number:	01-2120066934-47-0004

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

HOW CAN I REGISTER MY PRODUCT ACCORDING TO REACH?

Let's take a closer look at the REACH registration procedure on the example of pure nicotine. As it was mentioned before, a given company has an obligation to notify pure nicotine that it sells to the European Union if the amount of product is 1 ton or more per year. If you are an importer of a substance, you should add your registration to the registration of the main registrant.

You can make the registration on the REACH-IT website, using the IUCLID tool. To register, a manufacturer must collect and submit all data on the hazardous properties of substances. Then appropriate authorities evaluate the data. ECHA has to authorize substances of high concern such as carcinogens or mutagens. This ensures that risks from the use of such substances are either adequately controlled or justified.

REACH REGISTRATION PRACTICAL INFORMATION

Each substance that passes evaluation and authorization is considered fully registered with REACH and is given a REACH Registration Number. After completing full registration you will be able to find and confirm your status on echa.europa.eu. You can see Chemnovatic PureNic 99+'s REACH Registration Number on Safety Data Sheet.

HOW MUCH DOES REACH REGISTRATION COST?

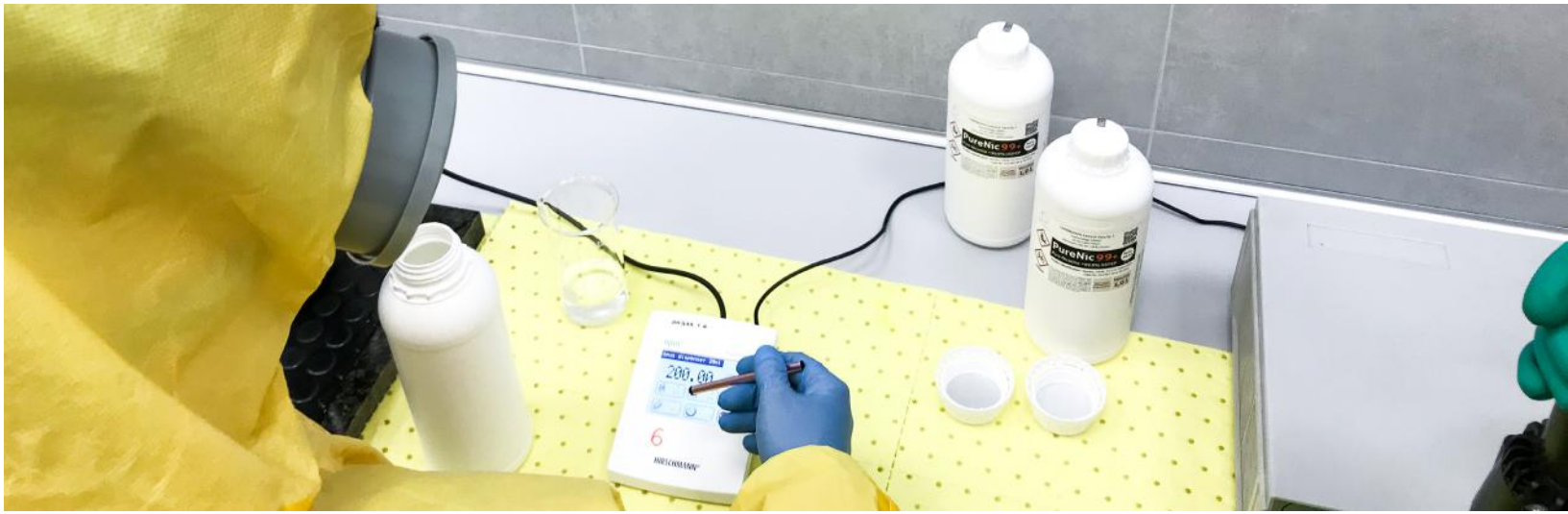
The REACH registration includes an annual cost to share between all registrants. The principal registrant may charge administration fees at his discretion. If the cost of registration in a given year is lower, the lead registrant reimburses part of the cost corresponding to the other registrants. Interestingly, outside the European Union, there are various relevant regulations corresponding to REACH. Other countries such as Turkey, Canada, or Korea adopted this idea to their own legislation.

Moreover, soon also UK will implement new, amended law on tobacco products. On 31 January 2020 the UK left the European Union. The UK is now in the transition period that will last until 31 December 2020. This means further amendments to the way in which the Tobacco and Related Products Regulations 2016 apply in Great Britain (GB) and Northern Ireland (NI) after the end of the transition period.

CLP

CHEMICAL INDUSTRY REGULATIONS – CLP

CLP is a regulation resulting from the REACH. It is an acronym that comes from words: Classification, Labelling, and Packaging. As you know those three issues are very important for the chemical industry. Nowadays, it may be obvious that chemical product on a shop shelf has a label informing you about any threats. This information and the way we display it on a product are subject to CLP regulation. Moreover, CLP aims to ensure a high level of health and environmental protection, as well as the free movement of substances, mixtures, and products.



CLP AND ITS IMPACT ON THE E-LIQUID INDUSTRY

Substances and their mixtures can have different properties. Some of them can cause no harm to human health or the environment and some of them can be extremely hazardous. That is why the first step is to always define the possible hazard. That kind of information is not only important for the end-user, but also for everyone who had to deal with it on the way. Starting from the producers, distributors, or even transporters and ending on consumers. Usually, in the EU, the chain of information starts with a manufacturer. However, if a company imports the substance from outside of the EU this obligation can belong to the importer.

CLP AFFECTS LABEL

When the chemical (in our case – nicotine base, flavoring, or e-liquid) is correctly classified, you can start designing the label and select the appropriate packaging. Depending on the threat level, the label of your product can have no extra marking or multiple mandatory pictograms, warning signs, hazard statements, and precautionary statements. Regulations even cater to blind people, providing a warning sign in the form of a convex triangle in case if the chemical poses a threat or child-proof mechanisms when needed. Moreover, designers must take into consideration all the above requirements when creating labels and packaging. Below you can see an example of pictograms on a NicShot packaging:

E-liquid industry regulations – TPD

Tobacco Products Directive (TPD) is a directive covering all Member States of the European Union. Based on the proposal of the European Commission the Directive entered into force in the EU Member States on 20 May 2016.

The products regulated by the directive include cigarettes, roll-your-own tobacco products, pipe tobacco, cigars, cigarillos, smokeless tobacco products, electronic cigarettes and refill containers as well as herbal products for smoking and novel tobacco products.

Although e-cigarettes are a completely separate product category in the EU Directive, the restrictions imposed by the current legislation align e-cigarettes with tobacco products and impose the same obligations and restrictions on entrepreneurs operating within this young industry as those applied to tobacco manufacturers - mainly large international companies.

MOST IMPORTANT TPD REGULATIONS FOR E-LIQUID INDUSTRY

The TPD equates e-cigarettes with traditional tobacco products in many aspects. Among others, TPD prohibits e-cigarette sales to minors or advertising and promotion. The use of e-cigarettes in public places is also prohibited. E-cigarette use in clubs or restaurants is allowed only on the condition that there is a smoking room on the premises.

The Directive has introduced many significant changes to the tobacco market. Regarding provisions directly related to the e-cigarette industry, the most important points regulated by the Directive are:

TPD NOTIFICATION

The directive has imposed an obligation for manufacturers and importers of electronic cigarettes and e-liquids to provide the competent authorities of the Member States with detailed information on, among others, the list of all components of these products and substances released as a result of using the product;

Each e-liquid manufacturer is obliged to carry out laboratory tests (emission tests) of e-liquids that will be entered into the European market. Thanks to obligatory laboratory tests, it is possible to exclude from sale any e-cigarette products that contain prohibited substances such as carcinogens, CMR substances or heavy metals.

The test results are then forwarded to Member State authorities. This is done within the process of TPD registration. Registration takes place in a system (EU-CEG) that has been created to notify e-liquids in a given Member State. EU-CEG is an EU common point for the transmission of data and information on tobacco products, electronic cigarettes and refill containers. Important: Notification does not apply to the country of production, but to the destined country of sale! For example, if you manufacture your e-liquids in Poland and would like to sell them in Germany, Spain and France, you need to TPD-notify your product in Germany, Spain and France.

TPD notification of e-liquids applies to the destined country of sale, not the country of production.

TPD-COMPLIANT PACKAGING

Manufacturers and importers of e-cigarette products are obliged to place appropriate health warnings on the unit and collective packaging of e-cigarettes and related products. TPD Directive sets the minimum size of these warnings as well as the appearance and content of unit packaging of the products in question; Packaging and appropriate restrictions regarding e-liquids constitute a broad topic. Refer to our series of articles covering TPD-compliant packaging: **Article 1**, **Article 2**.

Public Health England (PHE) states that „e-cigarettes are around 95% less harmful than smoking.

ADVERTISING BAN

TPD does not allow any promotion of tobacco products to the end consumers. For instance, the Directive does not allow the promotion of e-cigarette products in mass media such as television, radio or the press. The details and the extent to which the ban is implemented are determined by each Member State at the national level of legislation. Despite the fact that advertising of e-cigarettes and refill containers is not possible, authorities of some EU Member States promote e-cigarettes and vaping as effective replacement therapy for quitting smoking. Public Health England (PHE) states that „e-cigarettes are around 95% less harmful than smoking”(link). Additionally, British NHS (National Health Service) finds e-cigarettes as helpful to stop smoking aid: „E-cigarettes aren’t completely risk-free but they carry a small fraction of the risk of cigarettes. Quitting with an e-cigarette is particularly effective when combined with expert face-to-face support”(link).

ONLINE SALES

Some EU countries have introduced the prohibition of the online sale of e-cigarettes and related products. For the average e-cigarette user, this means that they cannot buy their favorite e-liquid online. This record has been introduced, among others to control the age of users purchasing e-liquids. Consumers can only buy liquids in retail stores or stationary sales outlets so-called “vape shops”.

For instance in Poland Internet sales to the end consumer (i.e. to an individual customer) is illegal. The situation is different when it comes to Internet sales to business entities, i.e. registered companies - in this case, internet sales of e-cigarette products is allowed.

DIFFERENCES BETWEEN EU COUNTRIES

The TPD leaves some flexibility for certain provisions. Each European Union country has adapted its legislation to the Directive, which means that in each country the regulations concerning the marketing and introduction of e-cigarette products on the market are slightly different. Some legislators have created a law that is much more strict than the European Commission guidelines. The complexity of the regulations for each country can be overwhelming for manufacturers who want to register their liquids in several countries, here Chemnovatic comes to help.

Transport regulations

Standard e-liquids, e-cigarettes and shortflls do not require any specific transport conditions. However, some raw materials used to manufacture the final product (e-liquid) are subject to special transport regulations. This is because of the exceptional chemical and physical characteristics that these substances have.

Customers ordering pure nicotine, nicotine salts or other sensitive and hazardous substances often ask about the possibility of shipping products with the use of regular shipping methods. Unfortunately, from the legal point of view and for security reasons it is not allowed. Dangerous products require ADR (road), IATA (air), or IMDG (sea) transport.

Pure nicotine, nicotine salts and nicotine bases with the content of nicotine above 36 mg/ml are treated as hazardous substances. Because of this fact, these products require special transport conditions, which are slightly different than ordinary courier transport.

TRANSPORT OF HAZARDOUS MATERIALS – BASIC REQUIREMENTS

The ADR/IATA/IMDG Conventions are international, very detailed regulations used in the transport of dangerous goods. They describe the risks posed by the transport of dangerous goods and how to prevent these risks. The above conventions enable quick and precise determination of transport requirements and contribute to a uniform interpretation of the rules in the field of transport of dangerous goods.

The ADR/IATA/IMDG Conventions also specifies the detailed conditions for the packing/labeling of dangerous goods, and vehicles marking (goods are required to be marked with warning stickers). ADR/IATA/IMDG Conventions determines provisions regarding vehicles and transport as well as requirements for the vehicle crew and all participating persons.

The addressees of the ADR/IATA/IMDG provisions are all participants of the transport, i.e. carriers, producers of hazardous materials and their consignors, designers of packaging and tanks, technical supervision (research and approval units), vehicle manufacturers and recipients of hazardous materials.

All hazardous materials are divided into 13 hazard classes. Each load must be given a special four-digit UN number that identifies the hazardous properties of the product.

QUANTITATIVE RESTRICTIONS ON THE TRANSPORT OF NICOTINE AND OTHER DANGEROUS GOODS

ADR (road) transport is a point-system transport. One vehicle cannot carry more goods whose total points exceed the number specified in the regulations. E.g. 1 kg of pure nicotine has certain number of points and 1 car can transport up to 1000 points, therefore it limits the maximum quantity to 333 L of pure nicotine within one vehicle provided that the vehicle is not loaded with other hazardous products, which in turn might decrease the total points capacity of a given vehicle.

This is the reason why ADR road shipments take some longer time than regular courier companies shipments – they simply need to wait in reloading storages for an available vehicle which can be loaded with a certain amount of points.

All low-concentration nicotine products (containing less than 36mg/ml of pure nicotine) fit into the category of standard, non-hazardous products and can be transported with the ordinary courier company. These products are not subject to the ADR/IATA/IMDG Conventions.

DANGEROUS SUBSTANCES TRANSPORT IS MORE TIME-CONSUMING

An important factor for which dangerous materials transport may take a little more time is the fact that it undergoes a number of documentation controls at reloading points which may also prolong the transportation time. All this results in longer and more expensive delivery than regular goods, which may be surprising for the recipients not used to ordering high-concentration nicotine products. Depending on the country of destination due to documents checks, dangerous substances transport takes more time than courier transport of non-dangerous products.

Nicotine products require special transport conditions.

COST OF SHIPPING

The cost of shipping of a given product depends on the weight of the total products ordered (the larger the order, the higher total shipping cost, but the lower cost per litre, assuming that the order effectively fits the vehicle shipping capacity). The total cost of shipping includes:

- the cost of insurance for some of the shipments (not always insurance is possible – it depends on the chosen transport company),
- the cost of certified packaging,
- tolls
- fuel charges
- the distance from the place of shipment to the destination
- of course, if products require ADR/IATA/IMDG transport, the cost of shipping will be higher.

When it comes to pure nicotine ADR transport, Chemnovatic as a manufacturer can usually send up to 4 kg of nicotine packed within one UN certified box, so this does not change the shipment value. Regardless whether the customer orders 1 kg or 4 kg, the price for shipping will be the same on the condition that the place of destination remains unchanged. Of course, that does not mean that we are limited to 4 kg packaging only, we are able to pack up to 140 pieces of 1 kg bottles into one UN certified box. We can also offer 30 kg barrels and one pallet can contain maximum quantity of 8 barrels. All in all, from the economic reasons it is better to order larger quantities, however, the value of each shipment is determined individually for a given order.

Packaging

CHEMNOVATIC ORIGINAL PURE NICOTINE PACKAGING ALWAYS CONSISTS OF:

- Chemnovatic security seal.
- PureNic 99+ label contains all required information, QR code for the Safety Data Sheet and warning symbols. The batch number and best before date are printed on the bottle.
- Styrofoam packaging for a 1 kg bottle.
- To prevent leakage styrofoam packaging is additionally packed into a plastic bag and secured with Chemnovatic tape.
- Absorbent mat and extra padding for safety reasons. All Chemnovatic PureNic 99+ nicotine shipments contain a Certificate of Analysis inside and Safety Data Sheet on the outside.
- UN certified packaging.
- The outside of the collective box is covered with UN markings “dangerous to the environment” and a “toxic product” in accordance with the given nicotine class and the ADR convention or IATA regulation.

Quality requirements

In addition to legal requirements, each e-liquid manufacturer must also meet quality requirements for the manufactured products. This is extremely important due to the fact that e-liquids come into direct contact with the human organism. For this reason, out of concern for the welfare of consumers, e-liquids should always be produced from the best, certified raw materials, while maintaining the highest production and hygiene standards.

PHARMACEUTICAL QUALITY RAW MATERIALS

Pharmaceutical quality raw materials is an advantage that manufacturers like to emphasize and should be proud of. Although pharmaceutical quality is not necessary for the e-liquids industry, some manufacturers want to surpass the quality standards. Therefore, many e-liquid manufacturers use pharmaceutical quality raw materials (like pure nicotine, PG/VG) in their production. In this part of our guide, we take a closer look at what you, as an e-liquid manufacturer or e-liquid brand owner should know about the quality of raw materials. Learn how to check if the product's quality is as high as you expect.

PHARMACOPEIA – WHAT IS IT, AND WHAT DOES IT DESCRIBE?

According to the definition, it is “an official list of drugs, containing binding standards for their composition, dosage, preparation, storage, as well as methods of testing their quality and evaluation”. To clarify, pharmacopeia is a reference point for chemical substances in the pharmaceutical industry. In other words, it is the main source of information for chemists and pharmacists regarding the purity, quality, preparation, and application of chemical substances like drugs, vaccines, antibiotics, etc.

Many countries have developed their own pharmacopoeial standards and own pharmacopeias. Nevertheless, the two main and most general reference points for chemists are European pharmacopeia (Ph. Eur. /EP) and American pharmacopeia (USP).

PHARMACEUTICAL QUALITY OF E-LIQUID RAW MATERIALS

The term “pharmaceutical quality” means that a given substance is of pharmacopeia standards. However, before being approved for production in the pharmaceutical industry, a given substance needs to go through a complicated way of pharmaceutical formal regulations. In this respect, not every substance of “pharmacopeia quality” can be used in pharmacy.

At the same time the term “pharmaceutical grade” means that a given substance is of pharmacopeia standards, meets all the criteria of pharmaceutical regulations and thus can be used in pharmacy.

To sum up and avoid any misunderstandings – although some raw materials for e-liquid production are of pharmaceutical quality, they usually can’t be named as pharmaceutical grade raw materials.

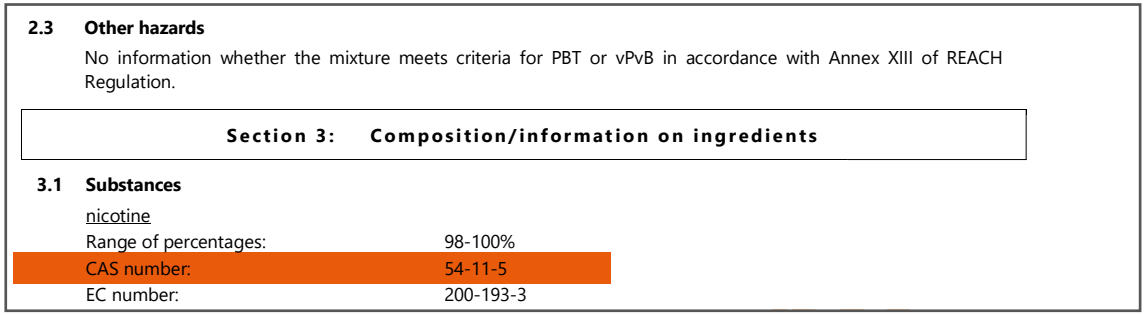
Raw materials used in the production of e-liquids do not need to comply with the pharmacopeia standards. Nevertheless, many e-liquid manufacturers use pharmaceutical quality raw materials like pure nicotine or PG/VG. It is because of the fact, that the most conscious and professional manufacturers want the best quality for their potential customers. It is out of concern for the welfare and health of e-liquid users.

HOW TO READ PRODUCT CERTIFICATES (MSDS, COA, COQ, TS, DS)?

So much for the theoretical knowledge, but how to check If an ingredient is of pharmaceutical quality, or not? Let's say, you are an e-liquid manufacturer and would like to buy pharmaceutical-quality pure nicotine. First of all, always ask your supplier for a Safety Data Sheet and other product certificates (which names may vary between different companies). At Chemnovatic we provide the following documents:

MSDS (Safety Data Sheet) for all of our products,
CoA (Certificate of Analysis) for pure nicotine,
TS (Technical Sptecification) for PG and VG,
CoQ (Certificate of Quality) for e-liquids and eliquid bases,
DS (Data Sheet) for flavours.

Another important element ensuring the products' quality is its composition. Be sure to ALWAYS check the CAS number! It is an identifier of a substance according to the Chemical Abstracts Service (CAS). Moreover, even in a situation when a manufacturer gives a misleading commercial name to its product, the CAS number will never lie to you. You can easily check CAS number authenticity at the European Chemicals Agency (ECHA). In addition to the CAS itself, you can obtain information on the registration of these substances, their CLP classification, and others. Below, you can see an example of how CAS number can be presented:



2.3 Other hazards

No information whether the mixture meets criteria for PBT or vPvB in accordance with Annex XIII of REACH Regulation.

Section 3: Composition/information on ingredients

3.1 Substances

nicotine

Range of percentages:	98-100%
CAS number:	54-11-5
EC number:	200-193-3

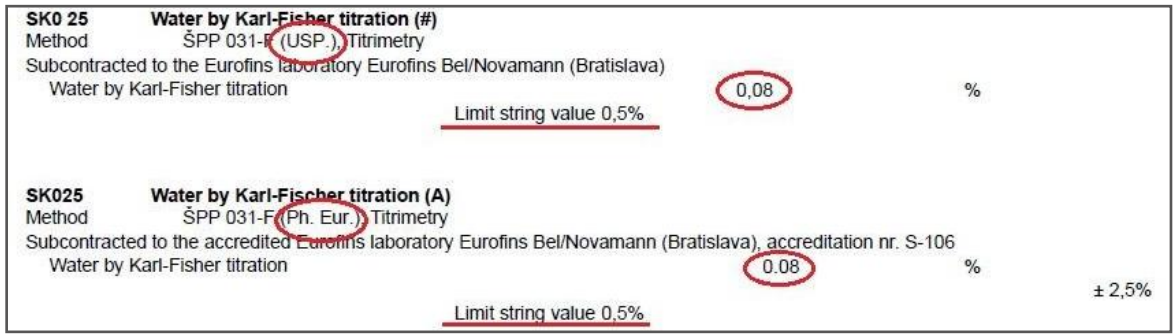
You can see the CAS number of nicotine which is 54-11-5. Moreover, from MSDS you can learn possible threats posed by a given substance, first-aid measures, and precautions to be taken. It is important for ensuring the safety of employees. MSDS also contains information on the storage and handling of a given product. If you would like to know more about storing and handling, we have published a vast article with many interesting details. Be sure to read it here.

HOW TO READ ANALYTICAL REPORTS?

Of course, MSDS and other documents (CoA, CoQ, TS, DS) are very important. However, these are internal documents that each enterprise prepares individually. How about checking the quality of products by a third party? It is a good idea to prove the quality of the products by presenting laboratory tests. A reliable supplier is able to provide laboratory analysis of a given product made in an external, independent laboratory. At Chemnovatic we test our flagship product PureNic 99+ pure nicotine in external, accredited laboratories. We test parameters of pure nicotine in terms of the European pharmacopeia (EP) and American pharmacopeia (USP) standards. You can see the full analytical report of the exemplary test on PureNic 99+ that we have ordered in .pdf format attachment to this article.

ANALYTICAL REPORT FOR PURENIC 99+

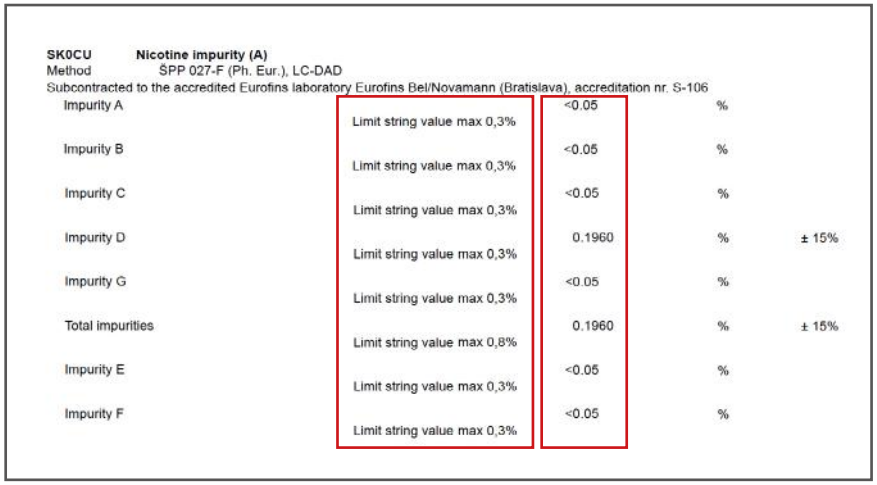
We test such parameters as water content, specific optical rotation, appearance, nicotine content, impurities, and heavy metals content. Testing all these parameters, and methods of testing are specified in Eur. Ph. and USP. However, describing all the methods of testing require specific chemical, complicated jargon. Nevertheless, we can and we SHOULD explain the results of the report. Let's take a closer look at the first parameter tested, which is water content.



You can see that the content of water was determined by Karl-Fisher titration method and it was tested twice. Firstly, in accordance with American pharmacopeia standards (USP), and secondly according to European Pharmacopeia (EP). You can clearly see that the Chemnovatic PureNic 99+ result is 0,08% as highlighted. Whereas the acceptable content of water in pure nicotine is 0,5% for USP, and from 0,5% for EP. You can see that the content of water in Chemnovatic pure nicotine is even lower than the acceptable level specified in pharmaceutical standards. In other words, in terms of tested parameters, Chemnovatic pure nicotine complies with pharmacopeia standards. Although our nicotine is not intended for use in pharmaceutical industries, it meets the qualitative requirements of the pharmacopeia in terms of the tested parameters confirming its identity and purity level.

COMPARE THE ANALYTICAL REPORTS WITH PRODUCTS' DOCUMENTATION

Another parameter that requires explanation is the content of impurities. As you can see, for each impurity there is a specified certain limit (Limit string value). Next to it, you can see the result of the testes PureNic 99+ sample. As you can see, each impurity is way below the pharmacopeia limit.



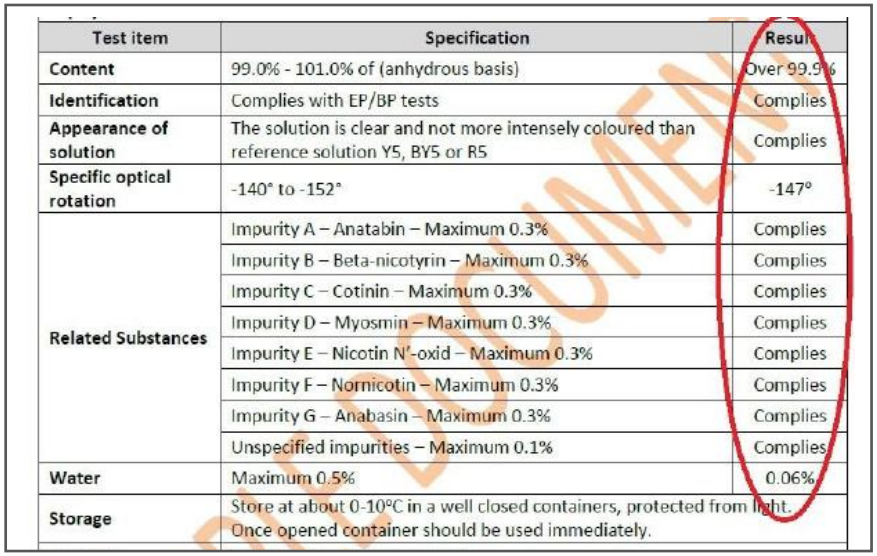
SK0CU **Nicotine impurity (A)**
Method SPP 027-F (Ph. Eur.), LC-DAD
Subcontracted to the accredited Eurofins laboratory Eurofins Bel/Novamann (Bratislava), accreditation nr. S-106

Impurity A	Limit string value max 0,3%	<0.05	%	
Impurity B	Limit string value max 0,3%	<0.05	%	
Impurity C	Limit string value max 0,3%	<0.05	%	
Impurity D	Limit string value max 0,3%	0.1960	%	± 15%
Impurity G	Limit string value max 0,3%	<0.05	%	
Total impurities	Limit string value max 0,8%	0.1960	%	± 15%
Impurity E	Limit string value max 0,3%	<0.05	%	
Impurity F	Limit string value max 0,3%	<0.05	%	

ANALYTICAL REPORT FOR PURENIC 99+

Importantly, the contaminants tested in the analytical report marked with letters A to G are identified in the CoA document. It is pictured as follows:

To cut a long story short, every parameter is tested by a given method. The results are compared to standards determined to European (EP) and USA (USP) pharmacopeia. On the basis of the two above examples, you can go step by step and read the full analytical reports of any substance.



Test item	Specification	Result
Content	99.0% - 101.0% of (anhydrous basis)	Over 99.9%
Identification	Complies with EP/BP tests	Complies
Appearance of solution	The solution is clear and not more intensely coloured than reference solution Y5, BY5 or R5	Complies
Specific optical rotation	-140° to -152°	-147°
Related Substances	Impurity A – Anatabin – Maximum 0.3%	Complies
	Impurity B – Beta-nicotyrin – Maximum 0.3%	Complies
	Impurity C – Cotinin – Maximum 0.3%	Complies
	Impurity D – Myosmin – Maximum 0.3%	Complies
	Impurity E – Nicotin N'-oxid – Maximum 0.3%	Complies
	Impurity F – Nornicotin – Maximum 0.3%	Complies
	Impurity G – Anabasin – Maximum 0.3%	Complies
	Unspecified impurities – Maximum 0.1%	Complies
Water	Maximum 0.5%	0.06%
Storage	Store at about 0-10°C in a well closed containers, protected from light. Once opened container should be used immediately.	

TOP-QUALITY NICOTINE BASES – WHAT YOU SHOULD KNOW?

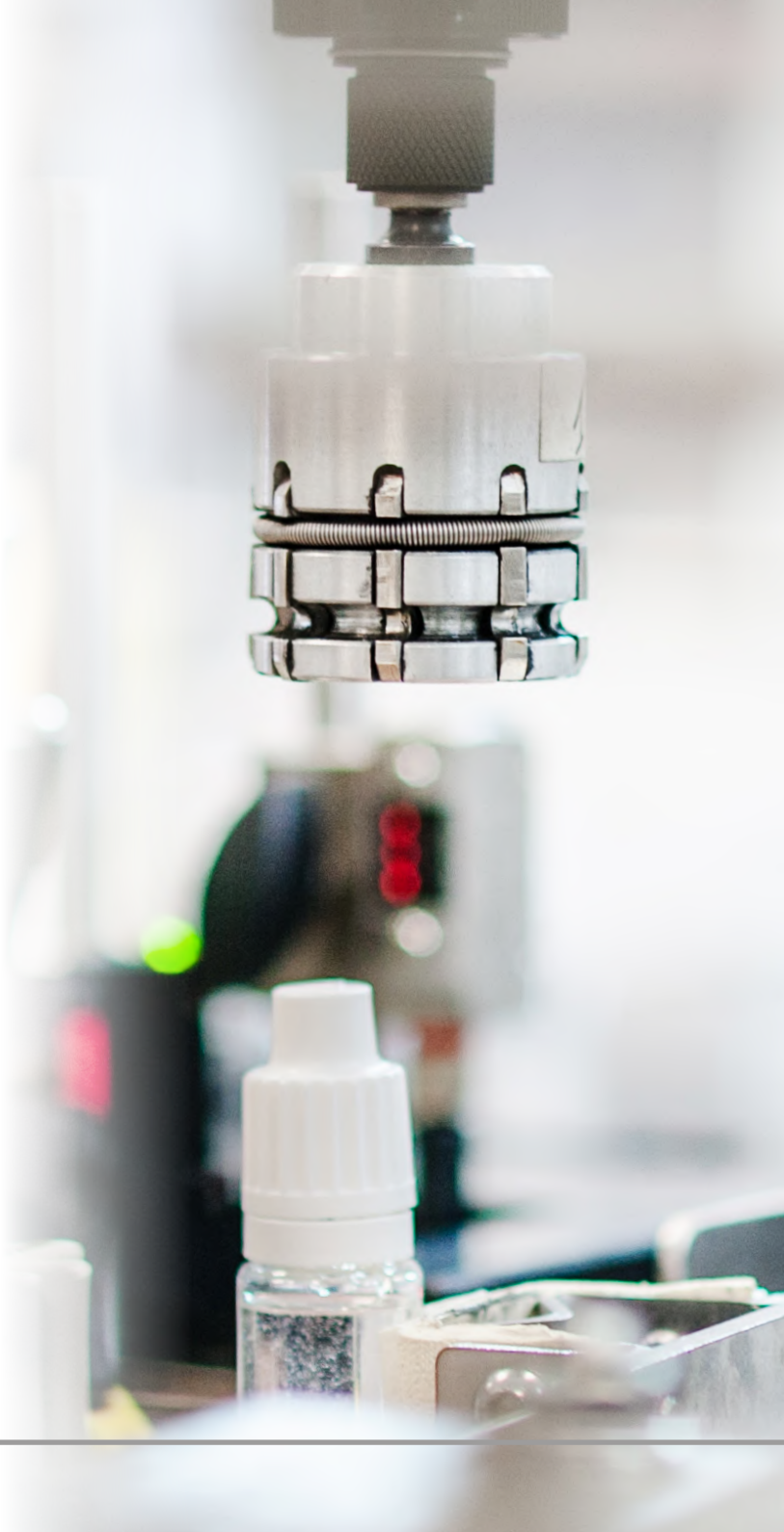
When buying semi-finished products for e-liquids, it is worth paying attention to the quality of the raw materials. Propylene glycol (PG) and vegetable glycerine (VG) that suppliers provide should also be in compliance with USP/EP standards. You can check its quality on the basis of MSDS and CoA. Unfortunately, not every producer of raw materials can boast of the pharmaceutical quality of their products. Probably the worst thing any e-liquid manufacturer can do is to waste great quality pure nicotine and mix it with subpar, low quality, cheap VG or PG.

Manufacturing quality requirements

Every enterprise that cares about the quality and satisfaction of its customers should apply the principles of quality management in its daily work. This is especially true for companies that manufacture products that go directly to the human body, such as e-liquids. What are the quality standards for e-liquid producers? Let's find out.

QUALITY MANAGEMENT SYSTEM

First of all, it is important to implement a strategy for delivering a certain quality. This strategy is called the quality management system. It is a system composed of rules, procedures, methods, tools, job descriptions, people, and relations between them. This is to achieve the set quality goals. And the main document in the quality management system is the quality policy.



CHEMNOVATIC QUALITY POLICY

To give a good example, in this case, can be the Chemnovatic quality policy. In the introduction, we can read: “The aim of Chemnovatic Sp. z o.o. is to constantly strive to satisfy our clients with the services and products we offer, i.e. the production and distribution of liquids for electronic cigarettes and raw materials for their production. We make sure that our services and products meet the current and future expectations of our customers, and in particular their safety expectations. For this purpose, we have implemented GMP, HACCP quality assurance systems, and a quality management system compliant with the ISO 9001: 2015 standard.”

CERTIFIED PRODUCTION

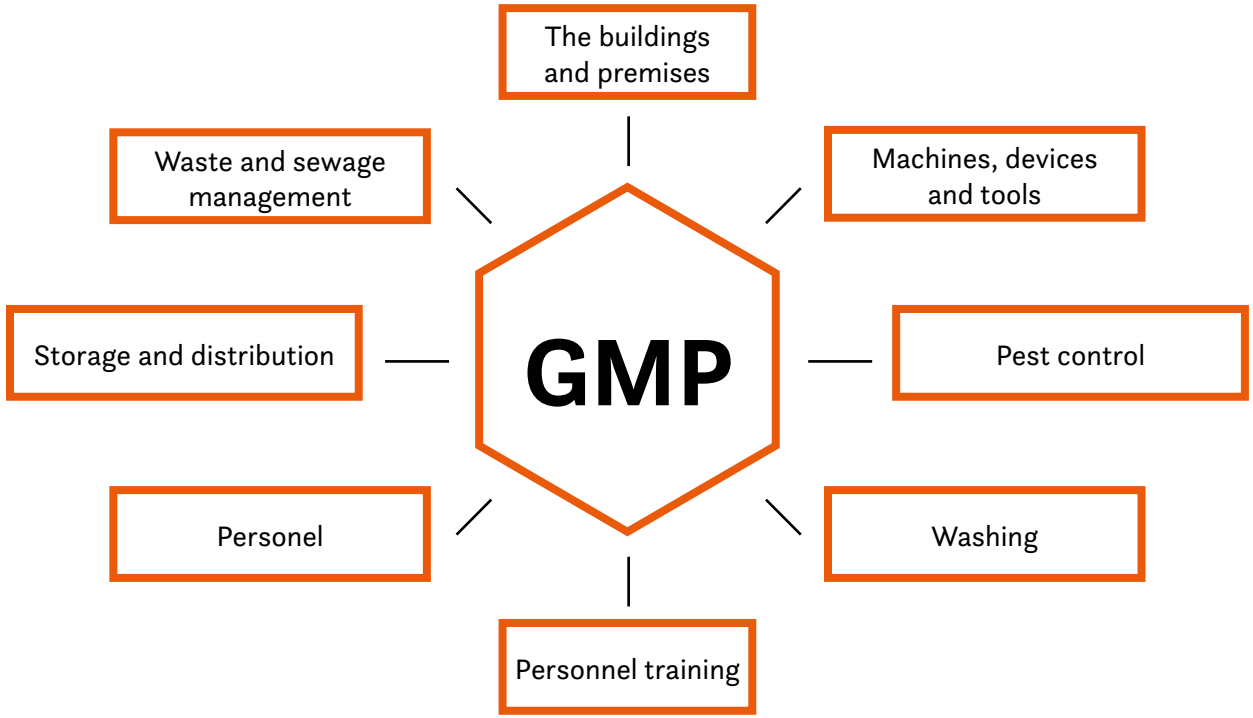
E-liquid manufacturers should constantly improve the production and management processes to increase the quality of our products. For this reason, it is a good idea to implement ISO, GMP, and HACCP standards to your production. ISO International Standards ensure safety, reliability, and quality of products. It is a set of strategic tools minimizing waste and human errors while increasing productivity. To give an example, Chemnovatic has implemented guidelines, policies and processes in line with the ISO 9001:2015 quality standards as set out by the ISO Quality Management System.

HACCP - HAZARD ANALYSIS AND CRITICAL CONTROL POINT

The system, which identifies, assesses, and controls threats essential for food safety and health quality (Food Code). HACCP is a method of ensuring the safety of food that relies primarily on risk prevention. It helps to ensure process reliability production, packaging, storage, and distribution of food. The HACCP system is beneficial for both the consumer and the entrepreneur. Due to the obligation to implement the HACCP system in companies, the consumer can be sure that the product is completely safe. Having a properly implemented and functioning system, an entrepreneur builds consumer confidence in the company and improves its image.

GHP/GMP

Good Hygiene Practice and Good Manufacturing Practice. Actions, which must be taken, and hygienic conditions, which must be met and controlled at all production or marketing stages to ensure the safety of food. The principles of Good Manufacturing Practice (GMP) take into account the principles of Good Hygiene Practice (GHP).



WHAT DO THE CERTIFICATES MEAN FOR CUSTOMERS?

Integrated systems of activities ensure product safety and quality minimizes human error, and waste while increasing productivity. The application of HACCP, GMP/GHP standards gives consumers a greater level of comfort and certainty as to the quality of the product manufactured in a plant where Good Manufacturing Practices are applied.

The benefits that can be achieved by implementing the HACCP, GMP/GHP systems, in addition to the overriding goal of ensuring food safety, include:

- meeting the requirements of food law,
- updating knowledge and raising awareness of staff,
- the discipline of the crew and tightening of cooperation between people on particular positions,
- meeting customer expectations, increasing the certainty and systematic repeatability of product quality,
- an active approach to solving quality problems, and product safety,
- enabling remedial actions to be taken before the problem occurs,
- improvement of the company's infrastructure,
- reduction of production losses, errors, and shortages.

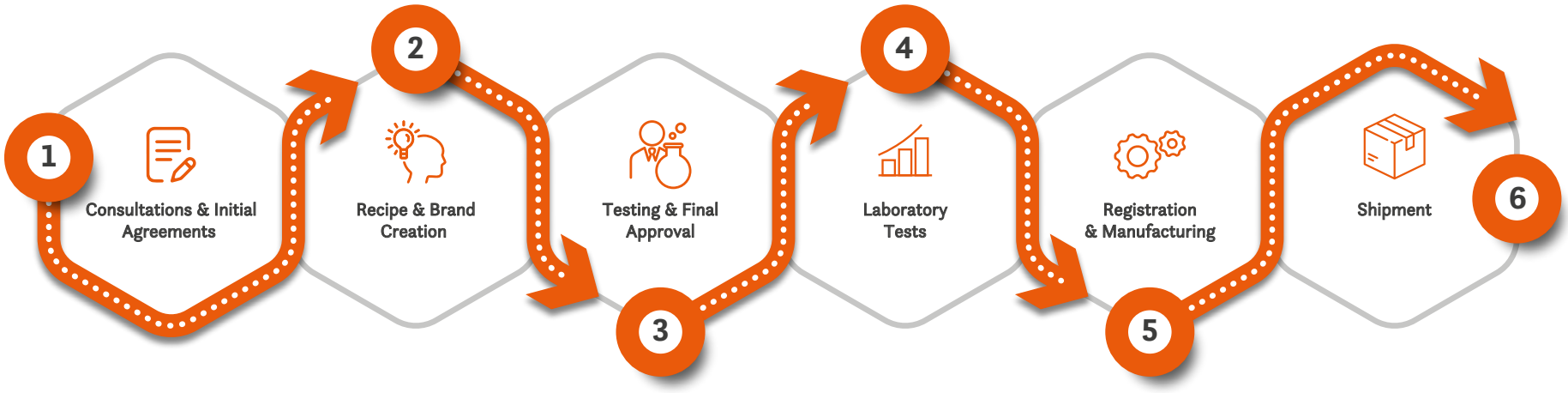
Many years of experience in the business branch of e-liquid manufacturing and a team of experts gave Chemnovatic the tools to support other companies from the same industry. We will be happy to share with you our expert knowledge and provide services in many fields.

Private label & regulatory requirements

OEM/ WHITE LABEL MANUFACTURING

The OEM/ White label manufacturing experience of Chemnovatic staff is exceptional in the whole e-liquids industry. Precision, engagement and flexibility are the keys to provide our customers with a service perfectly tailored to their needs.

We're a professional, experienced OEM/ White label company with the equipment and know-how necessary to create new, fail-safe businesses from the ground up. We can also manufacture custom e-liquids specifically for your company, starting with flavor development, through label, packaging design and certifications, and deliver them directly to your door – all around the world. You can closely overview the entire process.



RECIPE & BRAND CREATION

At Chemnovatic you can either personalize your unique e-liquid or you can outsource this task to our experienced flavourist. Possible ways of cooperation:

Your brand developed on the basis of your guidelines

Our product development team has experience with creating award-winning recipes. We will help you release your new line of delicious, top quality e-liquids.

Your brand created with your recipes

You can send us your own recipes and let us do the rest - we will put your idea into reality. Of course with confidentially agreement mutually signed and authorized.

Full flexibility

We can advise you on the recipes you would like to modify, use your own raw materials in our production or we can order raw materials (concentrates, additives) from different vendors – all to meet your customers' expectations.

While the recipe is being created, our skilled graphic designers work on eye-catching and unrepeatable projects that will help you spread your products and make them stand out from the crowd, not only because of the flavouring values, but also because of the attractive packaging design. Our designers can either work accordingly to your instructions, or they can propose their own unique solutions for your product.

LABORATORY TESTS

We provide our customers with TPD and laboratory tests, including toxicology and emission tests of ready e-liquids and composition tests of other tobacco harm reduction products. Our laboratory tests are accepted in every European country.

The exemplary tests that we perform:

- heavy metals determination
- volatile organic compounds determination
- aldehydes and ketones determination
- nicotine, propylene glycol and glycerin determination

Upon final approval, the agreement is signed by both parties the actual production begins.

REGISTRATION

We offer comprehensive service of TPD product registration and guidance throughout the whole process, as well as customer care after the process of registration. Our TPD compliance team will help you to determine whether you have any gaps and ensure that your products meet all requirements. We have conducted hundreds of TPD notifications and we can help you to register your products in all EU countries.

We will provide you with:

- TPD registration
- MSDS preparation
- TPD, REACH, CLP, UFI and ADR consultations

CHEMNOVATIC

Chemnovatic has the necessary know-how and experience to help you to register your products in all EU countries. If you want to talk to our consultants about industry regulations or any other topic related with e-liquid industry, please contact us at sales@chemnovatic.com.

www.chemnovatic.com