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1. Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Trade name : SUMATRIPTAN SUCCINATE
Product code : 15810.SUS
Identification of the product : butanedioic acid; dimethyl(2-{5-[(methylamino)methane]sulfonyl-1H-indol-3-yl}ethyl) amine
CAS No :103628-48-4
EC No :---
Annex No :---
REACH Ref. :---
Chemical formula : C18H27N3O6S
SMILE : CNS(=O)(=O)CC1=CC2=C(NC=C2CCN(C)C)C=C1 (Sumatriptan base, canonical)
RTECS nr : No data available.

1.2. Relevant identified uses of the substance or mixture and uses advised against

Use : Pharmaceutical industry.

1.3. Details of the supplier of the safety data sheet

Company identification :
MOEHS IBÉRICA, S.L.
Roma, 8 - P.I. Cova Solera
Tel. +34 93 586 05 20 / Fax + 34 93 699 8350
08191 Rubi SPAIN
hse@moehs.com
MOEHS CATALANA, S.L.
Cesar Martinell i Brunet, 12A - P.I. Rubi Sud
Tel. +34 93 586 05 20 / Fax + 34 93 699 8350
08191 Rubi SPAIN
hse@moehs.com

1.4. Emergency telephone number

Phone nr : Tel. +34 93 586 05 20 [9:00-17:00 h] [Office hours]

2. Hazards identification

2.1. Classification of the substance or mixture


Classification EC 67/548 or EC 1999/45

Classification : Xi; R36

Hazard Class and Category Code(s), Regulation (EC) No 1272/2008 (CLP)

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2. Hazards identification (continued)

Health hazards : Eye irritation - Category 2A - Warning (CLP : Eye Irrit. 2) H319

2.2. Label elements

Labelling EC 67/548 or EC 1999/45

Symbol(s)



Symbol(s)

: Xi : Irritant

R Phrase(s)

: R36 : Irritating to eyes.

S Phrase(s)

: S26 : In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
S36 : Wear suitable protective clothing.

Contains

: butanedioic acid; dimethyl(2-{5-[(methylamino)methane]sulfonyl-1H-indol-3-yl}ethyl) amine

Labelling Regulation EC 1272/2008 (CLP)

Hazard pictograms



Signal words

: Warning

Hazard statements

: H319 : Causes serious eye irritation.

Precautionary statements

• **Prevention**

: P264: Wash thoroughly after handling.
P280: Wear protective gloves, protective clothing, eye protection, face protection.

• **Response**

: P337+P313: If eye irritation persists: Get medical advice/attention.
P305+P351+P338: IF IN EYES : Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

Contains

: butanedioic acid; dimethyl(2-{5-[(methylamino)methane]sulfonyl-1H-indol-3-yl}ethyl) amine

2.3. Other hazards

Other hazards

: None under normal conditions.

3. Composition/information on ingredients

Substance / Preparation

: butanedioic acid; dimethyl(2-{5-[(methylamino)methane]sulfonyl-1H-indol-3-yl}ethyl) amine

CAS No :103628-48-4

EC No :---

Annex No :---

REACH Ref. :---

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SUMATRIPTAN SUCCINATE**15810.SUS****3. Composition/information on ingredients (continued)**

Synonymous : Substance.
: 3-[2-(Dimethylamino)ethyl]-N-methyl-1H-indole-5-methanesulfonamide

Hazardous component(s) : This product is hazardous.

Substance name	Contents	CAS No	EC No	Annex No	REACH Ref.	Classification
butanedioic acid; dimethyl(2-{5-[(methylamino)methane]sulfonyl-1H-indol-3-yl)ethyl)amine	100 %	103628-48-4	----	----	----	Xi; R36 ----- Eye irrit 2

Contains no other components or impurities which will influence the classification of the product.

4. First aid measures**4.1. Description of first aid measures**

Inhalation : Assure fresh air breathing. Allow the victim to rest.

Skin contact : Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse.

Eye contact : Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists : Get medical advice.

Ingestion : Do NOT induce vomiting. Rinse mouth. Obtain emergency medical attention.

4.2. Most important symptoms and effects, both acute and delayed**4.3. Indication of any immediate medical attention and special treatment needed**

General information : Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).

5. Fire-fighting measures**5.1. Extinguishing media**

Suitable extinguishing media : Foam. Dry powder. Carbon dioxide. Water spray. Sand.

Unsuitable extinguishing media : Do not use a heavy water stream.

Surrounding fires : Use water spray or fog for cooling exposed containers.


5.2. Special hazards arising from the substance or mixture

Hazardous combustion products : Under fire conditions, hazardous fumes will be present.

5.3. Advice for fire-fighters

Protection against fire : Do not enter fire area without proper protective equipment, including respiratory protection.

Special procedures : Exercise caution when fighting any chemical fire. Avoid (reject) fire-fighting water to enter environment.

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6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

For emergency responders : Equip cleanup crew with proper protection. Ventilate area.

For non-emergency personnel : Evacuate unnecessary personnel.

6.2. Environmental precautions

Environmental precautions : Prevent entry to sewers and public waters. Notify authorities if product enters sewers or public waters.

6.3. Methods and material for containment and cleaning up

Clean up methods : Store away from other materials. On land, sweep or shovel into suitable containers. Minimize generation of dust.

6.4. Reference to other sections

See section 8. Exposure controls/personal protection

7. Handling and storage

7.1. Precautions for safe handling

Handling : Wash thoroughly after handling.

Technical protective measures : Provide good ventilation in process area to prevent formation of vapour.

7.2. Conditions for safe storage, including any incompatibilities

Storage : Keep only in the original container in a cool, well ventilated place. Keep container closed when not in use.

Storage - away from : Strong bases. Strong acids. Sources of ignition. Direct sunlight.

7.3. Specific end use(s)

Specific end use(s) : None.

8. Exposure controls/personal protection

8.1. Exposure controls


Personal protection



MOEHS IBÉRICA, S.L.

Roma, 8 - P.I. Cova Solera Tel. +34 93 586 05 20 / Fax + 34 93 699 8350 08191 Rubi SPAIN

hse@moehs.com

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8. Exposure controls/personal protection (continued)

- | | |
|---------------------------------|---|
| Personal protection | : Avoid all unnecessary exposure. |
| • Respiratory protection | : Wear approved mask. |
| • Hand protection | : Wear protective gloves. |
| • Eye protection | : Chemical goggles or safety glasses. |
| • Others | : When using, do not eat, drink or smoke. |

8.2. Control parameters

- | | |
|-------------------------------------|----------------------|
| Occupational Exposure Limits | : No data available. |
|-------------------------------------|----------------------|

9. Physical and chemical properties


9.1. Information on basic physical and chemical properties

- | | |
|--|-------------------------------|
| Physical state at 20 °C | : Powder. |
| Molecular weight | : 413.5 (g/mol) |
| Colour | : White. |
| Odour | : Characteristic. |
| pH value | : 4 - 5.1 (in 1.68% aq. sol.) |
| Melting point [°C] | : 165 - 166 |
| Flash point [°C] | : 254.8 |
| Initial boiling point [°C] | : 497.7 (at 760 mmHg) |
| Solubility in water | : Complete. |
| Log Pow octanol / water at 20°C | : 0.8 |

9.2. Other information

Explosive properties

- | | |
|--|----------------------|
| • Layer minimum flammability temperature | : No data available. |
| • Cloud minimum flammability temperature [°C] | : No data available. |
| • Minimum ignition energy [mJ] | : No data available. |
| - Explosion Class | : No data available. |
| • Minimum explosive concentration [g/m³] | : No data available. |
| • Explosivity Pmax [bar-g] | : No data available. |
| • Explosión severity factor Kmax [bar-m/s] | : No data available. |
| Oxidising properties | : No data available. |

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10. Stability and reactivity

10.1. Reactivity

Reactivity : Not established.

10.2. Chemical stability

Chemical stability : Stable under recommended storage conditions.

10.3. Possibility of hazardous reactions

Hazardous reactions : Not established.

10.4. Conditions to avoid

Conditions to avoid : Direct sunlight. Extremely high or low temperatures.

10.5. Incompatible materials

Materials to avoid : Strong acids. Strong bases.

10.6. Hazardous decomposition products

Hazardous decomposition products : Fumes. Carbon monoxide. SOx. Carbon dioxide.

11. Toxicological information

11.1. Information on toxicological effects

Acute toxicity

- **Inhalation** : Based on available data, the classification criteria are not met.
- **Dermal** : Based on available data, the classification criteria are not met.
 - Subcutaneous rat LD50 [mg/kg] : 1680
- **Ingestion** : Based on available data, the classification criteria are not met.
 - Rat oral LD50 [mg/kg] : 2939
- **Other** : Based on available data, the classification criteria are not met.
 - Intravenous rat LD50 [mg/kg] : 43.112

Corrosion : Based on available data, the classification criteria are not met.

Irritation : Causes serious eye irritation.

Sensitization : Based on available data, the classification criteria are not met.

Mutagenicity : Not applicable.

Carcinogenicity : Not applicable. Not listed.


Toxic for reproduction : Based on available data, the classification criteria are not met.

STOT-single exposure : Based on available data, the classification criteria are not met.

STOT-repeated exposure : Based on available data, the classification criteria are not met.

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11. Toxicological information (continued)

- Aspiration hazard** : Based on available data, the classification criteria are not met.
Other : There is no evidence which establishes that Sumatriptan causes birth defects in humans.

12. Ecological information

12.1. Toxicity

- Toxicity information** : Not established.
96 H-LC50 - Rainbow trout [mg/L] : 100
48 Hour-EC50 - Daphnia magna [mg/l] : 290
EC50 72h Algae [mg/l] : 36

12.2. Persistence - degradability

- Persistence - degradability** : No data available.

12.3. Bioaccumulative potential

- Bioaccumulative potential** : Weak.

12.4. Mobility in soil

- Mobility in soil** : Not established.

12.5. Results of PBT and vPvB assessment

- Results of PBT and vPvB assessment** : The substance does not fulfil the criteria to be identified as PBT substance or vPvB substance according to Annex XIII of Regulation REACH.

12.6. Other adverse effects

- Environmental precautions** : Avoid release to the environment.

13. Disposal considerations

13.1. Waste treatment methods


- General** : Avoid release to the environment. Dispose in a safe manner in accordance with local/national regulations.

14. Transport information

14.1. Land transport (ADR-RID)

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14. Transport information (continued)

General information : Not regulated.

14.2. Sea transport (IMDG) [English only]

General information : Not regulated.

14.3. Air transport (ICAO-IATA) [English only]

General information : Not regulated.

15. Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

Safety, health and environmental regulations/legislation specific for the substance or mixture : Ensure all national/local regulations are observed.

15.2. Chemical Safety Assessment

Chemical Safety Assessment : It has not been carried out.

16. Other information

Revision : Revision - See : *

Abbreviations and acronyms : PBT: persistent, bioaccumulative and toxic.
vPvB: very persistent and very bioaccumulative

Sources of key data used : REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006

List of relevant R phrases (heading 3) : R36 : Irritating to eyes.

List of full text of H-statements in section 3 : H319 : Causes serious eye irritation.

Use : Active Ingredient for Medicinal / pharmaceutical use.

Therapeutic Category : Acute treatment of migraine headaches

Further information : See product bulletin for detailed information.

The contents and format of this SDS are in accordance with REACH Regulation (CE) N° 1907/2006.

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hse@moehs.com