

# Regulatory framework in Uruguay and Paraguay: An overview of existing regulations

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**Empowering Trust<sup>®</sup>**

# Agenda

- I. Introduction to UL
- II. Products and Services
- III. Uruguay and Paraguay Chemical Regulatory Framework
- IV. Uruguay
- V. Paraguay

If your question is not answered at the end of the workshop, please send it via email to: [Raissa.havens@ul.com](mailto:Raissa.havens@ul.com).



# Introduction to UL



Manufacturer > Brands > Distributors > Retailers > Consumers > End of life

EMBEDDED IN THE SUPPLY CHAIN of  
**70,000+** customers

UL PROVIDES MORE THAN  
**630,000+** product designers

with technical, safety and supplier data for

**510,000+**

materials, ingredients and components

Connecting manufacturers with suppliers sharing data for **hundreds of thousands** registered products



UL has supported more than a **CENTURY OF INNOVATION** from electricity to nanotechnology

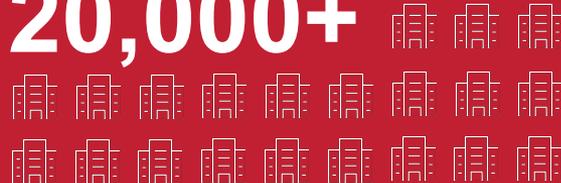


Chemical regulatory compliance



Science and global expertise

UL software is used by  
**20,000+**



ORGANIZATIONS *in*  
**OVER 10 INDUSTRIES**



**60+ REGULATORY PROFESSIONALS** with global expertise on chemical hazards and regulations

# Products and Services



# UL's Regulatory Database

- Regulatory data on chemical substances
- Comprehensive chemical data curated by regulatory and industry experts
- Accurate information with weekly updates



**7000+**  
*lists*

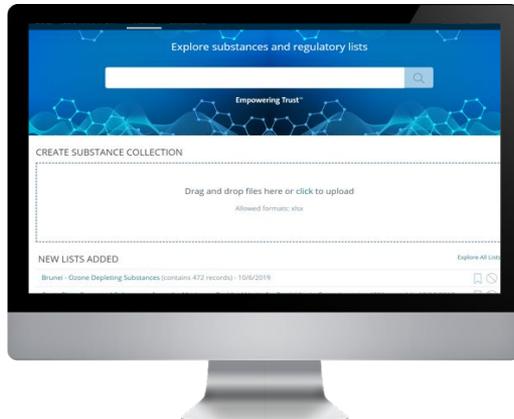
**0.5 million**  
*substances*

**130+**  
*countries*

**Hazard  
Classification**

**Product  
Compliance**

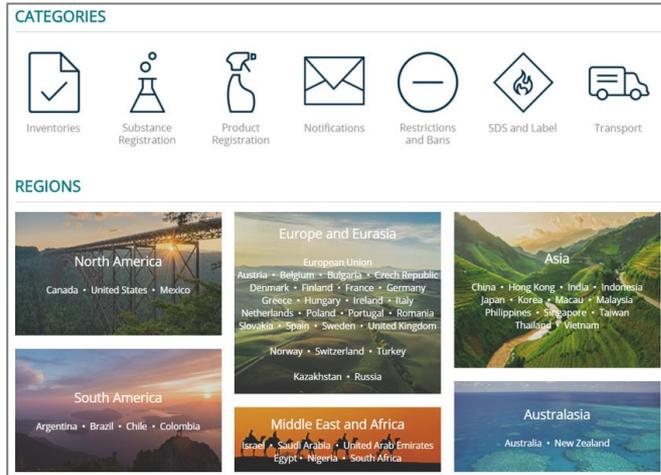
**Facility  
Compliance**



## UL's Illuminator

- Search and create personalized **collections** of relevant substances and topics
- Receive a **weekly report** on new and changing regulations as we update

# Navigator



- Chemical regulatory requirements in over 50 + countries.
- Includes summaries and links to sources on each categories.

# Regulatory Advisory Services

- Over 60 regulatory professionals
- Multi-lingual support in more than 30 languages
- Services:
  - Hazard communication consulting: SDS, hazard label, consumer label, audits and more
  - Product compliance reviews and monitoring
  - Registration and notification assistance: TSCA, REACH, and other global support
  - Transportation classification and advice



# Uruguay and Paraguay Overview on Chemical Management



# Framework

Paraguay

Uruguay



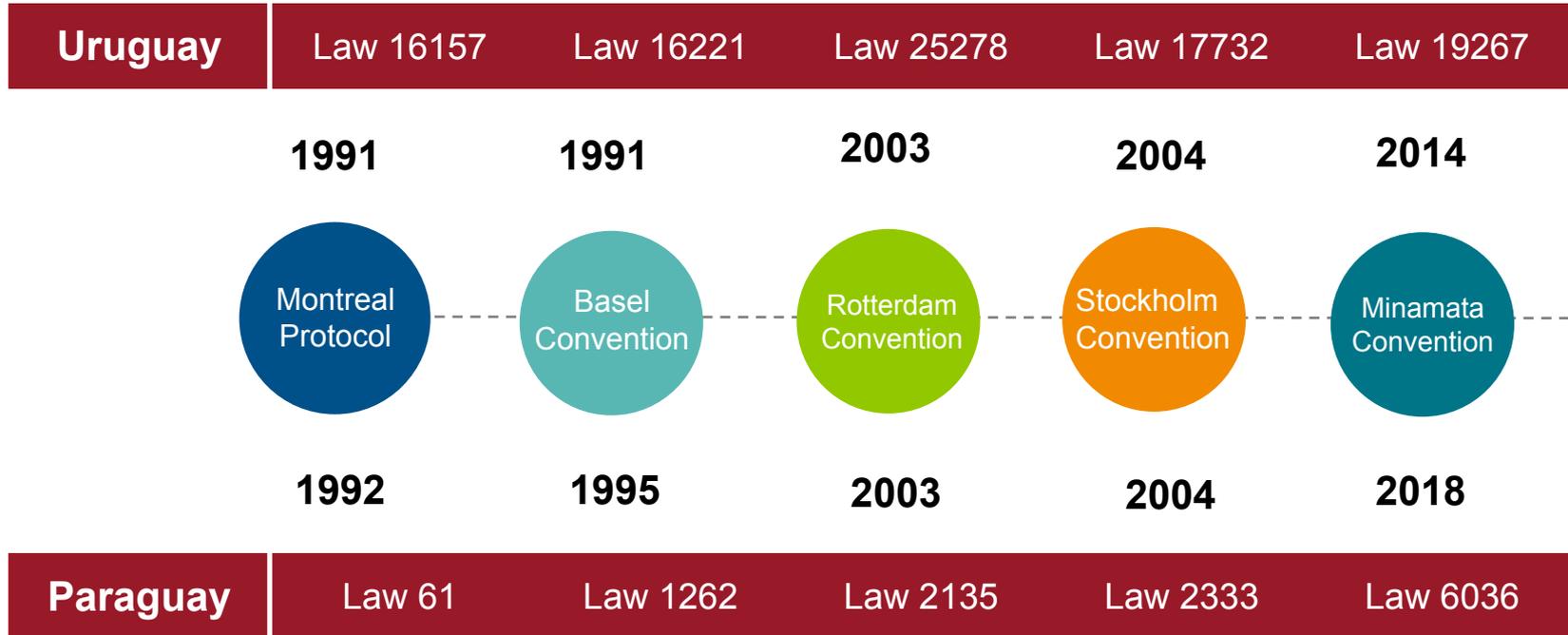
Centro Coordinador Convenio Basilea  
Centro Regional Convenio de Estocolmo  
Para América Latina y el Caribe

URUGUAY



RESPONSIBLE CARE®  
OUR COMMITMENT TO SUSTAINABILITY

# International Agreements



Uruguay



# Specific Regulations



Controlled Substances Division 

Importation  
authorization: 120  
days

Chemical Precursors

Cosmetics

Household Use  
Products

Phytosanitary  
Products

**1974:**

Decree-Law 14222 – Convention on Narcotics 1961

Decree-Law 14.294 - Narcotics law/New York convention/Psychotropic substances from Vienna

**1975:** Decree-Law 14369 - Convention on Psychotropic 1961

**1994:** Law 16579 - United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances, adopted in Vienna on December 20, 1988

**2002:** Decree 391 - Regulation of Precursors and Chemical Products and its Annexes I, II and III

**2020:** Decree 265 last updated the controlled substances list



# Specific Regulations



Chemical Precursors

Cosmetics

Household Use  
Products

Phytosanitary  
Products

- Classification - **Decree 428/2007**
  - Grade I and Grade II
  - Registration validity: 5 years
- Labels - **Decree 425/2007**
- Prohibitions and Restrictions on substances in cosmetics
  - **Decree 431/2007**
  - **Decree 277/2017**



# Specific Regulations



Chemical Precursors

Classification, definitions, labels, registration

Cosmetics

Risk I products – cleaning products in general

**Decree 219/2014**

Household Use  
Products

Risk II products – pesticides (antimicrobial action)

**Decree 37/2015**

Phytosanitary  
Products

→ Registration validity: 5 years

More label requirements

**Decree 257/2000**



# Specific Regulations



Chemical Precursors

Cosmetics

Household Use  
Products

Phytosanitary  
Products

## Registration - **Decree 317/007**



Registration validity: 4 years

## Labels - **Decree 149/1977** and **294/2004**

Filtrar por grupos *(Esta operación puede tardar unos segundos):*

Descripción del activo

Prioridad, Normativa y Kilogramos

Parámetros fisicoquímicos

Parámetros de toxicidad

Cultivos

Copiar

Excel

CSV

Buscar:

NOMBRE	ACTIVIDAD	FORMULA QUÍM.	GRUPO QUÍM.	No. CAS	DE
Buscar	Buscar	Buscar	Buscar	Buscar	Bu
2,4 D	Herbicida	C8H6Cl2O3	Ácido fenoxicarboxílico	94-75-7	
2,4,5 T	Herbicida	C8H5Cl3O3	Ácido fenoxiacético	95-95-4	
2,4,5 TP	Herbicida	C9H7Cl3O3	Ácido fenoxipropiónico	93-72-1	
2,4-DB	Herbicida	C10H10Cl2O3	Ácido ariloxialcanoico	94-82-6	
Abamectina	Insecticida	C48H72O14	Natural	71751-41-2	
Acefato	Insecticida	C4H10NO3PS	Organofosforado	30560-19-1	



# Globally Harmonized System Implementation



**Decree 307/2009**



**Decree 346/2011**

December 31, 2012 – substances

December 31, 2017 - mixtures

**National authority:** Ministry of Labor and Social Security

**OEL values:** ACGIH last publication



## Label

Spanish

Material: paper, PVC or similar characteristics

Package Size (L or equivalent)	Label area
>5	375 cm <sup>2</sup>
0.5-5	135 cm <sup>2</sup>
<0.5	as large as possible / brochure attached



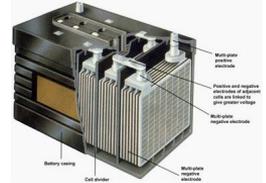
- United Nations Industrial Development Organization (**UNIDO**) and Global Environment Facility (**GEF**)
- Train technical staff and government officials, harmonize key aspects of e-waste policies and strengthen regional cooperation and knowledge exchange

**Law 19829/2019** - Integral management of waste

**Decree 15/2019** - regulates laws 19.267 and 17.283. Related to the environmental management of lamps and other waste with mercury

# Lead-Acid Battery

Decree 373/2003



## Obligations of Importers / Manufacturers

- Register in the DINAMA registry
- Submit a sworn statement to DINAMA
- Prepare and implement a master plan, assuming responsibility for the returnability and final destination of the batteries.
- Include documentation to facilitate the returnability for the holder

## Environmentally Sound Management of Used Lead-Acid Batteries - Webinar October 2020

- Current situation, proposal of modification and main challenges
- Minimum identification data on labels
- Minimum percentage of waste management

# Organizations



- Civil societies / professional or technical associations :

Uruguayan  
Institute of  
Technical  
Standards

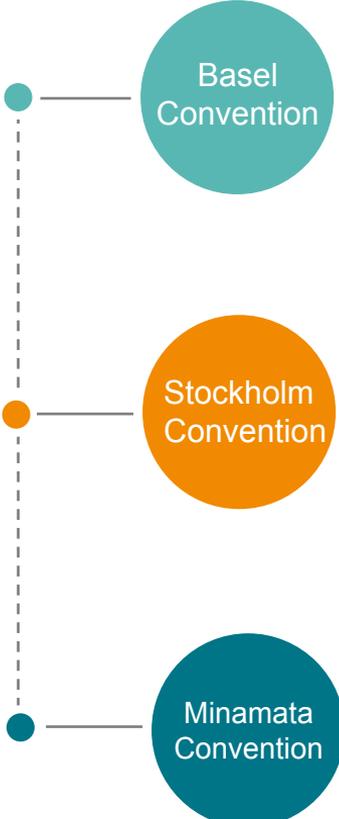


**ASIQUIR** -  
Uruguayan  
Chemical Industries  
Association



Paraguay





## Basel Convention

- **Law 7.103 / 2017** Registration of manufacturers and importers of incandescent and fluorescent lamps

Enforcement Authority: Ministry of Industry and Commerce

- **Resolution 627 / 2016:** prohibits the importation of used tires for direct reuse
- 

## Stockholm Convention

- **Resolution 1.402 / 2011:** Establish protocols for the treatment of polychlorinated biphenyls (PCBs)
  - **GAR - PCB Project :** "Strengthening the Environmentally Sound Management and Elimination of PCBs in Paraguay"
- 

## Minamata Convention

Action plans:

**Resolution 844 / 2014** – Reduction and replacement of the use of Mercury in the health sector

# Environmentally Sound Management and Elimination of PCBs



## Who

- Ministry of the Environment and Sustainable Development
- UNIDO as the implementing agency
- Funds from the Global Environment Facility (**GEF**)

## What

- Manage and eliminate 700 tonnes of PCB and waste related
- Help PCB holders to properly manage and dispose of PCBs and related wastes.

## When

- First meeting in 2019
- The project will have a duration of 5 years

[More information](#)



Stockholm  
Convention



# Implementation of Minamata Convention

## "Initial Evaluation of the Minamata Agreement in Paraguay" - 2017

- Promulgate the permissible standards of air and atmosphere pollution from fixed sources within the framework of Law No. 5211/14 "On Air Quality"
- Preparation of the inventory of mercury and products containing mercury
- Approval and dissemination of procedures in cases of spills or leaks of Mercury

## National Mercury Committee (CNM) made up of government agencies - 2016

Reduce the use of mercury in the artisanal and small-scale gold mining sector in 25% in 2021, 50% in 2022, 75% in 2023\*

Minamata  
Convention



\*Based on the amounts determined in the 2018 Reference Estimates

# Electronic Equipment

## Law 3,107 of 2006

Prohibited the manufacturing, transportation, warehousing, marketing and importation of primary batteries of carbon zinc and manganese and button cells whose content exceeds the following

## Resolution 970 of 2010

Registration and issuance of the Register of Manufacturers and Importers of Batteries and Primary Batteries, common carbon-zinc and alkaline magnesium



Mercury	0.010%
Cadmium	0.015%
Lead	0.200%
Mercury per cell	25 mg

# Chemicals at the Workplace



## Decree 14390/1992

### Label

- Product name
- Commercial designation
- Danger symbol
- Nature of the risks involved in the use of the product
- Safety precautions
- Name, address and telephone number of the provider
- Indication that SDS can be obtained from the employer with complementary information.

## Resolution 181/2017

- Threshold Limit Values for chemicals present in the workplace – ACGIH values and INSST from Spain





Decree 14390/1992

## Safety Data Sheet

1. Identification of the products and the manufacturer (including the trade name or common name, as well as information about the supplier/manufacturer)
2. Composition or information on its ingredients
3. Identification of risks
4. Measures in case of:
  - 4.1. First aid
  - 4.2. Fire
  - 4.3. Detachment or spillage
5. Manipulation and storage
  
6. Control in case of exposure and personal protection (including possible surveillance methods)
7. Toxicological information (including routes of possible penetration in the body and possibility of synergy with other chemical or biological products)

# Organizations



Law 862/1963



**APAQUINFA**

Paraguayan Association  
of Chemists of the  
Pharmaceutical Industry



# Thank You

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