



Coordinating Informational Center
of CIS Member States on approximation of regulatory practices

How to be ready for TR EAEU 041/2017, including SDS development under GOST 30333

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TR EAEU 041/2017 State registration timing

If an imported chemical product is a **SUBSTANCE**

Tonnage for one legal entity (LE) per year	START of state registration (DRAFT Decision)
> 1000 t/y	as soon as TR EAEU 041/2017 comes into force (30 November 2022 - at the earliest)
100-1000 t/y	30 November 2024
1-100 t/y	30 November 2026
< 1 t/y	Additional decision (Must be resolve by 30 November 2028)

If an imported chemical product is a **MIXTURE**

Tonnage for one LE per year	START of state registration (DRAFT Decision)
> 1000 t/y	30 November 2027
100-1000 t/y	30 November 2029
10-100 t/y	30 November 2031
< 1 t/y	Additional decision (Must be resolve by 30 November 2028)



Please note:

1. Timing may be changed by the Decision of EEC and EAEU members
2. Timing is applicable only for state registration
3. SDS under GOST 3033 and labelling under 31340 are required from the date TR EAEU 041/2017 comes into force



The main steps **after the date TR EAEU 041/2017 comes into force**

If your produced or exported chemical products which include into the area of distribution of TR EAEU 041/2017 follow the next steps



If there is no vertical technical regulation for your products



Only representative at EAEU territory



Choose the country



AM



BY



KZ



KG



RU

If there is a vertical technical regulation for your products



After the entry into force of the TR EAEU 041/2017 you need to have on products: a safety data sheet and a warning labeling

Link where you can see the responsible authorized bodies in the EAEU countries

http://www.eurasiancommission.org/ru/act/texnreg/deptexreg/tr/Pages/notified_body.aspx



Set of documents

Permit state registration



1. Application (form in Appendix No. 5 to TR)
2. Safety data sheet (information according to GOST 30333)
3. Research (test) protocols and (or) 4. documents with information from their official sources (if any)
4. Information specified in clause 48 (notification)
5. Other documents at the choice of the applicant

Notification state registration



1. Application (form in Appendix No. 5 to TR)
2. Safety data sheet (information according to GOST 30333)
3. Research (test) protocols and (or) documents with information from their official sources (if any)
4. Other documents at the choice of the applicant



SDS the main document for any kind of registration!



The SDS under GOST 30333 is not developing for:

- minerals in a state of occurrence
- finished medicinal products and finished veterinary medicinal products
- finished perfumery and cosmetic products
- radiating, nuclear and radioactive substances
- finished food products, including biologically active food additives, food additives and ready-made animal feed
- smoking and non-smoking tobacco products
- liquids for electronic nicotine delivery systems
- products, including medical devices



The main differences



Information sheet



List of used data sources



Language



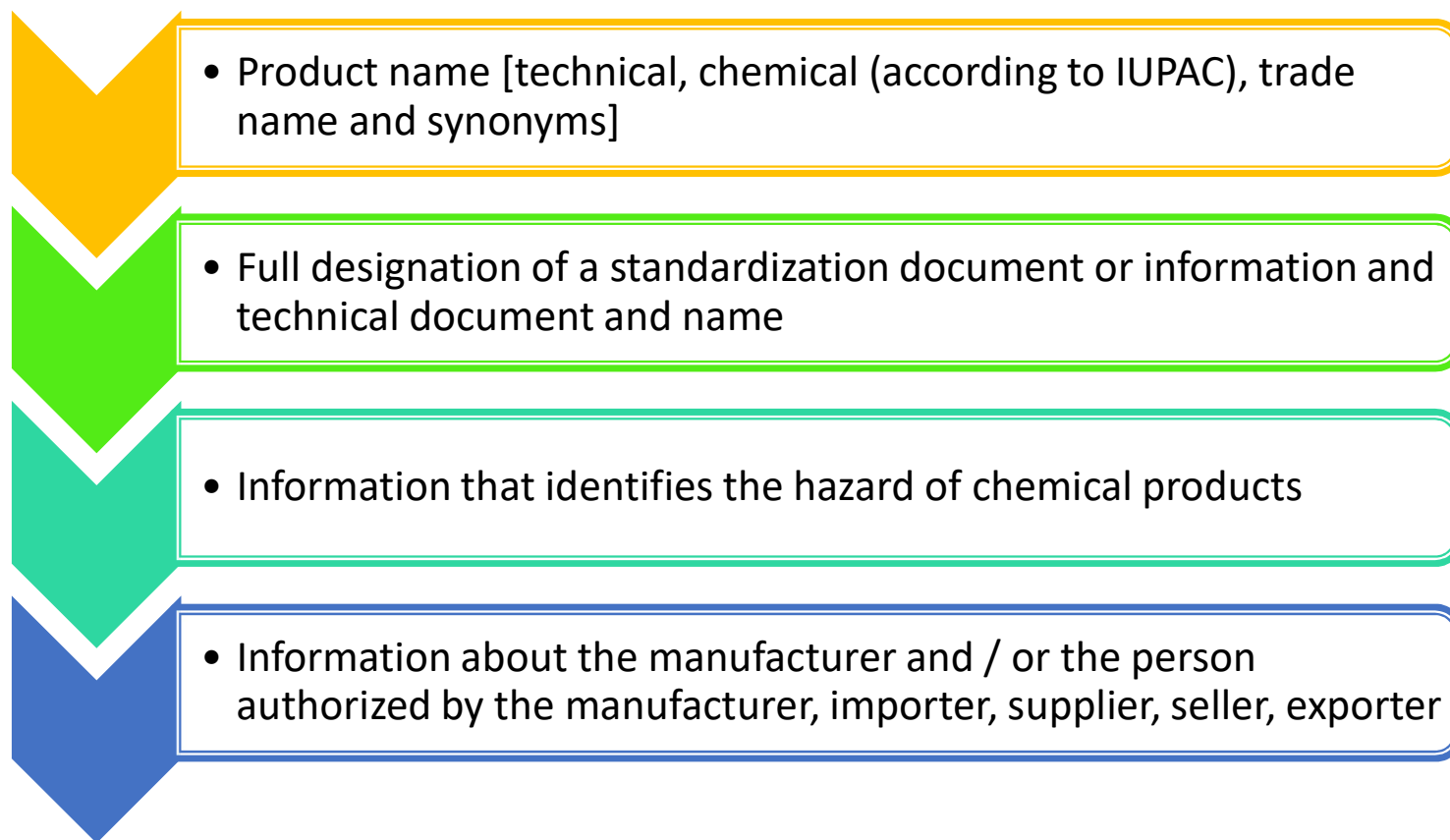
Section content of the Russian SDS

№ section	Section content
1.	IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/ UNDERTAKING
2.	HAZARDS IDENTIFICATION
3.	COMPOSITION/INFORMATION ON INGREDIENTS
4.	FIRST AID MEASURES
5.	FIRE-FIGHTING MEASURES
6.	ACCIDENTAL RELEASE MEASURES
7.	HANDLING AND STORAGE
8.	EXPOSURE CONTROLS/PERSONAL PROTECTION
9.	PHYSICAL AND CHEMICAL PROPERTIES
10.	STABILITY AND REACTIVITY
11.	TOXICOLOGICAL INFORMATION
12.	ENVIRONMENTAL INFORMATION
13.	DISPOSAL CONSIDERATIONS
14.	TRANSPORT INFORMATION
15.	REGULATORY INFORMATION
16.	ADDITIONAL INFORMATION



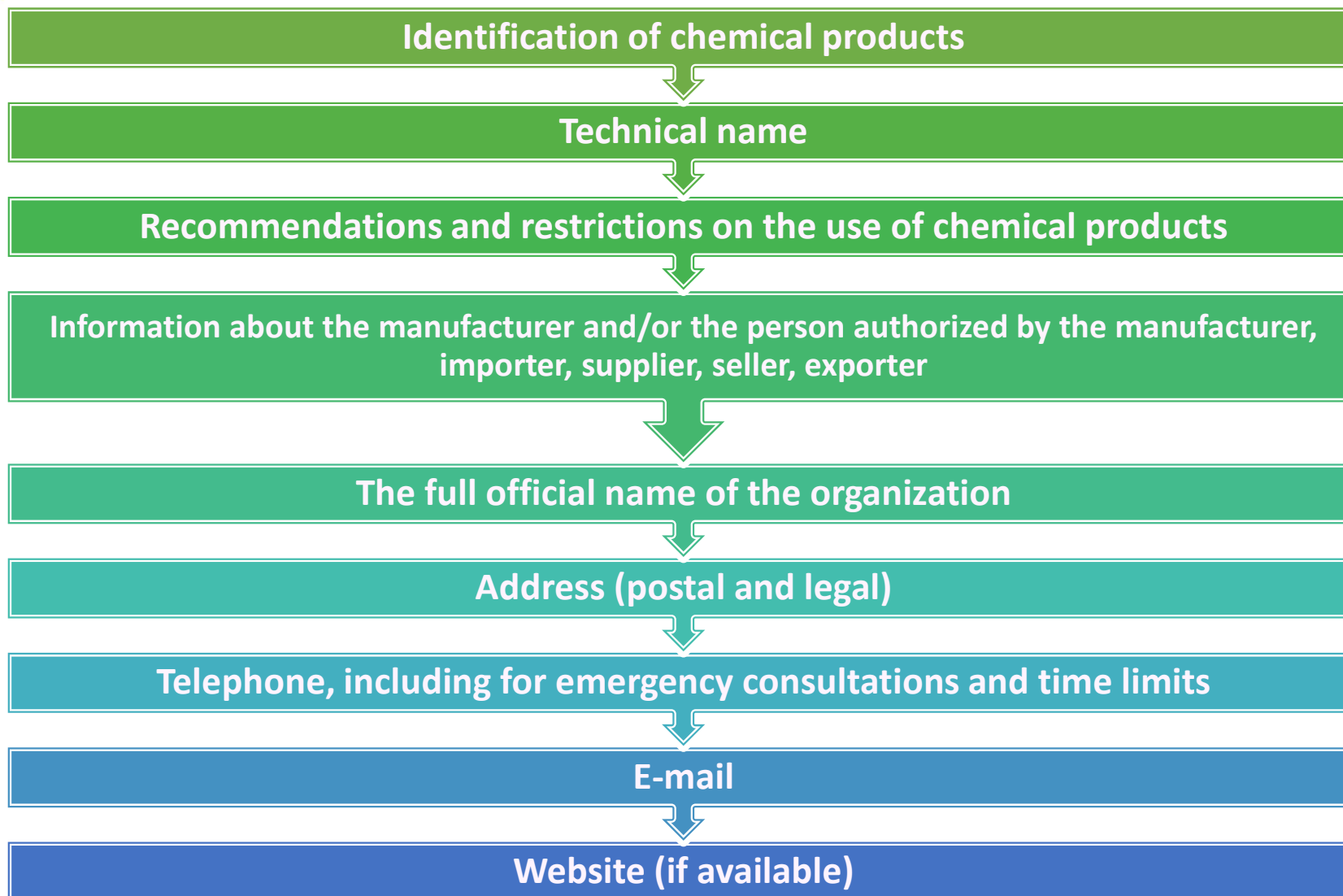
Information sheet

The SDS should contain a brief summary/conclusion of the data given, making it easy even for non-experts in the field to identify all the hazards for the hazardous substance/mixture





1 section Identification





2 section GHS label elements (as per GOST 31340-2013)

2. GHS label elements (as per GOST 31340-2013)

2.1. Classification of the substance or mixture:

(information on hazard classification in accordance with the Russian legislation (GOST 12.1.007-76) and GHS (GOST 32419-2013, GOST 32423-2013, GOST 32424-2013, GOST 32425-2013))

2.2. GHS label elements (as per GOST 31340-2013)

2.2.1 Signal word

2.2.2 Hazard symbol(s):

2.2.3 Hazard statement(s):

2. GHS label elements (as per GOST 31340-2013)

2.1. Classification of the substance or mixture:

(information on hazard classification in accordance with the Russian legislation (GOST 12.1.007-76) and GHS (GOST 32419-2013, GOST 32423-2013, GOST 32424-2013, GOST 32425-2013))

Substance hazard category 4 (low-hazard substance) in accordance with the Russian legislation (GOST 12.1.007-76) [1,2].

According to GHS:

- flammable liquid, hazard category 1;
- aspiration hazard, hazard category 1;
- skin corrosion/irritation, hazard category 2;
- serious eye damage/eye irritation, hazard category 2B;
- specific target organ toxicity, single exposure, hazard category 3;
- carcinogenicity, hazard category 1B;
- germ cell mutagenicity, hazard category 1B;
- reproductive toxicity, hazard category 1B;
- hazardous to the aquatic environment: long-term (chronic), hazard category 2 [3-7].

2.2. GHS label elements (as per GOST 31340-2013)

2.2.1 Signal word

2.2.2 Hazard symbol(s):

Danger [8].



Flammable [8].

Health hazard [8].

Harmful [8].

Environmental hazard [8].

2.2.3 Hazard statement(s):

H224: Extremely flammable liquid and vapour

H304: May be fatal if swallowed and enters airways

H315: Causes skin irritation

H320: Causes eye irritation

H336: May cause drowsiness or dizziness

H350: May cause cancer

H340: May cause genetic defects

H360: May damage fertility or the unborn child



3 section Composition (information on ingredients)

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

The product is a substance within the meaning of the REACH Regulation (1907/2006/EC).
The following table contains the main constituent at the top.

Chemical Name	Concentration, wt. %	CAS-No	EC-No Registration number	Index-No	CLP

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

3. Composition (information on ingredients)

3.1 General information about the product

3.1.1. Common chemical name
(IUPAC name)

Not applicable [1].

3.1.2. Chemical formula

Not applicable [1].

3.1.3. General description of the composition
(considering brand assortment; production process)

The products are obtained as a result of the processing of oils and gas condensates from various fields. Depending on the physical and chemical indicators, the products are produced in the form of grades A and B [1].

3.2. Ingredients

(chemical name, CAS and EC numbers, weight range totaled up to 100%, MAC (maximum allowable concentration) or SRLI (Safe Reference Levels of Impact) in the working zone area and hazard category (as per Russian exposure standard 2.2.5.3532-18), reference to data sources)

Table 1 [9,10]

Ingredients (chemical name)	Weight range, %	Exposure standards in the working zone area		№ CAS	№ EC
		MAC mg/m ³	Hazard category		
Stable gasoline	up to 100	300/100 vapour	4	8032-32-4	232-453-7



4 section First-aid measures

Observed symptoms

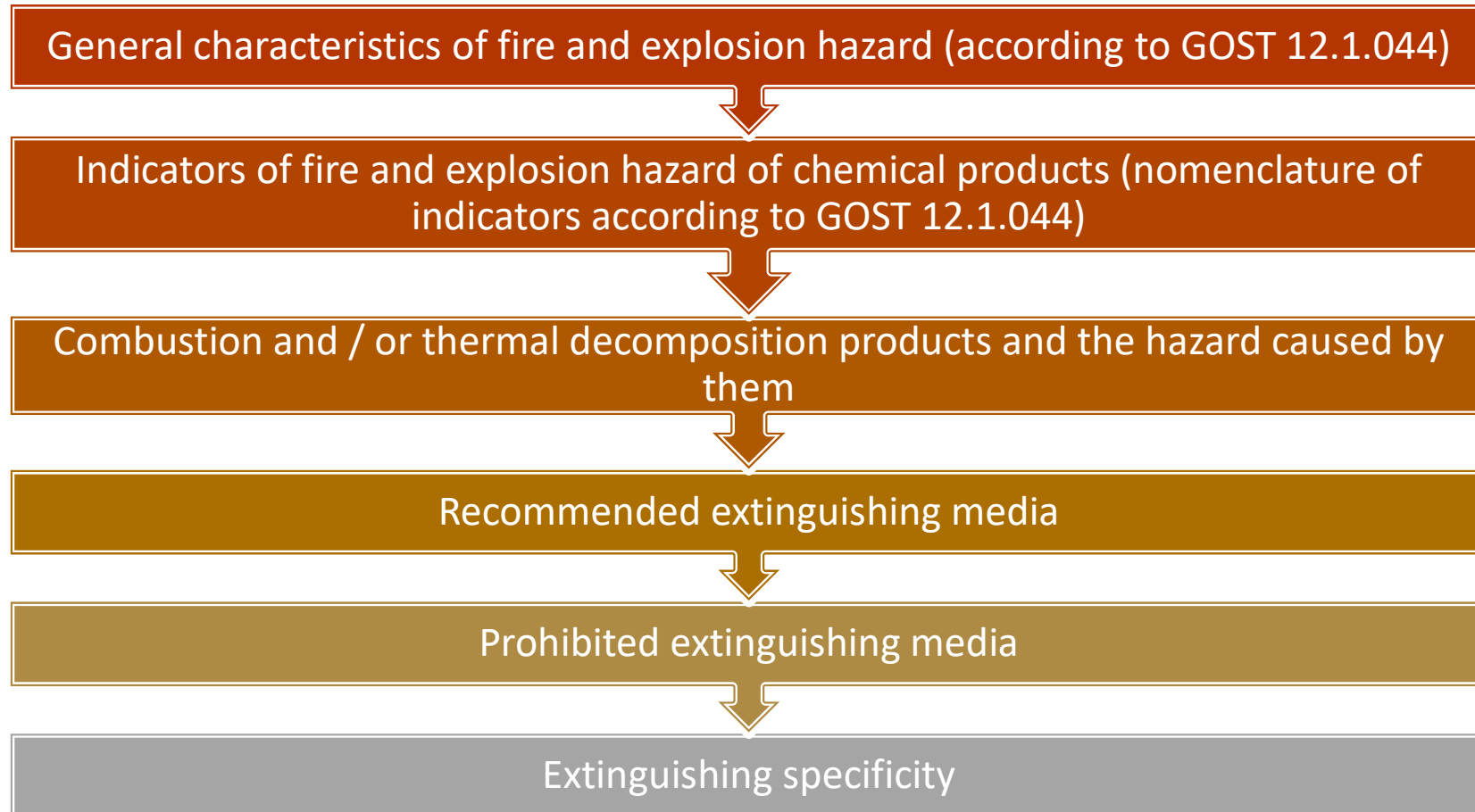
- In case of poisoning by inhalation (by inhalation)
- When exposed to the skin
- Eye contact
- For oral poisoning (if swallowed)

First aid measures for victims

- In case of poisoning by inhalation
- When exposed to the skin
- Eye contact
- In case of oral poisoning
- Contraindications



5 section Fire-fighting measures





6 section Measures to prevent and mitigate emergency situations and consequences

Measures to prevent harmful effects on people, the environment, buildings, structures, etc. in emergencies and emergencies

- General actions required in case of emergency and emergency situations
- Personal protective equipment in emergency situations (PPE of emergency teams)

Procedure for the elimination of emergencies and emergencies

- Actions in case of leaks, spills, spills (including measures for their elimination and precautions to ensure environmental protection)
- Fire action



7 section Handling and storage

Safety precautions when handling chemical products

- Engineering safety systems (including the organization of local and general ventilation, requirements for electrical equipment, measures to eliminate static electricity)
- Environmental protection measures
- Recommendations for safe handling and transportation

Storage rules for chemical products

- Conditions and terms of safe storage (including the warranty storage period or warranty period, shelf life or storage period); substances and materials incompatible during storage
- Containers and packaging (including materials from which they are made)
- Safety measures and rules of storage at home



8 section Exposure controls and personal protective equipment

The parameters of the working area, subject to mandatory control, in accordance with the requirements of the country (countries) on the market of which the products are circulated

Measures to ensure the content of harmful substances in permissible concentrations

Personal protective equipment for staff

- General recommendations
- Respiratory protection (types of RPE)
- Protective equipment (classification by purpose depending on protective properties and designation) (overalls, safety footwear, hand protection, eye protection)
- Protective equipment for household use



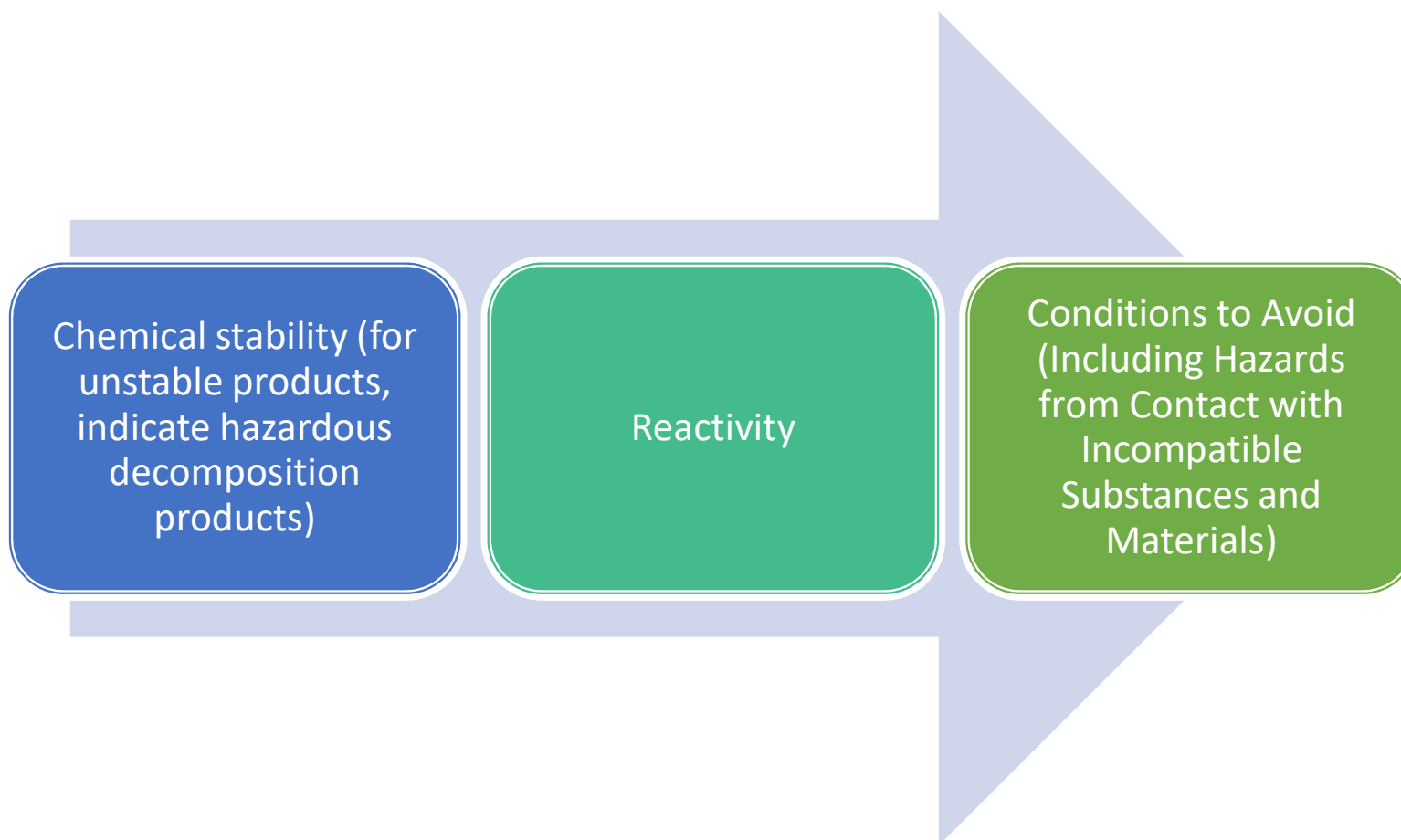
9 section

Physical and chemical properties

- Physical state (including state of matter)
- Colour
- Smell
- Melting point / freezing point
- Boiling point / boiling point / boiling range
- Flammability
- Upper and lower explosion limits / flammability limits
- Flash point
- Autoignition temperature
- Decomposition temperature
- pH
- Kinematic viscosity
- Solubility
- Coefficient of propagation n-octanol / water
- Vapor pressure
- Density and / or relative density
- Relative vapor density
- Parameters of solid particles



10 section Stability and reactivity





11 section Toxicological information

General characteristics of fire and explosion hazard (according to GOST 12.1.044)



Routes of exposure (inhalation, oral, skin and eye contact)



Affected organs, tissues and systems of a person



Information on health hazards resulting from direct contact with products, as well as the consequences of these effects (irritant effect on the upper respiratory tract, eyes, skin; skin resorptive and sensitizing effects)



Information about hazardous long-term effects of product exposure on the body (effect on reproductive function, carcinogenicity, mutagenicity, cumulativeness and other chronic effects)



Indicators of acute toxicity (LD50 (LD50), route of intake, animal species; LC50 (LC50), exposure time (h), animal species) It is allowed to give indicators obtained by theoretical or calculated methods



12 section Ecological information

12 Ecological information

12.1 Possible impact of the product to the environment; general description:
(air, water, soil)

12.2 Routes of releasing to the environment

In case of violation of the rules of handling, storage, transportation; unorganized disposal, burial or incineration of waste; as a result of accidents and emergencies.

12.3 The most important characteristics of the environmental impact:

12.3.1 Exposure standards:

(allowable concentrations in the air, water bodies, including fishing waters, soil)

Table 2 [...]

MAC or SRLI for atmospheric air mg/m ³ (LPV ¹ , hazard category)	MAC or SRLI for water ² , mg/l, (LPV, hazard category)	MAC or SRLI for fishing waters ³ , mg/l, (LPV, hazard category)	MAC or SRLI for soil, mg/kg (LPV)

12.3.2 Parameters of ecotoxicity:

(LC, EC for fish (96 h.), daphnia Magna (48 h.), algae (72 or 96 h.) etc.)

12.3.3 Migration and transformation in the environment due to biodegradation and other processes:

(oxidation, hydrolysis etc.)

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

Toxicity to fish:

Toxicity to daphnia and other aquatic invertebrates:

Toxicity to aquatic plants:

Long-term study fish/daphnia and other aquatic invertebrates/aquatic plants:

12.2 Persistence and degradability

12.3 Bioaccumulation potential

12.4 Mobility in soil

12.5 Results of PBT assessment and vPvB

12.6 Other adverse effects

Additional ecological information :



13 section Disposal considerations

Safety measures when handling waste generated during application, storage, transportation

Information about the places and methods of neutralization, utilization, burial or destruction of product wastes, including containers (packaging)

Recommendations for the disposal of waste generated during the use of products in everyday life



14 section Transport information

UN number (UN)

Proper shipping and shipping name

Applied modes of transport

Classification of cargo hazard according to GOST 19433

Hazard classification of cargo in accordance with (including packing group)

Manipulation signs in accordance with GOST 14192

Emergency cards (for rail, sea and other transportation)



15 section National legislation

Legislation of the country (countries) on the market of which the goods are traded
(Chemical control laws)

Information about the documentation
regulating the requirements for the
protection of humans and the environment

International conventions and agreements
(the Montreal Protocol, the Stockholm
Convention, etc.)



16 section

List of data sources used in compiling the safety data sheet (serial numbers of data sources should be given in each subsection of the SDS in the form of references)

16.2 List of used data sources

1. STO 75163429-005-018 Stable gasoline, grades A and B.
2. GOST 12.1.007-76 Occupational safety standards system. Harmful substances. Classification and general requirements.
3. Information card of a potentially hazardous chemical and biological substance: - Gasoline No. VT-000541 of July 12, 1995.
4. GOST 32419-2013 Hazard classification of chemical products.
5. GOST 32423-2013 Hazard classification of mixed chemical products by their effects on the body.
6. GOST 32425-2013 Hazard classification of mixed chemical products by environmental impact.
7. Information database of registered substances of the European Chemical Agency (ECHA). Access Mode: <http://echa.europa.eu/information-on-chemicals>.
8. GOST 31340-2013 Warning labeling of chemical products. General requirements.



List of Official Chemical Information Sources

- Global Information Portal of the Economic Organization
- Cooperation and Development (OECD) on the properties of chemicals eChemPortal
- TOXNET Databases platform
- INCHEM platform
- Portal of the joint research center European Union ChemAgora
- Online information from the Federal Register potentially hazardous chemical and biological substances
- Database of the European Chemicals Agency ECHA
- HSDB database
- Database of existing substances OECD
- List of carcinogenic factors of the International Agency for Cancer Research (IARC)
- PubChem database
- DART database
- ECOTOX database
- Database of properties of chemical substances GESTIS
- United States Toxicology Database substances and registries of diseases
- Database of properties of active ingredients of pesticides British University of Hertfordshire PPDB (Pesticide Properties DataBase)
- Information system for emergency services WISER



List of Official Chemical Information Sources part 2

- International Chemical Safety Cards ICSC
- Institute of Industrial Safety, Labor Protection and Social partnerships Automated Distributed Information Search System (ARIPS) "Hazardous Substances"
- RTECS database
- CPDB Carcinogenicity Database
- Report on Potential Carcinogens prepared by as part of the US National Toxicology Program (the Report on Carcinogens)
- US database, created in the framework of the national toxicology programs (includes information on toxic properties of substances and the ability to cause long-term effects)
- ChemIDplus database
- Database Haz-Map
- GENE-TOX database
- Databank EnviChem
- Brief document on the international assessment of chemical substances (CICADS) (Concise International Chemical Assessment Document)
- Integrated system containing risk information chemicals, US EPA
- US Occupational Safety and Health Agency database



List of Official Chemical Information Sources part 3

- Japan database containing classification results Chemical Hazards, J-GHS
- European inventory of existing chemicals (EINECS)
- Inventory of existing industrial substances in Australia (AICS)
- List of existing chemicals in Japan
- Register of CAS numbers of chemical abstracts service American Chemical Agency.
- Reaxys database
- Chemical SciFinder Structural Search Database Abstract Service (CAS)
- Portal for the selection of analogous substances SUBSPORT (Substitution Support Portal)
- OECD software product (QSAR Toolbox) for predicting the properties of a chemical based on its structures (structure-activity model)
- Software product (EMKG-Expo Tool) of the Federal German Institute for Occupational Safety and Health for the prediction inhalation effects of solid and liquid substances at work location
- Software tool (AMBIT) developed by The European Council of the Chemical Industry (CEFIC), for prediction of the hazardous properties of chemicals by structural analogs, etc.
- A software tool (BIOTS) developed by CEFIC for predictions of the biotransformation potential of chemicals

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Thank you for your interest!

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