according to Regulation (EC) No. 1907/2006



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

1.1 Product identifier

Trade name : Carbidopa / Levodopa Formulation

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

Use of the Sub- : Pharmaceutical

stance/Mixture

1.3 Details of the supplier of the safety data sheet

Company : Organon & Co.

30 Hudson Street, 33nd floor

07302 Jersey City, New Jersey, U.S.A

Telephone : 551-430-6000

E-mail address of person responsible for the SDS

EHSSTEWARD@organon.com

1.4 Emergency telephone number

215-631-6999

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)

Acute toxicity, Category 4 H302: Harmful if swallowed.

Reproductive toxicity, Category 2 H361d: Suspected of damaging the unborn child. Specific target organ toxicity - repeated H372: Causes damage to organs through pro-

exposure, Category 1 longed or repeated exposure.

Long-term (chronic) aquatic hazard, Cat-H412: Harmful to aquatic life with long lasting ef-

egory 3 fe

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms :





Signal word : Danger

Hazard statements : H302 Harmful if swallowed.

H361d Suspected of damaging the unborn child.

H372 Causes damage to organs through prolonged or re-

peated exposure.

H412 Harmful to aquatic life with long lasting effects.

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Precautionary statements : Prevention:

P201 Obtain special instructions before use.

P260 Do not breathe dust.

P270 Do not eat, drink or smoke when using this product.

P273 Avoid release to the environment.

P280 Wear protective gloves/ protective clothing/ eye protec-

tion/ face protection.

Response:

P308 + P313 IF exposed or concerned: Get medical advice/

attention.

Hazardous components which must be listed on the label:

Levodopa Carbidopa

2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Ecological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Toxicological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Dust contact with the eyes can lead to mechanical irritation.

Contact with dust can cause mechanical irritation or drying of the skin.

May form explosive dust-air mixture during processing, handling or other means.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
Levodopa	59-92-7 200-445-2	Acute Tox. 4; H302 Repr. 2; H361d STOT RE 1; H372 (Central nervous system) Aquatic Chronic 3; H412	>= 70 - < 90
Carbidopa	38821-49-7	Acute Tox. 4; H302 Aquatic Chronic 3; H412	>= 10 - < 20

For explanation of abbreviations see section 16.

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SECTION 4: First aid measures

4.1 Description of first aid measures

General advice : In the case of accident or if you feel unwell, seek medical ad-

vice immediately.

When symptoms persist or in all cases of doubt seek medical

advice.

Protection of first-aiders : First Aid responders should pay attention to self-protection,

and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

If inhaled : If inhaled, remove to fresh air.

Get medical attention.

In case of skin contact : In case of contact, immediately flush skin with soap and plenty

of water.

Remove contaminated clothing and shoes.

Get medical attention. Wash clothing before reuse.

Thoroughly clean shoes before reuse.

In case of eye contact : If in eyes, rinse well with water.

Get medical attention if irritation develops and persists.

If swallowed, DO NOT induce vomiting.

Get medical attention.

Rinse mouth thoroughly with water.

Never give anything by mouth to an unconscious person.

4.2 Most important symptoms and effects, both acute and delayed

Risks : Harmful if swallowed.

Suspected of damaging the unborn child.

Causes damage to organs through prolonged or repeated

exposure.

Contact with dust can cause mechanical irritation or drying of

the skin.

Dust contact with the eyes can lead to mechanical irritation.

4.3 Indication of any immediate medical attention and special treatment needed

Treatment : Treat symptomatically and supportively.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media : Water spray

Alcohol-resistant foam

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Carbon dioxide (CO2)

Dry chemical

Unsuitable extinguishing

media

None known.

5.2 Special hazards arising from the substance or mixture

Specific hazards during fire-

fighting

: Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a

potential dust explosion hazard.

Exposure to combustion products may be a hazard to health.

Hazardous combustion prod- :

ucts

Carbon oxides Metal oxides

5.3 Advice for firefighters

Special protective equipment :

for firefighters

In the event of fire, wear self-contained breathing apparatus.

Use personal protective equipment.

Specific extinguishing meth-

ods

Use extinguishing measures that are appropriate to local cir-

cumstances and the surrounding environment. Use water spray to cool unopened containers.

Remove undamaged containers from fire area if it is safe to do

SO.

Evacuate area.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions : Use personal protective equipment.

Follow safe handling advice (see section 7) and personal pro-

tective equipment recommendations (see section 8).

6.2 Environmental precautions

Environmental precautions : Avoid release to the environment.

Prevent further leakage or spillage if safe to do so. Retain and dispose of contaminated wash water.

Local authorities should be advised if significant spillages

cannot be contained.

6.3 Methods and material for containment and cleaning up

Methods for cleaning up : Sweep up or vacuum up spillage and collect in suitable con-

tainer for disposal.

Avoid dispersal of dust in the air (i.e., clearing dust surfaces

with compressed air).

Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. Local or national regulations may apply to releases and disposal of this material, as well as those materials and items

according to Regulation (EC) No. 1907/2006



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employed in the cleanup of releases. You will need to deter-

mine which regulations are applicable.

Sections 13 and 15 of this SDS provide information regarding

certain local or national requirements.

6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Technical measures Static electricity may accumulate and ignite suspended dust

causing an explosion.

Provide adequate precautions, such as electrical grounding

and bonding, or inert atmospheres.

Local/Total ventilation Advice on safe handling Use only with adequate ventilation. Do not breathe dust.

Do not swallow.

Avoid contact with eyes.

Avoid prolonged or repeated contact with skin.

Wash skin thoroughly after handling.

Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure as-

sessment

Minimize dust generation and accumulation. Keep container closed when not in use. Keep away from heat and sources of ignition.

Take precautionary measures against static discharges. Do not eat, drink or smoke when using this product.

Take care to prevent spills, waste and minimize release to the

environment.

If exposure to chemical is likely during typical use, provide eye Hygiene measures

flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contami-

nated clothing before re-use.

The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers

Keep in properly labelled containers. Store locked up. Store in

accordance with the particular national regulations.

Do not store with the following product types: Advice on common storage

Strong oxidizing agents Organic peroxides

Explosives Gases

7.3 Specific end use(s)

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Specific use(s) : No data available

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis		
Levodopa	59-92-7	TWA	500 μg/m3 (OEB 2)	Internal		
Carbidopa	38821-49-7	TWA	2,000 μg/m3 (OEB 1)	Internal		
Cellulose	9004-34-6	OELV - 8 hrs (TWA)	10 mg/m3	IE OEL		
	Further information: Where no specific short-term exposure limit is listed, a					
	figure three times the long-term exposure limit value should be used					
Starch	9005-25-8	OELV - 8 hrs	4 mg/m3	IE OEL		
		(TWA) (Respira-				
		ble dust)				
	Further information: Where no specific short-term exposure limit is listed, a					
	figure three times the long-term exposure limit value should be used					
		OELV - 8 hrs	10 mg/m3	IE OEL		
		(TWA) (inhalable				
		dust)				
	Further information: Where no specific short-term exposure limit is listed, a					
	figure three times the long-term exposure limit value should be used					
Magnesium stea-	557-04-0	OELV - 8 hrs	10 mg/m3	IE OEL		
rate		(TWA)				
	Further information: Where no specific short-term exposure limit is listed, a					
	figure three times the long-term exposure limit value should be used					

8.2 Exposure controls

Engineering measures

Use feasible engineering controls to minimize exposure to compound. All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.

Personal protective equipment

Eye protection : Wear safety glasses with side shields or goggles.

If the work environment or activity involves dusty conditions,

mists or aerosols, wear the appropriate goggles.

Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or

aerosols.

Hand protection

Material : Chemical-resistant gloves

Skin and body protection : Work uniform or laboratory coat.

Respiratory protection : If adequate local exhaust ventilation is not available or expo-

sure assessment demonstrates exposures outside the rec-

ommended guidelines, use respiratory protection.

Equipment should conform to I.S. EN 143

according to Regulation (EC) No. 1907/2006



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Particulates type (P) Filter type

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state powder

Colour No data available

Odour odourless

Odour Threshold No data available

Melting point/freezing point No data available

Initial boiling point and boiling

range

No data available

Flammability (solid, gas) May form explosive dust-air mixture during processing, han-

dling or other means.

No data available Flammability (liquids)

Upper explosion limit / Upper

flammability limit

No data available

Lower explosion limit / Lower

flammability limit

No data available

Flash point No data available

No data available Auto-ignition temperature

Decomposition temperature

Decomposition tempera-

ture

No data available

pΗ No data available

Viscosity

Viscosity, dynamic No data available

Viscosity, kinematic No data available

Solubility(ies)

Water solubility No data available

Partition coefficient: n-

octanol/water

No data available

Vapour pressure No data available

Relative density No data available

Density No data available

Relative vapour density No data available

Particle characteristics

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Particle size : No data available

9.2 Other information

Explosives : Not explosive

Oxidizing properties : The substance or mixture is not classified as oxidizing.

Evaporation rate : No data available

Molecular weight : No data available

SECTION 10: Stability and reactivity

10.1 Reactivity

Not classified as a reactivity hazard.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

Hazardous reactions : May form explosive dust-air mixture during processing, han-

dling or other means.

Can react with strong oxidizing agents.

10.4 Conditions to avoid

Conditions to avoid : Heat, flames and sparks.

Avoid dust formation.

10.5 Incompatible materials

Materials to avoid : Oxidizing agents

10.6 Hazardous decomposition products

No hazardous decomposition products are known.

SECTION 11: Toxicological information

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

Information on likely routes of : Inhalation

exposure Skin contact

Ingestion Eye contact

Acute toxicity

Harmful if swallowed.

Product:

Acute oral toxicity : Acute toxicity estimate: 1,952 mg/kg

Method: Calculation method

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Components:

Levodopa:

Acute oral toxicity : LD50 (Rat): 1,780 mg/kg

LD50 (Mouse): 2,363 mg/kg

Carbidopa:

Acute oral toxicity : LD50 (Rat): 4,810 mg/kg

LD50 (Mouse): 1,750 mg/kg

Skin corrosion/irritation

Not classified based on available information.

Components:

Carbidopa:

Species : Rabbit

Result : No skin irritation

Serious eye damage/eye irritation

Not classified based on available information.

Components:

Carbidopa:

Species : Rabbit

Result : Mild eye irritation

Respiratory or skin sensitisation

Skin sensitisation

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

Components:

Levodopa:

Species : Guinea pig

Result : Not a skin sensitizer.

Carbidopa:

Remarks : No data available

Germ cell mutagenicity

Not classified based on available information.

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Components:

Levodopa:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)

Result: negative

Test Type: Chromosomal aberration Test system: mouse lymphoma cells

Result: equivocal

Test Type: Micronucleus test

Test system: Chinese hamster lung cells

Result: positive

Test Type: sister chromatid exchange assay Test system: Chinese hamster lung cells

Result: positive

Carbidopa:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)

Result: positive

Test Type: In vitro mammalian cell gene mutation test

Result: positive

Genotoxicity in vivo : Test Type: Micronucleus test

Species: Mouse Application Route: Oral Result: negative

Carcinogenicity

Not classified based on available information.

Components:

Levodopa:

Species : Rat
Application Route : Oral
Exposure time : 2 Years
Result : negative

Carbidopa:

Species : Rat
Application Route : Oral
Exposure time : 96 weeks

: 135 mg/kg body weight

Result : negative

Reproductive toxicity

Suspected of damaging the unborn child.

according to Regulation (EC) No. 1907/2006



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Components:

Levodopa:

Effects on fertility : Test Type: Fertility

Species: Rat

Application Route: Oral

Fertility: NOAEL: 100 mg/kg body weight

Result: Animal testing did not show any effects on fertility.

Effects on foetal develop-

ment

Test Type: Development

Species: Rabbit

Application Route: Oral

Developmental Toxicity: LOAEL: 125 mg/kg body weight Symptoms: Skeletal malformations, Visceral malformations

Result: positive

Test Type: Development

Species: Rat

Application Route: Oral

Developmental Toxicity: LOAEL: 10 mg/kg body weight

Test Type: Development

Species: Mouse

Application Route: Oral

Developmental Toxicity: LOAEL: 500 mg/kg body weight

Symptoms: Effects on foetal development

Result: positive

Reproductive toxicity - As-

sessment

Some evidence of adverse effects on development, based on

animal experiments.

Carbidopa:

Effects on fertility : Test Type: Fertility

Species: Rat

Application Route: Oral

Fertility: NOAEL: 120 mg/kg body weight Symptoms: Reduced body weight

Result: Animal testing did not show any effects on fertility.

Effects on foetal develop-

ment

Test Type: Development

Species: Mouse

Application Route: Oral

Developmental Toxicity: NOAEL: 120 mg/kg body weight

Result: No teratogenic effects

Test Type: Development

Species: Rabbit Application Route: Oral

Developmental Toxicity: NOAEL: 120 mg/kg body weight

Result: No teratogenic effects

STOT - single exposure

Not classified based on available information.

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STOT - repeated exposure

Causes damage to organs through prolonged or repeated exposure.

Components:

Levodopa:

Exposure routes : Oral

Target Organs : Central nervous system

Assessment : Causes damage to organs through prolonged or repeated

exposure.

Repeated dose toxicity

Components:

Levodopa:

Species : Rat LOAEL : 100 mg/kg Application Route : Oral

Exposure time : 106 Weeks

Target Organs : Central nervous system

Symptoms : Salivation

Species : Monkey
LOAEL : 100 mg/kg
Application Route : Oral
Exposure time : 22 Weeks

Target Organs : Central nervous system

Carbidopa:

Species : Rat
LOAEL : 25 mg/kg
Application Route : Oral
Exposure time : 96 Weeks

Remarks : No significant adverse effects were reported

Species : Monkey
NOAEL : 135 mg/kg
Application Route : Oral
Exposure time : 1 yr

Remarks : No significant adverse effects were reported

Species : Dog
NOAEL : 5 mg/kg
LOAEL : 15 mg/kg
Application Route : Oral
Exposure time : 238 d

Symptoms : Diarrhoea, Vomiting, Tremors

Aspiration toxicity

Not classified based on available information.

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11.2 Information on other hazards

Endocrine disrupting properties

Product:

Assessment The substance/mixture does not contain components consid-

> ered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at

levels of 0.1% or higher.

Experience with human exposure

Components:

Levodopa:

Ingestion Symptoms: Nausea, central nervous system effects, Drowsi-

ness

Carbidopa:

Ingestion Symptoms: involuntary movement

SECTION 12: Ecological information

12.1 Toxicity

Components:

Levodopa:

aquatic invertebrates

Toxicity to daphnia and other : EC50 (Daphnia magna (Water flea)): 16 mg/l

Exposure time: 48 h

Carbidopa:

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): 35.3 mg/l

Exposure time: 48 h

Method: OECD Test Guideline 202

12.2 Persistence and degradability

No data available

12.3 Bioaccumulative potential

Components:

Levodopa:

Partition coefficient: n-

log Pow: -2.39

octanol/water

12.4 Mobility in soil

No data available

12.5 Results of PBT and vPvB assessment

Product:

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Assessment : This substance/mixture contains no components considered

to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of

0.1% or higher.

12.6 Endocrine disrupting properties

Product:

Assessment : The substance/mixture does not contain components consid-

ered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at

levels of 0.1% or higher.

12.7 Other adverse effects

No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product : Dispose of in accordance with local regulations.

According to the European Waste Catalogue, Waste Codes

are not product specific, but application specific.

Waste codes should be assigned by the user, preferably in

discussion with the waste disposal authorities.

Contaminated packaging : Empty containers should be taken to an approved waste han-

dling site for recycling or disposal.

If not otherwise specified: Dispose of as unused product.

SECTION 14: Transport information

14.1 UN number or ID number

Not regulated as a dangerous good

14.2 UN proper shipping name

Not regulated as a dangerous good

14.3 Transport hazard class(es)

Not regulated as a dangerous good

14.4 Packing group

Not regulated as a dangerous good

14.5 Environmental hazards

Not regulated as a dangerous good

14.6 Special precautions for user

Not applicable

14.7 Maritime transport in bulk according to IMO instruments

Remarks : Not applicable for product as supplied.

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SECTION 15: Regulatory information

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

REACH - Restrictions on the manufacture, placing on : Not applicable

the market and use of certain dangerous substances,

preparations and articles (Annex XVII)

REACH - Candidate List of Substances of Very High : Not applicable

Concern for Authorisation (Article 59).

REACH - List of substances subject to authorisation : Not applicable

(Annex XIV)

Regulation (EC) No 1005/2009 on substances that de- : Not applicable

plete the ozone layer

Regulation (EU) 2019/1021 on persistent organic pollu- : Not applicable

tants (recast)

Regulation (EC) No 649/2012 of the European Parlia: Not applicable

ment and the Council concerning the export and import

of dangerous chemicals

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.

Not applicable

Other regulations:

Take note of Directive 92/85/EEC regarding maternity protection or stricter national regulations, where applicable.

Take note of Directive 94/33/EC on the protection of young people at work or stricter national regulations, where applicable.

The components of this product are reported in the following inventories:

AICS : not determined

DSL : not determined

IECSC : not determined

15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

Other information : Items where changes have been made to the previous version

are highlighted in the body of this document by two vertical

lines.

Full text of H-Statements

H302 : Harmful if swallowed.

H361d : Suspected of damaging the unborn child.

H372 : Causes damage to organs through prolonged or repeated

exposure if swallowed.

H412 : Harmful to aquatic life with long lasting effects.

Full text of other abbreviations

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Acute Tox. Acute toxicity

Long-term (chronic) aquatic hazard **Aquatic Chronic**

Repr. Reproductive toxicity

Specific target organ toxicity - repeated exposure STOT RE

IE OEL Ireland. List of Chemical Agents and Occupational Exposure

Limit Values - Schedule 1

Occupational exposure limit value (8-hour reference period) IE OEL / OELV - 8 hrs (TWA) :

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: AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN -Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS -Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; GHS - Globally Harmonized System; GLP -Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL -International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of Very High Concern; TCSI - Taiwan Chemical Substance Inventory; TRGS -Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

Further information

compile the Safety Data

Sources of key data used to : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agen-

Sheet cy, http://echa.europa.eu/

Classification of the mixture: Classification procedure:

Acute Tox. 4 H302 Calculation method Repr. 2 H361d Calculation method STOT RE 1 H372 Calculation method Aquatic Chronic 3 H412 Calculation method

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