



# METAPHARMACEUTIC

Josep Plà, 163, 2n 5a / Tel. 933 089 976 / info@metaph

## TECHNIC

00254

<b>SU</b>	
DESCRIPTION DCI: ---	
CAS N°: 56038-13-2	EC N°: 259-952-2
MOL. WEIGHT: 397.64	MOL. FORMULA: C <sub>12</sub>

### ATTRIBUTES

Appearance	White or almos
Solubility	Freely soluble i acetate
Identification A	Complies
Identification B	Complies
Specific optical rotation	+84.0 / +87.5
Impurities H and I	
Sum impurities H and I	= < 0.1 %
Related substances	

All methods are validated by the official pharmacopoeias and/or I

002541-TDS-ENG-2023



## ICAL DATA SHEET

11-TDS-ENG-2023

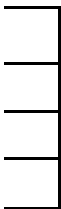
### ICRALOSA

	DESCRIPTION DOE: ---
	AEMPS CODE: ---
2H19CI3O8	ARTICLE CODE: 002541

### SHOULD BE

t white, crystalline powder

n water, soluble in anhydrous ethanol, slightly soluble in ethyl





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## TECHNICAL

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<b>SUBSTANCE</b>	
DESCRIPTION DCI: ---	
CAS N°: 56038-13-2	EC N°: 259-952-2
MOL. WEIGHT: 397.64	MOL. FORMULA: C <sub>12</sub> H <sub>18</sub> N <sub>2</sub> O <sub>2</sub>

### ATTRIBUTES

Impurity A	= < 0.5 %
Impurity B	= < 0.5 %
Impurity C	= < 0.5 %
Impurity D	= < 0.5 %
Impurity E	= < 0.5 %
Impurity F	= < 0.5 %
Impurity G	= < 0.5 %
Water	= < 2.0 %
Sulfated ash	= < 0.7 %

All methods are validated by the official pharmacopoeias and/or international standards.

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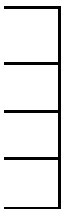
## ICAL DATA SHEET

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### ICRALOSA

	DESCRIPTION DOE: ---
	AEMPS CODE: ---
2H19CI308	ARTICLE CODE: 002541

SHOULD BE





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## TECHNIC

00254

<b>SU</b>	
DESCRIPTION DCI: ---	
CAS N°: 56038-13-2	EC N°: 259-952-2
MOL. WEIGHT: 397.64	MOL. FORMULA: C <sub>12</sub>

Assay

98.0 - 102.0 %

### COMPLIES WITH

European Pharmacopoeia 11.0

### STORAGE

Keep the containers tightly closed in a dry and well-venti

### REMARKS

Active ingredient permitted as food additive in complianc

Sucralose is subjected to the requirements of the ICH Q3  
EMA/CHMP/ICH/82260/2006.

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### ICRALOSA

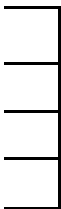
	DESCRIPTION DOE: ---
	AEMPS CODE: ---
2H19CI3O8	ARTICLE CODE: 002541

lated place.

e with specifications for food additives (Reg. EU 231/2012).

D "Elemental Impurities" guideline and the requirements of guid





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2.ENG

/2023



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<b>SU</b>	
DESCRIPTION DCI: ---	
CAS N°: 56038-13-2	EC N°: 259-952-2
MOL. WEIGHT: 397.64	MOL. FORMULA: C <sub>12</sub>

The product is not of animal origin and no animal product

The product is not derived from GMO. No genetically modified organisms in contact with the product during any stage of production

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### ICRALOSA

	DESCRIPTION DOE: ---
	AEMPS CODE: ---
2H19CI3O8	ARTICLE CODE: 002541

It is used in its production, so it is risk-free BSE/TSE.

A modified organism is used in its production and no GMO product contains.



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