

according to 1907/2006/EC, Article 31, (Commission Regulation (EU) 2020/878)

Trade name: **Azelaic Acid** Version: 7 Revision: 2023.11.20

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product identifier

Trade name Azelaic Acid CAS number 123-99-9

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

Recommended Use SU3 Industrial uses: Uses of substances as such or in

preparations at industrial sites

SU21 Consumer uses: Private households/general public/

consumers

SU22 Professional uses

Uses advised against Not determined

Product category PC39 Cosmetics, personal care products

Process category PROC 1: Chemical production or refinery in closed process

without likelihood of exposure or processes with equivalent

containment conditions.

PROC 2: Use in closed, continuous process with occasional

controlled exposure.

PROC 3: Use in closed batch process (synthesis or

formulation).

PROC 5: Mixing or blending in batch processes. PROC 8a: Transfer of substance or preparation

(charging/discharging) from/to vessels/large containers at

non-dedicated facilities.

PROC 8b: Transfer of substance or preparation

(charging/discharging) from/to vessels/large containers at

dedicated facilities.

PROC 9: Transfer of substance or preparation into small containers (dedicated filling line, including weighing).

PROC 14: Production of preparations or articles by tabletting,

compression, extrusion, pelletisation. PROC 15: Use as laboratory reagent

Environmental release category

ERC 2: Formulation into mixture

Application of the substance / the mixture

Cosmetic Skin cosmetics Cosmetic Active Agent Cosmetic auxiliary

1.3 Details of the supplier of the safety data sheet

Manufacturer/Supplier

CORUM INC.

6FL., No.360, Ruei Guang Rd., Neihu Dist., Taipei 114729, Taiwan Further information obtainable from marketing.support@corum.com.tw

1.4 Emergency telephone number

Company phone number CORUM Tel. 886-2-8751-6060

Fax. 886-2-8751-6363



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SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008

Skin Irrit. 2 H315 Causes skin irritation.

Eye Irrit. 2 H319 Causes serious eye irritation.

2.2 <u>Label elements</u>

Label according to Regulation (EC) No 1272/2008

The substance is classified and labelled according to the CLP regulation.

Hazard Pictograms



GHS07

Signal word

Warning

Hazard statements

H315 causes skin irritation.

H319 causes serious eye irritation.

Precautionary statements

P280 Wear protective gloves/protective clothing/eye protection/face

protection.

P264 Wash thoroughly after handling.
P302+P352 If on skin: wash with plenty of water.

P305+P351+P338 If in eyes: rinse cautiously with water for serval minutes.

Remove contact lenses, if present and easy to do. Continue

rinsing.

P337+P313 If eye irritation persists: Get medical advice/attention.
P362+P364 Take off contaminated clothing and wash it before reuse.

2.3 Other hazards

Results of PBT and vPvB assessment

PBT:

Based on available data, the ingredients of this mixture do not meet the PBT criteria (not PBT) according to (EC) 1907/2006, Annex XIII.

vPvB:

Based on available data, the ingredients of this mixture do not meet the vPvB criteria (not vPvB) according to (EC) 1907/2006, Annex XIII.

Determination of endocrine-disrupting properties

The product does not contain ingredients with endocrine-disrupting properties for humans.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Composition/information on ingredients

Name	Chemical name	Identification	Classification	SCLs, M-Factors	%
COMPONENT					
Azelaic Acid	Nonanedioic acid	(CAS No.) 123-99-9 (EC No.)	Skin Irrit. 2 H315 Eye Irrit. 2 H319	Skin Irrit. 2; H315: C ≥ 50 %	100%



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	204-669-1		

3.2 Mixtures

Not applicable

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

General information Take affected persons out into the fresh air.

Do not leave affected persons unattended.

Seek medical treatment.

After inhalation If breathing, move person into fresh air. If not breathing, give

artificial respiration. Get medical attention.

After skin contact Immediately rinse with water. Remove contaminated clothing,

contaminated footwear and dispose of safely. Wash clothing before reuse. Get medical attention if symptoms occur.

After eye contact Immediately flush eyes with copious amounts of water for at

least 15 minutes. Check for and remove any contact lenses. Do not let the victim rub eyes. Dust and process vapors may

cause eye irritation. Seek medical treatment.

After swallowing Do not induce vomiting; call for medical help immediately.

Rinse mouth with plenty of water. If a person is vomiting while laying on his back, place him in the recovery position (turned

onto his side).

4.2 Most important symptoms and effects, both acute and delayed

Symptoms Temporary skin irritation (pruritus, burning or and stinging)

Eye irritation

4.3 Indication of any immediate medical attention and special treatment needed

Note to physicians Treatment should be in general symptomatic to relieve any

effects.

SECTION 5: FIRE-FIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media

Use fire extinguishing methods suitable to surrounding conditions.

SMALL FIRE: Dry powder or carbon dioxide (CO₂) extinguisher, dry sand or fire fighting foam

LARGE FIRE: Use water spray, water fog or foam. DO NOT use direct water jet.

Unsuitable extinguishing media

Water with full jet.

5.2 Special hazards arising from the substance or mixture

In case of fire, the following can be released:

Carbon oxides (CO_X)



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Carbon monoxide (CO)

5.3 Advice for firefighters

Protective equipment:

Wear self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode

Additional Information

Combustible powder

Cool endangered receptacles with water spray.

See section 9: information on powder explosibility.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 <u>Personal precautions, protective equipment and emergency procedures</u>

Avoid contact with skin, eyes and clothes.

Ensure adequate ventilation.

Avoid formation of dust.

Keep away from ignition sources.

Use respiratory protective device against the effects of fumes/dust/aerosol.

Keep unnecessary and unprotected personnel from entering.

Avoid contact with the spilled material. Do not touch or walk through spilled material.

Stop or contain leak at the source if safe to do so.

6.2 Environmental precautions

Do not allow to enter sewers/surface or ground water.

Inform respective authorities in case of seepage into water course or sewage system.

6.3 Methods and material for containment and cleaning up

Use non-sparking tools.

* Small spillage:

Pick up mechanically. Clean the area with water.

Dispose of the material collected according to regulations.

* Large spillage:

Large spills may be shoveled into containers.

Finish cleaning by spreading water on the contaminated surface and allow to evacuate through the wastewater collection system. Keep in suitable, closed containers for disposal.

6.4 Reference to other sections

See Section 7 for information on safe handing.

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

SECTION 7: HANDLING AND STORAGE

7.1 Precaution for safe handling

Advice on safe handling Prevent formation of dust.

Ensure good ventilation/exhaustion at the workplace.

Open and handle receptacle with care.

Protect from heat.

Keep ignition sources away - Do not smoke.

Use explosion-proof apparatus / fittings and spark-proof tools.

Information about fire - and explosion protection:



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No special measures required.

7.2 Conditions for safe storage, including any incompatibilities

Storage conditions Protect from contacting with light, heat and moisture.

Store in tightly closed container at 25°C in a dry place.

Incompatible materials Store away from oxidizing agents.

Storage class (VbF) No

Requirements to be met by storerooms and receptacles

No special measures required.

Information about storage in common storage facility

Not required

Further information about storage conditions

None

7.3 Specific end use(s) No further relevant information available.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 <u>Control parameters</u>

Ingredients with limit values that require monitoring at the workplace

Exposure limits Not required

DNEL

CAS: 123-99-9 azelaic acid		
Oral	DNEL systemic effects, long-term	2.5 mg/kg bw/day (population)
Dermal	DNEL systemic effects, long-term	5 mg/kg bw/day (population)
		10 mg/kg bw/day (workers)
Inhalative	DNEL systemic effects, long-term	4.348 mg/m³ (population)
		17.632 mg/m³ (workers)

PNEC

CAS: 123-99-9 azelaic acid	
PNEC water (freshwater)	0.02 mg/L (Freshwater invertebrates)
PNEC water (marine water)	0.002 mg/L (Marine water invertebrates)
PNEC sediment (marine water)	0.00931 mg/kg sed dw (marine water sediment organisms)
PNEC soil	0.00687 mg/kg soil dw (soil micro-organisms)
PNEC STP	912 mg/L (Micro-organisms)
PNEC water (int releases)	0.16 mg/L (Fish)

Additional information The valid lists during this review were used as a basis.

8.2 **Exposure controls**

Appropriate engineering controls Applying good personal hygiene practices, such as the proper

handling of contaminated clothing, the use of washing facilities before entering public areas, and the restriction of eating, drinking, and smoking in designated areas are essential to

prevent chemical contamination.



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If user operations generate dust, fume or mist, use local exhaust ventilation or other engineering controls to keep exposure to airborne contaminants below the exposure limit. Ensure that dust-handling systems (such as exhaust ducts, dust collectors, vessels, and processing equipment) are designed in a manner to prevent the escape of dust into the work area (i.e., there is no leakage from the equipment). Ventilation equipment should be explosion-resistant if explosive concentrations of material are present.

Individual protection measures, such as personal protective equipment

General protective and hygienic measures

Avoid contact with the eyes and skin. Wash hands before breaks and at the end of work.

Personal protective equipment

Respiration protectionUse suitable respiratory protective device in case of

insufficient ventilation. Recommended exposure limits have not been established for this material. Whether there is a need for respiratory protection under court conditions of handling of this material should be evaluated by a qualified

health specialist.

Hands protection

Protective gloves

The glove material has to be impermeable and resistant to the product/the substance/the preparation. Due to missing tests no recommendation to the glove material can be given for the product/the preparation/the chemical mixture. Selection of theglove material on consideration of the penetration times,

rates of diffusion and the degradation

Material of gloves The selection of the suitable gloves does not only depend on

the material, but also on further marks of quality and varies

from manufacturer to manufacturer.

Penetration time of glove material The exact break through time has to be found out by the

manufacturer of the protective gloves and has to be bserved.

Eye protection

Tightly sealed goggles

Wear safety glasses meeting the specifications of ansi standard Z87.1 where no contact with the eye is anticipated. Chemical safety goggles meeting the specifications of ansi standard Z87.1 should be worn whenever there is the possibility of splashing or other contact with the eyes.

General protective measure Avoid contact with the eyes and skin.

Do not inhale dust/smoke/mist.

General hygiene measure All skin and mucous membranes with potential exposure have

to be protected with appropriate PPE.

Environmental exposure



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controls No further relevant information available

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 <u>Information on basic physical and chemical properties</u>

Physical StatePowderAppearancePowderColorWhite

Odor Characteristic
Oder threshold Not determined

Property

pH value (5%) Not determined

Melting point/Melting range105-109 °C (peer-reviewed literature)Boiling point/Boiling range357.1°C (peer-reviewed literature)

Flash point 180°C (Open cup)

Flammability (solid, gaseous) Product is not flammable.

Ignition temperatureNot determinedDecomposition temperatureNot determinedSelf-ignitingNot determined

Danger of explosion Product does not present an explosion hazard.

Explosion limit

Lower 50 g/m³ (0.75 micron powder)

Upper Not determined
Oxidizing properties Not determined
Explosive properties Not determined

Vapor pressure at 25°C <1.33E-4 hPa (peer-reviewed database)

Vapor density 1.03 g/cm³

Relative density at 25°C 1225 g/m3 (peer-reviewed literature)

Evaporation rate Not determined

Solubility

water at 20 °C: 2.4 g/l (peer-reviewed literature)

alcohols at 20 °C: N.D. g/l (SOLUBLE)

Partition coefficient

(n-octanol/water at 20 °C) 1.57 log POW (peer-reviewed database)

Kinematic Viscosity

Dynamic Viscosity

Not applicable

Not applicable

9.2 Other information

Important information on protection of health and environment, and on safety

Explosive properties The product is not explosive.

Softening point/range Not applicable

oxidizing properties.

Information with regard to physical hazard classes

Explosives Void

Flammable Gases and Chemically Unstable Gases

Void

Flammable Aerosols Void
Oxidising Gases Void



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Gases Under Pressure Void
Flammable Liquids Void
Flammable Solids Void
Self-reactive Substances and Mixtures

Pyrophoric Liquids Void
Pyrophoric Solids Void
Self-heating Substances and Mixtures
Void

Substances and Mixtures which in contact with water emit flammable gases

Void Void Void

Organic Peroxides Void
Substances and Mixtures corrosive to Metals

Void Desensitized Explosives Void

Surface tension Not applicable

Dissociation constant pKa: 4.55 International Union of Pure and Applied chemistry

London: Butterworth (1961), cited in HSDB

Granulometry Not determined

Additional information Azelaic acid powder explosibility data (test results for 0.75

micron powder)

Minimum oxygen for combustion (MOC): 11.59 %

Minimum Ignition Energy: 5-10 mJ

Maximum explosion pressure (Pmax): 7.7 bar

Maximum rate of pressure rise (DP/DT Max): 665 bar/sec

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

No hazardous reactions if stored and handled as prescribed/indicated.

10.2 Chemical stability

Oxidising Liquids

Oxidising Solids

The product is stable under ordinary condition.

Thermal decomposition/conditions to be avoided

No decomposition if used according to specifications.

10.3 Possibility of hazardous reactions

No hazardous reactions if stored and handled as prescribed/indicated.

10.4 Conditions to avoid

Avoid creating or accumulating fines or dusts.

Protect from contacting with light, heat and moisture.

10.5 Incompatible materials

Strong oxidizing agents.

10.6 <u>Hazardous decomposition products</u>

No hazardous decomposition products if stored and handled as prescribed/indicated.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects



Safety Data Sheet according to 1907/2006/EC, Article 31, (Commission Regulation (EU) 2020/878)

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Name	Azelaic Acid CAS:123-99-9
Acute toxicity	*According to DSD (67/548/EEC) or CLP (1272/2008/EC) classification criteria for acute toxicity, azelaic acid does not fulfill the criteria for classification and thus a non-classification is warranted for this endpoint. *Oral, LD50 >10,000 mg/kg bw (rat)
Skin corrosion/irritation	*Adverse effect observed (irritating). Skin irritation has been reported in exposure to animals and workers handling azelaic acid (peer reviewed database). Bingham, E.; Cohrssen, B.; Powell, C.H.; Patty's Toxicology Volumes 1-9 5th ed. ohn Wiley & Done New York, N.Y. (2001)., p. 5:772] Cutaneous compatibility is very good. (dilution at 10% and 20%)
Serious eye damage/irritation	*Adverse effects observed (irritating). Eye irritation has been reported in exposure to animals and workers handling azelaic acid (peer reviewed database). Bingham, E.; Cohrssen, B.; Powell, C.H.; Patty's Toxicology Volumes 1-9 5th ed. ohn Wiley & Dons. New York, N.Y. (2001)., p. 5:772]
Respiratory/skin sensitization	*No adverse effect observed (not sensitising). According to DSD (67/548/EEC) or CLP (1272/2008/EC) classification criteria for skin sensitisation, fatty acids do not fulfill the criteria for classification and thus a non-classification is warranted for this endpoint.
Respiratory tract	Not determined
Toxicokinetics, metabolism and distribution	*Azelaic acid is excreted through urine (mean of 76.9% of and distribution infused dose). Reported in HDSB, Bertuzzi A et al; Clin Pharmacokinet 20 (5):411-9 (1991)
Repeated dose toxicity	*Reliable studies on oral repeated dose toxicity are available for the following category members: Subchronic: NOAEL oral = ca. 5000 mg/kg bw/d; CAS# 143-07-7, C12 (Fitzhugh 1960) Subchronic: NOAEL oral = 1000 mg/kg bw/d; CAS# 112-85-6, C22 (Nagao 2002) According to DSD (67/548/EEC) or CLP (1272/2008/EC) classification criteria for repeated dose toxicity, fatty acids do not fulfill the criteria for classification and thus a non-classification is warranted for this endpoint.
Germ Cell mutagenicity	*No adverse effect observed (negative). According to DSD (67/548/EEC) or CLP (1272/2008/EC) classification criteria for genetic toxicity, fatty acids do not fulfill the criteria for classification and thus a non-classification is warranted for this endpoint. *Azelaic acid was not mutagenic in an Ames Salmonella test, Chinese hamster ovary HGPRT mutation assay, and a dominant lethal test (species not specified). Reported in HDSB [Bingham, E.; Cohrssen, B.; Powell, C.H.; Patty'sToxicology Volumes 1-9 5th ed. John Wiley & Sons. New York, N.Y. (2001)., p. 5:772]
Carcinogenicity	Based on available data, the classification criteria are not met.
Reproductive toxicity	*Oral NOAEL (repr) 1,000 mg/kg bw/day, rat (with CAS 112-85-6). According to DSD (67/548/EEC) or CLP (1272/2008/EC) classification criteria for toxicity to reproduction/developmental toxicity/teratogenicity, fatty acids do not fulfill the criteria for classification and thus a non-classification is warranted for this endpoint.
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.
Aspiration hazard	Based on available data, the classification criteria are not met.

^{*}from ECHA webpage registration data

11.2 <u>Information on toxicological effects</u>



according to 1907/2006/EC, Article 31, (Commission Regulation (EU) 2020/878)

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Endocrine disrupting properties Substance is not listed.

SECTION 12: ECOLOGICAL INFORMATION

Name	Azelaic Acid CAS:123-99-9
	*EC10 (static): 912 mg/L (Pseudomonas putida) (equivalent or similar to ISO 10712 with CAS 124-07)
	*LC50/96 h (static): >16 mg/L /meas. (geom (Oryzias latipes) ({OECD
	203} with CAS 334-48-5)
	*EC50/48h: >20 mg/L /based on mo (Daphnia sp.) ({OECD 202} with CAS 334-48-5)
12.1 Toxicity Aquatic toxicity	*EC50/72h: >67 mg/L /meas. TWA (Pseudokirchneriella subcapitata) ({2} with CAS 123-99-9)
	*NOEC (28d) (dynamic): 2 mg/L /based on mort (Danio rerio) ({OECD 305E} with CAS 629-25-4)
	*NOÉC/21d (static): 0.2 mg/L /semi-static (Daphnia sp.) ({OECD 211} with CAS 334-48-5)
	Based on available data, the classification criteria are not met.
	*Readily biodegradable.
	Based on ready bidodegradability studies with strucutral analogues
12.2 Persistence and	(category approach: fatty acids). Degree of degradability: 105 % in 30
degradability	days (closed bottle test, OECD 301D). The substance does not contain
	chromophores that absorb at wavelengths > 290 nm and therefore is not
	expected to be susceptible to direct photolysis by sunlight. *Literature data of a similar substance
	BCF: 3,162 L/kg ww or dimensionless
12.3 Bioaccumulative potential	The estimated BCF of 3 suggests the potential for bioconcentration in
	aquatic organisms is low.
	*log Koc: 1.02 (prediction KOCWIN v. 2.00, MCI-method)
	If released to soil, the substance is expected to have moderate mobility
	based upon an estimated Koc of 10.57.
12.4 Mobility in soil	The pKa of the substance is 4.55, indicating that this compound will exist
_	almost entirely in the anion form in the environment and anions generally
	do not adsorb more strongly to soils containing organic carbon and clay
	than their neutral counterparts.
12.5 Results of PBT and vPvB	PBT: Not applicable
assessment	vPvB: Not applicable
12.6 Endocrine disrupting	The product does not contain substances with endocrine disrupting
properties	properties.
	Water hazard class 1 (German Regulation) (Self-assessment): slightly
12.7 Other adverse effects	hazardous for water
	Do not allow undiluted product or large quantities of it to reach ground
	water, water course or sewage system.

^{*}from ECHA webpage registration data

SECTION 13: DISPOSAL CONSIDERATIONS

13.1	Waste treatment methods	
	Recommendation	Smaller quantities can be disposed of with household waste. Observe all federal, state and local environmental regulations.
	European waste catalogue HP4	Irritant - skin irritation and eye damage



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13.2 Uncleaning packaging

RecommendationDisposal must be made according to official regulations.

Water, if necessary together with cleansing agents.

SECTION 14: TRANSPORT INFORMATION

14.1 UN number or ID number

ADR/RID Not applicable
ADN Not applicable
IMDG Not applicable
IATA Not applicable

14.2 UN proper shipping name

ADR/RID Not applicable
ADN Not applicable
IMDG Not applicable
IATA Not applicable

14.3 <u>Transport hazard class(es)</u>

ADR/RID Not applicable
ADN Not applicable
IMDG Not applicable
IATA Not applicable

14.4 Packing group

ADR/RID Not applicable
ADN Not applicable
IMDG Not applicable
IATA Not applicable

14.5 Environmental hazard

Marine pollutant No

14.6 Special precautions for user

Special precaution for user Not applicable

14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code

Not applicable

14.8 ICAO/IATA - DGR

Not regulated as dangerous good

14.9 Maritime transport in bulk according to

IMO instruments

UN "Model Regulation"

Not applicable
Not applicable

SECTION 15: REGULATORY INFORMATION

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

Name	Azelaic Acid CAS:123-99-9
Inventory - United States - Toxic	Υ



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Y: listed, N: not listed, E: exempted

Directive 2004/42/EC

Seveso category

Substance is listed.

Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment - Annex II

Substance is not listed.

Regulation (EU) 2019/1148

Annex I - RESTRICTED EXPLOSIVES PRECURSORS (Upper limit value for the purpose of licensing under Article 5(3))

Substance is not listed.

Annex II - REPORTABLE EXPLOSIVES PRECURSORS

Substance is not listed.

Regulation (EC) No 273/2004 on drug precursors

Substance is not listed.

Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors

Substance is not listed.

Regulation (EC) No 1005/2009 on substances that deplete the ozone layer - ANNEX I (Ozone-depleting potential)

Substance is not listed.

National regulations

Other regulations, limitations, and prohibitive regulations

Not determined

Substances of very high concern (SVHC) according to REACH, Article 59(10)

Substance is not listed.



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15.2 Chemical safety assessment

A chemical safety assessment has not been carried out.

SECTION 16: OTHER INFORMATION

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Abbreviations and acronyms

NOAEL: Non Observed Adverse Effect Level LOAEL: Lowest Observed Adverse Effect Level NOEC: No Observed Effect Concentration

GHS: Globally Harmonized System of Classification and Labeling Chemicals EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstract Service (division of the American Chemical Society)

VbF: Ordinance on the storage of combustible liquids, Austria

DNEL: Derived No-Effect Level (REACH)

PNEC: Predicted No-Effect Concentration (REACH)

50: Lethal concentration, 50 percent LD50: Lethal dose, 50 percent

SVHC: Substances of Very High Concern PBT: Persistent Bioaccumulative and Toxic vPvB: very Persistent and very Bioaccumulative

STOT: Specific Target Organ Toxicity

ADR: Agreement on Dangerous Goods by Road

RID: Regulations concerning the Intl Transport of Dangerous Goods by Rail

ADN: The European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways

IMDG: International Maritime Dangerous Goods IATA: International Air Transport Association

BCF: Bioconcentration Factor ChV: Fish Chronic Toxicity Value

Sources

Own data from manufacture

Hazardous Substances Data Bank (HSDB), a database of the National Library of Medicine's

TOXNET system (http://toxnet.nlm.nih.gov)

REACH Registration data