Safety Data Sheet

According to Annex II to REACH - Regulation (EU) 2020/878 and to Annex II to UK REACH

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

1.1. Product identifier

Code:	**0302445B**
Product name	**GUSTO 3**
Chemical name and synonym	**Metaldehyde (3%) - Denatonium benzoate (0.03%).**

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

Intended use **Antiparasitic.**

Identified Uses	Industrial	Professional	Consumer
Professional uses: Public domain (administration, education, entertainment, services, craftsmen)	-	✔	-

1.3. Details of the supplier of the safety data sheet

Name	**Adama Agricultural Solutions UK Ltd**
Full address	**Third Floor East, 1410 Arlington Business Park**
District and Country	**Theale - READING RG7 4SA**
	United Kindom
	tel. 01635 860555
	fax 01635 861555
e-mail address of the competent person responsible for the Safety Data Sheet	**ukenquiries@adama.com**

1.4. Emergency telephone number

For urgent inquiries refer to

- Republic of Ireland: National Poisons Information Centre, Beaumont Hospital
Tel.: 01 809 2166 or 01 837 9964 (8 am – 10 pm, 7 days a week)
or
- The UK National Chemical Emergency Centre on
Tel.: +44 (0) 1865 407333 (24 hours, 7 days a week)

SECTION 2. Hazards identification

2.1. Classification of the substance or mixture

The product is classified as hazardous pursuant to the provisions set forth in (EC) Regulation 1272/2008 (CLP) (and subsequent amendments and supplements). The product thus requires a safety datasheet that complies with the provisions of (EU) Regulation 2020/878.
Any additional information concerning the risks for health and/or the environment are given in sections 11 and 12 of this sheet.

Hazard classification and indication:

Reproductive toxicity, category 2	H361f	Suspected of damaging fertility.
Serious eye damage, category 1	H318	Causes serious eye damage.

2.2. Label elements

Hazard labelling pursuant to EC Regulation 1272/2008 (CLP) and subsequent amendments and supplements.

Hazard pictograms:

Signal words: Danger

Hazard statements:

H361f	Suspected of damaging fertility.
H318	Causes serious eye damage.
EUH401	To avoid risks to human health and the environment, comply with the instructions for use.

Precautionary statements:

P102	Keep out of reach of children.
P201	Obtain special instructions before use.
P202	Do not handle until all safety precautions have been read and understood.
P280	Wear protective gloves / protective clothing / eye protection / face protection.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P310	Immediately call a POISON CENTER / doctor / . . .
P405	Store locked up.

Contains: METALDEHYDE
CALCIUM HYDROXIDE

SP1 Do not contaminate water with the product or its container.
Do not clean the operating equipment near surface water.

Prevent contamination of farms and roads by draining water.
SPe6 To protect wild birds and mammals, collect all accidental spills.

2.3. Other hazards

On the basis of available data, the product does not contain any PBT or vPvB in percentage ≥ than 0,1%.

The product does not contain substances with endocrine disrupting properties in concentration ≥ 0.1%.

Vapours may glow and form expolsive mixtures with air.

SECTION 3. Composition/information on ingredients

3.1. Substances

Information not relevant

3.2. Mixtures

Contains:

Identification	x = Conc. %	Classification (EC) 1272/2008 (CLP)
METALDEHYDE		
INDEX 605-005-00-7	3 ≤ x < 5	Flam. Sol. 2 H228, Repr. 2 H361f, Acute Tox. 3 H301, Aquatic Chronic 3 H412
EC 203-600-2		LD50 Oral: 283 mg/kg
CAS 108-62-3		
REACH Reg. 01-2120769329-40-XXXX		
CALCIUM HYDROXIDE		
INDEX -	3 ≤ x < 5	Eye Dam. 1 H318, Skin Irrit. 2 H315, STOT SE 3 H335
EC 215-137-3		
CAS 1305-62-0		
REACH Reg. 01-2119475151-45		
DENATONIUM BENZOATE		
INDEX -	0 ≤ x < 0,5	Acute Tox. 2 H330, Acute Tox. 4 H302, Eye Dam. 1 H318
EC 223-095-2		LD50 Oral: 749 mg/kg, LC50 Inhalation mists/powders: 0,2 mg/kg
CAS 3734-33-6		
REACH Reg. 01-2120102843-65-0003		
SALICYLIC ACID		
INDEX -	0 ≤ x < 0,5	Repr. 2 H361d, Acute Tox. 4 H302, Eye Dam. 1 H318
EC 200-712-3		LD50 Oral: 891 mg/kg
CAS 69-72-7		
REACH Reg. 01-2119486984-17		

The full wording of hazard (H) phrases is given in section 16 of the sheet.

SECTION 4. First aid measures

4.1. Description of first aid measures

EYES: Remove contact lenses, if present. Wash immediately with plenty of water for at least 15 minutes, opening the eyelids fully. If problem persists, seek medical advice.
SKIN: Remove contaminated clothing. Rinse skin with a shower immediately. Wash contaminated clothing before using it again.
INHALATION: Remove to open air. If the subject stops breathing, administer artificial respiration. Get medical advice/attention immediately.
INGESTION: Get medical advice/attention immediately. Do not induce vomiting. Do not administer anything not explicitly authorised by a doctor.

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

Specific information on symptoms and effects caused by the product are unknown.

CALCIUM HYDROXIDE
Calcium hydroxide does not cause acute toxicity by oral, dermal, or inhalation routes.
The substance is classified as irritating to the skin and respiratory tract and carries the risk of serious eye damage.
There is no concern for adverse effects because local effects (pH-effect) represent the greatest health risk.

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

Treat symptomatically.

SECTION 5. Firefighting measures

5.1. Extinguishing media

SUITABLE EXTINGUISHING EQUIPMENT
Extinguishing substances are: carbon dioxide, foam, chemical powder. For product loss or leakage that has not caught fire, water spray can be used to disperse flammable vapours and protect those trying to stem the leak.
UNSUITABLE EXTINGUISHING EQUIPMENT
Do not use jets of water. Water is not effective for putting out fires but can be used to cool containers exposed to flames to prevent explosions.

5.2. Special hazards arising from the substance or mixture

In case of fire, toxic gases can develop, such as nitrogen oxides (NOx), Carbon monoxide (CO), Formaldehyde.

HAZARDS CAUSED BY EXPOSURE IN THE EVENT OF FIRE
Excess pressure may form in containers exposed to fire at a risk of explosion. Do not breathe combustion products.

CALCIUM HYDROXIDE
Carbon oxides.

5.3. Advice for firefighters

GENERAL INFORMATION
Use jets of water to cool the containers to prevent product decomposition and the development of substances potentially hazardous for health. Always wear full fire prevention gear. Collect extinguishing water to prevent it from draining into the sewer system. Dispose of contaminated water used for extinction and the remains of the fire according to applicable regulations.
SPECIAL PROTECTIVE EQUIPMENT FOR FIRE-FIGHTERS
Normal fire fighting clothing i.e. fire kit (BS EN 469), gloves (BS EN 659) and boots (HO specification A29 and A30) in combination with self-contained open circuit positive pressure compressed air breathing apparatus (BS EN 137).

SECTION 6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

If there are no contraindications, spray powder with water to prevent the formation of dust.
Wear suitable protective equipment (including personal protective equipment referred to under Section 8 of the safety data sheet) to prevent any contamination of skin, eyes and personal clothing. These indications apply for both processing staff and those involved in emergency procedures.

6.2. Environmental precautions

The product must not penetrate into the sewer system or come into contact with surface water or ground water.

6.3. Methods and material for containment and cleaning up

Collect the leaked product and place it in containers for recovery or disposal. If there are no contraindications, use jets of water to eliminate product residues.
Make sure the leakage site is well aired. Evaluate the compatibility of the container to be used, by checking section 10. Contaminated material should be disposed of in compliance with the provisions set forth in point 13.

6.4. Reference to other sections

Any information on personal protection and disposal is given in sections 8 and 13.

SECTION 7. Handling and storage

7.1. Precautions for safe handling

Keep away from heat, sparks and naked flames; do not smoke or use matches or lighters. Without adequate ventilation, vapours may accumulate at ground level and, if ignited, catch fire even at a distance, with the danger of backfire. Avoid bunching of electrostatic charges. When performing transfer operations involving large containers, connect to an earthing system and wear antistatic footwear. In order to avoid the risk of fires and explosions, never use compressed air when handling. Open containers with caution as they may be pressurised. Do not eat, drink or smoke during use. Avoid leakage of the product into the environment.

7.2. Conditions for safe storage, including any incompatibilities

Store only in the original container. Store the containers sealed, in a well ventilated place, away from direct sunlight. Store in a cool and well ventilated place, keep far away from sources of heat, naked flames and sparks and other sources of ignition. Keep containers away from any incompatible materials, see section 10 for details.
The product is sensitive to heat, should not be stored above 30°C [CIPAC MT 46].

CALCIUM HYDROXIDE
Store in a cool place, away from humidity.
Avoid direct exposure to the sun.
Always keep containers closed, place containers on the ground.
Keep away from acids.
Deposit class: 13.

DENATONIUM BENZOATE
Suitable materials for containers: high density polyethylene (HDPE), high purity polymer,
1.4404 stainless steel.

7.3. Specific end use(s)

DENATONIUM BENZOATE
Denatonium benzoate is used as an alcohol denaturant and flavoring in pharmaceuticals.
It is also used in antifreeze, nail biting prevention, breathing mask fit test, animal repellent, liquid soaps and shampoos.
Also, it is used in air care products.
Acts like H1 antihistamine.
In addition to this, it is used as a disinfectant.

SECTION 8. Exposure controls/personal protection

8.1. Control parameters

Regulatory references:

ESP	España	Límites de exposición profesional para agentes químicos en España 2021
FRA	France	Valeurs limites d'exposition professionnelle aux agents chimiques en France. ED 984 - INRS
ITA	Italia	Decreto Legislativo 9 Aprile 2008, n.81
POL	Polska	Rozporządzenie ministra rozwoju, pracy i technologii z dnia 18 lutego 2021 r. Zmieniające rozporządzenie w sprawie najwyższych dopuszczalnych stężeń i natężeń czynników szkodliwych dla zdrowia w środowisku pracy
GBR	United Kingdom	EH40/2005 Workplace exposure limits (Fourth Edition 2020)
EU	OEL EU	Directive (EU) 2022/431; Directive (EU) 2019/1831; Directive (EU) 2019/130; Directive (EU) 2019/983; Directive (EU) 2017/2398; Directive (EU) 2017/164; Directive 2009/161/EU; Directive 2006/15/EC; Directive 2004/37/EC; Directive 2000/39/EC; Directive 98/24/EC; Directive 91/322/EEC.
	RCP TLV	ACGIH TLVs and BEIs – Appendix H

CALCIUM HYDROXIDE

Threshold Limit Value

Type	Country	TWA/8h		STEL/15min		Remarks / Observations
		mg/m3	ppm	mg/m3	ppm	
VLA	ESP	1		4		
VLEP	FRA	1		4		RESP
VLEP	ITA	1		4		RESP
NDS/NDSCh	POL	2		6		INHAL
WEL	GBR	5		4		RESP
OEL	EU	1		4		RESP

Predicted no-effect concentration - PNEC		
Normal value in fresh water	0,49	mg/l
Normal value in marine water	0,32	mg/l
Normal value for water, intermittent release	0,49	mg/l
Normal value of STP microorganisms	3	mg/l
Normal value for the terrestrial compartment	1080	mg/kg

Health - Derived no-effect level - DNEL / DMEL

	Effects on consumers				Effects on workers			
Route of exposure	Acute local	Acute systemic	Chronic local	Chronic systemic	Acute local	Acute systemic	Chronic local	Chronic systemic
Inhalation	4 mg/m3		1 mg/m3		4 mg/m3		1 mg/m3	

DENATONIUM BENZOATE

Predicted no-effect concentration - PNEC		
Normal value in fresh water	0,1	mg/l
Normal value in marine water	0,01	mg/l
Normal value for fresh water sediment	25	mg/kg/d
Normal value for marine water sediment	2,5	mg/kg/d
Normal value for water, intermittent release	1	mg/l
Normal value for the terrestrial compartment	4,95	mg/kg/d

Health - Derived no-effect level - DNEL / DMEL

	Effects on consumers				Effects on workers			
Route of exposure	Acute local	Acute systemic	Chronic local	Chronic systemic	Acute local	Acute systemic	Chronic local	Chronic systemic
Oral				0,51 mg/kg bw/d				
Inhalation				0,893 mg/m3				4,99 mg/m3
Skin				0,51 mg/kg bw/d				1,43 mg/kg bw/d

PARALDEHYDE

Threshold Limit Value

Type	Country	TWA/8h		STEL/15min		Remarks / Observations
		mg/m3	ppm	mg/m3	ppm	
RCP TLV		17,5				

SALICYLIC ACID

Predicted no-effect concentration - PNEC		
Normal value in fresh water	0,2	mg/l
Normal value in marine water	0,02	mg/l
Normal value for fresh water sediment	1,42	mg/kg
Normal value for marine water sediment	0,14	mg/kg
Normal value for water, intermittent release	1	mg/l
Normal value of STP microorganisms	162	mg/l
Normal value for the terrestrial compartment	0,16	mg/kg

Health - Derived no-effect level - DNEL / DMEL

	Effects on consumers				Effects on workers			
Route of exposure	Acute local	Acute systemic	Chronic local	Chronic systemic	Acute local	Acute systemic	Chronic local	Chronic systemic
Oral		4 mg/kg/d		1 mg/kg/d				
Inhalation			0,2 mg/m3	4 mg/kg				5 mg/m3
Skin				1 mg/kg/d				2,3 mg/kg/d

Legend:

(C) = CEILING ; INHAL = Inhalable Fraction ; RESP = Respirable Fraction ; THORA = Thoracic Fraction.

VND = hazard identified but no DNEL/PNEC available ; NEA = no exposure expected ; NPI = no hazard identified ; LOW = low hazard ; MED = medium hazard ; HIGH = high hazard.

8.2. Exposure controls

As the use of adequate technical equipment must always take priority over personal protective equipment, make sure that the workplace is well aired through effective local aspiration.
When choosing personal protective equipment, ask your chemical substance supplier for advice.
Personal protective equipment must be CE marked, showing that it complies with applicable standards.
Provide an emergency shower with face and eye wash station.

HAND PROTECTION
In the case of prolonged contact with the product, protect the hands with penetration-resistant work gloves (see standard EN 374).
Work glove material must be chosen according to the use process and the products that may form. Latex gloves may cause sensitivity reactions.
- METALDEHYDE
  Material: nitrile rubber.
  Break through time: > 480 min.
  The selected protective gloves have to satisfy the specifications of Regulation (EU) 2016/425 and the standard EN 374 derived from it.
- DENATONIUM BENZOATE
  Nitrile rubber.
  Minimum layer thickness: 0.11mm.
  Breakthrough time: 480 min.

SKIN PROTECTION
Wear category I professional long-sleeved overalls and safety footwear (see Regulation 2016/425 and standard EN ISO 20344). Wash body with soap and water after removing protective clothing.

EYE PROTECTION
Wear airtight protective goggles (see standard EN 166).

RESPIRATORY PROTECTION
None required, unless indicated otherwise in the chemical risk assessment.
- METALDEHYDE
  In the case of dust or aerosol formation use respirator with an approved filter.
  Half mask with a particle filter P2 (EN 143).

ENVIRONMENTAL EXPOSURE CONTROLS
The emissions generated by manufacturing processes, including those generated by ventilation equipment, should be checked to ensure compliance with environmental standards.
Product residues must not be indiscriminately disposed of with waste water or by dumping in waterways.

SECTION 9. Physical and chemical properties

9.1. Information on basic physical and chemical properties

Properties	Value	Information
Appearance	solid	
Colour	blue	
Odour	Slightly acrid	
Melting point / freezing point	not available	
Initial boiling point	not available	

Flammability	not flammable	Method: EEC A.10
Lower explosive limit	not available	
Upper explosive limit	not available	
Flash point	not available	
Auto-ignition temperature	not available	
Decomposition temperature	not available	
pH	10,0 - 11,0	Method: CIPAC MT 75.3 Concentration: 1 %
Kinematic viscosity	not applicable	Reason for missing data: Product in solid form
Solubility	Hydroleakable	
Partition coefficient: n-octanol/water	not available	
Vapour pressure	not available	
Density and/or relative density	0,64 - 0,74 kg/l	Method: CIPAC MT 159 Remark: Poured
Relative vapour density	not available	
Particle characteristics	not available	

9.2. Other information

9.2.1. Information with regard to physical hazard classes

Information not available

9.2.2. Other safety characteristics

Explosive properties	Not explosive
Oxidising properties	Not oxidant

SECTION 10. Stability and reactivity

10.1. Reactivity

There are no particular risks of reaction with other substances in normal conditions of use.

CALCIUM HYDROXIDE

In water, the $Ca(OH)_2$ dissociates, causing the formation of calcium cations and hydroxyl anions (if below the limit of solubility in water).

10.2. Chemical stability

The product is stable in normal conditions of use and storage.

10.3. Possibility of hazardous reactions

The vapours may also form explosive mixtures with the air.

CALCIUM HYDROXIDE

Calcium hydroxide reacts exothermically with acids.
When heated to more than 580 °C, calcium hydroxide dissociates to produce calcium oxide (CaO) and water (H_2O): $Ca(OH)_2 \rightarrow CaO + H_2O$.
Calcium oxide reacts with water and generates heat.
This poses a risk to flammable materials.

DENATONIUM BENZOATE

Oxidants (strong): fire and explosion hazard.

10.4. Conditions to avoid

Avoid overheating. Avoid bunching of electrostatic charges. Avoid all sources of ignition.

CALCIUM HYDROXIDE

Minimize exposure to air and moisture to avoid deterioration.

METALDEHYDE

Heat, flames and sparks.

DENATONIUM BENZOATE

Avoid contact with incompatible materials.
Avoid heat, flames, sparks and other sources of ignition.

10.5. Incompatible materials

Strong oxidizing agents and strong reducing agents.

CALCIUM HYDROXIDE

The calcium hydroxide reacts exothermically with acids to form salts.
The calcium hydroxide reacts with aluminum and brass in the presence of moisture and produces hydrogen $Ca(OH)_2 + 2Al + 6H_2O \rightarrow Ca[Al(OH)_4]_2 + 3H_2$

METALDEHYDE

Strong acids and strong bases.
Oxidizing agents.

DENATONIUM BENZOATE

Strong oxidizing agents.

10.6. Hazardous decomposition products

By thermal decomposition or in the event of fire, gases and vapors that are potentially harmful to health can be released: Nitrogen oxides (NOx), Carbon monoxide (CO), Formaldehyde.
In the event of thermal decomposition or fire, gases and vapours that are potentially dangerous to health may be released.

CALCIUM HYDROXIDE

Carbon oxides.

DENATONIUM BENZOATE

Oxides of nitrogen, monoxide and carbon dioxide.

SECTION 11. Toxicological information

In the absence of experimental data for the product itself, health hazards are evaluated according to the properties of the substances it contains, using the criteria specified in the applicable regulation for classification.
It is therefore necessary to take into account the concentration of the individual hazardous substances indicated in section 3, to evaluate the toxicological effects of exposure to the product.

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

Metabolism, toxicokinetics, mechanism of action and other information

Information not available

Information on likely routes of exposure

Information not available

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Information not available

Interactive effects

Information not available

ACUTE TOXICITY

ATE (Inhalation) of the mixture:	Not classified (no significant component)	
ATE (Oral, rat) of the mixture:	> 2000 mg/kg	[OECD 423]
ATE (Dermal, rat) of the mixture:	> 2000 mg/kg	[OECD 402 B.3 - OPPTS 870.1200]

CALCIUM HYDROXIDE

LD50 (Dermal):	> 2500 mg/kg Rabbit
LD50 (Oral):	> 2000 mg/kg Female rat

METALDEHYDE

LD50 (Dermal):	> 5000 mg/kg Rat [OECD Test Guideline 402]
LD50 (Oral):	283 mg/kg Rat [OECD Test Guideline 401]

DENATONIUM BENZOATE

LD50 (Dermal):	> 2000 mg/kg Rat [EPA OPP 81-2]
LD50 (Oral):	749 mg/kg Male rat
LC50 (Inhalation mists/powders):	0,2 mg/l/1h Rat

SALICYLIC ACID

LD50 (Dermal):	> 2000 mg/kg Rabbit
LD50 (Oral):	891 mg/kg Male rat
LC50 (Inhalation vapours):	> 0,9 mg/l/1h Rat

SKIN CORROSION / IRRITATION

Does not meet the classification criteria for this hazard class

CALCIUM HYDROXIDE
Irritating to skin (in vivo, rabbit).

METALDEHYDE
Not irritant - rabbit [OECD Test Guideline 404 - exposition time: 4 h]

DENATONIUM BENZOATE
Not irritating to the skin.
A study was conducted to evaluate the irritation potential of Denatonium benzoate (BITREX) to the skin of New Zealand white rabbits.
The study was conducted according to EPA 81-5.
Guidelines and 6 New Zealand white rabbits (3 / sex) were used for the study.
Based on the scores observed in the study and when using the ECHA guideline calculation method on the application of the CLP criteria v 5.0, none of the mean scores per animal (at 24, 48 and 72 hours) reached the cut value off of 2.3.
Hence, no animal is positive for skin irritation.
Therefore, in conclusion, Denatonium Benzoate (BITREX) is not classified as a skin irritant under CLP.

SERIOUS EYE DAMAGE / IRRITATION

Causes serious eye damage

CALCIUM HYDROXIDE
It carries the risk of serious eye damage (eye irritation studies (in vivo, rabbit)).

METALDEHYDE
Slightly irritant - rabbit [OECD Test Guidline 405]

DENATONIUM BENZOATE
Method: Guideline: EPA OPP 81-4 (acute eye irritation).
Species: rabbit (New Zealand White [rabbit]).
Vehicle: unchanged (no vehicles).
For the purposes of this study, the test material was ground to a fine powder.
One day before the test, both eyes of the test rabbit were examined under ultraviolet light, after treatment with Sodium Fluorescien BP.
The cornea, iris and conjunctiva lesions were examined.
Immediately prior to treatment, the rabbit eyes were re-examined with the aid of a light source from a standard ophthalmoscope. 0.1 ml volume (approximately 40 mg) of finely ground powder was instilled into the right conjunctival sac of the rabbit.
The upper and lower lids were held together for approximately one second immediately after application to prevent loss of the test material and then released. The left eye remained untreated and served as a control.
Ocular reaction assessment and scoring was performed approximately 1, 24, 48, and 72 hours after treatment.
Further observations were made on days 7.14 and 21 to verify the reversibility of the effects.
For ocular lesion scoring, eye examination was facilitated by the use of a standard ophthalmoscope.
Ocular reactions were marked according to the Draize method.
Result: Single application of the test material produced areas of translucent, iridescent opacity inflammation and moderate conjunctival irritation.
Corneal vascularization was present on day 7 and was still evident on day 21.
Ocular reactions were then considered be irreversible.
Therefore, it could cause eye damage.
Hence, Denatonium benzoate can be considered classified as "eye damage 1" for eye irritation.

RESPIRATORY OR SKIN SENSITISATION

Does not meet the classification criteria for this hazard class

METALDEHYDE
Not sensitizing - mouse [OECD 429]; Guinea pig [OECD 406]

DENATONIUM BENZOATE
Not sensitizing.
Skin sensitization: in vivo (not LLNA).
Guideline: EPA OPP 81-6 (skin sensitization).
Species: guinea pig.
A study was conducted to evaluate the skin sensitization potential of denatonium benzoate [BITREX] in guinea pigs.
Buehler delayed contact hypersensitivity method following EPA guidelines 81-6 was conducted in a GLP (Sustainability Support Services (Europe) AB certified laboratory has a letter of access).
Twenty tests and 10 Dunkin controls.
Male Hartley guinea pigs were used for the main study, 4 eyesight research study guinea pigs were used for the study.
a] Concentration selection for topical induction exposure 2 untreated guinea pigs were treated with 0.5 ml of the four test chemical concentrations in distilled water (75%, 50%, 25 and 10% w/w) .
The highest concentration causing mild to moderate irritation after 6 hours of occlusive exposure was selected as the concentration for topical induction.
b] Selection of concentration for topical challenge exposure: 2 guinea pigs were treated with 0.5 ml of two concentrations of test chemical in water distillate (50.75% w/w).
These animals were treated identically to the control animals in the main study on days 0.7 and 14.
The highest concentration of test material that produced no evidence of irritation 24 or 48 hours after a 6-hour occlusive exposure
selected for exposure to the topical challenge.
The concentrations obtained from these studies for topical induction and challenge are as follows:
Topical induction: 75% w/w in distilled water.
Topical challenge: 50, 75% w/w in distilled water.
During the induction step, 0.5 ml of the test material at the concentration of 75% w/w in distillate water was applied to the left flank of the test animals under an occlusive dressing for 6 hours.
The induction exposure procedure was repeated at the same site on days 7, 14 for a total of 3 6-hour exposures. Approximately 24 hours after each induction exposure (days 1, 8, 15), the degree of erythema and edema were quantified. The same procedure was followed for the control animals, except that the vehicle only was applied.
On day 28, the right flank of the test animals was cut hairless and 0.5 ml of the test material at concentrations of 75%, 50% w/w in distilled water was applied to the right flank under occlusive conditions for 6 hours .
After 6 hours, the patches were cut and the treatment sites were rinsed with distilled water and the test sites were marked with a permanent marker.
Approximately 24 to 48 hours after patch removal, the degree of erythema and edema was quantified. 2-Mercaptobenzothiazole was used as a positive control.
Contact sensitization

reactions were elicited in 3 of the 20 animals of the test group previously induced topically challenge.
The well-known contact sensitizer, 2-Mercaptobenzothiazole, therefore produced a Awareness rate of 15%.
This was considered a satisfactory sensitization response under test conditions.
Denatonium benzoate [BITREX] produced an awareness rate of 0% (0/20) and was considered be non-sensitizing to guinea pig skin.

Respiratory sensitization

CALCIUM HYDROXIDE
Irritating to respiratory tract.

Skin sensitization

CALCIUM HYDROXIDE
It does not cause sensitization.

GERM CELL MUTAGENICITY

Does not meet the classification criteria for this hazard class

METALDEHYDE
Negative - Salmonella typhimurium (in vitro) [OECD 471]
Negative - murine lymphoma cells (in vitro) [OECD 476]
Negative - Chinese hamster ovary cells (in vitro) [OECD 473]
Negative - mouse (in vivo) [OECD 474]

DENATONIUM BENZOATE
Genetic toxicity: in vitro:
Denatonium benzoate (Cas No 3734-33-6) was considered non-cytotoxic and non-clastogenic at 1.25 mg/mL for the in vitro chromosomal aberration test and has no clastogenic effect on human lymphocyte cells under experimental conditions.

CARCINOGENICITY

Does not meet the classification criteria for this hazard class

CALCIUM HYDROXIDE
Not listed as a suspected carcinogen.

METALDEHYDE
Non-carcinogenic - oral, mouse [OECD Test Guideline 451]
Non-carcinogenic - oral, rat [OECD Test Guideline 453]

DENATONIUM BENZOATE
Not listed as a carcinogen by ACGIH, IARC, NIOSH, NTP, OSHA, or CA Prop 65.
No observed adverse effect level (NOAEL) (related to chronic systemic effects and carcinogenicity) was considered to be 16 mg/kg per day.
When the mice were treated with Denatonium benzoate (3734-33-6) orally for 2 years.

REPRODUCTIVE TOXICITY

Suspected of damaging fertility

DENATONIUM BENZOATE
NOAEL was considered to be 60 mg / kg body weight when male and female Sprague-Dawley rats were treated with Denatonium Benzoate orally by gavage in water for 42 days and 63 days female rats [OECD TG 421] .

STOT - SINGLE EXPOSURE

Does not meet the classification criteria for this hazard class

STOT - REPEATED EXPOSURE

Does not meet the classification criteria for this hazard class

CALCIUM HYDROXIDE
The toxicity of oral calcium is directed at the maximum intake levels (UL) for adults determined by the "Scientific Committee on Food (SFC), being". UL= 2500 mg/d, corresponds to 36 mg/kg bw/d (70 kg person) for calcium.
The toxicity of $Ca(OH)_2$ via the dermal route is not considered relevant in view of the expected insignificant absorption via the skin and due to local irritation as the primary health effect (change in pH).
The toxicity of Ca(OH)2 by inhalation (local effect, irritation of mucous membranes) is 8-h TWA by the "Scientific Committee on Occupational Exposure Limits (SCOEL)" as 1 mg/mc respirable dust.

Target organs

METALDEHYDE
NOAEL:> 1000 mg / kg bw / day (skin, rabbit, exposure time: 21 days) - Number of exposures: 6 hours / day, 5 days / week; Dose: 100 - 300 - 1000 mg / kg / TAG [US-EPA].
Control group: yes.
Method: US-EPA - GLP: yes.
Rat (diet) - Doses: 21 - 64 - 215 mg / kg / TAG.
Control group: yes.
Method: MAFF, Japan - BPL: yes.

Route of exposure

DENATONIUM BENZOATE
Oral:
The NOAEL was considered to be 5359.05 mg / kg for mice exposed to denatonium orally for 3 weeks.
Cutaneous:
Given the low vapor pressure, inhalation and hence exposure is not likely this was considered for waiver.
Inhalation:
Considering the use of the chemical, repeated exposure to denatonium benzoate by the the dermal route is not very likely and therefore this was considered for the waiver.

ASPIRATION HAZARD

Does not meet the classification criteria for this hazard class

METALDEHYDE
There is no classification for aspiration toxicity.

11.2. Information on other hazards

Based on the available data, the product does not contain substances listed in the main European lists of potential or suspected endocrine disruptors with human health effects under evaluation.

CALCIUM HYDROXIDE
The substance/mixture does not contain components considered to have endocrine disrupting properties in accordance with Article 57(f) of REACH or Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

SECTION 12. Ecological information

To avoid risks to human health and the environment, comply with the instructions for use.

12.1. Toxicity

SALICYLIC ACID	
LC50 - for Fish	1380 mg/l/96h Pimephales promelas
EC50 - for Crustacea	870 mg/l/48h Daphnia magna
EC50 - for Algae / Aquatic Plants	> 100 mg/l/72h Desmodesmus subspicatus
CALCIUM HYDROXIDE	
LC50 - for Fish	457 mg/l/96h Gasterosteus aculeatus
EC50 - for Crustacea	158 mg/l/48h Crangon septemspinosa
EC50 - for Algae / Aquatic Plants	184,57 mg/l/72h Pseudokirchneriella subcapitata
DENATONIUM BENZOATE	
LC50 - for Fish	> 100 mg/l/96h Danio rerio [OECD TG 203]
EC50 - for Crustacea	> 500 mg/l/48h Daphnia magna [OECD TG 202]
EC50 - for Algae / Aquatic Plants	281556 mg/l/72h Chlorella vulgaris [OECD TG 201]
METALDEHYDE	
LC50 - for Fish	75 mg/l/96h Oncorhynchus mykiss [OECD TG 203]
EC50 - for Crustacea	> 100 mg/l/48h Daphnia magna [OECD TG 202]
EC50 - for Algae / Aquatic Plants	> 200 mg/l/72h Desmodesmus subspicatus [OECD Test Guideline 201]
Chronic NOEC for Fish	> 25 mg/l Danio rerio - 35 giorni [OECD TG 210]
Chronic NOEC for Crustacea	> 98 mg/l Daphnia magna - 21 giorni [OECD TG 211]
Chronic NOEC for Algae / Aquatic Plants	25 mg/l

12.2. Persistence and degradability

DENATONIUM BENZOATE
Biodegradation in water: not easily biodegradable. 28-day manometric respirometric test according to OECD guideline 301F to determine the ready biodegradability of the test element Denatonium benzoate (Cas No 3734-33-6) was conducted.
The test system included the control, the test element and the reference element.
The concentration of the test and the reference element (sodium benzoate) chosen for both the study was 100 mg/l, while that of the inoculum was 10 ml/l.

ThOD (theoretical oxygen demand) test the reference item was determined by calculation.
% Degradation was calculated using the values of BOD and ThOD for the test element and the reference element.
The BOD28 value of Denatonium benzoate (CAS no 3734-33-6) was found to be 0.436 mgO_2/mg.
ThOD was calculated as 2.40 mgO_2/mg.
Consequently, the% degradation of the test item after 28 days of incubation at 20 ± 1 ° C was determined according to the manometric respirometry test 18.17%.
Based on the results, the test item, under the test conditions, was considered to be not biodegradable at 20 ± 1 ° C for a period of 28 days.
Biodegradation in the soil:
denatonium benzoate is not considered to be significantly degraded in soil in 30 days at 15 ºC.

SALICYLIC ACID

Solubility in water	2000 mg/l (20 °C)

Entirely degradable

CALCIUM HYDROXIDE

Solubility in water	1184 mg/l

DENATONIUM BENZOATE

NOT rapidly degradable

METALDEHYDE

NOT rapidly degradable

28 giorni [OECD 301F]

12.3. Bioaccumulative potential

SALICYLIC ACID

Partition coefficient: n-octanol/water	2

METALDEHYDE

Partition coefficient: n-octanol/water	0,12 (pH = 6,7 @ 20 °C) [OECD TG 107]
BCF	11 Lepomis macrochirus - 28 giorni [OECD Test Guideline 305]

12.4. Mobility in soil

CALCIUM HYDROXIDE
Calcium hydroxide is moderately soluble and has low mobility in most soils.

DENATONIUM BENZOATE
[OECD TG 121].
The adsorption coefficient Koc in soil and sewage sludge of Denatonium benzoate (dust) (CAS No. 3734-33-6) was determined by the Reverse Phase High Performance.
Liquid chromatographic method according to OECD guideline n. 121 for testing chemicals.
The reference substances were selected according to Kocrange's estimate of the test substance and the generalized calibration graph was prepared.
The reference substances were 4 chloroaniline, 4 methylaniline, N methylaniline, 2 nitrophenol, nitrobenzene, 4- Nitrobenzamide, N, N-dimethylbenzamide, N-methylbenzamide, Benzamide, phenanthrene, having Kocvalue between 1.239 and 4.09.
The Log Koc value was determined to be 3.392 ± 0.007 at 25 ° C.
On the basis of the log Koc value it is concluded that the test chemical has a strong absorption in the soil and sediments and therefore there is negligible migration potential towards the aquifers.

12.5. Results of PBT and vPvB assessment

CALCIUM HYDROXIDE
This product is not, or does not contain, a substance defined as PBT or vPvB.
On the basis of available data, the product does not contain any PBT or vPvB in percentage ≥ than 0,1%.

12.6. Endocrine disrupting properties

CALCIUM HYDROXIDE
The substance/mixture does not contain components considered to have endocrine disrupting properties in accordance with Article 57(f) of REACH or Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.
Based on the available data, the product does not contain substances listed in the main European lists of potential or suspected endocrine disruptors with environmental effects under evaluation.

12.7. Other adverse effects

Information not available

SECTION 13. Disposal considerations

13.1. Waste treatment methods

Reuse, when possible. Product residues should be considered special hazardous waste. The hazard level of waste containing this product should be evaluated according to applicable regulations.
Disposal must be performed through an authorised waste management firm, in compliance with national and local regulations.
CONTAMINATED PACKAGING
Contaminated packaging must be recovered or disposed of in compliance with national waste management regulations.

SECTION 14. Transport information

The product is not dangerous under current provisions of the Code of International Carriage of Dangerous Goods by Road (ADR) and by Rail (RID), of the International Maritime Dangerous Goods Code (IMDG), and of the International Air Transport Association (IATA) regulations.

14.1. UN number or ID number

not applicable

14.2. UN proper shipping name

not applicable

14.3. Transport hazard class(es)

not applicable

14.4. Packing group

not applicable

14.5. Environmental hazards

not applicable

14.6. Special precautions for user

not applicable

14.7. Maritime transport in bulk according to IMO instruments

Information not relevant

SECTION 15. Regulatory information

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

Seveso Category - Directive 2012/18/EU: None

Restrictions relating to the product or contained substances pursuant to Annex XVII to EC Regulation 1907/2006

Product

Point	40

Contained substance

Point	75

Regulation (EU) 2019/1148 - on the marketing and use of explosives precursors

not applicable

Substances in Candidate List (Art. 59 REACH)

On the basis of available data, the product does not contain any SVHC in percentage ≥ than 0,1%.

Substances subject to authorisation (Annex XIV REACH)

None

Substances subject to exportation reporting pursuant to Regulation (EU) 649/2012:

None

Substances subject to the Rotterdam Convention:

None

Substances subject to the Stockholm Convention:

None

Healthcare controls

Workers exposed to this chemical agent must not undergo health checks, provided that available risk-assessment data prove that the risks related to the workers' health and safety are modest and that the 98/24/EC directive is respected.

15.2. Chemical safety assessment

A chemical safety assessment has not been performed for the preparation/for the substances indicated in section 3.

SECTION 16. Other information

Text of hazard (H) indications mentioned in section 2-3 of the sheet:

Flam. Sol. 2	Flammable solid, category 2
Repr. 2	Reproductive toxicity, category 2
Acute Tox. 2	Acute toxicity, category 2
Acute Tox. 3	Acute toxicity, category 3
Acute Tox. 4	Acute toxicity, category 4
Eye Dam. 1	Serious eye damage, category 1
Skin Irrit. 2	Skin irritation, category 2
STOT SE 3	Specific target organ toxicity - single exposure, category 3
Aquatic Chronic 3	Hazardous to the aquatic environment, chronic toxicity, category 3
H228	Flammable solid.
H361d	Suspected of damaging the unborn child.
H361f	Suspected of damaging fertility.
H330	Fatal if inhaled.
H301	Toxic if swallowed.
H302	Harmful if swallowed.
H318	Causes serious eye damage.
H315	Causes skin irritation.
H335	May cause respiratory irritation.
H412	Harmful to aquatic life with long lasting effects.

EUH401	To avoid risks to human health and the environment, comply with the instructions for use.

LEGEND:
- ADR: European Agreement concerning the carriage of Dangerous goods by Road
- ATE: Acute Toxicity Estimate
- CAS: Chemical Abstract Service Number
- CE50: Effective concentration (required to induce a 50% effect)
- CE: Identifier in ESIS (European archive of existing substances)
- CLP: Regulation (EC) 1272/2008
- DNEL: Derived No Effect Level
- EmS: Emergency Schedule
- GHS: Globally Harmonized System of classification and labeling of chemicals
- IATA DGR: International Air Transport Association Dangerous Goods Regulation
- IC50: Immobilization Concentration 50%
- IMDG: International Maritime Code for dangerous goods
- IMO: International Maritime Organization
- INDEX: Identifier in Annex VI of CLP
- LC50: Lethal Concentration 50%
- LD50: Lethal dose 50%
- OEL: Occupational Exposure Level
- PBT: Persistent bioaccumulative and toxic as REACH Regulation
- PEC: Predicted environmental Concentration
- PEL: Predicted exposure level
- PNEC: Predicted no effect concentration
- REACH: Regulation (EC) 1907/2006
- RID: Regulation concerning the international transport of dangerous goods by train
- TLV: Threshold Limit Value
- TLV CEILING: Concentration that should not be exceeded during any time of occupational exposure.
- TWA: Time-weighted average exposure limit
- TWA STEL: Short-term exposure limit
- VOC: Volatile organic Compounds
- vPvB: Very Persistent and very Bioaccumulative as for REACH Regulation
- WGK: Water hazard classes (German).

GENERAL BIBLIOGRAPHY
1. Regulation (EC) 1907/2006 (REACH) of the European Parliament
2. Regulation (EC) 1272/2008 (CLP) of the European Parliament
3. Regulation (EU) 2020/878 (II Annex of REACH Regulation)
4. Regulation (EC) 790/2009 (I Atp. CLP) of the European Parliament
5. Regulation (EU) 286/2011 (II Atp. CLP) of the European Parliament
6. Regulation (EU) 618/2012 (III Atp. CLP) of the European Parliament
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8. Regulation (EU) 944/2013 (V Atp. CLP) of the European Parliament
9. Regulation (EU) 605/2014 (VI Atp. CLP) of the European Parliament
10. Regulation (EU) 2015/1221 (VII Atp. CLP) of the European Parliament
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15. Regulation (EU) 2019/521 (XII Atp. CLP)
16. Delegated Regulation (UE) 2018/1480 (XIII Atp. CLP)
17. Regulation (EU) 2019/1148
18. Delegated Regulation (UE) 2020/217 (XIV Atp. CLP)
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22. Delegated Regulation (UE) 2022/692 (XVIII Atp. CLP)
- The Merck Index. - 10th Edition
- Handling Chemical Safety
- INRS - Fiche Toxicologique (toxicological sheet)

- Patty - Industrial Hygiene and Toxicology
- N.I. Sax - Dangerous properties of Industrial Materials-7, 1989 Edition
- IFA GESTIS website
- ECHA website
- Database of SDS models for chemicals - Ministry of Health and ISS (Istituto Superiore di Sanità) - Italy

Note for users:
The information contained in the present sheet are based on our own knowledge on the date of the last version. Users must verify the suitability and thoroughness of provided information according to each specific use of the product.
This document must not be regarded as a guarantee on any specific product property.
The use of this product is not subject to our direct control; therefore, users must, under their own responsibility, comply with the current health and safety laws and regulations. The producer is relieved from any liability arising from improper uses.
Provide appointed staff with adequate training on how to use chemical products.
CALCULATION METHODS FOR CLASSIFICATION
Chemical and physical hazards: Product classification derives from criteria established by the CLP Regulation, Annex I, Part 2. The data for evaluation of chemical-physical properties are reported in section 9.
Health hazards: Product classification is based on calculation methods as per Annex I of CLP, Part 3, unless determined otherwise in Section 11.
Environmental hazards: Product classification is based on calculation methods as per Annex I of CLP, Part 4, unless determined otherwise in Section 12.

Changes to previous review:
The following sections were modified:
01 / 02 / 03 / 04 / 05 / 07 / 08 / 09 / 10 / 11 / 12 / 15 / 16.