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

· **1.1 Product identifier**

· **Trade name: Palabond**

· **1.2 Relevant identified uses of the substance or mixture and uses advised against**
No further relevant information available.

· **Application of the substance / the mixture** Auxiliary for manufacture of dental prothesis

· **1.3 Details of the supplier of the safety data sheet**
· **Manufacturer/Supplier:**
Kulzer GmbH
Leipziger Straße 2, 63450 Hanau (Germany) Tel.: +49 (0)800 4372522

· **Informing department:** E-Mail: msds@kulzer-dental.com
· **1.4 Emergency telephone number:** Emergency CONTACT (24-Hour-Number): +49 (0)6132-84463

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SECTION 2: Hazards identification

· **2.1 Classification of the substance or mixture**
· **Classification according to Regulation (EC) No 1272/2008**

Flam. Liq. 2	H225 Highly flammable liquid and vapour.
Skin Corr. 1A	H314 Causes severe skin burns and eye damage.
Eye Dam. 1	H318 Causes serious eye damage.
Skin Sens. 1	H317 May cause an allergic skin reaction.
STOT SE 3	H335 May cause respiratory irritation.

· **2.2 Label elements**
· **Labelling according to Regulation (EC) No 1272/2008**
The product is classified and labelled according to the GB CLP regulation.
· **Hazard pictograms**

GHS02 GHS05 GHS07

· **Signal word** Danger

· **Hazard-determining components of labelling:**
methyl methacrylate
methacrylic acid
1,4-butandioldimethacrylate
· **Hazard statements**
H225 Highly flammable liquid and vapour.
H314 Causes severe skin burns and eye damage.
H317 May cause an allergic skin reaction.
H335 May cause respiratory irritation.
· **Precautionary statements**

P210	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P260	Do not breathe mist/vapours/spray.
P280	Wear protective gloves / eye protection.
P280	Wear protective clothing.
P302+P352	IF ON SKIN: Wash with plenty of soap and water.
P337+P313	If eye irritation persists: Get medical advice/attention.

· **2.3 Other hazards** -

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· **Results of PBT and vPvB assessment**
· **PBT:** Not applicable.
· **vPvB:** Not applicable.

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SECTION 3: Composition/information on ingredients

· **3.2 Mixtures**
· **Description:** Product based on methacrylates

· **Dangerous components:**

CAS: 80-62-6 EINECS: 201-297-1	methyl methacrylate Flam. Liq. 2, H225 Skin Irrit. 2, H315; Skin Sens. 1, H317; STOT SE 3, H335	75-90%
CAS: 79-41-4 EINECS: 201-204-4	methacrylic acid Acute Tox. 3, H311 Skin Corr. 1A, H314; Eye Dam. 1, H318 Acute Tox. 4, H302; Acute Tox. 4, H332; STOT SE 3, H335 ATE: LD50 oral: 1,320 mg/kg LD50 dermal: 500 mg/kg LC50/4 h inhalative: 11 mg/l Specific concentration limit: STOT SE 3; H335: C ≥ 1 %	5%
CAS: 2082-81-7 EINECS: 218-218-1	1,4-butandioldimethacrylate Skin Sens. 1B, H317	≥1-≤5%

· **Additional information** For the wording of the listed hazard phrases refer to section 16.

SECTION 4: First aid measures

· **4.1 Description of first aid measures**
· **After inhalation** Supply fresh air; consult doctor in case of symptoms.
· **After skin contact**
Instantly wash with water and soap and rinse thoroughly.
If skin irritation continues, consult a doctor.
· **After eye contact**
Rinse opened eye for several minutes under running water. If symptoms persist, consult doctor.
· **After swallowing**
Rinse out mouth and then drink plenty of water.
In case of persistent symptoms consult doctor.
Product based on methacrylates
· **4.2 Most important symptoms and effects, both acute and delayed**
No further relevant information available.
· **4.3 Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

SECTION 5: Firefighting measures

· **5.1 Extinguishing media**
· **Suitable extinguishing agents** CO2, sand, extinguishing powder. Do not use water.
· **For safety reasons unsuitable extinguishing agents** Water.
· **5.2 Special hazards arising from the substance or mixture**
Can form explosive gas-air mixtures.
Formation of toxic gases is possible during heating or in case of fire.
· **5.3 Advice for firefighters**
· **Protective equipment:** No special measures required.

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· ***Additional information*** -

SECTION 6: Accidental release measures

· ***6.1 Personal precautions, protective equipment and emergency procedures***
Wear protective equipment. Keep unprotected persons away.
Avoid contact with eyes and skin.
· ***6.2 Environmental precautions:*** *Prevent material from reaching sewage system, holes and cellars.*
· ***6.3 Methods and material for containment and cleaning up:***
Absorb with liquid-binding material (diatomite, universal binders, for small amounts tissues).
Do not flush with water or aqueous cleansing agents
Send for recovery or disposal in suitable containers.
· ***6.4 Reference to other sections***
See Section 13 for information on disposal.
See Section 8 for information on personal protection equipment.
-

SECTION 7: Handling and storage

· ***7.1 Precautions for safe handling***
Keep containers tightly sealed.
Keep away from heat and direct sunlight.
· ***Information about protection against explosions and fires:***
Keep ignition sources away - Do not smoke.
Protect from heat.
Protect against electrostatic charges.

· ***7.2 Conditions for safe storage, including any incompatibilities***
· ***Storage***
· ***Requirements to be met by storerooms and containers:*** *Store in cool location.*
· ***Information about storage in one common storage facility:*** *Not required.*
· ***Further information about storage conditions:***
Store cool (not above 25 °C).
Store in cool, dry conditions in well sealed containers.
Protect from heat and direct sunlight.
· ***7.3 Specific end use(s)*** *No further relevant information available.*

*

SECTION 8: Exposure controls/personal protection

· ***8.1 Control parameters***

· **Components with critical values that require monitoring at the workplace:**	
80-62-6 methyl methacrylate	
WEL (Great Britain)	Short-term value: 416 mg/m³, 100 ppm Long-term value: 208 mg/m³, 50 ppm
IOELV (European Union)	Short-term value: 100 ppm Long-term value: 50 ppm
79-41-4 methacrylic acid	
WEL (Great Britain)	Short-term value: 143 mg/m³, 40 ppm Long-term value: 72 mg/m³, 20 ppm

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· DNELs		
80-62-6 methyl methacrylate		
Oral	general population, long term, systemic	8.2 mg/Kg (not defined)
Dermal	worker industrial, long term, systemic	13.67 mg/Kg/d (not defined)
	general population, long term, systemic	8.2 mg/Kg/d (not defined)
Inhalative	worker industrial, acute, local	416 mg/m3 (not defined)
	worker industrial, long term, systemic	348.4 mg/m3 (not defined)
	worker industrial, long term, local	208 mg/m3 (not defined)
	general population, acute, local	208 mg/m3 (not defined)
	general population, long term, systemic	74.3 mg/m3 (not defined)
79-41-4 methacrylic acid		
Oral	general population, long term, systemic	5.35 mg/Kg (not defined)
Dermal	worker industrial, long term, systemic	4.25 mg/Kg/d (not defined)
	general population, long term, systemic	5.35 mg/Kg/d (not defined)
Inhalative	worker industrial, long term, systemic	39.3 mg/m3 (not defined)
	worker industrial, long term, local	44 mg/m3 (not defined)
	general population, long term, systemic	11.7 mg/m3 (not defined)
	general population, long term, local	8.8 mg/m3 (not defined)
2082-81-7 1,4-butandioldimethacrylate		
Oral	general population, long term, systemic	2.5 mg/Kg (not defined)
Dermal	worker industrial, long term, systemic	4.2 mg/Kg/d (not defined)
	general population, long term, systemic	2.5 mg/Kg/d (not defined)
Inhalative	worker professional, long term, systemic	14.5 mg/m3 (not defined)
	general population, long term, systemic	4.3 mg/m3 (not defined)

· PNECs	
80-62-6 methyl methacrylate	
freshwater	0.94 mg/l (not defined)
marine water	0.094 mg/l (not defined)
sewage treatment plant	10 mg/l (not defined)
sediment, dry weight, freshwater	10.2 mg/Kg (not defined)
sediment, dry weight, marine water	0.102 mg/Kg (not defined)
soil, dry weight	1.48 mg/Kg (not defined)
79-41-4 methacrylic acid	
freshwater	0.82 mg/l (not defined)
marine water	0.082 mg/l (not defined)
sewage treatment plant	100 mg/l (not defined)
sediment, dry weight, freshwater	3.09 mg/Kg (not defined)
sediment, dry weight, marine water	0.309 mg/Kg (not defined)
soil, dry weight	0.137 mg/Kg (not defined)
2082-81-7 1,4-butandioldimethacrylate	
freshwater	0.043 mg/l (not defined)
marine water	0.004 mg/l (not defined)
sewage treatment plant	2 mg/l (not defined)
sediment, dry weight, freshwater	3.12 mg/Kg (not defined)

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sediment, dry weight, marine water	0.312 mg/Kg (not defined)
soil, dry weight	0.573 mg/Kg (not defined)

· **Additional information:** The lists that were valid during the compilation were used as basis.

· **8.2 Exposure controls**
· **Appropriate engineering controls** No further data; see section 7.
· **Individual protection measures, such as personal protective equipment**
· **General protective and hygienic measures**
Keep away from foodstuffs, beverages and food.
Instantly remove any soiled and impregnated garments.
Wash hands during breaks and at the end of the work.
Avoid contact with the eyes and skin.
· **Breathing equipment:**
Not neccessary with efficient local exhaust. If exposition to vapours is possible, use breathing protective mask (filter A).
· **Hand protection**
The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation
If skin contact cannot be avoided, protective gloves are recommended to avoid possible sensitization.
Solvent resistant gloves
Check protective gloves prior to each use for their proper condition.
recommended
· **Material of gloves**
The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.
· **Penetration time of glove material**
The exact break trough time has to be found out by the manufacturer of the protective gloves and has to be observed.
· **For the permanent contact of a maximum of 15 minutes gloves made of the following materials are suitable:**
Butyl rubber, BR
Nitrile rubber, NBR
· **Eye/face protection** Tightly sealed safety glasses.
· **Body protection:** Light weight protective clothing

SECTION 9: Physical and chemical properties

· **9.1 Information on basic physical and chemical properties**
· **General Information**

· **Physical state**	Fluid
· **Colour:**	Colourless
· **Smell:**	Characteristic
· **Odour threshold:**	Not determined.
· **Melting point/freezing point:**	Not determined
· **Boiling point or initial boiling point and boiling range**	100 °C
· **Flammability**	Not applicable.

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· **Lower and upper explosion limit**	
· **Lower:**	2.1 Vol %
· **Upper:**	12.5 Vol %
· **Flash point:**	10 °C (80-62-6 methyl methacrylate)
· **Auto-ignition temperature:**	370.0 °C
· **Decomposition temperature:**	Not determined.

· **SAPT**

Palabond	> 60 °C

· **SADT**	
· **pH**	Mixture is non-soluble (in water).
· **Viscosity:**	
· **Kinematic viscosity**	Not determined.
· **Kinematic viscosity**	
· **dynamic at 20 °C:**	1 mPas
· **Solubility**	
· **Water:**	Not miscible or difficult to mix
· **Partition coefficient n-octanol/water (log value)**	Not determined.
· **Steam pressure at 20 °C:**	47 hPa
· **Vapour pressure:**	
· **Density and/or relative density**	
· **Density at 20 °C**	0.940 g/cm³
· **Relative density**	Not determined.
· **Vapour density**	Not determined.

· **9.2 Other information**	No further relevant information available.
· **Appearance:**	
· **Form:**	Fluid
· **Important information on protection of health and environment, and on safety.**	
· **Self-inflammability:**	Product is not selfigniting.
· **Explosive properties:**	Product is not explosive. However, formation of explosive air/vapour mixtures is possible.
· **Solvent content:**	
· **VOC EU**	841.2 g/l
· **Change in condition**	
· **Evaporation rate**	Not determined.

· **Information with regard to physical hazard classes**	
· **Explosives**	Void
· **Flammable gases**	Void
· **Aerosols**	Void
· **Oxidising gases**	Void
· **Gases under pressure**	Void
· **Flammable liquids**	Highly flammable liquid and vapour.
· **Flammable solids**	Void
· **Self-reactive substances and mixtures**	Void
· **Pyrophoric liquids**	Void
· **Pyrophoric solids**	Void
· **Self-heating substances and mixtures**	Void
· **Substances and mixtures, which emit flammable gases in contact with water**	Void
· **Oxidising liquids**	Void

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· **Oxidising solids**	Void
· **Organic peroxides**	Void
· **Corrosive to metals**	Void
· **Desensitised explosives**	Void

SECTION 10: Stability and reactivity

· **10.1 Reactivity** No further relevant information available.
· **10.2 Chemical stability**
· **Conditions to be avoided:** No decomposition if used and stored according to specifications.
· **10.3 Possibility of hazardous reactions** No dangerous reactions known
· **10.4 Conditions to avoid** No further relevant information available.
· **10.5 Incompatible materials:** No further relevant information available.
· **10.6 Hazardous decomposition products:** None
· **Additional information:**
If stored longer than recommended and/or above recommended temperature, product may polymerize generating heat.

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SECTION 11: Toxicological information

· **11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008**
· **Acute toxicity** Based on available data, the classification criteria are not met.

· **LD/LC50 values that are relevant for classification:**		
80-62-6 methyl methacrylate		
Oral	LD50	~7,900 mg/kg (rat)
Dermal	LD50	>5,000 mg/kg (guinea pig) (OECD 402)
Inhalative	LC50/4 h	29.8 mg/l (rat)
79-41-4 methacrylic acid		
Oral	LD50	1,320 mg/kg (ATE)
		1,320 mg/kg (rat) (OECD 401)
Dermal	LD50	500 mg/kg (ATE)
		500-1,000 mg/kg (rabbit)
Inhalative	LC50/4 h	11 mg/l (ATE)
		7.1 mg/l (rat) (OECD 403)
2082-81-7 1,4-butandioldimethacrylate		
Oral	LD50	10,066 mg/kg (rat) (OECD 401)

· **Skin corrosion/irritation**
Causes severe skin burns and eye damage.
· **Serious eye damage/irritation**
Causes serious eye damage.
· **Respiratory or skin sensitisation**
May cause an allergic skin reaction.
· **Germ cell mutagenicity** Based on available data, the classification criteria are not met.
· **Carcinogenicity** Based on available data, the classification criteria are not met.
· **Reproductive toxicity** Based on available data, the classification criteria are not met.
· **STOT-single exposure**
May cause respiratory irritation.
· **STOT-repeated exposure** Based on available data, the classification criteria are not met.
· **Aspiration hazard** Based on available data, the classification criteria are not met.

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· **11.2 Information on other hazards**

· **Endocrine disrupting properties**		
131-57-7	Oxybenzone	List II

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SECTION 12: Ecological information

· **12.1 Toxicity**

· **Aquatic toxicity:**	
80-62-6 methyl methacrylate	
EC50/21d	49 mg/L (daphnia) (OECD 211)
EC50/48h	69 mg/l (daphnia) (EPA OTS 797.1300)
NOEC / 21d	37 mg/l (daphnia) (OECD 211)
ErC50 / 72 h	>110 mg/l (algae) (OECD 201)
NOEC / 72h	110 mg/l (algae) (OECD 201)
NOEC / 48h	48 mg/l (daphnia) (EPA OTS 797.1300)
EbC50 / 72h	>110 mg/l (algae) (OECD 201)
NOEC/ 35d	9.4 mg/L (fish) (OECD 210)
LC50/ 35d	33.7 mg/L (fish) (OECD 210)
79-41-4 methacrylic acid	
EC50/48h	>130 mg/l (daphnia) (EPA OTS 797.1300)
LC50/96h	85 mg/l (fish) (EPA OTS 797.1400)
NOEC / 21d	53 mg/l (daphnia)
ErC50 / 72 h	45 mg/l (algae) (OECD 201)
NOEC / 72h	8.2 mg/l (algae) (OECD 201)
NOEC / 96h	12 mg/l (fish) (EPA OTS 797.1400)
NOEC / 48h	130 mg/l (daphnia) (EPA OTS 797.1300)
NOEC/ 35d	10 mg/L (fish) (OECD 210)
LC50/ 35d	42 mg/L (fish) (OECD 210)
2082-81-7 1,4-butandioldimethacrylate	
EC50/21d	14.1 mg/L (daphnia) (OECD 211)
EC50/48h	32.5 mg/l (fish)
NOEC / 21d	5.09 mg/l (daphnia) (OECD 211)
ErC50 / 72 h	9.79 mg/l (algae) (OECD 201)
NOEC / 72h	2.11 mg/l (algae) (OECD 201)
NOEC / 48h	25 mg/l (fish)
ErC10/72h	4.35 mg/L (algae) (OECD 201)

· **12.2 Persistence and degradability**	
80-62-6 methyl methacrylate	
Biodegradation	94 % /14d (not defined) (OECD 301C)
79-41-4 methacrylic acid	
Biodegradation	86 % /28d (not defined) (OECD 301D)
2082-81-7 1,4-butandioldimethacrylate	
Biodegradation	84 % /28d (not defined) (OECD 310)

· **12.3 Bioaccumulative potential** No further relevant information available.
· **12.4 Mobility in soil** No further relevant information available.

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· **12.5 Results of PBT and vPvB assessment**
· **PBT:** Not applicable.
· **vPvB:** Not applicable.
· **12.6 Endocrine disrupting properties**
For information on endocrine disrupting properties see section 11.
· **12.7 Other adverse effects**
· **Additional ecological information:**
· **General notes:**
Do not allow product to reach ground water, water bodies or sewage system.
Do not allow undiluted product or large quantities of it to reach ground water, water bodies or sewage system.
Danger to drinking water if even small quantities leak into soil.

SECTION 13: Disposal considerations

· **13.1 Waste treatment methods**
· **Recommendation**
Must not be disposed of together with household garbage. Do not allow product to reach sewage system.
Disposal must be made according to official regulations.
· **Uncleaned packagings:**
· **Recommendation:**
Disposal must be made according to official regulations.
Non contaminated packagings can be used for recycling.

SECTION 14: Transport information

· **14.1 UN number or ID number**
· **ADR, IMDG, IATA** UN2924

· **14.2 UN proper shipping name**
· **ADR** 2924 FLAMMABLE LIQUID, CORROSIVE, N.O.S. (METHYL METHACRYLATE MONOMER, STABILIZED, METHACRYLIC ACID, STABILIZED)
· **IMDG, IATA** FLAMMABLE LIQUID, CORROSIVE, N.O.S. (METHYL METHACRYLATE MONOMER, STABILIZED, METHACRYLIC ACID, STABILIZED)

· **14.3 Transport hazard class(es)**
· **ADR**

· **Class** 3 (FC) Flammable liquids.

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· **Label** 3+8

· **IMDG**

· **Class** 3 Flammable liquids.
· **Label** 3/8

· **IATA**

· **Class** 3 Flammable liquids.
· **Label** 3 (8)

· **14.4 Packing group**
· **ADR, IMDG, IATA** II

· **14.5 Environmental hazards:**
· **Marine pollutant:** No

· **14.6 Special precautions for user** Warning: Flammable liquids.
· **Kemler Number:** 338
· **EMS Number:** F-E,S-C
· **Segregation groups** Acids
· **Stowage Category** B
· **Stowage Code** SW2 Clear of living quarters.

· **14.7 Maritime transport in bulk according to IMO instruments** Not applicable.

· **Transport/Additional information:** -

· **ADR**
· **Limited quantities (LQ)** 1L
· **Excepted quantities (EQ)** Code: E2
Maximum net quantity per inner packaging: 30 ml
Maximum net quantity per outer packaging: 500 ml
· **Transport category** 2
· **Tunnel restriction code** D/E

· **IMDG**
· **Limited quantities (LQ)** 1L
· **Excepted quantities (EQ)** Code: E2
Maximum net quantity per inner packaging: 30 ml
Maximum net quantity per outer packaging: 500 ml

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· ***UN "Model Regulation":*** *UN 2924 FLAMMABLE LIQUID, CORROSIVE, N.O.S. (METHYL METHACRYLATE MONOMER, STABILIZED, METHACRYLIC ACID, STABILIZED), 3 (8), II*

*
SECTION 15: Regulatory information

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

· ***Directive 2012/18/EU***
· ***Qualifying quantity (tonnes) for the application of lower-tier requirements*** *5.000 t*
· ***Qualifying quantity (tonnes) for the application of upper-tier requirements*** *50.000 t*
· ***15.2 Chemical safety assessment:*** *A Chemical Safety Assessment has not been carried out.*

SECTION 16: Other information

These data are based on our present knowledge. However, they 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.
H302 Harmful if swallowed.
H311 Toxic in contact with skin.
H314 Causes severe skin burns and eye damage.
H315 Causes skin irritation.
H317 May cause an allergic skin reaction.
H318 Causes serious eye damage.
H332 Harmful if inhaled.
H335 May cause respiratory irritation.

· ***Abbreviations and acronyms:***
SADT: Self Accelerating Decomposition Temperature
SAPT: Self Accelerating Polymerisation Temperature
ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)
IMDG: International Maritime Code for Dangerous Goods
IATA: International Air Transport Association
GHS: Globally Harmonised System of Classification and Labelling of Chemicals
EINECS: European Inventory of Existing Commercial Chemical Substances
ELINCS: European List of Notified Chemical Substances
CAS: Chemical Abstracts Service (division of the American Chemical Society)
VOCV: Lenkungsabgabe auf flüchtigen organischen Verbindungen, Schweiz (Swiss Ordinance on volatile organic compounds)
DNEL: Derived No-Effect Level (UK REACH)
PNEC: Predicted No-Effect Concentration (UK REACH)
LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent
PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative
Flam. Liq. 2: Flammable liquids – Category 2
Acute Tox. 4: Acute toxicity – Category 4
Acute Tox. 3: Acute toxicity – Category 3
Skin Corr. 1A: Skin corrosion/irritation – Category 1A
Skin Irrit. 2: Skin corrosion/irritation – Category 2
Eye Dam. 1: Serious eye damage/eye irritation – Category 1
Skin Sens. 1: Skin sensitisation – Category 1
Skin Sens. 1B: Skin sensitisation – Category 1B
STOT SE 3: Specific target organ toxicity (single exposure) – Category 3

· **** Data compared to the previous version altered.***