

**PKB03 - Audisol Ear spray****SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING**

- 1.1 Product identifier:** PKB03 - Audisol Ear spray  
**Other means of identification:**  
 Non-applicable
- 1.2 Relevant identified uses of the substance or mixture and uses advised against:**  
 Relevant uses: Not defined  
 Uses advised against: All uses not specified in this section or in section 7.3
- 1.3 Details of the supplier of the safety data sheet:**  
 PK Benelux BV  
 Vluchtoord 17  
 5406 XP Uden - The Netherlands  
 Phone.: +31(0)413253338  
 www.pkbenelux.com
- 1.4 Emergency telephone number:** +31 (0) 413253338 Mon - Fri 8.30am - 5.30pm

**SECTION 2: HAZARDS IDENTIFICATION**

- 2.1 Classification of the substance or mixture:**  
**Directive 67/548/EC and Directive 1999/45/EC:**  
 In accordance with Directive 67/548/EC and Directive 1999/45/EC, the product is not classified as dangerous.  
 cellSection2\_1AntesEncabezado
- 2.2 Label elements:**  
**Directive 67/548/EC and Directive 1999/45/EC:**  
 In accordance with the legislation, the elements on the label are as follows:  
 Not classified as dangerous. Safety data sheet available to professional users that request it.
- 2.3 Other hazards:**  
 Product fails to meet PBT/vPvB criteria

**SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS**

- 3.1 Substance:**  
 Non-applicable
- 3.2 Mixture:**  
**Chemical description:** Mixture of substances  
**Components:**  
 In accordance with Annex II of Regulation (EC) No 1907/2006 (point 3), the product contains:

Identification	Chemical name/Classification	Concentration
CAS: 5343-92-0 EC: 226-285-3 Index: Non-applicable REACH: 01-2119491291-39-XXXX	<b>Pentane-1,2-diol</b> Self-classified	2,5 - <10 %
	Directive 67/548/EC Xi: R41	
	Regulation 1272/2008 Eye Dam. 1: H318 - Danger	
CAS: 577-11-7 EC: 209-406-4 Index: Non-applicable REACH: 01-2119491296-29-XXXX	<b>Docosate sodium</b> Self-classified	1 - <2,5 %
	Directive 67/548/EC Xi: R38, R41	
	Regulation 1272/2008 Eye Dam. 1: H318; Skin Irrit. 2: H315 - Danger	

To obtain more information on the hazards of the substances consult sections 11, 12 and 16.

This is a medical device according to Directive 93/42/EEC. No CLP regulation is applicable to this product.

**SECTION 4: FIRST AID MEASURES**

- 4.1 Description of first aid measures:**

- CONTINUED ON NEXT PAGE -

**PKB03 - Audisol Ear spray****SECTION 4: FIRST AID MEASURES (continued)**

The symptoms resulting from intoxication can appear after exposure, therefore, in case of doubt, seek medical attention for direct exposure to the chemical product or persistent discomfort, showing the SDS of this product.

**By inhalation:**

This product does not contain substances classified as hazardous for inhalation, however, in case of symptoms of intoxication remove the person affected from the exposure area and provide with fresh air. Seek medical attention if the symptoms get worse or persist.

**By skin contact:**

This product is not classified as hazardous when in contact with the skin. However, in case of skin contact it is recommended to remove contaminated clothes and shoes, rinse the skin or if necessary shower the affected person thoroughly with cold water and neutral soap. In case of serious reaction consult a doctor.

**By eye contact:**

Rinse eyes thoroughly with water for at least 15 minutes. If the injured person uses contact lenses, these should be removed unless they are stuck to the eyes, in which case removal could cause further damage. In all cases, after cleaning, a doctor should be consulted as quickly as possible with the SDS for the product.

**By ingestion/aspiration:**

Do not induce vomiting, but if it does happen keep the head down to avoid aspiration. Keep the person affected at rest. Rinse out the mouth and throat, as they may have been affected during ingestion.

**4.2 Most important symptoms and effects, both acute and delayed:****4.3 Indication of any immediate medical attention and special treatment needed:**

Non-applicable

**SECTION 5: FIREFIGHTING MEASURES****5.1 Extinguishing media:**

**Suitable extinguishing media:**

**Unsuitable extinguishing media:**

**5.2 Special hazards arising from the substance or mixture:**

As a result of combustion or thermal decomposition reactive sub-products are created that can become highly toxic and, consequently, can present a serious health risk.

**5.3 Advice for firefighters:**

Depending on the magnitude of the fire it may be necessary to use full protective clothing and self-contained breathing apparatus (SCBA). Minimum emergency facilities and equipment should be available (fire blankets, portable first aid kit,...) in accordance with Directive 89/654/EC.

**Additional provisions:**

Act in accordance with the Internal Emergency Plan and the Information Sheets on actions to take after an accident or other emergencies. Eliminate all sources of ignition. In case of fire, cool the storage containers and tanks for products susceptible to combustion, explosion or BLEVE as a result of high temperatures. Avoid spillage of the products used to extinguish the fire into an aqueous medium.

**SECTION 6: ACCIDENTAL RELEASE MEASURES****6.1 Personal precautions, protective equipment and emergency procedures:**

Isolate leaks provided that there is no additional risk for the people performing this task. Personal protection equipment must be used against potential contact with the spilled product (See section 8). Evacuate the area and keep out those who do not have protection.

**6.2 Environmental precautions:**

This product is not classified as hazardous to the environment. Keep product away from drains, surface and ground water.

**6.3 Methods and material for containment and cleaning up:**

It is recommended:

- CONTINUED ON NEXT PAGE -

## PKB03 - Audisol Ear spray

### SECTION 6: ACCIDENTAL RELEASE MEASURES (continued)

Absorb the spillage using sand or inert absorbent and move it to a safe place. Do not absorb in sawdust or other combustible absorbents. For any concern related to disposal consult section 13.

#### 6.4 Reference to other sections:

See sections 8 and 13.

### SECTION 7: HANDLING AND STORAGE

#### 7.1 Precautions for safe handling:

A.- Precautions for safe manipulation

Comply with the current legislation concerning the prevention of industrial risks. Keep containers hermetically sealed. Control spills and residues, destroying them with safe methods (section 6). Avoid leakages from the container. Maintain order and cleanliness where dangerous products are used.

B.- Technical recommendations for the prevention of fires and explosions

Product is non-flammable under normal conditions of storage, handling and use. It is recommended to transfer at slow speeds to avoid the generation of electrostatic charges that can affect flammable products. Consult section 10 for information on conditions and materials that should be avoided.

C.- Technical recommendations to prevent ergonomic and toxicological risks

Do not eat or drink during the process, washing hands afterwards with suitable cleaning products.

D.- Technical recommendations to prevent environmental risks

It is recommended to have absorbent material available at close proximity to the product (See subsection 6.3)

#### 7.2 Conditions for safe storage, including any incompatibilities:

A.- Technical measures for storage

Minimum Temp.: 5 °C

Maximum Temp.: 30 °C

Maximum time: 6 Months

B.- General conditions for storage

Avoid sources of heat, radiation, static electricity and contact with food. For additional information see subsection 10.5

#### 7.3 Specific end use(s):

Except for the instructions already specified it is not necessary to provide any special recommendation regarding the uses of this product.

### SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

#### 8.1 Control parameters:

Substances whose occupational exposure limits have to be monitored in the workplace (European OEL, not country-specific legislation):

There are no occupational exposure limits for the substances contained in the product

##### DNEL (Workers):

Identification		Short exposure		Long exposure	
		Systemic	Local	Systemic	Local
Pentane-1,2-diol CAS: 5343-92-0 EC: 226-285-3	Oral	Non-applicable	Non-applicable	Non-applicable	Non-applicable
	Dermal	25 mg/kg	Non-applicable	25 mg/kg	Non-applicable
	Inhalation	35,2 mg/m <sup>3</sup>	Non-applicable	17,6 mg/m <sup>3</sup>	Non-applicable
Docusate sodium CAS: 577-11-7 EC: 209-406-4	Oral	Non-applicable	Non-applicable	Non-applicable	Non-applicable
	Dermal	Non-applicable	Non-applicable	267,86 mg/kg	Non-applicable
	Inhalation	Non-applicable	Non-applicable	1889,1 mg/m <sup>3</sup>	Non-applicable

##### DNEL (General population):

- CONTINUED ON NEXT PAGE -

**PKB03 - Audisol Ear spray**
**SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION (continued)**

Identification		Short exposure		Long exposure	
		Systemic	Local	Systemic	Local
Pentane-1,2-diol CAS: 5343-92-0 EC: 226-285-3	Oral	1,25 mg/kg	Non-applicable	1,25 mg/kg	Non-applicable
	Dermal	12,5 mg/kg	Non-applicable	12,5 mg/kg	Non-applicable
	Inhalation	8,8 mg/m <sup>3</sup>	Non-applicable	4,4 mg/m <sup>3</sup>	Non-applicable
Docusate sodium CAS: 577-11-7 EC: 209-406-4	Oral	Non-applicable	Non-applicable	17,86 mg/kg	Non-applicable
	Dermal	Non-applicable	Non-applicable	160,71 mg/kg	Non-applicable
	Inhalation	Non-applicable	Non-applicable	559,01 mg/m <sup>3</sup>	Non-applicable

**PNEC:**

Identification				
Pentane-1,2-diol CAS: 5343-92-0 EC: 226-285-3	STP	5500 mg/L	Fresh water	0,5 mg/L
	Soil	0,076 mg/kg	Marine water	0,05 mg/L
	Intermittent	5 mg/L	Sediment (Fresh water)	1,85 mg/kg
	Oral	Non-applicable	Sediment (Marine water)	0,185 mg/kg
Docusate sodium CAS: 577-11-7 EC: 209-406-4	STP	12,2 mg/L	Fresh water	0,18 mg/L
	Soil	1,04 mg/kg	Marine water	0,018 mg/L
	Intermittent	0,152 mg/L	Sediment (Fresh water)	17,789 mg/kg
	Oral	Non-applicable	Sediment (Marine water)	1,779 mg/kg

**8.2 Exposure controls:**
**A.- General security and hygiene measures in the work place**

As a preventative measure it is recommended to use basic Personal Protective Equipment, with the corresponding <<CE marking>> in accordance with Regulation (EU) 2016/425. For more information on Personal Protective Equipment (storage, use, cleaning, maintenance, class of protection,...) consult the information leaflet provided by the manufacturer. For more information see subsection 7.1. All information contained herein is a recommendation which needs some specification from the labour risk prevention services as it is not known whether the company has additional measures at its disposal.

**B.- Respiratory protection**

The use of protection equipment will be necessary if a mist forms or if the occupational exposure limits are exceeded.

**C.- Specific protection for the hands**

Non-applicable

**D.- Ocular and facial protection**

Non-applicable

**E.- Body protection**

Non-applicable

**F.- Additional emergency measures**

It is not necessary to take additional emergency measures.

**Environmental exposure controls:**

In accordance with the community legislation for the protection of the environment it is recommended to avoid environmental spillage of both the product and its container. For additional information see subsection 7.1.D

**Volatile organic compounds:**

With regard to Directive 2010/75/EU, this product has the following characteristics:

V.O.C. (Supply):	0 % weight
V.O.C. density at 20 °C:	0 kg/m <sup>3</sup> (0 g/L)
Average carbon number:	Non-applicable
Average molecular weight:	Non-applicable

**SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES**
**9.1 Information on basic physical and chemical properties:**

For complete information see the product datasheet.

\*Not relevant due to the nature of the product, not providing information property of its hazards.

- CONTINUED ON NEXT PAGE -

## PKB03 - Audisol Ear spray

### SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES (continued)

**Appearance:**

Physical state at 20 °C:	Liquid
Appearance:	Not available
Colour:	Not available
Odour:	Not available
Odour threshold:	Non-applicable *

**Volatility:**

Boiling point at atmospheric pressure:	100 °C
Vapour pressure at 20 °C:	2350 Pa
Vapour pressure at 50 °C:	12381,01 Pa (12,38 kPa)
Evaporation rate at 20 °C:	Non-applicable *

**Product description:**

Density at 20 °C:	1030,7 kg/m <sup>3</sup>
Relative density at 20 °C:	1,031
Dynamic viscosity at 20 °C:	Non-applicable *
Kinematic viscosity at 20 °C:	Non-applicable *
Kinematic viscosity at 40 °C:	Non-applicable *
Concentration:	Non-applicable *
pH:	Non-applicable *
Vapour density at 20 °C:	Non-applicable *
Partition coefficient n-octanol/water 20 °C:	Non-applicable *
Solubility in water at 20 °C:	
Solubility properties:	Non-applicable *
Decomposition temperature:	Non-applicable *
Melting point/freezing point:	Non-applicable *
Explosive properties:	Non-applicable *
Oxidising properties:	Non-applicable *

**Flammability:**

Flash Point:	Non Flammable (>60 °C)
Heat of combustion:	Non-applicable *
Flammability (solid, gas):	Non-applicable *
Autoignition temperature:	Non-applicable *
Lower flammability limit:	Non-applicable *
Upper flammability limit:	Non-applicable *

**Explosive:**

Lower explosive limit:	Non-applicable *
Upper explosive limit:	Non-applicable *

**9.2 Other information:**

Surface tension at 20 °C:	Non-applicable *
Refraction index:	Non-applicable *

\*Not relevant due to the nature of the product, not providing information property of its hazards.

### SECTION 10: STABILITY AND REACTIVITY

**10.1 Reactivity:**

No hazardous reactions are expected because the product is stable under recommended storage conditions. See section 7.

- CONTINUED ON NEXT PAGE -

**PKB03 - Audisol Ear spray**
**SECTION 10: STABILITY AND REACTIVITY (continued)**
**10.2 Chemical stability:**

Chemically stable under the conditions of storage, handling and use.

**10.3 Possibility of hazardous reactions:**

Under the specified conditions, hazardous reactions that lead to excessive temperatures or pressure are not expected.

**10.4 Conditions to avoid:**

Applicable for handling and storage at room temperature:

Shock and friction	Contact with air	Increase in temperature	Sunlight	Humidity
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable

**10.5 Incompatible materials:**

Acids	Water	Oxidising materials	Combustible materials	Others
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable

**10.6 Hazardous decomposition products:**
**SECTION 11: TOXICOLOGICAL INFORMATION**
**11.1 Information on toxicological effects:**

The experimental information related to the toxicological properties of the product itself is not available

Contains glycols. It is recommended not to breathe the vapours for prolonged periods of time due to the possibility of effects that are hazardous to the health .

**Dangerous health implications:**

In case of exposure that is repetitive, prolonged or at concentrations higher than the recommended occupational exposure limits, adverse effects on health may result, depending on the means of exposure:

**A- Ingestion (acute effect):**

- Acute toxicity : Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for consumption. For more information see section 3.
- Corrosivity/Irritability: Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for this effect. For more information see section 3.

**B- Inhalation (acute effect):**

- Acute toxicity : Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for inhalation. For more information see section 3.
- Corrosivity/Irritability: Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for this effect. For more information see section 3.

**C- Contact with the skin and the eyes (acute effect):**

- Contact with the skin: Based on available data, the classification criteria are not met. However, it contains substances classified as dangerous for skin contact. For more information see section 3.
- Contact with the eyes: Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for this effect. For more information see section 3.

**D- CMR effects (carcinogenicity, mutagenicity and toxicity to reproduction):**

- Carcinogenicity: Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for the effects mentioned. For more information see section 3.  
IARC: Non-applicable
- Mutagenicity: Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for this effect. For more information see section 3.
- Reproductive toxicity: Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for this effect. For more information see section 3.

**E- Sensitizing effects:**

- Respiratory: Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous with sensitising effects. For more information see section 3.
- Cutaneous: Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for this effect. For more information see section 3.

**F- Specific target organ toxicity (STOT) - single exposure:**

- CONTINUED ON NEXT PAGE -

**PKB03 - Audisol Ear spray**
**SECTION 11: TOXICOLOGICAL INFORMATION (continued)**

Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for this effect. For more information see section 3.

G- Specific target organ toxicity (STOT)-repeated exposure:

- Specific target organ toxicity (STOT)-repeated exposure: Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for this effect. For more information see section 3.
- Skin: Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for this effect. For more information see section 3.

H- Aspiration hazard:

Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for this effect. For more information see section 3.

**Other information:**

Non-applicable

**Specific toxicology information on the substances:**

Identification	Acute toxicity		Genus
	LD50 oral	LD50 dermal	
Docusate sodium CAS: 577-11-7 EC: 209-406-4	4620 mg/kg	10000 mg/kg	Rat
	Non-applicable		Rabbit

**SECTION 12: ECOLOGICAL INFORMATION**

The experimental information related to the eco-toxicological properties of the product itself is not available

**12.1 Toxicity:**

Identification	Acute toxicity		Species	Genus
	LC50	EC50		
Pentane-1,2-diol CAS: 5343-92-0 EC: 226-285-3	1096 mg/L (96 h)	Non-applicable	Brachydanio rerio	Fish
	Non-applicable			
	Non-applicable			
Docusate sodium CAS: 577-11-7 EC: 209-406-4	28 mg/L (96 h)	36 mg/L (48 h)	Oncorhynchus mykiss	Fish
	Non-applicable		Daphnia magna	Crustacean

**12.2 Persistence and degradability:**

Identification	Degradability		Biodegradability	
	BOD5	COD	Concentration	Period
Pentane-1,2-diol CAS: 5343-92-0 EC: 226-285-3	Non-applicable	Non-applicable	28 mg/L	28 days
	Non-applicable		% Biodegradable	73 %
Docusate sodium CAS: 577-11-7 EC: 209-406-4	Non-applicable	Non-applicable	100 mg/L	28 days
	Non-applicable		% Biodegradable	91 %

**12.3 Bioaccumulative potential:**

Identification	Bioaccumulation potential	
	BCF	Pow Log
Docusate sodium CAS: 577-11-7 EC: 209-406-4	1	
	Low	

**12.4 Mobility in soil:**

Identification	Absorption/desorption		Volatility	
	Koc	Conclusion	Henry	Dry soil
Pentane-1,2-diol CAS: 5343-92-0 EC: 226-285-3	Non-applicable	Non-applicable	Non-applicable	Non-applicable
			Dry soil	Non-applicable
			Moist soil	Non-applicable

**12.5 Results of PBT and vPvB assessment:**

Product fails to meet PBT/vPvB criteria

**12.6 Other adverse effects:**

Not described

- CONTINUED ON NEXT PAGE -



**PKB03 - Audisol Ear spray**
**SECTION 13: DISPOSAL CONSIDERATIONS**
**13.1 Waste treatment methods:**

Code	Description	Waste class (Regulation (EU) No 1357/2014)
	It is not possible to assign a specific code, as it depends on the intended use by the user	Non dangerous

**Type of waste (Regulation (EU) No 1357/2014):**

Non-applicable

**Waste management (disposal and evaluation):**

Consult the authorized waste service manager on the assessment and disposal operations in accordance with Annex 1 and Annex 2 (Directive 2008/98/EC). As under 15 01 (2014/955/EC) of the code and in case the container has been in direct contact with the product, it will be processed the same way as the actual product. Otherwise, it will be processed as non-dangerous residue. We do not recommended disposal down the drain. See paragraph 6.2.

**Regulations related to waste management:**

In accordance with Annex II of Regulation (EC) No 1907/2006 (REACH) the community or state provisions related to waste management are stated

Community legislation: Directive 2008/98/EC, 2014/955/EU, Regulation (EU) No 1357/2014

**SECTION 14: TRANSPORT INFORMATION**

This product is not regulated for transport (ADR/RID,IMDG,IATA)

**SECTION 15: REGULATORY INFORMATION**
**15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture:**

Candidate substances for authorisation under the Regulation (EC) No 1907/2006 (REACH): Non-applicable

Substances included in Annex XIV of REACH ("Authorisation List") and sunset date: Non-applicable

Regulation (EC) No 1005/2009, about substances that deplete the ozone layer: Non-applicable

Article 95, REGULATION (EU) No 528/2012: Non-applicable

REGULATION (EU) No 649/2012, in relation to the import and export of hazardous chemical products: Non-applicable

**Seveso III:**

Non-applicable

**Limitations to commercialisation and the use of certain dangerous substances and mixtures (Annex XVII REACH, etc ....):**

Non-applicable

**Specific provisions in terms of protecting people or the environment:**

It is recommended to use the information included in this safety data sheet as a basis for conducting workplace-specific risk assessments in order to establish the necessary risk prevention measures for the handling, use, storage and disposal of this product.

**Other legislation:**

The product could be affected by sectorial legislation

**15.2 Chemical safety assessment:**

The supplier has not carried out evaluation of chemical safety.

**SECTION 16: OTHER INFORMATION**
**Legislation related to safety data sheets:**

The SDS shall be supplied in an official language of the country where the product is placed on the market. This safety data sheet has been designed in accordance with ANNEX II-Guide to the compilation of safety data sheets of Regulation (EC) No 1907/2006 (Regulation (EC) No 2015/830).

**Modifications related to the previous Safety Data Sheet which concerns the ways of managing risks.:**

Non-applicable

- CONTINUED ON NEXT PAGE -



**PKB03 - Audisol Ear spray****SECTION 16: OTHER INFORMATION (continued)****Texts of the legislative phrases mentioned in section 3:**

The phrases indicated do not refer to the product itself; they are present merely for informative purposes and refer to the individual components which appear in section 3

**Directive 67/548/EC and Directive 1999/45/EC:**

R38: Irritating to skin

R41: Risk of serious damage to eyes

**CLP Regulation (EC) No 1272/2008:**

Eye Dam. 1: H318 - Causes serious eye damage.

Skin Irrit. 2: H315 - Causes skin irritation.

**Advice related to training:**

Minimal training is recommended in order to prevent industrial risks for staff using this product and to facilitate their comprehension and interpretation of this safety data sheet, as well as the label on the product.

**Principal bibliographical sources:**

<http://echa.europa.eu>

<http://eur-lex.europa.eu>

**Abbreviations and acronyms:**

ADR: European agreement concerning the international carriage of dangerous goods by road

IMDG: International maritime dangerous goods code

IATA: International Air Transport Association

ICAO: International Civil Aviation Organisation

COD: Chemical Oxygen Demand

BOD5: 5-day biochemical oxygen demand

BCF: Bioconcentration factor

LD50: Lethal Dose 50

LC50: Lethal Concentration 50

EC50: Effective concentration 50

Log-POW: Octanol-water partition coefficient

Koc: Partition coefficient of organic carbon

The information contained in this safety data sheet is based on sources, technical knowledge and current legislation at European and state level, without being able to guarantee its accuracy. This information cannot be considered a guarantee of the properties of the product, it is simply a description of the security requirements. The occupational methodology and conditions for users of this product are not within our awareness or control, and it is ultimately the responsibility of the user to take the necessary measures to obtain the legal requirements concerning the manipulation, storage, use and disposal of chemical products. The information on this safety data sheet only refers to this product, which should not be used for needs other than those specified.

- END OF SAFETY DATA SHEET -