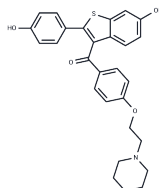


SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product form : Substance
Substance name : Raloxifene
CAS-No. : 84449-90-1
Product code : NB-64-10140
Formula : C₂₈H₂₇NO₄S
Chemical structure :



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

No additional information available

1.3. Details of the supplier of the safety data sheet

Manufacturer

NeoBiotech SAS
74 Rue des Suisses
92000 Nanterre
France
T +33 9 77 40 09 09, F +33 9 77 40 10 11
tech@neo-biotech.com, <https://www.neo-biotech.com/>

Distributor

CliniSciences
Rue des Suisses 74
92000 Nanterre
France
T +33 9 77 40 09 09, F +33 9 77 40 10 11
info@clinisciences.com, www.clinisciences.com

1.4. Emergency telephone number

| Country/Area | Organisation | Emergency number |
|--------------|--|------------------|
| Italy | Centro Antiveleni di Bergamo. Azienda Ospedaliera Papa Giovanni XXIII. Piazza OMS - Organizzazione Mondiale della Sanità, 1 24127 Bergamo. | 800 88 33 00 |
| | Centro Antiveleni di Milano. Ospedale Niguarda Ca' Granda. Piazza Ospedale Maggiore 3 20162 Milan. | 02 6610 1029 |
| | Centro Antiveleni di Roma. CAV Policlinico "A. Gemelli". Dipartimento di Tossicologia Clinica Universita Cattolica del Sacro Cuore. Largo Agostino Gemelli, 8 00168 Rome. | 06 305 4343 |
| | Centro Antiveleni di Roma. CAV Policlinico "Umberto I". Università di Roma. Viale del Policlinico, 155 00161 Rome. | 06 4997 8000 |
| | Centro Antiveleni di Firenze. Az. Osp. "Careggi" U.O. Tossicologia Medica. S.O.D. di Tossicologia Clinica/cologia Clinica. Largo Brambilla, 3 50134 Florence. | 055 794 7819 |
| | Centro Antiveleni di Pavia. CAV Centro Nazionale di Informazione Tossicologica. Istituti Clinici Scientifici Maugeri Spa. Via Salvatore Maugeri, 10 27100 Pavia. | 03 822 4444 |

Raloxifene

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

| Country/Area | Organisation | Emergency number |
|--------------|--|------------------|
| | Centro Antiveleni di Roma. CAV "Osp. Pediatrico Bambino Gesù" Dip. Emergenza e Accettazione DEA. Piazza Sant'Onofrio, 4 00165 Rome. | 06 6859 3726 |
| | Centro Antiveleni di Foggia. Az. Osp. Univ. Foggia. V.le Luigi Pinto, 1 71122 Foggia. | 800 183 459 |
| | Centro Antiveleni di Napoli. Az. Osp. "A. Cardarelli". Via A. Cardarelli, 9 80131 Naples. | 081 54 53 333 |

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Not classified

Adverse physicochemical, human health and environmental effects

To our knowledge, this product does not present any particular risk, provided it is handled in accordance with good occupational hygiene and safety practice.

2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

No labelling applicable

2.3. Other hazards

No additional information available

SECTION 3: Composition/information on ingredients

3.1. Substances

| Name | Product identifier | % | Classification according to Regulation (EC) No. 1272/2008 [CLP] |
|------------|---------------------|-------|---|
| Raloxifene | CAS-No.: 84449-90-1 | 99.39 | Not classified |

SECTION 4: First aid measures

4.1. Description of first aid measures

| | |
|---------------------------------------|--|
| First-aid measures general | : If you feel unwell, seek medical advice. |
| First-aid measures after inhalation | : Remove person to fresh air and keep comfortable for breathing. |
| First-aid measures after skin contact | : Wash skin with plenty of water. |
| First-aid measures after eye contact | : Rinse eyes with water as a precaution. |
| First-aid measures after ingestion | : Call a poison center or a doctor if you feel unwell. |
| Self protection of the first-aiders | : Even though no specific hazards are defined, first-aiders should wear eye protection, gloves and disposable half mask. Consider additional protection if repeated or prolonged exposition is likely. |

Raloxifene

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

4.2. Most important symptoms and effects, both acute and delayed

| | |
|-------------------------------------|--|
| Symptoms/effects after inhalation | : None under normal conditions. Dust of the product, if present, may cause respiratory irritation after excessive inhalation exposure. |
| Symptoms/effects after skin contact | : None under normal conditions. Dust may cause irritation in skin folds or by contact in combination with tight clothing. |
| Symptoms/effects after eye contact | : None under normal conditions. Dust from this product may cause eye irritation. |
| Symptoms/effects after ingestion | : None under normal conditions. |

4.3. Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

| | |
|--------------------------------|------------------------------------|
| Suitable extinguishing media | : Water spray. Dry powder. Foam. |
| Unsuitable extinguishing media | : Do not use a heavy water stream. |

5.2. Special hazards arising from the substance or mixture

| | |
|--|--------------------------------|
| Fire hazard | : No fire hazard. |
| Explosion hazard | : No direct explosion hazard. |
| Hazardous decomposition products in case of fire | : Toxic fumes may be released. |

5.3. Advice for firefighters

| | |
|--------------------------------|---|
| Firefighting instructions | : Fight fire from safe distance and protected location. Do not enter fire area without proper protective equipment, including respiratory protection. |
| Protection during firefighting | : Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing. |

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

| | |
|------------------|---|
| General measures | : Notify authorities if product enters sewers or public waters. Absorb spillage to prevent material damage. |
|------------------|---|

For non-emergency personnel

| | |
|----------------------|---|
| Protective equipment | : Wear recommended personal protective equipment. |
| Emergency procedures | : Ventilate spillage area. |

For emergency responders

| | |
|----------------------|---|
| Protective equipment | : Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection". |
| Emergency procedures | : Evacuate unnecessary personnel. |

6.2. Environmental precautions

Avoid release to the environment.

6.3. Methods and material for containment and cleaning up

| | |
|-------------------------|---|
| For containment | : Using a clean shovel, put the material in a dry container and cover without compressing it. |
| Methods for cleaning up | : Mechanically recover the product. |
| Other information | : Dispose of materials or solid residues at an authorized site. |

6.4. Reference to other sections

For further information refer to section 13.

Raloxifene

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

SECTION 7: Handling and storage

7.1. Precautions for safe handling

| | |
|-----------------------------------|---|
| Additional hazards when processed | : Not expected to present a significant hazard under anticipated conditions of normal use. |
| Precautions for safe handling | : Ensure good ventilation of the work station. Wear personal protective equipment. |
| Hygiene measures | : Do not eat, drink or smoke when using this product. Always wash hands after handling the product. |

7.2. Conditions for safe storage, including any incompatibilities

| | |
|---------------------|---|
| Technical measures | : Keep in a cool, well-ventilated place away from heat. |
| Storage conditions | : Keep cool. Protect from sunlight. |
| Packaging materials | : Always store product in container of same material as original container. |

7.3. Specific end use(s)

No additional information available

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

No additional information available

8.2. Exposure controls

Appropriate engineering controls

Appropriate engineering controls:

Ensure good ventilation of the work station.

Personal protection equipment

Personal protective equipment:

Wear recommended personal protective equipment.

Personal protective equipment symbol(s):



Eye and face protection

Eye protection:

Safety glasses

Skin protection

Skin and body protection:

Wear suitable protective clothing

Hand protection:

Protective gloves

Respiratory protection

Respiratory protection:

In case of insufficient ventilation, wear suitable respiratory equipment

Environmental exposure controls

Environmental exposure controls:

Avoid release to the environment.

Raloxifene

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

| | |
|---|---|
| Physical state | : Solid |
| Colour | : Not available |
| Odour | : Not available |
| Odour threshold | : Not available |
| Melting point | : 250-253°C |
| Freezing point | : Not applicable |
| Boiling point | : 728.2°C at 760 mmHg |
| Flammability | : Non flammable |
| Lower explosion limit | : Not applicable |
| Upper explosion limit | : Not applicable |
| Flash point | : 394.2°C |
| Auto-ignition temperature | : Not applicable |
| Decomposition temperature | : Not available |
| pH | : Not available |
| pH solution | : Not available |
| Viscosity, kinematic | : Not applicable |
| Solubility | : Organic solvent:DMSO: 29.41 mg/mL (62.1 mM),Sonication is recommended. Ethanol: 9 mg/mL (19 mM),Sonication is recommended |
| Partition coefficient n-octanol/water (Log Kow) | : Not available |
| Vapour pressure | : Not available |
| Vapour pressure at 50°C | : Not available |
| Density | : 1.289 g/cm ³ |
| Relative density | : Not available |
| Relative vapour density at 20°C | : Not applicable |
| Particle size | : Not available |

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

The product is non-reactive under normal conditions of use, storage and transport.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

10.4. Conditions to avoid

None under recommended storage and handling conditions (see section 7).

10.5. Incompatible materials

No additional information available

10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity (oral) : Not classified (Based on available data, the classification criteria are not met)

Raloxifene

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

| | |
|-----------------------------------|---|
| Acute toxicity (dermal) | : Not classified (Based on available data, the classification criteria are not met) |
| Acute toxicity (inhalation) | : Not classified (Based on available data, the classification criteria are not met) |
| Skin corrosion/irritation | : Not classified (Based on available data, the classification criteria are not met) |
| Serious eye damage/irritation | : Not classified (Based on available data, the classification criteria are not met) |
| Respiratory or skin sensitisation | : Not classified (Based on available data, the classification criteria are not met) |
| Germ cell mutagenicity | : Not classified (Based on available data, the classification criteria are not met) |
| Carcinogenicity | : Not classified (Based on available data, the classification criteria are not met) |
| Reproductive toxicity | : Not classified (Based on available data, the classification criteria are not met) |
| STOT-single exposure | : Not classified (Based on available data, the classification criteria are not met) |
| STOT-repeated exposure | : Not classified (Based on available data, the classification criteria are not met) |
| Aspiration hazard | : Not classified (Based on available data, the classification criteria are not met) |

Raloxifene (84449-90-1)

| | |
|----------------------|----------------|
| Viscosity, kinematic | Not applicable |
|----------------------|----------------|

11.2. Information on other hazards

No additional information available

SECTION 12: Ecological information

12.1. Toxicity

| | |
|---|---|
| Ecology - general | : The product is not considered harmful to aquatic organisms nor to cause long-term adverse effects in the environment. |
| Hazardous to the aquatic environment, short-term (acute) | : Not classified (Based on available data, the classification criteria are not met) |
| Hazardous to the aquatic environment, long-term (chronic) | : Not classified (Based on available data, the classification criteria are not met) |

12.2. Persistence and degradability

Raloxifene (84449-90-1)

| | |
|-------------------------------|------------------------|
| Persistence and degradability | Not rapidly degradable |
|-------------------------------|------------------------|

12.3. Bioaccumulative potential

No additional information available

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Endocrine disrupting properties

No additional information available

12.7. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

| | |
|---------------------------------|---|
| Regional waste regulation | : Disposal must be done according to official regulations. |
| Waste treatment methods | : Dispose of contents/container in accordance with licensed collector's sorting instructions. |
| Sewage disposal recommendations | : Disposal must be done according to official regulations. |

Raloxifene

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

| | |
|--|---|
| Product/Packaging disposal recommendations | : Comply with applicable regulations for solid waste disposal. Disposal must be done according to official regulations. |
| Additional information | : Do not re-use empty containers. |
| Ecological waste information | : The waste of the product should be considered as hazardous as the product itself, with the likelihood of impacting the environment in the same way. Consider the handling and disposal of the waste as defined by the product itself. |

SECTION 14: Transport information

In accordance with ADR / IMDG / IATA / ADN / RID

| ADR | IMDG | IATA | ADN | RID |
|---|---------------|---------------|---------------|---------------|
| 14.1. UN number or ID number | | | | |
| Not regulated for transport | | | | |
| 14.2. UN proper shipping name | | | | |
| Not regulated | Not regulated | Not regulated | Not regulated | Not regulated |
| 14.3. Transport hazard class(es) | | | | |
| Not regulated | Not regulated | Not regulated | Not regulated | Not regulated |
| 14.4. Packing group | | | | |
| Not regulated | Not regulated | Not regulated | Not regulated | Not regulated |
| 14.5. Environmental hazards | | | | |
| Not regulated | Not regulated | Not regulated | Not regulated | Not regulated |
| No supplementary information available | | | | |

14.6. Special precautions for user

Overland transport

Not regulated

Transport by sea

Not regulated

Air transport

Not regulated

Inland waterway transport

Not regulated

Rail transport

Not regulated

14.7. Maritime transport in bulk according to IMO instruments

Not applicable

SECTION 15: Regulatory information

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

EU-Regulations

REACH Annex XVII (Restriction List)

Not listed on REACH Annex XVII

REACH Annex XIV (Authorisation List)

Not listed on REACH Annex XIV (Authorisation List)

Raloxifene

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

REACH Candidate List (SVHC)

Not listed on the REACH Candidate List

PIC Regulation (Prior Informed Consent)

Not listed on the PIC list (Regulation EU 649/2012)

POP Regulation (Persistent Organic Pollutants)

Not listed on the POP list (Regulation EU 2019/1021)

Ozone Regulation (2024/590)

Not listed on the Ozone Depletion list (Regulation EU 2024/590)

Council Regulation (EC) for the control of dual-use items

Not listed on the COUNCIL REGULATION (EC) of dual-use items.

Explosives Precursors Regulation (EU 2019/1148)

Not listed on the Explosives Precursors list (EU)

Drug Precursors Regulation (EC 273/2004)

Not listed on the Drug Precursors list (EU)

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Abbreviations and acronyms:

| | |
|---------|---|
| ACGIH | American Conference of Governmental Industrial Hygienists |
| ADN | European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways |
| ADR | European Agreement concerning the International Carriage of Dangerous Goods by Road |
| ATE | Acute Toxicity Estimate |
| BCF | Bioconcentration factor |
| BLV | Biological limit value |
| BOD | Biochemical oxygen demand (BOD) |
| CAS-No. | Chemical Abstracts Service number |
| CLP | Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008 |
| COD | Chemical oxygen demand (COD) |
| CSA | Chemical safety assessment |
| DMEL | Derived Minimal Effect level |
| DNEL | Derived-No Effect Level |
| EC-No. | European Community number |
| EC50 | Median effective concentration |
| ED | Endocrine disruptor |
| EN | European Standard |
| EWC | European waste catalogue |
| IARC | International Agency for Research on Cancer |
| IATA | International Air Transport Association |
| IMDG | International Maritime Dangerous Goods |
| LC50 | Median lethal concentration |

Raloxifene

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

| Abbreviations and acronyms: | |
|-----------------------------|--|
| LD50 | Median lethal dose |
| LOAEL | Lowest Observed Adverse Effect Level |
| Log Kow | Partition coefficient n-octanol/water (Log Kow) |
| Log Pow | Partition coefficient n-octanol/water (Log Pow) |
| MAK | maximum workplace concentration |
| NOAEC | No-Observed Adverse Effect Concentration |
| NOAEL | No-Observed Adverse Effect Level |
| NOEC | No-Observed Effect Concentration |
| N.O.S. | Not Otherwise Specified |
| OECD | Organisation for Economic Co-operation and Development |
| OEL | Occupational Exposure Limit |
| OSHA | Occupational Safety & Health Administration |
| PBT | Persistent Bioaccumulative Toxic |
| PNEC | Predicted No-Effect Concentration |
| PPE | Personal protection equipment |
| RID | Regulations concerning the International Carriage of Dangerous Goods by Rail |
| SDS | Safety Data Sheet |
| STP | Sewage treatment plant |
| TF | Technical function |
| ThOD | Theoretical oxygen demand (ThOD) |
| TLM | Median Tolerance Limit |
| TWA | Time Weighted Average |
| VOC | Volatile Organic Compounds |
| vPvB | Very Persistent and Very Bioaccumulative |
| UFI | Unique Formula Identifier |

The classification complies with : ATP 12

Safety Data Sheet (SDS), EU

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.