REPUBLIC OF COLOMBIA

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MINISTRY OF HEALTH AND SOCIAL PROTECTION MINISTRY OF LABOR MINISTRY OF COMMERCE, INDUSTRY AND TOURISM MINISTRY OF ENVIRONMENT AND SUSTAINABLE DEVELOPMENT

DECREE No ._____

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"By which the integral management of the chemical substances of industrial use and other determinations are made "

THE PRESIDENT OF THE REPUBLIC OF COLOMBIA

In exercise of the powers conferred in numeral 11 of article 189 of the Political Constitution and in development of article 32 of Decree-Law 2811 of 1974, Law 9 of 1979, Law 55 of 1993 and Law 1523 of 2012,

CONSIDERING:

That the Political Constitution in its article 78 establishes that in accordance with the law "who will be responsible in the production and marketing of goods and services, threaten health, safety and adequate supply to consumers and users " and article 79 states that all people have right to enjoy a healthy environment and that it will be the State that encourages the protection of the diversity and integrity of the environment.

That Article 32 of Decree 2811 of 1974, provides that in order to prevent environmental deterioration or damage to the health of man and other living beings, Requirements and conditions for importation, manufacturing, transportation, storage, marketing, management, employment or disposal of toxic or dangerous substances and products.

That in letter e) of article 80 of Law 09 of 1979, is established among others aspects, as one of the objectives of this law is to protect the population against health risks from production, storage, transport, sale, use or disposal of substances dangerous to health public. In turn, Article 104 states that in the face of agent control chemical and biological resources and, in particular, their disposal must be carried out in way that does not cause environmental pollution even outside the workplace, and article 132, that people who carry out transport, employment or

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disposal of hazardous substances during which damage occurs for the public health or the environment, will be responsible for the damages.

That in this sense, Law 9 of 1979 in articles 130 to 135, establishes that in the Ministry of Health, today the Ministry of Health and Social Protection resides competition for the adoption of various measures for the handling of substances chemicals throughout its production chain, among which are foreseen, registration, labeling and prohibition of chemical substances.

That numerals 10, 14 and 25 of article 5 of Law 99 of 1993, indicate how

functions of the Ministry of Environment and Sustainable Development those of: i) on environment to which activities should be subject mining, industrial, transport and in general any service or activity that can directly or indirectly generate environmental damage; ii) define and regulate administrative instruments and mechanisms necessary for the prevention and control of environmental deterioration factors and determine the criteria for environmental evaluation, monitoring and management of economic activities; iii) regulate the manufacture, distribution, use, disposal or dumping of substances causing environmental degradation.

That numeral 25 of article 2 of Decree-Law 210 of 2003, as amended by the Decrees 4269 of 2005 and 4176 of 2011, establish as a function of the Ministry of Trade, Industry and Tourism, bring the foreign trade register of importers and exporters, of national production, of marketers international organizations, users of free zones, exporting associations and the national production, technology contracts and other trade users outside, and issue the relevant certifications.

That Article 45 of Law 489 of 1998 empowers the National Government to create intersectoral committees for the coordination and superior guidance of the execution of certain public functions and services, without prejudice to the specific competences of each of them.

That the document CONPES 3868 of 2016 "Policy of associated risk management to the use of chemical substances ", seeks to integrate processes consistently of risk management and the life cycle stages of chemical substances in industrial use, recommending the establishment of the technical and regulatory elements for managing the risk associated with the use of chemical substances for use industrial.

That the United Nations (UN), with the participation of the International Labor Organization (ILO) and other organizations, has developed the Globally Harmonized System for the Classification and Labeling of Chemical Products (SGA), with the objective of normalizing and harmonizing the classification and communication of hazards of chemical products.

That the National Government, through inter-institutional work in which the Ministries of Environment and Sustainable Development participated; Health and Social Protection; of Labor and Commerce, Industry and Tourism, developed different instruments for the management of chemical substances for industrial use, for the sake of protecting human health and the environment. Page 3

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That taking into account all of the above, it is necessary to adopt the instruments for the management of chemical substances for industrial use.

In light of the foregoing,

DECREE:

TITLE I

GENERAL DISPOSITION

UNIQUE CHAPTER

Object, scope and definitions

Article 1. *Object*. The purpose of this decree is to protect health and the environment, through the adoption of mechanisms and other provisions for the management of chemical substances for industrial use, whether or their homogeneous mixtures, which meet the requirements laid down in through the annex that is incorporated as an integral part of this decree.

Article 2. *Scope of application.* The provisions contained in this decree are applied throughout the national territory to natural and legal persons manage the substances referred to in the previous article, within the framework of its activities of production, import, use, marketing, distribution or transport.

Paragraph 1. This decree does not apply to the management of the following substances:

- a) Those subject to control by the special provisions that regulate them, such as They are:
 - Pesticides.
 - Pharmaceutical products, both finished products, semi-finished products and conditioned.
 - Explosives or substances that are destined to the manufacture of the same.
 - Narcotics.
 - Psychotropic substances.

- Radioactive substances.
- Medicines, cosmetics, domestic hygiene products and additives food
- Mercury.
- Those chemical substances that are in the scope of application of the convention on the prohibition of development, production, storage and use of chemical weapons and their destruction.
- b) Those of natural origin without chemical processing. This exception does not apply for asbestos in any of its forms.
- c) Polymers. This exception does not apply to monomers.

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d) Those that are in customs transit.

e) Intermediates not isolated.

f) Samples without commercial value.

Paragraph 2. Substances whose importation or production is subject to environmental license, are exempt from compliance with the provisions of Articles 8 and 10 of this decree.

Article 3. Definitions. For the purposes of this Decree, it is understood as:

Mutual Data Acceptance (AMD): it is a system for the evaluation of chemical substances adopted by the OECD Council in 1981 through the instrument "Council Decision on Mutual Acceptance of Data in the Assessment of Chemicals [C (81) 30 / Final] ". This instrument consists of a multilateral agreement by means of which a security study does not clinical trial conducted by a member country or full adherent to the AMD agreement of the OECD using test methodologies (Test Guidelines) and the principles of

Evandation purposes and the member of the new Schutzer and antistrents to the Aford agreement.

Good Laboratory Practices (GLP) of the Organization for the Cooperation and Economic Development (OECD): they represent a system of Quality assurance relative to the organization of safety studies non-clinical issues related to health and the environment and the conditions in which Studies are planned, executed, controlled, recorded, archived and reported.

Non-clinical safety study: refers to a trial or set of trials relative to the health or the environment in which a product or substance is examined under laboratory or field conditions, including work made in greenhouses. Its objective is to obtain the data of its properties or concerning their safety, intended for the competent regulatory authorities for registration purposes.

Chemical substance: chemical element and its compounds in their natural state or obtained through any production process, including additives necessary to preserve the stability of the product and the resulting impurities of the process used and excluding solvents that can be separated without affecting to the stability of the substance or modify its composition.

Pure chemical substance: a chemical substance, defined according to its composition, in which a major component is given at least 80% by weight weight (p / p) and which is identified by CAS registration number (for English Chemical Abstracts Service).

Chemical substances in a homogeneous mixture: group or solution of substances chemicals in homogeneous phase composed of two or more substances, in which Each constituent is present in a concentration $\geq 10\%$ (w / w) and less than 80% (p / p) and which are identified by CAS registry number.

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Non-isolated intermediate chemical: substance that is manufactured and consumed or uses for chemical processes of transformation into another substance (synthesis), which during this process is not intentionally extracted (except to take samples).

Chemical of natural origin without chemical processing : substance present as such in a natural way, not processed or processed only by means manual, mechanical or gravitational; or by dissolving in water, by flotation, or by extraction with water, or by steam distillation or by heating only to remove the water; or that is obtained from the atmosphere By Any Means.

Industrial use: refers to all transformation, formulation, consumption, storage, conservation, treatment, packaging, transfer, mixing, production of an article or any other use of a chemical in the industry.

TITLE II

MAIN PROVISIONS

CHAPTER I

Instruments for the Management of Chemical Substances for Industrial Use

Article 4. Instruments of management of chemical substances of use

industrial. The instruments for the management of chemical substances of use which are regulated through this regulation, are the following:

- Register of chemical substances for industrial use.
- Evaluation of the risk to health or to the environment, according to the use specific.
- Risk reduction and management programs for the environment or for the Health.

Article 5. Registration of Chemical Substances for Industrial Use . The Registry of

Chemical Substances for Industrial Use is a mechanism for capturing information that aims to identify and have updated information on chemical substances for industrial use that are marketed in the country to which refer articles 1 and 2 of this Decree. For this purpose, the manufacturers or importers of chemical substances for industrial use should incorporate in the registry information on the identification, classification of dangers of such substances and the specific use of them, among others that determine.

The Ministries of Commerce, Industry and Tourism, Health and Social Protection and Environment and Sustainable Development, will have a term of one (1) year from the publication of this decree in the Official Gazette, to regulate the administration of the registry, the operation of the registry, the type of information

which manufacturers or importers of chemical substances must supply industrial use and the conditions under which certain manufacturing activities or can be exempted from the registration.

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For purposes of the identification and classification of hazards of substances chemicals referred to in this article, the Globally System should be applied Harmonized Classification and Labeling of Chemicals (SGA) of the United Nations Organization, sixth edition revised and published in 2015 or one that is accepted by the Colombian legal system.

Article 6. Obligation to carry out risk assessments for the

environment or for health. Within a period of two (2) years, counted from the entry into force of the regulation of the registry that the article deals with above, if chemical substances for industrial use that intend to be imported or manufactured and according to their specific use, are not in the registry, they should have a risk assessment for the environment or for health, in the terms indicated in articles 8 and 9 of this decree, notwithstanding that in any case they must be registered.

The Ministries of Environment and Sustainable Development and of Health and Protection Social, each within the framework of its competences, will define those activities of production and importation that, in consideration of its particular conditions, they must be understood exempt from the requirements established in this article.

Article 7. Obligation to carry out management and reduction programs

risk to the environment or to health. Within two (2) years, counted from the entry into force of the regulation of the registry that deals with Article 5 of this decree, chemical substances for industrial use that pretend to be imported or manufactured, which according to the classification of hazards have been identified as carcinogenic, mutagenic, toxic to the reproduction or with properties of persistence or bioaccumulation or danger to short term for the environment, will require programs to reduce and manage

risk to the environment or to health, as appropriate, prepared by the manufacturer or importer.

The manufacturer or importer must make an annual report on the execution of the actions proposed in the risk reduction and management programs for the environment or for health.

The Ministries of Environment and Sustainable Development and of Health and Protection Social, each one within the framework of its competences, will define those activities of production and importation that, in consideration of its particular conditions, they must be understood exempt from the requirements established in this article.

Article 8. Risk assessment for the environment. All manufacturers or

importers of the chemical substances for industrial use referred to in Article 6 must have a risk assessment for the environment based on the guidelines for the effect issued by the Ministry of Environment and Development Sustainable.

The Ministry of Environment and Sustainable Development will define the information contained in the risk assessment document that should be disclosed by the manufacturers or importers through their web pages or, failing that, any another means of mass disclosure, so that it is permanently available to users and for monitoring and control by the competent authorities.

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Article 9. *Health risk assessment.* All manufacturers or importers of the chemical substances for industrial use referred to in Article 6 must have a risk assessment for health based on the guidelines for the effect issued by the Ministry of Health and Social Protection.

The Ministry of Health and Social Protection will define the information contained in the risk assessment document that must be disclosed by the manufacturers or importers through their web pages or, failing that, any other means

of mass disclosure, so that it is permanently available to the users and for monitoring and control by the competent authorities.

Article 10. *Program of reduction and risk management for the environment*. In relationship with risk reduction and management programs for the environment that Article 7 of this Decree establishes the Ministry of Environment and Development Sustainable will define the guidelines for the preparation of these programs and the annual compliance report, establishing that information that should be disclosed by the manufacturers or importers through its web pages or, in its defect, any other means of mass disclosure, so that it is permanently available to users and for monitoring and control by part of the competent authorities.

Article 11. *Program for the reduction and management of risk to health.* In relationship with the risk reduction and management programs for health that Article 7 of this Decree establishes the Ministry of Health and Protection Social will define the guidelines for the preparation of these programs and the annual compliance report, establishing that information that should be disclosed by the manufacturers or importers through its web pages or, in its defect, any other means of mass disclosure, so that it is permanently available to users and for monitoring and control by part of the competent authorities.

Article 12. *Responsibility.* The manufacturer or importer will be responsible for the information that is included and disseminated about the evaluation and reduction and risk management for the environment or for health.

CHAPTER II

Monitoring and Performance of the Management of Chemical Substances of Use Industrial

Article 13. Environmental monitoring of chemical substances of use

industrial. The Ministry of Environment and Sustainable Development will define and regulate the mechanisms for capturing and analyzing information resulting from the monitoring of the emission or discharge into the air, water and soil of the subject substances of this decree, as well as its transfer in the development of activities industrial

Article 14. *Monitoring of health effects from the use of substances Chemicals for industrial use.* The Ministries of Health and Social Protection and Work should design and implement a management and information system toxicology to advise, assist in the prevention, diagnosis and treatment of Page 8

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the adverse effects generated by exposure to chemicals from industrial use and provide information on the need and type of treatment to be received by the appropriate personnel. This system will collect and will analyze toxicological information on chemical substances for industrial use that are commercialized in the country.

Article 15. Intersectoral Committee for the Follow-up of the Management of Chemical Substances for Industrial Use - CISQUIN. The Committee is created Intersectorial Monitoring of the Management of Chemical Substances of Use Industrial - CISQUIN to guide and coordinate the follow-up of the implementation of the instruments of management of chemical substances of use established in the present decree.

Article 16. Integration of the Intersectoral Committee for the Follow-up of Management of Chemical Substances for Industrial Use - CISQUIN. The committee Intersectorial Monitoring of the Management of Chemical Substances of Use Industrial - CISQUIN, will be integrated by two (2) officials of each one of the following Ministries:

- Ministry of Health and Social Protection.
- Ministry of Labor.
- Ministry of Commerce, Industry and Tourism.
- Ministry of Environment and Sustainable Development.

Paragraph 1. One of the two representatives of each ministry should have managerial character.

Paragraph 2. The CISQUIN may invite its sessions to the institutions and people who can contribute to the topics to be dealt with in the development of their functions.

Article 17. Functions of the Intersectoral Committee for the Follow-up of Management of Chemical Substances for Industrial Use - CISQUIN. The committee will have at least the following functions:

- a) Review the information collected and analyzed based on environmental monitoring and of the toxicological management system.
- b) Study the effectiveness of chemical substances management instruments of industrial use contemplated in this decree and generate recommendations about them.
- c) Identify the research needs related to the management of the risk for a specific industrial chemical substance, promoting its development between public and private entities.
- d) Recommend actions to be taken in advance, in cooperation with other countries, research programs related to risk management associated with chemical substances for industrial use and allow the exchange of information resulting from them among the member countries of the Organization for Economic Cooperation and Development (OECD).
- e) Recommend the measures to be adopted in relation to the use of substances specific chemicals for industrial use, among which are the

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prohibition, restriction of use, substitution processes and other established by law.

f) Give your own regulations.

CHAPTER III Of the obligations

Article 18. *Of the obligation of importers or manufacturers.* The manufacturer or importer of chemical substances for industrial use shall:

- a) Guarantee the integral management of chemical substances for industrial use in the manufacturing and import stages.
- b) Identify, classify, label and prepare the Safety Data Sheet (SDS) of chemical substances for industrial use, according to the System Globally Harmonized Classification and Labeling of Chemical Products (SGA). (FDS) of those substances registered should include the number of assigned record.

- c) Register and provide the information requested in the registry that they define, To this end, the Ministries of Commerce, Industry and Tourism, Environment and Sustainable Development and Health and Social Protection.
- d) Make and disseminate through its web pages, or, failing that, any another means of mass dissemination, risk assessments for the environment or for health, chemical substances for industrial use, according to the guidelines issued by the Ministry of Environment and Development Sustainable and the Ministry of Health and Social Protection.
- e) Design, implement, disseminate and keep updated through their web pages or, failing that, any other means of mass dissemination, the programs that contain the risk management actions for the environment or for the health of chemical substances for industrial use, as guidelines issued by the Ministry of Environment and Development Sustainable and the Ministry of Health and Social Protection.
- f) Make the adjustments requested by the competent authorities with respect to risk assessments and risk management programs for health or for the environment.
- g) Prepare, disseminate through its web pages or, failing that, any other means of mass disclosure, and have available to the authorities competent authorities, the annual compliance report to the management programs of the risk to health or to the environment.
- h) Support and participate in the research processes on risk management associated with chemical substances for industrial use.
- i) Comply with the provisions of section 8 of chapter 7 of title 1 of the Book 2 of Decree 1079 of 2015, Single Decree of the Administrative Sector of Transportation or the regulations that modify, add or replace it, when Send chemical substances for industrial use to be transported.

Article 19. Of the obligations of the marketer or distributor. He

marketer or distributor of chemical substances for industrial use should comply with the following obligations:

a) Guarantee the integral management of chemical substances for industrial use in the stages of commercialization or distribution.

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- b) Verify that the chemical substances are labeled according to the System Globally Harmonized Classification and Labeling of Chemical Products (SGA) and that have their respective Safety Data Sheet (SDS).
- c) In case of re-packaging, label the chemical substances of use in accordance with the Globally Harmonized System of Classification and Labeling of Chemical Products (SGA), based on the information provided by the importer or manufacturer in the Data Sheet of Security (FDS).
- d) Carry out the actions that correspond to them according to the management programs of the risk to the environment or to the health that the importer implements or maker.
- e) Follow the safe handling instructions supplied by the manufacturer or importer of chemical substances for industrial use.
- f) Comply with the provisions of section 8 of chapter 7 of title 1 of the Book 2 of Decree 1079 of 2015, Single Decree of the Administrative Sector of Transportation or the regulations that modify, add or replace it, when transport chemical substances for industrial use.

Article 20. *Of the obligations of the transporter.* The transporter chemical substances for industrial use must comply with the provisions of section 8 of chapter 7 of title 1 of book 2 of Decree 1079 of 2015, Single Decree of the Administrative Transport Sector or the regulations that the modify, add or replace, when transporting chemical substances of use industrial.

Article 21. *Of the obligations of the user.* The user of chemical substances industrial use must guarantee the integral management of the same, of compliance with risk management programs for the environment or for the published by the importer or manufacturer in the cases that apply, for which will comply with the following obligations:

- a) Verify that the chemical substances are labeled according to the Globally Harmonized System of Classification and Labeling of Products Chemicals (SGA) and that have their respective Safety Data Sheet (FDS).
- b) Inform the manufacturer or importer of the new uses to which the substance and that are not related in the SDS.
- c) Request the importer or manufacturer of chemical substances for industrial use that require risk management programs for the environment or for the health, the additional information it deems pertinent to implement the actions that correspond to them in said program.
- d) Carry out the corresponding actions in the management programs of the risk to the environment or to health implemented by the importer or manufacturer, adapted to their particular conditions of use.
- e) Inform the competent authorities when it is evidenced that the manufacturer

or importer has not published the risk management programs for the the published information.

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CHAPTER IV OF GENERATION AND USE OF INFORMATION

Article 22. *Existing reliable data.* The data used in the management instruments defined in article 4 of this decree, must come from reliable sources of information that meet some of the The following requirements:

- a) Data that would have been generated by a test entity under the principles of Good Laboratory Practices (GLP) of the OECD, inspected by the National Accreditation Body of Colombia (ONAC) as Authority National Monitoring of the Principles of the BPL of the OECD or inspected by a National OCDE BPL Monitoring Authority whose monitoring program is part of the Mutual Acceptance Agreement of Data.
- b) Data that would have been generated through tests carried out in laboratories accredited under ISO / IEC 17025 by the Agency National Accreditation Commission- ONAC or other agencies of accreditation that is part of the multilateral recognition agreements subscribed by the ONAC.
- c) The data found in databases recommended by the Ministries of Health and Social Protection, Labor and Environment and Sustainable development.

Article 23. *Mutual acceptance of data*. When data is not available existing and require non-clinical safety studies at the chemical substances for industrial use, these must be generated by a

testing entity in accordance with the Principles of Good Practices Laboratory (BPL) of the OECD, where the test methods of the OECD or its equivalents. The test entities must be inspected by the National Accreditation Body (ONAC) in Colombia and when it is of trial entities outside national territory these should be inspected by its national monitoring authority for the principles of OECD BPLs, whose monitoring program forms part of the Agreement on Mutual Acceptance of Data.

Paragraph. When there is no test entity in Colombia with recognition in the OECD BPL for the performance of the tests corresponding to non-clinical safety studies, methods will be accepted established and standardized by international reference bodies recognized and accepted in the country.

Article 24. *Of the right to the use of information.* The person who uses third party information for registration, evaluations or reduction programs or risk management of chemical substances for industrial use, must demonstrate its right to use it.

Article 25. *Non-confidential information.* It will not be confidential The following information about chemical substances for industrial use:

a) The denomination of chemical substances.

b) General data on the uses of chemical substances.

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- c) Physical and chemical data related to the chemical substance, except for the data revealing the identity of the substance, in which case only Value ranges should be provided. These ranges must keep proportion to the actual composition of the substance.
- d) The effects on health, environment and safety, including figures and interpretations of them.
- e) The methods and recommended measures to reduce the risks of

- handling, storage, transportation and use. f) The methods of treatment, exploitation or elimination foreseen for the chemical substance used and its containers.
- g) Safety and handling measures in case of accident.
- h) First aid and medical treatment that must be provided in case of causing bodily harm.

Article 26. *Of the exchange of confidential information.* The National Government may, on strict basis of reciprocity, create conditions for the exchange of confidential information about chemical substances with others countries, after consulting with the person who presented such information and under parameters previously established under an international agreement ratified by Colombia, which as a minimum must:

- a) Limit such exchange to that information that is requested in writing in each case, which is relevant for the protection of human health and the environment and that could not have been obtained by the other means by the country applicant.
- b) Establish a mechanism that allows the traceability of the chain of custody of the information transmitted and that ensures that it will be treated with the same degree of confidentiality or one greater than that taught in Colombia. The above will be determined according to a case by case evaluation.
- c) Establish a mechanism to compensate the consequences of incompatible use with the parameters established in terms of custody and confidentiality of information.
- d) Limit such exchange to cases in which there are no distortions to the international trade, or disadvantage the interests of the residents in the national territory against nationals of the country requesting the information.
- e) Restrict the exchange of information when the requesting country does not have competition or is prohibited from requiring in accordance with its legislation internal
- f) Establish mechanisms to ensure effective compliance at the agreed on the corresponding parameters.

CHAPTER V On inspection, monitoring and control

Article 27. Inspection, monitoring and control. The entities

corresponding, each within the scope of their competences, shall exercise Inspection, surveillance and control functions against compliance with sanitary, occupational safety and health, environmental and trade contained in this Decree, in accordance with the rules applicable for each sector. The principle of coordination may apply for the execution of these actions.

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TITLE III

FINAL PROVISIONS UNIQUE CHAPTER

Article 28. *Validity*. This Decree governs from its publication in the Official Gazette.

PUBLISH AND COMPLY

Given in Bogotá, DC, at

MINISTER OF HEALTH AND SOCIAL PROTECTION

ALEJANDRO GAVIRIA URIBE

MINISTER OF LABOR

GRISELDA JANETH RESTREPO GALLEGO

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MINISTER OF COMMERCE, INDUSTRY AND TOURISM

MARIA LORENA GUTIERREZ BOTERO

MINISTER OF ENVIRONMENT AND SUSTAINABLE DEVELOPMENT

LUIS GILBERTO MURILLO URRUTIA

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REPUBLIC OF COLOMBIA

ANNEXED

Requirements for chemical substances for industrial use:

I. **Characteristics of danger to health.** Substances for industrial use that are identified and classified with the following dangers and categories, depending on the SGA:

Hazard Class	Category (s)
Acute oral toxicity	Category 1, 2 and 3
Acute cutaneous toxicity	Category 1 and 2
Acute toxicity gases	Category 1 and 2
Acute toxicity vapors	Category 1 and 2
Acute toxicity dusts and mists	Category 1 and 2
Corrosión, irritación cutánea	Category 1
Lesiones oculares graves / Irritación ocular	Category 1
Mutagenicidad en células germinales	Categoría 1 y 2
Carcinogenicidad	Categoría 1 y 2
Toxicidad para la reproducción	Categoría 1 y 2
Toxicidad sistémica específica de órganos	Category 1
diana tras exposiciones repetidas	
Peligro por aspiración	Category 1

II. **Características de peligro para el ambiente.** Las sustancias de uso industrial que sean identificadas y clasificadas con los siguientes peligros y categorías, según el SGA:

Clase de Peligro	Categoría(s)
Peligro a corto plazo (agudo) para el medio	Categoría 1 y 2
ambiente acuático	
Peligro para la capa de ozono	Category 1

III. Propiedades de índole ambiental. Las sustancias de uso industrial que sean identificadas y clasificadas como persistentes (no aplica para compuestos inorgánicos) y bioacumulables. Para lo anterior se aplicarán los siguientes criterios:

Sustancia química bioacumulable: una sustancia que su factor de

bioconcentración (BFC) en especies acuáticas es superior a 2000.

Sustancia química persistente: una sustancia que cumple cualquiera de los siguientes criterios:

a) Su vida media de degradación en aire supera los 2 días.

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- b) Su vida media de degradación en agua marina supera los 60 días.
- c) Su vida media de degradación en agua dulce o estuarina supera los 40 días.
- d) Su vida media de degradación en sedimentos marinos supera los 180 días.
- e) Su vida media de degradación en sedimentos de agua dulce o estuarina supera los 120 días.