



# Global GHS Training Course

## No.2. EAEU GHS features and EAEU-REACH



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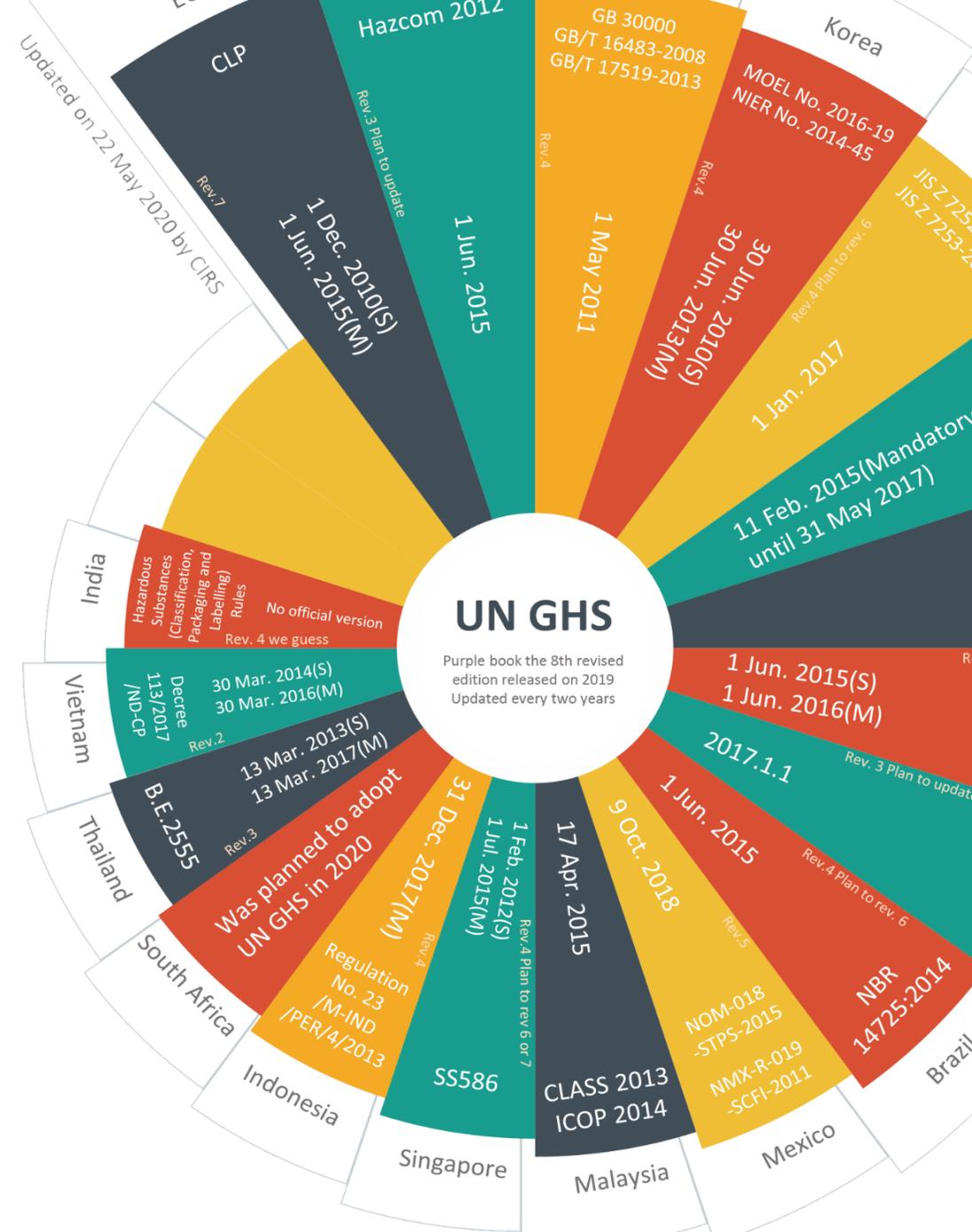
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**REGARTIS**  
ART OF REGULATORY

# Upcoming Technical Regulation 041/2017 in Eurasian Economic Union, Inventory of existing substances in Russian Federation

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ANO ESC “EAST” (EcoVostok)



2020

# Introduction

- ▶ EcoVostok has been providing support to companies in Russia exporting their products to Europe since 2008.
- ▶ From 2017, we have started offering our services regarding new TR 041/2017 to the companies who are placing or planning to place their goods onto the EUEA market.



<https://ecovostok.ru/in-english/>

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## Part 1. What is the TR EAEU\* 041/2017?

- ▶ TR EAEU 041/2017 often referred to as the «EAEU REACH» - is the new EAEU Technical Regulation “On the Safety of Chemical Products” that was adopted by the decision of the Council of the Eurasian Economic Commission on March 3, 2017 and **is expected to enter into force on June 2, 2021.**

This technical regulation is a set of requirements for chemical products in the customs territory of the EAEU. This technical regulation is not a guideline for the implementation of these requirements. To comply with the requirements of this technical regulation, various standards (GOST) and guidelines are developed: both national and interstate.

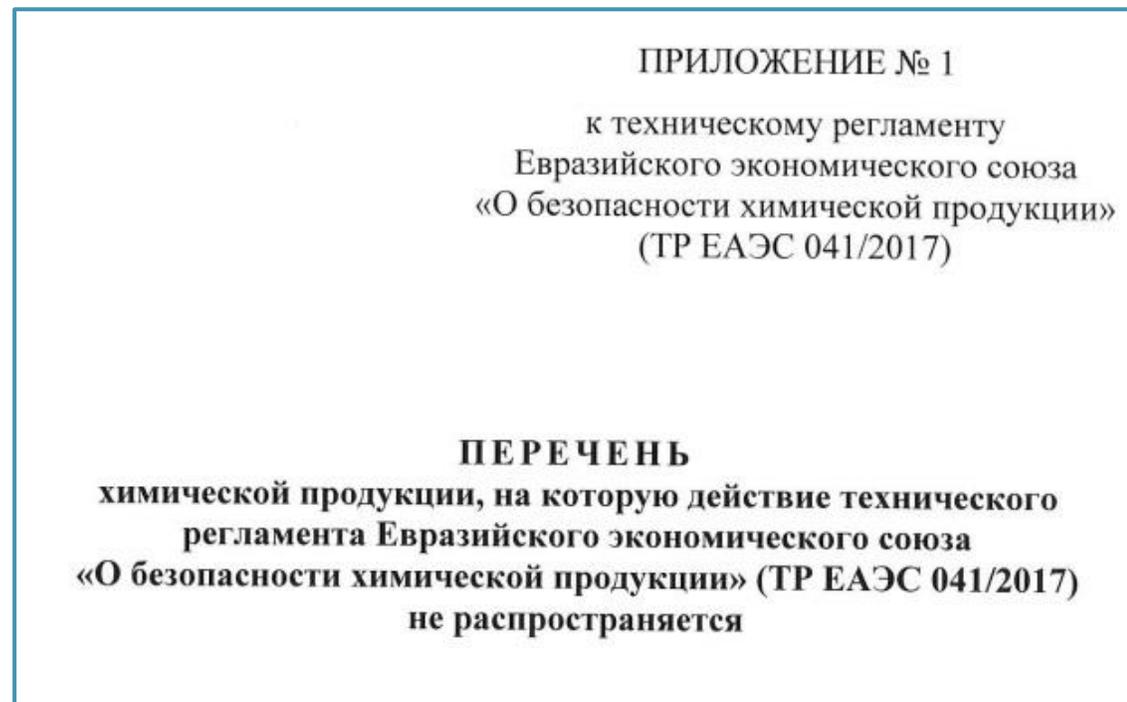
\*EAEU - Eurasian Economic Union - is an economic union of states located in central and northern Asia and Eastern Europe that includes Armenia, Belarus, Kazakhstan, Kyrgyzstan and Russian Federation.

# Key points and purpose of the TR 041/2017

- ▶ This technical regulation has been developed with the aim of:
  - **Protecting** human life and health, property, the environment, life and health of animals and plants, preventing actions that mislead consumers (purchasers).
  - **Establishing the uniform requirements** for the application and execution in the customs territory of the Eurasian Economic Union (hereinafter referred to as the Union) **for chemical products put into circulation in the customs territory of the Union, as well as the rules and forms for assessing its compliance**, identification rules, requirements for terminology, labeling and rules for applying it.

## Section 1. Application area

- ▶ This technical regulation applies to **all chemical products** put into circulation in the customs territory of the Union, with the **exception** of the list of products **in accordance with Appendix № 1**



# Appendix №1: The list of chemical products to which the TR 041/2017 does not apply:

- ▶ 1. Chemical products intended for use in scientific research and development and/or obtained as a result thereof
- ▶ 2. Minerals in their natural state of occurrence, as well as the following products, if not chemically changed: minerals, ores, ore concentrates, cement clinker, natural gas, liquefied gas, gas condensate, process gas and its components, dehydrated, desalted and stabilized oil, associated petroleum gas, coal, coke;
- ▶ 3. Medical products and drugs for veterinary use;
- ▶ 4. Perfumes and cosmetics;
- ▶ 5. Chemical products serving as a source of ionizing radiation (including wastes of such products), including their hazard classification, labeling and information on hazards due to the presence of radiation;
- ▶ 6. Food products, including biologically active supplements and food additives, as well as finished animal feed;
- ▶ 7. Products in articles which during treatment in the customs territory of the EAEU do not change their chemical composition and which are not subject to decomposition or oxidation processes, and which do not form dusts, vapours and aerosols containing chemicals that are hazardous to the life and health of humans, animals or plants, the environment, or property;
- ▶ 8. Wastes from the production and consumption of chemical products, if they are to be recycled;
- ▶ 9. Chemical products that are subject to the procedure of customs transit through the territory of the EAEU.

## Section 2. Basic concepts

- ▶ For the purposes of applying this technical regulation, the list of concepts and their definitions is used, for example:
  - “**Importer**” is a resident of the Union who has concluded a foreign trade contract with a non-resident of the Union for import of chemical products to the territory of the Union , sells chemical products and is responsible for its compliance with the requirements of this technical regulation;
  - “**Chemical product**” - a chemical substance or mixture;
  - “**Basic chemical substance**” - a component of chemical products that is not an additive or impurity, constitutes a significant part of this product and is therefore used as a name for the chemical product and its detailed identification;
  - “**New chemical substance**” - a chemical substance the information on which is not included in the register of chemical substances and mixtures of the Union;

# Section 3. Rules for the identification of chemical products

- ▶ The identification of chemical products is carried out by the manufacturer (the person authorized by the manufacturer), the importer of these products.
- ▶ Identification of chemical products includes:
  - a) Establishment of the name of chemical products;
  - b) The attribution of chemical products to chemicals or mixtures;
  - c) The establishment of a chemical name for the chemical according to the nomenclature of the International Union for Theoretical and Applied Chemistry (hereinafter referred to as the nomenclature of the International Union) and the identifier of the chemical entered in the register of the Chemical Abstract Service of the American Chemical Society (hereinafter - the substance number in the chemical identifier register) availability);
  - d) Determination of the chemical composition of the mixture with the identification for each of the constituent components of the identifiable components according to the nomenclature of the International Union and the substance number in the chemical identifier register (if any);
  - e) Establishing the presence of new chemical substances in chemical products in concentrations of more than 0.1 percent;
  - f) Assignment of chemicals in chemical products:
    - to new chemicals;
    - to chemical substances prohibited for use on the territory of the Union;
    - to chemicals restricted to use on the territory of the Union;
  - g) Definition of the field of application of chemical products;
  - h) Other necessary information.

## Section 3. Rules for the identification of chemical products: State of things

- ▶ This technical regulation lists only the basic rules for identifying chemicals. And at present, there is no universally accepted document with identification rules for all EAEU countries. Each member country has its own national standards.
- ▶ For example, Russia has a number of standards that determine the procedure for identifying chemicals. For example: **GOST R 57443-2017 "Identification of chemical products. General provisions."** and **GOST R 57444-2017 "Identification of chemical products. Rules for laboratory tests."**



## Section 4. Rules for the circulation of chemical products on the market

- ▶ Chemical products are issued for circulation on the customs territory of the EAEU when it complies with the requirements of this technical regulation, as well as with the requirements of other technical regulations that apply to it, and provided that it has passed an assessment of compliance with the technical regulations that apply to it.
- ▶ In the absence of information on chemical products in the register of chemicals and mixtures, the new chemicals in its composition should be notified, and information on them is included in the register of chemicals and mixtures in accordance with paragraphs 46-48 of this technical regulation before release into circulation on the customs territory of the EAEU of chemical products containing such chemicals.
- ▶ The procedure for the formation and maintenance of the register of chemicals and mixtures is established by the Eurasian Economic Commission .

## Section 5. Requirements for classification of chemical products

- ▶ Classification of chemical products is carried by the manufacturer (person authorized by the manufacturer) or an importer of such products.
- ▶ **Classification of chemical products is carried out in accordance with the standards included in the list of documents for standardization**, as a result of which the voluntary compliance with requirements of the Technical Regulations.
- ▶ For example:
  - GOST 32423-2013 “Hazard classification of mixed chemical products by their effects on the body”
  - GOST 32424-2013 “Classification of the hazard of chemical products by environmental impact. Key Points”
  - GOST 32425-2013 “Hazard classification of mixed chemical products by environmental impact”

## Section 6. General safety requirements

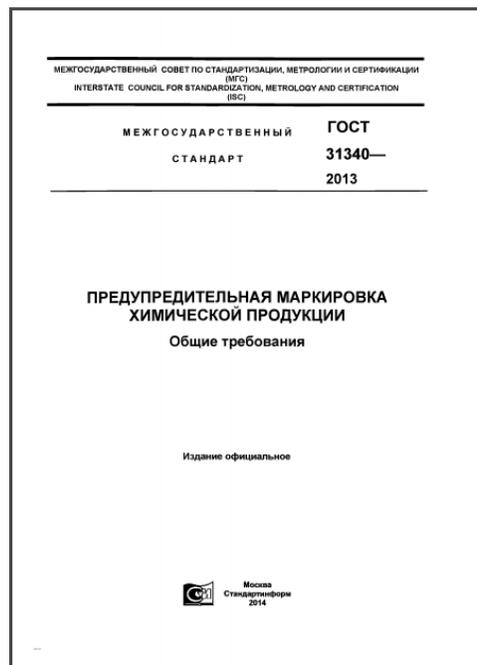
- ▶ The safe handling of chemical products should be ensured by means of:
  - a) compliance by the manufacturer (person authorized by the manufacturer), importer of chemical products with the requirements of this technical regulations;
  - b) the intended use by the consumer (purchaser) of chemical products;
  - c) assessment of compliance of chemical products with the requirements of these technical regulations;
  - d) the implementation by the manufacturer (the person authorized by the manufacturer), the importer and consumer (purchaser) of chemical products of preventive measures when handling chemical products;
  - e) the replacement of hazardous chemicals with chemicals of a lower hazard class or those not classified as hazardous (if possible);
  - f) informing the consumer (purchaser) about the dangerous properties of chemical products in relation to human life and health, property, environment, life and health of animals and plants, as well as measures for its safe handling in the customs territory of the Union, including in case of expiration date or unsuitability of use;
  - g) informing the consumer (purchaser) about the methods of safe disposal and neutralization of chemical products.

## Section 7. Requirements for labeling of chemicals

- ▶ Labeling of chemical products manufactured in circulation in the territory of the Russian Federation, should be prepared in Russian.
- ▶ Labeling of chemical products must include the following information:
  - a) Mark of market access
  - b) name of the chemical product, when it is set identification (name of the chemical product may further include commercial (brand) name);
  - c) the name, location (legal address), including the country, and the manufacturer (manufacturer's authorized phone number of the person), chemical products importer;
  - d) the name of chemicals and mixtures classified as hazardous and contained in the composition of chemical products in quantities exceeding the concentrations specified in the standards listed standardization documents, as a result of which the voluntary compliance with requirements of this technical regulation;
  - e) storage conditions;
  - f) the designation of the document, according to which chemical products made (if any);
  - g) information on the hazardous properties of chemicals, including warning markings.

# Section 8. Requirements for precautionary labeling

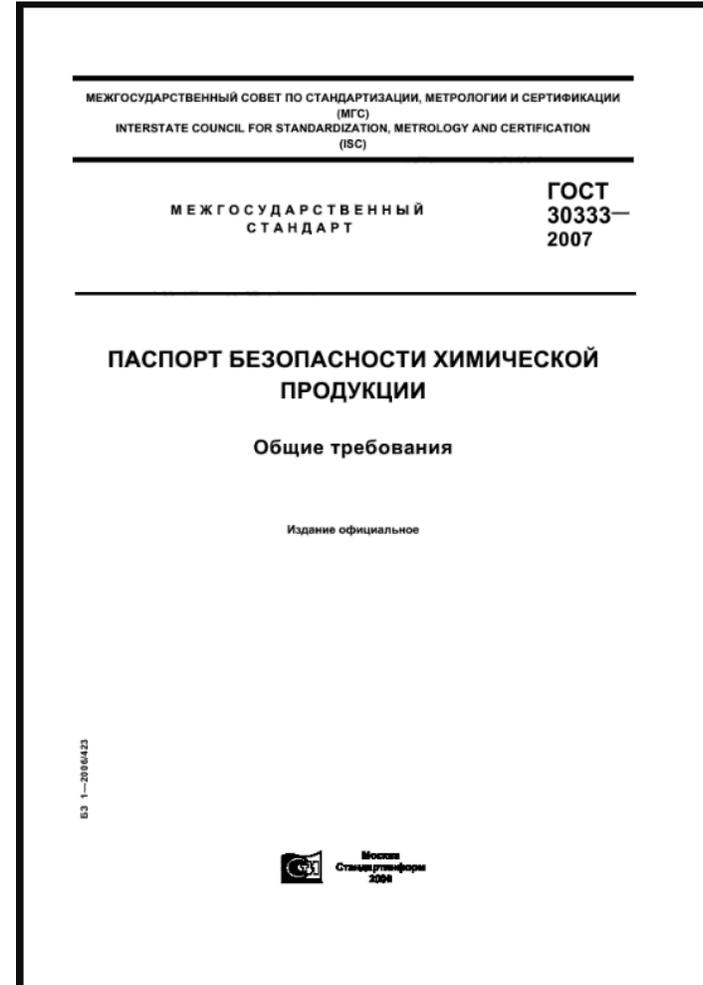
- ▶ Precautionary labeling is applied as a sign of danger, the danger symbol, signal word and contains a description of the measures for the prevention of danger in accordance with **GOST 31340-2013 “Precautionary labeling of chemical products. General requirements”** and should be distinguished in comparison with other information contained in the labeling of chemical products.



<p>Пламя</p> 	<p>Пламя над окружностью</p> 	<p>Взрывающаяся бомба</p> 
<p>Жидкости, выливающиеся из двух пробирок и поражающие металл и руку</p> 	<p>Баллон для газа</p> 	<p>Череп и скрещенные кости</p> 
<p>Восклицательный знак</p> 	<p>Сухое дерево и мертвая рыба</p> 	<p>Опасность для здоровья человека</p> 

## Section 9. Requirements for Safety Data Sheet

- ▶ The manufacturer (authorized representative of the manufacturer) or the importer of chemicals producing these products in circulation in the territory of the Union, compiles a safety data sheet.
- ▶ The requirements for the information to be contained in the safety data sheet are indicated in **GOST 30333-2007 "Safety Data Sheet of chemical products. General requirements"** and have not brought any significant changes in SDS requirements.



## Section 10. Ensuring compliance of chemical products with the requirements of technical regulations

- ▶ **Methods of research (testing) of chemical products are established in the standards included in the list of international and regional (interstate) standards, and in case of their absence - national (state) standards containing the rules and methods of research (testing) and measurements, including selection rules samples necessary for the application and enforcement of the requirements of these technical regulations and the assessment of conformity of chemical products.**

# Section 11. Notification of new chemical substances

- ▶ Notification of new chemical substances is carried out by entering information about them in the register of chemical substances and mixtures.
- ▶ The information sent by the applicant to the authorized body for the purpose of notification of new chemical substances must include:
  - a) a chemical safety report in accordance with the structure according to the Appendix № 3;
  - b) Chemical name according to the nomenclature of the International Union;
  - c) the chemical structural formula;
  - d) substances Registry number of the chemical ID (if available);
  - d) Data of instrumental analysis of the chemical;
  - e) the degree of purity chemical;
  - g) the intended application of the chemical;
  - h) the estimated disposal methods (processing) of the chemical;
  - i) a method of transporting chemical substances and measures to prevent and eliminate any emergencies;
  - a) analytical methods of control;
  - l) The physico-chemical data of the chemical;
  - m) the data on chemical toxicity;
  - n) data ecotoxicity chemical;
  - a) the name of a new chemical in the English language;
  - f) copy of the data (protocol) (tests) to determine the chemical bioaccumulation , carcinogenicity, mutagenicity, toxicity, carried out in test laboratories (centers), recognized by the relevant principles of good laboratory practice in accordance with the Federal Law "On Technical Regulation" . Allowed studies (tests) in other laboratories (centers), accredited in accordance with the Federal Law "On accreditation in national accreditation system" and having the appropriate scope of accreditation for 2 years from the date of entry into force of this technical regulation.

## Section 12. Conformity assessment to the requirements of this TR

- ▶ All chemical products are subject to conformity assessment before being put into circulation in the customs territory of the Union.
- ▶ Conformity assessment of chemical products to the requirements of the technical regulation is carried out in the forms of:
  - a) **Notification** state registration;
  - b) **Permissive** state registration.

**Beginning dates as well as any deadlines are not established yet!**

**Differences in the Registration process for different tonnage-bands are not established yet!**

**No authority bodies are established yet!**

**No fees or costs are established yet!**

## Section 12. Conformity assessment

### Notification state registration:

- ▶ Notification state registration of chemical products is carried out if information on chemical products is included in the register of chemicals and mixtures of the Union and one of the following requirements is fulfilled:
  - a) The composition of chemical products does not include prohibited and (or) restricted to use chemicals and mixtures included in the register of chemical substances and mixtures of the Union;
  - b) Chemical products contain chemicals and mixtures that are restricted for use, information about which is included in the register of chemicals and mixtures of the Union, in concentrations below the established limit according to Appendix No. 4.
  
- ▶ The validity of the certificate of notification of state registration of chemical products and the registration mark in electronic form is not limited.

## Section 12. Conformity assessment

### Permissive state registration:

- ▶ Permissive state registration is carried out in relation to:
  - a) New chemical products (after the procedure of “notification of a new substance”);
  - b) Chemical products that contain chemicals and mixtures that are restricted for use, information about which is included in the register of chemical substances and mixtures of the Union, in concentrations exceeding the maximum content established in Appendix No. 4 to this technical regulation.

Chemical Hazards	Concentration (C),% (weight)
Carcinogens (classes 1 and 2)	0.1
Mutagens (class 1)	0.1
Mutagens (class 2)	1
Affecting Reproductive Function (classes 1 and 2)	0.1
Chronic aquatic toxicity (Class 1)	1

## Section 12. Conformity assessment

### Permissive state registration:

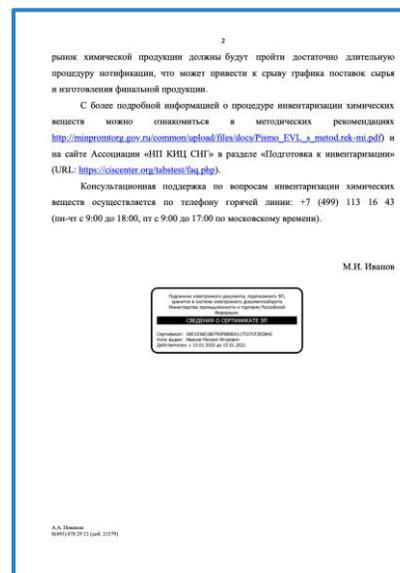
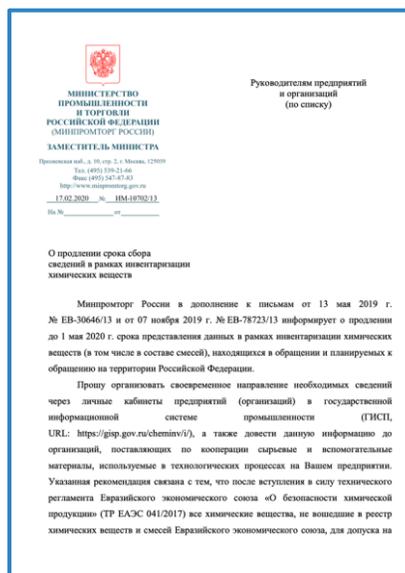
- ▶ The validity of an official permission for the use of chemical products lasts for **5 years** from the date of its issue.

If within 5 years from the date of issue of the permit for the use of chemical products **there are no comments** from the authorized body **on the non-compliance of the chemical products with the requirements** of these technical regulations, the authorized body automatically re-registers these products.

- ▶ Chemical products, when changing their component composition, are subject to repeated notification state registration or permissive state registration if, with such a change, the concentration of hazardous chemicals in its composition in relation to their initial concentration exceeded the permissible deviations specified in Appendix No. 2 to this technical regulation.

# Current state of things in Russian Federation

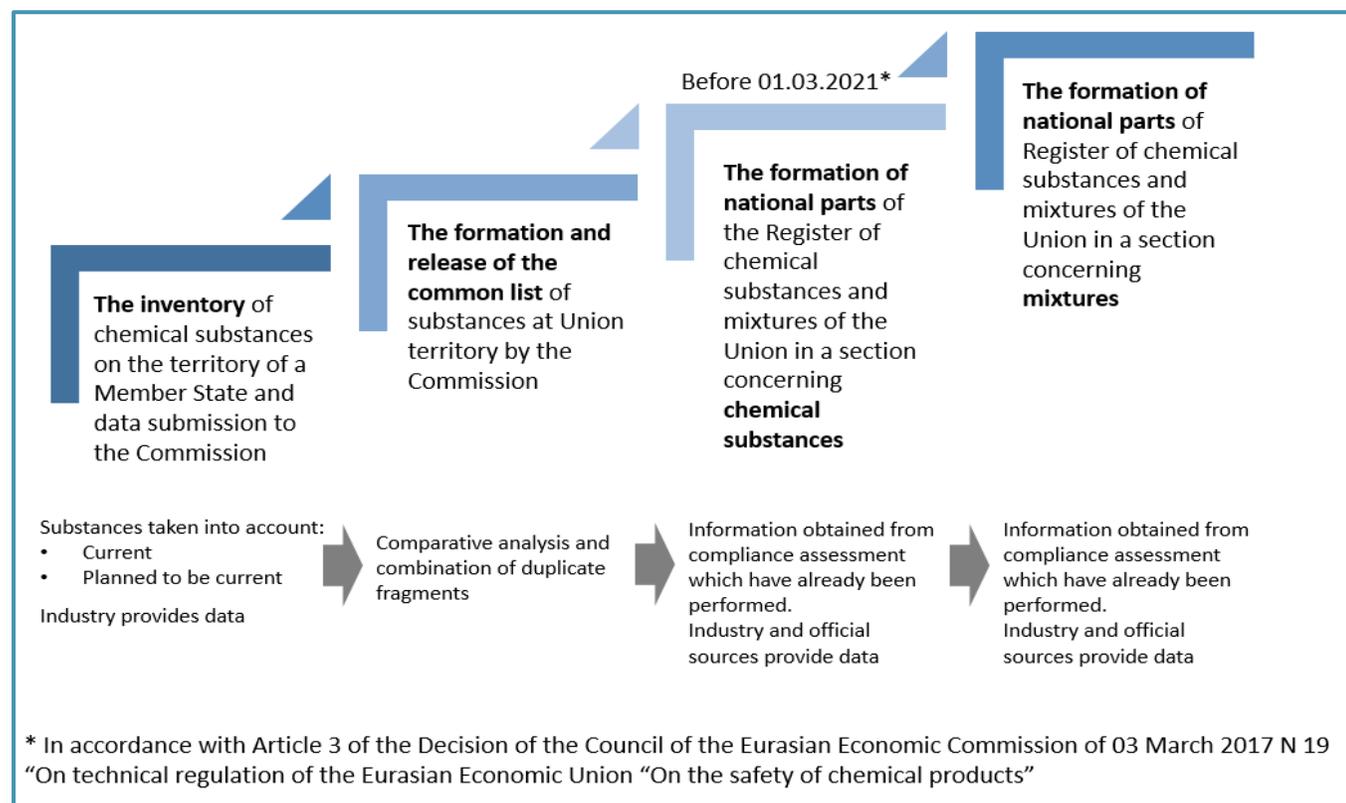
- ▶ The process of forming the inventory of chemical substances was launched in 2019 on the territory of Member States as parts of forming a Register of Chemical Substances and Mixtures of the Union and data submission to the Commission that will be later formed in this Register.



- ▶ Draft second-tier documents, which determine the procedure and maintenance of the Register of Chemicals and Mixtures of the Eurasian Economic Union, as well as the procedure for the Notification of New Chemicals in the framework of the TR EAEU 041/2017, are available in the public portal of the Union for public discussion and are expected to be revealed soon.

## Part 2. Description of the Inventory of existing substances in Russian Federation

- ▶ In the Russian Federation, chemical substances Inventory formation is a part of a timed action plan\* aimed at preparing the industry for the entry into force of the Technical Regulation of the Eurasian Economic Union “On the Safety of Chemical Products” (known as TR EAEU 041/2017).



# Key points:

## Purpose of the Inventory

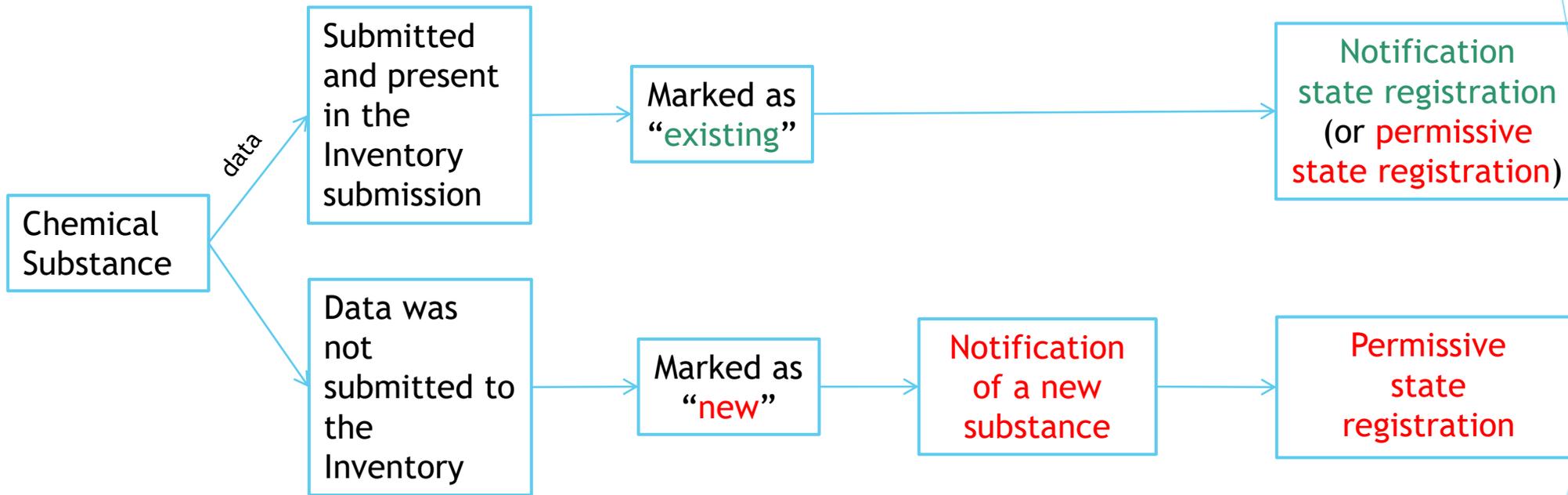
- ▶ The data submission to the Inventory is the first stage in the formation of the national part of the Register of Chemical Substances and Mixtures of the Union.

Chemical substances inventory is a voluntary procedure in which a company has the right to submit data on chemical substances for inclusion in the inventory list, thereby declaring them as “existing” in the customs territory of the Union.

- ▶ The data obtained from the Inventory submission will serve as the basis for the formation of the national part of the Register of Chemicals and Mixtures of the Union.

# Key points:

## Purpose of the Inventory



- ▶ The presence of information on a chemical substance in the register after the entry into force of the requirements of the TR EAEU 041/2017 will eliminate the necessity of identifying this substance as a “new one” for the customs territory of the Union and therefore avoid the “**Notification of a new chemical substance**” - a comprehensive study of hazardous properties and a chemical safety report (stated in the Section 11 of the TR).

# Key points:

## Why do you need to participate in the inventory

- ▶ After the entry force of the TR EAEU 041/2017 in the 2021, all chemical substances that are not in the Register will be considered as “new” for the customs territory of the Union. Before the releasing of any chemical product containing such new substance to the EAEU market, you must undergo a procedure of [notifying a new substance](#).

**Notification of a New Chemical Substance** is a comprehensive study of hazardous properties and analysis of risks to human health and the environment with filling in a chemical safety report. It is expected that only really new and unexplored chemicals will undergo notification procedure.

- ▶ Right now, at the inventory stage, the regulator requests a piece of minimum information on chemical substances. The submission of information does not require the attaching of any documents confirming the fact of a substance circulation in the Russian Federation.

# Requirements for inventory submission

- ▶ All chemical substances as such or within the mixture that your company is releasing or just planning to release for Russian (or Union) market are subject of inventory.
- ▶ For chemical product released for Union's market as a chemical substance, you need to do an inventory of the **main component** and **all impurities** and **supplements** presented in a concentration of **more than 0.1%** (by weight).
- ▶ For **mixtures**, it is necessary to take into account all components presented in their composition in a concentration of **more than 0.1%** (by weight). In a case, if some substance is present in a concentration of less than 0.1%, but there is a probability of increasing of content - it is **officially recommended** putting such substance into inventory, too.

The **substances can be excluded** from the inventory submission process **if they are a part of** chemical products that specified in **Annex 1** of TR EAEU 041/2017

# Requirements for inventory submission

## About polymers and complex substances:

- ▶ Information about polymers is presented for monomers and all additives (plasticizers, polymerization activators, etc.) at a concentration of more than 0.1% according to the recipe.

Due to the high variety of polymers, notification of them is not applicable and information about them is optional for the inventory.

- ▶ Information on substances with a complex and variable composition (which cannot be identified on the basis of molecular and structural formulas and are determined by the production technology, feedstock, typical component content and characteristic physicochemical parameters) is presented for the chemical substance as a whole (without separation on components) with the CAS identification number assigned to it (if any).

# Requirements for inventory submission

## Information presented at the inventory stage includes:

- ▶ a) Chemical identification numbers, including:
  - CAS number (mandatory information, unless CAS number is not applicable);
  - EU number (mandatory information, unless CAS number is not applicable);
  - RTECS number (if available);
  - code of foreign trade activities of the EAEU (if available);
  
- ▶ b) The name of the chemical, including:
  - name according to IUPAC nomenclature in Russian (mandatory information);
  - name according to IUPAC nomenclature in English (mandatory information);
  - name in English (mandatory information);
  - synonyms (must be in Russian language only);
  - abbreviations;

# Requirements for inventory submission

## Information presented at the inventory stage includes:

- ▶ c) Molecular formula;
- ▶ d) Structural formula (preferably in the «InChi=» format);
- ▶ e) Uses;
- ▶ f) The volume of production (import), tons / year - **the average value for the last 3 years or the planned amount** - (confidential information)

If a substance is supplied to the RF market **only as part of a mixture or polymer**, then the field is filled with the phrase “**as part of the mixture**” or “**as part of the polymer,**” respectively;

- ▶ g) Hazard classification (types and hazard classes) according to **GOST 32419** and **GOST 32424**;

# Requirements for inventory submission

## Information presented at the inventory stage includes:

- ▶ h) information about the manufacturer (the person authorized by the manufacturer) or the importer of the chemical substance, including:
  - full name of the organization (in accordance with the constituent documents);
  - short (abbreviated) name of the organization (if any);
  - applicant category: manufacturer or person authorized by the manufacturer or importer;
  - address;
  - telephone (to clarify the data as part of the inventory);
  - e-mail (to clarify the data as part of the inventory).

# Requirements for inventory submission

## Who can submit the data on substances and when:

- ▶ In Russian Federation, data may be submitted only by the resident of Russian Federation (Russian legal entity).
- ▶ A foreign company can appoint a Russian representative by a mutual agreement for data submission.

In accordance with a letter from the Ministry of Industry and Trade № ИМ-28857/13 of April 4, 2020 due to the COVID-19 the deadline for submitting data as part of the inventory is set until August 1, 2020.

The deadline has been previously postponed 2 times since 2019, so we believe that this will be the last postponement.

# How can we help you?

Currently EcoVostok offers applicant services for foreign chemical exporters to Russian Federation for conducting the inventory as well as consulting services about the coming of the TR EAEU 041/2017 into force.

Feel free to contact us:



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**Thank you for your attention!**

2020

# Technical Regulation №041/2017 (“EAEU REACH”)

SDS (Safety Passport) in Russia vs. REACH SDS

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**CIRS**



**REGARTIS**  
ART OF REGULATORY

# Introduction

- In February 2020 two Czech regulatory consultancies EcoMole s.r.o. and ReachSpektrum s.r.o. joint their regulatory efforts under the wings of REGARTIS s.r.o.
- Building on experience in the area of chemical regulatory affairs, supported by scientific and practical background, our team ensures high quality services in assisting you to place your products on the European market.
- Together with our partners, we are offering the compliance services in other countries.



[www.regartis.com](http://www.regartis.com)

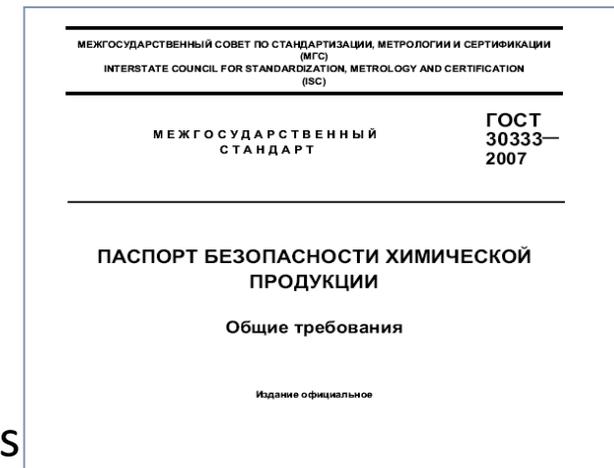


# Compilation of the SDSs

The SDS should be compiled in line with the requirements of ...

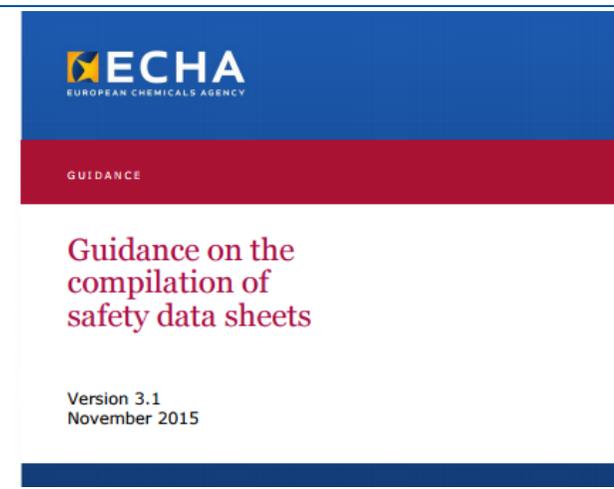
## *EAEU – REACH*

- GOST 30333-2007 – structure and section's content requirements ( Safety Passport)
- P 50.1.102-2014 Recommendations for Standardization of the SDS compilation Russian language
  - Section IX, Art. 36-43 – SDS main requirements



## *REACH SDS*

- Art. 31 REACH
- Annex II (Regulation 2015/830)
- Guidance on the SDS compilation



# Compilation of the SDSs

For which chemical products the SDS should be compiled mandatorily without request:

## *EAEU - REACH*

“For all chemical products released on the Eurasian Union market”

- Chemical substance
- Mixture
- Material
- Production waste products

## *REACH*

Substance classified as hazardous according to CLP; or PBT, vPvB; or included in Candidate List REACH.

Mixture classified as hazardous according to CLP, or not classified but contain:

- Hazardous substance  $\geq 1\%$  w/w. for non gaseous and  $\geq 0,2\%$  v/v for gaseous mixtures; or
- PBT or vPvB, substance from the Candidate List ( $\geq 0,1\%$  w/w)
- Substance, with the EU workplace exposure limits



# Compilation of the SDSs

## How many SDS should be compiled for various brands of one product?

### *EAEU – REACH*

- **Separate SP should be compiled for one product if:**
  - ❑ trade brands of one product have different physical state;
  - ❑ trade brands require different permits ( i.e. different uses);
  - ❑ trade brands composition / hazardous properties differs;
  - ❑ For the products with the same name, but produced according to different technical documents. ( TU)

### *REACH*

It is allowed to compile one SDS for several brands with using the most strict classification. When the product is the substance – all trade brands should be covered by one registration dossier.



# Compilation of the SDSs

## When to provide the SDS?

### *EAEU – REACH ( Art. 37, 38)*

The SDS should be included in the accompanying documentation to the product.

The SDS is issued prior to the release of chemical products on the territory of the Eurasian Union market.

### *REACH (Art.31.8)*

A safety data sheet shall be provided [...] no later than the date on which the substance or mixture is first supplied.



# Compilation of the SDSs

## To whom the SDS should be provided?

### *EAEU – REACH ( Art. 43)*

- To the authorized body (within the registration requirements)
  - Customers ( purchasers) of product:
    - Legal persons
    - Physical persons individual entrepreneurs
    - Physical persons
- } On request

### *REACH (Art.31.1)*

The Safety Data Sheet shall be provided [...] to the recipient of the substance or mixture.

*Art. 31.4* The SDS for hazardous substances or mixtures offered or sold to the general public

- Need NOT be supplied if the product have sufficient information to enable users to take necessary measures as regards the protection of human health, safety and environment
- Unless requested by a downstream user or distributor.



# Compilation of the SDSs

## Registration of the SDS

### *EUEA – REACH ( Art 39, 40)*

- No requirement for registration in the Eurasia-REACH text. However
- Requirements for the information to be contained in SP are specified in GOST 30333-2007.
- GOST 30333-2007, point. 4.2.9 : the SP is the subject of state registration in the state competent authority.
- The SP original hard copy is kept by the manufacture / importer / authorized person. The original should contain the registration stamp.
- The registration authority from 11.06.2014 - CIC (КИЦ, Coordinating Information Center)

### *REACH*

No registration concept for the SDSs.



# Compilation of the SDSs

## SDS structure

### *EUEA – REACH*

- No requirements for the Title page in Eurasia – REACH and in GOST
- Recommendations for the Title list in P 50.1.102-2014 (p.5.2)
- 16 Sections

### *REACH*

16 Sections

Annexes - Exposure Scenarios according to the uses indicated in the section 1.2. REACH SDS.



# Compilation of the SDSs

## Title page of the Russian SP:

- Information about state registration, SP validity
- Information on the chemical product:
  - Name (technical, IUPAC, trade, synonyms),
  - Code TN VED, OKPD
  - Regulatory document for the product (GOST, TU, OST....)
- Hazard characteristic (signal word, description)
- List of hazardous constituents (with PDK in the air of the working place, hazard class, CAS, EC)
- Information on the submitter
- Emergency telephone number

Систематический номер VVVV по SDS VVVV	РД № 0000000.00 Действителен до	стр. 2 из 2		
<b>ПАСПОРТ БЕЗОПАСНОСТИ ХИМИЧЕСКОЙ ПРОДУКЦИИ</b>				
Внесен в Регистр Паспортов безопасности				
РД № 00000000.20	00 г. «	20__ г.		
	Действителен до «	202__ г.		
Ассоциация «Биохимическое партнерство» «Корпоративно-информационный центр государственных СНИП по объектам регулирования» Заместитель директора _____ И.М. Муратов и.о.				
<b>НАИМЕНОВАНИЕ</b>				
техническое (по ИСД)	Синтетический каучук			
химическое (по IUPAC)	Полимер этиленбутадиена с бутадил-1,3-оном			
товарное	Синтетический каучук			
синонимы	англ. JSR NBR520M Synthetic rubber			
Код ОКПД 2	Код ТН ВЭД ЕАЭС			
2 0 - 1 7 - 1 0 - 1 3 0	4 0 0 2 1 9 3 0 0 0			
Условные обозначения и наименование нормативного, технического или информационного документа на продукцию (ГОСТ, ТУ, ОСТ, СТО, МРД)D				
SDS от 14.06.2019 (версия 1.1) компания SUPER COMPANY, (Чехия) на JSR NBR520M				
<b>ХАРАКТЕРИСТИКА ОПАСНОСТИ</b>				
Сигнальное слово	Отсутствует			
Краткая (словесная) характеристика по степени воздействия на организм продукции по ГОСТ 12.1.007. Гормона продукция. Вредна для водных организмов с долгосрочным послепоступком. Подробнее в 16-ти прилагаемых разделах Паспорта безопасности.				
<b>ОСНОВНЫЕ ОПАСНЫЕ КОМПОНЕНТЫ</b>	<b>ПДК р.з., мг/м³</b>	<b>Класс опасности</b>	<b>№ CAS</b>	<b>№ EC</b>
Полимер этиленбутадиена с бутадил-1,3-оном	10 (по полимеру на основе стирол)	4	9005-10-8	611-170-2
2,6-Диэтил-1,4-диоксан-4-карбинол	10,4 (из 4-(1,3-Диметил-2-пропанон))	2	121-17-0	204-881-4
<b>ЗАЯВИТЕЛЬ</b> Супер компания JSR _____ МОСКВА _____ (полное наименование организации) (фамилия, имя, отчество)				
Тип заявителя: производитель, поставщик, импортер, продавец, экспортер (укажите тип заявителя)				
Код ОКПО	0 0 0 0 0 0 0 0	Контактный телефон компании	+420 222 22 22	
Руководитель организации-заявителя _____ Иван Петров _____				

IUPAC	- International Union of Pure and Applied Chemistry (Международный союз теоретической и прикладной химии)
GHS (CTC)	- Рекомендации ООН ST-SG/AC.10/30 «Globally Harmonized System of Classification and Labelling of Chemicals (Согласованная на глобальном уровне система классификации опасности и маркировки химической продукции (CTC))»
ОКПД 2	- Общероссийский классификатор продукции по видам экономической деятельности
ОКПО	- Общероссийский классификатор предприятий и организаций
ТН ВЭД ЕАЭС	- Товарная номенклатура внешнеэкономической деятельности
№ CAS	- номер вещества в реестре Chemical Abstracts Service
№ EC	- номер вещества в реестре Европейского химического агентства
ПДК р.з.	- предельно допустимая концентрация химического вещества в воздухе рабочей зоны, мг/м³
Сигнальное слово	- слово, используемое для акцентирования внимания на степени опасности химической продукции и выбираемое в соответствии с ГОСТ 31340-2013

# Compilation of the SDSs

Structures of both SDSs are similar but the content is different in all sections...

1. Identification of the substance / mixture and of the company
2. Hazards identification
3. Composition / Information on ingredients
4. First aid measure
5. Fire-fighting measures
6. Accidental release measures
7. Handling and storage
8. Exposure control / personal protection
9. Physical and chemical properties
10. Stability and reactivity
11. Toxicological information
12. Ecological information
13. Disposal consideration
14. Transport information
15. Regulatory information
16. Other information



# Section 2. Hazard identification

## *EAEU – REACH*

### 2.1 Degree of the hazard of the chemical product

- Classification and general safety requirements according to GOST 12.1.007-76
- Classification according to GHS (GOST 32419-2013, 32421-2013, 32423-2013, 32424-2013, 31340-2013, 12.1.007-76 ....)

## *REACH*

### 2.1. Classification of the substance and mixture according to CLP



## Section 2. Hazard identification

*Difference between GHS ( GOSTs: 32419-2013, 32421-2013, 32423-2013, 32424-2013, 31340-2013, 12.1.007-76 ... and CLP*

GHS	CLP Regulation
Flammable liquids hazard category 1,2,3,4	Flammable liquids hazard category 1,2,3
Acute toxicity ( health) hazard category 1,2,3,4,5	Acute toxicity ( health) hazard category 1,2,3,4
Skin corrosion / irritation hazard category 1,2,3	Skin corrosion / irritation hazard category 1,2
Serious eye damage/eye irritation hazard category 1, 2A, 2B	Serious eye damage/eye irritation hazard category 1, 2
Respiratory of skin sensitization hazard category 1A, 1B	Respiratory of skin sensitization hazard category 1
Aspiration toxicity category 1, 2	Aspiration toxicity category 1
Hazardous to the aquatic environment ( acute toxicity) category 1,2,3	Hazardous to the aquatic environment ( acute toxicity) category 1



# Section 2. Hazard identification

## *EUEA – REACH*

*According to GOST 12.1.007, as per the degree of exposure to the human body, the fraction of normal pentane belongs to hazard class 4 ( low hazard substance) .  
Flammable liquid. Vapors form explosive mixtures with air. May cause drowsiness or dizziness. Contact with skin and eyes causes irritation. Toxic to flora and fauna with long lasting effects.*

Example:  
N-pentane

## *REACH*

<u>Hazard identification</u>	<u>Hazard classes/categories</u>
EUH066	Skin Irrit. 2
H225	Flammable Liquid cat. 2
H304	Aspiration Hazard cat. 1
H336	STOT SE 3
H411	Hazardous to the aquatic environment - chronic cat. 2



# Section 2. Hazard identification

## *EUEA – REACH*

Symbols



Signal word



Опасно



Precautionary measures

Держать в герметичной таре. Беречь от источников воспламенения. Не курить. Использовать взрывобезопасное оборудование и освещение. Беречь от статического электричества. Использовать искробезопасный инструмент. Хранить в прохладном, хорошо вентилируемом месте. Использовать средства индивидуальной защиты органов дыхания, глаз, кожи. Избегать вдыхания паров.

Example  
N-pentane

## *REACH*

Signal word

Danger

Pictograms



Precautionary phrases

P210  
P243  
P301+P310  
P331

Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.  
Take precautionary measures against static discharge.  
IF SWALLOWED: Immediately call a POISON CENTER/doctor/physician.  
Do NOT induce vomiting.



# Section 3. Composition / Information on ingredients

## *EUEA – REACH*

### 3.1 Product information

3.1.1 Chemical name (IUPAC)

3.1.2 Chemical formula

3.1.3 General characteristics of the composition ( method of production, assortment)

3.2 Constituents (**full composition**), PDK (max. acceptable concentration in the work place or OBUV ( estimated safe exposure levels of hazardous substances in the air of the working area), hazard classes, source of information.)

*“it is planed to work out the rules of exchange of confidential information”*

*GOST R 57443-2017 on identification – Data on the components should be provided to the extent that can guarantee safety of human and environment.*

*GOST R 31340-2013 on labelling - all components contributing to the hazardous profile of the product should be mentioned on the label.*

*GOST 30333-2007 - all components contained in the product in concentration 0,1% and above should be indicated.*



# Section 3. Composition / Information on ingredients

*EUEA – REACH*

*Management of Confidentiality?*

*How to proceed if one or more components in the product are confidential?*

*1 way* to indicate the concentration range, if confidentiality applies on this and not on the identification parameters:

*2 way* Only for the constituents of 3 and 4 hazardous classes - Instead of the chemical nature of the constituent to indicate its function. For example: NOT citric acid, BUT acidity regulator. And if you are “hiding” component which have the PDK (concentration limits for the work place) it is still have to be mentioned in the SP.

*3 way* Test the product and show all hazards in the tests protocols. This will allow not to disclose the composition at all.

For first two ways the full composition should be provided to the competent authority for the SDS verification and registration.



# Section 3. Composition / Information on ingredients

## *REACH*

### 3.1. Substance

Identification parameters of the substance (name, EC No, CAS No, Index No), registration number, concentration (range), CLP classification, description of hazardous impurities

## *REACH*

### 3.2. Mixture:

- Identifier, concentration range, classification and labelling according CLP for all constituents classified as hazardous for human health, or PBT/vPvB.... And contain in the mixture in the concentrations exceeding the concentration limits
- Registration numbers of the mixture components
- Alternative names of the constituents, when ECHA confirmed.



# Section 3. Composition / Information on ingredients

## *EUEA – REACH*

Component	Mass fraction, %	PDK wp, mg/m <sup>3</sup>	Hazard class
Н-пентан, не менее (CAS 109-66-0))	95%	900/300	4

Example:  
N-pentane

## *REACH*

### Identification parameters

#### **1 mL C-Test mixture in n-pentane**

Chemical: <i>n-pentane</i>		CAS No.: 109-66-0
Concentration: 80 - <100 %		
Formula: C <sub>5</sub> H <sub>12</sub>		
REACH Reg. No.: 01- 2119459286-30-xxxx		
EC No.: 203-692-4	Indice No.: 601-006-00-1	
RTECS: RZ9450000	MFCD: 00009498	
TSCA Inventory: listed		
KE No.: KE-27968		
acc. 1999/45/EC: R 12-51/53-65-66-67	acc. CLP (GHS): H225, H304, H336, H411, EUH066	
Chemical: <i>test chemical(s) (ppm)</i>		CAS No.: -
Concentration: 0,01 - <0,1 %		
acc. 1999/45/EC: -	acc. CLP (GHS): not necessary	

Classification





# Russian Safety Passport in future and TR 041/2017

**According to TR 041/2017 Safety Passport is the obligatory document to be provided within the state registration of chemical product**

**From of 01 June 2022 the new SP GOST R 58475-2019 will come into force (in case there will be no interstate SP GOST)**



**ПАСПОРТ БЕЗОПАСНОСТИ  
ХИМИЧЕСКОЙ ПРОДУКЦИИ**

**Общие требования**

Издание официальное



# Russian Safety Passport for the imported chemical products – messages to “take home”

*Currently ALL chemical products imported into Russian market should be accompanied by the Safety Passport compiled in accordance with GOST.*

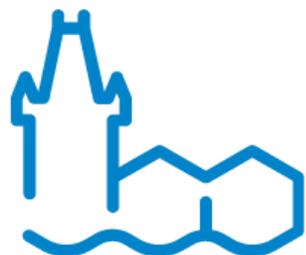
The Safety Passport can be compiled by the experts based on:

- REACH-like SDS in English language
- REACH-like SDS translated into the Russian language

All SDSs are the subject of the state registration, which is accompanied with the fee. The fee depends on the timeline of the registration processing.



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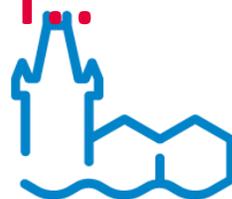
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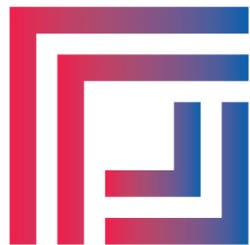
**THANK YOU for your attention, I will be happy to answer your questions...**



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**+420 774 183 227**



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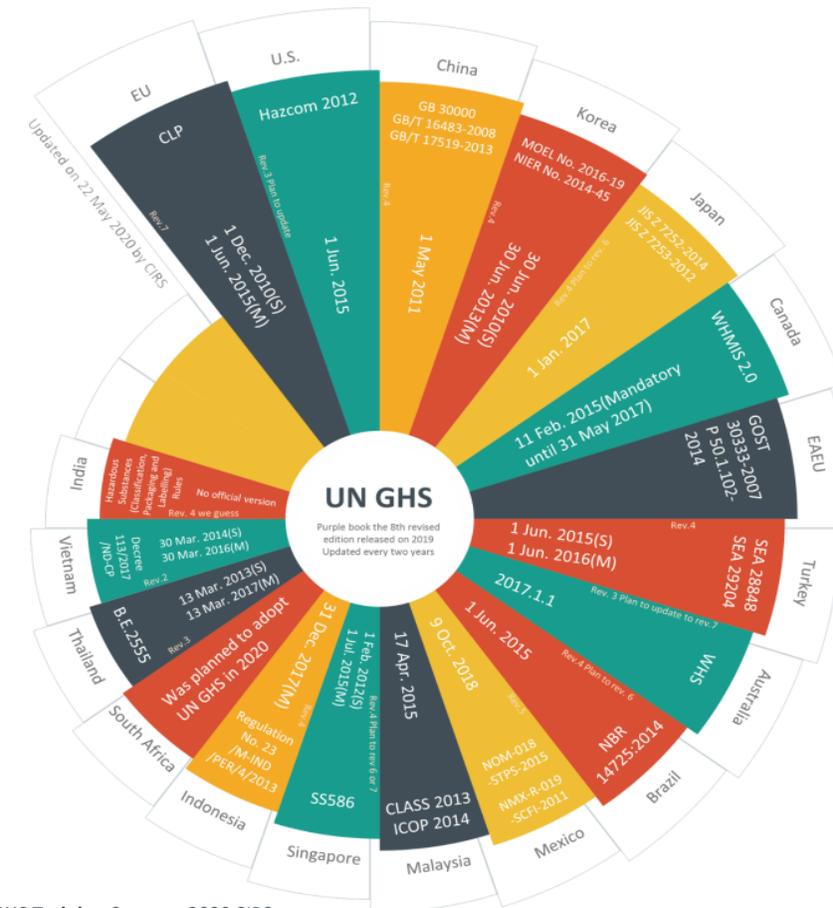


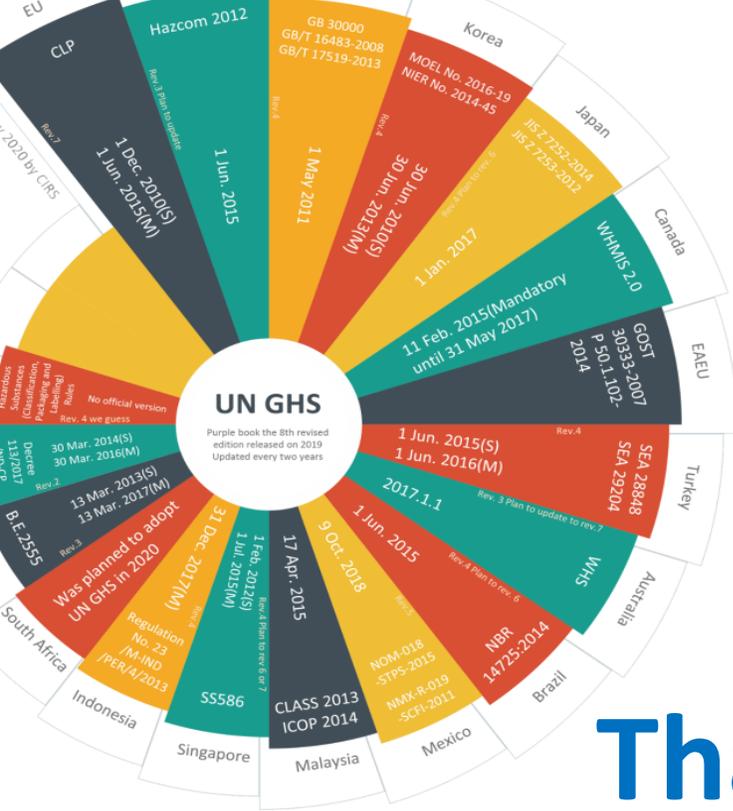
# Q&A section

Following our event, please always click

<http://www.cirs-reach.com/news-and-articles/2020-CIRS-Training-Courses-Global-GHS.html>

to find out the updates





**Thank you for your attention!**

