# **GPS Product Safety Summary**

# **Imidazolon HCI**

## **General Statement**

This safety summary is provided within the scope of ICCA Global Product Strategy (GPS) and is not intended to give in-depth safety and health information and does not replace the Safety Data Sheet (SDS) of the chemical substance. GPS summaries are not intended for use in the management of emergencies by professionals.

Imidazolon HCl is a white to off-white, odourless solid in powder or granules form and used as starting material of a Active Pharmaceutical Ingredient. It is used in chemical synthesis and is not sold directly to the consumer, therefore the workplace is the most likely place for potential exposure.

# **Chemical identity**

EC Name: 2-Butyl-1,3-diazaspiro[4.4]non-1-en-4-one hydrochloride

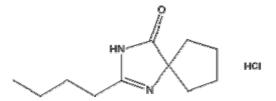
**EC-No.**: 424-560-4 (ELINCS)

**CAS-No.**: 151257-01-1

CAS name: 1,3-Diazaspiro[4,4]non-1-en-4-one, 2-butyl hydrochloride

Molecular formula:  $C_{11} H_{18} N_2 O$ . HCI

Structural formula:



# **Uses and applications**

Imidazolon HCl is used under strictly controlled conditions as starting material for the synthesis of an API.

# **Physico-chemical properties**

Imidazolon HCl is not classified based on its physico-chemical properties (REGULATION (EC) No 1272/2008).

PROPERTY	RESULT
Melting point/range:	261-267 °C
Boiling point/boiling range:	Decomposition starts at 265 °C

Molecular Weight:	230.74 g/mol
Bulk density:	300-400 kg/m3 (20 °C)
Water solubility:	44.11 g/l at 23 °C
Solubility:	Isopropanol: soluble; Methanol: > 50 g/l
Partition coefficient n-octanol/water:	Log Pow 0.02 (20 °C)
Flammability	Not flammable
log Kow:	No data available
Explosiveness:	Not explosive
Oxidizing properties:	Not oxidizing

# **Health effects**

Imidazolon HCl is considered as harmful if swallowed and as eye irritant, based on its health effects (REGULATION (EC) No 1272/2008).

EFFECT ASSESSMENT	RESULT
Acute Toxicity (oral/dermal/inhalation)	Harmful if swallowed; Acute Toxicity Cat. 4, oral
Irritation/Corrosivity (skin/eye/respiratory tract)	Not irritant to skin but serious irritant to eyes; Eye irr. Cat. 2
Sensitization	The substance is not a skin sensitizer
Repeated Exposure	Based on the results of a 28-day oral study in rats, Imidazolon
	HCl is not classified for repeated dose toxicity.
Mutagenicity	Non-mutagenic in a bacterial reverse mutation assay (Ames test) and in an in-vitro UDS-test. A chromosome aberration test on human lymphocytes showed a clastogenic response in absence of metabolic activation
Carcinogenicity	Not tested.
Reproductive Toxicity	Not tested.

# **Environmental effects**

Imidazolon HCl is not classified based on its environmental fate and ecotoxicological properties (REGULATION (EC) No 1272/2008).

EFFECT ASSESSMENT	RESULT
Aquatic Toxicity	No toxic effects on aquatic organisms observed

FATE AND BEHAVIOR	RESULT
Biodegradation	Not readily biodegradable
Bioaccumulation potential	Not bioaccumulative based on biodegradation and water solubility data
PBT/vPvB conclusion	Not considered to be either PBT or vPvB

# **Exposure**

#### **Human Health**

Imidazolon HCI is consumed during chemical syntheses and is therefore no longer present in the final products. Consumer exposure is therefore not expected. The substance is handled in closed systems under strictly controlled conditions, therefore no exposure of workers is expected.

#### **Environment**

Imidazolon HCl is handled in closed systems under strictly controlled conditions, therefore, there will be no release to the environment.

# **Risk management recommendations**

Avoid contact with skin, eyes and clothing. Wash hands before breaks and immediately after handling the product. In the case of vapor formation use a respirator with an approved filter. Chemically resistant gloves and tightly fitting safety goggles should be worn. Wash off any contamination immediately. Handle the material in accordance with good industrial hygiene and safety practice and provide appropriate training to workers.

Use in tightly closed reaction vessel only. Waste or remaining substance has to be incinerated in an authorized incineration facility equipped with flue-gas scrubbing. Prevent product from entering drains. Contaminated process waters have to be pre-treated in an industrial waste water treatment plant before discharging. Contain spillage, and then collect with non-combustible absorbent and dispose according to local / national regulations.

## State agency review

Imidazolon HCI has been ELINCS-notified (Notification no. 07-05-0609-00) and can be considered as REACH-registered (Registration No. 01-0000017102-85-0004).

# Regulatory information/classification and labeling

Classification of the substance according to REGULATION (EC) No 1272/2008:

**Acute toxicity:** Category 4; Oral; H302 Harmful if swallowed. **Skin irritation:** Category 2; H319 May cause serious eye irritation.

Labeling according to REGULATION (EC) No 1272/2008:

**Pictograms:** 



Signal word: Warning

**Hazard statements:** H302: Harmful if swallowed.

H319: May cause serious eye irritation

# **Contact information within company**

For further information on this substance or product safety summaries in general, please contact:

Company: Lonza Ltd.

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# **Glossary**

Acute toxicity Harmful effect resulting from a single or short term exposure to a

substance.

Biodegradation Decomposition or breakdown of a substance under natural conditions

(actions of microorganisms etc).

Bioaccumulation Progressive accumulation in living organisms of a chemical

substance present in the environment.

Carcinogenicity Substance effects causing cancer.

Chronic toxicity Harmful effect after repeated exposures or long term exposure to a

substance.

Flash point The lowest temperature at which vapor of the substance may form an

ignitable mixture with air.

Genotoxicity Substance effect that causes damage to genes, including

mutagenicity and clastogenicity.

Hydrolyze Undergo hydrolysis; decompose by reacting with water.

Mutagenicity Substance effect that cause mutation on genes. PBT Persistent, bioaccumulative, toxic chemical.

Persistence Refers to the length of time a compound stays in the environment,

once introduced.

Reprotoxicity Including teratogenicity, embryotoxicity and harmful effects on fertility.

Sensitizing Allergenic.

Sediment Topsoil, sand and minerals washed from land into water forming in

the end a layer at the bottom of rivers and sea.

Vapor pressure A measure of a substance's property to evaporate.

νΡνΒ Very persistent, very bioaccumulative.

### Date of issue

September 2012

# Revision

Version 1.0

# **Disclaimer**

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