IVD dispositivo medico-diagnostico in vitro

Eosin alcoholic solution Safety data sheet according to 1907/2006/EC, Article 31. Modified according to rules CE 453/2010 Printing date 12.12.2021 Version number 2. Revision: 12.12.2021 Generic EU MSDS - no country specific data - No OEL data Material safety data sheet code 09-209 Product code 09-209 Package 1000 ml or on request Stability of products properly conserved at 15-25°C 24 months.

* 1 Identification of the substance preparation and of the company undertaking

Commercial name. laboratory and analytical use Laboratory chemical. Industrial uses.

Manufacturer supplier DDKItalia S.r.l Via Marche 19 • 27029 Vigevano (Pv) info@ddkitalia.com • www.ddkitalia.com

in case of emergency UE number	2	112
in case of emergency UK number	T	999

* 2 Hazards identification

	Classification according to GHS				
Section	Hazard class	Hazard class and category	Hazard statement		
2.6	flammable liquid	(Flam. Liq. 2)	H225		
3.3	serious eye damage/eye irritation	(Eye Irrit. 2)	H319		



GHS02 H225 Highly flammable liquid and vapour



GHS07 H319 Causes serious eye irritation

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Label elements

Labelling according to Regulation (EC) No 1272/2008

The product is classified and labelled according to the CLP regulation. Hazard pictograms



Hazard statements H225 Highly flammable liquid and vapour H319 Causes serious eye irritation

Precautionary statements - prevention P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

P233 Keep container tightly closed.

Precautionary statements - response

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

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

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Additional information: Restricted to professional users. Other hazards -Results of PBT and vPvB assessment PBT: Not applicable. vPvB: Not applicable.

* 3 Composition information on ingredients

Chemical characterization. Description: mixture made by the following substances Dangerous components:

CAS n°	component	classification	description	pictogram's	%
64-17-5	ethyl alcohol	H225	Flammable liquis and vapour		99%
17372-87-1	disodium trihydrate	H319	Causes serious eye irritation		≤2,5%

* 4 First-aid measures



General notes Take off contaminated clothing. Following inhalation Provide fresh air. Following skin contact Rinse skin with water-shower. Following eye contact Irrigate copiously with clean, fresh water for at least 10 minutes, holding the eyelids apart. In case of eye irritation consult an ophthalmologist. Following ingestion Rinse mouth. Call a doctor if you feel unwell. Most important symptoms and effects, both acute and delayed Irritation, Vertigo, Abdominal pain, Nausea, Vomiting, Narcosis, Breathing difficulties Indication of any immediate medical attention and special treatment needed

* 5 Fire-fighting measures



Suitable extinguishing media

Co-ordinate fire-fighting measures to the fire surroundings

water spray, alcohol resistant foam, dry extinguishing powder, carbon dioxide (CO₂)

Unsuitable extinguishing media water jet. Special hazards arising from the substance or mixture

Combustible. In case of insufficient ventilation and-or in use, may form flammable-explosive vapour air mixture. Hazardous combustion products

In case of fire may be liberated: carbon monoxide (CO), carbon dioxide (CO₂)

Advice for firefighters

Solvent vapours are heavier than air and may spread along floors. Beware of reignition. Fight fire with normal precautions from a reasonable distance. Wear self-contained breathing apparatus.

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* 6 Accidental release measures



Personal precautions, protective equipment and emergency procedures

For non-emergency personnel. Do not breathe vapour-spray. Avoid contact with skin, eyes and clothes. Removal of ignition sources. Environmental precautions. Keep away from drains, surface and ground water. Danger of explosion. Methods and material for containment and cleaning up. Advice on how to contain a spill. Covering of drains. Advice on how to clean up a spill. Absorb with liquid-binding material (e.g. sand, diatomaceous earth, acid-or universal binding agents). Other information relating to spills and releases. Place in appropriate containers for disposal. Ventilate affected area. Reference to other sections

Hazardous combustion products: see section 5. Personal protective equipment: see section 8. Incompatible materials: see section 10. Disposal considerations: see section 13.



Precautions for safe handling. Provide adequate ventilation as well as local exhaustion at critical locations. Keep container tightly closed. Measures to prevent fire as well as aerosol and dust generation



Keep away from sources of ignition - No smoking. Take precautionary measures against static discharge. Advice on general occupational hygiene. Do not eat, drink or smoke when using this product. Wash hands before breaks and after work. Use barrier cream. Conditions for safe storage, including any incompatibilities. Store in a well-ventilated place. Keep container tightly closed. Protect from sunlight. Incompatible substances or mixtures. Observe hints for combined storage. Consideration of other advice. Ground/bond container and receiving equipment. Ventilation requirements. Use local and general ventilation. Specific designs for storage rooms or vessels Recommended storage temperature: 15 - 25 °C.

Specific end use(s). No information available





Control parameters National limit values Occupational exposure limit values (Workplace Exposure Limits)

Country	Name of agent	CAS No	Identifier	STEL [ppm]	Source
IE	Ethanol	64-17-5	OELV	1.000	S.I. n° 619 of 2001

Note

Ceiling-C Ceiling value is a limit value above which exposure should not occur

STEL Short-term exposure limit: a limit value above which exposure should not occur and which is related to a 15-minute period (unless otherwise specified)

TWA Time-weighted average (long-term exposure limit): measured or calculated in relation to a reference period of 8 hours' time-weighted average (unless otherwise specified)

Relevant DNELs/DMELs/PNECs and other threshold levels. Human health values

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Endpoint	Threshold level	Protection goal, route of exposure	Used in	Exposure time
DNEL	1.900 mg/m ³	human, inhalatory	worker (industry)	acute - systemic effects
DNEL	343 mg/kg	human, dermal	worker (industry)	chronic - systemic effects
DNEL	950 mg/m³	human, inhalatory	worker (industry)	chronic - systemic effects

Environmental values

Endpoint	Threshold level	Environmental compartment
PNEC	0,79 mg/cm ³	marine water
PNEC	2,75 mg/cm ³	
PNEC	3,6 mg/cm ³	freshwater sediment
PNEC	580 mg/cm ³	sewage treatment plant (STP)
PNEC	0,63 mg/cm ³	soil
PNEC	0,96 mg/cm ³	freshwater

Individual protection measures (personal protective equipment) Eye-face protection



Use safety goggle with side protection.





Hand protection

Wear suitable gloves.

Chemical protection gloves are suitable, which are tested according to EN 374. For special purposes, it is recommended to check the resistance to chemicals of the protective gloves mentioned above together with the supplier of these gloves. The times are approximate values from measurements at 22 °C and permanent contact. Increased temperatures due to heated substances, body heat etc. and a reduction of the effective layer thickness by stretching can lead to a consider- able reduction of the breakthrough time. If in doubt, contact manufacturer. At an approx. 1.5 times larger - smaller layer thickness, the respective breakthrough time is doubled - halved. The data apply only to the pure substance. When transferred to substance mixtures, they may only be considered as a guide.

Type of material

Butyl caoutchouc (butyl rubber) material thickness 0,7 mm. breakthrough times of the glove material >480 minutes (permeation: level 6) other protection measures

Take recovery periods for skin regeneration. Preventive skin protection (barrier creams/ointments) is recommended.

Flame-retardant protective clothing.

Respiratory protection

Respiratory protection necessary at

Aerosol or mist formation.

Type: A (against organic gases and va- pours with a boiling point of > 65 °C, colour code: Brown).

Environmental exposure controls

Keep away from drains, surface and ground water.

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Respiratory protection



In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device

Respiratory protection necessary at. Aerosol or mist formation. Type: A (against organic gases and vapours with a boiling point of > 65 °C, colour code: Brown).

Environmental exposure controls. Keep away from drains, surface and ground water

* 9 Physical and chemical properties



Form Colour Odour Other physical and chemical parameters pH (value) Melting point/freezing point Initial boiling point and boiling range Flash point Evaporation rate Flammability (solid, gas) (fluid) explosive limits lower explosion limit (LEL) upper explosion limit (UEL) Explosion limits of dust clouds Vapour pressure Density Vapour density Bulk density Relative density Solubility Water solubility Partition coefficient n-octanol/water (log KOW) Auto-ignition temperature Decomposition temperature Viscosity dynamic viscosity Explosive properties Oxidising properties Other information Temperature class (EU, according to ATEX) fluid reddish red yellow reddish alcohol like

7 (water: 10 ^g/l, 20 °C) -114 °C 78 °C at 1.013 hPa 12 °C (c.c.) no data available not relevant

3,5 vol% 15 vol% not relevant 59 hPa at 20 °C

0,79 ^g/_{CM³} at 20 °C this information is not available. not applicable information on this property is not available

≥1.000 ^g/_I at 20 °C miscible in any proportion

-0,31 (exp. (TOXNET)) 455 °C at 1.013 Pa - (DIN 51794) no data available

1,2 mPa s at 20 °C shall not be classified as explosive none

T2 (Maximum permissibile surface temperature on the equipment: 300°C)

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10 Stability and reactivity



Reactivity Risk of ignition. Vapours can form explosive mixtures with air. Chemical stability. The material is stable under normal ambient and anticipated storage and handling conditions of temperature and pressure. Possibility of hazardous reactions. Violent reaction with: Alkali metals, Alkaline earth metal, Acetic anhydride, Peroxides, Phosphorus oxides (e.g., P2O5), Strong oxidiser, Nitric acid, Nitrate, Perchlorates, => Explosive properties Conditions to avoid. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Incompatible materials plastic and rubber. Hazardous decomposition products Hazardous combustion products: see section 5.

11 Toxicological information



Information on toxicological effects. Acute toxicity. Shall not be classified as acutely toxic.

Exposure route	Endpoint	Value	Species	Source
inhalation: vapour	LC50	95,6 mg/l/4h	rat	Toxnet
oral	LD50	7.060 mg/kg	rat	Toxnet

Skin corrosion/irritation. Shall not be classified as corrosive/irritant to skin. Serious eye damage-eye irritation. Causes serious eye irritation. Respiratory or skin sensitization. Shall not be classified as a respiratory or skin sensitizer. Summary of evaluation of the CMR properties. Shall not be classified as germ cell mutagenic, carcinogenic nor as a reproductive toxicant. Specific target organ toxicity - single exposure. Shall not be classified as a specific target organ toxicant (single exposure). Specific target organ toxicity - repeated exposure. Shall not be classified as a specific target organ toxicant (repeated exposure). Aspiration hazard. Shall not be classified as presenting an aspiration hazard. Symptoms related to the physical, chemical and toxicological characteristics. If swallowed, nausea, vomiting, abdominal pain. Causes damage to liver through prolonged or repeated exposure if swallowed. If in eyes, causes serious eye irritation. If inhaled, vertigo, Inebriation, narcosis, breathing difficulties If on skin, prolonged or repeated skin contact may cause removal of natural fat from the skin resulting in dermatitis (skin inflammation). Other information. None

* 12 Ecological information

	Toxicity. Ac	quatic toxicity (acute)			
	Endpoint	Value	Species	Source	Exposure time
	LC50	8.140 mg/l	orfe (Leuciscus idus)	IUCLID	96 h
	EC50	9.000–14.000 mg/l	daphnia magna	IUCLID	48 h
Process of degradability. Theoretical Oxygen Demand: 2,084 mg/mg. Theoretical Carbon Dioxide: 1,911 mg/mg					
		Process	Degradation rate	time	

EC50 Bio accumulative potential. Does not significantly accumulate in organisms.

-0,31 Mobility in soil. Data are not available. Results of PBT and vPvB assessment. Data are not available. Other adverse effects. Data are not available.

n-octanol/water (log KOW)

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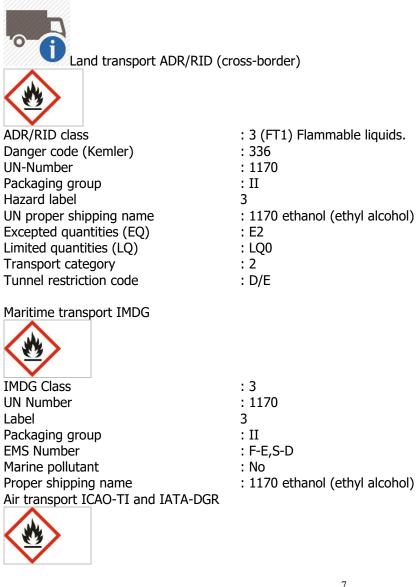
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13 Disposal considerations



Waste treatment methods. Recommendation. Must not be disposed together with household garbage. Do not allow product to reach sewage system. Reutilise if possible or contact a waste processor for recycling or safe disposal. Waste disposal key. The European union does not establish uniform rules for the disposal of chemical waste, which are special waste. Their treatment and elimination of the domestic legislation of each country. So, in each case, you should contact the relevant authorities, or those companies legally authorized for elimination of waste 2001/573/EC: Council Decision of 23 July 2001 amending the list of wastes contained in Decision 2000/532/EC. Council Directive 91/156/EEC of 18 March 1991 amending Directive 75/442/EEC on waste. Uncleaned packaging. The containers and packing materials contaminated with dangerous substances or preparations, have the same treatment products. Directive 94/62/EC of the European Parliament and the Council of 20 December 1994 on packaging and packaging waste. Recommendation: disposal must be made according to official regulations. Packaging that may not be cleansed are to be disposed of in the same manner as the product. Recommended cleansing agents: water, if necessary, together with cleansing agents

14 Transport information



7

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ICAO/IATA Class	: 3
UN/ID Number	: 1170
Label	3
Packaging group	: II
Proper shipping name	: 1170 ethanol (ethyl alcohol)
Special precautions for user Warning	Flammable liquids Transport in

Special precautions for user Warning. Flammable liquids. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code not applicable.

* 15 Regulatory information

Safety, health and environmental regulations/legislation specific for the substance or mixture. Relevant provisions of the European Union (EU). Regulation 649/2012/EU concerning the export and import of hazardous chemicals (PIC). Not listed. Regulation 1005/2009/EC on substances that deplete the ozone layer (ODS). Not listed. Regulation 850/2004/EC on persistent organic pollutants (POP). Not listed.Restrictions according to REACH, Annex XVII

* 16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship. Relevant phrases H225 Highly flammable liquid and vapour

H319 Causes serious eye irritation

References

ECDIN (Environmental Chem. Data and Information Network) IUCLID (International Uniform Chemical Information Database) NIOSH - Registry of Toxic Effects of Chemical Substances Roth - Wassergefährdende Stoffe Verschueren - Handbook of Environmental Data on Organic Chemicals ChemDAT - Safety Data Sheets from E.Merck on CD-ROM Merian - Metals and their compounds in the environment

Abbreviations and acronyms:

Abbr.	Descriptions of used abbreviations
2006/15/EC	Commission Directive establishing a second list of indicative occupational exposure limit values in implementation of Council Directive 98/24/EC and amending Directives 91/322/EEC and 2000/39/EC
Acute Tox.	acute toxicity
ADN	Accord européen relatif au transport international des marchandises dangereuses par voies de navigation intérieures (European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways)
ADR	Accord européen relatif au transport international des marchandises dangereuses par route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
ATE	Acute Toxicity Estimate
BCF	bioconcentration factor
BOD	Biochemical Oxygen Demand
CAS	Chemical Abstracts Service (service that maintains the most comprehensive list of chemical substances)
CLP	Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures
CMR	Carcinogenic, Mutagenic or toxic for Reproduction
COD	chemical oxygen demand
DGR	Dangerous Goods Regulations (see IATA/DGR)

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DMEL	Derived Minimal Effect Level
DNEL	Derived No-Effect Level
EC50	Effective Concentration 50 %. The EC50 corresponds to the concentration of a tested substance causing 50 % changes in response (e.g. on growth) during a specified time interval
EC No	The EC Inventory (EINECS, ELINCS and the NLP-list) is the source for the seven-digit EC number, an identifier of substances commercially available within the EU (European Union)
EH40/2005	EH40/2005 Workplace exposure limits (<u>http://www.nationalarchives.gov.uk/doc/open-government-licence/)</u>
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of Notified Chemical Substances
EmS	Emergency Schedule
ErC50	≡ EC50: in this method, that concentration of test substance which results in a 50 % reduction in either growth (EbC50) or growth rate (ErC50) relative to the control
Flam. Liq.	flammable liquid
GHS	"Globally Harmonized System of Classification and Labelling of Chemicals" developed by the United Nations
IATA	International Air Transport Association
IATA/DGR	Dangerous Goods Regulations (DGR) for the air transport (IATA)
ICAO	International Civil Aviation Organization
IMDG	International Maritime Dangerous Goods Code
index No	the Index number is the identification code given to the substance in Part 3 of Annex VI to Regulation (EC) No 1272/2008
IOELV	indicative occupational exposure limit value
LC50	Lethal Concentration 50%: the LC50 corresponds to the concentration of a tested substance causing 50 % lethality during a specified time interval
log KOW	n-octanol/water
MARPOL	International Convention for the Prevention of Pollution from Ships (abbr. of "Marine Pollutant")
NLP	No-Longer Polymer
PBT	Persistent, Bio accumulative and Toxic
PNEC	Predicted No-Effect Concentration
ppm	parts per million
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
RID	Règlement concernant le transport International ferroviaire des marchandises Dangereuses (Regulations concerning the International carriage of Dangerous goods by Rail)
STEL	short-term exposure limit
STOT SE	specific target organ toxicity - single exposure
SVHC	Substance of Very High Concern
TWA	time-weighted average
VOC	Volatile Organic Compounds
vPvB	very Persistent and very Bio accumulative
WEL	workplace exposure limit

Key literature references and sources for data Regulation (EC) No. 1907/2006 (REACH), amended by 2015/830/EU Regulation (EC) No. 1272/2008 (CLP, EU GHS) Dangerous Goods Regulations (DGR) for the air transport (IATA) International Maritime Dangerous Goods Code (IMDG)

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Sources

DIR. 67/548/EC, in the latest valid version. DIR. 1999/45/EC, in the latest valid version. Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006, REACH. Globally Harmonized System, GHS Regulation (EC) N° 1272/2008 of the European Parliament and of the Council of 16 December 2008, CLP, in the latest valid version. ADR2015

CE

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Sector of Use

SU3 Industrial uses: Uses of substances as such or in preparations at industrial sites SU9 Manufacture of fine chemicals

SU10 Formulation [mixing] of preparations and/or re-packaging (excluding alloys)

SU24 Scientific research and development

Product category

PC19 Intermediate

PC20 Products such as ph-regulators, flocculants, precipitants, neutralization agents

PC21 Laboratory chemicals

PC29 Pharmaceuticals

PC39 Cosmetics, personal care products

PC40 Extraction agents

Process category

PROC1 Use in closed process, no likelihood of exposure

PROC2 Use in closed, continuous process with occasional controlled exposure

PROC3 Use in closed batch process (synthesis or formulation)

PROC4 Use in batch and other process (synthesis) where opportunity for exposure arises

PROC5 Mixing or blending in batch processes for formulation of preparations and articles (multistage and/ or significant contact)

PROC9 Transfer of substance or preparation into small containers (dedicated filling line, including weighing) PROC15 Use as laboratory reagent

Environmental release category

ERC1 Manufacture of substances

ERC2 Formulation of preparations

ERC4 Industrial use of processing aids in processes and products, not becoming part of articles ERC6a Industrial use resulting in manufacture of another substance (use of intermediates)

Application of the substance - the mixture Chemical products for laboratory

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Annex: Exposure scenario

Short title of the exposure scenario Substance manufacturing Sector of Use Industrial use.

Product category

PC20 Processing aids such as pH-regulators, flocculants, precipitants, neutralization agents

PC21 Laboratory chemicals

PC29 Pharmaceuticals

PC40 Extraction agents

Process category

PROC1 Chemical production or refinery in closed process without likelihood of exposure or processes with equivalent containment conditions.

()

Environmental release category ERC1 Manufacture of the substance

Description of the activities - processes covered in the

Exposure Scenario See section 1 of the annex to the Safety Data Sheet.

Conditions of use According to directions for use.

Customary application according to section 1.

Duration and frequency 5 workdays-week.

Physical parameters

The data on the physical - chemical properties in the Exposure Scenario is based on the properties of the preparation.

Physical state Fluid

Concentration of the substance in the mixture

The substance is main component.

Used amount per time or activity

According to directions for use.

Other operational conditions Observe the general safety regulations when handling chemicals.

Other operational conditions affecting environmental exposure

No special measures required.

Observe section 6 of the Safety Data Sheet (Accidental release measures).

Other operational conditions affecting worker exposure Avoid contact with the skin.

Do not breathe gas-vapour-aerosol.

Take precautionary measures against static discharge.

Keep away from sources of ignition - No smoking.

Respiratory protection is required in work areas with inadequate ventilation and during spraying application.

Other operational conditions affecting consumer exposure No special measures required.

Other operational conditions affecting consumer exposure during the use of the product Not applicable.

Risk management measures

Worker protection

Organisational protective measures Keep good industrial hygiene. Ensure that activities are executed by specialists or authorised personnel only. No special measures required. For special applications, it is recommended to verify the chemical resistance of the above stated protective gloves with the manufacturer. Provide sufficient washing facilities. Work clothes must not consist of textiles that exhibit dangerous melting behaviour in case of fire.

Technical protective measures Provide explosion-proof electrical equipment. Ensure that suitable extractors are available on processing machines Ensure good ventilation/exhaustion at the workplace.

Personal protective measures Do not inhale gases - fumes - aerosols. Avoid contact with the skin. In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device. Suitable respiratory protective device recommended in case of leakages or handling in open devices. The selected respiratory protection must comply with standard EN 136/140/143/145/149. Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation Rubber gloves Protective gloves

The selected protective gloves have to satisfy the specifications of REGULATION (EU) 2016/425 and the standard EN 374 derived from it.

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Only use chemical-protective gloves with CE-labelling of category III.

Avoid direct contact with the chemical-the product- the preparation by organisational measures. In case of pouring big amounts or disconnecting pipes. Protective work clothing Safety glasses

The usual precautionary measures are to be adhered to when handling chemicals.

Detailed measures on hand protection according to Safety Data Sheet, section 8.

Measures for consumer protection

Ensure adequate labelling.

Environmental protection measures

Water No special measures required.

Notes In case of unintended release of the product:

See section 6 of the Safety Data Sheet.

Disposal measures

Disposal must be made according to official regulations. Ensure that waste is collected and contained.

Disposal procedures Must not be disposed together with household garbage.

Do not allow product to reach sewage system.

Waste type Partially emptied and uncleaned packaging

Exposure estimation

Consumer Not relevant for this Exposure Scenario.

Guidance for downstream users No further relevant information available.

Whether the downstream user acts within the scope of the Exposure Scenario can be verified based on the information in sections 1 to 8.