

SECTION 1: Identification of the substance/mixture and of the company/undertaking**1.1. Product identifier**

Product form	: Substance
Trade name	: ACEBUTOLOL HYDROCHLORIDE
Chemical name	: (±)-N-[3-acetyl-4-[2-hydroxy-3-[(isopropyl)amino]propoxy]phenyl]butyramide
IUPAC name	: (±)-N-[3-acetyl-4-[2-hydroxy-3-[(isopropyl)amino]propoxy]phenyl]butyramide
EC-No.	: 251-980-3
CAS-No.	: 34381-68-5
Product code	: 70030
Type of product	: Active Ingredient for Medicinal / Pharmaceutical Use
Formula	: C ₁₈ H ₂₈ N ₂ O ₄ .HCl
Synonyms	: Acebutolol hydrochloride; N-[3-acetyl-4-[2-hydroxy-3-(propan-2-ylamino)propoxy]phenyl]butanamide monohydrochloride
Other means of identification	: SMILE: CCCC(=O)NC1=CC(C(C)=O)=C(OCC(O)CNC(C)C)C=C1.Cl

1.2. Relevant identified uses of the substance or mixture and uses advised against**1.2.1. Relevant identified uses**

Main use category	: API, Industrial use, Medicinal use
Industrial/Professional use spec	: Active Ingredient for Medicinal / Pharmaceutical Use Industrial For professional use only
Use of the substance/mixture	: beta-adrenoreceptor blocking agent
Use of the substance/mixture	: Pharmaceuticals
Function or use category	: Pharmaceuticals

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet**Head office**

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1.4. Emergency telephone number

Emergency number	: +34 93 586 05 20 (9:00 - 17:00)
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SECTION 2: Hazards identification**2.1. Classification of the substance or mixture****Classification according to Regulation (EC) No. 1272/2008 [CLP]**

Acute toxicity (dermal), Category 4	H312
Serious eye damage/eye irritation, Category 2	H319

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Skin sensitisation, Category 1

H317

Full text of H- and EUH-statements: see section 16

Adverse physicochemical, human health and environmental effects

Harmful in contact with skin. Causes serious eye irritation. May cause an allergic skin reaction.

2.2. Label elements

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

Hazard pictograms (CLP)

:



GHS07

Signal word (CLP)

: Warning

Hazard statements (CLP)

: H312 - Harmful in contact with skin.

H317 - May cause an allergic skin reaction.

H319 - Causes serious eye irritation.

Precautionary statements (CLP)

: P261 - Avoid breathing dust, mist, spray.

P264 - Wash hands, forearms and face thoroughly after handling.

P280 - Wear protective gloves, eye protection, protective clothing, face protection.

P302+P352 - IF ON SKIN: Wash with plenty of water.

P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P333+P313 - If skin irritation or rash occurs: Get medical advice/attention.

P337+P313 - If eye irritation persists: Get medical advice/attention.

P362+P364 - Take off contaminated clothing and wash it before reuse.

P501 - Dispose of contents/container to a hazardous or special waste collection point.

2.3. Other hazards

Other hazards which do not result in classification : Dust may form explosive mixture in air.

vPvB: not relevant – no registration required

SECTION 3: Composition/information on ingredients

3.1. Substances

Substance type

: Mono-constituent

Name	Product identifier	%
ACEBUTOLOL HYDROCHLORIDE	CAS-No.: 34381-68-5 EC-No.: 251-980-3	100

3.2. Mixtures

Not applicable

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general

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

First-aid measures after inhalation

: Allow affected person to breathe fresh air. Allow the victim to rest.

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First-aid measures after skin contact	: If skin irritation occurs: Get medical advice/attention. Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse. Immediately call a POISON CENTER/doctor. Specific measures (see supplemental first aid instruction on this label). Wash with plenty of water/.... Wash contaminated clothing before reuse. If skin irritation or rash occurs: Get medical advice/attention. Specific treatment (see supplemental first aid instruction on this label).
First-aid measures after 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/attention.
First-aid measures after ingestion	: Call a poison center or a doctor if you feel unwell. Rinse mouth. Do NOT induce vomiting. Obtain emergency medical attention.

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

Symptoms/effects	: If you feel unwell, seek medical advice.
Symptoms/effects after inhalation	: May cause respiratory irritation. May cause an allergic skin reaction.
Symptoms/effects after skin contact	: May cause an allergic skin reaction. Repeated exposure to this material can result in absorption through skin causing significant health hazard. Harmful in contact with skin.
Symptoms/effects after eye contact	: Causes serious eye irritation.

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

Never give anything by mouth to an unconscious person.

SECTION 5: Firefighting 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.

5.2. Special hazards arising from the substance or mixture

Hazardous decomposition products in case of fire	: Thermal decomposition generates : fume. Carbon monoxide. Carbon dioxide. Nitrogen oxides. Toxic fumes may be released.
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5.3. Advice for firefighters

Precautionary measures fire	: Stop leak if safe to do so.
Firefighting instructions	: Use water spray or fog for cooling exposed containers. Exercise caution when fighting any chemical fire. Prevent fire fighting water from entering the environment.
Protection during firefighting	: Do not enter fire area without proper protective equipment, including respiratory protection.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures	: No open flames. No smoking. No flames, no sparks. Eliminate all sources of ignition.
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6.1.1. For non-emergency personnel

Protective equipment	: Breathing equipment.
Emergency procedures	: Avoid breathing dust, mist, spray. Evacuate unnecessary personnel.

6.1.2. For emergency responders

Protective equipment	: Equip cleanup crew with proper protection.
Emergency procedures	: Shovel or sweep up and put in a closed container for disposal. Stop leak if safe to do so. Ventilate area.

6.2. Environmental precautions

Avoid release to the environment. Prevent entry to sewers and public waters. Notify authorities if liquid enters sewers or public waters.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up	: On land, sweep or shovel into suitable containers. Minimise generation of dust. Store away from other materials.
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Other information : Dispose of materials or solid residues at an authorized site.

6.4. Reference to other sections

See Section 8. Exposure controls and personal protection.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Ensure good ventilation of the work station. Avoid dust formation. Prevent the build-up of electrostatic charge. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Provide good ventilation in process area to prevent formation of vapour. Avoid breathing dust/fume/gas/mist/vapours/spray.

Hygiene measures : Do not eat, drink or smoke when using this product. Separate working clothes from town clothes. Launder separately. Wash hands, forearms and face thoroughly after handling. Contaminated work clothing should not be allowed out of the workplace. Wash contaminated clothing before reuse.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store in a well-ventilated place. Store at room temperature. Keep away from ignition sources. Keep only in the original container in a cool, well ventilated place away from : Keep container closed when not in use.

Incompatible products : Strong bases. Strong acids.

Incompatible materials : Sources of ignition. Direct sunlight.

Storage area : Store in a well-ventilated place. Store away from heat.

7.3. Specific end use(s)

Pharmaceuticals.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.1.1 National occupational exposure and biological limit values

No additional information available

8.1.2. Recommended monitoring procedures

No additional information available

8.1.3. Air contaminants formed

No additional information available

8.1.4. DNEL and PNEC

No additional information available

8.1.5. Control banding

Control banding : MOEHS occupational exposure band: 3 (0.01 - 0.1 mg/m³)

8.2. Exposure controls

8.2.1. Appropriate engineering controls

Appropriate engineering controls:

Ensure good ventilation of the work station. Dust extraction (suction). Breathing equipment. Emergency eye wash fountains and safety showers should be available in the immediate vicinity of any potential exposure.

8.2.2. Personal protection equipment

Personal protective equipment:

Gloves. Safety glasses. Dust/aerosol mask. Avoid all unnecessary exposure.

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Personal protective equipment symbol(s):



8.2.2.1. Eye and face protection

Eye protection:

Chemical goggles or safety glasses

Eye protection		
Type	Field of application	Standard
Safety goggles	Dust, Fine dust	EN 166

8.2.2.2. Skin protection

Skin and body protection:

Wear suitable protective clothing

Skin and body protection	
Type	Standard
Disposable gowns, Reusable gowns, Tyvek® Gown/Coveralls	EN 13034, EN 1149-1

Hand protection:

Wear protective gloves.

Hand protection		
Type	Material	Standard
Disposable gloves	Natural rubber, Polyvinylalcohol (PVA), Polyvinylchloride (PVC), Latex	EN ISO 374

8.2.2.3. Respiratory protection

Respiratory protection:

Wear appropriate mask

Respiratory protection			
Device	Filter type	Condition	Standard
Dust mask	Type P3	Dust protection	EN 143

8.2.2.4. Thermal hazards

No additional information available

8.2.3. Environmental exposure controls

Environmental exposure controls:

Avoid release to the environment.

Other information:

Do not eat, drink or smoke during use.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state : Solid
Colour : white.

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Molecular mass	: 372.9 g/mol
Odour	: characteristic.
Odour threshold	: Not available
Melting point	: 143 °C
Freezing point	: Not available
Boiling point	: Not available
Flammability	: May form combustible dust concentrations in air, Non flammable.
Explosive properties	: May form combustible dust concentrations in air.
Explosive limits	: Not applicable
Lower explosion limit	: Not applicable
Upper explosion limit	: Not applicable
Flash point	: 265 – 325 (Acebutolol base flash point) Estimated by ACD/Labs
Auto-ignition temperature	: Not applicable
Decomposition temperature	: Not available
pH	: Not available
pH solution	: Not available
Viscosity, kinematic	: Not applicable
Solubility	: Water: 259 [Acebutolol Base] Ethanol: Partially soluble
Partition coefficient n-octanol/water (Log Kow)	: 1.7 [Acebutolol Base; at 20°C; expkow database]
Vapour pressure	: Not available
Vapour pressure at 50°C	: Not available
Density	: Not available
Relative density	: Not available
Relative vapour density at 20°C	: Not applicable
Particle size	: Not available
Particle size distribution	: Not available
Particle shape	: Not available
Particle aspect ratio	: Not available
Particle aggregation state	: Not available
Particle agglomeration state	: Not available
Particle specific surface area	: Not available
Particle dustiness	: Not available

9.2. Other information

9.2.1. Information with regard to physical hazard classes

No additional information available

9.2.2. Other safety characteristics

Minimum ignition energy	: 4-5
Additional information	: Minimum ignition energy : 4-5 mJ. Dust Cloud minimum Flammability Temperature : 450°C. Layer Minimum flammability Temperature : >400°C. Explosivity Pmax : 8.7 bar. Explosion Severity Factor Kmax (bar.m/s) : 242. Explosion Class : 2

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 in use and storage conditions as recommended in item 7. Not established.

10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use. Not established.

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10.4. Conditions to avoid

Direct sunlight. Extremely high or low temperatures.

10.5. Incompatible materials

Strong acids. Strong bases.

10.6. Hazardous decomposition products

Nitrogen oxides. fume. Carbon monoxide. Carbon dioxide.

SECTION 11: Toxicological information

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

Acute toxicity (oral)	: Not classified
Acute toxicity (dermal)	: Harmful in contact with skin.
Acute toxicity (inhalation)	: Not classified

ACEBUTOLOL HYDROCHLORIDE (34381-68-5)

LD50 oral rat	6620 mg/kg
LD50, oral, mouse	4050 mg/kg
LD50, acute, intraperitoneal, rat	222 mg/kg
LD50, acute, oral, rabbit	296 mg/kg
LD50, subcutaneous, rat	1310 mg/kg
LD50, intraperitoneal, rat	222 mg/kg
LD50, intravenous, rat	103 mg/kg
LD50, intraperitoneal, mouse	185 mg/kg
LD50, subcutaneous, mouse	291 mg/kg
LD50, intravenous, mouse	53 mg/kg

Skin corrosion/irritation	: Not classified
Additional information	: Based on available data, the classification criteria are not met
Serious eye damage/irritation	: Causes serious eye irritation.
Respiratory or skin sensitisation	: May cause an allergic skin reaction.
Germ cell mutagenicity	: Not classified
Additional information	: Based on available data, the classification criteria are not met
Carcinogenicity	: Not classified
Additional information	: Based on available data, the classification criteria are not met
Reproductive toxicity	: Not classified
Additional information	: Based on available data, the classification criteria are not met
STOT-single exposure	: Not classified
Additional information	: Based on available data, the classification criteria are not met
STOT-repeated exposure	: Not classified
Additional information	: Based on available data, the classification criteria are not met
Aspiration hazard	: Not classified
Additional information	: Based on available data, the classification criteria are not met

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

Adverse health effects caused by endocrine disrupting properties	: The substance is not included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605
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11.2.2. Other information

Potential adverse human health effects and symptoms : Harmful in contact with skin.
Other information : Likely routes of exposure: inhalation, skin and eye.

SECTION 12: Ecological information

12.1. Toxicity

Hazardous to the aquatic environment, short-term (acute) : Not classified
Hazardous to the aquatic environment, long-term (chronic) : Not classified

12.2. Persistence and degradability

ACEBUTOLOL HYDROCHLORIDE (34381-68-5)

Persistence and degradability	Not established.
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12.3. Bioaccumulative potential

ACEBUTOLOL HYDROCHLORIDE (34381-68-5)

Bioconcentration factor (BCF REACH)	0.1339 [Acebutolol Base]
Partition coefficient n-octanol/water (Log Kow)	1.7 [Acebutolol Base; at 20°C; expkow database]
Bioaccumulative potential	Not established.

12.4. Mobility in soil

ACEBUTOLOL HYDROCHLORIDE (34381-68-5)

Organic Carbon Normalized Adsorption Coefficient (Log Koc)	1.4 [Acebutolol base; PCKOCWIN v1.66]
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12.5. Results of PBT and vPvB assessment

ACEBUTOLOL HYDROCHLORIDE (34381-68-5)

vPvB: not relevant – no registration required

12.6. Endocrine disrupting properties

Adverse effects on the environment caused by endocrine disrupting properties : The substance/mixture has no endocrine disrupting properties.

12.7. Other adverse effects

Additional information : Avoid release to the environment.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Product/Packaging disposal recommendations : Dispose in a safe manner in accordance with local/national regulations. Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.
Additional information : Industrial waste.
Ecology - waste materials : Avoid release to the environment.

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SECTION 14: Transport information

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

14.1. UN number or ID number

UN-No. (ADR)	: Not regulated
UN-No. (IMDG)	: Not regulated
UN-No. (IATA)	: Not regulated
UN-No. (ADN)	: Not regulated
UN-No. (RID)	: Not regulated

14.2. UN proper shipping name

Proper Shipping Name (ADR)	: Not regulated
Proper Shipping Name (IMDG)	: Not regulated
Proper Shipping Name (IATA)	: Not regulated
Proper Shipping Name (ADN)	: Not regulated
Proper Shipping Name (RID)	: Not regulated

14.3. Transport hazard class(es)

ADR

Transport hazard class(es) (ADR)	: Not regulated
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IMDG

Transport hazard class(es) (IMDG)	: Not regulated
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IATA

Transport hazard class(es) (IATA)	: Not regulated
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ADN

Transport hazard class(es) (ADN)	: Not regulated
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RID

Transport hazard class(es) (RID)	: Not regulated
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14.4. Packing group

Packing group (ADR)	: Not regulated
Packing group (IMDG)	: Not regulated
Packing group (IATA)	: Not regulated
Packing group (ADN)	: Not regulated
Packing group (RID)	: Not regulated

14.5. Environmental hazards

Dangerous for the environment	: No
Marine pollutant	: No
Other information	: 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

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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

15.1.1. 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)

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 (1005/2009)

Not listed on the Ozone Depletion list (Regulation EU 1005/2009)

Explosives Precursors Regulation (2019/1148)

Contains no substance(s) listed on the Explosives Precursors list (Regulation EU 2019/1148 on the marketing and use of explosives precursors)

Drug Precursors Regulation (273/2004)

Contains no substance(s) listed on the Drug Precursors list (Regulation EC 273/2004 on the manufacture and the placing on market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances)

15.1.2. National regulations

Germany

Water hazard class (WGK) : Not classified according to Regulation Governing Systems for Handling Substances Hazardous to Waters (AwSV).

Hazardous Incident Ordinance (12. BImSchV) : Is not subject of the Hazardous Incident Ordinance (12. BImSchV)

Netherlands

SZW-lijst van kankerverwekkende stoffen : The substance is not listed

SZW-lijst van mutagene stoffen : The substance is not listed

SZW-lijst van reprotoxische stoffen – Borstvoeding : The substance is not listed

SZW-lijst van reprotoxische stoffen –

Vruchtbaarheid

SZW-lijst van reprotoxische stoffen – Ontwikkeling : The substance is not listed

Denmark

Danish National Regulations : Young people below the age of 18 years are not allowed to use the product
Pregnant/breastfeeding women working with the product must not be in direct contact with the product

Switzerland

Storage class (LK) : LK 11/13 - Solids

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

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

SECTION 16: Other information

Abbreviations and acronyms:	
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
BCF	Bioconcentration factor
CLP	Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008
DMEL	Derived Minimal Effect level
DNEL	Derived-No Effect Level
DPD	Dangerous Preparations Directive 1999/45/EC
DSD	Dangerous Substances Directive 67/548/EEC
EC50	Median effective concentration
IATA	International Air Transport Association
LC50	Median lethal concentration
LD50	Median lethal dose
LOAEL	Lowest Observed Adverse Effect Level
vPvB	Very Persistent and Very Bioaccumulative
NOAEL	No-Observed Adverse Effect Level
PBT	Persistent Bioaccumulative Toxic
PNEC	Predicted No-Effect Concentration
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail
SDS	Safety Data Sheet

Data sources : 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.

Other information : None.

Full text of H- and EUH-statements:	
Acute Tox. 4 (Dermal)	Acute toxicity (dermal), Category 4
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
H312	Harmful in contact with skin.
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.
Skin Sens. 1	Skin sensitisation, Category 1

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.